

OPHTHALMIC LASER UPDATE -- January 2004

12/30 Ted Huber of **Wachovia Securities**, issued an update report on **VISX**, entitled: "**EYE: Dec. Consumer Confidence Dips But Outlook Remains Favorable**". Some of his comments included:

* 12/03 CONSUMER CONFIDENCE NEUTRAL FOR VISX: On 12/30, the **Conference Board** reported December consumer confidence fell to 91.3 from 92.5 in November. The second consecutive confidence reading above 90 continued to demonstrate a favorable economic and consumer environment for LASIK procedures.

* NO CHANGE TO VOLUME GROWTH FORECASTS: Our 4Q03 and 1Q04 forecasts for 15% and 11% volume growth assumes consumer confidence near 80. While we view the last three months data at or above 80 as positive, Custom LASIK penetration and advertising remain primary volume growth drivers.

* CUSTOM LASIK AS STANDARD OF CARE REMAINS A QUESTION: While limited clinical data suggests Custom LASIK produces 20/20 vision in over 90% of recipients with 1/3 less higher order aberrations versus standard LASIK, clinician opinion on Custom as a standard of care remains mixed. Until consensus forms (unlikely in near-term), 2004 Custom mix may be limited to a maximum of 50%.

* INCREASING CONFIDENCE IN Q403 FORECASTS: Based on consumer confidence levels above 90 in November and December, as well as field checks with refractive surgeons showing Custom mix in the 30-50% range, we have increasing confidence in our Q403 \$38.4 MM revenue (volume growth = 15%, Custom mix = 28%) and \$0.15 EPS forecasts. Our 2004 EPS forecast of \$0.79, based on volume growth of 10.5% and Custom mix of 33%, remains unchanged.

1/5 **Refocus Group, Inc.** announced that it had received approval from the FDA to begin Phase II clinical trials of the company's Scleral Implants and Scleral Spacing Procedure for the surgical treatment of presbyopia. The FDA approval is conditioned on the company's submittal of certain final documentation concurrent with the initiation of the clinical study. Presbyopia impacts virtually 100% of the population over age 40.

"We believe we are now on the threshold of confirming, through this clinical investigation, the first truly viable surgical treatment for presbyopia," said Terry Walts, president and CEO of Refocus Group. "Finding a mainstay treatment for presbyopia has often been described as the 'last frontier' of eye care, and our internal estimates project the potential market for viable surgical solutions to presbyopia to be equivalent to or larger over time than today's LASIK market worldwide."

The Phase II clinical trial will be a multi-center, randomized study, with 100 patients receiving the Scleral Spacing Procedure and another 50 patients designated as control patients. Refocus Group has approval to begin immediate enrollment of patients for the

clinical trials in up to 10 clinical sites within the U.S. Additional patients would be added upon submittal and FDA review of the preliminary results of the trials.

- 1/5 According to *OptiStock*, refractive surgery stock growth headlined an upbeat 2003 for the Vision Industry. Stocks of companies involved in LASIK and other surgical refractive correction saw large percentage gains in 2003, accounting for six of the top 10 best-performing stocks in the vision care industry.

Leading the top 10 gainers for 2003 were **LCA-Vision (LCAV)**, **TLC Vision (TLCV)**, **Escalon Medical (ESMC)**, **STAAR Surgical (STAA)** and **ISTA Pharmaceuticals (ISTA)**. Other top 10 companies for the year can be found at **www.OptiStock.com**. The site also lists the top 10 performers for December, and for the fourth quarter. The vision industry's top 10 stocks in 2003 rose from 98% to 828%, with fourth quarter top-10 gainers ranging from 21% to 80%.

- 1/6 **LaserSight, Incorporated** announced that it had received the settlement proceeds from a Shareholder derivative suit which had been pending in the United States District Court, Southern District of New York. The original action, in which LaserSight was a nominal defendant, was filed pursuant to Section 16 of the Securities Exchange Act of 1934. The company received, net of court ordered fees and costs, approximately \$250,000 of the \$400,000 settlement.

On November 20, 2003, the company filed its monthly operating report for the period October 1, 2003 through October 31, 2003 (the Operating Report) and on December 19, 2003 filed its monthly operating report for the period November 1, 2003 through November 30, 2003; with the U.S. Bankruptcy Court for the Middle District of Florida -- Orlando Division -- (the Bankruptcy Court). Copies of the operating report may be obtained for a fee from the Bankruptcy Court's website located at **www.flmb.uscourts.gov/**.

On January 5, 2004, the company filed its Reorganization Plan with the U.S. Bankruptcy Court. The Plan was a result of negotiations with the various parties involved and provides in part for Debtor in Possession (DIP) financing to be provided by **New Industries Investment Consultants (H.K.) LTD (NII)**. NII is the Hong Kong based affiliate of **Shenzhen New Industries Medical Development Co. (Shenzhen New Industries)**, Shenzhen, the People's Republic of China. Shenzhen New Industries is a company that specializes in advanced medical treatment services; medical device distribution and medical project investment and is the company's largest customer. NII was the holder of LaserSight's Series H Convertible Preferred Stock issued during 2002. The company has already received the first two transfers of funds from NII as part of the \$2.0 million of DIP loans. Copies of the Plan may be obtained for a fee from the Bankruptcy Court's website.

The company's workforce has been recalled from its previously announced furlough and has commenced ordering inventory component parts and resumed limited manufacturing operations.

As previously disclosed in its most recently filed SEC Form 10-Q Quarterly Report (Q1, May 15, 2003) and Form 10-K Annual Report, the company indicated that it had suffered recurring losses from operations and has a significant accumulated deficit that raises substantial doubt about its ability to continue as a going concern. The financial statements included in the previously filed SEC reports do not include any adjustments that might result from the outcome of these uncertainties, including the bankruptcy and subsequent reorganization.

Once the company's Plan is approved, the company may be required to adopt "fresh start" reporting in accordance with the American Institute of Certified Public Accountants' Statement of Position 90-7, Financial Reporting by Entities in Reorganization Under the Bankruptcy Code (SOP 90-7). Fresh-start reporting may result in material changes to the company's balance sheet, including valuation of assets at fair value in accordance with principles of the purchase method of accounting, valuation of liabilities pursuant to provisions of the Plan (when and if approved) and valuation of equity based on the reorganization value of the ongoing business.

1/6 According to *Reuters*, the FDA issued a warning letter to **Staar Surgical** for problems about how it handled complaints regarding products, the agency said Tuesday on its Web site. The FDA said Staar failed to analyze complaints involving blurred or cloudy vision and other factors for its implantable contact lens (ICL), as well as matters about validating test raw materials and finished devices.

The FDA's letter was issued December 22 to the company, but was published on its Web site (www.fda.gov/foi/warning_letters/g4454d.pdf) on January 6th.

The FDA's warning letter followed an inspection on August 12 through September 4.

Staar's response to the investigator's comments was "inadequate. We believe that the information contained in your firm's record reasonably suggests that Staar Surgical company received information that should have been reported to FDA as MDRs," the FDA said in its letter. An MDR is how the FDA receives information about adverse events from manufacturers, importers and user facilities. The FDA said Staar's response about how it would meet "Current Good Manufacturing Practice" requirements about methods to test raw materials was "adequate."

The FDA said Staar's response to the warning letter should include the steps Staar is taking to rectify its MDR reporting procedures.

"We acknowledge that some improvements are needed in that area," CFO John Bily said. "We hope to have them resolved very soon. We are certain to comply with the FDA 100% in what we do...We think we'll have that done in a reasonable amount of time."

1/7 The company issued its own press release on the situation the following day.

STAAR Surgical company announced that it was aggressively pursuing corrective actions to remedy issues cited in a Warning Letter received by the company on December 29, 2003 from the FDA. The company is committed to invest the resources required to do whatever is necessary to implement the corrective actions identified. At this point in time, management believes the costs that will be incurred to implement corrective actions to successfully resolve these issues will not be material. The company is cooperating fully with the FDA to address their concerns.

The issues cited in the Warning Letter were identified during inspection audits conducted by the FDA Office of Compliance between August 12 and September 4 as part of the approval process for STAAR's Implantable Contact Lens (ICL). The first issue identified by the inspections determined that STAAR has not developed maintained and implemented written Medical Device Reporting (MDR) procedures for reports of serious injuries attributed to the company's cartridges and injectors. Specific instances mentioned in the FDA's letter concerned only the IOL lens. The second issue concerned the procedure for approving an outside testing laboratory. This procedure did not assure that the methods used to test raw materials and finished devices by that testing laboratory had been validated. The letter also stated that "no premarket submissions for Class III devices to which the Quality system regulation deficiencies are reasonably related would be cleared until the violations have been corrected."

"We believe that the actions required to correct the issues cited by the FDA in its Warning Letter can be successfully resolved in a reasonable time-frame and we are cooperating fully with the FDA to implement corrective actions," said David Bailey, president and CEO of STAAR Surgical. "At this point in time, we don't believe the costs that will be incurred to implement the correction actions will be material and we are confident about our ability to earn FDA approval for the ICL. The complaints discussed on the first point of the FDA warning letter (diopter shift, cloudy vision, blurred vision and capsular tears) were reported for Intraocular Lenses used in cataract surgery and not in ICL for Myopia being considered for approval. The company is extremely confident that all of the ICL related complaints in the US FDA Study have been accurately and completely reported to the FDA, and were disclosed prior to the October 3, 2003 panel meeting."

Several analysts following Staar Surgical weighed in on the situation.

Jayson Bedford, of **Adams, Harkness, & Hill**, wrote:

* Stock down 17% on concern over FDA warning letter, which raised two specific issues: 1) an under-reporting of MDRs related to the IOL (and not the ICL), and 2) a failure to properly assess its vendor's validation process (w/ respect to the collamer material used in both the IOL and the ICL).

* STAA has already responded to issue #2, which may be "adequate," and has until mid-January to respond to the FDA regarding the MDRs; these issues must be rectified before the agency grants approval and management feels a late 1Q'04 approval is achievable (we now model domestic ICL revenue beginning in 2Q'04).

* For 4Q, we remain comfortable with our \$13M revenue estimate (helped by a weak US\$) but believe upside potential is limited; due to increased launch costs, our FY04 EPS estimate is now \$(0.04) (from \$0.03) and we model profitability in 4Q'04.

* Lowering rating to Buy (from Strong Buy) and assigning a 12-month price target of \$12 (down from \$15); our rating reflects our long-term belief in the technology and the opportunity but also takes into consideration the increased uncertainty around the timing of ICL approval.

John Calcagnini, of **CIBC World Markets Inc.** wrote:

STAAR has received an FDA warning letter related to two issues: First, the letter said that it failed to meet the FDA's good manufacturing practice compliance standards by not validating an outside vendors testing of the Collamer material, which is used in both the ICL and IOLs. Second, STAAR did not report all required complaints or sufficient detail on all complaints to the FDA under the agency's MDR regulations. STAAR "failed to perform root cause analysis of complaints involving diopter shift, blurred vision, and posterior capsule tears" for its IOLs. STAAR still hopes to get FDA approval for the ICL by April 3, 2004, but the company will still have to convince the FDA that new compliance procedures for tracking complaints/adverse events is satisfactory and have its manufacturing re-inspected to ensure compliance.

The company will not ask the FDA for a re-inspection until February, so an approval by April 3 looks tight. We believe the company has a cash position in the \$6-\$7 mm range based on nearly \$10 mm at 9/30/03. It may have to raise additional capital once these FDA issues are resolved.

We rate the stock Sector Underperformer (Speculative) because we think the market for the ICL is small in the \$30-\$50 million range given a narrow target market of high diopter patients and our conversations with ophthalmologists that tell us they would not do it on themselves, given that little is known about long-term complications. We are concerned about the endothelial cell loss that occurs with each surgery, especially given that revisions may be needed. Lasik now takes several forms which has broadened the universe of patients that can be treated, further limiting the market for an ICL. STAAR

is not making money in its base IOL business and has been losing market share over the last several years.

Therefore, we have a hard time justifying that the company has a \$171 million market value before a new financing. STAAR expects to have four-year follow-up data for its ICL on 125 patients in 1Q04.

Joanne Wuensch of **Harris Nesbitt** also reported on Staar Surgical, with her report entitled: **STAA--Egg on the Face Makes for a Good Breakfast; STAA's FDA War.**

* Event--The company hosted a conference call to discuss receipt of an FDA warning letter. The warning letter's issues consisted of 1) the company's inadequate reporting of complaints and 2) inappropriate procedures for approving vendors that are used for testing materials and finished devices.

* Impact--Increases near-term volatility and creates a binary event: either the company receives FDA approval for its phakic IOL within the anticipated time frame (before the end of 1Q04) or this creates a significant delay.

* Forecasts--Management indicated that 4Q03 revenues would be \$12.5 million, below our \$14.1 million estimate. We have lowered our 4Q03 revenue and EPS estimate to \$12.6 million and a loss of \$0.06 from \$14.1 million and a loss of \$0.01, respectively. For 2004, our revenue and EPS estimates are lowered to \$58.3 million (up 16.1%) and \$0.08 (N.A.) from \$59.1 million and \$0.12, respectively. For 2005, our estimates are lowered to \$69.3 million (up 18.7%) from \$69.9 million and to \$0.24 from \$0.29.

* Valuation--Our price target remains within the range of \$14-17 based on 4-5x 2005 revenues, but is lowered to \$14 from \$15.

* Recommendation--Maintain OUTPERFORM; increased near-term risk.

1/9 The January issue of *Ophthalmic Market Perspectives* featured a review of the 2003 ophthalmic industry, with stories on refractive highlights (by David Harmon); cataract device industry highlights (by William Freeman); and a review of the retinal industry (by Roy Freeman). In addition, Dave Harmon wrote about the restructured **LASIK Vision Institute**, a privately-held laser vision center management company, known for its low price advertising.

In the 2003 refractive highlights, Harmon noted that global demand during the year grew 5.1% to 3.02 million procedures, up from the 2.87 million performed in 2002. He said that demand for LASIK and other excimer laser-based procedures grew about 2%, while the smaller segment of other refractive technologies, including phakic IOLs, accommodating IOLs, multifocal IOLs, and CK more than doubled in size to

approximately 80,000 procedures. The global market for refractive surgical products at the manufacturers level grew 15.1% to \$401.1 million, up from \$348.6 million in 2002.

Global LASIK procedures were up slightly when compared to 2002, with rapid growth in Asian markets offset by declines in most other regions. Although refractive surgery in Asia accounted for less than 9% of worldwide procedures, rapid growth in demand in China, India, and other developing Asian countries influenced global results. Severe economic problems in Argentina and Brazil that led to dramatic declines in disposable income and high levels of unemployment reduced demand for LASIK in South America.

In the U.S., improving economic conditions and additional regulatory approvals for wavefront-driven LASIK during the second half of 2003 produced the first signs of turnaround after a two-year slump in LASIK demand. Economic forecasts remain positive at year-end, with record increases in GDP and signs of economic growth in other key world markets are expected to produce healthy growth in 2004.

Global sales of new excimer lasers declined significantly when compared to prior years with an estimated 486 new excimer lasers sold during the year. Demand for new lasers in the U.S. continued to lag past year's levels, with an estimated 136 new excimer lasers sold. The only place worldwide where demand was strong was in the developing economies of China and India.

It should also be noted that **IntraLase** made significant progress during the year, convincing surgeons of the value of its premium-priced femtosecond laser keratome, with its share of U.S. procedures growing to more than 10% by year's end.

As also reported by Harmon, LASIK Vision Institute (LVI) was restructured with a change in ownership, a new management team, and plans for a new laser platform. **Summit Partners**, a private equity and venture capital firm, has purchased a majority ownership position. Other owners include the Musa family (the original founders of LVI), and members of the new management team. LVI operates 20 laser centers located primarily in the South and Midwest, and is known best for its marketing strategy focusing on \$299 and \$499 per eye prices in local newspapers. The technique has been controversial as local news agencies have written about alleged "bait and switch" techniques, with only very few patients able to "qualify" for the advertised low prices.

LVI utilizes **Nidek** and **VISX** lasers at its centers, however, a recent press release announced plans to transition to the **Bausch & Lomb** Technolas system. According to James Usdan, president and CEO of **Vision Care Holdings** (the parent holding company for LVI), "The Bausch & Lomb system will cost us more to operate, but we know we can more than offset the higher costs with premium pricing we can achieve with the Bausch & Lomb system." According to Harmon, the announcement may foreshadow a slight shift in marketing strategy to promote the Technolas laser with Zyoptix as a premium-priced procedure (rather than the VISX laser now utilized) and utilizing the Nidek laser treatment as a lower cost alternative.

1/12 **IntraLase Corp.** announced the placement of 26 INTRALASE FS lasers for revenue in the fourth quarter ended December 31, 2003, bringing its number of 2003 laser placements to 67. IntraLase has now placed a total of 106 lasers globally, including placements in Canada, Puerto Rico, Japan, Korea and Malaysia. The company sold 27,372 procedures during the fourth quarter ended December 31, 2003, an increase of 136% as compared to the comparable quarter a year ago. The fourth quarter of 2003 also marked the completion of sales to three prestigious ophthalmic teaching institutions: Bascom Palmer Eye Institute, University of Miami; Kellogg Eye Center, University of Michigan; and Stanford University Hospital and Clinic in California.

Robert Palmisano, IntraLase president and CEO, commented, "We are gratified by the rapid acceptance of our technology in the vision correction industry, and the adoption by key opinion leaders, including major teaching hospitals, as IntraLase strives to become the new standard of care in LASIK vision correction."

The INTRALASE FS laser increases the safety and predictability of laser vision correction surgery by replacing the microkeratome, a bladed mechanical device used to create the corneal flap in the first step of LASIK surgery. IntraLase, which develops and manufactures the INTRALASE FS laser, commercially introduced the laser to the US market in late 2001. Important clinical data recently presented at the American Academy of Ophthalmology meeting in Anaheim (November 2003) demonstrated superior visual outcomes among patients whose surgery was performed using the INTRALASE FS laser to create the corneal flap. Dr. Daniel Durrie of Overland Park, Kansas reported improved outcomes using the INTRALASE FS laser plus **Alcon Inc.'s** CustomCornea excimer laser treatment. In his study, 75% of patients achieved 20/20 or better uncorrected vision at day one versus 63% with the traditional microkeratome approach and the same Alcon CustomCornea treatment.

For the year ended December 31, 2003, IntraLase reported a total of 84,230 procedures sold, an increase of 184% compared to the year ending December 31, 2002, representing approximately 10% of all fourth quarter 2003 US laser vision correction procedures, according to **MarketScope LLC**, a leading market research firm reporting on the industry. "Increased procedure volume in 2003 was driven by the growing installed base and number of surgeons converting their practices to IntraLase technology. Credible clinical data, as well as patient preference, is now convincing surgeons that the INTRALASE FS laser provides a compelling advantage in the care of their patients," concluded Palmisano.

The company plans to demonstrate its INTRALASE FS laser to the European market in late January at the 2004 *European Society of Cataract and Refractive Surgeons Meeting* in Barcelona. Commercialization is expected to follow during the second quarter, pending CE certification.

1/12 **LCA-Vision Inc.** provided guidance on the company's financial and operational performance in fiscal 2004. The company currently expects earnings per share for 2004

to be in the range of \$0.80 to \$0.85 on approximately 13.6 million shares outstanding, which includes 2.4 million shares sold by the company in a public offering in December 2003. This earnings-per-share guidance represents an increase of approximately 50% compared with the company's 2003 EPS guidance of \$0.52 to \$0.57 per share.

Assuming that industry demand for laser vision correction grows between 8% and 10% in 2004, the company expects laser refractive surgery revenues for 2004 to be approximately \$110 million. In addition, LCA-Vision expects to open 6 to 8 LasikPlus vision centers during 2004. The timing of vision center openings is expected to be spread throughout the year. Consistent with previous goals, the company expects each new LasikPlus vision center to achieve profitability within six months of opening.

"Our results for 2003 and the beginning of 2004 appear to be stronger than expected. We look forward to announcing our 2003 financial results in late February, and are optimistic about the prospects for LCA-Vision during fiscal 2004. We remain confident in the power of our business model and in trends for further growth in revenues, profitability and cash flow," said Stephen Joffe, chairman and CEO of LCA-Vision.

- 1/12 *Optistock* reported that privately held **Refractec** announced that it had exceeded its sales goal for its Viewpoint CK System. The company anticipates receiving FDA pre-market approval in early 2004 for the System to correct for presbyopia. By the end of Q1 2004, the company expects to have more than 450 nationwide surgeons offering the procedure.
- 1/15 Jennifer Hsu, Phil Nalbone, and Sam Chang of **RBC Capital Markets** issued a preview report on **VISX's** fourth quarter financial release, entitled: **Q4 Preview - Results Should At Least Meet Expectations.**

Some of their comments included:

Investment Opinion

* **Expecting A Solid Quarter:** We expect VISX to meet or exceed our expectations for the fourth quarter. We are looking for revenues of \$37.8 million (up about 5% year-over-year) and EPS of \$0.14 (consensus), roughly double that of the year-ago quarter.

* **Looking For Another Quarter of Growth in Procedure Volumes:** With continued signs of an improving economy and increasing adoption of custom LASIK technology, our checks with physicians suggest another quarter of solid growth in U.S. procedure volumes for VISX. Our models forecast mid-teens growth in procedures and CustomVue penetration of 29%. And with an improving product mix, we are forecasting Q4 gross margins of 66.7%.

* **2004 Should Be A Strong Year:** We think the rebound in procedure volumes will be sustainable and we are comfortable with our 2004 revenue projection of \$169.3 million

(+18%), which reflects our assumption of 10% procedure volume growth and 37% CustomVue penetration. On the bottom-line, we are forecasting EPS of \$0.74, in-line with consensus and at the high-end of management's guidance. And with the strong leverage from an improving product mix, we think there could be a chance for upside to our EPS number for the year.

* Valuation: Our \$29 price target represents a multiple of 30x our 2005 EPS estimate of \$0.95. EYE is rated Outperform with Above Average Risk.

VISX reports Q4 financial results on Tuesday, January 27, after the close of market. We expect VISX to at least meet our expectations for the December quarter. We are looking for revenues of \$37.8 million (up about 5% year over year) and EPS of \$0.14 (consensus), up about 96% year-over-year. We expect growth in the quarter to be driven primarily by license revenues, with continued increases in CustomVue penetration to 29% and procedure volume growth in the mid-teens. As a result, we forecast overall growth in license & other revenues of almost 60% year-over-year to \$25.7 million.

For system revenues, we are looking for sales of \$7.7 million, down about 30% sequentially as the company had aggressively marketed its WaveScan units and pushed some sales forward in the third quarter ahead of **Bausch & Lomb's** launch of its competing Zyoptix custom system. With the increasing mix of license to system revenues for VISX in the fourth quarter, we expect to see increasing margins. For the fourth quarter, we are forecasting gross margins of 66.7%, up about 8.3 percentage points sequentially.

Looking forward, with continued signs of an improving economy and increasing adoption of custom LASIK technology, we think VISX -- as the market leader in laser vision correction -- remains in the best position to take advantage of a rebound in U.S. laser vision correction procedures. Management provided guidance for 2004 at its analyst meeting on November 7, and we think management will reiterate this guidance on the earnings call - the company expects revenues of \$167-\$171 million (up 16%-19%) with EPS between \$0.70-\$0.74 (up 55%-65%). For the year, we expect procedure volumes to be up about 10% year over year and we forecast CustomVue penetration of 37%. We are forecasting total revenues this year of \$169.3 million (up 18%) and EPS of \$0.74 (consensus). And with the anticipated improving product mix and increasing margins, we think there's a chance that earnings in 2004 could perhaps even top the high end of management's guidance.

In 2004, we also expect VISX to continue to enhance and expand the indications for its technology. VISX is developing a new algorithm for its wavefront machine that could provide even more precise measurements than the current generation of wavefront aberrometers. This could be particularly important for patients with abnormal corneas or pathology. We think this new software algorithm could be available in the U.S. early this year. And in the second half of this year, we expect VISX to receive FDA approval for two expanded indications for CustomVue -- hyperopia and high myopia.

Valuation — Given the improving profitability outlook for VISX -- with increasing adoption of CustomVue, a more favorable product mix, and higher margins -- we rate VISX shares Outperform with Above Average Risk. Our \$29 price target is based on a multiple of 30x our 2005 earnings estimate of \$0.95. Over the past five years, VISX shares have traded at an average forward P/E multiple of 26, with a very wide range during that period (from 12x to 60x). Breaking it down further, the average P/E in late 1998 through 1999 was close to 40x as procedure volumes, revenues, and earnings were all growing at robust rates. Then from 2000 through the end of 2002, when procedure volumes and earnings were declining, the average P/E was below the five-year average at roughly 20x. And now that we are at a turning point for VISX in terms of renewed growth, we think a multiple at a premium to the company's five-year average is justified -- we are using a 30 multiple.

Price Target Impediment — Our earnings estimates reflect our expectations for improving growth and profitability for VISX with increasing penetration of the higher-margin CustomVue procedure and high single- to- low double-digit growth in procedure volumes. Significant deviations from our assumptions could alter our EPS outlook and delay the attainment of our price target.

- 1/16 In an in-depth Roundtable Forum, sponsored by *The Wall Street Transcript*, Matthew Dodds, a Managing Director with **SG Cowen Securities Corporation**, Peter Bye, a vice president in SG Cowen's medical technology group and Sara Michelmores, a vice president in SG Cowen's medical technology group, examined the outlook for the sector and share specific stock recommendations. This interview excerpt is part of an in-depth Roundtable Forum from our 190-page Medical Supplies and Devices Issue featuring in-depth interviews from five analysts and top management from thirty one sector firms discussing changes at the FDA, latest drug approvals, drug candidates in late approval stages, joint ventures with major pharma, new technologies, unmet medical needs in oncology, government-funded programs, new products in cardiology, growth prospects in cardiology and orthopedics and more. This issue is available to subscribers by telephoning 212-952-7400 x1799 or through The Wall Street Transcript.

Part of the interview follows:

TWST: Matt, we're talking about medical supplies and devices. How have these stocks performed?

Mr. Dodds: As of last week, our med-tech composite index's performance has exceeded the S&P, up 32% year to date. That's very surprising because we typically underperform the market when you see S&P earnings being revised upward and that's exactly what's been going on this year after three tough years. I would expect med tech to underperform because the group is one of the most non-cyclical sectors you'll find and in an economic upturn, people typically rotate out of the most non-cyclical sectors.

The reason it is classified as non-cyclical is that it is based mainly on a steady increase in worldwide surgical procedures driven by an aging population in the US, Western Europe, Japan and the healthcare infrastructure build in several emerging markets. As I'm sure we'll run through later on, these trends have driven steady 8%-9% sales growth for the industry for the past 10 years. On the flip side, this steady growth rarely leads to large swings in our group's EPS growth. Hence, med tech can power through the bad times, but won't blow away Street estimates in the good times. In contrast, as the economy has improved, we have seen several other sectors in the S&P turn dramatically and start blowing out Street expectations.

TWST: Where do we go from here on the vision side?

Mr. Bye: There are two factors that are driving EPS for **VISX**. One is that it's highly leveraged to any kind of growth in procedures. One thing I forgot to mention is that with the custom product, VISX gets about a 150% premium for each custom procedure, so you've got a conversion of more and more custom procedures happening each quarter. Coupled with growth in the underlying procedures, you're talking about pretty dramatic growth in EPS for the company. That really started to kick in Q3 of 2002, and so you're going to have a gradual conversion of patients to custom as compared to regular lasik in 2004. So instead of getting \$100 for each eye, they're going to get \$240, and then you're actually going to see some rebounding growth in procedures. The incremental fee collected for custom procedures essentially drops straight to the bottom line, after tax.

Based on our estimate of modest growth in the underlying growth of procedures coupled with a continued conversion to custom procedures, we've estimated EPS of \$0.75 for VISX in 2004. That's up considerably over our estimate for 2003 of \$0.45, so you're taking about 67% EPS growth. And you're still only at a 5% penetration of the underlying market, as well.

TWST: They've got a fairly clear field, then.

Mr. Bye: As far as our favorite name in ophthalmology, we do like VISX, but it's a high beta name, and there's just not a lot of medium-term visibility on it; we believe it remains a quarter-to-quarter story in the near term. To that end, near-term trends still look very positive, and we expect a solid earnings report for Q4 and for management to raise current consensus estimates for Q1 when the company reports at the end of January. Nonetheless, longer-term forecasts for the industry and laser vision correction procedure growth were wildly underestimated at the start and then sort of wildly overestimated in the 2000-2002 time frame, so there's probably not a lot of confidence about what's going to happen next year. However, the five-year plan looks pretty rosy, given the underpenetration and the improving results and the like, but at this stage, it's still a little bit of a quarter-to-quarter story. As we mentioned, Q4 looks quite good. Meanwhile, January bookings (which is the biggest month of the year) are way ahead of expectations.

While we like VISX and think it can outperform, we are cognizant of the fact that there is the potential for some volatility in the shares due to a lack of medium-term visibility. Meanwhile **Alcon** is our favorite name in the space and is sort of the bellwether in the group. They compete in every segment of ophthalmology except for contact lenses. They're a recent (2002) spinout from **Nestle**, although Nestle does maintain majority ownership. The first stage of Alcon's earnings story included a dominant but stable position in the ophthalmology market with ~10% top-line growth leveraged to 25% plus EPS growth through margin consolidation and margin improvements, primarily through improvements in SG&A and deleveraging on the debt front. This led to the company continuing to under-promise and out-deliver in terms of EPS growth over the past several quarters. However, clearly a deleveraging and margin consolidation story has a finite time frame. While the most important part of the story (Alcon's dominant position in ophthalmology) does not change, there is clearly less room in the P&L to leverage SG&A costs in 2004. Nonetheless, we have maintained our bullishness on the stock as we believe their story changes and gets better as we head into 2005 through the 2007 plus time frame. They've got four home-grown proprietary products that we conservatively estimate have the potential to move Alcon from a 9%-10% top-line grower to a potentially 11%-13% top-line grower and really drive operating income growth potentially north of 20% during those years as we estimate each of these products will have contribution margins well north of the corporate average of 25%-27%.

- 1/19 According to *Optistock.com*, privately held **Addition Technology** announced Q4 2003 sales of Intacs inserts increased 85% compared to the same quarter in 2002, and 32% ahead of Q3 2003. Sales in Europe and North America increased following news that the company received European regulatory approval for the treatment of keratoconus.
- 1/19 **QLT Inc.** announced a temporary discount to physician customers that will allow the purchase of Visudyne at a reduced cost of \$1,295, down from the current price of \$1,350. This decision was made in response to the reduction in reimbursement for Visudyne by Medicare on January 1, 2004, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed the rate of reimbursement for drugs that are covered by Medicare Part B. In general, the law specifies that the 2004 reimbursement for Medicare Part B drugs, which are not paid on a cost or prospective payment basis, will be 85% of the April 1, 2003 average wholesale price (AWP). In the case of Visudyne, the April 1, 2003 AWP was \$1,535, thus the current Medicare allowable reimbursement rate is \$1,304.75.

On December 31, 2003, the **QLT/Novartis** alliance filed a letter with the Centers for Medicare and Medicaid Services (CMS) requesting an exception to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 for Visudyne. By making CMS aware of the fact that physicians administering this sight-saving therapy are not just inadequately reimbursed, but actually financially disadvantaged, it is the hope of QLT and Novartis that CMS will make an appropriate adjustment to the 2004

reimbursement rate for Visudyne. They expect to hear from CMS on April 1, 2004 with their allowable price calculation response.

QLT will issue a press release on January 22, 2004, to coincide with Novartis' earnings release announcing Visudyne sales for 2003. In addition, QLT will announce results for the fourth quarter and full year 2003 and provide guidance for 2004 in a press release on February 11, 2004.

1/20 **STAAR Surgical Company** provided an overview of its meeting with the FDA held on Wednesday, January 14, 2004. As the company communicated during its conference call on January 7, the meeting was scheduled to discuss the Warning Letter received by STAAR Surgical on December 29, 2003. According to David Bailey, chairman and CEO of STAAR Surgical, the company provided a written response to the Warning Letter within the required 15 business days and just prior to the Wednesday meeting. The meeting with the FDA, which was attended by Bailey and senior members of STAAR's management team, lasted approximately two hours and included attendees from various branches of the agency, including the Los Angeles office that carried out the inspections resulting in the issuance of the Warning Letter. During the meeting STAAR made a formal presentation of its response to the Warning Letter including a review of the action plan that had already been implemented to address the various issues raised by the FDA and a review of the Company's overall quality system.

"We believe the meeting was a very productive exchange that communicated to the FDA the company's commitment to aggressively address the FDA's issues and provided us with valuable input on how to fine tune our action plan," said Bailey. "We discussed with the agency the deficiencies in complaint handling and reporting of MDRs related to the Company's IOLs, shared with the agency the findings of some of our root cause analysis into the IOL product complaints highlighted in the letter, and reviewed the results of our efforts since receiving the letter on December 29th. While we have much work to do before we request a re-audit, I am pleased with the progress to date."

Bailey noted that STAAR will continue to implement corrective actions for the issues raised in the Warning Letter while awaiting response from the agency to STAAR's corrective action plan. The company currently has no indication when it will receive the response to the plan. "As we discussed during our conference call on January 7th, we must resolve the issues cited in the Warning Letter to the agency's satisfaction before approval of any new device, such as the ICL, can be granted. Returning to compliance with the FDA's guidelines is our number one priority. The issues raised in the Warning Letter clearly put a major strain on our original goal of receiving approval for the ICL four to six months after the FDA Panel meeting on October 3, 2003. Based on Wednesday's meeting, we continue to believe our original goal is possible to achieve, but much has to be accomplished for us to be successful. We will not request re-audit until we are confident we have taken all of the corrective actions necessary in all areas of our quality system. When we are ready for a re-audit, our expedited review status of the ICL will result in the local agency giving priority to the re-audit. We will issue a news release

when the company receives response to the company's corrective action plan," Bailey concluded.

1/21 On the following day, Joanne Wuensch of **Harris Nesbitt** issued her take on the Staar/FDA meeting -- **STAA--Discussion w/FDA Constructive; Solid Action Plan to Remedy Warning Letter Issues**. Some of her comments included:

- * Event--STAAR Surgical reported its 1/14/04 meeting with the FDA to discuss its 12/29/03 warning letter. The two-hour meeting resulted in a solid action plan, with many of the steps already taken (e.g., the company has completed the root cause analysis). Within a short-time frame, management has a lot of work to accomplish to prepare the company for a re-audit by the FDA to remain on track for an FDA approval of its phakic IOL.

- * Impact--We believe the company is stuck between a rock and a hard place: not wanting to disappoint the Street with a later-than-anticipated launch date for the phakic IOL and a tremendous human resource effort needed to meet the FDA requests. We believe they are rising to the challenge to try and meet the original approval goal of six-months post FDA-Panel date (April 3).

- * Forecasts--We maintain our forecasts. Should there be a delay in approval, we have but \$175,000 in US revenue associated with the phakic IOL in 1Q04E.

- * Valuation--Valuation range of 4-5x revenues in 2005 leads us to \$14-\$17 price target in 12-18 months.

- * Recommendation--We maintain our OUTPERFORM rating.

And Jayson Bedford of **Adams, Harkness & Hill** provided his thoughts on the Staar/FDA meeting: **STAA: Meeting w/FDA: ICL timing still uncertain**

Some of his comments included:

Key Points:

- * STAA meets w/ FDA and provides a written response (w/in the 15-day mandatory period) to the warning letter it received on December 29; STAA's response included a detailed plan of action and outlined the steps the company is currently taking to remedy the agency's concerns over MDRs and validation of outside testing firms.

- * Next steps include: 1) FDA's response to STAA's proposal, 2) STAA request for a re-audit of its facilities, and 3) an FDA inspection; STAA did not provide a timeline but noted that this process and the ICL approval process are following parallel paths within two arms of the FDA (however, we remind investors that the warning letter must be resolved before ICL approval).

* While management reiterated its goal for ICL approval before quarter's end, we continue to believe this may be optimistic; we model domestic ICL revenue beginning in 2Q'04.

* To come in-line with the company's 4Q pre-announcement, we are lowering our revenue estimate to \$12.5M (from \$13.1M), our net loss estimate is now \$0.12/ share (down from \$(0.10)); no change to our FY04 forecast.

* We reiterate our Buy rating and our 12-month price target of \$12; our rating reflects our long-term belief in the technology and the opportunity but also takes into consideration the increased uncertainty around the timing of ICL approval, which should persist in the near term.

1/22 **QLT Inc.** reported that its alliance partner, **Novartis**, announced global Visudyne (verteporfin) sales of approximately US\$95.9 million for the quarter and US\$357 million for the year ended December 31, 2003. Visudyne sales for the fourth quarter and the full year represent increases of 24% and 24% over sales in the fourth quarter and annual sales in 2002 respectively.

1/22 Michael Lachman of **ThinkEquity Partners** issued a preview of **VISX's** upcoming release of fourth quarter results: **EYE: Channel Checks Support Our Above-Consensus Q4 EPS Estimate**

Some of his comments included:

VISX reports its Q4-03 results after the market close on January 27. We forecast EPS of \$0.15 (versus guidance of \$0.13-0.15 and consensus of \$0.14). Our recent channel checks support our above-consensus estimate. Feedback from LASIK service providers (corporate centers and individual surgeon practices) is consistent with our forecast of 5% sequential growth in procedures in Q4. We are also comfortable with our CustomVue conversion forecast of 31% for Q4, ahead of the high 20%'s company guidance. Current visibility on a strong Q1-04 suggests about \$0.01-0.02 of upside to our \$0.20 estimate. We suspect that Q1 guidance will be consistent with this \$0.21-0.22 outlook, but would not expect management to raise full year guidance by more than \$0.01-0.02, if at all, given the dependence of the LASIK market upon consumer confidence and the lack of strong visibility beyond the current quarter.

Investment Highlights -- VISX reports its Q4-03 results after the market close on January 27. We are forecasting \$37.9 million in revenue, and EPS of \$0.15 (versus guidance of \$0.13-0.15 and consensus of \$0.14).

Our recent channel checks support our above-consensus \$0.15 EPS estimate for Q4. The key inputs to our model that drive current earnings performance are LASIK procedure growth, the rate of conversion to CustomVue wavefront-guided procedures, and operating expenses. We note that hardware system sales can be quite variable and

unpredictable from quarter to quarter, making total revenues tough to peg, but hardware variability tends to have a negligible impact on EPS due to the narrow margins. Feedback we have received from LASIK service providers (corporate centers and individual surgeon practices) points to procedure volumes in Q4 that were somewhat ahead of Q3 levels. This is consistent with our model, which calls for 5% sequential growth in procedures in Q4. We are also comfortable with our CustomVue conversion forecast of 31% for Q4, ahead of the high 20s company guidance.

Sensitivity analysis: what would it take to drive another penny of EPS upside? While we do not foresee Q4 EPS of \$0.16 or higher, we are often asked what it would take to get there. We offer the following sensitivities from our VISX model:

- * We are forecasting 195,000 VISX procedures for Q4, representing 5.4% sequential growth. In order to drive an additional penny of EPS, procedures would have to grow 8.6% sequentially, to 201,000. We do not believe that our channel checks support this level of sequential growth for Q4.

- * Our estimate for Q4 CustomVue conversion stands at 31%. This estimate is above company guidance and we believe above Street consensus for Q4, but we are comfortable with this number following our recent field contacts. In order to drive a penny of EPS upside, CustomVue conversion would have had to reach 35% in Q4, which is unlikely given the company's 2004 full-year guidance of 33-37%, issued on November 7.

- * Operating expenses would have to come in \$800,000 lower for Q4 than we are forecasting to drive an additional penny of EPS. Given the fact that the American Academy of Ophthalmology meeting took place in Q4, and our expectation that VISX will continue to invest in growth during the current LASIK market resurgence, we would not expect a spending shortfall at this time.

Visibility on a strong Q1-04 suggests upside to our current \$0.20 estimate. We are currently forecasting 8% sequential and 12% year/year procedure growth for Q1, to 211,000 total VISX procedures. Our channel checks indicate that January procedure volumes have been very strong, and February is shaping up to be stronger than usual as well. If year/year procedure growth reaches 15-20% in Q1, versus our current 12% forecast, there could be \$0.01-0.03 of EPS upside in the quarter. We would note, however, that our current 40% CustomVue conversion forecast for Q1 is probably aggressive, and lowering this estimate to the mid-30%'s subtracts a penny from EPS. Netting this out, there is probably up to \$0.02 of upside to our current estimate for Q1, and to our full year estimate of \$0.75 as well if we assume no change to our Q2-Q4 forecasts. Over the past week, as Q1 visibility has solidified, the consensus estimate for Q1 has inched up from \$0.20 to \$0.21 and the full year consensus has gone from \$0.74 to \$0.75.

We suspect that Q1 guidance issued on next week's call will be consistent with this \$0.21-0.22 outlook, but would not expect management to raise full year guidance of

\$0.70-0.74 by more than \$0.01-0.02, if at all. While 2004 has started out strong, it remains to be seen if this level of strength will continue beyond Q1. The LASIK market is highly dependent upon consumer confidence, which makes medium and long-term visibility difficult. While the service providers with whom we have spoken report solid visibility into February surgery schedules, they are generally reluctant to project more than "cautious optimism" into the spring season and beyond. We note that achievement of our Q2-Q4 estimates does not require heroic procedure growth: we project only 6% year/year procedure growth for VISX during this period. Procedure growth for Q2-Q4-2004 would have to reach 9% year/year (consistent with 8-10% company guidance) if we were to moderate our CustomVue conversion forecast from 47% down to 42% for the full year.

Valuation and price target: While VISX stock is currently trading at 34x our 2004 EPS estimate of \$0.75, which somewhat exceeds the small-mid cap medical device peer group average of 31x, we base our 12-month price target of \$29 on a 30x multiple applied to our 2005 EPS estimate of \$0.97. Our \$29 price target represents 12% upside from current price levels.

Risks to Target Price and Investment Thesis --Laser vision correction (LVC) procedure fees generate a majority of VISX's profits. Risks to procedure volumes include continued sluggishness in the U.S. economy and any resulting impact on consumer confidence, market share losses to competitors, and saturation of the potential market of patients interested in LVC. Any reduction in the per-procedure fee that VISX receives, and/or any limitation in the company's ability to garner a premium fee for CustomVue ablations, would also impact procedure-fee revenue. Slower-than-expected customer conversion to CustomVue would impact procedure revenue forecasts. Any such challenges in the market for LVC procedures would also likely impact the company's hardware business as well. Any regulatory action against VISX, resulting from real or perceived clinical complications, could limit the company's ability to sell hardware or receive procedure fees. Because LVC is an elective procedure, regulatory scrutiny could be more intense than normal for a medical technology, and the company could suffer a marketing backlash even in the absence of formal regulatory action. As the LVC market leader, VISX could be affected by problems experienced by a competitor.

- 1/22 As reported in the January 2004 issue of *EuroTimes*, Cheryl Guttman wrote about a study presented at the recent ESCRS meeting in Munich: **"Early study results shows differences in LASIK systems"**

A comparison study of leading LASIK systems demonstrates differences between wavefront aberrometers with respect to how and what they measure, which may reflect differences in clinical outcomes. Researchers at the Magill Research Center, Storm Eye Institute are conducting a prospective, randomized clinical trial of several available systems for conventional and customized LASIK. Helga Sandoval, MD presented the design and early findings from the study at the *XXI Congress of the European Society of Cataract and Refractive Surgeons*. The investigation will involve a total of 120 eyes of 60

patients who will undergo conventional LASIK with the LADARVision (**Alcon**), Technolas 217z (**Bausch & Lomb**), or the S4 (**VISX**) systems, or custom ablation with CustomCornea (Alcon), CustomVue (VISX), or Zyoptix (Bausch & Lomb) systems.

The LADARWave (Alcon), WaveScan (VISX), and Zywave (Bausch & Lomb) aberrometers are being used to measure higher order aberrations (HOAs) in all patients pre- and postoperatively. Baseline and follow-up assessments also include contrast sensitivity testing (Optec 3500, Stereo Optical) at spatial frequencies of 1, 3, 6, 12, and 18 cycles/degree, and determination of subjective vision quality with a questionnaire. The preliminary results presented at the ESCRS included 16 patients who reached the one-month postoperative visit. Two of those patients had conventional treatment with the Visx S4, three with the Alcon LADARVision lasers and one with the Bausch & Lomb Technolas 217A laser. Ten patients had custom ablation, half with the Visx CustomVue system and half with the Alcon CustomCornea system. Dr Sandoval reported an apparent benefit for custom versus conventional treatment when comparing the two Alcon systems. Patients receiving the custom ablation procedure had significantly fewer HOAs at the one month follow-up.

She also noted improvements in contrast sensitivity and driving vision following the custom treatment relative to conventional LASIK. So far, use of CustomVue has not been associated with a benefit for minimizing induction of HOAs relative to conventional LASIK with the S4, although that may coincide with the finding that conventional LASIK with the S4 laser seems to induce less HOA than conventional treatment with the LADARVision system. "There has been a paradigm shift in evaluating outcomes of refractive surgery to consider not just attainment of 20/20 or better Snellen acuity, but also the quality of vision. Therefore, it is important to understand the effects of our treatments on lower and higher order aberrations and aim to reduce or at least avoid inducing higher-order aberrations.

This study is designed to evaluate the potential benefits of custom ablation for achieving those goals and to compare different lasers. However, we want to emphasize that these findings are just preliminary and from a small sample size, and it remains to be seen if they are maintained or change as more patients are enrolled and our follow-up continues," said Dr. Sandoval. The preliminary comparisons of measurement of HOA RMS values presented were based on data from the 32 eyes that have completed one month. Data for all three instruments were standardized for a 6.0 mm pupil size. At baseline, mean values were lowest with the WaveScan and highest with the Zywave, and while all systems demonstrated an increase in both mean total HOA and mean spherical aberration RMS after surgery, there were also differences between devices in the amount of change measured.

"With the WaveScan, aberrations are measured without pupil dilation, and since pupil size is not 6.0 mm in all eyes, this reduces the sample size for comparison," Dr. Sandoval observed. Comparison of total HOA measured with the LADARWave aberrometer showed that the ten eyes undergoing CustomCornea treatment and six undergoing

conventional LADARVision LASIK had comparable levels of mean total HOA RMS at baseline. However, total HOA RMS increased almost 100% after conventional LASIK versus only 10% following CustomCornea treatment. Measurements performed with the WaveScan aberrometer in a smaller cohort of eyes yielded different results. Comparing data from six eyes treated with CustomCornea and four eyes treated with conventional LADARVision LASIK showed that the mean total HOA was lower in the conventional LASIK group at baseline and increased more than 100%.

By comparison, WaveScan aberrometry indicated that the mean total HOA in the CustomCornea group decreased slightly from baseline. The researchers also measured total HOAs before and one month after LASIK in four eyes undergoing conventional LASIK with the Visx S4 and seven eyes undergoing custom ablation with the WaveScan aberrometer. At baseline, mean total HOA was about 0.1-microns lower in the conventional ablation group, 0.3 vs. 0.4-microns. But at one month total HOAs were essentially unchanged in both groups. Using the LADARWave aberrometer to measure total HOA in the same patients showed baseline values were the same as those measured with the WaveScan. However, the LADARWave results indicated both treatments increased total HOA with the increase being greater with conventional LASIK.

Contrast sensitivity studies performed with low illumination and no glare showed CustomCornea treatment was associated with an improvement of at least 25% at all spatial frequencies tested, while contrast sensitivity was generally unchanged after conventional LADARVision treatment or following CustomVue or conventional treatment with the VISX S4. Consequently, the preliminary comparison of the effects of the Alcon and VISX customised ablation treatments showed a slight difference between CustomCornea and CustomVue. When testing was performed under low illumination with a glare source, contrast sensitivity was still improved by about 25% at all spatial frequencies after CustomCornea treatment whereas it was relatively unchanged or worsened after conventional LADARVision and CustomVue treatment. Consistent with those findings, results from the questionnaire responses showed a significant benefit for improved driving vision after CustomCornea treatment compared with conventional LADARVision, which was associated with no change in driving vision score.

Glare also improved after CustomCornea treatment, while it worsened after conventional LADARVision treatment. The difference between treatments showed only a trend to statistical significance. While these findings are some of the first to compare LASIK systems head to head, the results are preliminary and part of an ongoing study. More comprehensive results will be presented as the study proceeds.

Helga Sandoval, MD Magill Research Center for Vision Correction Storm Eye Institute, Medical University of South Carolina, Charleston SC sandoval@musc.edu

1/23 **QLT Inc.** announced that its Registration Statement on Form S-3, with respect to the resale of its \$172.5 million aggregate principal amount 3.0% Convertible Senior Notes due 2023 and the common shares issuable thereunder, was declared effective on Friday,

January 23, 2004, by the U.S. Securities and Exchange Commission. QLT will not receive any proceeds from the resale of the Notes and underlying common shares.

- 1/26 **TLC Vision Corporation** announced it's subsidiary, **TLC Michigan, LLC**, had acquired a majority ownership interest in **The Blake Woods Surgery Center** located in Jackson, Michigan. The Blake Woods Surgery Center provides both patients and physicians with a surgical environment ensuring patient care of the highest quality. Fully staffed by a proven team of medical professionals, Blake Woods' 10 physicians represent several surgical specialties, with the majority providing ophthalmic procedures. The doctors of Blake Woods have been practicing in the Jackson area medical community for an average of 15 years.

Dr. Paul Ernest, an innovator of sutureless cataract surgery and one of the most respected and highest volume cataract surgeons in North America, is Chairman of TLC Michigan. Dr. Ernest said, "I am very excited about being associated with The Blake Woods Surgery Center. This ambulatory surgery center offers patients a more pleasant --- and less stressful -- experience. It was purposely designed for comfort, convenience and efficiency. The center is staffed by a team of experienced professionals and committed to achieve results."

Elias Vamvakas, TLCVision's chairman and CEO, commented "As we've stated in the past, we expect to continue to acquire or develop similar centers in association with some of the country's most prominent surgeons, all of which will immediately contribute to TLCVision's cash flow and profitability."

OPHTHALMIC LASER UPDATE -- February 2004

- 1/27 **Advanced Medical Optics, Inc.** announced preliminary financial results for the year ended December 31, 2003. The company expects to post net revenue of approximately \$600 million, compared to \$538 million in 2002. AMO's preliminary 2003 net revenue grew approximately 12%, compared to 2002. Excluding the effect of currency, 2003 preliminary net revenue grew approximately 3%.

AMO expects pro forma 2003 earnings per share to be \$0.79 to \$0.80, representing an approximate 30% increase over pro forma 2002 earnings per share of \$0.61, and ahead of earlier company guidance for 2003 of \$0.77 to \$0.78.

"These preliminary 2003 results exceed our previously announced guidance and demonstrate our continued success in positioning AMO for sustained growth in both of our core businesses," said James Mazzo, president and CEO. "During our first full year of independence, we stabilized and re-established growth in both businesses, re-prioritized our R&D pipeline, solidified our manufacturing strategy, recapitalized our balance sheet and delivered innovations to the marketplace that improve practitioner productivity and patient outcomes. As a result, AMO delivered superior financial performance to shareholders."

1/27 **VISX, INCORPORATED** announced financial results for the fourth quarter and twelve months ended December 31, 2003. Fourth quarter revenues increased 6% to \$38.2 million from \$36.1 million for the comparable period of the prior year. Net income was \$8.8 million (17 cents per share) in the fourth quarter of 2003 compared with a net loss of \$1.5 million (3 cents per share) in the comparable period of the prior year.

Revenues for the twelve months were \$143.9 million compared with \$139.9 million for the comparable period of the prior year. Net income was \$23.3 million (46 cents per share) compared with net income of \$15.3 million (29 cents per share) in the comparable period of the prior year. The 2002 fourth quarter and fiscal year end results included a litigation settlement pre-tax charge of \$9.0 million.

Liz Davila, chairman and CEO of VISX, stated, "Strong CustomVue procedure conversion continued this quarter, increasing our license and other revenue by 48% compared with last year's fourth quarter. CustomVue represented approximately 29% of the procedures ordered in the quarter and contributed significantly to our increase in gross margin from 58% in last year's fourth quarter to 70% in the fourth quarter this year. We shipped 97 WaveScan units in the fourth quarter, bringing total shipments to 440 in 2003 and to over 700 WaveScan placements since we began shipping the product. Our focus on CustomVue's success resulted in incremental sales and marketing expenses in the quarter that were more than offset by a \$3.0 million legal insurance reimbursement." Davila continued, "For the fiscal year, VISX growth in revenue and earnings compared to last year is directly associated with our introduction of CustomVue procedures. As the economy continues to improve, we believe that we will see market growth that should further impact our financial performance. We are very pleased with our results and believe that we will experience continued top and bottom line growth in 2004."

2003 Highlights:

- * VISX introduced the CustomVue procedure in the U.S. in June 2003. CustomVue offers individualized treatment of vision and has the potential to offer better vision than contacts or glasses.

- * VISX purchased all technology related to its WaveScan product from **20/10 Perfect Vision**. WaveScan provides the diagnostic evaluation for CustomVue procedures.

- * VISX purchased 3.5 million shares of its stock, bringing its total purchases to 23.6 million at an average price per share of approximately \$14.98.

- * VISX generated \$27 million in cash from operations in 2003 and ended the year with a cash and equivalents balance of \$86 million.

Financial Outlook:

VISX reiterated its 2004 outlook of revenue in the range of \$167 million to \$171 million and earnings per share of \$0.70 to \$0.74. It anticipates that first quarter 2004 revenue will increase compared with the first quarter last year and be in the range of \$41 million to \$43 million and earnings will increase significantly to \$0.18 to \$0.20 per share.

Following the announcement and subsequent teleconference, several analysts issued updated reports.

Jason Mills of **First Albany Capital -- EYE/Neutral: 4Q03 Results Mixed - Disappointing Procedural Volume; Reiterate Neutral**. Some of his comments included:

- * VISX's 4Q reported EPS of \$0.17 included \$3M insurance reimbursement offset by a \$0.5M one-time charge. Excluding one-time items, we estimate EPS were in line with our \$0.14 estimate. Revenue (\$38.2M) was lower than \$39.6M estimate.

- * Procedure volume results disappointed -- estimated 7.6% y/y growth (166,000 estimate) vs. our 18.3% estimate (183,000) -- at roughly 17,000 procedures lower, which drove licensing revenue shortfall excluding royalties (\$22.7M estimated) vs. our estimate (\$24.6M).

- * CustomVue conversion (29%) was in line (30% estimate), yet the shortfall in procedures drove lower CV cards (48,225 estimated) vs. our estimate (54,826).

- * The gross margin was notably higher than our estimate by 590 basis points (70%), owing to a favorable mix and a rebound in system margins, giving us confidence in our expectations that the company will sustain this gross margin level in 2004 (estimate 70.4%).

- * We think business' fundamentals, while strong currently relative to past 3 years, are tracking modestly below our expectations.

Primary concerns: 1) procedure shortfall in 4Q, 2) 1Q:04 guidance below our estimates, 3) 2004 guidance reiterated, but not raised, 4) lack of visibility (of procedure volumes), namely 2H04, and 5) competition intensifying.

- * We believe EYE common is modestly over-valued at current levels. We are lowering our 12-month price target to \$26 and reiterating our Neutral stance.

Joanne Wuensch of **Harris Nesbitt -- EYE--Good Quarter, But Is the Cart Ahead of the Horse?**

- * **Event** -- VISX reported 4Q03 results of \$38.2 million in total revenues (up 5.7%), which exceeded our estimate of \$37.1 million and EPS of \$0.17 (up an impressive 134.1%), besting our and the First Call consensus for \$0.14. Excluding a \$3-million insurance reimbursement, EPS would have met our \$0.14 estimate.

* **Impact** -- While 4Q03 showed continued business improvement with solid custom ablation adoption, 1Q04 management guidance did not meet Street consensus: VISX guided for revenue of \$41-\$43 million and EPS of \$0.18-\$0.20, but Street consensus is \$0.21. Further, turning to the full-year 2004, management guidance is for EPS is in the range of \$0.70-\$0.74, but consensus EPS is \$0.75 (ranging from \$0.63 to \$0.79).

* **Forecasts** -- We are increasing our revenue estimate for 1Q04 to \$41.8 million (up 21.3%) from \$40.9 million and our EPS by a penny to \$0.19 from \$0.18. In 2004, our revenue estimate increases to \$157.7 million (up 9.6%) from \$154.5 million and our EPS estimate rises to \$0.66 from \$0.63. In 2005, our revenue and EPS estimates of \$166.5 million (up 5.6%) and \$0.82 are up from \$165 mn and \$0.79.

* **Valuation** -- Our price target is \$24 based on 30x our 2005 EPS estimate \$0.82.

* **Recommendation** -- We maintain our NEUTRAL rating, in a POSITIVE sector rating.

Michael Lachman of **ThinkEquity Partners** -- **EYE: Growth Outlook Remains Intact Following Solid Q4 Report.**

We maintain our Overweight-2 rating and 12-month price target of \$29 on VISX shares following a solid Q4 report that met our \$38 million revenue estimate and our \$0.15 EPS expectation after adjusting for one-time items (\$0.17 reported). We believe that the VISX growth outlook remains intact, although some investors may be disappointed that management did not focus more attention on the strong start to 2004 and provide higher guidance for Q1. Management reiterated prior guidance for 2004, and guided below consensus for Q1 based on normal trends for February and March, despite what we believe has been a very strong month of January for LASIK procedures. We maintain our \$0.20 estimate for Q1, at the top end of \$0.18-0.20 guidance, as well as our \$0.75 estimate for 2004, in-line with consensus and above the guidance range of \$0.70-0.74.

Investment Highlights -- VISX reported Q4 revenue of \$38.2 million, slightly ahead of our estimate of \$37.9 million. On a full year basis, the company recorded 2003 revenue of \$144 million and EPS of \$0.46. Revenues were driven by higher-than-expected equipment sales of 97 WaveScan diagnostic units and 30 excimer lasers, versus our estimates of 70 and 22, respectively. Given the highly competitive nature of the laser equipment market at present, just under half of all laser systems in Q1 were placed on operating leases, which defer hardware revenue recognition into future periods. For Q1, management is guiding to 45 WaveScan systems and 20-25 laser placements. Strong hardware revenue in Q4 was offset by 29% CustomVue conversion that came in slightly below our above-consensus forecast of 31% (but in-line with high 20%'s guidance), and by flat sequential LASIK procedure volume that fell short of our 5% sequential growth estimate. Procedures volumes in Q4 were impacted by a slowdown in late December, but 2004 has gotten off to a fast start.

VISX reported EPS of \$0.17 in Q4, exceeding our estimate of \$0.15 but meeting our expectation after adjusting for unusual items. In the quarter, VISX recorded a \$3 million legal insurance reimbursement, the last reimbursement of this type the company will receive, which reduced SG&A and added about \$0.04 to EPS. Management chose to spend about \$1.5 million of this windfall on incremental discretionary promotional activity (about \$1 million accounted for in SG&A and the other \$500,000 reflected as an offset to revenue). This incremental spending reduced EPS by about \$0.02, resulting in net upside to earnings of about \$0.02 in the quarter. Without these two items, EPS would have been in-line with our \$0.15 estimate.

We are maintaining our EPS estimates for 2004 and 2005 but fine-tuning assumptions within our model. Management reiterated its prior guidance for 2004, originally issued during the November analyst meeting, of \$167-171 million in revenues and \$0.70-0.74 in EPS. The company also guided to Q1 revenues and EPS (\$41-43 million, \$0.18-0.20) that fall short of current consensus estimates (\$44 million, \$0.21). Based on industry feedback pointing to a strong start to Q1, we had expected management to guide closer to the consensus numbers for Q1, and to possibly roll some of the upside into its full year outlook. For Q1, our revenue and EPS estimates remain at \$42 million and \$0.20, respectively. For the full years 2004 and 2005, we have increased our revenue estimates slightly, from \$166 million to \$167 million for 2004 and from \$188 million to \$190 million for 2005. Our full-year EPS estimates remain unchanged, with 2004 EPS of \$0.75 in-line with consensus and slightly above company guidance of \$0.70-0.74. In 2005, our EPS estimate remains \$0.97, representing 30% annual growth.

We have adjusted our model to reflect stronger industry-wide procedure growth trends, offset by slightly lower CustomVue conversion rates, in both cases closer to company guidance for 2004. Our industry-wide LASIK procedure growth forecast now stands at 10% for 2004, up from our previous forecast of 6% and lies at the middle of the company guidance range of 8-12% procedure growth. We lowered our full year 2004 CustomVue conversion forecast from 47% to 42%, which remains above the company's outlook for 33-37%.

Management updated the scheduled timelines for additional CustomVue indications. In mid-2004, VISX plans to launch CustomVue in international markets to treat presbyopia in hyperopic patients, and to begin enrolling patients in a clinical trial in the US. The company still expects H2-04 FDA approval for CustomVue to treat hyperopia with astigmatism, which would expand the addressable market for CustomVue from 70-75% today to about 90% of potential LASIK patients. VISX has pushed out the timeframe for approval for CustomVue in high myopia with astigmatism from H2-04 to H1-05, based on a decision to launch this indication with the latest version of the CustomVue software. High myopia represents a relatively small portion of the potential LASIK population, so we do not view this delay as meaningful in the context of our estimates.

VISX continues to reinforce its cash position and strong balance sheet. Cash flow from operations totaled \$13 million in Q4 and \$27 million for full year 2003. As of year-end,

the company carried \$86 million in cash and equivalents, and no long-term debt on its balance sheet.

Valuation and price target: We maintain our Overweight-2 rating on shares of VISX. Our 12-month price target of \$29 is based on a 30x P/E multiple applied to our 2005 EPS estimate of \$0.97. The 30x P/E multiple is in-line with current the peer group average for small and mid-cap medical device stocks. Our \$29 price target represents 11% upside from the current price.

Ted Huber of **Wachovia Securities -- EYE: Q403 Growth Disappoints Case For Big Upside Fades.**

* **The downgrade:** Though VISX hit our Q403 EPS target and our \$0.79 2004 forecast stands, disappointing Q403 volume growth, in the wake of an improving economy and successful Custom LASIK launch, reduces the odds for big 2004 EPS upside. Our now lower valuation and Market Perform rating reflect the slimmer odds for upside to our estimates.

* **Q4 Light:** License revenue grew just 3% adjusted vs. guidance of 8% to 12%. While Custom Mix (29%) hit VISX's and beat our target, volume growth disappointed; we calculate it at 7% y/y and down 1% sequentially. Adjusted EPS were \$0.15 (excluding a \$1.5mm one time net insurance benefit), \$0.01 ahead of guidance and in line with our estimate. Better than expected hardware sales (30 lasers and 90 wavefront devices) offset the procedure volume miss.

* **Cautious guidance reaffirmed:** VISX is sticking at \$0.70-0.74 in 2004 and rolled out a \$0.18- 0.20 Q104 estimate (consensus is \$0.75 and \$0.21). VISX still sees 8% to 10% volume growth in 2004 but higher in Q1 based on January results. We view these EPS targets as conservative by a penny or two per quarter. Our \$0.21 Q104 estimate is based on 32% Custom Mix and 11% volume growth. We remain confident in \$0.79 for 2004. Strong Q403 Wavefront placements bode well for 2004 Custom Mix but a delay in a high myopia Custom approval until 2005 caps the upside.

1/28 Even *The Dow Jones Business News* wrote up the **VISX** results in a story by Tiffany Kary: Visx Inc.'s shares lost 23% Wednesday as analysts said slowing procedure volumes for eye surgery may put fiscal 2004 earnings below Wall Street's optimistic estimates. Visx, which makes the equipment used to provide vision correction surgery, reiterated its earlier guidance for 2004, projecting earnings of 70 cents to 74 cents a share. The news came late Tuesday in a fourth-quarter report that beat estimates with the help of a legal insurance reimbursement.

But as Visx has seen success with the launch of its more precise, and higher margin, CustomVue Lasik procedure, analysts had been projecting 2004 earnings above the company's own estimates. Wall Street's consensus was for earnings of 75 cents a share, and many said individually that they had seen earnings even higher.

While many analysts said Wednesday that they believed the company's guidance is still conservative, some said that lower procedure volumes may indeed take a toll on 2004's results. The new data about procedure volumes put the stock close to a fair value, analysts said. **Goldman Sachs** noted that procedure volumes in the fourth quarter declined 1.8% sequentially, something which indicates "variability in procedure growth trends" since the fourth quarter is usually a strong one. Analyst Lawrence Keusch also said that the stock looks fairly valued in light of the data on procedure volumes. "We believe shares are priced to perfection in light of the risk that the procedure market stagnates should the economy not continue to improve," said Keusch.

Visx was downgraded by **Wachovia** due to similar concerns about disappointing fourth-quarter procedure volumes. But analyst Theodore Huber said he still sees the company's 2004 guidance as conservative. "Disappointing fourth quarter volume growth, in the wake of an improving economy and successful Custom Lasik launch, reduced the likelihood for a big 2004 earnings per share upside," Huber wrote. Nevertheless, Huber said he still sees the company earning 79 cents a share for the year.

S.G. Cowen analyst Peter Bye said the lower procedure volumes also affected the company's first-quarter guidance, which came in below analysts' expectations. "Analysis suggests that it was fourth-quarter procedures that were less than robust and sequential growth in the first quarter looks on track," Bye said.

In 4 p.m. EST trading on the New York Stock Exchange, Visx shares were at \$ 20.01, down 23%, or \$6.09. Visx's director of investor relations, Jackie Cossmon, said the company's fourth-quarter results and full-year projections were in line with estimates and said slower procedure volumes in the fourth quarter were a result of the holidays in late December.

Shares of **LCA-Vision Inc.**, which does the actual procedures, and is a customer for Visx's equipment, also declined Wednesday as the company reiterated its outlook for 2004 earnings of 80 cents to 85 cents a share on revenue of \$110 million. The earnings projection is slightly below Wall Street's estimates for 86 cents a share. The stock fell \$2, or 8.2%, to \$22.50 at 4 p.m. Wednesday on the Nasdaq National Market.

Maxim Group analyst Andrew Scott said the decline was due mostly to investors taking money off the table as the stock has rocketed to more than 10 times its year low of \$2.77, hit last February. He also said he believes the company's latest earnings forecast is still conservative.

David Harmon, president of ophthalmology research firm **Marketscope**, said that industry wide, procedures don't seem to be slowing. According to Market Scope's data, vision-correction surgeries for the fourth quarter likely rose about 8% from a year earlier. He did note that shares in both Visx and LCA-Vision had run-ups on high hopes for new, higher-margin custom procedures and said that "excitement got ahead of realistic expectations" among some Wall Street analysts.

- 1/29 **Carl Zeiss Meditec AG** participated in *Arab Health* - the most important medical exhibition in the Arabian world in Dubai. The company considered its participation as a success. In the commercial hub of the United Arab Emirates the company displayed its premium products for early recognition of widespread eye diseases such as glaucoma and age-related macular degeneration (AMD). The supplier of ophthalmic solutions was able to sign contracts for the supply of systems worth over Euro 100,000 and negotiate further major projects to the signature stage. Ulrich Krauss, president and CEO of Carl Zeiss Meditec, offered words of praise, "We are pleased that our attendance at this exhibition has once again demonstrated our global presence. Premium technologies and innovative power are available to our customers in all four corners of the earth."

Carl Zeiss Meditec AG is preparing a further major project in Dubai -- the establishment of a reference centre in a newly-constructed hospital. The first equipment system, a state-of-the-art MEL 80 excimer laser for the treatment of vision defects, is due to be installed there within the next few days. Ulrich Krauss explained, "We are certain that the Carl Zeiss Meditec reference centre will send out positive impulses to the whole Arabian peninsular. As the commercial centre of the region, Dubai has invested large sums in establishing a highly developed health system and offers an excellent standard of medical care."

- 1/29 **QLT Inc.** and **Novartis Pharma AG, Ophthalmics**, the eye health unit of **Novartis AG**, announced that the Centers for Medicare & Medicaid Services (CMS) had determined that the evidence supports reimbursement for patients treated with Visudyne for age-related macular degeneration (AMD) with occult and minimally classic lesions that are four disc areas or less in size and have evidence of recent disease progression. Medicare already offers coverage for Ocular Photodynamic Therapy (OPT) in AMD with predominantly classic lesions.

"This is a significant event for the many people who suffer from the occult and minimally classic forms of AMD who presently have no treatment options available to them," said Paul Hastings, president and CEO of QLT Inc.

"Age-related macular degeneration is the leading cause of blindness in people over the age of 50, and during the last 3 years, OPT has helped to reduce the risk of vision loss for tens of thousands of patients. We believe many more will now benefit from the therapy," said Flemming Ornskov, MD, president and CEO of Novartis Ophthalmics Inc.

Developed by Novartis Ophthalmics Inc. and QLT Inc., OPT is marketed under the trade name Visudyne.

- 1/29 **Bausch & Lomb** reported worldwide sales of \$550.1 million in the fourth quarter ended December 27, 2003, an increase of 15% (or 7% on a constant-currency basis) over the \$477.4 million reported in the prior-year period. GAAP earnings per share were \$0.92 in 2003, compared to \$0.60 in the year-ago quarter. Excluding certain non-recurring

items discussed below, comparable-basis earnings per share in the 2003 fourth quarter were \$0.83, a 38% increase over 2002.

Full-year 2003 net sales were \$2.02 billion, up \$202.8 million or 11% from 2002, and up four% on a constant-currency basis. GAAP earnings per share from continuing operations were \$2.36, compared to \$1.34 in 2002. Comparable-basis net earnings from continuing operations were \$2.27 in 2003, up 31% from \$1.73 in 2002.

Bausch & Lomb chairman and CEO Ronald Zarrella said, "We are very satisfied with our 2003 financial results, which were in line with our expectations for mid-single-digit constant-currency revenue growth and margin expansion from our profitability improvement programs. In the end, the cost savings delivered by those programs surpassed our initial expectations and foreign currency worked to our benefit, resulting in bottom-line results ahead of our original thinking. We have now posted two solid years of improved financial performance, and look forward to building on that in 2004 and beyond."

Refractive Surgery: Double-digit increases in constant-currency refractive surgery revenues in both the Americas and Asia offset moderate declines in Europe. Higher sales of laser equipment and per-procedure cards primarily reflected the fourth-quarter U.S. Food and Drug Administration approval of the company's Zyoptix system for customized LASIK surgery. Refractive sales for the quarter were \$43.9 million, and for the year, \$133.0 million.

Several analysts issued update reports following the B&L financial release.

Joanne Wuensch of **Harris Nesbitt -- BOL--4Q03 Results; Expense Management Creates Upside Surprise.**

* **Event** -- Bausch & Lomb reported better-than expected 4Q03 results that were driven by expense management and foreign exchange. Revenue and EPS of \$550.1 million (up 15.2%; up 7% on a constant-currency basis) and \$0.83 (up 38.1%) bested our \$515 million and \$0.79 estimates (consensus was also \$0.79).

* **Impact** -- We believe the company's corporate restructuring and expense leveraging initiatives put in place over the last several years are reaping the benefits.

* **Forecasts** -- We have increased our revenue and EPS estimates in 2004 to \$2.169 billion (up 7.4%) and \$2.62 (up 16%) from \$2.116 billion and \$2.53, respectively. In 2005 our revenue and EPS is increased to \$2.321 billion (up 7%) and \$3.00 (up 15.6%) from \$2.253 billion and \$2.85, respectively.

* **Valuation** -- In valuing BOL, we have tried to balance potential upside to estimates coming from the company's restructuring efforts against a single-digit top-line growth rate. Our valuation range for BOL is 1.2x to 1.3x its long-term growth rate or 18x-20x

our 2005 EPS estimate of \$3.00 yielding a price target range of \$54-\$60. Our single-point price target is remains \$57.

*** Recommendation** -- We maintain our NEUTRAL rating with a POSITIVE sector rating.

Jason Mills of **First Albany Capital** -- **BOL/Strong Buy : Strong 4Q:03 Results - Upside Train Keeps Chugging Along - Reiterate Strong Buy.**

*** Upside Revenue** -- \$550M beat our \$528M estimate - Constant currency (CC) growth of 7% vs. 5.5% estimate. Product line CC guidance suggests upside potential to total sales guidance (+4-6%). Notable strong performance in contact lenses, lens care, and refractive.

*** Upside EPS** -- \$0.83 (ex-\$0.09 net gain) exceeded \$0.79 estimate. We think solid visibility into expense accounts, and conservative top-line growth guidance will translate into further upside. Estimate FX contributed \$0.02.

*** Margins Impacted by FX** -- GM of 57% was below our 59% estimate, as favorable top-line FX impact was offset in GM (naturally hedged to Euro). OI margins made up 140 bps of the difference - only modestly below our target (14.1% vs. 14.7%).

*** Guidance Raised (Again)** -- Raised 2004 EPS guidance to \$2.60-\$2.65 from \$2.50-\$2.60. Raising our estimate to \$2.65 from \$2.62. In 2005, our EPS target goes up a penny, to \$3.11.

*** More Upside Lurking in 2005?** We find it hard to believe there isn't potential upside to 2005 EPS estimates as well. Our model calls for an 80 bps improvement in GM (guidance 100 bps), yet only an incremental 20 bps leverage from op-ex, even though we expect most of the leverage from the planned IT consolidation to favorably impact the P&L in 2H:05.

Michael Lachman of **ThinkEquity Partners** -- **BOL: Another Solid Quarter, Currency Tailwind Still at Bausch's Back.**

We are raising our 12-month price target for Bausch & Lomb shares from \$56 to \$58, based on higher EPS estimates, and maintaining our Equal Weight-4 (positive bias) rating. Bausch reported another solid quarter, beating top and bottom line estimates, with most business segments meeting or exceeding our forecasts. Currency remains a positive contributor, accounting for nearly all of the revenue outperformance in the quarter, and cost cutting progress remains on track. Beyond FX, the quarter was very much in-line with expectations, with earnings upside driven by below-forecast R&D spending and a number of small positive variances below the line. Our ongoing Equal Weight rating anticipates continued solid business execution, offset by risks associated with a thin

product pipeline and the potential top and bottom line impacts should the dollar strengthen against foreign currencies.

Investment Highlights -- Bausch & Lomb reported another solid quarter, beating our top and bottom line estimates, boosted by currency and continued cost reductions. Total revenues of \$550.1 million (+15%, +7% constant currency) beat our \$530.7 million estimate. However, we estimate that the weakening dollar during Q4 could have contributed an incremental 3-4% to reported revenue growth, accounting for most of this difference. Recognizing the natural hedges that are in place due to international operations and looking to the gross profit line, we note that gross profit of \$313.6 million was in-line with our forecast.

Most business segments performed well, meeting or exceeding our forecasts when adjusted for incremental FX benefit. Vision Care sales increased 14% (+6% constant currency) to \$290.3 million, with both contact lenses and lens care performing in-line with our expectations. Pharmaceutical revenues were up 19% (+10% constant currency) to \$126.8 million, below our forecast on an FX-adjusted basis. Surgical sales were up 15% (+7% constant currency) to \$133.0 million, ahead of our forecast. Within Surgical, cataract and vitreoretinal products met our revenue expectations, while refractive surgery solidly outperformed following the early Q4 FDA approval of the Zyoptix system.

Business Segment Highlights -- Vision Care. Sales of contact lenses increased 15% (6% constant currency) and lens care solutions increased 12% (6% constant currency). By geography, the contact lens segment grew 14% in the Americas, 16% in Europe and 16% in Asia (or 12%, 1% and 6% respectively on a constant currency basis). The company's core group of specialty and frequent replacement product lines grew a strong 38% (26% constant currency) and continue to be key drivers of domestic and international sales growth. We expect growth in contact lenses to continue in 2004 as SofLens66 Toric and SofLens Multifocal are marketed in additional geographies and as SofLens one day lenses are launched in Japan this quarter. Daily disposable contact lenses in Japan represent a \$300 million-plus market segment, dominated today by Johnson & Johnson, making this the most important new product opportunity for Bausch & Lomb in 2004.

Contact lens care sales growth was solid, given the backdrop of flat to low-single-digit market growth. Once again driven by strong ReNu sales, the Americas division continued to gain market share while posting growth of 14% (12% constant currency), supported by solid results in Asia (+11%, +3% constant currency). Lens care sales in Europe (+9%, -5% constant currency) suffered from declining sales of older products. The company plans a global launch of its next generation solution platform in 2004.

Pharmaceuticals. Pharmaceutical revenues were up 19% (+10% constant currency) to \$126.8 million, below our forecast on an FX-adjusted basis, with growth led by Ocuvite PreserVision ocular vitamins. Pharmaceutical sales grew 7% in the Americas and 33% (13% constant currency) in Europe. Bausch & Lomb continues to dominate the ocular vitamin arena, with US market share holding steady at over 70%. Vitamins are growing

at about 30% annually, and should continue to be a positive contributor to pharmaceutical sales growth in 2004. We expect Bausch & Lomb to maintain or grow its share in this market as the company defends its newly issued patents for these products. For 2004, positive contributors to pharmaceutical sales growth should be continued growth in ocular vitamins, along with the H2-04 launch of an anti-inflammatory antibiotic combination product (loteprednol plus tobramycin). Continuing weakness in proprietary and US generic product lines, and the negative impact of German pricing legislation, will likely offset growth.

Management also made an official announcement regarding the halting of Retisert development for diabetic macular edema (DME) and age-related macular degeneration (AMD) indications, which had been widely anticipated. The company remains on track to submit an NDA filing for Retisert for posterior uveitis in Q3-04, and upon approval, plans to launch the product in 2005.

Surgical. Within Surgical, cataract and vitreoretinal sales increased 10% (2% constant currency) overall, 2% (+1% constant currency) in the Americas, 22% (+6% constant currency) in Europe, and 3% (-6% constant currency) in Asia. Drivers include the SofPort system and Akreos acrylic IOL, which should see healthy year-over-year comparisons in 2004. The Akreos lens will likely not enter the US market before late 2005. The company lost share in the Japanese IOL market, due to lack of an acrylic IOL product.

The Refractive business was led by the Americas (over 50% growth) and Asia (up 15%, 10% constant currency) divisions, offset by sluggish sales in Europe (+7%, -7% constant currency). Revenue growth in the Americas business was propelled by pent-up demand for upgrades (about 80% of existing sites were upgraded in Q4) and new lasers following the early Q4 FDA approval of the Zyoptix wavefront-guided LASIK system. Refractive revenue growth in Q4 was driven by roughly equally by equipment sales and procedure card sales. The company has a stated medium-term goal of 20% procedure share in the US LASIK market, which remains a challenging objective. The recently announced deal with discount service provider Lasik Vision Institute should begin to contribute revenues in Q1. In 2004, the company plans to launch a new microkeratome and precision blades, which should help stem share losses in this area.

Ted Huber of **Wachovia Securities -- BOL: Zyoptix Leads Strong Q403, Raising Estimates.**

*** Q403 Beats forecasts (again):** Bausch's \$0.83 operating EPS beat consensus \$0.79, driven by 7% constant currency revenue growth (highest since Q302). Strong pharmaceutical sales (10% constant currency) were led by ocular vitamins, with the Zyoptix launch driving 19% constant currency refractive growth. The lens care business posted 6% constant currency growth in a market that is flat to down, while gross margins of 57% were negatively impacted by foreign exchange (100 bps).

* **Raising forecasts:** We are increasing our 2004 EPS estimate to \$2.64, at the high end of management's \$2.60-\$2.65 guidance range. We are also increasing our 2005 EPS forecast to \$3.05 from \$3.03. 2004 model changes include a higher constant currency growth (10 bps to 5.1%), augmented by a larger currency contribution (150 bps to 3.1%), partially offset by a corresponding negative gross margin impact (80 bps to 58.3%).

* **Turnaround on track:** Bausch delivered its eighth straight quarter of upside to consensus EPS forecasts and is well on its way to unlocking the \$3.50+ potential earnings power of a 14% operating margin on our 2005 revenue base. Demonstrating the strength of the margin improvement, BOL plans to increase its R&D budget by 20% in 2004 (up 35% normalized for Retisert program cut). Improving visibility into the efficiency of the incremental R&D spend is critical to viewing Bausch as a growth story.

1/30 Tiffany Kary of *DOW JONES NEWSWIRES*, wrote about **LCA Vision** and an interview with its chairman, Stephen Joffe.

The chief executive of LCA-Vision Inc. expects the provider of corrective eye surgery to report a 56% gain in fourth-quarter revenue and said he is "extremely comfortable" with Wall Street's earnings estimates. The company's guidance would put fourth-quarter revenue at \$20.7 million, above the average analyst estimate of \$19.6 million. The company will report fourth-quarter results in late February.

Chief Executive Stephen Joffe told Dow Jones Newswires that the company's strong revenue growth came from three factors: increased volume in eye surgery procedures, which rose by 32% year-over-year; increasing market share; and a higher number of more costly Custom Lasik procedures.

LCA-Vision's guidance comes on the heels of concerns that procedure volumes may not be keeping pace with Wall Street's expectations. Visx Inc. which makes equipment for the procedures, issued 2004 earnings guidance late Tuesday that was below Wall Street's expectations, and analysts said slowing procedure volumes for eye surgery may hurt results.

Joffe said LCA gained market share from private practitioners, which make up about 60% of the market for corrective vision surgery, as well as other corporate providers. He also noted that the growth in procedure volumes was four times the projection for industry growth. David Harmon, president of ophthalmology research firm **Market Scope**, said Wednesday that industry wide, vision-correction surgeries for the fourth quarter likely rose about 8%.

LCA-Vision, though, couldn't give details about price differences or procedure numbers for Custom Lasik procedures versus regular procedures until its official fourth-quarter report, Joffe said. Joffe added that he was "extremely comfortable" with Wall Street's earnings estimates for the fourth quarter and all of 2003.

Analysts surveyed by **Thomson First Call**, on average, expect earnings of 11 cents a share for the fourth quarter and 57 cents a share for the year. A year ago, the company reported losses of 18 cents a share in the fourth quarter and 57 cents a share for the year.

LCA-Vision reiterated its guidance for 2004 earnings earlier this week, maintaining its earnings per share estimate of 80 cents to 85 cents on revenue of \$110 million. Despite the reiteration, the earnings projection was still below Wall Street's estimate of 86 cents a share. Joffe said Friday that the company's fourth-quarter guidance doesn't affect its previous outlook for fiscal 2004.

Shares of LCA-Vision closed Friday up \$2.16, or 9.7%, at \$24.50. Volume was 583,800 shares, compared with average daily volume of 283,700.

2/2 **LCA-Vision Inc.** provided guidance on growth in revenues and procedure volume for the fourth quarter of 2003. LCA-Vision reported that revenues increased approximately 56% for the fourth quarter of 2003, compared with the fourth quarter of 2002. The company also reported that revenues at LasikPlus centers open at least 12 months increased by 44%, and overall procedure volume grew by 32%, both compared with the prior-year fourth quarter.

"During the fourth quarter we continued to gain market share, with procedure volume up more than four-fold compared with estimated industry growth rates," said Stephen Joffe, chairman and CEO of LCA-Vision. "By offering consumers a choice in laser technology for Lasik and Custom Lasik procedures, we are able to be the technology leader and the service provider of choice to a growing number of patients. We are pleased to see Custom Lasik procedures continue to grow as a percent of total procedures."

2/2 **IRIDEX Corporation** announced that *Cahaba Government Benefit Administrators*, the Medicare Part B Carrier for Mississippi, published a Local Medical Review Policy (LMRP) allowing reimbursement to ophthalmologists performing Transpupillary Thermotherapy (TTT) treatment of wet age-related macular degeneration (AMD). The TTT protocol primarily uses the IRIS Medical OcuLight SLx laser by IRIDEX to treat AMD.

The Cahaba LMRP (L13872) states the following indications of coverage under CPT Level III code 0016T, "Transpupillary Thermotherapy is indicated for exudative senile macular degeneration occurring beneath the fovea, malignant neoplasm of the retina, malignant neoplasm of the choroid, benign neoplasm of the retina, and benign neoplasm of the choroid."

Theodore Boutacoff, president and CEO of IRIDEX commented, "We believe that the growing body of favorable clinical outcomes, enthusiasm from retina specialists performing the procedure, and the cost savings compared to alternative treatments has played a major role in recent Medicare coverage of TTT. The Mississippi allowable

amount around \$800 per treatment is similar to the allowable amount from the majority of other states paying for the procedure."

Medicare coverage and payment for TTT has been determined on a carrier-by-carrier basis since September 2000 when the Centers for Medicare and Medicaid Services (CMS) issued a program memorandum listing these procedures. As elaborated in the 2001 Federal Register, Medicare Part B Carriers were given the freedom to establish relative value units and payment amounts for these services, generally on a case-by-case basis following review of documentation such as an operative report. There are now 17 states with written reimbursement coverage policies on TTT: Alaska, Arizona, California, Colorado, Hawaii, Iowa, Idaho, Mississippi, North Carolina, North Dakota, Nevada, Oregon, Pennsylvania, South Dakota, Tennessee, Washington and Wyoming.

2/2 **Refocus Group, Inc.** announced it had signed a License Transfer and Transition Services Agreement with **CIBA Vision**, the eye care unit of **Novartis AG**, to reacquire the sales and marketing rights to its PresVIEW Scleral Implant and Surgical Spacing Procedure. The medical device and surgical procedure is for the treatment of presbyopia, ocular hypertension and primary open-angle glaucoma -- all very large eye care markets and opportunities.

Under the original license agreement signed with CIBA Vision in March 2002, Refocus Group was to receive a percentage royalty from CIBA Vision on net sales of its technology. In August 2003, CIBA Vision announced its intention to explore strategic alternatives for its Surgical Unit, including its potential sale. CIBA Vision has since decided to exit the ophthalmic surgical business, and during January 2004 both companies discussed alternatives for the license rights, including a sale to a third party. However, Refocus Group's Board of Directors determined that the reacquisition of the license would be most advantageous to the company.

"This agreement helps us in three important ways: It restores to us complete control over final development and commercialization of our PresVIEW Scleral Implant and Surgical Spacing Procedure; it affords us an opportunity to experience more significant revenues than those generated from our prior royalty-based business model; and it allows us to explore other strategic alternatives," said Terry Walts, president and CEO of Refocus Group. "I want to thank CIBA Vision for all its support and assistance during the period of its license, and in contributing to the significant improvements in the technology and protocol over the last two years."

During the term of the license, CIBA Vision and Refocus Group completed essential development of the automated PresVIEW Incision System, which has simplified and standardized the procedure and is expected to provide improved and more consistent surgical outcomes. Refocus Group will reassume manufacturing, regulatory, marketing and other operational matters regarding its products. CIBA Vision will provide certain transition services during 2004 in connection with the transfer of the license back to

Refocus Group. Details of the transaction will be contained in a Form 8-K filing with the Securities and Exchange Commission later today.

As previously announced, Refocus Group received FDA approval for the start of Phase II clinical trials of its procedure for the treatment of presbyopia. The clinical trials are expected to begin shortly at three to five clinical sites in the United States involving 150 patients, subject to concurrent submission of some final data to the FDA.

- 2/4 Michael Lachman of **ThinkEquity Partners** hosted a call with Dr. Jason Slakter, a leading retinal specialist, to discuss the evolving space of wet AMD treatments in a review of **Alcon Laboratories**. His takeaway from the call was very positive for Visudyne (**QLTI**), Retaane (**ACL**) and modestly negative for Macugen (**EYET; Not covered**); details below. We reiterate our Overweight ratings on QLTI and ACL based on our analyses of Visudyne and Retaane, which were reinforced by Dr. Slakter's comments.

Highlights from the Conference Call

Alcon (Overweight)

1. Dr. Slakter is the principal investigator for Alcon's Retaane (anecortave acetate), and on the call highlighted the product's differentiated method of action and dosing/administration. Retaane is neither an anti-VEGF compound nor a steroid (although it is derived from a steroid), and as such acts at a different step in the vessel development pathway. In contrast to the VEGFs and intravitreal steroids, Retaane is delivered alongside the posterior portion of the eye rather than injected into the eye, and is administered less frequently (every six months versus every 6-9 weeks). This has resulted in an excellent safety profile to date. Retaane appears to deliver strong long-term vessel growth suppression, but lacks the "wow factor" provided by the anti-VEGFs due to their immediate anti-permeability effect, and by the rapid vessel closure provided by PDT. We expect that Retaane will ultimately be used in combination with PDT and/or VEGFs/steroids, given its unique mechanism of action, although there is little data thus far to support combination therapy.

2. Data published late last year from the first Phase II/III trial (Retaane vs. placebo, 24-month follow-up) confirmed 12-month results and demonstrated that Retaane preserves vision, prevents severe vision loss, and inhibits lesion growth in patients with predominantly classic CNV lesions. This Phase II/III trial data will be a key component of the PMA filing, along with Phase III data from a head-to-head trial versus PDT using Visudyne. Enrollment in this Phase III study was completed last year, and patients will be followed for one year prior to filing. The final PMA module should be submitted in Q4-04, after one-year follow-up, and 12-month data should be available in September or October. FDA approval is expected in H1-2005 following a priority review.

3. While use of Visudyne is expected to rapidly expand beyond predominantly classic CNV to both minimally classic and occult lesions, and initial grouped Macugen data appears to address all three lesion types, Retaane studies thus far have been limited to predominantly classic lesions. This will limit the initial market opportunity for Retaane, although we believe that Alcon will be able to demonstrate efficacy in a broader patient population over time.

4. Retaane has shown promise in reducing the risk of progression of advanced dry AMD to the more severe wet AMD. Late last year, Alcon announced that it would initiate two new Phase III studies of Retaane for this indication, and enrollment is expected to begin very soon (possibly even this week). In numerous animal models, Retaane has demonstrated an ability to reduce the risk of vessel development prior to the onset of wet AMD. Retaane's solid safety record, along with its differentiated dosing and administration (placement alongside the eye every six months), support its use for dry AMD. There is no treatment currently approved for this indication, other than the recommended use of antioxidant vitamins, and few treatments are even under investigation at this time. After completion of enrollment, the studies will occur over a period of four years and will include approximately 2,500 patients who will be enrolled at 100 sites worldwide. The FDA has given "Fast Track" designation to this development, because it represents a significant unmet medical need for a serious condition. This new indication, if successful, could be approved in the 2007-2008 timeframe, with lack of reimbursement as the greatest barrier to off-label use prior to FDA approval.

QLTI (Overweight)

1. Expect the market for Visudyne to almost triple in the U.S. with the new CMS reimbursement coverage for the occult and minimally classic indications. Previously, approximately 52,000 patients (predominantly classic lesions only) were eligible for reimbursement; the number of patients now increases to approximately 130,000 (predominantly classic, minimally classic and occult lesions). Subsequently Visudyne peak sales potential increases from \$400MM-\$500 to \$1B- \$1.2B.

2. Expect Visudyne to be the backbone for potential combination therapy in wet AMD. It has a different mechanism of action and route of administration than potential competitors. We expect that Visudyne will be used in combination therapy with steroids, Macugen, Lucentis, Retaane or any other competitor product, depending on the full data and FDA approval of these potential therapies. The real fight for market share will be between the new therapies rather than with Visudyne.

3. Expect number of Visudyne treatments to decline with combination therapy. Currently average use is 2.2 to 2.4 treatments in the first year, which may get reduced to 1.2 to 1.4 with combination therapy. We expect that this will be more than offset by 1) use in patient subtypes who did not qualify for Visudyne therapy before, 2) increase in the overall number of treatments as patients potentially slow their disease progression for a longer period, 3) retreatment of patients who have progressed on or stopped showing a

benefit with Visudyne, and 4) patients who progress on pharmaceutical therapies may still benefit from Visudyne or combination therapy.

4. Room for growth even after the positive CMS decision: Currently CMS has decided to reimburse for minimally classic and occult AMD, when lesion size is of disc area ≤ 4 (approximately 50% of the patients). Clinical trial data indicates that Visudyne could be effectively used in lesion size < 9 (roughly 75% of the market), if used in combination therapy. We expect that as more clinical trial data becomes available in 2005 from the VIO, VIM and combination therapy trials, it could further expand Visudyne's potential market.

5. Expect minimal impact on physician incentive for using Visudyne despite a drop in the CMS reimbursement rate from 95% of AWP to 85% of AWP. Physicians would like to receive a higher mark up or be reimbursed at a higher rate, however, their decisions are clinically based, i.e., they will finally do what is required. As an example, physicians spend much more time in retinal detachment surgeries, which involve a lot of time and paperwork, which, comparatively, results in an even less attractive reimbursement. However it does not prevent them from conducting those surgeries. With Visudyne, the physician also makes money on the diagnosis, examination, angiography, procedure, etc. On the whole, it is still highly beneficial to the physician financially. We expect minimal impact from the CMS reimbursement rate reduction especially as 1) there is no other alternative until at least mid-2005 and 2) even when there alternative treatments, we do not believe that they will be much more financially attractive. In administering Visudyne, the procedure takes 30 to 40 minutes, but very few minutes of the physician's time. However, the procedure to administer anti-VEGF's is expected to take almost an hour where the physician will be required for a significant majority of the time.

Eyetech (EYET, not covered)

1. Do not expect Macugen to take away market share from Visudyne on the basis of the known data. If positive, sub group analysis could lead to Macugen being used preferentially for patients with big lesions, where Visudyne is ineffective.

2. There are too many unknowns with Macugen - and it is unclear as to why the data analysis has not yet been made public. The big questions are 1) safety (1.3% endophthalmitis), 2) duration of action for Macugen, and 3) which subgroups or which lesion types does Macugen work best in (Phase III data was combined analysis).

3. Expect CMS to revise the reimbursement rate for intravitreal injections downwards, once they expect widespread use (the same had happened for the procedure cost of Visudyne).

4. Known efficacy of Macugen is similar to Visudyne making it an unattractive option when mode of administration is considered: 2.4 treatments of Visudyne (IV + laser) versus nine intravitreal injections for Macugen.

5. Expect **Pfizer** marketing muscle to have minimal impact, except in the education of patients and referring physicians, which could increase the overall market opportunity. There are currently 1800 retinal specialists in the U.S. and almost all of them are expected to be aware of the potential new treatments.

6. Expect Macugen to be combined with Visudyne, and possibly Retaane, but not with intravitreal steroids or other anti-VEGF compounds (i.e., Lucentis), as the mechanism of action and mode of administration are somewhat similar.

Alcon Investment Thesis -- Alcon is our top pick for 2004 in ophthalmic devices, based on improving visibility on a strong 2005-2006 product pipeline. Stocks of medical device and pharmaceutical companies typically perform best into and through strong new product cycles. We recommend that investors initiate or add to positions opportunistically in advance of what we believe will be a 2005-2006 period in which Alcon should deliver high-quality, high-teens EPS growth driven by a number of important new products. These products include RETAANE for wet AMD, Patanase for nasal allergy, the Travatan/Timolol combination for glaucoma, the AcrySof ReStor multifocal IOL, and 15(S)-HETE for dry eye. We expect to see pivotal Phase III data for RETAANE in the September-October timeframe, followed by a Q4 NDA filing if all goes according to plan. A six-month expedited review could have the product on the U.S. market by mid-2005.

Valuation and price target: Our 12-month price target of \$68 is based on a 26.5x average P/E multiple for large-cap surgical device and specialty pharmaceutical stocks, applied to our 2005 EPS estimate of \$2.55.

2/4 **IRIDEX** announced sales for the fourth quarter ended January 3, 2004 of \$8.8 million, down from \$9.5 million in the corresponding 2002 quarter. Sales for the fourth quarter 2002 included a significant initial OEM stocking order for the Millennium EndoLase module sold by **Bausch & Lomb**. Net income for the fourth quarter 2003 was \$491,000 (7 cents per share) compared to net income of \$598,000 (9 cents per share) in the corresponding quarter of 2002.

Sales for the 2003 fiscal year were \$31.7 million, up 3% from \$30.6 million reported in 2002. Net income for 2003 increased 147% to \$371,000 (5 cents per share) compared to \$150,000 in net income (2 cents per share) for 2002.

For the fiscal year 2003, ophthalmology sales totaled \$26.2 million, an 8% increase from the \$24.1 million for the 2002 fiscal year. Sales of dermatology products totaled \$5.5 million in 2003 compared to \$6.5 million for 2002. Sales in the United States improved to \$20.1 million in 2003 compared to \$19.6 million for 2002. Additionally, international sales in 2003 increased to \$11.6 million from \$11.1 million in the prior year.

"We began to see the impact of our efforts to improve bottom line performance during 2003," commented Theodore Boutacoff, president and CEO. "Our asset management

programs were highly successful, resulting in a stronger balance sheet and additional cash reserves. Even with increased sales in 2003, inventories were reduced by \$2.0 million and accounts receivables declined by \$1.5 million. At year end, our combined cash position increased by \$4.8 million to \$16.3 million, which provides the resources to capitalize on the emerging opportunities for our Minimal Intensity Photocoagulation (MIP) technology."

"We were especially pleased to see additional support and increasing evidence that our MIP approaches to treat age-related macular degeneration (AMD) and other sight threatening diseases are gaining acceptance world wide. In addition, we are encouraged by the growing number of states establishing reimbursement schedules for the use of our devices to treat this chronic and terrible disease using our Transpupillary Thermotherapy (TTT) and Feeder Vessel Therapy (FVT) protocols," continued Boutacoff.

Boutacoff stated, "Looking forward to 2004, without the benefit of any definitive favorable results from the AMD (TTT4CNV) clinical trials, we see slightly improved year-over-year sales growth. As has been the case the last two years, we expect the second half of 2004 to be stronger than the first half. Additionally, based on our expected introductions of new products and product mix we believe that gross margins should improve slightly for 2004 and that the overall growth in sales and continued operating efficiencies should increase profitability."

2/4 **CIBA Vision Corporation**, the eye care unit of **Novartis AG**, announced that it had completed the sale of a significant portion of its surgical business. **Bear, Stearns & Co. Inc.** acted as CIBA Vision's exclusive financial advisor in relation to the transactions. The specifics of the sale agreements are as follows:

- **IOLTECH, SA** has purchased CIBA Vision's Vivarte and Vivarte Presbyopic phakic refractive lens, CV232 SRE intraocular lens, Tear Saver7 and Tear Saver7 PLUS punctum plugs, UniVisc viscoelastic, VisThesia a viscoelastic that includes anesthesia, and Ophthalin and Ophthalin Plus viscoelastics. IOLTECH has also purchased certain marketing and distribution rights to the PRL phakic refractive lens.

- **Optonol Ltd.** and CIBA Vision have agreed on a mutual release of contract for the Ex-PRESS Mini Glaucoma Shunt. Optonol will assume distribution of the Ex-PRESS shunt in the United States and Canada. Optonol currently distributes the Ex-PRESS throughout the European Union.

- CIBA Vision will retain its equity share in **Refocus Group**; however, Refocus will reassume the licensing and all marketing rights worldwide to its PresVIEW Scleral Implant and the Surgical Spacing Procedure for the treatment of presbyopia, glaucoma and ocular hypertension.

Negotiations for the remaining products within the Surgical portfolio are ongoing. CIBA Vision had previously announced it was considering strategic alternatives for its Surgical business, including the potential sale of that unit on August 18, 2003.

"We did not have the scale or necessary presence in the market to fully capitalize on the surgical portfolio and this will also allow us to focus on our core lens and lens care businesses," said Joe Mallof, CIBA Vision's CEO. "We are confident that the promise of the products and technologies in the surgical portfolio will be better realized by the new owners. Our commitment to our customers is that we will ensure a smooth transition."

CIBA Vision will provide transitional services on a case-by-case basis to the new owners to minimize the effect on customers and their patients.

- 2/4 Glenn Hagele, Executive Director of CRSQA said that the following memo was sent out to all wavefront-guided excimer laser users on January 30th, re: communicating to patients regarding the limits of FDA approval of excimer lasers regarding correction of high order aberrations (HOA):

It has come to our attention that patients are commonly being told the wavefront-guided excimer laser proposed for LASIK surgery is approved by the Food and Drug Administration (FDA) to treat and correct high order aberrations (HOA), defined as those optical aberrations measured and expressed in Zernike polynomials level three and greater.

A review of the relevant documentation will find the FDA approvals do not include language that supports the contention that wavefront-guided excimer lasers are FDA approved to correct HOA.

Our organization's goal is to promote full and truthful communications between physician and patient in a positive and cooperative environment where patients are appropriately and accurately informed. In the interest of the dissemination of accurate information, we respectfully ask that you carefully compare the FDA-approved labeling for your laser system with your current patient information materials to affirm that the information you circulate accurately reflects FDA approval status regarding high order aberration correction for your particular laser.

The Council for Refractive Surgery Quality Assurance (CRSQA) is a nonprofit patient/consumer advocacy organization formed to provide balanced, objective, and factually substantiated information to the public regarding refractive surgery issues. Our 50 Tough Questions For Your Doctor have been a roadmap to a quality refractive surgeon for hundreds of thousands of patients. Additionally, CRSQA evaluates and certifies refractive surgeons based upon patient outcomes. For more information, visit www.USAeyes.org or contact me at 916/381-0769.

If you are not a user of a wavefront-guided excimer laser, please disregard this notice and accept our apologies for the intrusion.

In the February 13th issue of *Cataract & Refractive Surgery e-News*, the editors interviewed Glenn Hagele, and wrote about the above advisory.

The Council for Refractive Surgery Quality Assurance (CRSQA) issued an Advisory Memorandum to all US refractive surgeons, stating that patients have reported to CRSQA that they are commonly being told that the wavefront-guided excimer lasers proposed for LASIK surgery are approved by the FDA to treat and correct high-order aberrations, defined as those optical aberrations measured and expressed in Zernike polynomials level three and greater.

"The memorandum was intended to be a catalyst to get everyone to revisit the issue of what the FDA did and did not approve, and to re-evaluate exactly what they were telling their patients," Glenn Hagele, Executive Director of CRSQA told *Cataract & Refractive Surgery Today*. "It is in everyone's best interest that patients receive correct information." According to Hagele, he did a survey of about a dozen clinics nationwide, at random, where Hagele presented himself as a patient who had been evaluated with higher-order aberrations, and asked very specifically if the clinic's laser was approved by the FDA to correct existing elevated higher-order aberrations. According to Hagele, in 100% of the cases he was told that the laser was approved for the correction of higher-order aberrations.

"It was very clear that the clinics staff didn't completely or correctly understand the limits of the FDA approval," Hagele said. None of the three approved lasers have language in their approval letters that clearly states an approval to correct high-order aberrations. The approvals are specifically for the correction of myopia and astigmatism.

According to Hagele, the regulatory people at each company had absolutely no knowledge of the miscommunication of information between clinics' staff and patients, however, when presented with the facts, they were very quick to respond and to ensure that the proper and accurate message is being communicated by physicians and their staff to patients.

2/4 *Reuters* reported that **Advanced Medical Optics** and **Ophtec USA** will seek support from a U.S. FDA panel of experts on Thursday for a new implantable lens that aims to eliminate or reduce nearsightedness. Privately-held Ophtec USA, which makes the device, will present data for the Verisyse lens to the FDA Ophthalmic Panel. Advanced Medical Optics holds global distribution rights for the lens.

Ophtec USA is a subsidiary of the Netherlands-based **OPHTEC B.V.** The lens is already marketed under the name Artisan in other countries.

2/4 Joanne Wuensch of **Harris Nesbitt** issued an update on Staar Surgical pending the outcome of the FDA panel hearing -- **STAA--Near-Term Uncertainty Leads Us To A NEUTRAL Rating**

* **Event** -- We are downgrading STAA to a NEUTRAL from OUTPERFORM within a Positive sector rating, based on several near-term uncertainties that lead us to believe that the stock will not outperform the group in the near term.

* **Impact** -- We want to note that our downgrade does not change our longer-term enthusiasm for the stock or the company and its products, but is a call anticipating continued near-term volatility and uncertainty.

* **Forecasts** -- For 2004, we lowered our revenue estimate declines to \$56.2 million (up 11.7%) from \$58.3 million and our EPS estimate to \$0.01 from \$0.08; break-even for the company is pushed out one quarter from 2Q04 to 3Q04. For 2005, we cut our revenue estimate to \$68.6 million from \$69.3 million and our EPS estimate to \$0.21 from \$0.24.

* **Valuation** -- Applying a multiple of 6-7 times refractive product revenue plus 2-3 times the company's cataract and glaucoma revenue leads us to a price target range of \$9-13. Excluding the refractive opportunity, we are left with a \$5-\$8 price range. Therefore, we are lowering our target to \$9 from \$14.

* **Recommendation** -- We rate STAA NEUTRAL. We continue to believe in the longer-term story and that the company could be an acquisition candidate, but near-term issues have us downgrade the stock from OUTPERFORM.

2/6 **OPHTEC USA, Inc. and Advanced Medical Optics, Inc.** announced that the FDA's Ophthalmic Devices Panel of the Center for Devices and Radiological Health (CDRH) met yesterday and recommended that the ARTISAN/VERISYSE phakic intraocular lens be approved by the FDA. Yesterday's panel recommendation was on OPHTEC's PMA (pre-market approval application) for its ARTISAN lens. The lens will be marketed in the U.S., under AMO's exclusive distribution agreement with OPHTEC, under the VERISYSE brand.

The panel recommended that the FDA approve the IOL, with conditions, for patients with myopia, or nearsightedness. "The panel's positive recommendation means that, assuming approval by the FDA, the lens could be one of the first phakic IOLs offered commercially in the U.S.," said Rick McCarley, president and CEO of OPHTEC USA. "We are pleased with today's result and believe OPHTEC's three-year FDA study in the U.S. demonstrated to the panel that the ARTISAN/VERISYSE phakic IOL is a safe and effective vision correction alternative."

"Today's announcement represents an important milestone in AMO's commitment to play a leadership role in the development of the refractive IOL marketplace and to provide leading-edge technologies to ophthalmic surgeons and their patients," said Jane Rady,

corporate vice president of strategy and technology for Advanced Medical Optics. "Phakic IOLs are an exciting alternative for patients with severe nearsightedness that cannot be corrected through laser surgery. For these individuals, spectacles and contact lenses are currently the only options, and in cases of extreme nearsightedness spectacles are very thick and offer only a limited visual field. The VERISYSE lens, if approved for commercial use in the U.S., will give ophthalmologists an important additional tool in treating the needs of myopic patients."

The Ophthalmic Devices Panel is an advisory panel comprised primarily of ophthalmic practitioners and scientists. Although the FDA is not bound by the recommendations of its panels, it has historically accepted their advice. Among the conditions recommended by the panel for VERISYSE approval was an anterior chamber depth of more than 3.2 mm, as well as a post-market study. A final FDA decision is expected in approximately six months.

OPHTEC and AMO formed an agreement related to phakic IOLs while the current FDA study was already under way. OPHTEC was responsible for designing and conducting the study, and AMO provided assistance with the study analysis and the FDA review process.

Commenting on refractive IOL products, Dr. Doyle Stulting, MD, who is on staff at the Department of Ophthalmology at the Emory University Eye Center where he is a professor of ophthalmology and the director of the university's Cornea Service, said, "As evidenced by the successful 13-year track record of this lens in Europe, it clearly would fill an unmet market need in the U.S. Approximately 90 million people in the U.S., or roughly one-third of the total U.S. population, are nearsighted. Based on the study's results, the VERISYSE phakic IOL provides excellent refractive outcomes -- 95 percent of study participants achieved manifest refraction spherical equivalents that were within 1 diopter of target. "During the FDA study, lenses in whole-diopter increments were used. Once approved, lenses with 0.50 diopter increments will be introduced so that uncorrected vision is likely to be even better," Dr. Stulting added.

AMO, which has global distribution rights, currently markets the phakic IOL under the name VERISYSE in Europe, South America and portions of the Asia Pacific region. AMO will be the exclusive distributor for VERISYSE in North America and Japan. In addition, OPHTEC will continue to market the product under the trade name ARTISAN in Europe. Even with approval of the VERISYSE lens in the U.S., AMO does not expect sales of phakic IOLs to make a material contribution to revenues in the near term.

Several analysts provided additional information about the approval and what it might mean for competitor **Staar Surgical**.

Perhaps the best summary was provided by Michael Lachman of **ThinkEquity Partners** -- **AVO: Verisyse/Artisan Panel - If This Was Victory...**

Advanced Medical Optics (AMO) and its partner Ophtec went before the FDA Ophthalmic Devices Panel yesterday to present its PMA application for the Verisyse/Artisan phakic IOL. Our top line prediction was correct: panel approvability, with conditions, following a lengthy debate on endothelial cell loss. But the tone of the meeting was more negative than we had expected, and the victory was narrower. The panel voted 7-6 for approvability, requiring a tie-break from the chair. Attached to the recommendation is a laundry list of conditions that could delay approval (due to additional data analysis) and limit the commercial opportunity (due to narrowed indications). We remind investors that our expectations for this product have always been modest, given the niche market of very high myopes that the product will address and competition from the **Staar Surgical ICL**. We would be buyers on any weakness in AMO shares following this panel meeting.

Investment Highlights -- Advanced Medical Optics (AMO) and its partner Ophtec escaped Gaithersburg, MD yesterday with the narrowest of victories, a 7-6 vote by the FDA Ophthalmic Devices Panel for approvability of the Verisyse (known as Artisan outside the US) phakic IOL. We had expected a positive panel recommendation, with conditions. However, the vote was closer than we would have anticipated and the conditions were more significant. We still believe, as we did going into the panel meeting, that the safety and efficacy data for the Verisyse lens is similar in most respects to the data for the Staar Surgical ICL. Recall that on October 3, the ICL was reviewed by this panel. After a meandering debate on the topic of endothelial cell loss, the ICL panel ended on a positive note and the vote for approvability (also with conditions) was 8-3. We were surprised by the fact that the October ICL panel did not push harder on the issues of cataract formation and the overall risk/benefit of the ICL at lower levels of myopia and in younger patients, and we suspect that the FDA may have expected more heated debate on these issues as well. Things were certainly different yesterday, and the tone and outcome of the meeting more closely resembled what we had expected to see last October. There was a greater focus yesterday on the integrity and presentation of the clinical data. Interestingly, of the eight panelists that voted at both meetings, five voted against approvability yesterday, and three of these five had voted in favor of the ICL. Among the five new voters, the vote was 4-1 in favor of Verisyse approvability.

The panel appeared to be better educated and more prepared yesterday, particularly on the issue of endothelial cell loss. While this issue dominated the debate at the October ICL panel, the resulting conditions with respect to endothelial cell loss were less precise following that meeting: the panel recommended that the ICL be used in patients with normal endothelial cell densities, and that this issue should be monitored post-marketing. The conditions were much more clearly articulated and more precise at yesterday's Verisyse panel, and will likely result in labeling that will meaningfully limit the patient population based on a combination of age and cell density measurements. Specifically, the FDA will likely label the product for patients at least 30-40 years of age, rather than the 21+ age range sought by the company. In addition, there will likely be a requirement that patients have a measured endothelial cell density of at least 2400-2500, well above the clinical trial inclusion criteria of at least 2000. The panel also recommended that the

Verisyse lens be approved only for high levels of myopia (-9D to -20D), well above the -5D lower limit sought by the company and the -3D lower limit sought and recommended for the ICL. We do note that our commercial expectations call for these first generation phakic IOLs to be used almost entirely in high myopes (-10D and beyond), given the attractive LASIK alternative for most myopes below this level.

We suspect that many of the issues highlighted at yesterday's Verisyse panel could be active topics of debate behind closed doors at the FDA with regard to approval, indications, and labeling for the ICL. Even though the October ICL panel did not recommend limitation to only high levels of myopia and the establishment of lower limits on patient age and endothelial cell density, we see the risk profiles of the two products as similar and would not rule out the possibility that such limitations could ultimately be a part of an ICL approval.

What did the panel like about the Verisyse/Artisan lens? The panel's vote for approvability was driven by solid overall efficacy (visual acuity, predictability, and stability) in the high myopia patient population. The panel ultimately concluded that the Verisyse lens represents favorable risk/reward for high myopes, as long as approved indications are limited to those with few other options and acceptable risk factors (particularly with respect to age and endothelial cell density). Beyond the endothelial cell issue, the panel generally (but not unanimously) viewed most other safety parameters as acceptable. The data regarding post-operative best spectacle corrected visual acuity (BSCVA) was particularly strong. Some of the panelists also looked favorably on the fact that this lens has been used successfully outside the US for many years. An earlier version of the lens has been implanted in over 400,000 eyes over the past 25 years, and the current version has been implanted in over 100,000 eyes since 1991. The company claims roughly 2/3 share of the phakic IOL market in regions of the world where more than one product is available.

There were a number of issues that weighed on the minds of the panelists, resulting in a long list of conditions and a narrow vote for approvability.

- * In general, the panel viewed the currently available clinical data as insufficient to assure safety. There was concern over a lack of long-term data beyond three years, and less than desirable patient follow-up rates at the two and three year intervals.

- * There were also a number of concerns regarding the reporting of adverse event (AE) data: confusion over definitions of complications and adverse events, reporting of AEs on a per-eye but not a per-patient basis, a need for better reporting the time-dependence of AEs, and the exclusion from the statistics of some eyes that possibly should have been included.

- * A relatively high percentage (27%) of patients in the trial did not meet the original protocol criteria, and there was a desire for more complete data analysis for this diverse group of patients.

* The protocol did not require measurement of intraocular pressure, raising questions with regard to the risk of glaucoma, particularly among African-Americans and others with dark irises.

* Many issues were raised with regard to the risk of long-term endothelial cell loss. There is a fundamentally high variability in the measurement of endothelial cell counts, which makes data analysis difficult. In the full, original data set, there was little consistency with respect to measurement equipment and methodology, making the data even noisier. This led to a recounting method that lowered the standard deviation of the endothelial cell data but also significantly reduced the number of eyes in the data set. There was no good indication from the data that the rate of loss of endothelial cells decelerated by the third and fourth years, leading to uncertainty regarding the long-term shape of the curve. The real concern is not short-term reduction in endothelial cell count, but cell densities after much longer periods of time; given the perils of extrapolation, the risk of endothelial cell loss over a 20-40 year period is fundamentally unquantifiable given 2-4 year data that has not yet stabilized.

Conditions of Approvability. The panel recommended the following conditions with respect to approvability of the Verisyse lens:

1. Anterior chamber depth (ACD) >3.2mm.
2. Myopia between -9D and -20D. (A suggestion that the range be lowered to -8D was voted down.)
3. Based on the clinical data, the FDA is to establish lower limits on patient age and preoperative endothelial cell density. These limits, in very rough terms, are to be based on the need for patients to maintain an acceptable cell density (1200-1600) by an age at which cataract removal is expected (about 75), assuming an annual loss rate of roughly 2%. (A proposal to specify a minimum age of 30 years was voted down.)
4. The company must conduct post-market surveillance of the product. A new cohort of patients is to be followed for 2-3 years, with particulars of the studies to be determined.
5. The existing clinical data is to be re-analyzed to determine the risk of increased intraocular pressure for certain minority groups and those with dark irises.
6. Data regarding adverse events and adverse reactions is to be re-evaluated in order to more clearly state the risks for patients and physicians.
7. Safety and efficacy data for patients that fell outside the original protocol criteria is to be made available to the FDA.
8. Labeling is to incorporate a number of changes and additions, including several modifications to reported safety data, a discussion of pupil size versus optic size,

disclosure of the risk of future cataract formation and retinal detachment, and elaboration on the unknown but potentially serious long-term risks of endothelial cell loss.

Ted Huber of Wachovia Securities -- AVO: FDA Panel Recommends ARTISAN Phakic IOL

*** AVO Phakic IOL gets fda panel approval recommendation:** Yesterday, an FDA Ophthalmic Devices Panel recommended that AVO's ARTISAN/VERISYSE phakic IOL be approved by the FDA. Recommendation limitations included: (1) patients with refractive error of -9.0D to -20D (<2% of the population), (2) anterior chamber depth = or > 3.2 mm (removes 10-20% of population), and (3) contraindication on age and endothelial cell count (nobody < 30 years old).

*** Split panel increases approval risk:** The recommendation for the ARTISAN was split 6-6, with the Chairman breaking the tie. Given the narrow approval, label contraindications, and diopter restrictions, the risk of an FDA non-approval of Staar's ICL or AVO's ARTISAN increases. However, we note that bruising panels are common, and the odds still favor approval.

*** Niche market for phakic IOLs:** As stated in our 10/8/03 report, we believe the PIOL high-myope opportunity is limited to 1.3 MM Americans. With a 2-4% annual market penetration, this equates to \$40-\$80 MM in annual revenues. Based on current recommended ARTISAN diopter restrictions, we believe Staar has an advantage over AVO in selling into the U.S., assuming FDA approval.

*** Product impact on AVO:** We continue to view the ARTISAN as potential 2005 revenue upside of \$5-10MM, or 1-2% incremental growth. Our 2004 and 2005 EPS forecasts remain \$1.02 and \$1.20.

And the impact on Staar Surgical:

Joanne Wuensch of Harris Nesbitt -- STAA--Competitive Phakic IOL from Ophtec; Panel Recommended by Slim Vote

*** Event --** Ophtec, a competitor of STAAR Surgical, had its FDA PMA panel meeting on February 5 and received panel recommendation for its phakic IOL (trade named Verisyse). The FDA panel meeting raised many of the same issues and concerns as STAAR's panel, including endothelial cell loss, cataract formation, glaucoma, and retinal detachment. Recommendation was for a narrower cohort of patients, including those with -9 to -20D of myopia, an anterior chamber depth of greater than 3.2 mm, recommendations on age (>30), and a post-market surveillance study. Final vote was 6-to-6 with the chairperson breaking the tie by voting in favor of the recommendation.

* **Impact** -- Neutral to slightly negative. On the one hand the recommendation brings another competitor into the market, yet on the other hand the panel did not heartily endorse the Ophtec lens and recommended it for a narrower patient cohort.

* **Forecasts** -- No change.

* **Valuation** -- We believe the stock is fairly valued given the near-term uncertainties outlined in our 2/4/04 note.

* **Recommendation** -- NEUTRAL.

John Calcagnini of CIBC Capital Markets -- STAA Competitor Ophtec Gets FDA Panel Recommendation for Artisan Phakic IOL

Staar's competitor Ophtec (private) on 2/5 received FDA panel recommendation for approval, with a long list of conditions and labeling items (discussed below), for its Artisan Phakic IOL, by a narrow margin of 7-6. We believe the market for phakic IOLs is less than \$50M.

* We believe there are excellent, less risky alternatives for treating most myopia patients (e.g., glasses, lasik). The panel spoke about high and unquantified adverse event risk we believe is relevant for Phakic IOLs (e.g., retinal detachment, cataract risk, glaucoma, glare, halos, starbursts).

* One panel member joked that they may be recommending approval of a device that no one is qualified to get. The panel decided that use should be limited to patients with >9D of refractive error, anterior chamber depth of 3.2 mm or >, and a minimum endothelial cell count at implant.

* The panel indicated that Artisan should not be implanted in younger patients (they suggested 30-40 years+), and they wanted a post-market study with more data on adverse events, cataract formation, glaucoma, retinal detachment, and corneal decompensation.

In our view, the market and patient population for phakic intraocular lenses, like the STAAR ICL or the Artisan from Ophtec, is limited given the surgical and long-term risks and the fact that there are viable and less risky alternatives for most myopia patients. As a result, we continue to rate STAA Sector Underperformer (Speculative) given that the company will likely need to raise money again, the base business in cataract surgery/IOLs has not been very competitive, and the small market for the ICL combined with the latest regulatory snafu.

Jayson Bedford of Adams Harkness & Hill -- STAA: Ophtec Get Panel Nod; STAA Still in Favorable Position

Key Points:

* FDA Panel narrowly votes 7-6 to recommend approval for competitor **Ophtec's** Verisyse phakic IOL (the Panel chair broke the deadlock); Panel members took issue with the variability of endothelial cell loss data and the lack of data on patients w/ low myopia.

* Specifically, the Panel recommendation came with various conditions including; a diopter range of -9 to -20 (versus -3 to -20 for STAAR) and anterior chamber depths (ACD) of >3.2mm (vs. >3.0mm for STAA); we believe these conditions limit the attractiveness and the potential market size for Ophtec.

* While Ophtec has distribution strength with its partner Advanced Medical Optics (AVO), we continue to believe STAAR has a superior product and is in a favorable competitive position.

* We model a Q204 approval for STAAR's implantable contact lens (ICL) and believe STAAR will have a two- to three-month head-start on AVO; as a reminder, STAAR must resolve the December 22 FDA warning letter before approval is granted.

* We reiterate our Buy rating and our 12-month price target of \$12; our rating reflects our long-term belief in the technology and the opportunity but also takes into consideration the increased uncertainty around the timing of ICL approval, which should persist in the near term.

2/6 As reported by *EyeWorld Week*, The FDA's Ophthalmic Devices Panel also recommended approval, with conditions, of **Refractec's** (Irvine, Calif.) View Point Conductive Keratoplasty (CK) System. It is the first ophthalmic surgical device indicated to improve near vision and monovision approved by the panel. The procedure, which uses radio waves instead of a laser or scalpel, focuses energy on the corneal collagen in a ring of uniformly placed spots intended to steepen the cornea. The approval recommendation for temporary reduction of spherical hyperopia in patients at least 40 years old with 1 D to 2.25 D was slightly more restricted than the company's request. Refractec officials said they were pleased with the decision, and noted that 90,000 patients could still qualify for the procedure. The panel focused much attention on the temporary nature of the procedure's vision improvement, and required the label conditions to clearly state that fact. CK is not guaranteed to last for any specific amount of time but clinical trial data indicated it could last from a couple years to an entire decade. The unanimous approval, according to panel members, was based largely on the fact that U.S. surgeons have performed the procedure about 27,000 times off-label since the View Point received FDA approval for a separate indication in April 2002.

2/9 **Bausch & Lomb** announced that it was launching the first TV advertising campaign for its advanced laser eye surgery system -- the Bausch & Lomb Technolas 217z Zyoptix System for Personalized Laser Vision Correction. The multi-million dollar consumer campaign for the Zyoptix System also includes a print ad in the March issue of *Prevention* magazine.

The new TV spot for the Zyoptix System is the first in a \$20 million TV campaign this year that also features commercials for three other key Bausch & Lomb products: ReNu MultiPlus Multi-Purpose Solution, the market-leading soft contact lens care solution; SofLens Multi-Focal contact lenses, the No. 1 prescribed multifocal lenses in the U.S.; and OcuVite PreserVision, the only patented eye health vitamin and mineral supplement clinically proven effective by the National Eye Institute. Those three ads first aired nationwide last spring.

"Our Zyoptix System TV ad is the first of its kind in which a manufacturer has launched a nationwide consumer advertising campaign for laser vision technology," said Robert Moore, Bausch & Lomb vice president of Marketing for The Americas Region. "The campaign allows us to showcase the exceptional safety and personalized lifestyle benefits that the Bausch & Lomb Zyoptix System delivers."

The commercial, which will run during the February ratings period on both network and cable shows, directs viewers to the company's website, **www.bausch.com**, to get more information about the procedure and to locate a surgeon certified in using the Bausch & Lomb Zyoptix System.

The 30-second spot shows a woman's frustrations with the inconveniences associated with wearing eyeglasses while her husband describes her desire for laser surgery and her concerns about selecting a surgeon to perform the procedure. She visits a surgeon certified to use the Bausch & Lomb Zyoptix System while a narrator explains the system's precise, wavefront diagnostics that result in excellent outcomes. The commercial ends by showing the woman without her glasses as her husband tells how thrilled she is with her improved vision after the Zyoptix System procedure.

Launched in the U.S. during the fourth quarter of 2003, the Bausch & Lomb Zyoptix System has been the leading laser technology for personalized vision correction outside the U.S. since its introduction in 2001.

2/11 **Alcon, Inc.** reported global sales of \$851.7 million for the fourth quarter of 2003, an increase of 13.7 percent over global sales in the fourth quarter of 2002, or 7.8 percent excluding the impact of foreign exchange fluctuations. Net earnings for the fourth quarter of 2003 increased 57.5 percent to \$133.9 million, or \$0.43 per share on a diluted basis, compared to \$85.0 million, or \$0.26 per share, for the fourth quarter of 2002.

For the full year 2003, Alcon reported global sales of \$3,406.9 million, an increase of 13.2 percent over global sales of \$3,009.1 million for the full year 2002, or 9.0 percent excluding the impact of foreign exchange fluctuations. Net earnings for the full year 2003 increased 27.5 percent to \$595.4 million, or \$1.92 per share on a diluted basis, compared to \$466.9 million, or \$1.53 per share, for the full year 2002.

Tim Sear, chairman, president and CEO of Alcon, commented, "Our fourth quarter and full year results reflect the success we have had across all of our geographic regions and

product lines. We continued to capitalize on our global infrastructure to grow operating profit and net earnings faster than sales. Alcon introduced an array of new products in 2003 that aided performance in 2003; and we believe they position us for continued growth in the years to come. This year we also expect to submit for approval several key pipeline products that may have the potential to expand the eye care market during the next decade."

Fourth Quarter Earnings Analysis -- The major factors that led to the sharp increase in net earnings for the fourth quarter of 2003 compared to the fourth quarter of 2002 were a higher gross profit margin (69.8 percent versus 68.9 percent) and a modest 5.4 percent increase in selling, general and administrative expenses. The primary reason for the improvement in gross profit margin was that gross profit in the fourth quarter of 2002 was reduced by about \$5.9 million as a result of inventory write-offs associated with the recall of the SKBM microkeratome. Changes in product mix also contributed to the quarter-over-quarter improvement in gross profit margins. The 2002 SKBM recall also increased selling, general and administrative expenses in the fourth quarter of 2002 by \$14.1 million. Research and development expenses were \$95.0 million (11.2 percent of sales) in the fourth quarter of 2003, \$1.1 million lower than in the fourth quarter of 2002.

During the fourth quarter of 2003, the company completed the sale of its contact lens care manufacturing plant in Madrid, Spain. The sale resulted in a gain of \$8.2 million before taxes.

Refractive sales of \$16.0 million (compared with \$16.7 million both in the third quarter and in last year's fourth quarter) had a negative impact on surgical sales growth, as increased procedural revenues arising from the trend toward higher priced custom procedures were not sufficient to offset a decline in equipment purchases, especially outside the U.S.

Following the announcement of earnings, two analysts discussed the results.

Michael Lachman of ThinkEquity Partners -- ACL: Steady Progress on Pipeline Keeps Investment Thesis Intact

With continued progress on Alcon's promising product development efforts, our investment thesis remains intact: Alcon is a strong 2005-2006 pipeline story, and we recommend owning this stock into this new product cycle. Although Alcon beat revenue and earnings estimates for Q4, we view the results as in-line with expectations given the boost from currency on the top line and an extra penny in EPS from a one-time asset sale. Alcon plans to file later this year for approval for RETANE not only for predominantly classic AMD lesions, but for minimally classic and occult lesions as well. While FDA approval for these less severe indications cannot be assumed at this time, there is significant upside to the market opportunity for this drug if CMS chooses to reimburse for these indications, as it has done for Visudyne. Alcon should also file for approval this year for Patanase and the ReStor multifocal IOL.

Investment Highlights -- Even though Alcon beat revenue and earnings estimates for Q4, we view the results as in-line with expectations. EPS of \$0.43 beat our estimate (and consensus) of \$0.42. However, a one-time gain on the sale of a manufacturing plant contributed \$8.2 million pre-tax, offset by a related \$3 million charge to COGS, boosted EPS by \$0.01. We also note that R&D expenses came in over \$5 million ahead of our expectations. Newly issued 2004 guidance was consistent with our and consensus estimates, with some upside on the top line driven by the continued devaluation of the dollar.

Tweaking estimates: rolling the penny of upside forward. Even though the penny of EPS upside in the quarter resulted from a one-time sale of a plant, management indicated that resulting cost savings would have a similar bottom line impact on an annual basis going forward. We are raising our 2004 EPS estimate slightly, from \$2.17 to \$2.18, corresponding to the top end of the new guidance range of \$2.15-2.18. We are also raising our 2004 revenue estimate, from \$3.66 billion to \$3.74 billion, which is consistent with newly issued guidance of \$3.7-3.8 billion. We note that the bottom end of this guidance range is representative of what revenues would be without any FX impact, and the top end of the range corresponds to a scenario in which the dollar remains at current levels throughout 2004. For 2005, our revenue estimate goes from \$4.04 billion to \$4.11 billion, and our EPS estimate goes from \$2.55 to \$2.57.

Revenues of \$852 million (+13.7%) beat our \$828 million estimate, but the continued weakening of the dollar during Q4 likely accounted for most or all of this 3% difference (currency contributed 6% overall). The revenue upside was almost completely negated on the gross profit line, through natural hedges. Pharmaceuticals outperformed our expectations in Q4 following a below-forecast Q3. Surgical sales were in-line, and the Consumer business underperformed. The company provided updates on several key 2003-2004 new product introductions:

* Vigamox (fourth-generation fluoroquinolone antibiotic): The switch from Ciloxan to Vigamox continues, with 49% of total fluoroquinolone prescriptions having been converted by the end of Q4 (up from 43% at the end of Q3). Among ophthalmologists and optometrists, which account for about 45% of total prescriptions, conversion has reached 76% (up from 64% one quarter ago). This implies 27% conversion (up from 20% at the end of Q3) among prescribers outside of the eye care specialties, where the remaining 55% of prescriptions originate. By the time the Ciloxan patent expires and generics enter the market in June, the company hopes to have nearly all of the prescriptions among eye care specialists converted to Vigamox and close to 40% conversion among general prescribers, resulting in close to 70% overall conversion. Beyond cannibalization of sales from its own anti-infective franchise, Alcon management believes that the company gained two points of US market share in this category in 2003 as a result of the Vigamox introduction in May.

* Infiniti Vision System (cataract removal): Although the first commercial shipments of this new system came in August, Infiniti accounted for 36% of Alcon's cataract

equipment units and about 50% of dollar sales for 2003. Alcon is successfully converting business from its Legacy system, and obtaining a premium price as well. This is a multi-year product ramp, as Alcon upgrades its surgical customer base and also targets competitive accounts.

* AcrySof Natural IOL (blue-blocking lens): Shipments in the US began in August/September, and by December this lens accounted for 20% of the company's US IOL volume on a unit basis. The company estimates that it gained over two points of IOL market share in the US in 2003, from 45.7% to 48.3%.

Pipeline Update -- Not surprisingly, Alcon's Q4 earnings call focused heavily on the company's promising new product pipeline, which continues to make steady progress.

* RETAANE (anecortave acetate) for wet AMD: Whereas Alcon management previously believed that RETAANE could be up to a year behind Macugen in the US, the company now believes that the product may be less than one quarter behind. The company acknowledges that the first pivotal Phase II/III trial did have a higher-than-expected dropout rate, but that the patient numbers are still large enough to provide acceptable statistical power. The current Phase III trial (head-to-head versus Visudyne), which is still blinded, has had a much lower dropout rate of just under 5%. In this trial, the last 12-month patient data will be collected in August, and the company plans to release top line data from this study shortly thereafter. Enrollment is scheduled to begin very soon in the recently announced Phase III clinical studies of RETAANE for reducing the risk of progression of advanced dry AMD to the more severe wet AMD, although management is not yet prepared to discuss specific timelines given the very early stage of these studies.

* On the call, management indicated that it plans to file for FDA approval for RETAANE for not only predominantly classic lesions, but for minimally classic and occult lesions as well. In clinical studies in which data has already been made available, the company claims that over 100 patients with either minimally classic or occult lesions have been treated. The ongoing pivotal trial is likely to provide some data for these types of lesions as well. Among patients with lesion sizes less than 4 disc areas, RETAANE has shown efficacy similar to that shown in predominantly classic lesions. The patient numbers submitted to the FDA for these less severe lesion types are likely to be small, and we think it best to assume at this time that RETAANE will be initially approved for predominantly classic lesions only. Having said that, the precedent recently set by CMS in its decision to reimburse for Visudyne in minimally classic and occult lesions without FDA approval for these indications suggests the possibility of broader-than-expected reimbursement for RETAANE upon its US launch. Such a reimbursement decision would significantly enhance the market opportunity for RETAANE.

* Patanase for nasal allergy: The double-masked safety and efficacy trials have been completed, and an additional trial to demonstrate long-term safety is ongoing. The study

should be completed in Q3, and the company plans to file its NDA as soon as possible thereafter.

* AcrySof ReStor multifocal/accommodating IOL: The pivotal US study has completed enrollment, and Alcon plans to file its PMA with the FDA in Q3 of this year with approval expected in 2005. The company intends to position this product not only for cataract patients but eventually for presbyopic patients with healthy crystalline lenses as well. Accordingly, the company plans to price the product at 2-3x the price for standard IOLs. Anecdotally, initial studies indicate that over 80% of ReStor patients do not require spectacles for near, intermediate, or distance vision, and another 10% require only occasional use of glasses for near or intermediate vision. As points of reference, clinical studies of the AMO Array multifocal IOL have shown that nearly 90% of patients are able to read small print without glasses (similar to the anecdotal results for ReStor), but only about 40% of patients never wear glasses. It will be difficult to make meaningful comparisons without actual clinical data for the ReStor lens in-hand, and we suspect that issues related to quality of vision will be very important as well.

* Travatan/Timolol combination therapy for glaucoma: Alcon filed the NDA for this product in November, the FDA accepted the filing in January, and there has been no feedback from the FDA as of yet. There is no such combination product (prostaglandin plus beta blocker) approved in the US for glaucoma, although many patients already use both types of drops. The FDA has made the approval process difficult for these fixed combination glaucoma medications, as companies must demonstrate statistically significant superiority over either agent alone, necessitating complex three-arm trials. We believe that the interest among clinicians in such combination products is high and that if approved they will eventually see significant usage. Pfizer and Allergan also have active development programs, and the first company with an approved combination glaucoma treatment is likely to take market share from all monotherapy prostaglandins in this category. Alcon released preliminary data from three ongoing Phase III trials in a press release last month. In one trial, the combination drug reduced intraocular pressure slightly more than Travatan alone. In the other two, there was little or no difference noted. It is still not clear to us that the statistics will be strong enough to support approval - the company may have to rely on the benefits of easier dosing and better compliance. Safety results look good, similar to separate dosing of the two drugs.

* CustomCornea wavefront guided LASIK: Approval for the treatment of astigmatism is expected in Q3. This indication is necessary in order to close the gap between Alcon and its primary competitors in refractive surgery, VISX and Bausch & Lomb.

* 15(S)-HETE for dry eye: The company did not provide a meaningful update on this product. Follow-up studies are ongoing, and we still expect a late 2004 NDA filing and a 2006 US launch.

Alcon Investment Thesis -- Alcon is our top pick for 2004 in ophthalmic devices, based on improving visibility on a strong 2005-2006 product pipeline. Stocks of medical device

and pharmaceutical companies typically perform best into and through strong new product cycles. We recommend that investors initiate or add to positions opportunistically in advance of what we believe will be a 2005-2006 period in which Alcon should deliver high-quality, high-teens EPS growth driven by a number of important new products. These products include RETAANE for wet AMD, Patanase for nasal allergy, the Travatan/Timolol combination for glaucoma, the AcrySof ReStor multifocal IOL, and 15(S)-HETE for dry eye. We expect to see pivotal Phase III data for RETAANE in the September-October timeframe, followed by a Q4 NDA filing if all goes according to plan. A six-month expedited review could have the product on the U.S. market by mid-2005.

Valuation and price target: Our 12-month price target of \$68 is based on a 26.5x average P/E multiple for large-cap surgical device and specialty pharmaceutical stocks, applied to our 2005 EPS estimate of \$2.57.

Ted Huber of **Wachovia Securities** -- **ACL: Q403 In Line; Broader RETAANE Label Sought**

Pharma and IOL strength balances other weakness: Alcon delivered "in-line" performance, excluding a \$0.01 gain from asset sales. EPS were up 26.5% on 13.7% reported revenue growth after a 5.9% currency contribution. Another strong quarter in pharma (up 21.3% reported) and IOLs (up 14.9%) offset lower than expected "other cataract" growth (up 9.8%) and consumer, (up 7.1%). Each of these growth rates include currency and key new product launches (Infinity in cataracts and Sustaane artificial tears in Consumer).

Expanded Retaane labeling strategy: Alcon announced a regulatory strategy to expand Retaane's initial FDA NDA application to include most major forms of wet AMD. Previously, we expected Retaane's filing to cover "classic" lesions, some 25% of wet AMD patients. Though the probability of winning a broader label is lower than with Alcon's "classic" AMD indication, the new approach at least doubles the potential market opportunity (to over \$4 billion) that Retaane can address.

No change to estimates: We remain comfortable with an EPS estimate of \$2.16 for 2004 on revenue of \$3.79 billion, within management's guidance range of \$2.15 to \$2.18 on revenue of \$3.7 to \$3.8 billion. Our constant currency revenue target of 7.4% and EPS growth of 13% are each down from 2003 due the Ciloxan patent expiration and spending ahead of 2005 product launches.

Market perform rating; \$60 to \$65 valuation range: Our 6-12 month valuation range is \$60-65, 24-26x our 2005 EPS estimate of \$2.51. Our multiple range is based on a blend of comparable growth, market leading medical device (25.4x 2004 EPS) and specialty pharma comps (28.8x 2004 EPS). Risks include any negative pipeline news and decelerating pharma growth.

2/11 **QLT Inc.** announced earnings per share, for the three months and full year ended December 31, 2003 were \$0.13 and \$0.65, respectively, in line with company guidance for the full year.

2003 Sales -- As previously announced, Visudyne sales were \$95.9 million for the quarter and \$357 million for the year ended December 31, 2003. Visudyne sales figures for the fourth quarter and the full year represent increases of 24% over both sales in the fourth quarter and annual sales in 2002. "This past year we have enjoyed many successes, including continued growth in sales and earnings, as well as the recent CMS intention to expand coverage of Visudyne for certain people with occult and minimally classic AMD," said Paul Hastings, president and CEO. "In 2004 we expect to build on the success of 2003, see continued growth in both the top and bottom line, demonstrate further progress in our clinical development programs, and once again set realistic financial targets and goals and demonstrate our ability to meet them."

2004 Guidance -- Based on recent sales results and current trends in Visudyne sales, QLT is guiding to 2004 sales in the range of \$420 million to \$455 million at current exchange rates. EPS for 2004 are expected to range from \$0.74 to \$0.86, or growth over 2003 of 14% to 32%.

2003 Results

Revenues -- The company's revenues reached \$39.5 million for the quarter and \$146.8 million for the year in 2003, growing by 20% and 33% from the 2003 fourth quarter and year, respectively. QLT's share of Visudyne net profit (excluding the recovery of manufacturing and other costs) for the fourth quarter and the year were 28% and 30% of Visudyne sales, respectively. This compares to 2002 profit share rates of 32% in the fourth quarter and 27% for the year.

Research and Development -- Expenditures for research and development (R&D) were \$12.3 million for the fourth quarter and \$44.9 million for the full year 2003. This compares to 2002 R&D expenditures of \$12.7 million in the fourth quarter and \$42.3 million for the year.

2004 Outlook

Revenues -- Total revenues for the company are expected to range from \$165 million to \$180 million in 2004. The company expects that its share of profit from its alliance with Novartis (excluding the recovery of manufacturing and other costs) will be approximately 30% to 31.5% of Visudyne sales for 2004.

Research and Development -- The company expects R&D spending (net of tax credits) in the range of \$42 million to \$47 million, due mainly to the company's ongoing Phase III clinical studies for Visudyne to expand labeling and pursue combination studies, and

additional clinical studies to progress QLT0074 in androgenic alopecia, benign prostate hyperplasia, and other 0074 preclinical dermatology programs.

Clinical Update -- The Phase III multiple basal cell carcinoma (MBCC) study that has been enrolling patients since October 2002 is being discontinued. As previously communicated this trial had been slow to enroll patients due to the trial design imposing surgical resection at the end of the trial period in all patients. It has become clear that the current design and trial will not lead to an appropriate assessment of efficacy in a manner to achieve a timely registration. Given the length of time required to complete the MBCC trial and its relatively small market potential we are discontinuing this trial and feel that the resources required to pursue this opportunity are better spent maximizing Visudyne's potential in AMD and other pipeline opportunities. Due to the recent good news regarding the CMS's intention to expand coverage for Visudyne, there are several Visudyne maximization in AMD initiatives in planning, including expanding trials with Visudyne in combination with triamcinolone as well as developing Visudyne using reduced light fluence to further improve efficacy in larger lesions.

- 2/11 The February issue of *Ophthalmic Market Perspectives* discussed the year and fourth quarter results for refractive surgery procedures, including the impact that wavefront-driven LASIK was having on both procedures and pricing. According to David Harmon, encouraging signs of improvements in the U.S. economic conditions and excitement over wavefront-driven LASIK helped boost Q4-2003 procedures to 261,900, up 6.6% over exceptionally weak Q4-2002 results. Including U.S. patients traveling to Canada and Mexico, Q4 procedures were 268,400, up 6.2% over Q4-2002.

However, for the year, 1.150 million procedures were performed, down from the 1.176 million done in 2002, a 2.2% reduction.

The newsletter reported that the number of U.S. refractive surgeons and laser centers were up slightly in the fourth quarter, compared to preceding quarters. While many low-volume surgeons stopped offering LASIK in 2001 and 2002, the trend has slowed as the introduction of wavefront-driven LASIK has sparked higher interest among surgeons and prospective patients.

Demand for new lasers rose during the period due to seasonally stronger capital spending, a net increase in laser centers, increases in centers with multiple lasers, and aggressive trade-in programs by manufacturers (especially **Bausch & Lomb**). The recent approval for **WaveLight** has also sparked interest as a fourth alternative for laser buyers. In addition, WaveLight's marketing message of "results as good as custom without the extra effort" is resonating with some surgeons.

An estimated 46 new excimer lasers were sold in the U.S. during the quarter, up from 29 in the preceding quarter and from 38 during the same quarter last year.

Wavefront-driven LASIK continues to be the bright spot in the industry, with VISX reporting that 29% of procedure cards sold during the fourth quarter were for CustomVue. The percentage of wavefront-driven procedures performed by wavefront capable centers grew to 42% (with an estimated 80% of high volume centers adopting the new technology). According to a graphic accompanying the article, about 34% of all procedures were custom.

Along with the increase in custom procedures, average LASIK prices have increased about \$100 to \$1764, a 24-month high. Harmon now forecasts a Q1-2004 procedure level of 360,000, up 11.7% over the same month last year, and 34% over Q4-2003.

(Also see Ted Huber's report on the refractive market based on an interview with David Harmon, shown below in the February 17th brief.)

- 2/12 In the first quarter of the financial year 2003/2004 **Carl Zeiss Meditec AG** further improved its profit situation, despite a slight downturn in sales. Consolidated net income grew by more than a third to E3.5m (previous year: E2.5m). This is mainly attributable to a continued improvement in the gross margin of 43.7% due to innovative products and optimized manufacturing costs (previous year: 40.4%). Changes in exchange rates between the euro and US dollar and Japanese yen caused sales to fall slightly by 3.3% to E58.4m compared to E60.4m in the same period of the previous year. Had exchange rates remained constant, however, sales would have increased by 6.7% to E64.5m.

Accounting for 53.5% of sales, America is still the most important market, followed by Europe (21.6%) and Asia (17.4%). In order to set stage for planned growth there has been an expansion of activities in the marketing & sales and research & development sectors. Despite this, the EBIT margin increased slightly over the previous year. In the first quarter the latter stood at 10.5% (previous year: 10.2%). This corresponds to a value of E6.1m (previous year: E6.1m). There has been a significant improvement in cash flow from operating activities. Compared to the same period of the previous year, the latter grew by 156.6% to E5.0m (previous year: E2.0m).

Ulrich Krauss, president and CEO: "Despite the adverse trends in exchange rates, in particular the US dollar, we are continuing to improve our profit situation. That will remain so in the future. In doing so we are laying a solid foundation for our future expansion course, for which we this year -- as announced -- intend to create important strategic prerequisites." As recently as 17 December last year the company acquired software specialist **hiko medical communication**. In this way, the company's equipment and systems business is to be expanded to include special cross-platform software solutions for the field of ophthalmology. Other strategic priorities in the current year are a further increase in market penetration and the expansion of the company's product portfolio. Thanks to the profitable course of business, it was possible to finance the hiko acquisition for the main part from cash flow from operating activities. As a result, cash and cash equivalents fell only slightly to E43.4m at the end of the quarter (30 September 2003: E45.0m). The equity ratio has improved several times in succession and now stands

at 61% (30 September: 59%). Net debt again decreased to E18.8m (30 September 2003: E24.2m).

As of 31 December 2003 Carl Zeiss Meditec had 800 employees, including 40 employees at hiko. In addition there were 27 trainees. The corresponding figures for the previous year were 867 employees, plus 26 trainees. Carl Zeiss Meditec is upholding its plans to double sales and increase EBIT to at least 15% in the next five years. Ulrich Krauss, president and CEO: "This year we will be laying further foundation stones for achieving our ambitious goals. Due to exchange rate trends and under the assumption of a continued strong euro we anticipate a single-digit percentage growth in sales in 2004. On the other hand, a further improvement in profitability is expected. A further goal is to secure a substantial improvement in return on sales."

2/12 **InView**, formerly **Emory Vision**, Atlanta's research-based leader in vision correction, announced the results of a follow-up survey that gathered data from patients who participated in the original FDA clinical trial of LASIK surgery that began in 1995. The survey questioned patients on their need for corrective lenses, post-operative symptoms and overall satisfaction with the surgical procedure. The results showed the majority of respondents believe that LASIK improved their overall quality of life and would recommend the procedure to others.

"We are pleased to see such a positive response from patients who participated in the original LASIK trial, now five years later," said Keith Thompson, MD, co-founder of Emory Vision, now InView. "These survey results are important as they demonstrate lasting results for the surgery and very positive patient satisfaction with the procedure."

Background -- From June 1995 to February 1999, Dr. Thompson, George Waring, MD, and Jonathan Carr, MD, of InView, conducted the first physician-sponsored FDA clinical trial for LASIK. The original clinical trial included a total of 267 patients and determined that 96% of post-operative patients reported being free of the need for full-time distance optical correction following LASIK surgery. When asked to compare their vision prior to surgery with spectacles or contact lens directly following surgery:

- 73% of patients reported seeing the same or less glare
- 52% reported the same or less halo
- 79% reported the same or less ghost images

In late 2003, Drs. Thompson, Waring and Carr began the follow-up survey to understand the long-term results of LASIK with the group of patients who participated in the original FDA clinical trial. Of the original 267 patients, 149 responded to the survey. Patients completed a subjective questionnaire of 10 questions used in the original post surgical follow-up study.

Key Findings

Satisfaction with Results -- Of the 149 patients surveyed, 95% reported satisfaction or high satisfaction with the results of their LASIK surgery. A major contributing factor to the high satisfaction rate is the fact that 90% of patients surveyed reported being free from full-time use of glasses or contacts. About 51% reported no dependency on any optical correction devices.

"The majority of patients relying on glasses use them for close work or reading. Those using reading glasses in most cases were older patients," explained Thompson.

Post-Operative Symptoms: Glares, Halos, Ghost Images -- Patients who reported experiencing glare, halo or ghost images were less than those who had reported these symptoms in the original study, due to stabilization and improvement of vision beyond the initial post-operative study.

- 63% of patients reported no glare
- Of those reporting glare, it generally occurred immediately following surgery and diminished over time
- 62% showed no halos
- Those with halos reported mild to moderate halos directly following surgery
- The majority of respondents (89%) experienced no ghost images

Overall Satisfaction with LASIK -- Based on their experience, 94% would repeat LASIK, supporting the high overall satisfaction of patients five years after surgery. Ninety-one percent of patients reported that LASIK improved the overall quality of life and would recommend the procedure to others.

About InView -- InView is a state-of-the-art vision surgery center founded in 1994 by faculty of Emory University School of Medicine. It is the only center in the country to offer the revolutionary InterWave technology, a new system of vision measurement and individualized, patient-interactive treatment in LASIK surgery. InView surgeons have performed more than 40,000 LASIK procedures and the Center offers patients the widest range of options for vision correction surgery and treatment. InView is located at 4170 Ashford Dunwoody Road, Suite 300, Atlanta, Ga. 30319. For more information, go to www.inviewvision.com or call 404-843-EYES (3937).

2/17 Ted Huber of **Wachovia Securities** issued an update report on the **Refractive Surgery Market**.

Survey says..... We talked with **Market Scope's** Dave Harman for 30 minutes last Friday about his Q403 refractive industry survey (250 refractive surgeons, completed in early January) and the latest outlook for the refractive surgery industry. The survey revealed Q403 LASIK volume growth of 6% vs. Q402 and down slightly from Q303. Custom LASIK mix was 34% for Q403, up from 24% in the Q303 Market Scope Survey. This sequential increase in mix was largely driven by new surgeons offering Custom LASIK. For the surgeons offering custom LASIK during Q403, their procedure Custom mix was

42%, vs. 41% for Q303. Q403 growth and Custom mix figures each came in modestly below Market Scope's expectations for Q403; a discussion of factors that could have contributed to this short fall follows.

Market Scope forecasts: Market Scope is now forecasting 13% volume growth for 2004 over 2003 and custom Mix that increases by near 2% points sequentially each quarter, exiting 2004 in the low 40% range. For Q104, Market Scope expects volume growth of 13%.

It's the economy:...In the absence of any significant label expansions or new technologies, Harman views macro-economic factors, best captured by Consumer confidence, as the single most important determinant of LASIK volumes in 2004. Though Harman sees warning signs in soft employment figures, we note that January's *Michigan Consumer Confidence* measure of 103.8 (released Friday) was up sharply from December's 92.6 and is the highest recorded level since 107.6 in November 2000.

Competitive hardware market but steady procedure pricing: Market Scope reports that card prices are holding but that manufacturers are using deep equipment discounts and marketing subsidies to compete. **BOL** is offering some of the most aggressive hardware deals as it drives for higher installed base share in 2004. **VISX** retains an installed base lead with near 50% of placements with BOL still in the teens. BOL took hardware and procedure share during Q403 and appears poised for more gains with its aggressive placement program and **LASIK Vision Account Institute** win.

Phakic IOLS, narrow approvals ahead: Based on the FDA Ophthalmic Panel's recent narrow positive vote, and several follow up concerns, with the Verysise Phakic IOL, Harman expects both **AVO's** Verysise lens and **Staar Surgical's** lens to receive FDA approval but only for high myopia populations and with additional restrictions.

Wachovia perspectives: Our model calls for 10% growth and 35% Custom Mix for VISX in 2004. With tougher 2H04 volume growth comps and active Custom surgeons peaking at an average low 40% mix, we expect VISX's revenue and profit growth to be front end loaded in 2004. BOL is best positioned for share gains in 2004, we conservatively forecast its refractive growth at 16%; higher growth is possible if its new microkeratome can hold off further share losses to the **Intralase** laser flap maker.

2/18 **LCA-Vision Inc.** reported net income for the three months ended December 31, 2003 of \$2.2 million (19 cents per share) compared with a net loss of \$1.9 million (18 cents per share) for the three months ended December 31, 2002.

For the fourth quarter, total revenues grew approximately 56% to \$20.8 million compared with \$13.3 million in the fourth quarter of 2002. The company reported that revenues at vision centers open at least 12 months increased 44% during the quarter. Fourth quarter procedure volume rose 32% to 16,060, and average price per procedure increased 19% to \$1,293, both compared with the fourth quarter of 2002.

For the year ended December 31, 2003, the company reported net income of \$7.3 million (66 cents per share) compared with a net loss of \$3.8 million (35 cents per share) for the year ended December 31, 2002. Total revenues grew approximately 32% to \$81.4 million in 2003, compared with \$61.8 million in 2002. Net cash provided by operations during the year ended December 31, 2003 was \$12.5 million. Cash and short-term investments were \$64.9 million as of December 31, 2003, reflecting both the completion of a public offering of common stock in December 2003 that raised approximately \$37 million in proceeds for the company and the cash provided by operations.

"We are pleased with our exceptional financial and operational performance in the fourth quarter of a very strong year for the company," said Stephen Joffe, chairman and CEO of LCA-Vision. "The fact that in 2003 fourth quarter revenues surpassed first quarter revenues is particularly impressive, given the historic seasonality of our business. Procedure volume growth for the fourth quarter was up over four-fold compared with the 7% growth estimated by laser vision correction industry sources for the market as a whole. For the quarter, Custom LASIK represented approximately 12% of our procedure volume, up from 7% in the third quarter of 2003. With the price premium Custom LASIK commands, it accounted for approximately 16% of our total revenues. We are confident in our ability to capture additional market share in the large, expanding market for laser vision correction. With our value pricing and the range of technology options available to our patients, we plan to continue opening LasikPlus vision centers in select markets that we believe can contribute to growth in the company's profitability and cash flow. With approximately \$65 million in cash at the end of 2003, strong cash flow and seasoned management, we believe we have the resources to execute this strategy successfully."

Revised 2004 EPS Guidance -- Based on the company's strong financial results during 2003 and market share gain, as well as a proven business model and growth strategy, LCA-Vision is increasing guidance for full-year 2004 diluted EPS to \$0.90-\$0.95, up from our prior guidance of \$0.80-\$0.85.

2/18 **NovaMed Eyecare, Inc.** reported results for the fourth quarter and twelve months ended December 31, 2003. Net income from continuing operations in the fourth quarter was \$1.3 million (6 cents per share) as compared to \$587,000 (3 cents per share) for the fourth quarter of 2002. The fourth quarter 2003 results included a pre-tax gain on the sale of minority interests of \$966,000. The fourth quarter 2002 results included a pre-tax gain on the sale of minority interests of \$1.0 million, income of \$1.0 million from the reduction of a previously established restructuring reserve and a goodwill impairment loss of \$1.3 million.

Net income from continuing operations for 2003 was \$3.5 million (16 cents per share) as compared to \$3.7 million (15 cents per share) for 2002. Net income, including discontinued operations and the cumulative effect of a change in accounting principle, was \$3.5 million (16 cents per share) for 2003 as compared to \$210,000 (1 cent per share) for 2002. The 2002 results included a charge of \$1.8 million (7 cents per share)

as a cumulative effect of a change in accounting principle related to the impairment of goodwill as well as a loss of \$1.9 million (7 cents per share) on the disposal of discontinued operations.

For the quarter, total net revenue was \$13.6 million compared to \$13.7 million for the prior year fourth quarter. Net revenue from surgical facilities was \$9.2 million compared to \$9.2 million in the prior year fourth quarter. Total surgical procedures increased 7% over the prior year fourth quarter with cataract procedures down 4%, laser vision correction procedures up 2% and other procedures up 31%. On a same-facility basis, cataract procedures were down 8% and other procedures were up 27% compared to the prior year fourth quarter. NovaMed measures same-facility results using only those facilities that it has owned and operated for the entire current and prior year periods reported. The new Kansas City surgical facility opened in September 2003 negatively impacted same-facility results as the cataract surgeon performing procedures at this facility had previously used one of our other surgical facilities in the Kansas City market. Product sales and other revenue was \$4.4 million in the fourth quarter, down 2% over the prior year fourth quarter.

For 2003, total net revenue was \$55.5 million compared to \$53.8 million for 2002. Net revenue from surgical facilities was \$36.4 million, up 8% from \$33.7 million in 2002, primarily due to a 17% increase in cataract procedures and a 43% increase in other procedures. This growth more than offset the 29% decrease in laser vision correction procedures. In 2003, revenue from laser vision correction procedures represented approximately 9% of our surgical facilities revenue as compared to 18% in 2002. Surgical facilities revenue from procedures other than laser vision correction increased 19% over the prior year and 8% on a same-facility basis. On a same-facility basis, cataract procedures grew 6% and other procedures grew 32% over the prior year. Product sales and other revenue was \$19.1 million in 2003 as compared to \$20.1 million in 2002.

In December 2003, NovaMed sold a 20% minority interest in its New Albany, IN surgical facility to two physicians and a 3% minority interest in its Chicago, IL surgical facility to a physician. In February 2004, NovaMed sold certain assets of its Chattanooga, TN physician practice to a local ophthalmologist as well as a 22.5% interest in its Chattanooga surgical facility to the same ophthalmologist and three other physicians.

"Although we did not acquire any new surgical facilities in 2003, I am pleased with the results of our core surgical facilities business for the year," commented Stephen Winjum, NovaMed chairman, president and CEO. "With our recent minority interest sales, we now have physician-partners in 14 of our 17 surgical facilities which further strengthens our portfolio. We ended 2003 with a cash balance of approximately \$12 million and no outstanding borrowings under our \$30 million credit facility which provides us with significant capital resources to grow the company in 2004 and beyond. In 2004, our priorities are to increase the utilization of our existing surgical facilities and to acquire additional surgical facilities, including multi-specialty surgical facilities, that will contribute to the growth of the company."

NovaMed acquires, develops and operates ambulatory surgery centers in partnership with physicians. NovaMed currently owns a majority interest in 17 centers located in 10 states. NovaMed's executive offices are located in Chicago, Illinois.

- 2/23 **Refocus Group, Inc.** announced that it had officially begun its FDA Phase II Clinical Trials with the completion of initial patient procedures. Two patients with presbyopia received Refocus Group's scleral implant as part of the company's Scleral Spacing Procedure. The procedures were performed by Gene Zdenek, MD, a noted ophthalmologist and head of the Zdenek Eye Institute in Reseda, Calif.

Dr. Zdenek is one of five investigators in the United States who has been approved initially to participate in the Phase II trials. The other investigators are finishing initial patient recruitment and screening and will begin their presbyopia surgeries shortly. The trials are being conducted as a multi-center, randomized study, with 100 patients receiving the Scleral Spacing Procedure and another 50 patients designated as control patients. Additional patients would be added at up to 10 total sites upon submittal and FDA review of the preliminary results of the trials. Completion of enrollment and surgeries for Phase II patients is anticipated sometime this summer.

"We have tremendous optimism for our scleral implant and Scleral Spacing Procedure's potential as a new mainstay treatment option for presbyopia, which is seen by some in the ophthalmic community as the last great frontier of eye care," said Terry Walts, president and CEO of Refocus Group. "We will provide an update on the status and outcome of these trials after more data becomes available."

OPHTHALMIC LASER UPDATE -- March 2004

- 2/24 **Advanced Medical Optics, Inc.** announced financial results for the fourth quarter and full year of 2003. Net revenue in the fourth quarter rose 13.5% over the same period last year to \$167.0 million, reflecting solid sales gains in the company's ophthalmic surgical and eye care businesses and favorable foreign currency exchange rates. On a pro forma basis, net income for the fourth quarter of 2003 was \$10.4 million (34 cents per share) compared to \$9.5 million (33 cents per share) in the year-ago quarter.

For the full year, net revenue was \$601.5 million, up 11.8% compared to 2002. Excluding the effect of currency, revenue grew 2.9% for both the fourth quarter and full year, compared to the same periods in 2002. Full-year 2003 pro forma net income was \$24.0 million (80 cents per share) compared to pro forma net income of \$17.6 (61 cents per share) for 2002.

The company revised upward its 2004 revenue guidance to a range of \$620 million to \$630 million and reaffirmed its pro forma diluted earnings per share guidance of \$0.98 to \$1.00.

Two analysts provided their take on the financial result:

Michael Lachman of **ThinkEquity Partners**, **AVO: Visibility on EPS Upside Creeps into 2004 - Reiterate Overweight**. Some of his comments included:

We reiterate our Overweight-3 rating on shares of Advanced Medical Optics (AMO), and raise our 12-month price target from \$23 to \$26, as solid top line performance and ongoing profitability initiatives provide improving visibility into earnings upside in 2004 and beyond. Our investment case has been based on the potential for earnings upside in 2005 and beyond, driven by AMO's organizational realignment and a potential accretive acquisition of **Pfizer's** cataract surgery business. While we still see the primary focus for 2004 as operational execution and the achievement of milestones, we anticipate some earnings upside this year as well, driven by above-forecast operating margins. We raise our 2004 pro forma EPS estimate from \$1.00 to \$1.03, above unchanged (and we believe conservative) guidance of \$0.98-\$1.00. For 2005, we go from \$1.19 to \$1.25. Our new \$26 price target is based on a 21x multiple applied to this new 2005 EPS estimate.

Investment Highlights -- We reiterate our Overweight-3 rating on shares of Advanced Medical Optics (AMO), as solid top line performance and ongoing profitability initiatives provide improving visibility into earnings upside in 2004 and beyond. We view AMO as a company that will find ways to achieve above average top- and bottom-line growth in the slow but steady markets in which it competes. We have characterized the primary focus for AMO in 2004 as operational execution and the achievement of milestones in the company's organizational realignment program, with earnings upside to follow in 2005 and beyond. We have raised our operating margin forecast for 2004 from 10% to 11%, resulting in a higher EPS estimate. However, we are still conservative relative to management's 12% operating margin target for the year, leading to improving visibility on EPS upside in 2004. We have also raised our 2005 operating margin forecast, from 11% to 13%, but note that management plans to exit the year at 15%, suggesting upside to our estimate. We note that each 100bp of incremental operating margin in 2004 and 2005 results in additional pro forma EPS of about \$0.10.

We are raising our 2004 revenue forecast from \$614 million to \$644 million to more accurately reflect current foreign exchange rates, and raising our 2004 pro forma EPS estimate from \$1.00 to \$1.03, above unchanged (and we believe conservative) guidance of \$0.98-\$1.00. Our revenue growth estimate of 7% reflects constant currency growth of 4% and an FX boost of 3%, with the FX impact highest in Q1 and diminishing in subsequent quarters. We note that our new 2004 revenue estimate goes beyond the new guidance range of \$620-630 million, which we believe anticipates a reversal of favorable currency trends in H2-04 -- certainly a possibility. While our higher revenue and operating margin assumptions for 2004 drive higher EPS as well, this upside is offset somewhat by the GAAP accounting treatment of the company's convertible debt, with AMO's stock price fast approaching the \$24.65 conversion benchmark. This issue is described more fully below. The company is basing its guidance on a mid-year conversion, resulting in lower interest expense (about \$5 million annually) and a higher share count (6.8 million additional shares), and we have chosen to model this as well. We estimate that the annual dilutive impact of the debt conversion accounting is about

\$0.07-0.08. We have also raised our tax rate forecast for 2004, from 35.6% to 37.8%, consistent with the company's mid-to-high 30's guidance. On the call, management admitted that it is attempting to be conservative in its EPS guidance, and we view above-forecast operating margins as the primary source of earnings upside in our model. The company's organizational realignment program should result in some non-recurring charges beginning in Q2-2004, but these have not been quantified.

Ophthalmic Surgical sales were \$86.5 million, versus our estimate of \$81.3 million. Sales growth was solid across all geographies and product lines, particularly AMO's silicone and acrylic IOLs, and the Sovereign phaco platform. Sovereign system placements increased 48% over Q4-02 despite the launch of **Alcon's** Infiniti platform. We expect phaco sales to continue to grow as the bimanual/cold phaco technique gains physician acceptance and drives product traction. In 2004, sales of these products should be augmented by new products launches, including the AMO Gemini vitreoretinal system in Europe, the next generation Array multifocal IOL, an advanced microkeratome for LASIK surgery, the StabilEyes capsular tension ring, a multilingual version of Sovereign Compact, and the Verisyse anterior chamber phakic IOL. Following the recent FDA Ophthalmic Devices Panel recommendation, AMO expects to launch the Verisyse lens in the US in Q3. The company plans a controlled rollout, with focus on training and proctoring of implanting surgeons. We maintain a modest near-term outlook for phakic IOLs, viewing them as niche products for very high-level myopes.

Ted Huber of **Wachovia Securities, AVO: Surgical Hardware Gains Share; Rev. Growth Outlook Limited.**

*** Q403 Results in line:** The fourth straight quarter of 3% cc revenue growth helped deliver EPS of \$0.34, in line with our forecast and consensus. Surgical revenue growth of 5.1% constant currency led the results while Eye care growth remained positive (0.7%). With operating expenses growing faster than revenues, EBITDA decreased 8.6% Yr/Yr in Q403, and increased 3.5% for full year 2003.

*** Increased 2004 operating guidance, eps unchanged:** \$0.98-\$1.00 EPS guidance is unchanged. While share count should increase by 20% in 2003 (expected exercise of convert Q204) management's increased its revenue forecast (\$620-\$630 MM from \$605-615 MM) and now expects a 12% operating margin (vs. 9.9%) in 2003. We model \$1.02 EPS on 3% CC growth.

*** Moving parts limit 2004 visibility:** Q403 share gains from the Whitestar platform and Complete solution lines strengthen our confidence in 3% 2004 constant currency revenue growth. This, and management's record (6 quarters of solid execution and expectations management) add confidence to 2004. But visibility into a 180 basis point operating margin improvement remains limited given complicating currency impacts, rising 2003 costs, and execution on new manufacturing. Our model calls for flat 2004 SG&A growth following a 13% rise 2003 (influenced by new public company costs) and 2004 gross margins increase 290 basis points from Q1 to Q4 with execution on new manufacturing.

2/24 **20/10 PERFECT VISION Optische Geräte GmbH** announced that it had received 510(k) clearance from the FDA to market its new FEMTEC Laser Microkeratome. The FEMTEC device is a revolutionary femtosecond laser system for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea. The FEMTEC Laser is fully automated and features a patented and unique curved patient interface, which does not appanate the cornea. FEMTEC's solid-state femtosecond laser uses ultrashort infrared light pulses for direct intrastromal tissue interaction.

"This new FDA clearance is a big step for the field of ophthalmic surgery," commented Dr. Frieder Loesel, CEO of 20/10 PERFECT VISION. "Surgeons have now access to a device that is technologically advanced, versatile and provides convenient ease of use." Dr. Loesel also added, "This is exciting technology, and we're eager to move on with our production and marketing plans."

20/10 PERFECT VISION of Heidelberg, Germany, develops, manufactures and markets innovative technologies for raising refractive surgery well beyond current expectations. The company is continually expanding its efforts to deliver a variety of exciting new applications for the FEMTEC platform, set to revolutionize the ophthalmic surgery market, while keeping ease-of-use and patient safety as primary objectives. 20/10 PERFECT VISION has also developed WaveScan, the award-winning wavefront diagnostic device for refractive surgery, commercialized by **VISX, Inc.** The ISO-certified company is further pioneering the field of adaptive optics in ophthalmology. The FEMTEC femtosecond laser is being marketed directly through 20/10 PERFECT VISION and underlines the company's technology leadership position in Personalized Vision Care.

2/25 Jason Mills of **First Albany Corporation** met with management of **Bausch & Lomb** and filed this update report: **Meetings with CFO Augment Our Thesis; Reiterate Strong Buy.**

Action -- Reiterate Strong Buy rating. Incremental data points from management meetings in San Francisco augment our bullish thesis. We believe BOL has good visibility into financial targets, especially projects that could further expand operating margins. We believe our 2004 and 2005 operating margin estimates (12.2% and 13.2%, respectively) are conservative, which coupled with incremental, potential top-line drivers in 2004 (Zyoptix, ZyLet & One-Day in Japan), could portend upside potential to estimates.

Key Points

- **Meetings with Management Augment Bullish Thesis** - Incremental data points from our recently hosted management meetings in San Francisco augment our bullish thesis.

- **Good Visibility, in our view** - We believe BOL has good visibility into financial targets, especially projects that could further expand operating margins.

- **Operating Margin Targets Conservative** - We believe our 2004 and 2005 operating margin estimates (12.2% and 13.2%, respectively) are conservative. Supported by data points drawn from these meetings, we suggest BOL could achieve 14% operating margins or better in 2005.

- **Upside to EPS Estimates** - Continuing to execute on the metrics of the operating profit improvement plan announced in mid-2002, coupled with incremental top-line drivers in 2004 (Zyoptix, ZyLet, and One-Day in Japan), could portend upside potential to estimates.

- **EPS Leverage Example** - At the 14% OI level in 2005, all things being equal (i.e., debt level and interest rates), EPS could be \$3.33, implying \$0.22 upside potential to our current estimate and \$0.28 to the consensus estimate.

Valuation -- We reiterate our 12-month price target of \$64 per share. To arrive at our price target, we use a 20.6x P/E multiple, which is a 20% discount to the FAC Mid-Cap medical device group average of 25.8x relative to CY04 estimates, carried forward and applied to our 2005 estimate of \$3.11, to which we believe there is material upside potential.

Discussion

The Bottom Line - What Matters Most. We hosted a series of investor meetings in San Francisco recently with Bausch & Lomb Chief Financial Officer Steve McCluski. Following these meetings, and consistent with our ongoing thesis on the company, we find it hard to believe there isn't potential upside to EPS estimates. In 2005, for example, our model calls for 80 bps expansion in the GM versus the 2004 estimated level (guidance is 100 bps), but we only model an incremental 20 bps leverage from operating expenses, even though we expect most of the leverage from the planned IT consolidation to favorably impact the P&L (i.e., a potential "step function" reduction of SG&A expenses of 250 bps) in 2H:05. Moreover, our 2005 EPS estimate of \$3.11 builds off our operation margin target for the year of 13.2%. Yet, it is our belief, supported by data points drawn from these recent meetings, that BOL could realistically achieve 14% operating margins or better in 2005. At that level, all things being equal (i.e., debt level and interest rates), EPS would be \$3.33, implying \$0.22 upside potential to our current estimate, and \$0.28 for the consensus. In sum, our primary takeaway from these meetings is the EPS upside potential to our forward estimates, as discussed above, which we believe is predicated on these fundamental metrics:

- **Revenue performance** - We model only 6% CAGR (including currency benefit) through FY05, but believe upside is possible, depending on the performance of new product launches in 2004-05 including the OneDay soft contact lens launch in Japan

(estimate March 2004), Zyoptix Custom LASIK platform launch in U.S. (started in 4Q:03), ZyLet combo antibiotic (2H:04E), Retisert for non-infectious uveitis (mid 2005E - not in our model).

- **Continuing to execute on the metrics of the operating profit improvement plan announced in mid-2002, including:** 1) consolidation of manufacturing (projects completed) and increasing yields (ongoing), 2) improving product mix to increase margins (under way), 3) reallocating spending and lower procurement costs (under way), and 4) global IT Platform development - i.e., consolidation of legacy systems onto a global enterprise system (2H:05E completion).

- **Balance Sheet Drivers** - Plan to pay down net debt of \$195M by August 2005 and continue to improve DSOs and inventory levels.

Other Key Takeaways

Refractive - Driven by approval for Zyoptix in October, the Americas refractive revenue sprinted ahead over 50% in 4Q, as BOL's Zyoptix procedure card sales quadrupled, while plano (conventional) card sales increased 33% - well ahead of market rates (VISX [EYE-\$17.70 Neutral] put up 7.5% growth in 4Q procedure volume). We think BOL will continue to take share in the U.S. market, augmented by a recent "customer win," as **Laser Vision Institute** (recently purchased by **Summit Partners**) - the 3rd largest corporate LASIK provider in terms of procedures - announced its intention to use Zyoptix exclusively for its Custom procedures. We estimate LVI centers perform roughly 100K procedures annually. While the company's growth objective (20% y/y) in 2004 was the only "aggressive" guidance given for the year, in our view, we still doubled our estimate to 16% growth from 8%. While it's not in our model, refractive could be source of EPS upside in 2004, if the high-margin procedure card sales continue to increase as a percentage of the internal mix, and track toward the 20% share target the company has identified for the business.

3/1 Wavefront-guided LASIK corrects higher-order optical distortions and provides significantly improved contrast sensitivity compared with standard LASIK. This is the conclusion of a study appearing in the March 2004 issue of *Ophthalmology*, the clinical journal of the *American Academy of Ophthalmology*. Contrast sensitivity is the visual system's ability to detect subtle shades of gray between an object and its background.

In this comparative study conducted in Israel, 24 eyes of 13 patients were treated with wavefront-guided LASIK and 22 eyes of 12 patients were treated with standard LASIK. At one month after surgery, it was found that 88% of the contrast sensitivity measurements improved in the wavefront group, whereas only 40% improved in the standard group. Also, uncorrected visual acuity of 20/20 or better was achieved by 72 percent of the wavefront group and by 70% of the standard group.

Igor Kaiserman, MD, an ophthalmologist at Hadassah Medical Center in Jerusalem and lead author of the study, explained, "LASIK has a high rate of improving uncorrected visual acuity, but it can degrade the quality of vision, resulting in reports of reduced night vision clarity, glare and halos. This is the result of reduced contrast sensitivity, which is greater among patients with high degrees of nearsightedness. One reason for reduced contrast sensitivity is the increased higher-order distortions caused by the LASIK procedure. Because wavefront measurement provides a more precise and detailed map of the visual system's distortions, wavefront-guided LASIK reduces these distortions, resulting in an improved quality of vision."

Academy spokesperson Scott MacRae, MD, professor of ophthalmology and visual science at the University of Rochester Medical Center, Rochester, New York, said, "I agree that customized wavefront treatments should be incorporated into refractive surgery practices because they minimize higher-order aberrations that are created by conventional LASIK. Customized treatments make LASIK safer, and allow some patients to have sharper vision with greater contrast sensitivity. However, because this study was done on a small number of different patients, the results do not provide conclusive evidence that the wavefront treatment is better for every patient. A paired, bilateral study in which each patient has a wavefront correction and a conventional treatment would be more compelling."

3/3 **STAAR Surgical company** announced financial results for its fourth quarter and full year 2003, which ended January 2, 2004. Total product sales for the fourth quarter were \$12.8 million compared with \$13.2 million reported in the same quarter last year. Excluding the impact of changes in currency fourth quarter sales were \$11.8 million compared with \$13.2 million reported in the fourth quarter of 2002.

Total product sales for the full year were \$50.4 million up 5% compared with 2002. Excluding the impact of changes in currency 2003 total product sales were \$46.8 million compared with \$47.9 million reported in 2002. Total revenue for the full year 2003 was \$50.5 million (\$46.8 million in constant currency), compared with \$48.2 million for the full year 2002. The difference between total revenue and product sales was the result of royalties previously generated by technology licenses that terminated as of March 31, 2003.

The net loss for the quarter was \$3.5 million (19 cents per share) compared with a net loss of \$9.9 million (58 cents per share) during the same period one year ago. The net loss for the full year was \$8.4 million (47 cents per share) compared with a net loss in 2002 of \$16.8 million (98 cents per share). The net income comparison results in a year over year decline of 7%, despite a year over year comparable operating expense increase of 14%.

"Although overall product sales were down in the fourth quarter and full year, we were encouraged by the performance of our latest generation Collamer and VISIAN ICL lenses," said David Bailey, president and CEO of STAAR Surgical. "During the fourth

quarter Collamer lens sales increased 18% compared with the fourth quarter of 2002 and ICL sales were up 20%. For the full year Collamer and ICL sales also improved and were up 20% and 31% respectively. Our U.S. IOL sales continue to be constrained by the lack of effective injection systems. Internationally we are benefiting from our outstanding preloaded silicone lens system, which was launched late last year. Early sales indicate that this system is gaining traction and we believe it will become the standard of care going forward. However, in the U.S. we continue to examine methodologies to make our older insertion technology more competitive. Resolving these issues remains one of our top priorities and we continue to make progress toward improving our whole injector range in order to bring improved systems to market."

"Despite the significant planned and executed increases in marketing and selling and research and development, throughout the year we were able to continue to successfully streamline our U.S. operating infrastructure," continued Bailey. "Although general and administrative expenses increased overall in the fourth quarter and the full year due to bad debt reserves recorded internationally, administrative expenses in the U.S. decreased as a percentage of total sales during those same periods. 2003 was a year of turnaround and investment for STAAR. During the year we made progress on many of our strategic objectives. The exciting steps we took to further develop our ICL lens, including an expedited review and a very successful review by the FDA Ophthalmic Devices panel should not overshadow the other operational milestones we have achieved this year which include the retirement of all outstanding legacy litigation involving STAAR, the pay down of \$2.9 million in debt, the collection of \$3.3 million of notes of former officers, the strong international growth of ICL sales and seven consecutive quarters of improving gross profits."

"We remain excited about the potential approval from the FDA for marketing the ICL in the U.S. but are well aware of the compliance issues we need to resolve before this can happen," continued Bailey. "As we discussed during our conference call in January we continue to work diligently to prepare for a re-audit of our manufacturing facility and our overall quality system. During January, we had a very productive meeting with the FDA Office of Compliance to discuss our pending approval and the re-audit process. In addition, on February 12, 2004 we had another meeting with the local FDA district to update them on our progress. During the meeting the FDA confirmed their willingness to work with us to accommodate a re-audit once they receive a formal request from the company. In response to specific issues in the Warning Letter we have also completed a root cause analysis and were able to conclude that our patented Collamer material was not the underlying cause of the 26 reported incidents, out of more than 160,000 lenses implanted, concerning certain post-surgical refractive changes. Finally, we have also received an indication that as part of the pre-approval process the FDA is likely to audit our Nidau, Switzerland manufacturing facility for the ICL. Although we have not received a formal request, we believe a successful audit of this facility will be a requirement for ICL approval. As part of our efforts to complete the entire auditing process, we have engaged professional external auditors to review both the Switzerland and Monrovia facilities. The reviews will be completed this week."

Looking ahead, Bailey offered this outlook for the full year 2004. "We believe that it is prudent to provide revenue guidance without any U.S. ICL contribution given the uncertainty of the exact approval date. Without this contribution we believe we can achieve low double digit revenue growth for the full year. Gross margins are expected to improve while sales and marketing and research and development spending will have moderate increases on an absolute basis. Based on these dynamics, the net loss for 2004 should be approximately 50% less than the net loss for 2003."

Several analysts provided their viewpoints on the Staar results:

Joanne Wuensch of **Harris Nesbitt; STAA--4Q03 EPS Loss Greater than Expected; Timing of FDA Approval**

* **Event** -- STAAR Surgical reported 4Q03 revenue of \$12.8 million (down 3.6%) and an EPS loss of \$0.19, which compare with our \$12.6 million and loss of \$0.06 estimates (consensus was for a loss of \$0.09). Management continues to move through the FDA process with its phakic IOL, anticipating a review of its Switzerland manufacturing facility in the next 1-2 months. For the portions of the process that the company has control over, we believe that it is exerting significant effort. Unfortunately, much of the process is out of its control. STAA ended the quarter with \$7 million in cash on the balance sheet, enough to hit break even (now projected in 2005 from 3Q04), but it should be running on fumes at that time.

* **Impact** -- Negative.

* **Forecasts** -- Management guidance: "given the uncertainty of the exact approval date...we can achieve low double-digit revenue growth for the full year...net loss for 2004 should be approximately 50% less than the net loss for 2003." No change to our revenue estimates, but given guidance and STAA's expense trends, we are cutting our EPS estimates to a loss of \$0.18 from \$0.01 for 2004 and \$0.14 from \$0.21 for 2005.

* **Valuation** -- Our price target remains \$9.

* **Recommendation** -- We maintain our NEUTRAL rating and anticipate near-term volatility.

Jason Bedford of **Adams, Harkness & Hill; STAA: Reports 4Q: another pushout in the ICL timeline**

Key Points:

* 4Q revenue of \$12.8M came in slightly higher than the pre-announced \$12.5M but was still down 4% y/y; ICL sales grew 20% OUS but were offset by lower U.S. revenue; net loss came in at \$(0.19) versus our estimate of \$(0.12) and consensus of \$(0.09).

* The FDA will now review STAA's Swiss plant, which could take another month or two, pushing back FDA approval for the implantable contact lens (ICL); we expect approval in 3Q.

* STAA offered FY04 guidance of low-double-digit revenue growth and a net loss of roughly \$4M; we lower our net loss estimate to \$(0.21)/share, down from our street-low estimate of \$(0.04)/ share; for FY05, our estimates are \$69M in revenue and \$0.21 in EPS.

* Management's revenue guidance excludes any impact from an ICL approval, which we think could add \$1.5M in '04 revenue; STAA will have 60 physicians capable of performing the procedure immediately and expects to train another 740 by year-end.

* We reiterate our Buy rating but are lowering our 12-month price target to \$11; while we expect the stock to be weak at the open and be range bound in the near term, our rating reflects our long-term belief in the technology.

John Calcagnini of CIBC World Markets; STAAR Surgical company 4Q03 Revenues In Line But EPS Well Below Estimates Due to High SG&A

* We reiterate our Sector Underperformer (Spec.) rating on STAAR following the company's 4Q03 earnings release on March 3. Revenues were \$12.8 million, down 3%, versus \$13.2 million a year ago, in line with our and consensus estimates. Excluding F/X, revenues were down 10%.

* Net loss was substantially higher than we were expecting at \$3.5M, or \$0.19 per share, vs. a net loss last year of \$900,000, or \$0.05 per share. This increase in net loss was driven by increased SG&A in the quarter related to preparation for the ICL launch in the U.S. and unfavorable F/X.

* The previous management estimate -- for approval of the ICL by April -- we think will most likely be pushed out further given the FDA will audit STAAR's Monrovia, CA and Swiss facilities for its next review and the company's decision to have pre-audits performed prior to having the FDA audit.

* We believe the market for the ICL will be limited due to concerns about the potential for endothelial cell loss, cataracts, and unknown long-term outcomes in general. We believe that few patients will be pursuing this procedure. Further, LASIK can treat patients up to -10D of refractive error.

3/4 **TLC Vision Corporation** announced its financial results for the three and twelve month periods ended December 31, 2003.

Three Months Ended December 31, 2003: Q4-03 total net revenues were \$48.5 million, up 19% from \$40.8 million in Q4-02 and up 6% from \$46.0 million in the previous

quarter. Revenues from other healthcare services continued to demonstrate steady growth and represented 29% of total revenues in Q4-03 compared to 26% in the same three month period a year ago and 27% last quarter. Q4-03 paid laser procedure volumes were over 38,600 compared to 37,700 in the same period a year ago and 39,300 in the previous quarter. This result was due to 5% year-over-year and 1% quarter-over-quarter growth in the owned and managed centers offset by a 1% year-over-year and a 6% quarter-over-quarter volume decline in the access business, which has a lower variable margin. The procedure volume mix in Q4-03 was 59% owned and managed centers versus 41% access.

CustomLASIK procedures represented approximately 43% of Q4-03 owned and managed center volumes. Higher pricing and gross margins associated with CustomLASIK procedures, combined with a more favorable volume mix led to significantly improved operating performance.

On a GAAP basis, TLCVision reported a net loss of \$2.9 million (4 cent per share) in the fourth quarter of 2003 which included \$623,000 in research and development expense related to the company's ongoing investment in **Vascular Sciences Corporation** and \$320,000 in restructuring and other costs. TLCVision reported a net loss of \$39.7 million (63 cents per share) for the same period a year ago and \$4.1 million (6 cents per share) in Q3-04.

Twelve Months Ended December 31, 2003: Total fiscal year 2003 net revenues were \$195.7 million, up 19% from \$164.6 million in the same twelve-month period in 2002. Revenues from other healthcare services generated 25% of total net revenues compared to 20% in the 2002 twelve-month period. The 2003 net loss was \$9.4 million (15 cents per share). For the same twelve-month period in 2002 the company recorded a net loss of \$144.7 million or \$2.68 per share.

The company ended the twelve-month period in a strong financial position with cash and short-term investments totaling \$30.3 million.

Q1-04 Financial Outlook: Refractive surgery is traditionally a seasonal business, with the first quarter being the strongest of the year. In a highly leveraged fixed-cost business model like TLCV's, profitability levels are also particularly sensitive to total procedure volumes, average variable contribution margin per procedure and procedure mix. Greater than expected improvements in all three of those profit drivers have been realized thus far in the first quarter of 2004.

For Q1-04, based on preliminary financial analysis, the company expects to report adjusted EBITDA in an approximate range of \$12 million - \$14 million and net income in an approximate range of \$6.5 million - \$8.5 million. Actual Q1-04 results could vary and will be announced in early May.

RHEO Update: The patented Rheopheresis blood filtration process is performed using the Rheofilter MDF System which is designed to deplete certain high molecular weight plasma proteins and lipoproteins from the blood which are believed to contribute to the development, or promote the progression, of dry AMD. Dry AMD is the leading cause of vision loss in people over the age of 50 in the western world. The majority of dry AMD patients will gradually lose their central vision, potentially to a point of legal blindness. While success in treating AMD is often only measured by the ability to slow down or halt the disease's progression, in many instances RHEO has actually improved patients' vision. RHEO is currently the subject of a pivotal (phase III) study in the U.S. known as the MIRA-1 Protocol.

Given the increased attention that its RHEO business has recently received, TLCVision has commenced a process to explore structural alternatives to maximize the value of the business for TLCVision and its shareholders.

- 3/8 *EyeWorld Week* reported that **Gebauer Medizintechnik** (Neuhausen, Germany) announced positive clinical results for the first 100 Epi-LASIK patients treated in Europe using its minimally invasive, alcohol free Epi-Lasitome. The Epi-Lasitome has received the European CE Mark, and based on its positive clinical evaluation, Gebauer has begun its commercial introduction in several European countries. The company plans to file a 510(k) premarket notification submission with the Food and Drug Administration within the next 60 days seeking marketing clearance in the United States. "I was extremely pleased with the ease with which the Epi-Lasitome created an epithelial flap without incident and without the use of alcohol or other chemicals. The clinical results were excellent," said lead clinical investigator Chris Lohmann, MD, University Eye Clinic, Regensburg, Germany. "Six of the first 100 patients treated were prior LASEK re-treatments. Making the Epi-flap in this group posed no problems and the outcomes were no different."

The newsletter also reported that LASIK performed well during military freefall training. Although non-incisional refractive surgery is strongly preferred for special operations soldiers, even those with LASIK may be able to pass military freefall training safely, said Lt. Col. Scott Barnes, MD, fellow, Massachusetts Eye & Ear Infirmary, Boston, and recent deputy surgeon for the U.S. Army Special Operations Command. The Army wants its special operations members to have surface ablation if necessary rather than LASIK, Barnes said. But if the Army wanted to look past the LASIK issue to accept an especially qualified candidate for special operations, Barnes' study could help justify such recruiting. That's because 12 soldiers that underwent LASIK subjected their eyes to winds between 120 and 160 mph in a wind tunnel trainer (along with 12 non-LASIK soldiers as the control group), but their flaps caused no problems. Results were obtained using pre- and post-flight exams, which assessed visual, traumatic, topographic and subjective effects of unprotected eyes in the wind tunnel.

- 3/10 Michael Lachman of **ThinkEquity Partners** issued an update report on **VISX: EYE: Concerns Over Procedure Growth Create Buying Opportunity**

Some of his comments included:

We reiterate our Overweight-2 rating on shares of VISX, and introduce a 12-month price target range of \$24-29 (36-64% above current levels), versus our previous target of \$29. We believe that VISX's disappointing Q4 report, in the face of accelerating Street expectations, has led to a high degree of confusion over procedure growth rates and excessive concern over Q1 results, creating a unique buying opportunity. Our bullish channel check supports our 15% y/y procedure growth forecast and \$0.20 Q1 EPS estimate, at the upper end of guidance. Our \$24-29 price target range, based on a multiple of 25-30x applied to our 2005 EPS estimate of \$0.97, together with the scenario analysis featured in this report, supports our Overweight-2 rating and suggests positive risk/reward in the stock at current levels.

Investment Highlights: Our channel checks point to strong Q1 LASIK industry procedure growth, and support our VISX procedure forecast for Q1, which calls for 15% growth y/y and 19% growth on a sequential basis. This procedure growth rate is in-line with the 16% y/y growth rates reported by VISX in each of the last two quarters. While management has not provided Q1 procedure growth guidance, we note that our procedure forecast equates to licensing revenue growth of 26.7% on a sequential basis, on the upper end of management's 23-27% sequential growth guidance.

* We believe that January was a very strong month for LASIK procedures. While procedures undoubtedly declined sequentially in February, as is the usual seasonal pattern, we believe that the decline was less pronounced than in most years, making February an even stronger month than January on a year-over-year basis. Some centers are indicating a sequential increase in March, while others are suggesting a sequential decline; we are encouraged by overall trends for March, particularly following two strong months. Center operators are still discussing strong procedure volumes in the present tense, not just in reference to the first 1-2 months of the year. With regard to future quarters, bookings appear to be solid over the near term, but as usual, service providers are hesitant to extrapolate positive trends too far into the future, and in general remain cautiously optimistic.

* Service providers with whom we have spoken seem to be averaging over 40% custom LASIK penetration at present. We assume that our sample is somewhat biased - we find these numbers encouraging with respect to custom adoption, but are not increasing our CustomVue penetration forecast for Q1 (currently 33%) in line with our survey data.

Investor sentiment made a 180-degree turn after VISX reported its Q4 results. Heading into the Q4 report, we had some concern over long-term valuation, with the stock having climbed to within 11% of our \$29 price target, but we had a high level of conviction with respect to near-term (next 2-3 quarters) procedure growth rates and financial results. Instead, Q4 disappointed investors. There were two key investor concerns coming out of the Q4 call:

1. Procedure growth in Q4 did not meet high Street expectations. We believe that management did a poor job on the conference call of addressing questions on this topic and that the consensus view afterward reflected procedure growth that was below actual levels. We had forecast y/y growth of 24% in Q4, and after the Q4 report we backed into an 18% y/y procedure growth rate for the period. However, we believe that the consensus view was that year-over-year procedure growth in Q4 was in the range of 5-10%. Only recently has company management provided the data point that procedure card volume grew 16% y/y in Q4 (reasonably close to our 18% number), and management insists that this growth rate was not driven by either current period stocking or prior period de-stocking. (We have adjusted our model to reflect management's 16% number.) According to management, procedures for the quarter were actually flat versus Q3 (we had forecast 5% sequential growth), although we believe that most analysts concluded that volumes dropped sequentially at a low-single-digit rate. Why a single set of financial results can be interpreted to imply such a wide range of procedure growth rates is, we believe, due to the complexity of the business model and the closeness with which VISX management has always guarded actual procedure numbers.

We also note that management's assertion that procedure growth in Q4 would have been even better (and closer to their own expectations) if there had not been a late-December slowdown did not ring true with investors. Information from the corporate LASIK providers, during Q4 channel checks and later in their own quarterly reports, did not confirm VISX's observation of a late-December slowdown. The explanation that VISX management now provides is that while the corporate centers remained open and treating patients during late December, many individual practitioners (that perform the majority of LASIK procedures) took time off during the holidays. While this certainly could be viewed as an attempt to fit the hypothesis to the data, we do believe that such an explanation is plausible.

2. Expectations for 2004, and Q1 in particular, had grown too high in the weeks leading up to VISX's Q4 report. Management's failure to raise guidance in-line with these expectations, or to even acknowledge strong procedure growth in January, left investors worried about Q1. Consensus estimates for Q1 had grown to \$0.21 prior to the Q4 report. While we had not raised our \$0.20 estimate, we had anticipated in our preview that guidance for Q1 could drift up to the \$0.21-0.22 range. When management provided Q1 EPS guidance of \$0.18-0.20, and left full year guidance unchanged at \$0.70-0.74, investors were clearly disappointed. Specific investor concerns regarding the business in 2004 include possible market share losses to **Bausch & Lomb** (BOL - Equal Weight-4 - Price Target \$58), which has been placing an increasing number of lasers in the field. While we do believe that Bausch & Lomb has been aggressive in building its installed base of lasers, it is not yet clear to us that the company will gain significant procedure share or that this share will come primarily at the expense of VISX.

Valuation and Price Target:

* We believe that the stock's valuation is currently depressed as a result of negative investor sentiment following Q4, and concerns that the company will disappoint again in Q1. VISX is now trading at only 23.6x our 2004 EPS estimate of \$0.75, and only 18.2x our 2005 estimate of \$0.97. At \$25, prior to the Q1 report, the stock was trading at 33x our 2004 EPS estimate and above the small-mid-cap medical device average of about 30x at the time, reflecting expectations of near-term outperformance. As we have pointed out, we had some concern over long-term valuation at those levels, with the stock having climbed to within 11% of our \$29 price target, but we had a high level of conviction with regard to near-term results.

* We believe that the VISX investment case has shifted significantly in recent weeks, with long-term growth and valuation driving the investment thesis and near-term uncertainty creating a buying opportunity. We still believe that VISX can meet our expectations of \$0.75 in earnings in 2005 and \$0.97 in 2005, and in our valuation we are counting on neither upside to these numbers nor an outsized P/E multiple. At less than \$18, we believe that the stock already discounts a disappointing Q1, which we are not anticipating. We are comfortable with our \$0.20 estimate for Q1-04, at the top end of management's guidance of \$0.18-0.20, based on our positive intra-quarter channel check. Given current investor nervousness, we believe that current quarter is more likely to relieve than disappoint investors.

* We are updating our 12-month price target, which previously stood at \$29, by instituting a range of \$24-29 (+36-64% versus current stock price). While we have not changed our EPS estimates, we acknowledge that sentiment has turned less positive with respect to VISX. We still base the upper end of our target range on a P/E multiple of 30x, just shy of the 32x average P/E on 2004 earnings for small-mid-cap medical device stocks, applied to our 2005 EPS estimate of \$0.97. However, we recognize that the fundamentally lower long-term visibility versus other medical device businesses, due to the dependence upon consumer confidence and discretionary spending to support LASIK adoption, will weigh on the stock at times. As such, we establish a lower end to our target 12-month price range, based on a more modest 25x P/E multiple, which is just above the stock's current 24x multiple on 2004 EPS.

* To complement the above price target calculation, we have performed a scenario analysis in order to identify a wider range of possible outcomes for the stock. We believe that this analysis supports the investment case, suggesting that downside in the stock is limited at current levels and that the potential for appreciation far outweighs it.

Model Update and Scenario Analysis: While we have not changed our EPS estimates for any of the forecast periods in our model, we have made a few adjustments to the inputs. We have made no changes to our revenue assumptions for hardware systems, service, or parts. We have also not made changes to our COGS model.

* We have lowered our procedure growth forecast slightly for 2004, from 12% to 10% (it had stood at 8% prior to our most recent model update). Management guidance for

2004 procedure growth stands at 8-12%. For 2005, we remain at 6%. We believe that there is long-term upside to our LASIK procedure growth forecast, driven by new indications for CustomVue (hyperopia, high myopia, and presbyopia), the potential for a sustained economic recovery, and LASIK adoption by an increasing number of low-level myopes based on the improving risk/reward ratio for custom LASIK.

* We have also lowered our CustomVue penetration assumption for 2004, from 42% to 39%, still above guidance of 33-37%. For Q1, we have lowered our forecast from 35% to 33%, consistent with low-30s guidance. For 2005, we have reduced our forecast from 62% to 52%. We expect that CustomVue penetration will increase steadily for the foreseeable future, as individual surgeons receive training and catch up to penetration rates already achieved for thought-leading surgeons and some of the corporate service providers.

* Offsetting these more modest top line assumptions, we have lowered our operating expense (SG&A plus R&D) forecast for 2004, from \$65.7 million to \$64.6 million, still slightly above guidance of \$62.0-64.3 million.

We have always found it helpful to look at earnings sensitivity to key business parameters for VISX. Earnings for the company over the next few years will largely be driven by procedure growth rates and CustomVue conversion. We have calculated the following sensitivities:

* Each percentage point of procedure growth impacts EPS by about 1.5 cents in 2004 and by 1.8 cents in 2005.

* Each percentage point of CustomVue penetration impact EPS by about 1.3 cents in 2004 and by 1.4 cents in 2005.

We have modeled optimistic and pessimistic scenarios, and assigned appropriate valuation metrics to them, in order to evaluate a range of potential outcomes for VISX stock. In order to maintain a conservative bias, we have modeled a lower degree of upside in our optimistic scenario than we have modeled downside in our pessimistic scenario. Even with this, we find about 10% downside in the stock in the pessimistic scenario, versus >80% upside in the optimistic scenario.

* In our pessimistic scenario, we model procedure growth of 8% in 2004 (versus our 10% forecast) and 4% in 2005 (versus our 6% forecast). We also model CustomVue penetration of 35% in 2004 and 43% in 2005 (versus our 39% and 52% forecasts). Resulting EPS are \$0.70 in 2004 and \$0.84 in 2005, assuming that operating expenses are held constant on a percentage-of-revenue basis. Resulting EPS are \$0.67 in 2004 and \$0.77 in 2005, assuming that operating expenses are held constant on an actual dollar basis.

* Applying a 21x P/E multiple (the average current P/E multiple on 2004 EPS for eye care stocks BOL, AVO, COO, and OCLR) to our \$0.77 pessimistic 2005 EPS results in a stock price of \$16 in one year, about 10% below the current level of \$17.70.

* In our optimistic scenario, we model procedure growth of 11% in 2004 (versus our 10% forecast) and 8% in 2005 (versus our 6% forecast). We also model CustomVue penetration of 40% in 2004 and 55% in 2005 (versus our 39% and 52% forecasts). Resulting EPS are \$0.77 in 2004 and \$1.02 in 2005, assuming that operating expenses are held constant on a percentage-of-revenue basis. Resulting EPS are \$0.78 in 2004 and \$1.05 in 2005, assuming that operating expenses are held constant on an actual dollar basis.

* Applying a 32x P/E multiple (the average current P/E multiple on 2004 EPS for small-mid cap medical device stocks) to our \$1.02 optimistic 2005 EPS results in a stock price of \$33 in one year, about 86% above the current level of \$17.70.

3/11 **WaveLight Laser Technologie AG** continued along the growth path taken in fiscal 2002/2003 in the first six months of the new fiscal year. In the first half of 2003/2004, WaveLight reported revenues of E28,113 thousand for year-on-year growth of 33% (prior year: E21,177 thousand). EBIT also improved substantially, climbing 78% to E2,370 thousand compared to the prior-year period (E1,333 thousand). At the end of the first six months, all four divisions of the medical Erlangen-based laser reported revenue growth. The Ophthalmology division remained the key driver behind revenue development. This division generated revenues of E19,163 thousand, up 29% over the same period of the previous year (E14,847 thousand). As a result, products for ophthalmologic applications accounted for around 68% of the company's total revenues. This increase is due not least to the global technological superiority of the ALLEGRETTO WAVE excimer laser system. The Aesthetics division's results for the first half of the fiscal year were also positive, with a significant increase in revenues. With revenues of E4,308 thousand – an increase of 30% as against the same period of the previous year (E3,325 thousand) – this division contributed approximately 15% of the company's total revenues. The Surgery division also generated substantial revenue growth, with total revenues amounting to E2,088 thousand. Compared to the first six months of fiscal year 2002/2003 (E655 thousand), this segment's result improved by a total of 219%. Lasers for industrial applications also saw positive performance in the first half of the year. This division's revenues amounted to E2,554 thousand, up around 9% compared to the prior-year period (E2,350 thousand). The positive revenue development in all four divisions confirms WaveLight Laser Technologie AG's growth path "The Aesthetics division, which reported further growth in the first half-year, has proven to be the second important pillar for our business," according to CEO Max Reindl. "This division continues to be a promising growth segment that we will aim to expand continually," Reindl continued.

The company is also optimistic about the second half of fiscal year 2003/2004. "In the future, WaveLight will not only expand its position as a technological leader, but will also take its place as a global player on the medical laser market," Reindl said.

WaveLight aims to further cement its market position, especially in the USA. The FDA approval and systematic market development activities by its US subsidiary, **WaveLight Laser, Inc.**, will allow Wavelight Laser Technologie AG to successfully penetrate the US medical laser market. The company will also steadily expand its market presence in Asia in order to better exploit the region's market potential.

- 3/11 **Lumenis Ltd.** announced that during discussions to restructure its relationship with **WaveLight Laser Technologie AG** of Erlangen, Germany it received from Wavelight a notice of termination of the distribution agreement covering Europe and other areas outside the U.S. Lumenis is evaluating its response to the notice. Lumenis markets, sells and services the ALLEGRETTO WAVE Excimer Laser under exclusive agreements in the U.S., in most major countries in Europe and in China.

Avner Raz, president and CEO, said, "As part of our Turnaround Plan we have been evaluating all of our business activities to improve our profitability. An important step was to renegotiate the distribution agreements with Wavelight, which did not meet our profitability objectives. We are disappointed that Wavelight has decided to issue a notice of termination during these discussions. We will of course work to restructure the agreements or terminate them in an orderly fashion. During this period we will continue to provide full support to our customers."

The parties intend to also discuss the future of the U.S. Sales Representative Agreement between the parties and their continued cooperation in the U.S. market. Under the European and ROW agreements, Lumenis acts as the exclusive distributor of the ALLEGRETTO WAVE with sales of approximately \$15 million for the first 9 months of 2003. Under the U.S. agreement, Lumenis serves as the exclusive sales agent in the U.S. responsible for marketing, sales and service and support.

WaveLight provided its take on the above announcement: WaveLight Laser Technologie AG announced the termination of its distribution contracts with U.S.-based Lumenis, Inc. This ends the distribution partnership between WaveLight and Lumenis in the field of refractive surgery for the sales territories of Europe and the rest of the world. In the future, WaveLight will implement a new sales concept that aims to promote a more independent, focused, and intensive approach to developing the relevant sales markets.

"Our new sales concept creates a foundation that will enable us to market our leading laser systems for refractive surgery even more efficiently and flexibly in the future," commented Max Reindl, CEO of WaveLight.

WaveLight has already intensified its activities and established contacts on the Asian market in the past fiscal year 2002/2003. The company will begin leveraging its efforts there immediately and will consistently expand its market position there in the future. In other regions of the world, WaveLight will systematically drive forward the establishment of the new sales organization to optimally place its products and to

adequately and successfully serve regional markets for medical lasers for refractive surgery.

With regard to the existing contractual relationship in the USA, WaveLight and Lumenis will reach an agreement that will allow the company to drive forward the expansion of its U.S. market presence in future. Its wholly-owned subsidiary, WaveLight Laser, Inc. has already established and expanded customer support facilities, and product and patient marketing structures.

- 3/15 **LCA-Vision Inc.** announced plans to open its 37th U.S. LasikPlus vision center in San Antonio, Texas, its first facility serving the greater San Antonio area. The new vision center will be equipped with technologically advanced lasers and diagnostic equipment, offering customers a choice of laser for LASIK and Custom LASIK procedures. Nader Iskander, MD, a board-certified ophthalmologist, will head the San Antonio medical team.

"We are delighted to be expanding our reach into a new marketplace, and look forward to bringing the many benefits of LasikPlus to the residents of San Antonio," said Stephen Joffe, chairman and CEO of LCA-Vision. "The San Antonio LasikPlus vision center represents our third opening in large metropolitan U.S. markets in the last three months, following on the heels of our recent openings in Houston, Texas, and Orlando, Florida. "We selected San Antonio based on an analysis of various criteria that we believe will allow us to reach breakeven within six months of opening," said Joffe. "Adding new vision centers is a key component of our growth and profitability strategy, and we remain on track to open a total of six to eight vision centers this year. Based on our new vision center openings and solid same store growth, we believe we are well positioned to capture additional market share in the large and growing laser vision correction services market."

LCA-Vision currently operates 41 laser vision correction centers, including 37 wholly owned LasikPlus vision centers located in large metropolitan markets throughout the United States, three joint ventures in Canada and one joint venture in Europe.

- 3/15 **NIDEK Inc.** announced that it had partnered with **Mercy Ships International** to provide the NIDEK YC-1600 Nd:YAG Ophthalmic Laser to the poor in developing nations. The NIDEK YC-1600 Laser System will provide Mercy Ships with a state-of-the-art ophthalmic laser system that is lightweight, compact; fully featured system with superb optics, versatility and excellent clinical performance. The laser unit will be used onboard Mercy Ships around the world.

"We are very pleased and excited with this partnership and joint effort with Mercy Ships," stated Ted Shimomura, executive vice-president & General Manager of NIDEK Inc. "With the NIDEK YC-1600 Laser, Mercy Ships will be able to offer and perform sight restoring surgeries with accuracy, efficiency and excellent clinical outcomes. The design of the product will especially suit and benefit Mercy Ships, as the unit is portable

and has a small footprint -- ideal for use on ocean going vessels. The unit has also gone through rigorous development and testing to ensure accurate treatments and laser energy delivery. The NIDEK YC-1600 is considered by many ophthalmic surgeons around the world a "laser work-horse," added Shimomura.

Dr. Glenn Strauss, Director of Eye Care Services for Mercy Ships International, stated: "I am so pleased about the commitment NIDEK has shown to eye care for the poor around the world. The NIDEK YC-1600 YAG laser will enable Mercy Ships to be a more effective treatment platform for those who most need hope and healing."

- 3/15 *EyeWorld Week* reported that the results from an FDA Phase I clinical study indicated that PresView Scleral Implants (**Refocus Group Inc.**, Dallas) showed promise for the correction of presbyopia, according to Barrie Soloway, MD, director of vision correction, New York Eye and Ear Infirmary, New York. Six centers and 29 eyes of 29 patients were involved in the study. An increase in the accommodative amplitude of the experimental eyes of 1.7 D + 1.5 D was obtained with a starting point of 70 cm, he said. It cannot yet be determined how the PresView Scleral Implants work, but clinically, they do work, he said.

However, Adrian Glasser, Ph.D., associate professor, College of Optometry, University of Houston, said scleral expansion does not restore accommodation and urged other practitioners that perform the procedure to learn more about its mechanism of action.

- 3/16 **Ophthonix Inc.**, a vision care company developing a "high definition vision" technology that provides up to 20/10 visual acuity with superior clarity and crispness to any available vision correction, has received its first patent for the company's technology to manufacture its wavefront guided, customized eyeglasses, the Z-Lens.

"This is a significant milestone in the development of our unique technology to deliver the first ever fully customized eyeglasses," said Andreas Dreher, CEO of Ophthonix. "We expect that the Z-Lens will optimize vision beyond anything possible today and enable consumers to see at the pinnacle of their optical system capability." The company's first issued patent has broad coverage and addresses the combination of wavefront measurements with obtaining biometric parameters necessary to make customized eyeglasses, such as the measurement of a patient's pupil size, pupil distance, vertex distance, pantoscopic tilt and other fitting parameters. It also enables the customization of eyeglass frame features. Added Shui Lai, chief technical officer, "This patent is the first one issued of a series of allowed applications that are at the core of our technology and define a broad boundary for Ophthonix, encompassing an innovative method for manufacturing ophthalmic lenses."

The Z-Lens is the first ever fully customized approach to spectacle lenses. Existing refraction technologies only correct for nearsightedness and farsightedness. The Ophthonix system now also separately measures and corrects high order aberrations including coma, trefoil, spherical aberration, quadrefoil, distortion and increasing levels

of astigmatism. Consequently, by matching the exact optical needs of the patient, the Ophthonix lens provides the best acuity available, up to 20/10 with enhanced contrast sensitivity, crispness and clarity. The Z-Lens eyeglasses are expected to be available to consumers at the end of this year.

- 3/18 **Carl Zeiss Meditec AG** invited its shareholders to its second general meeting on Friday 19 March. About 200 shareholders and guests are expected. Ulrich Krauss, president and CEO commented, "We have seen further growth in the last financial year -- both in terms of sales and profits. We are on the right track and can present a balance sheet to the shareholders which is, in the best sense of the word, a success."

In the first quarter of the current financial year Carl Zeiss Meditec again confirmed its position as a sound company with good growth prospects. The company is looking to further expand its position as the leading global supplier of ophthalmic systems and devices and double its sales within the next five years. Profitability is to be further improved.

- 3/19 Jason Mills of **First Albany Capital** issued a status report on two companies: **Bausch & Lomb** and **VISX**. Some of his comments included:

Bausch & Lomb (BOL, \$58.17, Strong Buy, \$64 P/T)

- * Continue to believe company will post upside to current EPS estimates in both the near term and medium term.

- * Recent concerns over BOL's exposure to foreign currency swings (60% of revenue OUS) are overdone, in our view.

- * Repatriation Act – if it passes this year – could be a boon for BOL. Has about \$400M in off-shore cash it could bring back to the U.S. and use for either debt pay down (which would be accretive to EPS) or acquisitions. Sources suggest the Act has a 60%-plus chance of passing.

VISX (EYE, \$18.56, Neutral, \$26 P/T)

- * Channel checks suggest 1Q procedures are tracking well above 4Q levels, which is as expected

- * We model 211,000 procedures in 1Q (12.5% y/y growth)

- * DCF sensitivity analysis suggests trough/peak valuation range from \$16 to \$28 – i.e., the stock is starting to look more attractive on risk/reward basis.

- * Need a few additional data points regarding procedure volume trends in 1H04, as procedure volume is primary catalyst to EPS upside, before becoming more positive.

* Do not see much, if any, upside potential to near-term estimates...but simply meeting 1Q estimates (\$42.6M in sales and 20 cents EPS) should drive the stock higher.

3/22 **Refractec Inc.** announced that the FDA had granted approval of the ViewPoint CK System for performing the NearVision CK (Conductive Keratoplasty) procedure. It is the first and only FDA-approved vision technology that improves near vision in the millions of baby boomers with presbyopia, the age-related eye condition that sets in after age 40. NearVision CK uses radio waves to reshape the cornea and bring near vision back into focus. NearVision CK is minimally invasive and painless and performed in less than three minutes in the doctor's office with only eye-drop anesthesia. The procedure is laser-free and extremely safe; there is no cutting and no removal of tissue.

"Presbyopia is the one inescapable vision disorder that will eventually affect us all," said Daniel Durrie, MD, associate clinical professor, University of Kansas and medical monitor for the FDA clinical trial of presbyopia. "The frustration many people feel with the on-again, off-again annoyance of reading glasses cannot be overemphasized. NearVision CK is just what baby boomers have been waiting for to help them get rid of their reading glasses and safely see like they did when they were young."

NearVision CK is the only vision procedure designed specifically for baby boomers who want a safe, minimally invasive procedure to free them of reading glasses. CK has become the fastest-growing new refractive procedure since the introduction of LASIK according to research firm **Market Scope**. More than 30,000 CK procedures have been performed since the FDA first approved it in 2002 for age-related farsightedness (hyperopia), a condition that differs from presbyopia in its effect on the eye's ability to focus, but has similar symptoms.

The FDA based its approval on clinical trial data collected at the 12-month follow-up visit in which NearVision CK demonstrated effectiveness in significantly improving patients' near vision.

- 98% of patients could see J5 (magazine- and newspaper-size print) in the eye that was treated;
- 87% of patients could see 20/20 in the distance and also read J3 or phonebook-sized print (significantly smaller than news print).
- There were NO reported serious, sight-threatening or unanticipated safety events.

"During the clinical trials, everyone we treated had an improvement in near vision," said Marguerite McDonald, MD, clinical professor of ophthalmology at Tulane University, director of the Southern Vision Institute, New Orleans, La., and medical monitor for Refractec, Inc. "Doctors and patients alike are excited about the safety and simplicity of

the procedure. NearVision CK has the potential to expand the refractive market and for the first time, help millions of Americans improve their near vision."

About NearVision CK

NearVision CK is performed using a probe thinner than a strand of hair that releases radiofrequency energy. Applied to the cornea in a circular pattern, the radio waves shrink small areas of collagen to create a constrictive band (like the tightening of a belt) that increases the curvature of the cornea, bringing near vision back into focus.

NearVision CK is indicated for the temporary improvement of near vision in emmetropic presbyopes (those who require only reading glasses) and hyperopic presbyopes (those who require reading and distance glasses). The procedure is typically performed on just one eye, improving near vision without compromising the patient's binocular distance vision.

Refractec, based on the Baltimore Eye Study, has determined that close to 90 million "baby boomers" fall into the presbyopic cohort, and approximately half of them could benefit from the CK procedure. Two of the strengths of the procedure, after its admitted safety, are that the initial overshoot is less than 0.5 diopters after six months, and the treated eye regresses less than 0.25 diopters during the following 12 to 18 months.

- 3/22 At the second annual general meeting of the company on March 19th, the shareholders of **Carl Zeiss Meditec AG** set the course for continued growth. They authorized the Management and Supervisory Boards to increase the company's current share capital of E28.4 million by up to E13.2 million. Ulrich Krauss, president and CEO: "This enables us to keep our options open for reacting flexibly to growth opportunities." In the next five years Carl Zeiss Meditec wants to double its revenue by way of internal growth and acquisitions, thereby consolidating its position as global leader in the supply of ophthalmic equipment and systems.

Dr. Michael Kaschke, chairman of the Supervisory Board, said: "The successes achieved in the financial year 2002/2003 would not have been possible without the great commitment of all employees of Carl Zeiss Meditec AG. Sincere thanks go to them on behalf of the Supervisory Board. I would also like to express my appreciation to the company's shareholders for the open and constructive atmosphere at the AGM. We will make every effort to ensure that the success story of Carl Zeiss Meditec continues in future."

The acts of the Management and Supervisory Boards were ratified by the shareholders by a large majority.

- 3/24 John Calcagini of **CIBC World Markets** reported on the highlights from a conversation with management of **Staar Surgical**. Some of his comments included:

We checked in with Staar Surgical and it sounds like they are slowing down ICL marketing preparation activities and they do not have the capital to invest in launch inventories as their cash position is probably below \$7 mm at this point. We would also anticipate that it would be difficult to go out and raise cash given that they need to respond to the FDA warning letter related to their failure to comply with good manufacturing standards.

STAA has completed the re-audits of their lens manufacturing operations in Switzerland and Monrovia, California using outside consultants and they hope to be in a position to invite the FDA back in to do audits of their own in the near future.

Management now expects to miss their previous expectation that the ICL could be approved in the U.S. by early April and it seems possible at this point that the Artesan lens from competitor Ophtec could be approved first.

With regard to adverse events reported for the Collamer IOL, they expect to revise the label to caution about the potential for dioper shift. The 3-piece Collamer IOL approval in the U.S. has been delayed by the need to commercialize an insertion system. They expect approval here in late 2004.

- 3/26 **NovaMed Eyecare, Inc.** announced that it had changed its name to **NovaMed, Inc.** The name change was accomplished through the merger of a newly formed subsidiary, NovaMed, Inc., into NovaMed Eyecare, Inc. The company's Nasdaq symbol, NOVA, remains unchanged.

"Last year we announced our intention to expand our surgical facilities business into additional medical specialties. Since then we have added new surgical procedures, such as pain management and podiatry, at some of our existing surgical facilities and we are also pursuing the acquisition of surgical facilities in other specialties," explained Stephen Winjum, NovaMed chairman, president and CEO. "Although we expect eye surgery to remain a very significant part of our surgical facilities business, we believe that this name change better reflects our future growth strategy."

NovaMed acquires, develops and operates ambulatory surgery centers in partnership with physicians. NovaMed currently owns a majority interest in 17 centers located in 10 states. NovaMed's executive offices are located in Chicago, Illinois

- 3/29 **Miravant Medical Technologies** announced consolidated financial results for the fourth quarter and the year ended December 31, 2003. The net loss for the quarter was \$1.6 million (6 cents per share) compared to a net loss \$4.0 million (16 cents per share) for the same period in 2002. The company reported a net loss for the year of \$7.5 million (30 cents per share) compared to a net loss of \$16.0 million (78 cents per share) for the same period in 2002. The company had cash of \$1.0 million at December 31, 2003, and \$5.7 million available under a debt agreement that provides up to \$1.0 million monthly through June 30, 2004, subject to certain requirements.

Gary Kledzik, chairman and CEO, stated, "Last year we continued to adhere to our cost restructuring program, which has helped reduce overall costs. Our available resources were primarily directed towards the preparation of Miravant's first New Drug Application (NDA) seeking marketing approval of PhotoPoint SnET2 as a treatment for the wet form of age-related macular degeneration (AMD). We are very excited to be finalizing the documents for this submission, planned on or about March 31, 2004."

"I am also proud of the progress we made last year in other development programs, particularly our accomplishments in cardiovascular studies," Dr. Kledzik added. "We have generated a substantial body of preclinical data to support further investigations of intravascular PhotoPoint PDT as a potential treatment for atherosclerosis and vulnerable plaque, and we are working towards human clinical trials."

Financings: As of December 31, 2003, the company had borrowed \$6.3 million under a 2002 Debt Agreement that allows borrowings up to \$1.0 million per month through June 2004, not to exceed \$12.0 million and subject to certain requirements. In August 2003, the company entered into a Convertible Debt and Warrant Purchase Agreement (2003 Debt Agreement) with a group of private accredited investors, pursuant to which the company received gross proceeds of \$6.0 million. In September 2003, the company settled its \$10.0 million debt with **Pharmacia AB**, a wholly owned subsidiary of Pfizer, Inc., the terms of which included payments by the company of \$1.0 million and 390,000 shares of its Common Stock. In December 2003, the company completed the sale of its investment in an affiliate, **Xillix Technologies Corporation**, providing net cash proceeds of \$1.6 million. Subsequent to the end of fiscal year 2003, the company issued debentures under a \$2.0 million Unsecured Convertible Debenture Purchase Agreement, resulting in proceeds to the company of \$2.0 million. In addition, through the exercise of warrants in fiscal 2004 related to the August 2003 Debt Agreement, the company has received proceeds of \$1.4 million.

Ophthalmology Program: NDA Submission Planned for Wet AMD. In January 2003, Miravant announced its intention to submit its first NDA to the FDA seeking marketing approval of SnET2 as a treatment for the wet form of AMD, a leading cause of blindness in older adults. The company expects to submit its NDA on or about March 31, 2004. The planned NDA is based on the clinical results in the "per protocol" study population, which consists of those patients who received the exposure to the SnET2 treatment regimen pre-specified in the clinical protocol. In November 2003, clinical investigators presented the SnET2 Phase III clinical results for the first time at the American Academy of Ophthalmology conference in Anaheim, California.

Dermatology Program: PhotoPoint MV9411 in Phase II Study. During 2003, the company continued a Phase II dose-escalation clinical trial of topical drug MV9411 for the treatment of psoriatic plaques. Psoriasis is a chronic skin condition in which the immune system triggers accelerated growth of the epidermis, causing inflamed, scaly skin plaques. Miravant expects the Phase II study to be completed in 2004 and then a

determination will be made about continuance of the program based on clinical trial results and available resources.

Cardiovascular Program: Preclinical Results Presented at Major Scientific Meetings.

Miravant has several preclinical development programs underway to address large potential markets in coronary artery disease, including the treatment of atherosclerosis, atherosclerotic vulnerable plaque and the prevention and treatment of restenosis. Miravant is also testing a local PhotoPoint treatment to inhibit failure of vascular access grafts in hemodialysis patients. During 2003, key academic collaborators presented encouraging preclinical results for all these programs at cardiovascular conferences, including *Transcatheter Cardiovascular Therapeutics*, *American College of Cardiology*, *International Conference on Cardiovascular Medicine and Science*, and *Cardiovascular Radiation Therapy*.

Oncology Program: PhotoPoint PDT for Tumor Cells and Blood Vessels. During 2003, Miravant continued its preclinical research studies of PhotoPoint MV6401 to treat solid tumor cells and the new blood vessels that support tumor growth. The results of this research, if favorable, could lead to future development programs in breast, lung, brain and/or prostate cancers.

OPHTHALMIC LASER UPDATE -- April 2004

3/29 **QLT Inc.** announced today that it will be acquiring **Kinetek Pharmaceuticals, Inc.**, a Vancouver-based privately-held biopharmaceutical company. The acquisition required the approval by special resolution of Kinetek shareholders, as well as that of the B.C. Supreme Court, both of which were obtained today.

"As a result of our previous involvement with Kinetek, we are well acquainted with Kinetek's scientific programs," said Paul Hastings, QLT's president and CEO. "Given QLT's research and development capabilities and resources, we feel the Kinetek science has strong potential in our hands, particularly in the area of oncology, an area of research that we did not have rights to in our collaboration."

Since June of 2001, QLT and Kinetek have collaborated on a research and early development program to develop signal transduction inhibitors for the treatment of eye, immune system and kidney diseases. Kinetek has a unique proprietary position on Integrin-linked kinase or ILK. Inhibition of the kinase activity of ILK has the potential of a broad range of clinical applications including cancer, inflammation, kidney, and eye diseases. In cancer, peer-reviewed published studies of small molecule ILK inhibitors discovered by Kinetek have recently shown that they block tumor angiogenesis and cause tumor shrinkage in animal models.

"We are pleased to be able to gain access not only to the target, but the proprietary ILK inhibitor small molecules in development," said Dr. Mohammad Azab, QLT's Chief Medical Officer and executive vice-president of Research and Development. "Inhibition

of angiogenesis by targeting ILK through a small molecule may represent a potential advantage over current anti-angiogenic drugs in development."

The acquisition transaction is expected to close on Wednesday, March 31, 2004. Under the terms of the acquisition, QLT will make an aggregate cash payment to Kinetek shareholders of approximately \$2.7 million. The net result of the acquisition transactions, which will include the recognition of a tax asset, will be favorable to EPS by between 14 and 16 cents. Further, QLT expects that the ongoing investments in developing the acquired targets could cost up to 5 cents per share in 2004. As a result, the effect of this transaction is an increase of 10 cents on the EPS guidance range of \$0.74 to \$0.86, provided in QLT's earnings press release on February 11, 2004, bringing the EPS range to \$0.84 to \$0.96.

3/31 **Miravant Medical Technologies** announced that it had submitted a New Drug Application (NDA) to the FDA seeking marketing approval of SnET2-PDT as a new treatment for patients with wet age-related macular degeneration (AMD). Wet AMD, a vision-threatening disorder, is characterized by the growth of abnormal blood vessels (subfoveal choroidal neovascularization, or CNV) at the back of the eye. The CNV lesions leak fluid and blood that can lead to severe loss of central vision. SnET2-PDT uses a light-activated drug designed to selectively destroy the abnormal blood vessels and stabilize vision loss.

Miravant's NDA submission is based on clinical data from two randomized, placebo-controlled, parallel group Phase III studies conducted at 60 U.S. ophthalmology centers. The study population included patients with CNV associated with AMD who were followed for two years and evaluated for re-treatment every 13 weeks.

SnET2-PDT has been designated a Fast Track product by the FDA, and Miravant is requesting priority review status for the drug. Within 60 days of NDA submission, the FDA will make a determination to accept or refuse to file the NDA and, if accepted, will designate its review status. As a part of the NDA submission, a Premarket Approval Application (PMA) was submitted for the light device used to activate SnET2 during the ocular PDT procedure. This device, the **IRIS Medical** OcuLight 664 Ophthalmic PDT Laser, was co-developed by Miravant and **Iridex Corporation**, a leading manufacturer of semi-conductor based diode lasers. SnET2-PDT is classified as a combination drug and device product, and thus the NDA and PMA are reviewed by the respective FDA drug and device divisions.

Gary Kledzik, chairman and CEO, stated, "I would like to recognize the very distinguished group of retinal specialists who administered the SnET2 therapy in clinical research studies and the many patients who volunteered to participate over the course of two years. We thank them for their dedicated efforts in support of finding new treatments for this serious eye disease. I am extremely proud of the quality and scope of Miravant's first NDA submission, a milestone achievement after years of rigorous drug development. We are optimistic that, if approved by the FDA, SnET2-PDT may allow

physicians in the future to treat a broader range of patients, with a shorter and more well defined treatment regimen than currently available."

- 3/31 On March 26, 2004, the Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the District Court's December 20, 2002 post-trial order overturning a jury's determination that **Nidek** was infringing **Summit Technology Inc.'s** patents covering broad-beam excimer laser technology.

Alcon, which acquired Summit Technology Inc. in 2000 and therefore owns the patents, is disappointed with the appellate court's conclusion, but does not believe the cost of further appeals is warranted. In addition, due to advances in technology since the lawsuit began, Alcon believes the outcome of this lawsuit will have little impact on its position in the refractive surgery market or on its financial results.

- 3/31 **IntraLase Corp.** announced that it had received the CE mark for its INTRALASE FS laser and has also received certification of registration that their Quality Management System meets the requirements of ISO 13485. IntraLase developed and manufactures the laser which has been shown in studies to increase the safety and predictability of laser vision correction surgery by replacing the microkeratome, a bladed mechanical device used to create the corneal flap in the first step of LASIK surgery. "We are pleased to be the only femtosecond laser manufacturer approved to commercialize this technology into the European market, further establishing IntraLase as a global leader in the field of femtosecond laser technology for ophthalmology," stated Robert Palmisano, president and CEO of IntraLase Corp.

Commercialized in the US late in 2001, IntraLase has now placed a total of 120 lasers globally, including Canada, Japan, Korea, Malaysia, Mexico and most recently Israel. Dr. Lucio Buratto of Italy has received the first laser in the European Community, and featured the technology at his annual Video Refrattiva meeting, which was held on March 19 and 20 in Milan

"Today, the INTRALASE FS laser is used in 1 out of every 10 LASIK procedures in the United States," continued Palmisano. For the year ended December 31, 2003, IntraLase reported a total of 84,230 procedures sold, representing approximately 10% of all fourth quarter 2003 US laser vision correction procedures, according to data from **MarketScope LLC**, a leading market research firm reporting on the industry. "A growing body of compelling clinical data has greatly contributed to the rapid adoption of IntraLase technology across the United States. Among 26 new laser placements in the fourth quarter of 2003, 25 have already converted 85% or more of their procedure volume to IntraLase--and at a premium price," concluded Palmisano.

In preparation for the European launch, distributors have been established in Benelux, Italy and Spain, as well as in Israel and Turkey.

The upcoming *American Society of Cataract & Refractive Surgeons* meeting in San Diego, May 1-4, will mark the debut of IntraLase as a global partner to the field of ophthalmology.

- 3/31 **STAAR Surgical company** announced preliminary revenue results for the first quarter ending April 2, 2004. The company currently expects total revenue for the first quarter to range between \$13.3 million and \$13.5 million, up four to five percent from the \$12.77 million reported in the first quarter of 2003. International sales of the company's implantable contact lens (ICL), marketed under the Visian brand, are also expected to increase approximately 30% compared with sales during the first quarter of 2003.

"During the quarter we continued to execute well on our plan to grow sales of our innovative ICL, resulting in both sequential and year-over-year revenue growth," said David Bailey, president and CEO of STAAR Surgical. "We believe that the ICL is continuing to take market share in Europe from competing technology. In addition, we have significantly reduced our cash burn in February and March. This reduction and stabilization of our spending should have a positive impact on our cash position this year," Bailey said.

The company also announced it had received a formal response from the FDA regarding the Warning Letter received by STAAR on December 29, 2003. In the response, the FDA deemed STAAR's plans to address the issues raised in the letter as "adequate." This plan was developed internally by STAAR and presented to the FDA on January 14, 2003. In an effort to ensure that the company's response to the FDA's Warning Letter would be as comprehensive as possible, STAAR engaged the services of two outside consulting firms to perform audits on the company's facilities in Nidau, Switzerland and Monrovia, California. Both of these audits were completed during the first quarter and STAAR is actively pursuing a plan to implement the auditors' suggestions. To assist the company in completing this process, STAAR has engaged the services of **Quintiles Consulting**, a firm with in-depth experience in regulatory support, including submissions and communications with Global agencies. This engagement is effective April 1, 2004 and will remain in place through the entire re-audit process to help ensure STAAR's full compliance with the FDA's requirements on a broader basis.

"We have completed a thorough internal audit and believe we are well on the way to fully correct the issues raised by the FDA in the Warning Letter," Bailey continued. "In addition, with Quintiles' help we are proactively addressing other issues identified in the audits, which go well beyond the boundaries of the FDA's Warning Letter. We believe these issues are correctable over the short term and will issue a press release when we are ready to request a re-audit by the FDA of our Monrovia facility. We will provide a comprehensive update on all of this activity, including our expected timeline for audit of our Swiss facility, during our quarterly conference call to discuss our final first quarter results on April 29, 2004," concluded Bailey.

3/31 Ted Huber of **Wachovia Securities** issued an update report on **Bausch & Lomb: BOL: Better Visibility Follows Investor Meetings; Raising EPS**. Some of his comments included:

*** CREDIT WHERE CREDIT IS DUE:** In Wachovia sponsored investor meetings this week, BOL management profiled its product pipeline and reiterated confidence in hitting "mid teens" operating margin by 2005. The case is compelling for BOL to grow EPS in the mid to high teens for several years through accelerating top line growth, margin improvement and debt paydown.

*** RAISING EPS ESTIMATES:** We are increasing our EPS estimates for 2004 and 2005 to \$2.66 and \$3.10 due to better pipeline visibility, better margin visibility and the strong yen. We have added one point of revenue growth in 2006 (now 6%) and added 30 basis points to margins in 2004 and 2005. We are also smoothing 2004 EPS growth to better match company guidance, resulting in the shift of \$0.02 out of 1Q04 into subsequent quarters.

*** KEY DRIVERS INCLUDE CONTACT LENSES, PHARMA:** Our new 9% 2005 growth targets for pharma and contact lenses are supported by anti-infective product launches, extension of BOL's ocular vitamin line and several new lens launches in Japan, including this week's launch of a daily disposable lens into a \$300mm segment served exclusively by J&J. Retisert for Uveitis and the re-launch of PureVision extended wear contact lenses are not in our 2005 model but each represent tens of millions of incremental revenue by 2006.

4/1 Michael Lachman of **ThinkEquity Partners** initiated coverage of **TLC Vision: TLCV: Focus on Rheo - Initiating Coverage With Overweight-2 Rating**. Some of his comments included:

Investment Highlights: We are initiating coverage of TLC Vision Corp. with an Overweight-2 rating. Our investment thesis is centered on a belief that the company's emerging treatment for dry AMD, Rheopheresis blood filtration, is undervalued as an embedded option within the stock. Rheopheresis could address a huge potential patient population, significantly larger than the wet AMD population. Yet there is little competition, as industry efforts have been focused on the treatment of wet AMD. Clinical outcomes have been excellent so far, and the US pivotal trial is ongoing. We believe competitive barriers will be high, based on patents, trade secrets, and clinical/regulatory lead-time. Management intends to explore and elaborate on strategic alternatives that could "unlock" the value of this business for the company and its shareholders, and we would recommend purchase of the stock ahead of these catalysts. We view the base LASIK service business as stable, benefiting from positive LASIK market trends that we have written about extensively in the context of VISX (EYE - \$19.52 - Overweight-2 - \$24-29 Price Target). However, we view the stock as overvalued absent the Rheopheresis opportunity.

Our 12-month price target of \$16 is based on \$8 for the base eye care service business and \$8 for the emerging Rheopheresis opportunity. The drivers and risks for each of these two components of the TLC Vision story are outlined separately below.

Base Eye Care Service Business: Stable and Fairly Valued. TLC Vision's principal current business is focused on the laser vision correction (LVC) industry. The company owns and manages refractive surgery centers, and offers to surgeons the equipment necessary to perform procedures on a per-use basis. The company's LVC businesses accounted for 75% of 2003 revenue. In addition, the company owns and operates cataract surgery centers and provides equipment for cataract surgery on a mobile basis in 40 states. Through its subsidiaries, TLC Vision provides a number of services to ambulatory surgery centers (ASCs), hospitals, and independently owned optometry practices.

Base Business Investment Drivers:

* TLC Vision is benefiting from current positive trends within the refractive surgery market: a rebound in LASIK procedure growth driven by improving consumer confidence and the custom/wavefront technology cycle. New custom LASIK indications should drive incremental market-wide growth, with approvals for VISX's CustomVue system for hyperopia expected in H2-04, for high myopia in H1-05, and for hyperopic presbyopia in late 2006. We are forecasting procedure growth generally in-line with overall market growth rates; share gains provide an opportunity for upside.

* The competitive environment for laser vision correction (LVC) service providers has improved and stabilized over the past 12-18 months. Procedure pricing has stabilized, and custom LASIK pricing premiums have provided a much-needed boost. Importantly, many of the deep-discount providers that captured significant market share a few years ago (but did so unprofitably) have gone out of business.

* TLC Vision's co-management business model, which relies upon a loose network of 12,500 optometrists to provide patient referrals and pre-op/post-op care, is unique within the LVC market. We believe that these relationships can be leveraged into patient referrals in the company's cataract business, and in the future Rheopheresis business as well. This model is distinct from the advertising-driven and price-driven models of **LCA-Vision** (LCAV - \$23.64 - Not Rated) and LASIK Vision Institute (LVI - private). We do not view the TLC Vision co-management model as fundamentally better or worse than competing models, but as one of a number of approaches that can be successful in this market. Because referring optometrists remain involved in pre-op and post-op care, TLC Vision provides a "safe haven" for referrals, allowing optometrists to avoid the risk of permanently losing patients to ophthalmologists for future eye care. As optometric co-management continues to fall out of favor with refractive surgeons, we believe that TLC Vision becomes a more attractive partner for affiliated optometrists.

* TLC Vision has positioned itself as a technology leader, and as a premium-quality, premium-price provider. The company was fully equipped to roll out VISX's CustomVue

technology upon FDA approval last summer, and has driven conversion well above the industry average (just over 50% of procedures in owned/managed centers at present, versus a low-30% rate for the overall industry). TLC Vision's Canadian centers often allow the company to become proficient with new technologies prior to US approval, and several of the company's Canadian surgeons are on the leading edge of refractive research.

* A high degree of operating leverage results from the high fixed cost nature of the business, and profitability trends are positive at present. Following the acquisition of **LaserVision Centers** two years ago and necessitated by the LASIK market downturn, the company has aggressively reduced its costs and closed unprofitable centers. The volume of procedures at which the company breaks even has come down steadily over past several quarters, and could come down a bit further. Procedures performed in the company's owned and managed centers generate incremental profit contribution of roughly \$900 each, while the per-procedure contribution margin within the access segment is only about \$225. The mix of procedures has shifted, from only 45% in owned/managed centers in mid-2002 to about 60% today. This positive mix shift should continue, and is expected to drive improved profitability.

* Our channel checks indicate that Q1-04 was a strong quarter for the industry, and we expect results for the company at high end of guidance ranges. By mid-2004, procedure growth comps should get easier for the company, as the closing of unprofitable centers will have largely anniversaried.

* We view the company's diversification into mobile cataract surgery and ambulatory surgery centers (ASCs) as a steadying influence in an otherwise volatile business, and as a good fit with the company's optometric co-management model. The cataract and ASC segments offer opportunities for accretive acquisitions and expansion.

* TLC Vision's management team brings many years of experience in the refractive surgery market, and represents the best of both pre-merger TLC Vision and LaserVision Centers. The refractive and cataract businesses are led by strong operating managers. The company's "visionary" founder/CEO remains focused on opportunities beyond the core refractive and cataract businesses, and the company's emerging Rheophoresis business is a result of this focus.

(A more complete analysis of TLC's Rheophoresis business by Michael Lachman is available. Let me know if you are interested in receiving it.)

4/1 **NovaMed, Inc.** announced that it had acquired a majority interest in both the **Nashua Eye Surgery Center** located in Nashua, New Hampshire and the **NH Eye Surgicenter** located in Bedford, New Hampshire. Terms of the transactions were not disclosed.

"Both of these surgery centers are well established and supported by two of the largest ophthalmology practices in the state," said NovaMed chairman, president, and CEO

Stephen Winjum. "These acquisitions provide us with a strong position in the New Hampshire market with barriers to entry due to the certificate of need process in the state. The ophthalmologists currently supporting these two surgery centers performed over 2,600 surgical procedures in 2003. We are excited about the future growth potential and operating synergies of these surgery centers which are well situated in southern New Hampshire on the edge of the fast growing metropolitan Boston market," said Winjum.

- 4/1 **QLT Inc. and Novartis Ophthalmics**, the eye health unit of **Novartis AG** announced that as of today, the Centers for Medicare and Medicaid Services (CMS) will implement its decision to provide coverage for ocular photodynamic therapy (OPT) with Visudyne (verteporfin) to patients with age- related macular degeneration (AMD) who have occult and minimally classic lesions that are four disc areas or less in size and show evidence of recent disease progression.

Implementation of the CMS ruling immediately expands access to OPT to include the majority of patients with all forms of "wet" AMD, the more severe and aggressive form of the disease. Medicare already offers coverage for OPT in AMD patients with predominantly classic lesions.

"Now that the CMS decision has taken effect, many more patients who are candidates for Visudyne therapy will have access to treatment that may reduce the risk of vision loss and maintain quality of life," said Paul Hastings, president and CEO of QLT Inc.

"We are pleased the CMS determined that the Visudyne data supports coverage for patients with the occult and minimally classic forms of AMD," said Flemming Ornskov, MD, president and CEO of Novartis Ophthalmics Inc. "Our research to explore Visudyne's full potential is continuing, and is a reflection of our commitment to advancing patient care and our understanding of AMD and its treatment."

- 4/2 **QLT Inc.** reported that the United States District Court for the Southern District of New York had entered an order in favor of QLT dismissing with prejudice the consolidated securities class action complaint which was commenced in 2001 against QLT, Dr. Julia Levy and Kenneth Galbraith.

In granting QLT's motion to dismiss, the Court reviewed the claims made by the plaintiffs in the complaint and found that the plaintiffs failed to state a valid claim for securities fraud. QLT was represented in the securities class action lawsuit by Greg Markel of the law firm of **Cadwalader, Wickersham & Taft**.

- 4/2 Jason Mills of **First Albany Corporation** wrote an update report on **VISX: EYE/Buy: Upgrade to Buy; Risk/Reward Profile Attractive, Favorable Survey Data**

* Upgrading EYE to Buy from Neutral for three reasons :

1. Consensus expectations have come down markedly in the last few months and are achievable (if not beatable), in our view. We believe EYE should trade up vis-à-vis executing in line with current guidance.

2. Favorable risk/reward profile – Based on P/E/G and DCF metrics, the shares have become attractive, in our view, following a significant pullback since January. Our \$26 price target offers 25% appreciation potential.

3. Our quantitative on-line survey of LASIK surgeons suggests procedure volume and conversion to custom (CTC) are tracking favorably relative to our 1Q and 2004 estimates, respectively.

* 1Q:04 Procedure Volume Tracking Well - Our survey, including responses from 32 high-volume LASIK surgeons (100-120 procedures per month average), suggests 1Q:04 procedure volume is tracking in line with our 12.5% y/y growth estimate for VISX.

* 2004 Procedure Volume Trends Look Solid (Relative to our 9.7% estimate) - Our survey data suggest our 9.7% procedure growth estimate for 2004 is well within range, and could prove conservative.

* Favorable Conversion to Custom (CTC) Trends Cited as Well – 71% of respondents are running at a CTC rate north of 31%, while 35% have converted a rate of 51% or more. Over the ensuing three months, nearly 75% expect CTC of 31% or more, while 50% expect CTC of 51% or more.

4/5 **IntraLase Corp.** announced closing the first quarter ended March 31, 2004 with 17 lasers placed for revenue, bringing the company's placements to 123 units globally. Procedures sold for the quarter climbed to 41,094, a 165% increase over the first quarter of 2003. According to data from **MarketScope LLC**, a leading market research firm reporting on the industry, IntraLase procedures accounted for approximately 12% of all LASIK procedures performed in the United States during the first quarter of 2004.

IntraLase received the CE mark for its INTRALASE FS laser on March 31, 2004. Including sales to Italy and Spain, with additional placements in Israel and Saudi Arabia, the existing installed base also includes units in Canada, Japan, Korea, Malaysia and Puerto Rico.

IntraLase is the only company to receive the CE mark for a femtosecond laser keratome, and the company also received certification of registration that its Quality Management System meets the requirements of ISO 13485. "These two certifications enable us to immediately expand into international markets which will represent approximately 30% of our laser placements in 2004," commented Robert Palmisano, president and CEO. "We have invested appropriately in the infrastructure required to establish our business internationally, and we will have a strong presence at major ophthalmic symposia throughout Europe and Asia this year."

- 4/5 **Lasik America, Inc.** announced that it had retained the services of **PMR and Associates, LLC** of Del Mar, California, to provide consulting services in areas ranging from corporate finance, acquisitions, business development and investor relations. Under the leadership of Patrick Rost, PMR and Associates has developed a strong track record in creating shareholder value for numerous NASDAQ and OTC BB clients by integrating a broad range of services into the corporate strategy of its clients.

Lasik America, Inc. is a public company trading under the ticker symbol LSIK.OB. The company currently operates a medical facility in Albuquerque, New Mexico, providing laser vision correction surgery procedures. The medical staff of ophthalmologists, optometrists and medical support staff utilize the latest state of the art technology based upon the FDA's approval of excimer lasers primarily manufactured by **Summit Technology, Inc. (?)** and **VISX, Inc.** Lasik America, Inc. intends to expand its operation by opening additional laser eye surgery clinics and additionally is exploring numerous other options in the medical arena to spearhead the companies growth plans.

Eyemakers, Inc., headquartered in Del Mar, California, also announced that it had retained the services of PMR and Associates, LLC. Eyemakers, Inc. is a publicly traded international healthcare company trading under the ticker symbol EYEM.PK. The company's primary business is the development of LASIK eye care centers and kidney dialysis centers in the US and in Europe. Currently, the company has a kidney dialysis project underway in Italy, which is expected to be formally launched in the spring of 2004.

- 4/6 *The American Academy of Ophthalmology* praised the *Department of Veterans Affairs (VA)* secretary Anthony Principi for his confirmation last week that a "moratorium" had been put in place on all optometric laser surgery in the Department of Veterans Affairs health system. Secretary Principi's comments were made at last week's *AMA Leadership* meeting, where a physician asked what the VA was doing to ensure that patient safety measures were being addressed in regard to optometric laser eye surgery in the VA.

Last month, VA under secretary Robert Roswell, MD, sent a letter to all VA facilities asking that optometric surgical credentialing be halted until negotiations for a solution, led by the Academy and the Veterans Eye Treatment Safety Coalition, were complete. Secretary Principi's reference to the direction given to the VA facilities today as a "moratorium" clarifies the intent behind the letter. The Academy and the Vets Coalition continue to garner cosponsors for the "Veterans Eye Treatment Safety Act," H.R. 3473, with a current total of 64 cosponsors.

Fueling the debate, the Academy recently was made aware of credentialing sheets from VA facilities in Los Angeles that include surgical privileges for multiple eye procedures, including "focal photocoagulation of microvascular fundus lesions," "pan-retinal photocoagulation for proliferative retinopathy and iris neovascularization," and "parenteral injection of pharmaceutical agents for treatment of complex diseases or conditions of the eye." In Tuscon, YAG capsulotomy is not even listed on

ophthalmology's privileging sheet, but does appear on optometry's, along with "local subcutaneous injection of pharmaceutical agents," and "excision of minor lid lesions" -- evidence of optometry's effort to establish these surgical procedures as part of its standard of care.

"These surgeries being moved from ophthalmology to optometry's list of procedures is a huge red flag and validates our argument for grave patient safety concerns within the VA health system," said Catherine Cohen, Academy vice president of governmental affairs.

4/13 Leonard Zehr of the *GlobeandMail.com*, wrote about the resurgence of laser vision surgery.

After being mired in the doldrums for three years, laser vision surgery is staging a dramatic comeback as new 'custom' technology is reducing fears of complications and enticing people to fork over up to \$4,500 for the promise of better than 20/20 eyesight.

According to ophthalmic industry research firm **MarketScope**, laser eye correction procedures in the United States are expected to increase by up to 12% this year and jump 35% next year, reaching 1.7 million surgeries in 2005 and matching the industry's record in 2000. All of which should have industry leader **TLC Vision Corp.** of Mississauga seeing dollars signs.

But these days, the company has its fingers crossed about an experimental blood filtering treatment to prevent blindness in seniors caused by the "dry" type of age-related macular degeneration (AMD). "Even if we get up to five million [laser procedures a year], I'd take rheo any day," declares TLC's chief executive officer Elias Vamvakas.

Rheo stands for rheopheresis, a German invention that uses a specially designed Japanese filter to remove excess levels of large proteins and fatty substances from blood. Too many of these substances have been shown to reduce blood viscosity and blood flow. Nobody knows what causes dry AMD, where blood vessels at the back of the eye essentially harden and dry out, causing a loss of central vision. But rheo proponents contend that many patients with the disease have unusually high levels of things like LDL (bad) cholesterol, fibrinogen and certain macroglobulins under the retina. And clinical studies suggest that filtering out these substances allows blood to flow more freely through tiny capillaries in the eye, stabilizing vision and, in some cases, even reversing vision loss.

Analysts suggest that TLC and its **Vascular Sciences** affiliate are sitting on a potential bonanza if rheo, the only treatment for dry AMD, clears clinical trials and U.S. regulatory hurdles for a proposed launch as early as mid-2005. Of about 15 million Americans suffering from AMD, 90 per cent have the dry version, with about more than one million new AMD cases each year. Dry AMD often progresses to "wet" AMD, where blood vessels leak at the back of the eye, resulting in a rapid progression to legal blindness.

Moreover, a recent study of AMD has found that there are some eight million dry AMD patients most at risk of developing wet AMD, which represents the likely target group for TLC's rheo treatments.

There are no approved treatments for dry AMD other than vitamin supplements sold by **Bausch & Lomb**, which can reduce the risk of progression to wet AMD.

"The aging of the baby boomer generation is likely to increase the number of dry AMD patients over time," **Orion Securities** analyst Aaron Bennett said in a recent report. "It is estimated that 42 million Americans will be living with the disease by the year 2030."

At a projected cost of about \$2,000 (U.S.) for each of eight recommended rheo procedures per patient, TLC figures each patient represents \$8,000 in filter sales and \$4,000 in profit, of which it would receive 63% under its venture with Vascular Sciences.

Treating only 1% of the AMD population, or 150,000 patients, represents \$1.2-billion in sales and \$600-million in profit, TLC estimates. "Getting reimbursement is the real question," Vamvakas said. "There's no way the U.S. government will cover everybody's treatments. If it did, TLC would get a check for \$200-billion and that's not going to happen."

Those kind of numbers are attracting analysts to resume coverage of TLC after a three-year hiatus that was sparked by a price war in laser eye surgery and resulting industry shakeout. Many analysts are recommending investors take "overweight" positions in TLC, even though the stock price has nearly doubled this year, closing at \$12.06 on the Nasdaq Stock Market yesterday.

While rheo is still being tested in the United States, TLC has treated 60 to 70 patients at a clinic in its Mississauga head office in the past year with encouraging results. One of the early patients, for example, was able to read three additional lines of an eye chart, the company has disclosed, a dramatic outcome because no treatment for AMD has ever shown any improvement in vision and patients with the disease usually get worse.

The U.S. Food and Drug Administration was so impressed with the interim trial results of rheo testing that it shortened the time frame of the pivotal trial this year, reduced the number of patients needed for approval and demanded that all placebo patients receive rheo treatments after the study, a rare recommendation.

"It's great that we can make people get rid of their glasses and see better [with laser surgery] but rheo is really significant for what it can do to stop people going blind," Vamvakas said.

If rheo reaches its potential, it would represent another ophthalmic breakthrough by TLC, which pioneered laser eye surgery, or lasik, in the early 1990s and the new "custom" procedure three years ago. CustomLasik, as it's called, measures the eye from back to

front, using new "wave-front technology," which creates a specific 3-D computer map of the cornea for each patient. The technology, which received FDA approval last summer, is cutting the risk of complications and raising the odds for improved vision.

Vamvakas said studies are showing that CustomLasik is giving 90% of patients 20/20 vision or better, nearly twice the rate with traditional laser surgery. Moreover, 70% of patients are obtaining 20/15 vision, which is better than average vision. (20/15 vision means you can see something at a distance of 20 feet that the average person can see at 15 feet.)

"CustomLasik is changing the industry by expanding the pool of people that want to see better than with glasses," Vamvakas said. But the new procedure comes with a price. TLC, which has a 17% market share in North America, is charging a premium of \$300-to-\$500 per eye above traditional lasik surgery for CustomLasik, or a total of about \$2,250 per eye, on average.

4/14 **TLC Laser Eye Centers** recently conducted a patient survey in which 99% of respondents said they would refer family and friends to TLC. The results also indicated that 93% of surveyed TLC patients feel that their surgery met or exceeded their expectations.

"That 99% level of patient loyalty found in the survey is significant because TLC has never been the low-price leader in laser vision correction. Our patients feel the combination of high quality care provided by our doctors and the miracle of clear vision is worth every penny. Laser vision correction is an experience that our thousands of happy patients can't wait to share with others," said Anna Austin, vice president of Corporate Marketing for **TLC Vision Corporation**, TLC Laser Eye Centers' parent company.

Though not part of this survey, one TLC patient in particular, Tiger Woods, has been very satisfied with his results. Tiger had the procedure with TLC Laser Eye Centers in 1999, and is celebrating his fifth anniversary as a TLC patient. "My doctors and the staff at TLC had the reputation that I was looking for," Woods said. "Before I had LASIK, I wouldn't have been able to see the ball on the tee without my contacts. Now my vision is as good as the day after the procedure, I'm 20/20 with no contacts," Woods continued.

TLC Laser Eye Centers is also celebrating its 10 year anniversary in 2004. TLC doctors were the first to perform LASIK in North America, and to date TLC doctors have performed more than 500,000 laser vision correction procedures.

TLC's study mirrors the recent *Harris Interactive Survey* commissioned by the *Eye Surgery Education Council (ESEC)*. That survey was the first nationwide quality of life survey assessing life implications for laser vision correction patients.

Both the TLC survey and the Harris survey show that laser vision correction has a profound positive impact on overall quality of life and job performance. However, the TLC survey results outperformed those of the Harris survey in almost all areas, indicating that the surveyed TLC patients experienced the highest quality of patient care and achieved excellent results.

The TLC survey, concentrating solely on TLC patients, also found:

- * 97% of those surveyed indicated that their quality of life improved - a 12% increase over the Harris survey!
- * 96% of those surveyed said their daily routine improved - a 7% increase over the Harris survey! (Significant improvements in personal appearance and safety were also noted by the TLC patients.)
- * 73% of those surveyed agree that the benefits of laser vision correction are much greater than expected - a 9% increase over the Harris survey!

Austin said that patients should always take into account such factors as surgeon experience and company reputation when choosing to have LASIK, and that potential patients should not use price as the main factor in their decision. She observed, "A great way to learn about laser vision correction is to first talk to someone you know who has had the procedure. That is an excellent way to have your initial curiosity satisfied, then of course you can ask your eye care professional any medical questions you have. The 99% patient loyalty figure illustrates the quality of our laser vision correction procedure; simply ask a previous TLC patient."

The survey was conducted by emailing a web link to 4,659 TLC Laser Eye Centers patients who had laser vision correction with TLC in the year 2002. 1,209 people completed the survey, or 26%.

4/15 Jason Mills of **First Albany Corporation** issued an update report on the medical technology sector. Among the companies covered were **Bausch & Lomb** and **VISX**.

Bausch and Lomb (\$64.49-Strong Buy) - Expect Another Strong Quarter and Potential Upside; Believe Estimates Need to Go Up

* We believe there is potential for upside to our 1Q:04 revenue and EPS estimates of \$483.7M and \$0.36, respectively, driven by strong growth in contact lenses (estimate 10.3% Y/Y growth) and pharma (7.3%), as well as an improving refractive surgical franchise, augmented by a favorable foreign exchange (FX) translation. The consensus EPS estimate stands at \$0.37. We believe there is upside potential to both FAC and consensus estimates.

* The operational improvement plan established in 2002 has produced strong margin expansion and EPS growth over the last two years, and we believe 1Q:04 margins will continue to rise. Driven by sales growth of 8.0% and operational improvements expected

in 1Q:04, our model calls for BOL to report a gross margin of 56.2%, an operating margin of 8.7% (both basically flat Y/Y), and a net margin of 4.0% (30-bp improvement over a year ago). We think there is 20-40 bps upside potential to our operating margin target, which would imply an incremental 1-2 cents to EPS.

* The recent launch (circa March 23) of the daily disposable lens in Japan will not be consequential to 1Q results, in our view, but should impact 2Q through 4Q favorably. Nonetheless, we expect another solid quarter from Bausch's contact lens franchise, modeling 10.2% Y/Y growth. We are also optimistic Zyoptix laser sales and increasing procedure fees will invigorate refractive sales and potentially drive upside to our surgical revenue estimate. In pharma, we expect continued strong growth in ocular vitamins and a bounce back in proprietary pharma, partially offset by headwinds in pharma pricing/reimbursement in Germany. Our lens care solutions growth estimate of 1.7% will likely be eclipsed, owing to favorable FX and relatively easy comparisons to 1Q:03. We expect in-line performance in cataract/vitroretinal sales relative to our 7.2% Y/Y growth estimate.

* We believe management's 2004 guidance (4%-6% ex-FX sales growth and \$2.60-\$2.65 EPS) is conservative, and also believe continuing operating margin expansion will drive us (and the consensus) to raise 2005 targets again (FAC: \$3.11; Consensus: \$3.06). We think 14% operating margins in 2005 (full year) are attainable; this level implies earnings power north of \$3.30 per share.

* We believe the company has good visibility into mid-2004, coupled with likely upside to forward EPS estimates, continuing strong execution on the operating side, and relatively low hurdles (with upside potential) on the top line (with an FX tailwind as a kicker). Consequently, we continue to favor BOL shares, even though the stock moved above our current price target (again) of \$64. We expect to reevaluate our forward estimates - and therefore our price target.

VISX Inc. (\$19.25-Buy-\$26 PX) - Expect a Rebound to Double-Digit Procedure Growth and Strong CTC; Good Risk/Reward Entry Point, in Our View.

* We expect VISX to post 1Q:04 results that are in line with to modestly ahead of our revenue (\$42.6M) and EPS (+\$0.20) estimates.

* Our revenue estimate is predicated on: 1) 12.5% Y/Y growth in the LASIK procedural volume (we estimate total LASIK procedures in the quarter at about 211,000 vs. 187,000 in 1Q:03), 2) 33% penetration of CustomVue procedures relative to total VISX procedures, 3) 16 domestic laser sales at an ASP of \$179,000, 4) 8 OUS laser sales at an ASP of \$152,000, 5) 50 WaveScan system sales at an ASP of \$43,000, and 6) Parts/service/royalties revenues of \$6.2M (up 6.7% Y/Y).

* We anticipate gross margins of 71.1% versus 61.7% a year ago, reflecting the combination of a higher mix of higher-margin CustomVue procedure and stronger

growth in the total LASIK procedure volume Y/Y. We expect operating margins (35.9% vs. 23.5% a year ago) and net margins (22.8% vs. 15.9% a year ago) to benefit from the same positive trends as gross margins.

* In the first half of 2004, we believe VISX will benefit from easy year-over-year comps, as the company in 1H:03 faced a very lackluster procedure market, as well as a lack of CustomVue, which was ultimately approved by the FDA in May 2003 and launched in mid-June. Consequently, we think procedure volume growth will be strongest in 1H:04 (we estimate 12.5% and 12.3% in 1Q:04 and 2Q:04, respectively), and moderate in 2H:04 (5.1% and 8.7% in 3Q and 4Q, respectively).

* We recommend purchase of VISX shares at current levels - owing to moderated (and achievable if not beatable) expectations, favorable risk/reward valuation profile (based on both DCF and earnings metrics), and our recent LASIK surgeon survey suggesting favorable procedure and CTC trends in 1Q and 2004, respectively.

* We maintain our 12-month price target of \$26, based on a 28.6x P/E applied to our \$0.90 CY05 EPS estimate. Our target multiple is in line with our three-year EPS CAGR estimate of 28% and represents greater than 25% upside from current levels.

4/20 **Alcon, Inc.** reported global sales of \$963.6 million for the first quarter of 2004, an increase of 19.4% over global sales in the first quarter of 2003, or 13.0% excluding the impact of foreign exchange fluctuations. Net earnings for the first quarter of 2004 increased 46.7% to \$191.0 million (61 cents per share) compared to \$130.2 million (42 cents per share) for the first quarter of 2003.

Tim Sear, Alcon's chairman, president and CEO commented, "This was a phenomenal quarter where virtually all factors worked in our favor. The new products we introduced last year continued to build momentum and gain share, while most existing lines added to their already strong market shares. Currency was very positive for us, which not only boosted sales, but also enabled us to leverage sales growth into faster operating income and net profit growth. Geographically, we had strong performances from all our regions, but it was especially encouraging to see that Japan showed good growth once again, after a couple of difficult years of dealing with reimbursement declines and local competitive pressures."

Refractive revenue declined 14.6% to \$15.8 million because of a sharp decline in global equipment sales. However, stable demand for LASIK procedures and a significant shift toward higher-priced custom procedures caused U.S. procedural revenues to rise.

Financial guidance for 2004

* Full year sales are expected to be between \$3,750 million and \$3,850 million.

* Diluted earnings per share are expected to be between \$2.23 and \$2.26.

* Growth rates in sales and earnings are expected to be slower in the next three quarters than in the first quarter of 2004 because of the expiration of a patent on Ciloxan, additional increases in marketing expenses for new product launches, generally higher promotional spending on a global basis, timing of consumer advertising in the U.S. and Japan and higher research expenses related to potential new studies of Retaane.

Two analysts provided their input about Alcon's results:

Joanne Wuensch of **Harris Nesbitt: ACL--Increasing Estimates After Superlative Quarter**

* **Event:** Alcon hosted its 1Q04 conference call to review an outstanding quarter: revenue of \$963.6 million (up 19.4%) surpassed our \$883.7-million estimate and the consensus of \$885.8 million. Excluding foreign exchange, revenue increased 13%. EPS were \$0.61 (up 45.9%) versus our estimate for \$0.48 and consensus of \$0.49.

* **Impact:** Positive. Management appears to have its core businesses running on all cylinders with full product pipeline pushing potential for 2005, 2006, and beyond.

* **Forecasts:** In 2004, our revenue estimate is increased to \$3.84 billion (up 12.6%) from \$3.7 billion and EPS is increased to \$2.29 (up 19.7%) from \$2.16. In 2005, our revenue estimate increases to \$4.31 billion (up 12.4%) from \$4.11 billion and EPS is increased to \$2.68 (up 16.9%) from \$2.53.

* **Valuation:** Our price target is increased to \$83 from \$73 based on 31x our new 2005 EPS estimate of \$2.68

* **Recommendation:** When we initiated coverage of ACL our investment thesis was that it housed a core, leading ophthalmology franchise with the potential for significant upside from key new product introductions. We believe that this thesis remains and that reported quarters such as this one, although a surprise, show the strength in the company's franchise. Maintain OUTPERFORM rating.

Michael Lachman of **ThinkEquity Partners: ACL: Raising Estimates and Price Target, Reiterating Overweight-2**

We reiterate our Overweight-2 rating on shares of Alcon, and raise our 12-month price target from \$68 to \$80, following a Q1 blowout. EPS upside of \$0.11 versus our estimate was top-line driven, and boosted by timing of promotional spending. Because management may choose to reinvest additional earnings upside, full year guidance was raised by only \$0.08. Our new 2004 EPS estimate of \$2.26 is at the upper end of guidance, and we believe there is still an upward bias to numbers this year. Alcon remains our top pick for 2004 in ophthalmic devices, based on improving visibility on a strong 2005-2006 product pipeline. Alcon should file for approval this year for Retaane

for wet AMD, Patanase for nasal allergy, and the ReStor multifocal IOL. Our new price target of \$80 is based on a 30x multiple applied to our new 2005 EPS estimate of \$2.67.

- 4/20 **Carl Zeiss Meditec** announced it had submitted an Investigational Device Exemption (IDE) application to the FDA for LASIK refractive surgery using the MEL 80 Excimer Laser System in the correction of myopia and hyperopia, with and without astigmatism. Roger Steinert, MD, of Ophthalmic Consultants of Boston, will be the medical monitor for the prospective, randomized, multi-center IDE trial, and the investigators will include John Doane, MD, of Discover Vision Centers in Kansas City, MO, Steven Dell, MD, of Texas Eye Care in Austin, TX, Mark Packer, MD, of Drs. Fine, Hoffman and Packer, LLC in Eugene, OR and Captain Steven Schallhorn, MD with the Naval Training Center's Refractive Surgery Clinic in San Diego, CA.

The MEL 80's state-of-the-art, high speed scanning spot excimer laser technology is commercially available in all major markets worldwide, with the exception of Japan and the United States, and has received broad clinical and market acceptance.

- 4/20 As reported on the *Ocular Surgery News* website, a study published in the April issue of *Archives of Ophthalmology* noted that refractive errors affect one-third of U.S. and Western European populations.

About one-third of people over 40 years of age in the United States and Western Europe are affected by refractive errors, as are up to one-fifth of Australians in the same age group, according to a meta-analysis of population-based studies.

The Eye Diseases Prevalence Research Group obtained data on refractive error from six eye studies. Data were extracted for the year 2000 and projected out to 2020. The total population of the six studies was 29,281 people from the United States, Western Europe and Australia. The subjects were stratified by sex, race or ethnicity and 5-year age intervals.

The population included people with phakic eyes, with and without spherical equivalent refractive error in the worse eye of at least +3 D, -1 D or worse, and -5 D or worse.

In the United States, the estimated crude prevalence for hyperopia of +3 D or more was 9.9%, in Europeans the rate was 11.6%, and in Australians the prevalence was 5.8%. In total population figures, the condition affects 11.8 million U.S. residents, 21.6 million Western European residents and 470,000 Australians.

Myopia of at least -1 D had a crude prevalence rate of 25.4% among U.S. residents (30.4 million), 26.6% among Western Europeans (49.6 million) and 16.4% among Australians (1.3 million). The prevalence of higher myopia (-5 D or worse) was 4.5% among U.S. residents (5.3 million), 4.6% among Western Europeans (8.5 million), and 2.8% among Australians (230,000).

According to the authors, the projected prevalence rates for 2020 are similar.

4/21 **Bausch & Lomb** reported worldwide sales of \$510.3 million for its first quarter ended March 27, 2004, an increase of 14% (or six percent on a constant-currency basis) over the \$448.0 million reported in the first quarter of 2003. Constant-currency sales growth was reported in the company's contact lens, pharmaceuticals, refractive surgery and lens care categories, with a slight decline reported for cataract surgery products.

Net earnings per share were \$0.43, compared to earnings per share from continuing operations of \$0.31 in 2003's first quarter and net earnings per share of \$0.29, which reflected a \$0.02 per share cumulative impact from adopting a new accounting principle.

Bausch & Lomb chairman and CEO Ronald Zarrella said, "Our first-quarter results were solid, with constant-currency sales growth in line with, and operating margins somewhat above, our original projections. These operational factors generated about half the earnings per share upside as compared to our previous guidance, with the rest coming from lower-than-anticipated net financing expense." Zarrella continued, "We remain comfortable with our projections for full-year 2004 constant-currency revenue growth in the mid-single digits and expect full-year operating margins above 12%, reflecting leverage from favorable mix shifts and continuing benefits from our profitability improvement programs. Combined with the results reported today, those trends should result in earnings per share in the range of \$2.70 to \$2.75 for the year, assuming currency rates remain relatively consistent with current levels."

Refractive surgery sales grew in each geographic segment, reflecting higher revenues from equipment placements, Zyoptix system upgrades and per-procedure cards. Particularly strong performance was registered in the United States, where revenues grew close to 40%, following the late-2003 approval of the Zyoptix system for customized surgery. Refractive sales worldwide were \$38.9 million, up 30% over last year's first quarter.

Several analysts provided their analysis of BOL's performance:

Jason Mills of First Albany Capital: BOL/Strong Buy: Strong 1Q:04 - Sales/EPS Upside - Raising Estimates and Price Target to \$75

* Revenue Upside to both reported and constant currency expectations - Sales of \$510mn beat our \$484mn estimate by over \$25mn. Importantly, constant currency growth was 6% y/y (vs. 5% estimate).

* EPS of \$0.43 dwarfed our \$0.36 estimate - Higher sales, gross margins and in-line operating margins drove 4 pennies of operating upside, with \$0.03 of upside coming from lower financing expense and currency translations.

* Guidance raised again - Management raised EPS guidance for 2004 to \$2.70-\$2.75 from \$2.60-\$2.65. We are raising both our 2004 and 2005 estimates to \$2.74 and \$3.21, respectively.

* Solid top-line performance across the board (except in cataract) -Contact lenses (up 18%; 8% CC), Pharma (up 17%; 8% CC), Refractive (up 29%; 22% CC) and Lens care solutions (up 7%; 2% CC), offset by cataract (up 7%; down 1% CC). These results met or exceeded our projections.

* Reiterate Strong Buy - Raising PX to \$75 - BOL continues to execute; most notably higher constant currency sales, meeting or exceeding margin targets and paying down debt, which is driving earnings upside and higher guidance. We think BOL has solid visibility into cost control targets, coupled with accelerating contribution from higher margin products (CL, pharma, refractive), both of which should translate into continued stock outperformance, in our view.

Joanne Wuensch of **Harris Nesbitt: BOL--Impressive EPS, but Top-Line Growth Carried by Foreign Exchange**

* **Event:** Bausch & Lomb posted better-than-expected 1Q04 results: revenue and EPS were \$510.3 million (up 13.9%, up 6% ex-FX) and \$0.43 (up 40.7%), respectively, versus our estimates of \$483.5 million and \$0.35 (consensus was for \$0.37).

* **Impact:** Neutral to positive.

* **Forecasts:** Our 2004 revenue estimate is increased to \$2.21 billion (up 9.5%) from \$2.17 billion and our EPS estimate is increased to \$2.72 (up 21.2%) from \$2.62. For 2005, our revenue and EPS are increased to \$2.38 billion (up 7.8%) from \$2.32 billion and to \$3.09 (up 14.2%) from \$3.00. We are introducing a 2006 revenue and EPS estimate of \$2.57 billion (up 8.0%) and \$3.43 (up 11.6%), respectively.

* **Valuation:** Trading at 21x our 2005 EPS estimate of \$3.09, the stock is neither expensive nor inexpensive versus the ophthalmology group's 20.5x average and the mid-large cap medical technology average of 23.3x.

* **Recommendation:** We maintain our NEUTRAL rating on shares of BOL. While we admit that the company's cost controls are moving forward nicely and foreign exchange has been working in its favor, we grapple with the company's new product pipeline and its potential impact on its growth profile once foreign exchange and the "low hanging" operating efficiencies work their way through the income statement.

Ted Huber of **Wachovia Securities:** BOL: Lenses and Refractive Pace Solid Quarter; Inc. Est. Again

* **BEATS CONSENSUS AGAIN:** BOL's \$0.43 beat consensus (\$0.37) and our EPS estimates (\$0.36) handily, for the company's 9th consecutive quarter of EPS upside. Revenue growth at 13.9% beat expectations due to currency; fx neutral growth was in line at 6%. Refractive revenues were up 22% constant currency on 70% U.S. procedure volume growth. Strong ocular vitamin sales paced 8% constant currency growth in pharma and several new products drove 8% cc contact lens growth.

* **STRONG OPERATING PROFIT:** Though reported operating profit growth was just 9%, we calculate a normalized growth closer to 16%. This excludes a near \$3mm currency benefit (yen) and \$6mm unexpected non-cash cost related to "mark to market" on stock comp plans. EPS would have been \$0.48 were it not for the required accounting on the stock comp plans necessitated by BOL stock price rise during Q104. Lower than expected financing costs (\$8mm) also drove the upside in the quarter.

* **INCREASING ESTIMATES AGAIN:** We raised our 2004 EPS estimate to \$2.75 (high end of BOL's new \$2.70-2.75 EPS guidance). Changes include increased revenue (Japanese 1 day lens launch) and gross margins (mix shift) and decreased SG&A (expenses loaded into Q1) vs. our prior model. Our 3.18 estimate for 2005 represents modest 6% cc revenue growth and 50 bp of EBIT margin expansion.

4/21 **VISX, Incorporated** announced financial results for the first quarter ended March 31, 2004. First quarter revenues increased 27% to \$43.8 million from \$34.4 million for the comparable period of the prior year. Net income increased 115% to \$11.8 million (23 cents per share) compared with net income of \$5.5 million (11 cents per share) in the first quarter of 2003.

License revenue grew 65% from the first quarter of 2003, driven by higher sales of VISX's new CustomVue procedure and strong demand for laser vision correction. Laser vision correction procedure volume grew 20% over the prior year's first quarter and VISX's CustomVue procedures increased to 34% of total VISX U.S. procedure volume in the quarter.

"We are extremely pleased with the strong demand for laser vision correction," stated Liz Davila, VISX chairman and CEO. "This is the third consecutive quarter that we have seen healthy procedure growth, with year-over-year quarterly increases of 20% this quarter, and 16% and 17% in Q4 and Q3 of 2003, respectively. This is especially encouraging since industry reports indicate that VISX procedures are growing faster than the market. We believe that the awareness of the benefits of CustomVue, as well as favorable economic conditions, are contributing to our increased volume."

Davila continued, "Increasing conversion to CustomVue and higher procedure volume leveraged our financial results. We expanded gross margin to 77%, operating margin to 44%, and net profit margin to 27% for the quarter. This yielded EPS of \$0.23, more than double our EPS for last year's first quarter."

VISX generated approximately \$21 million in operating cash flow during the quarter, and now has over \$100 million in cash and equivalents. The company repurchased approximately 420 thousand shares of stock in the quarter under its board-approved stock repurchase program.

Financial Outlook: VISX's first quarter is seasonally strong due to tax free medical reimbursement plans that patients use to supplement payment for the laser vision correction procedure. VISX believes that second quarter revenues will exhibit healthy year-over-year growth and be in the range of \$39 million to \$41 million. EPS is expected to double from last year's second quarter and be in the range of \$0.16 to \$0.18 for the quarter.

As a result of a better than expected first quarter and positive signs of future growth, VISX is raising its 2004 guidance. The company is now targeting percentage procedure volume growth in the low to mid-teens, up from its original estimate of 8% to 12%, and stronger CustomVue conversion percentage in the high thirties, up from its previous estimates of 33% to 37% for the year. VISX now anticipates higher EPS in the range of \$0.76 to \$0.80, versus earlier guidance of \$0.70 to \$0.74.

Several analysts provided their take on VISX's results:

Jason Mills of First Albany Capital: EYE/Buy: Upside in 1Q:04; Raising Estimates and Price Target; Reiterate Buy

- * Strong 1Q - Upside Across the Board - VISX posted a strong first quarter, in which results exceeded our expectations in all key areas - procedure volume, conversion to CustomVue, and license revenue mix (% sales) - which drove upside to total revenue, margins, and EPS.

- * Revenue of \$43.8mn exceeded our \$42.6mn estimate, driven by upside in procedure volume (20% growth vs. our 12.5% estimate), conversion to CustomVue (33.5% vs. 33% estimate), offset by lower system sales (14 vs. 24 estimate).

- * Gross and operating margins significantly exceed our targets, coming in at 77.5% and 43.7% vs. our 71.1% and 35.9% estimates, respectively, driven by a higher mix of procedure revenue (~95% margin) vs. system sales (< 10% margin), as well as cost control and timing of expenditures in SG&A.

- * EPS Upside - Raising Estimates - EPS of \$0.23 beat our \$0.20 estimate (same as consensus). We are raising our 2004 and 2005 EPS estimates to \$0.78 and \$0.97 from \$0.73 and \$0.90, respectively. Management raised their EPS guidance for 2004 to the \$0.76-\$0.80 range, and suggested EPS would grow 25%-30% y/y in 2005, implying upside potential to our estimate (24.3% y/y growth estimate).

* Reiterate Buy rating and recommend beginning or adding to positions in EYE common. We are raising our price target to \$28 from \$26.

Joanne Wuensch of **Harris Nesbitt: EYE--Better-Than-Expected 1Q04, but Sustainability of Business Model Keeps Us Neutral**

* **Event:** VISX reported better-than-expected 1Q04 results with revenues of \$43.8 million (up 27.2%) and EPS of \$0.23 (up 120.5%). The revenue results topped our estimate of \$41.8 million and EPS surpassed our \$0.19 estimate and the First Call consensus of \$0.20.

* **Impact:** Positive.

* **Forecasts:** For 2004, our revenue and EPS estimates are increased to \$163.2 million (up 13.4%) from \$157.7 million and to \$0.76 from \$0.66. For 2005, our revenue and EPS estimates are increased to \$179 million (up 9.7%) from \$166.5 million and to \$0.90 (up 18.6%) from \$0.82. The consensus estimates prior to the conference call for 2004 and 2005 were \$0.73 and \$0.92, respectively.

* **Valuation:** Currently trading at 23x our new 2005 EPS estimate for \$0.90, VISX does not look expensive, nor does it look inexpensive.

* **Recommendation:** For our estimates to work, we assume that the economy continues to improve, customized ablation continues to be adopted and that momentum maintains post 2Q04 annualization of this new technology. We, therefore, end up betwixt and between on our opinion of VISX. While we anticipate the stock to trade up on the company's solid, if not good quarter, we also can't navigate the sustainability of the many factors that drive VISX's earnings growth. We, therefore, maintain our NEUTRAL rating.

Michael Lachman of **ThinkEquity Partners: EYE: Fundamentals Accelerated in Q1 - Reiterate Overweight-2**

We reiterate our Overweight-2 rating and 12-month price target of \$24-29 on shares of VISX following a Q1-04 report that delivered earnings upside driven by accelerating LASIK industry fundamentals. We had recommended purchase of the stock in front of the quarter, based on a belief that Q1 results would reassure or positively surprise investors after a disappointing Q4 report. VISX delivered, reporting EPS of \$0.23, ahead of our \$0.20 estimate, driven by strong 20% LASIK procedure growth and 34% CustomVue conversion. Management also raised its outlook for both procedure growth and CustomVue conversion for 2004, resulting in a \$0.06 increase in EPS guidance to a new range of \$0.76-0.80. We are raising our 2004 EPS estimate from \$0.75 to \$0.79. VISX's strong results also bode well for the company's largest customer, TLC Vision (TLCV - \$12.04 - Overweight-2 - Price Target \$16), which reports its Q1 results on May 10.

Ted Huber of Wachovia Securities: EYE: Upside from 20% Volume Growth Dampened by Co-op Spend

* **STRONG Q104 RESULTS:** VISX reported EPS of \$0.23, above our \$0.21 forecast (consensus = \$0.20). 20% volume growth (= to market growth) and 34% Custom mix were well ahead of our estimates (11% and 32%). Gross margins of 77% reflected positive mix shift toward licensing fees. Hardware sales (50 Wavescans and 14 lasers) continued to be slow, reflecting a saturated laser market and hardware share gains by Bausch & Lomb and Wavelight.

* **CO-OP SPEND HOLDS BACK UPSIDE:** We calculate that cooperative marketing expenses (booked in a contra revenue account) accelerated to near \$2.6mm in Q104, representing a near 5% discount on VISX's \$245 per procedure fee. While volume growth is better than expected, the new co-op marketing expenditures are consuming the EPS upside we once thought possible for 2004. The \$10.6mm we now estimate VISX will spend on these customer rebates represents \$0.13 in 2004.

* **MODEST CHANGES TO EPS ESTIMATES:** We are increasing our 2004 EPS to \$0.80, on 13% volume growth and 37% Custom mix. Our now higher growth estimates are largely offset by the co-op marketing spend we not model in. This also drives the reduction in our 2005 EPS forecast to \$1.01 from \$1.03. With an expected Alcon astigmatism approval coming at ASCRS and continued BOL gains, we expect VISX growth to decelerate in the coming quarters.

4/22 **Advanced Medical Optics, Inc.** announced financial results for the first quarter of 2004. Net revenue rose 14.6% to \$150.3 million compared with last year's first quarter, reflecting solid sales gains in the company's ophthalmic surgical and eye care businesses and favorable foreign currency exchange rates. Excluding the effect of currency, revenue grew 5.4% for the first quarter, compared to the same period in 2003.

Pro forma net income for the first quarter of 2004 was \$4.6 million (15 cents per share) compared to \$91,000, or breakeven performance on a earnings-per-share basis in the year-ago quarter. Reported net income for the first quarter, which includes the unrealized gain on derivative instruments, was \$4.7 million, or \$0.15 per diluted share, compared to a net loss of \$93,000, or breakeven earnings-per-share performance, in the year-ago quarter.

"AMO continues to achieve strong sales growth in both businesses," said James Mazzo, president and CEO. "The differentiated new technologies we launched in 2003, including our COMPLETE MoisturePLUS solution and Sovereign Compact system with WhiteStar technology, are further expanding our already strong lineup of ophthalmic surgical and eye care product lines. This success demonstrates the strength of our strategy to deliver sustainable technologies that improve practitioner productivity and patient outcomes."

Commenting on regional performance, Mazzo added, "Our international sales growth during the quarter was solid. Our sales performance in the Americas, which was up 12 percent compared to the same period last year, continued to gain momentum, reflecting the benefits of our increased focus and investment in the U.S. sales organization."

AMO is revising upward its revenue and earnings-per-share guidance for 2004. The company now expects net revenue for 2004 to be between \$635 million and \$645 million, and pro forma earnings per share to be between \$1.02 and \$1.04. The company expects second-quarter 2004 pro forma earnings per share to be \$0.24 or \$0.25. This guidance excludes any impact associated with the company's planned acquisition of **Pfizer Inc.'s** surgical ophthalmology business.

AMO also announced that it had signed a definitive agreement to acquire the Pfizer surgical ophthalmology business in a strategic transaction valued at \$450 million. AMO will acquire the Healon line of viscoelastic products used in ocular surgery, CeeOn and Tecnis intraocular lenses (IOL) used in cataract surgery and the Baerveldt glaucoma shunt. These assets generated annual sales of approximately \$150 million in 2003. AMO will also acquire manufacturing and R&D facilities in Groningen, Netherlands, Uppsala, Sweden and Bangalore, India. AMO expects the transaction to be accretive to pro forma earnings in 2004 and beyond, excluding certain transaction costs. After closing the transaction and finalizing the capital structure, AMO expects to provide more detailed guidance regarding the level of accretion and integration plans associated with the transaction.

Commenting first on the acquisition of Pfizer's ophthalmic surgical business, Ted Huber of Wachovia Securities wrote: **AVO: Transformed By Rooster Juice--Upgrade To Outperform**

* THE UPGRADE: AVO's purchase of the Pfizer cataract surgery franchise (PCS) is highly accretive and instantly transforms AVO into a higher growth, more formidable cataract surgery franchise. The deal foretells dramatically higher margins and EPS, making AVO stock an attractive purchase below \$30.

* THE DEAL: Last night, AVO announced plans to buy PCS for \$450mm. Its lead product was the first and is now the #2 viscoelastic, Healon (manufactured from rooster combs). The business generated near \$150 MM in 2003 revenue (~75% viscoelastics, ~20% IOLs) with 75%+ gross margins, we believe. Revenue growth was negative in recent years following elimination of a dedicated sales force.

* NEAR PERFECT STRATEGIC FIT: We expect the deal to be accretive to AVO's growth, margins and EPS. It fills the company's one cataract surgery product gap (viscoelastics) in a business where bundling is critical to market share. AVO can sell the products with its existing sales force and should have very modest incremental SG&A investments to make.

* **HIGHLY ACCRETIVE:** Transaction detail is sparse but we've patched together an analysis from sources familiar with PCS. We expect the transaction will be at least \$0.22 accretive in 2005 assuming 35% incremental EBIT margin and 5% revenue growth. EBIT margin over 45% is possible given the overlap of these two cataract franchise; PCS 2005 revenue growth over 10% is possible given the recent neglect of the business by corporate parents. These assumptions yield a \$0.48 2005 accretion.

He then commented on the financial release: **AVO: Share Gains in Lens Care; Holding Own in Hot Cataract Mkt**

* **Q104 IN-LINE WITH PRE-ANNOUNCEMENT:** EPS of \$0.15 on revenue of \$150mm (up 14.6% reported and 5.4% cc) was in line with pre-set expectations. Operational performance was strong with share gains in Lens Care and 7% cc growth in Surgical. Seasonal smoothing of costs helped drive EBITDA up 70% and a doubling of operating margin (to 7%).

* **INCREASING ESTIMATES:** We are inching up our 2005 estimate to \$1.22 and holding our 2004 target of \$1.05 on revenue of \$640, up 3.5% cc. This compares to management's new range of \$1.02-1.04 for 2004EPS on revenue of \$635-645. We view these as conservative earnings targets but point out that this model will be reconstructed and dramatically increased with the closing of the Pfizer Cataract transaction this summer.

* **AN INTERESTING TID-BIT ON THE PFIZER DEAL:** Yesterday's CC offered little new on this transaction announced the prior night. Guidance on accretion and financing specifics will have to wait until the transaction closes this summer. Interestingly, management said on the call the deal should deliver a 20+% return on invested capital. Our "aggressive case" accretion analysis with \$0.48 of EPS upside for 2004 carries a 16.4% IRR.

Michael Lachman of **ThinkEquity Partners** also commented on the Pfizer pickup: **AVO: Finally Pulls the Trigger on Pfizer Deal - Maintain Overweight-3**

We have long anticipated that Advanced Medical Optics (AMO) would emerge as the acquirer of the Pfizer cataract business, and view the deal favorably, although we would not be surprised to see initial weakness in AMO's stock this morning. We suspect that many investors will view the \$450 million price tag, equating to 3x revenues of \$150 million, as rich in the context of AMO itself, which trades at just over 1x sales. However, we believe that the higher profitability of the acquired business justifies a higher revenue multiple. Investors will likely also be concerned about the amounts of debt and equity that will be used to finance the deal. Our analysis suggests the potential for significant earnings accretion, and AMO management believes that the deal will be immediately accretive. We maintain our Overweight-3 rating on shares of AMO and would be buyers on any significant weakness following this announcement.

4/22 **QLT Inc.** reported that its alliance partner, **Novartis**, announced global Visudyne (verteporfin) sales of approximately US\$101.1 million for the quarter ended March 31, 2004. This represents an increase of 23% over sales in the first quarter of 2003.

4/23 **QLT Inc.** announced that Visudyne (verteporfin), currently the only treatment for some forms of "wet" age-related macular degeneration (AMD), was approved for reimbursement by the Japanese Ministry of Health, Labour and Welfare (MHLW), following approval in October 2003 for the "wet" form of AMD with all types of subfoveal choroidal neovascularization (CNV).

"Visudyne therapy is the first approved drug treatment for this devastating condition and we are very pleased to now be in a position to make this therapy available to the Japanese marketplace," said Paul Hastings, president and CEO of QLT Inc. "This is another major milestone in making Visudyne therapy available to improve the lives of so many people on a worldwide basis."

Approval was based on the results of a well-designed 12-month clinical study conducted in Japan, which confirmed the efficacy and safety profile of Visudyne as demonstrated in 3 large randomized controlled trials conducted in the rest of the world. In fact, approximately 3 patients out of 4 participating in this study either maintained or improved their vision as a result of Visudyne therapy. Visudyne was evaluated in Japan as a therapeutic drug for the wet form of AMD following its designation as an orphan drug in June 1997.

4/23 *HealthDayNews* reported that LASIK surgery results can be hurt by warm temperatures and high humidity, increasing the number of people who require follow-up procedures, according to a Wake Forest University Baptist Medical Center study. This study, the first to show that environmental factors can affect LASIK outcomes, found that a 10% increase in treatment room humidity meant an additional nine out of every 100 LASIK patients later needed an enhancement procedure.

Outdoor temperatures and humidity in the weeks before a person had LASIK also influenced surgery results, the study found.

The number of eyes requiring enhancement procedure was 0 percent in the winter and 50 percent in September, when outdoor humidity was highest. In less humid months, there was a tendency to overcorrect vision. During humid months, there was a tendency to undercorrect vision.

The study, which included LASIK surgery on 368 eyes of 191 patients, evaluated 12 variables suspected to affect LASIK results. These factors included age, sex, curvature of the cornea, and environmental factors such as room and outdoor temperature and humidity.

An analysis of these variables revealed that indoor humidity had the most impact on whether a person required an enhancement procedure. The findings appear in the current issue of the *Journal of Cataract and Refractive Surgery*.

"Environmental data should play a role in how the [LASIK] equipment is programmed to further refine the visual outcome," study author Dr. Keith Walter, an assistant professor of ophthalmology, said in a prepared statement. "Our study doesn't mean that consumers should avoid LASIK surgery during the summer. But they should make sure that their physicians compensate for temperature and humidity," Walter said.

4/26 Ted Huber of **Wachovia Securities** wrote a preview of the upcoming ophthalmic meetings: **Show Time! - A Preview of This and Next Week's Ophthalmology Trade Shows ARVO and ASCRS**

* ARVO (Advanced Research in Vision and Ophthalmology) will take place in Fort Lauderdale, FL on April 25-29 and ASCRS (American Society for Cataract and Refractive Surgery) will take place in San Diego, CA on May 1-5. This report offers a preview of key clinical data presentations at the conferences. We will report back on new data and physician reactions to it.

* ASCRS REFRACTIVE - CUSTOM VS. STANDARD LASIK and HEAD TO HEAD LASIK TRIALS: 10 presentations comparing standard to Custom LASIK and head to head vendor comparisons should shed light on competitive shifts and the trajectory of Custom LASIK in 2004. Preliminary data from VISX sponsored trials on Custom LASIK treatment of hyperopia, high myopia and presbyopia are important to the longer term growth potential of Custom LASIK and VISX.

* ASCRS REFRACTIVE - WHO WILL MAKE THE FLAPS? There are 5 data presentations comparing safety and visual acuity of traditional microkeratomes to the IntraLase Femtosecond Laser. These data and data on Bausch and Lomb's new XP microkeratome are important to the potential of the Femtosecond laser as an alternative LASIK Flap technology.

* ASCRS CATARACT - FOCUS ON IOLS: Alcon will offer new data on toric and multi-focal lenses. Data on the Tecnis Lens (soon to be acquired by AVO from Pfizer and offering a new "superior contrast sensitivity" FDA label) compares it to other IOLs.

* ARVO - FOCUS ON OPHTHALMIC PHARMA - NO MAJOR NEW RETINAL DATA: Though AMD remains a big focus of this meeting with over 2 dozen data presentations, we see no presentations of new clinical data. Physician reactions to the latest Visudyne and Eyetech's Macugen data are most important. In Glaucoma, Alcon has the stage with three presentations of data on its Travatan/Timolol combination product, slated for a H2 2004 NDA filing. In anti-infectives, several presentations will compare the new fourth generation fluoroquinolone antibiotics Vigamox and Zymar from Alcon and Allergan.

- 4/26 As reported by *EyeWorld Week*, **Ellex Medical** (Australia) introduced the Laserex Solo laser for the treatment of open angle glaucoma at the ASCRS meeting in San Diego. The Laserex Solo is an Nd:YAG laser that performs selective laser trabeculoplasty. The Laserex Solo is the world's first fully integrated SLT-only laser. Because the laser is integrated into a slit lamp microscope, the resultant configuration does not impair the ophthalmologist's operation of the instrument. The Laserex Solo features dual handed controls and a large working distance and a large format display. Laserex Solo technology uses short three nanosecond pulses of 532 nm light to selectively target melanin-rich cells in the trabecular meshwork. The laser pulses affect only the melanin-rich cells, leaving the surrounding structure of the trabecular meshwork unaffected. This triggers the release of macrophages to clear the affected cells and rebuild the meshwork so that it again functions effectively, thus reducing intraocular pressure.

OPHTHALMIC LASER UPDATE -- May 2004

- 4/27 **LCA-Vision Inc.** reported financial results for the three months ended March 31, 2004. Highlights from the first quarter of 2004 include:

- * Earnings per share of \$0.93, or \$0.50 excluding an income tax benefit, up significantly from earnings per share of \$0.16 in the first quarter of 2003
- * Revenues of approximately \$31.7 million, up 58% from revenues of approximately \$20.0 million reported in the first quarter of 2003
- * Revenue growth at LasikPlus vision centers open at least 12 months, up 48% from the first quarter of 2003
- * Procedure volume of 24,270, up 43% from 17,028 in the first quarter of 2003
- * Revenue per procedure of \$1,304, up 11% from \$1,173 in the first quarter of 2003
- * Operating income increased to 21.4% of revenues, compared with 8.2% of revenues in the first quarter of 2003
- * Net cash provided by operations of approximately \$6.9 million, up 109% from the approximately \$3.3 million of net cash provided by operations in the first quarter of 2003
- * Opening new LasikPlus vision centers in San Antonio, Texas; Orlando, Florida; and the company's third vision center in Toronto, Ontario
- * Appointing Anthony Woods and Craig Joffe to the company's board of directors

Net income for the first quarter of 2004 was \$12.7 million (93 cents per share) compared with first quarter 2003 net income of \$1.8 million (16 cents per share). Included in 2004 first quarter financial results was an income tax benefit of \$5.9 million to reverse a

portion of the valuation allowance on the company's deferred tax assets. Without the benefit of the reversal of this allowance, the company reported first quarter 2004 net income of \$6.8 million (50 cents per share). Management believes earnings per share excluding the benefit of the reversal of the reserve is a meaningful disclosure, facilitating year-over-year comparison on a consistent basis.

Revenues for the first quarter of 2004 increased to \$31.7 million, up more than 58% compared with revenues of \$20 million in the first quarter of 2003. Revenues at LasikPlus vision centers open for at least 12 months increased by 48% in the first quarter of 2004 compared with the first quarter of 2003.

Stephen Joffe, chairman and CEO of LCA-Vision, stated, "We anticipate additional revenue growth during 2004 as we increase our market share, benefit from overall industry growth and open new LasikPlus vision centers. We have very specific criteria for vision center locations, and each vision center is opened with the expectation of reaching breakeven within six months. With our strong balance sheet, we believe we are well positioned to actively pursue our planned expansion. As a result of our exceptional financial performance in this year's first quarter, our proven operating model and our current outlook for the remainder of 2004, we are increasing our 2004 financial guidance from the prior guidance we provided in February of this year. We now expect to report pretax income in 2004 of \$16.6 million to \$18.2 million. We expect revenues to be in the range of \$115 million to \$117 million, up from our prior guidance of \$110 million. We expect to report 2004 earnings per share in the range of \$1.55 to \$1.65, which is an increase from our prior EPS guidance of \$0.90 to \$0.95, and includes the \$5.9 million benefit recorded in the first quarter of 2004 for the partial reversal of the deferred tax valuation allowance."

4/27 **Miravant Medical Technologies** announced that it had closed a \$10.3 million private placement of 4.6 million shares of common stock with a group of institutional investors, with full proceeds to the company. There were no warrants or placement fees associated with the offering. The funds will be used for general corporate purposes.

The company also announced that investigational drug SnET2 provided a visual acuity benefit and slowed the progression of problematic neovascular lesions in two independent phase III clinical trials of patients with wet age-related macular degeneration (AMD). The clinical results were presented by SnET2 clinical investigators at the *Association for Research in Vision and Ophthalmology (ARVO)* meeting, Ft. Lauderdale. In March 2004, Miravant submitted a New Drug Application (NDA) to the FDA seeking marketing approval for the SnET2 treatment.

Edgar Thomas MD, Los Angeles, presented two-year visual acuity outcomes in the per protocol study population, which forms the basis of Miravant's NDA submission. Dr. Thomas said, "SnET2 provided a consistent visual acuity benefit over placebo early in the course of treatment and at all time points over two years. It is interesting to note that very few treatments were required to achieve this outcome, and the results were

demonstrated in all lesion compositions, regardless of percent classic or occult components. I believe that SnET2 can be a valuable first-line therapy for a broad range of AMD patients."

Ronald Danis MD, University of Wisconsin Fundus Photography Reading Center, Madison, presented angiographic outcomes that showed SnET2-PDT reduced the growth of fluorescein leakage, subretinal fluid, choroidal neovascularization (CNV) and total lesion area relative to placebo at all time points during the two-year studies.

"Vessel leakage and the resultant subretinal fluid accumulation are considered to be indicative of disease activity in patients with macular degeneration," Dr. Danis stated. "I believe it is very important that the SnET2 treatment clearly reduced these physiologic processes. The angiographic assessments support the primary visual acuity outcome that SnET2 significantly reduced the risk of vision loss in drug-treated AMD patients versus placebo patients."

Carl Regillo MD, Wills Eye Hospital, Philadelphia PA, presented safety results in the total study population. Dr. Regillo concluded, "SnET2 demonstrated an excellent safety profile. The treatments were well tolerated in study population, with a very low overall incidence of treatment-related adverse events."

Key results presented at the ARVO conference are summarized below:

- * In two independent clinical studies, the SnET2 treatment showed equivalent, statistically significant visual acuity (VA) benefit compared to placebo at two years, as assessed by the proportion of patients losing less than 15 letters on a standardized ETDRS eye chart (primary efficacy analysis). Pooled results from the two phase III studies (231 SnET2-treated patients vs. 119 placebo patients) demonstrated that SnET2-PDT reduced the risk of visual acuity loss relative to placebo in patients with subfoveal CNV lesions secondary to AMD (58% SnET2 vs. 42% placebo, p less than 0.005).

- * Secondary efficacy analyses were statistically significant and supported the primary analysis. Treated patients demonstrated better VA outcomes in terms of mean change from baseline and reduced severe vision loss (greater than 30 letters).

- * In other analyses, treatment response was demonstrated across all CNV lesion compositions, regardless of percent classic or occult components.

- * Treatment response was also demonstrated across all visual acuity (VA) strata, particularly patients with higher baseline VA, suggesting that vision can be stabilized at higher VA levels without the need for watchful waiting.

- * Maximal treatment response was observed with a regimen of 3 treatments over the first 6 to 9 months, a finding that may provide a useful re-treatment guideline for retinal specialists.

* SnET2-PDT significantly impacted CNV lesion characteristics, reducing the physiologic processes of neovascular leakage and fluid accumulation relative to placebo.

* The most common side effect was a transient dermal photosensitivity (skin sensitivity to sunlight), occurring in 4.9% SnET2 infusions vs. 1.1% placebo infusions. The majority of reports were mild and transient in nature, resulting in a mild erythema (reddening) of the skin of short onset and duration that resolved without treatment. There were no serious adverse events related to photosensitivity.

Phase III Studies: The clinical data are derived from two randomized, placebo-controlled, parallel group phase III studies conducted at 60 U.S. ophthalmology centers of patients with CNV associated with wet AMD. Patients were followed for two years and evaluated for re-treatment every 13 weeks. Two drug doses were tested, and 0.5mg SnET2/kg was determined to be the more efficacious. The Per Protocol study population received the minimum exposure to the 0.5 mg SnET2/kg treatment regimen pre-specified in the clinical protocol and is the basis of the company's NDA submission.

4/27 **QLT Inc.** reported financial results for the first quarter ended March 31, 2004, and updated guidance for 2004.

Q1 2004 Sales: As previously announced, Visudyne sales were \$101.1 million for the quarter ended March 31, 2004. Visudyne sales for the first quarter increased 23.2% over sales in the first quarter of 2003. Sales in the United States accounted for approximately \$45.5 million, representing 45% of total Visudyne sales for the first quarter. The remaining \$55.6 million relates to sales in the rest of the world, primarily Europe.

2004 Annual Guidance: Based on recent events and current trends in Visudyne sales, QLT is narrowing its Visudyne sales range from \$420-\$455 million to a new range of \$430-\$455 million, which represents top-line growth of 20% to 27% over 2003. The company has also updated EPS guidance for 2004 to \$0.81 - \$0.91 treating the convertible notes on an "as converted" basis or to \$0.86 - \$0.96 on a "not converted" basis.

"We are pleased to record our first \$100M plus quarter," said Paul Hastings, president and CEO. "Based on the current trend and the April implementation date of reimbursement for occult and minimally classic in the U.S., we have narrowed our Visudyne sales and EPS range. Our focus continues to be to set realistic expectations for the business and meet them while maximizing growth on both the top and bottom line."

Q1 Results/Revenues: The company's revenues reached \$41.3 million in the first quarter, growing by 25.3% from the prior year. Revenues from Visudyne comprised \$40.5 million of this total, up 28.9% from the same period in 2003. QLT's share of Visudyne net profit (excluding the recovery of manufacturing and other costs) for the first quarter was 31.8% of Visudyne sales. The alliance profit share rate in Q1 was slightly above our guidance of 30% to 31.5% for the full year due to lower spending.

4/28 **Lumenis Ltd.** announced that it had entered into new agreements to restructure its global sales and marketing relationship with **WaveLight Laser Technologie AG** of Erlangen, Germany. The new agreements will continue with Lumenis as the exclusive distributor for the ALLEGRETTO WAVE Excimer Laser in China, Hong Kong, Taiwan and Japan. Lumenis will no longer sell in the U.S. or in Europe.

Avner Raz, president and CEO, said "As part of our Turnaround Plan we have been evaluating all of our business activities to improve our profitability. An important step was to restructure our relationship with WaveLight for the benefit of both parties. Continuing our business in the China region and in Japan builds on our strengths in those markets where we have successfully placed approximately 100 systems. In the other markets, it allows us to focus our sales and marketing activities in our core ophthalmic products. We will provide assistance to WaveLight as they take over these regions to assure our customers receive full support during the change."

Lumenis will retain exclusive distribution rights in China and Hong Kong under substantially the same terms as existed previously. Lumenis will also continue its agreement in Japan and expects to actively seek MHLW approval for the ALLEGRETTO WAVE as soon as possible. WaveLight will assume direct distribution in the U.S. and Europe. Under the new agreements, WaveLight will acquire the distribution rights from Lumenis, assume all outstanding warranty and service obligations and purchase certain inventories and other assets from Lumenis. Revenue in 2003 from the regions terminated was approximately \$10 million.

WaveLight's wholly-owned U.S. subsidiary, **WaveLight Laser, Inc.**, which is headquartered in Sterling, Virginia (near Washington D.C.), will take over sales activities in the United States. In order to ensure a smooth, mutually agreed transition, WaveLight Laser Technologie AG is planning to absorb Lumenis employees responsible to date for sales activities in the U.S. The U.S. subsidiary will continue to expand its activities in the areas of customer support as well as patient and product marketing in future.

Max Reindl, CEO of WaveLight Laser said, "The Chinese market is especially important to us, since our laser systems for refractive surgery have enjoyed a high acceptance rate here in the past. This market has excellent growth potential. The rapid sales growth of our lasers would not have been possible without our sales partner."

4/29 **STAAR Surgical company** announced financial results for its first quarter of 2004, which ended April 2, 2004. Total product sales for the first quarter were \$13.6 million compared with \$12.8 million reported for the same quarter last year and \$12.8 million reported for the fourth quarter of 2003. Net loss for the quarter was \$1.3 million (7 cents per share) compared with a net loss of \$958,000 (6 cents per share) for the same period one year ago and a net loss of \$3.5 million (19 cents per share) reported for the fourth quarter of 2003.

"Continued strength in U.S. sales of Collamer IOLs and international sales of the Visian ICL and preloaded silicone product drove our sequential sales growth during the first quarter," said David Bailey, president and CEO of STAAR Surgical. "U.S. sales of our Collamer lenses increased more than 18% compared with last year. In addition, the ICL continued to gain traction in the international markets and grew more than 26% compared with the first quarter of 2003; a growth rate that was higher than the 20% growth achieved during the fourth quarter. Perhaps most notable during the quarter was the tremendous growth in our preloaded silicone lens systems sales, which continued to gain acceptance with cataract surgeons internationally," said Bailey.

"U.S. IOL sales continue to be negatively impacted by the need to make our current lens injection systems more competitive," continued Bailey. "However, we were somewhat encouraged that the rate of the year-over-year sales decline was slightly lower than that of the fourth quarter. We remain focused on our strategy to improve our older insertion technology in the U.S. and continue to regard the resolution of these technology issues as one of our key goals for 2004."

"In preparation for the U.S. launch of the ICL, we continued to invest in our sales and marketing efforts," said Bailey. "We have increased our U.S. headcount and added additional direct sales representatives to our newly established Pacific Northwest region, and are confident that we will be fully prepared to support a strong launch of the ICL in the U.S."

The company also announced that it had received a second Warning Letter on April 26, 2004 from the FDA as a result of four instances of non-compliance discovered during an inspection by the FDA's Los Angeles District Office in December 2003. The issues raised relate to events that occurred from 1997/1999 through 2001. It is worth noting that these issues primarily involved clinical study procedures which have been addressed by the current management team, and do not impact the integrity of the clinical data upon which the FDA panel granted an approvable recommendation in October 2003 following an expedited panel review. On January 6, 2004, STAAR submitted a written response to the FDA to address their objections and advise them of the company's planned corrective actions. In the Warning Letter, the FDA indicates that certain specified corrective actions appear "adequate." The company does not anticipate that the letter will have an impact on the timing of its pending Pre-Market Approval application for the Visian ICL. The letter is available on the STAAR web site for investors to view and will also be posted to the FDA's website some time in the near future.

"We remain excited about the potential approval from the FDA for the ICL lens in the U.S.," continued Bailey. "We are also confident that we are doing everything we can to overcome our regulatory challenges and move the approval process along. We remain in close contact with the FDA and believe that we are well positioned to quickly address any potential concerns or issues as they develop. As we announced last quarter, the FDA indicated that a successful audit of our Nidau, Switzerland facility would need to be completed before the Agency would grant its approval for the ICL. We have recently

been informed that the dates of this inspection have been officially scheduled for June 14 through June 17, 2004. We have been working very closely with our consulting firm, Quintiles, to pre-audit and implement any necessary changes at both facilities, and we believe that we are fully prepared for the FDA inspection process. In addition, we will submit a request next week to the FDA for a re-audit of our Monrovia facility, to take place as early as mid July, which will lead us to the final stage of the approval process," said Bailey.

Looking ahead, Bailey offered this outlook for the remainder of 2004: "Despite our belief that we will receive approval for the ICL and anticipate a full launch of the product at the *American Academy of Ophthalmology (AAO)* meeting in late October, we continue to believe that it is most prudent for us to provide revenue guidance without any U.S. ICL contribution. Without U.S. ICL sales, our outlook remains unchanged from our previous update. We continue to believe we can achieve low double digit revenue growth for the full year; gross margins are expected to improve from the level achieved during the first quarter and for the full year 2004 should be higher than full year 2003; and sales and marketing and research and development spending will continue to have moderate increases throughout 2004 in absolute terms. Net loss for 2004 is anticipated to be approximately 50% less than the net loss for 2003."

Two analysts provided their input about the company's announcements:

Joanne Wuensch of Harris Nesbitt: STAA--Quarter Meets Preannouncement; Visian Phakic IOL Hits Further Delays

* **Event:** STAAR Surgical reported 1Q04 results with revenues of \$13.6 million (up 5.8%; down 1% on constant currency), which were in line with the company's March 31 preannouncement for revenues of \$13.3-\$13.5 million and our estimate for \$13.2 million. EPS for the quarter was a loss of \$0.07, which was better than our estimate for a loss of \$0.09 and the First Call consensus for a loss of \$0.10.

* **Impact:** Negative. With the preannounced quarter in the bag, hot topics on the call included the FDA approval process for the Visian phakic IOL (now anticipated in 4Q04 versus the 4/3/04 expectation), the delay in the Collamer IOL inserter system (end of 2004 versus mid-2004), and a second FDA warning letter (received 4/26/04).

* **Forecasts:** No change to estimates. Our 2004 revenue and EPS estimates remain \$56 million (up 11.3%) and a loss of \$0.18. For 2005, our revenue and EPS estimates are also unchanged at \$69 million (up 22.8%) and \$0.14.

* **Valuation:** Our \$9 price target is arrived at by applying a 6-7x multiple to our 2005 refractive revenues plus 2-3x our 2005 cataract and glaucoma revenues.

*** Recommendation:** Even though we continue to believe in the potential of the phakic IOL market opportunity, given the near-term uncertainty regarding regulatory approval followed by initial sales ramp, we maintain our NEUTRAL rating.

John Calcagnini of CIBC World Markets: STAA: Reports Another Unspectacular Quarter and Discloses 2nd FDA Warning Letter

STAA reported that 1Q04 revenues increased 6% to \$13.6 mm, which was in-line with their preannounced guidance of \$13.3-\$13.5 mm. Sales were down 1% before the positive impact of foreign exchange on the international IOL and ICL businesses in particular.

ICL sales were up an est. 26% to \$1.1 mm in the qtr. Note that this is all Europe as the product is not approved in the U.S. The Euro was up about double digits versus the dollar. We also believe that the sales were generated by replacing and stocking new distributors in Italy and the U.K.

U.S. sales for the company as a whole were down 3% in the quarter, while international sales were up 14% reported and up 1% in CC. We have the total cataract business flat versus a year ago at \$12 mm, but the high margined U.S. business continues to decline in silicone lenses.

Domestic IOL sales continue to be plagued by the company's need for a better injection system and cartridge in both its silicone and collamer IOL lens businesses, which they plan to introduce later this year. AquaFlow was up slightly from a year ago at around \$270,000.

4/30 **20/10 PERFECT VISION Optische Geräte GmbH** announced that it had received the CE mark for its new FEMTEC laser. The FEMTEC is a revolutionary femtosecond laser for creating the corneal flap in patients undergoing LASIK surgery. The FEMTEC laser features a patented curved patient interface and is fully automated.

"The FEMTEC product is the first ophthalmic femtosecond laser which does not need to applanate the cornea during the laser procedure," commented Dr. Frieder Loesel, CEO of 20/10 PERFECT VISION. "With our curved patient interface the FEMTEC makes full use of the gentle procedures possible with femtosecond laser technology. After receiving FDA 510(k) clearance in February, we are delighted about this recent CE marking of the FEMTEC, which now allows us to serve the surgeons in our European home markets."

5/3 **CIBA Vision Corporation**, the eye care unit of **Novartis AG** announced that it had sold its Epi-LASIK surgical product line to Australian medical devices company, **Norwood Abbey Ltd.** The product line includes the Centurion SES system and EpiEdge epikeratome separator, which was approved by the FDA and has received European CE Mark.

CIBA Vision announced on August 18, 2003 that it was considering strategic alternatives for its Surgical business, including the potential sale of that unit. This unit had a broad portfolio of products addressing a number of surgical eye-correction platforms. "This is a key step in the sale of our surgical business and allows us to focus fully on our core lens and lens care businesses," said Robin Terrell, president of CIBA Vision's Surgical Business. "Epi-LASIK offers an exciting breakthrough in refractive surgery and the EpiEdge separator plays a key role in making this valuable technology available to ophthalmologists. CIBA Vision Surgical has developed a portfolio of highly promising technologies, including the Epi-LASIK products. As a specialist medical devices company, we believe Norwood is well positioned to realize the value of the Centurion SES EpiEdge epikeratome."

In addition to purchasing the Centurion SES EpiEdge, Norwood has also exclusively licensed the worldwide rights to Epi-LASIK from **FOS Holdings SA**. The inventor of the Epi-LASIK technology, Professor Ioannis Pallikaris, will act as a consultant to Norwood as a founding member of its clinical advisory board.

Bear, Stearns & Co. Inc. acted as CIBA Vision's exclusive financial advisor in relation to these transactions.

5/3 **Advanced Medical Optics, Inc.** announced a one-year research and evaluation licensing agreement with **Quest Vision Technologies, Inc.** to develop accommodating intraocular lens (IOL) designs. Under terms of the agreement, AMO will own a minority interest in Quest Vision, with an option to purchase the company after one year. No other terms were disclosed. The Quest Vision accommodating IOL designs, FocusIOL and FlexOptic, are being developed to address presbyopia, which is the progressive loss of the natural lens' ability to change focus from far to near objects. Quest's original design concepts were patented by ophthalmologist Randy Woods in 1988. Recent studies indicate that, in the United States alone, presbyopia will affect 90 million people over the next 10 years. The FocusIOL and FlexOptic lenses are designed to mimic the qualities of the eye's natural crystalline lens by accommodating in response to changes in the eye's natural ciliary muscle mechanism.

"Accommodating IOLs hold great promise as a new vision correction option for millions of presbyopes who now rely on eyeglasses," said James Mazzo, AMO president and CEO. "With this agreement, AMO will pursue its goal to offer ophthalmic surgeons and their patients an even wider selection of advanced technologies for correction of refractive conditions. This agreement is consistent with our strategy to complement our internal scientific and engineering expertise with strategic alliances, acquisitions and other corporate development activities that allow us to play a major role in the development of the burgeoning refractive IOL marketplace."

With the agreement, AMO gains access to novel accommodating IOL technologies that could add breadth to its growing refractive IOL offering, which currently includes the Array multifocal IOL and Verisyse phakic IOL. In addition, AMO expects to acquire the

Tecnis multifocal IOL, a progressive diffractive lens technology, as part of its planned acquisition of **Pfizer Inc.**'s surgical ophthalmology business, which is slated to close this summer. Both the Array and the Tecnis multifocal are approved for correction of presbyopia in Europe.

Under the agreement, AMO will have access to a number of issued and pending patents for various design approaches that encompass both axial movement and shape-changing technology.

"We are delighted to be working with AMO on the further development and commercialization of the Quest Vision technology and are confident that we have chosen the ideal partner," said Dr. John Hunkeler, chairman of Quest Vision Technologies, Inc., chairman of the Department of Ophthalmology at the University of Kansas School of Medicine and founder and medical director of Hunkeler Eye Institute in Kansas City, Mo. "For the past four years, Quest Vision has been working diligently to raise the performance bar on the correction of presbyopia. We have created two accommodative lens products for both the cataract and refractive markets. These technologies have shown great promise in animal and engineering models, and we look forward to merging our technology into AMO's product development portfolio."

5/3 Several analysts provided their reports on the ASCRS meeting.

Michael Lachman of ThinkEquity Partners: ASCRS Halftime Report: Refractive Surgery Outlook Remains Robust

We reiterate our Overweight-2 ratings on shares of **VISX** (EYE - \$21.89 - Price Target \$24-29) and **TLC Vision** (TLCV - \$11.94 - Price Target \$16) based on continued robust LASIK procedure trends and improving visibility on multiple refractive surgery market growth drivers. At the annual meeting of the *American Society of Cataract and Refractive Surgery (ASCRS)*, we believe that consensus is building with regard to the superiority of custom LASIK, and that procedure growth trends remain positive through the first part of Q2. Interest is also building in the AcrySof ReStor multifocal/pseudoaccommodating IOL from **Alcon** (ACL - \$74.25 - Overweight-3 - Price Target \$80), supported by newly released pivotal trial data. Sentiment within the ophthalmic industry is positive with respect to the strategic fit and potential earnings accretion of the acquisition of **Pfizer's** cataract business by **Advanced Medical Optics** (AVO - \$31.54 - Overweight-3 - Price Target \$31-34), although the acquisition price exceeded most expectations.

Investment Highlights: Based on feedback we have received from surgeons and industry contacts in attendance at the ASCRS meeting in San Diego, refractive surgery (LASIK) market trends remain robust following a strong start to 2004. Consensus seems to be building with regard to the superiority of custom/wavefront-guided LASIK over standard treatment, and the procedure growth outlook remains favorable heading into the summer months. In an instant poll of surgeons attending a custom LASIK symposium this weekend, 60% indicated that their procedure volumes were up 10% or more in Q1-04

versus Q1-03; 70% of the same group indicated an expectation for 10%-plus procedure growth for the full year 2004. Also, in our view, the current and near-future emergence of a number of new refractive products (phakic and accommodating IOLs, and a recently approved RF-based treatment for presbyopia) will not only lead to growth in the overall refractive surgery category but will support LASIK procedure growth as well.

We believe that the debate regarding the superiority of custom/wavefront-guided ablations is subsiding, and that there is growing consensus within the surgical community that custom is better than standard LASIK on all three major laser platforms. When VISX's CustomVue system was FDA-approved last summer, the "out of the box" procedure tended to under-correct myopic patients, leading to less-than-ideal outcomes. With many surgeons having climbed the learning curve and having adjusted their treatment nomograms, outcomes have improved over the past six months. Superiority of custom versus standard LASIK is manifesting itself in a number of ways:

- * Higher percentage of patients achieving 20/20 and better visual acuity
- * Lower incidence of night vision problems
- * Lower rate of enhancement/re-treatment procedures
- * Better quality of vision (including contrast sensitivity). In survey data from over 1,000 refractive surgeons presented at ASCRS (Solomon, et. al.), 85% of respondents believe that wavefront ablation improves quality of vision.

In addition, we believe that there are a number of incremental LASIK market drivers that should allow both VISX and TLC Vision to meet or beat our procedure growth estimates over the next several quarters. For VISX, we are now forecasting procedure growth of 13% this year and 6% in 2005. For TLC Vision, we are forecasting 6.5% procedure growth this year and 6% growth in 2005. Our 2004 TLC Vision procedure growth forecast represents a mix of about 20% growth in owned and managed centers and a 10% procedure decline in the Access business. Our conversations with TLC Vision customers at ASCRS lead us to believe that trends in the Access business may be better than previously believed. Some of the incremental LASIK market growth drivers are as follows:

- * New indications for custom LASIK: We expect VISX to receive FDA approval for CustomVue treatment for hyperopia later this year. Hyperopia is not as well suited to LASIK as is myopia, and currently accounts for 10% or less of total US procedures. Clinical data continues to demonstrate clear superiority of CustomVue treatment for hyperopia over standard treatment. Upon approval, we expect procedures to convert relatively quickly to custom and anticipate some incremental hyperopia procedure volume, although we expect hyperopia to remain a small portion of the LASIK market. VISX expects CustomVue approval for higher degrees of myopia (beyond -6D) in H1-06. The high myopia patient population is relatively small, and the more tissue-hungry nature of wavefront-guided ablations will limit conversion to some extent, but early clinical data is very encouraging. LASIK treatment of presbyopia is a potential longer-term driver, but we do not expect US approval until late 2006 or 2007.

* The average age of LASIK patients and the average level of myopic correction both seem to be trending lower. We suspect that the improved risk/reward perception associated with custom LASIK is attracting patients with lower levels of myopia - this could become a meaningful long-term procedure growth driver, given the large population of low-level myopes.

* New refractive surgery products are a less obvious LASIK growth driver, given the potential competition for patients, but we suspect that higher patient flow at refractive practices will result in increased LASIK volumes. A number of high profile new refractive products have recently been approved in the US, or will be in the near future. These include: (1) the Crystalens accommodating IOL (approved last November) from private company **eyeonics, inc.**, with Alcon's competing ReStor pseudoaccommodating lens to follow in 2005; (2) NearVision CK (conductive keratoplasty) for presbyopia/monovision (approved in March) from private company **Refractec**; and (3) two phakic IOLs, expected to be approved by this fall (see below for additional discussion). While we expect all of these products to carve out niches of various sizes (we're most bullish on the accommodating IOLs), we believe that positive PR surrounding all of these products will drive additional patients into refractive surgery practices, where a meaningful percentage will be treated with LASIK. In particular, Refractec has done a tremendous job in generating positive PR since its recent presbyopia approval, although many of the patients that seek treatment will ultimately be treated with LASIK. We believe that most of the ideal patients for these new modalities are either older or more myopic than the current LASIK population, suggesting little direct competition and cannibalization.

Pricing trends remain positive among LASIK service providers, which is favorable for the industry. The 2004 refractive survey cited above (Solomon, et. al.) indicates that over the past two years the percentage of surgeons charging more than \$1,500 per eye has increased. An increasing number of refractive surgeons are now charging a flat rate for LASIK procedures, whether they perform standard or custom treatment. In these practices, wavefront diagnostics are performed on all patients, custom ablations are performed on those who qualify, and the higher custom rate is charged. Surgeons following this model avoid the process of up-selling patients from standard to custom LASIK.

Alcon's AcrySof ReStor diffractive, multifocal, pseudoaccommodating acrylic IOL is generating an increasing amount of interest as the potential 2005 FDA approval approaches. When Alcon reported its Q1 results less than two weeks ago, the planned PMA filing date appeared to have moved up one quarter, from Q3-04 to Q2. Yesterday, Alcon announced that it has already filed for approval. The eyeonics Crystalens, which was FDA-approved last November, is currently blazing a trail that the Alcon ReStor is likely to follow. The Crystalens is being positioned as a premium-priced refractive product for pre-Medicare-age patients (cataract and otherwise), and the product is generating a high level of interest in the cataract/refractive community. We hear from our surgeon contacts that Alcon is planning to aggressively bundle the ReStor lens with its

other products in order to leverage the high interest in this lens into sales of other IOLs, Infiniti phaco products, and Vigamox anti-infective.

ReStor data released over the weekend at ASCRS confirms the anecdotal outcomes presented by the company in February. Alcon reported results from Phase III studies in the US and Europe, consisting of 566 ReStor patients and 194 control patients with monofocal IOLs.

* Distance visual acuity: 99% of ReStor patients and 98% of monofocal patients reported uncorrected visual acuity (UCVA) of 20/40 or better (versus the FDA benchmark of 92%). Results were also statistically equivalent at 20/25 or better: 88% for ReStor versus 92% for monofocal patients.

* Near visual acuity: 85% of ReStor patients and 61% of monofocal patients reported UCVA of 20/40 (J3) or better, which corresponds to functional intermediate vision (ability to read regular newspaper type). At 20/25 (J1), which corresponds to functional near vision (ability to read small type, such as stock quotes), the ReStor results stand out, with 74% of patients meeting this metric versus only 14% of monofocal control patients.

* Use of spectacles: 80% of ReStor patients reported no use of glasses for either near or distance vision, while only 8% of monofocal patient reported this result. As a point of reference, clinical studies of the AMO Array multifocal IOL have shown that about 40% of patients never wear glasses for near or distance vision.

* Contrast sensitivity: At lower spatial frequencies, which the company says are the most relevant to daily activities, there was not a clinically or functionally significant difference between the ReStor and monofocal groups. Loss of contrast sensitivity is one of the most important potential drawbacks of multifocal lenses, so this result warrants further examination once more detailed data is available.

Sentiment within the ophthalmic industry is positive with respect to the strategic fit and potential earnings accretion of the acquisition of Pfizer's cataract business by Advanced Medical Optics (AMO). The overall perception is that the acquired Healon viscoelastic products will fill a critical void in AMO's cataract product line, although the purchase price for this business was higher than most people in the industry expected it would be. We suspect that **Bausch & Lomb** (BOL - \$62.83 - Equal Weight-4 - \$71 Price Target) emerged as a late bidder, based on a combination of genuine interest in the business and a desire to force up the deal price for the eventual acquirer.

We expect the first two phakic IOLs to receive FDA approval in the US this fall. Our industry sources suggest that FDA approval is likely this fall (possibly in October, in time for the *American Academy of Ophthalmology* meeting) for both AMO's Verisyse anterior chamber lens and **Staar Surgical's** (STAA - \$8.50 - Not Rated) Visian ICL posterior chamber lens. We perceive that surgeon interest in these products is relatively high, but expect surgeons to restrict their use of both lenses to the relatively small population of

high myopes (-8D to -10D and beyond). Although the clinical data we have seen does not seem to strongly favor either product over the other, we still think that the Visian ICL will be the preferred product in the US based on surgeons' comfort level with the implantation technique, which is more like a standard cataract procedure.

Joanne Wuensch of **Harris Nesbitt: MEDTEC--ASCRS Weekend Highlights**

- * We are attending the ongoing American Society for Cataract and Refractive Surgery (ASCRS) conference: hot topics include the benefits of customized laser correction vision surgery and phakic IOLs.

- * Next technology steps for VISX: 2005E introduction of high myopia and hyperopia and a 2006E introduction of custom presbyopia.

- * Surgeon poll indicates LVC procedural volumes in 2004 up 10% (in line with our model).

- * A small head-to-head study of Alcon's customized ablation technology vs. Visx's could help stem ACL's soft LVC system sales.

- * Several papers were presented on the effectiveness of fourth-generation fluoroquinolones: we believe these findings can continue to help Vigamox sales growth, maintain its US market leadership of fluoroquinolone sales and help to offset Ciloxan going off patent next month.

- * A packed symposium on phakic IOLS indicates physicians' desires to add these devices to their refractive arsenals (although it could play a niche role in the treatment of myopia).

Jason Mills of **First Albany: ASCRS Summary/Reinvigorated Demand Drives Strong Growth in the Refractive Market**

The *American Society of Cataract and Refractive Surgeons (ASCRS)* conference, which is the most important meeting of the year for cataract and refractive companies and surgeons, provided a forum for companies in the refractive market to display what we perceived to be reinvigorated momentum following two and a half years of lackluster demand for refractive procedures leading up to mid-2003. Since that time, the domestic LASIK procedure market has produced three consecutive quarters (3Q:03-1Q:04) of positive year-over-year growth, which we estimate at 7.6%, 13.3%, and 16.6%, respectively. Over this period, our analysis suggests industry leader and Buy-rated VISX (EYE-\$22.19-Buy) has grown its share of U.S. procedures each quarter on a Y/Y basis. We suggest reinvigorated demand and accelerating growth in the domestic LASIK market is a product of a new product cycle (Custom LASIK) and a stronger economy. The former is driving better patient outcomes and arguably less negative press (actually positive press, in our view), while the latter translates into a higher discretionary income

level relative to times of economic recession/uncertainty (2001-03), when LASIK procedures declined.

VISX's Leverage to LASIK Should Work in Its Favor in Currently Bullish LASIK Market; Raising Estimates Slightly -- Against a backdrop of strong demand for refractive procedures, we expect strong top- and bottom-line results for VISX in 2Q:04. We estimate 11.2% y/y procedure growth and 37.4% conversion to CustomVue (CTC), and we are modestly raising our 2Q:04, 2004, and 2005 revenue and EPS estimates. Our EPS estimates for 2Q go from \$0.17 to \$0.18 (high end of guidance range of \$0.16-\$0.18); 2004 EPS go to \$0.80 from \$0.78 (high end of guidance range: \$0.76-\$0.80); and 2005 EPS go to \$0.99 from \$0.97 (up 24%, and at the low end of EPS growth guidance for 2005 of 25%-30%).

Bausch & Lomb Is Poised to Gain Share in LASIK Market; Tougher Row to Hoe in Cataract; Reiterate Strong Buy Rating. We maintain our recently upwardly revised estimates on Strong-Buy rated Bausch & Lomb (BOL-\$62.98-Strong Buy) and continue to expect the company to gain share in the U.S. LASIK market (both laser placements and procedures), primarily from Alcon (ACL-\$74.61-Not Rated) and **Nidek**(private). On the cataract side, BOL must fill a lean product pipeline and reinvigorate its sales force in the U.S. to have any hopes of competing more effectively against cataract industry stalwart Alcon, as well as Advanced Medical Optics (AVO-\$33.10-Not Rated), which recently purchased the **Pharmacia** cataract franchise from Pfizer (PFE-\$36.22-Buy).

Key Points:

• Key Refractive Industry Takeaways

1. Custom LASIK evolving toward standard of care.
2. Surgeons take ownership of the Custom/Conventional LASIK decision based on clinical superiority of the former.
3. CustomVue = Better Results = Positive Word-of-Mouth = Higher Demand for LASIK (if the economy is better, which it certainly seems to be).
4. Does FDA Approval for Higher Levels of Myopia Really Matter?
5. Presbyopia - Next Leg of Growth in the Refractive Industry? Which Concept Ultimately Wins - Accommodating IOLs, Multi-Focal IOLs, Presbyopic LASIK, or Conductive Keratoplasty (CK)?

• Key VISX Takeaways

1. Ease of Use & Patient Flow noted by several surgeons as CustomVue hallmarks.
2. Next-generation CustomVue technology (Fourier polynomials, iris recognition software [2H:04E]) could further optimize CustomVue and drive even better patient outcomes.
3. Hyperopic CustomVue Coming (2H:04E) - Will Expand Target Patient Population Moderately.

4. The one notable attack on VISX came from an Alcon-paid surgeon, for which according to many surgeons, the *primary drawback was that it did not allow for nomogram changes to optimize the Custom LASIK surgery*.
5. VISX holds a commanding position in the refractive surgery market, which enjoys reinvigorated momentum, as evidenced by a new product cycle and stronger economy.
6. Raising EPS Estimates Slightly - 2Q:04 to \$0.18 from \$0.17; 2004 to \$0.80 from \$0.78; and 2005 EPS to \$0.99 from \$0.97. Reiterate Buy Rating.

• **Key Bausch & Lomb Takeaways**

1. Zyoptix - Good Showing - Expect More Share Gain.
2. Cataract Strategy - Must Improve Product Pipeline & Sales Distribution.
3. We maintain our recently upwardly revised EPS estimates - \$2.74 and \$3.21 for 2004 and 2005, respectively.
4. Reiterate Strong Buy rating.

Ted Huber of **Wachovia Securities: ASCRS/ARVO Overviews**

* WHO ARE THE WINNERS AND LOSERS FROM THIS YEAR'S ASCRS: We see incremental positives for AVO, ACL and VISX from ASCRS and incremental negatives for BOL. Alcon and AVO appear to be moving from strength to strength in cataract surgery and are each poised to launch premium priced IOLs for refractive surgery use. VISX records a win with a very strong Custom LASIK showing. BOL's surgical franchise offers a mixed bag of opportunity: its Zyoptix excimer laser platform is gaining share and well received by surgeons but share losses should continue for its microkeratome (delayed product launch and threat of substitutes) and cataracts (thin pipeline).

* HAVE OUR VIEWS ON OPHTHALMOLOGY STOCKS CHANGED? No. ASCRS underscored our enthusiasm for AVO shares as a 20%+ secular grower, driven by a multi year accelerating top line, margin expansion and debt pay down. Though ASCRS highlighted the weaknesses in BOL's surgical franchise, this is not new news. We rate BOL Outperform based on the strength of its consumer and pharma businesses and significant margin expansion potential. Though Custom LASIK took a significant step forward at ASCRS, a positive for VISX, we view the shares as fairly valued given questions about VISX's chances for sustainable long term growth. Positive data and surgeon reaction to Alcon's Restor lens is a plus for the company but does not change our view that current valuation fully reflects the company's strength.

5/4 **NIDEK, Inc.** announced that it had completed and submitted 3-month clinical data for its new hyperopia study to the FDA. This marks an important milestone in the study process, as additional treatment eyes will be initiated in the study protocol effective immediately. NIDEK also received approval from the FDA to expand the clinical study to 300 eyes under the current treatment protocol. The expansion will include 150 eyes

each for spherical hyperopia and hyperopic astigmatism. NIDEK has worked closely with the FDA on the design, initiation and evaluation of the clinical study.

"We are excited and very pleased with these initial results of the new hyperopia software for the US EC-5000 platform. The study expansion approval to 300 eyes marks an important milestone for the hyperopia trial. We look forward to evaluating the 6-month follow-up data in short order, as this initial data sample is an excellent step in getting the new hyperopia approved for the US Market", commented George Waring, III, MD, Medical Monitor for the NIDEK US Hyperopia Study and Chairman of NIDEK's Medical Advisory Group.

Ted Shimomura, executive vice president and general manager of NIDEK, Inc. stated, "We are very happy with the initial clinical trial results and we look forward to expediting collection and review over the coming months. NIDEK is dedicated to providing the highest quality solutions and treatment therapies for quality patient care and surgical outcomes. The EC-5000 provides expanded treatment options, parameters and an innovative, technologically advanced platform for Refractive Surgery. The NIDEK EC-5000 platform is designed for surgeons' present use as well as future needs, as the field of Refractive Surgery continues to advance and grow. NIDEK is actively working on developing and launching its own custom ablation and wavefront technology platform with the NIDEK EC-5000 Excimer Laser System. Currently this technology is available internationally and will soon be introduced in the U.S. once clinical studies and regulatory processes are done."

NIDEK has begun detailed discussions with the FDA for the initiation of additional studies to evaluate hardware and software for the NIDEK EC-5000 Excimer Laser System. Additionally, NIDEK and the FDA will review and perform analysis of international experiences with new technologies. NIDEK's EC-5000 Excimer Laser System is currently approved for the reduction and elimination of myopia in the low, moderate and high ranges from -0.75 to -14.00 diopters and moderate myopia with astigmatism ranging in severity from -1.00 to -8.00 D, with a refractive astigmatism from -0.50 to -4.00 D cylinder by manifest refraction, using LASIK (Laser in-situ Keratomileusis) or PRK (Photorefractive Keratectomy).

5/4 **RHEO CLINIC**, a subsidiary of **TLC Vision Corporation** announced Institutional Review Board (IRB) approval and the official launch of patient enrollment in a new study called the Prospective Evaluation of Visual Functioning with Rheopheresis Treatment for Age-related Macular Degeneration in Canada (PERC).

The PERC study's principal investigator is retinologist David Wong MD. Co-investigators are Yoel Abells MD, Sanjive Jain MD, Kelly Wong MD, and Lorne Langer MD. The protocol was designed by Trefford Simpson, PhD.

PERC is a single centre, prospective, study designed to examine the effect of rheopheresis treatments on the outcome variables for 60 patients. Each patient will

receive a series of 8 "RHEO" treatments over a ten to twelve week period. Clinical data will be collected at 3-month intervals for one year following the initial treatments.

One objective of the study is to develop a complete description of the physiological changes produced by RHEO therapy. This will be done using structural, functional and subjective measures of vision in its broad context. This includes retinal morphometry, retinal electrophysiological and vascular function as well as general visual performance using standard measurements of acuity, reading speed, color and contrast sensitivity. Subjective vision assessments using the National Eye Institute Visual Functioning Questionnaire-25, will also be evaluated to gain understanding about general quality of life and AMD-specific visual symptoms.

Enrollment in the study is expected to be completed in or around the third quarter of 2004. Dr. Wong commented, "Interim results from the largest Rheopheresis trial to date, known as the MIRA-1 (Multi-Center Investigation of Rheopheresis for AMD), which is being conducted by **Vascular Sciences Corporation**, demonstrated statistically significant effects of RHEO therapy on preserving and in some cases improving visual function of Dry AMD patients when compared to a placebo group. The PERC study will give us greater understanding of the treatment's method of action."

5/5 **NovaMed, Inc.** reported results for the first quarter ended March 31, 2004. Net income from continuing operations in the first quarter of 2004 increased 34% to \$747,000 (3 cents per share) from \$559,000 (3 cents per share) in the prior year first quarter. The first quarter results for 2004 and 2003 included pre-tax gains on the sale of minority interests of \$190,000 and \$115,000, respectively. Net income, including discontinued operations, was \$1.3 million (6 cents per share) in the first quarter of 2004 compared to \$563,000 (3 cents per share) in the prior year first quarter. Late in the first quarter of 2004, NovaMed received approximately 365,000 of its shares as payment for an outstanding note receivable due from a former affiliated physician. The company reversed the valuation allowance previously established against the note resulting in net income from discontinued operations of \$594,000.

For the first quarter ended March 31, 2004, total net revenue was \$14.2 million compared to \$13.5 million for the prior year first quarter. Net revenue from surgical facilities was \$9.3 million, up 9% from \$8.5 million in the prior year first quarter. This revenue increase was primarily due to a 13% increase in total surgical procedures performed in the first quarter of 2004 as compared to the same period in the prior year. On a same-facility basis, surgical facilities net revenue increased 8% over the prior year first quarter. Product sales and other revenue was \$4.9 million in the first quarter of 2004, down 2% over the prior year first quarter. Operating income in the first quarter of 2004 increased 29% to \$1.8 million, or 13% of net revenue, from \$1.4 million, or 10% of net revenue, in the same period last year.

"I am pleased with our operating results in the first quarter, particularly our same-facility revenue growth of 8%," commented Stephen Winjum, NovaMed chairman, president and

CEO. "In addition, our significant increase in operating income shows that we are improving the efficiency of our operations. With our recent acquisition of a majority interest in two surgical facilities located in New Hampshire, we are also making progress in executing our external growth strategy. We expect these two acquisitions to be accretive to earnings immediately. I remain optimistic that with our current deal pipeline, cash balance and untapped credit facility we will be able to complete a number of additional acquisitions in 2004."

NovaMed acquires, develops and operates ambulatory surgery centers in partnership with physicians. NovaMed currently owns a majority interest in 19 centers located in 11 states. NovaMed's executive offices are located in Chicago, Illinois.

5/6 **Michael Lachman of ThinkEquity Partners issued an update report on TLC Vision: TLCV: Expect Strong Q1 Report Based on Solid LASIK Market Fundamentals**

We reiterate our Overweight-2 rating and 12-month price target of \$16 on shares of TLC Vision. The company reports its Q1 results before the market open on Monday, May 10, and we expect a strong Q1 report based on favorable current fundamentals in the laser vision correction (LASIK) market. We also believe that Q2 has gotten off to a solid start, with strong LASIK procedure volumes in April and a positive bookings outlook for May. We remind investors that although the core LASIK market is providing a favorable backdrop at present, our investment thesis on TLC Vision is based on our belief that the company's emerging Rheopheresis technology for dry AMD is an undervalued embedded option within the stock. On the Q1 call, we expect management to provide an update on the "structural alternatives" that is pursuing to unlock the value of this business for shareholders.

Investment Highlights:

- * We reiterate our Overweight-2 rating and 12-month price target of \$16 on shares of TLC Vision. The company reports its Q1 results before the market open on Monday, May 10.

- * Our Q1 EPS estimate of \$0.12 exceeds the consensus estimate by a penny. We expect the company to meet or beat our estimate based on strong current fundamentals in the laser vision correction (LASIK) market.

- * We are forecasting year-over-year procedure growth in Q1 of 6.5% for TLC Vision. This is well below the 20% procedure growth in Q1 reported by VISX (EYE - \$22.13 - Overweight-2 - Price Target \$24-29), although we note that TLC's closing of a number of unprofitable sites during 2003 makes for more difficult procedure comps. Our conversations with TLC Vision management and surgeons at this week's ASCRS conference lead us to believe that the corporate centers are growing procedures in-line with the market, as modeled, but that the Access business is likely performing better than we have forecast. This could provide a source of upside.

* Feedback from the company during the course of Q1 indicated that although January was a very strong month in absolute terms (it is always the seasonally strongest month of the year due to flex-spending account utilization among LASIK patients), both February and March were even stronger than January in terms of year-over-year procedure growth. company management and affiliated surgeons at the ASCRS indicated to us that April was another strong month and that May bookings are encouraging, suggesting a good start to Q2 as well.

* We remind investors that although the core LASIK market is providing a favorable backdrop at present, our investment thesis on TLC Vision is based on our belief that the company's emerging Rheopheresis technology for dry AMD is an undervalued embedded option within the stock. Enrollment in the pivotal MIRA-1 trial is ongoing; we expect enrollment to be completed this fall and anticipate a possible FDA approval by mid-2006. Management has stated that it will "explore structural alternatives to maximize the value of the business for TLC Vision and its shareholders." We are not aware of the specific approach being pursued by the company or the timing of next steps, but we believe that management has been making progress in this area and will provide an update on its Q1 earnings call.

* Valuation: Our 12-month price target of \$16 represents \$8 for the Rheopheresis business (dry AMD) and \$8 for the base service business (LASIK, cataract, and ambulatory surgery centers). Our Rheopheresis price target is based on a 25x forward earnings multiple applied to forecasted 2008 net profits of \$46 million, discounted back to 2005 at a 30% annual rate, and adjusted downward to reflect an 80% probability of FDA approval. Our 12-month price target for the base service equates to 18x our estimated 2005 EPS of \$0.45 and 10x estimated 2005 EBITDA of \$54 million.

5/10 **WaveLight Laser Technologie AG** presented its innovative high-end ALLEGRETTO WAVE Concerto excimer laser system for refractive surgery at this year's *ASCRS* congress (*American Society of Cataract and Refractive Surgery*) in San Diego.

"In developing this high-end system, we have finally succeeded in achieving our vision. We have constructed a best-of-breed laser that implements the current state of the art in terms of technology, and in doing so have again set new standards in refractive surgery" said Max Reindl, WaveLight Laser's CEO.

The laser's technology leadership and exclusivity are to be seen above all in its innovative technical components, such as the 500 Hz pulse frequency (and built-in non-contact pachymetry) and the increased security technology, as well as in the design. The system has been designed for an audience that places the highest expectations on it and the range of services that come with it. The congress attendees were keenly interested in the excellent features offered by the new high-end ophthalmology laser, which were demonstrated at the presentation at the WaveLight exhibition stand.

In addition to its new top-of-the-range model, the company also exhibited the other treatment systems belonging to the ALLEGRETTO WAVE product family to participants. The ALLEGRETTO WAVE Eye-Q excimer laser and the ALLEGRO Analyzer and ALLEGRO Topolyzer diagnostic systems, for example, were also presented, along with the ALLEGRETTO WAVE, which has already been approved for the U.S. market.

The first U.S. user meeting for the ALLEGRETTO WAVE also took place at the ASCRS congress. The fast-growing user community in the USA appeared highly satisfied with the proven laser system for refractive surgery. Its safety and excellent ease of use in particular were warmly praised, as were the outstanding results obtained with patients. WaveLight also had the opportunity to make new key contacts with business and sales partners at the ASCRS congress and to strengthen its existing ones.

5/10 Ted Huber of **Wachovia Securities** issued a followup report on the recent ASCRS meeting: **A Review of ASCRS With MarketScope - Custom LASIK Shines**

* ASCRS POST-VIEW CONFERENCE CALL: Last Friday we held a conference call with Dave Harmon of **Market Scope** to review new clinical data and surgeon sentiment from this year's recently concluded ASCRS trade show. This note includes summary comments from the call.

* CUSTOM LASIK: Market Scope's view is that Custom LASIK had a strong showing at ASCRS. Highlights included lower visual aberrations, better night vision and better distance vision measurements for Custom vs. standard LASIK in most clinical trials. Market Scope believes it's too early to view Custom as a standard of care but such a label looks like a matter of time and additional regulatory approvals. Custom Penetration has levelled off in the 40% range among surgeons that are using it already - this penetration should accelerate with these results from ASCRS.

* 2004 LASIK VOLUME GROWTH: Q104 growth was 17% based on Market Scope Surveys. Surgeons at ASCRS said this type of growth was continuing into the 2nd quarter. In prior years, June has been a soft month (this happened in 2001 and 2002). June volumes could be an important indicator for growth for the balance of the year. Market Scope estimate that the range of procedure volume growth in 2004 should be 8% to 17% with a most likely case around 13%.

* WHO WILL TREAT THE HIGH MYOPE: **Alcon** should be the first to get a high myopia LASIK approval. This is expected this quarter and should allow treatment up to -9.5D. **B&L** and **VISX** also have trials for high myopia ongoing and could win even broader labels (2005 approvals). Market Scope views Phakic IOLs (2H04 approval), as an important solution for very high myopes (-10D or more) but that the improving Custom LASIK results in high myopia make LASIK the choice below -10D.

* **PRESBYOPIA - SIGNIFICANT OPPORTUNITY**: Presbyopia is a large un-addressed opportunity. Patients aged from the mid 40s to 60s are pre-cataract but need near vision solutions given lost accommodative ability of the crystalline lens. Market Scope sees several new products (Alcon's Restore Multifocal IOL, **Refractec's** CK and **Eyeonics** Crystalens accommodating IOL) as leading candidates for treating this population. Market Scope believes that changes to Medicare reimbursement practice could come quickly that would significantly expand the market potential for near vision correction into the cataract aged population.

- 5/10 According to *EyeWorld Week*, earnings are up for refractive surgeons. Even in the midst of an economic downturn, ophthalmologists are earning more on refractive surgery than they were just a year ago. **Marketscope** survey findings found ophthalmologists earned an average of \$1,750 per eye by the fourth quarter of 2003, up from an average of \$1,556 per eye earlier that year, said Shareef Mahdavi, ophthalmic consultant. The income jump followed a slide in refractive profits that began after prices peaked at an average of \$2,050 per eye in late 1999. The recovery of refractive prices was credited in large part to the approval of more-expensive custom ablation procedures and **IntraLase** (Irvine, Calif.) treatments.

EyeWorld Week also noted: **WaveLight Laser Technologies AG** (Erlangen, Germany) officials said that they would have the Cadillac of excimer lasers if their Allegretto Wave Concerto is approved in any market worldwide. The laser includes a pulse frequency of 500 Hz, company officials said.

Moria (Antony, France) officials haven't yet officially launched the Epi-K, their new epithelial microkeratome, but physicians that have used it said that they are optimistic about its utility.

Ellex Medical (Adelaide, Australia) is expected to unveil a new surgical treatment for open angle glaucoma (SLT) that does not scar the trabecular meshwork, thus allowing repeated treatments.

- 5/10 Beth Herskovits, writing in the May issue of *OCULAR SURGERY NEWS EUROPE/ASIA-PACIFIC EDITION*, wrote about the new titanium sapphire laser device from **SOLX: DeepLight offers potential for more selective tissue ablation**

Laser trabeculoplasty using a new titanium sapphire device allows deeper penetration of clogged tissue with less scarring than argon laser trabeculoplasty and deeper penetration than other currently available modalities, according to a glaucoma surgeon who conducted a pilot study with this treatment. The 790-nm wavelength of Solx's DeepLight laser provides approximately four times more tissue penetration than selective laser trabeculoplasty (SLT), allowing surgeons to treat not only the trabecular meshwork but also the uveoscleral pathway, according to Gabriel Simon, MD, PhD.

In titanium sapphire laser trabeculoplasty (TiSaLT), surgeons employ an infrared laser to create spots around 180° of the trabecular meshwork at a depth of 200 µm. The laser energy targets and is absorbed by pigment, inciting shock waves through the tissue, ablating the tissue and unclogging blocked passageways. Like SLT, which uses a green laser to target pigmented tissue, the procedure causes minimal thermal damage and can be repeated if necessary, Dr. Simon said.

Pilot study: In the pilot study of TiSaLT, Dr. Simon treated 68 eyes of 57 patients with optic nerve damage due to primary open-angle glaucoma and inadequately controlled IOP. Patients were treated at the Instituto Oftalmico Gabriel Simon in Barcelona and Madrid. Patients were classified into four groups: high-risk (nine eyes being treated with three or more medications), normal-risk (20 eyes on two or fewer medications), prior failed ALT (10 eyes) and re-treated TiSaLT (five eyes, including one with prior failed ALT). All eyes were taken off medication 10 days prior to treatment and continued without medication until medical judgment indicated introduction of medical management was needed.

Dr. Simon collected 12 months of data on 43 eyes and 18 months of data on 38 eyes. Two high-risk eyes and one normal-risk eye exited the study for surgery before the 6-month follow-up.

Procedure: Under topical anesthesia, eyes receive laser energy through a slit-lamp ophthalmoscope and a handheld Goldman three-mirror gonioscope, according to the study. A red He-Ne laser is employed as an aiming beam. Treatment begins with the administration of low energy pulses (25 mJ to 50 mJ) 8 ms in duration. Dr. Simon then increases the energy in 25 mJ increments until a clinically significant effect is achieved (slight movement of the treated structures, depigmented spots of roughly 200 µm, the appearance of "micro-bubbles" in the meshwork, or slight audible feedback).

At 12 months, mean postoperative IOP was 17.5 ± 2.4 mm Hg, compared to 25 ± 3.9 mm Hg preoperatively. In addition, 60.4% of eyes had achieved the ideal "compliance free" outcome, requiring no further medication. Among prior failed ALT eyes, none required more than one medication postoperatively (with a mean of 0.3 medications). All of the eyes that had two treatments within the first 2 weeks achieved the ideal outcome.

Doug Adams, founder and chief executive officer of Solx, noted that there are currently 10 DeepLight systems being used in Europe. The European Union granted DeepLight the CE Mark in November 2003.

5/10 **VisiJet, Inc.** announced it had acquired the exclusive worldwide distribution, sales and marketing rights for the LASIK and Epi-Lasik products from **Gebauer Medizintechnik GmbH** of Neuhausen, Germany. **Starboard Capital Markets LLC**, a registered broker dealer based in Philadelphia, assisted the company in the financing of the acquisition. In addition, **SBI Brightline II, LLC** an affiliate of **SBI USA, LLC**, and **Trilogy Investment** have increased their original financing commitment of \$4.5 million by \$5 million to

provide \$9.5 million in capital for product development and working capital. The funding is subject to certain contingencies, including the effectiveness of a Registration Statement with the Securities and Exchange Commission.

"The acquisition of the distribution rights for the products -- the LasiTome and the Epi-Tome -- complements our ophthalmic surgical products under development and provides immediate revenue opportunities for the company," said Randy Bailey, CEO and president of VisiJet. "Gebauer, a known international innovator, has improved upon existing technologies and developed these ground-breaking microkeratomes with unique cutting and separating methods that should eliminate many postoperative problems. With the Epi-Tome, LasiTome, and HydroKeratome approved and launched, VisiJet will be the only company able to offer the surgeon the option of preparing the cornea for both surface ablation or stromal ablation."

The Epi-Tome is currently CE marked and already being sold in Europe and other countries accepting that designation. The company anticipates filing for FDA approval within the next few weeks. The Epi-Tome and LasiTome join a growing refractive surgery market estimated in excess of \$4 billion annually worldwide.

Dr. Ronald Krueger, MD, Medical Director of Refractive Surgery, Cole Eye Institute, The Cleveland Clinic Foundation, anticipates superior results with the Gebauer Epi-Tome as it maintains the structure of the cornea. "The blade of the Epi-Tome is designed to 'ride' on the Bowman's plane, directing the cutting force upwards, away from the stroma," explained Dr. Krueger. "The resulting flap is smooth, intact and easily repositioned on the eye. Also the blade is steel, not plastic, and its sharper edge produces a clean more precise and accurate separation of tissue." Dr. Krueger believes because the Epi-Tome keeps the stroma intact and the technique does not require alcohol, problems such as postoperative pain, and dry eye will be eliminated or greatly reduced. "The Epi-Tome is an advance in LASIK with important advantages for both patient and surgeon," stated Dr. Krueger. "I believe it will have a prominent place in refractive surgery."

5/10 **TLC Vision Corporation** announced its financial results for the three month period ended March 31, 2004. Q1-04 total net revenues were \$65.2 million, up 22% from \$53.6 million in Q1-03 and up 34% from \$48.5 million in the previous quarter. First quarter total paid laser procedure volumes were over 56,800. Procedure volumes include procedures of a former subsidiary that became an equity investment in 2004. Same-store year-over-year volume growth of 16% in the centers was partially offset by the closing of unprofitable centers and lower, but still positive, 4% year-over-year volume growth in the access business. The result was that Q1-04 procedure volumes were up 6% from the 53,500 reported in the same three month period a year ago and represented an increase of 47% sequentially from the 38,600 refractive procedures performed last quarter. The procedure volume mix in Q1-04 was 58% centers versus 42% access. Custom LASIK procedures represented approximately 49% of owned or managed center volumes in Q1-04.

On a GAAP basis, TLCVision reported a Q1-04 net profit of \$8.1 million (12 cents per share). This represents more than a 7-fold increase from \$1.1 million (2 cents per share) for the same three month period a year ago, and compares to a loss of \$2.9 million (4 cents per share) last quarter. First quarter 2004 adjusted EBITDA was \$13.3 million, up 88% from the \$7.1 million for the same period last year and an increase of 237% from \$3.9 million in Q4-03.

Elias Vamvakas, TLCVision's chairman and CEO, commented "I believe that our operations team did an outstanding job in preparing TLCVision to capitalize so well financially on procedure volume growth in the seasonally strong first quarter. Year-over-year growth trends improved throughout the first quarter and that momentum has so far continued into Q2. Indeed, April 2004 total paid laser procedure volumes were up more than 20% from April 2003 levels. I am very pleased with what we have accomplished thus far and am confident that we will continue to build on TLCVision's world-leading position going forward."

During a teleconference call following release of its financial information, TLCVision's chairman and CEO, said the company believes that a separation and initial public offering of the patented Rheopheresis blood filtration process business (RHEO) may be the way to maximize its potential and result in the highest value for TLCV and the company's shareholders. To help facilitate that, TLCVision and the other major shareholders of **Vascular Sciences Corporation (VSC)** have in principle agreed to a plan to proceed with a re-organization that would combine VSC and **OccuLogix LP** into a new stand-alone device company focused on development of the RHEO procedure and the sales and distribution of RHEOfilters and OctoNova pumps. The primary question facing the company is one of timing and there are a number of factors that can affect that. Vamvakas went on to say that "If I had to guess now, I'd say we would either be looking at sometime this fall or, if not, probably after the clinical data and PMA have been submitted."

Michael Lachman of **ThinkEquity Partners** issued an updated report: **TLCV: Solid Q1, Growth Accelerating in Q2 - Upgrade to Strong Buy**

We are upgrading shares of TLC Vision from Overweight-2 to Strong Buy-1 based on high visibility into accelerating LASIK procedure growth in Q2 following a solid Q1, and our continued belief that Rheopheresis for dry AMD represents an undervalued embedded option within the stock. Q1 earnings met our above-consensus estimate of \$0.12. Although overall year-over-year procedure growth came in at just 6% in Q1, same-store growth in owned/managed Centers was more in-line with the market at 16%. Growth has been accelerating month by month throughout 2004, and is tracking at over 20% so far in Q2. Importantly, this is an overall growth number, and includes both the Access business and the impact of the closure of unprofitable centers. On the Rheopheresis front, enrollment is on track in the MIRA-1 US pivotal trial, and the company is targeting an IPO of this business in the fall of 2004.

Investment Highlights: We are upgrading shares of TLC Vision from Overweight-2 to Strong Buy-1. Our investment thesis for TLC Vision is based primarily on a belief that the company's emerging Rheopheresis technology for dry AMD represents an undervalued embedded option within the stock. At present, the company is also benefiting from improving fundamentals within the core LASIK service business: LASIK procedure growth is accelerating in Q2 following a solid Q1.

Q1 earnings met our above-consensus estimate of \$0.12. Although overall year-over-year procedure growth came in at just 6% in Q1, this metric was held back by two factors: (1) A number of unprofitable Centers, accounting for 2,333 LASIK procedures in Q1-03, were closed over the past year. Overall procedure growth (Centers plus Access) would have been 11% without these Center closures, and same-store growth in owned/managed Centers was 16%, which is more in-line with our view of market-wide growth in Q1. (2) Procedure growth in the Access business of 4% year-over-year reduced the corporate average growth rate, but this was a positive surprise in Q1 given our forecast of declining Access procedures.

LASIK procedure growth at TLC Vision has been accelerating month by month throughout 2004, and is tracking at over 20% so far in Q2. Importantly, this is an overall growth number, not a same-store or Centers-only number; it includes both the Access business and the impact of the closure of unprofitable Centers. We estimate that the Access business is now growing at a rate approaching the market-wide growth rate, and that volume in the Centers is growing at an above-market rate. Our new company-wide procedure growth forecast is 18% for Q2-04 (25% in Centers, 35% same-store in Centers, and 10% in Access), and 11% for the full year (14% in Centers and 7% in Access). As a result of stronger procedure growth trends, we are increasing our Q2-04 EPS estimate from \$0.07 to \$0.09, and our full year estimate from \$0.27 to \$0.29. For 2005, our EPS estimate goes from \$0.45 to \$0.47.

On the Rheopheresis front, enrollment is on track in the MIRA-1 US pivotal trial, and the company is targeting an IPO of this business in the fall of 2004. We still expect enrollment in the MIRA-1 trial to be completed this fall, and six-month follow-up data to be made available in H1-05, with a PMA submission to follow. Progress on the IPO of the Rheopheresis business is discussed more fully below.

So, why was TLCV stock down 12% following the seemingly positive Q1 report? There's no way to know for sure, but here are a few possibilities:

1. Even though Q2 has gotten off to a very strong start, management declined to provide detailed revenue, earnings, or EBITDA guidance for the quarter. This was likely interpreted by some investors as a sign that management lacks confidence in its ability to either execute or fully understand its business. On the contrary, we believe that the company is gaining more control, not less, over its business operations with the cutting of costs, the closure of unprofitable centers, and integration of the TLC and **LaserVision** platforms. We view the lack of guidance as consistent with management's normal mode

of operation, reflecting conservatism, not pessimism. Management did acknowledge a greater comfort level with the upper end of its 5-10% market-wide LASIK procedure growth outlook for 2004, versus its previous bias toward the lower end of this range. Following the call, management also acknowledged that the \$0.07 consensus EPS estimate for Q2-04, which it would have previously considered aggressive, should be realistic or conservative if procedure growth remains strong through the rest of May and June.

2. Even though EPS beat consensus by a penny, revenues fell short of our estimate (and consensus) by \$1.5 million. There is a valid explanation, but some investors are skeptical. During the quarter, management chose to settle a long-standing dispute involving its California-based Centers by selling a portion of its ownership stake back to its joint venture partner in that state. TLC Vision received cash in this transaction, and its share of the JV was reduced from about 51% to about 30%. As a result of this change, revenues from these Centers are no longer consolidated into company revenues, and the JV partner's 49% share of the profits are no longer recorded under minority interest. Instead, TLC Vision will record its roughly 30% of profits from these Centers below the line as "earnings from equity investments," and will still include California-based Center procedures in its reported LASIK procedure volumes (these Centers performed about 4,000 procedures in Q1-04). Without this change, reported revenues would have exceeded estimates (by as much as \$3 million in the quarter, driven primarily by better-than-expected procedure pricing in both Centers and Access). Some investors with whom we have spoken expressed concern that the selling of controlling stakes in Centers by TLC Vision could be repeated in other areas, to the detriment of the company. However, we believe that this JV structure was unique within the TLC network and do not expect additional similar transactions.

3. Even though the company is making progress toward an IPO of the Rheopheresis business and is targeting a fall 2004 timeframe, some investors were likely expecting more rapid progress in this area. In our view, this timing is consistent with the many steps that must be completed in this complex transaction. TLC Vision has had to obtain the agreement of other shareholders in OccuLogix LP and Vascular Sciences Corporation (VSC), including privately held German company **Diamed**. OccuLogix and VSC will first be merged into a new stand-alone device company focused on development of the RHEO procedure and the sales and distribution of RHEOfilters and OctoNova pumps. While the company is targeting a fall IPO (with an S-1 filing in late June or July and a possible road show in September), management made it clear that it will push the IPO into 2005 if market conditions are not conducive to the fall timing, or if valuation considerations necessitate the publication of pivotal trial data prior to an IPO. We view this approach and timing as pragmatic, and remind investors that management is pursuing this path not because it needs a cash influx by a specific date but as a way to unlock the value of the Rheopheresis business. If the value is not achievable at a particular time, it makes sense to wait for a better window of opportunity.

We believe that TLC Vision's positive near-term outlook bodes well for VISX (EYE - \$21.92 - Overweight-2 - Price Target \$24-29). TLC Vision is VISX's largest single customer, accounting for 29% of total Q1 revenues according to VISX's recent 10-Q filing. While a majority of LASIK procedures at TLC and LaserVision Centers have historically been performed on VISX lasers, we believe that VISX's share within TLC Vision has grown in recent quarters given the company's CustomVue approval to treat astigmatic patients during a prolonged period in which Alcon's (ACL - \$72.62 - Overweight-2 - Price Target \$80) LADARVision system has lacked a similar indication.

Q1-04 Financial Review and Changes to Model: TLC Vision reported Q1 EPS of \$0.12, in-line with our estimate and a penny above consensus, and revenue of \$65.2 million, below our projection of \$66.7 million. The impact of procedures from minority-owned California-based Centers, previously consolidated in Center revenues (-\$4.7 million) was offset by higher-than-expected ASPs in both the Center and Access businesses (+\$4.8 million). The balance of the variation between our estimate and reported revenue can be attributed to slightly lower Center procedure mix of 58% versus our estimate of 60% (-\$1 million), custom LASIK conversion rate 2% below our forecast in the Center business (-\$190k), and overall procedure growth 30 bp below our estimate (-\$170k). By segment, the Center business delivered revenue of \$38.8 million, \$3 million below our projection of \$41.8 million, largely as a result of reclassification of revenue from California-based Centers. Access revenues of \$12 million surpassed our forecast of \$9.8 million, with faster-than-expected custom LASIK conversion and upside to our ASP assumptions. Other revenues came in at \$14.3 million, below our estimate of \$15.1 million.

We are increasing our procedure growth forecast for 2004 based on improving visibility heading into Q2-04. Our Q2-04 revenue estimate increases from \$59.1 million to \$61.4 million, and our 2004 revenue estimate increases slightly, from \$236.8 million to \$237.3 million. We have increased our company-wide procedure growth rate projections for the remainder of 2004, going from 6.5% to 18% in Q2-04, from 6.1% to 10% in Q3, and from 7% to 9% in Q4. This results in a full year overall procedure growth rate of 10.6% versus our prior estimate of 6.4%. However, we now forecast 57% Center/Access mix for the year, versus 60% previously, as the Access business is proving to be more robust than previously forecast. Based on higher-than-expected Q1-04 net procedure pricing of \$1,188 (after doctor costs) in the Center business, our Q2-04 average pricing estimate goes from \$1,120 to \$1,180, and our full year estimate goes from \$1,140 to \$1,180. In the Access business, we have increased forecasted net ASPs from \$430 to \$510 for Q2-04, and from \$460 to \$510 for the full year, based on Q1 net ASP of \$500 per procedure.

We are increasing our 2004 EPS projection to \$0.29 from \$0.27, driven by our new Q2-04 estimate of \$0.09, up \$0.02 from our previous estimate. Due to decreased depreciation & amortization, our EBITDA estimate for 2004 is reduced to \$41.3 million from \$45 million. For Q2-04, we are increasing our EBITDA estimate to \$11.9 million from our prior estimate of \$11.5 million. We made some adjustments in our operating expense estimates, holding our G&A estimates steady, while decreasing marketing

expenditures slightly to a run rate of \$3 million per quarter (down from about \$3.8 million). Below the operating line, we are now modeling for the profit contribution of the California Centers (TLC has roughly 30% ownership) under "earnings from equity investments." We have also updated our minority interest estimates to reflect correlation with the level of procedure volume in any given quarter, arriving at our new 2004 estimate of \$5.5 million versus \$4 million previously.

Valuation and Price Target: Our 12-month price target of \$16 represents \$8 for the Rheopheresis business (dry AMD) and \$8 for the base service business (LASIK, cataract, and ambulatory surgery centers).

Our Rheopheresis price target of \$8 is based on a 25x forward earnings multiple applied to forecasted 2008 net profits of \$46 million, discounted back to 2005 at a 30% annual rate, and adjusted downward to reflect an 80% probability of FDA approval.

Our 12-month price target of \$8 for the base service equates to 17x our new estimated 2005 EPS of \$0.47, below the 18x peer group average on 2004 EPS and below the 22x multiple for the company's closest comparable company, LCA-Vision (LCAV). Our price target also equates to 9.8x estimated 2005 EBITDA of \$52 million, above the group average 2004 EBITDA multiple of 7.6x but below the 11.7x multiple for LCA-Vision.

Adding these two price targets together results in a full price target of \$16. This represents 50% appreciation from current levels, consistent with our Strong Buy-1 rating.

5/10 Ted Huber of **Wachovia Securities** issued an update report on **American Medical Optics: AVO: Investor Meetings Highlight Improving Market Position**

* A POST-SPIN REPORT CARD: In Wachovia sponsored investor meetings last week, AVO reviewed its post-spin progress. The **Pharmacia** acquisition caps a two-year performance that includes: (1) balance sheet restructuring of restrictive covenants, (2) rebuilt eye care franchise (new US sales force and Complete Moisture Plus), (3) innovative new technologies (Sovereign Compact phaco platform and Opti-Edge IOLs). Results include 2 gained share points in the Americas solutions market, and according to management, Q403 and Q104 yr/yr phaco placement growth of 47% and 92%.

* NEW PRODUCTS FROM R&D, LICENSING: AVO intends to ramp R&D spending to 8% of sales. With 7 major products expected to launch in 2004, we forecast accelerating 2004 surgical and eye care constant currency revenue growth of 5.5% and 1.6%. Key areas of longer term growth for AVO include the presbyopic market (Array multifocal lens and recently licensed Quest Vision Focus and FlexOptic accommodating IOLs) and artificial tears (post the 6/05 Allergan non-compete expiration).

* HEALON + TECHNIS + AVO DISTRIBUTION = ACCRETION: Management described the Pharmacia acquisition as "highly accretive" since high margin products slot into an existing cataract infrastructure. We expect accelerating top line - Technis IOL has

grown in the teens and management is confident in again growing the Healon visco franchise. While EPS accretion specifics aren't due until the deal closes (early summer), management did not balk at our \$0.21 \$0.47 range for possible 2005 EPS accretion.

- 5/12 The May issue of *Ophthalmic Market Perspectives* noted that refractive procedures for the first quarter had "soared", driven by encouraging signs of improvement in the U.S. economic situation and excitement over wavefront-driven LASIK (WFL), along with increased advertising. All contributed to help boost Q1-2004 procedures significantly over the same period last year. For the first quarter, estimated U.S. refractive procedures were 368,500, up 17.2% when compared to the 314,500 performed in the first quarter of last year. When U.S. patients traveling to Mexico and Canada are included, Q1-2004 procedures were 376,300, up 16.8% over the same period last year.

As noted by Dave Harmon, historically, LASIK demand is highest during the first quarter due to flex-account spending and first of the year resolutions. Harmon also noted that the number of U.S. refractive surgeons and laser centers were up slightly compared to preceding quarters. While many low-volume surgeons stopped offering LASIK during 2001 and 2002, the trend has now reversed due to higher LASIK demand resulting from the improving economic conditions and premium prices for IntraLase and WFL. According to the newsletter, there were 1221 total laser centers in operation during Q1-2004, compared to 1210 in Q4-2003 and 1192 in Q1-2003.

WFL continues to grow, with VISX reporting 34% of procedure cards purchased during Q1-2004 were for CustomVue. WFL was available at almost 80% of all U.S. laser centers, with the percentage of WFL growing to 37.7% during the quarter, up from 32.5% during Q4-2003. (I have compiled a chart of analysts predictions of wavefront conversions for VISX-centers, along with the analysts predictions for U.S. refractive procedure volumes for both this year and next. The two charts accompany this newsletter.)

With the switch over to WFL, average LASIK prices have continued their increase, with the average now at \$1798 for Q1-2004. This resulted both from the premium charged for WFL, along with a premium charged for IntraLase-produced flaps.

Dave Harmon now predicts that the refractive industry is well positioned for healthy growth in 2004, based on a combination of improving U.S. economic conditions, new technologies, and increased advertising. He currently forecasts 330,000 procedures for Q2-2004, up 14.9% compared to the same quarter last year, and full year procedures forecast at 1,300,000, for a growth of 13% over 2003. (Again, see the accompanying chart of analyst forecasts, along with both Harmon's and mine.)

- 5/13 **Miravant Medical Technologies** announced consolidated financial results for the first quarter ended March 31, 2004. The net loss for the quarter was \$5.5 million (20 cents per share) compared to a net loss of \$3.4 million (14 cents per share) for the same period in 2003. The company had cash of \$1.2 million at March 31, 2004. Subsequent to the end

of the quarter, on April 23, 2004, the company completed a \$10,269,000 private placement of 4,564,000 shares of common stock with a group of institutional investors, with full proceeds to the company.

Gary Kledzik, stated, "Miravant completed a landmark event during the first quarter, submitting a New Drug Application (NDA) for marketing approval of our proprietary drug SnET2. We believe this drug has the potential to be a valuable first-line therapy for patients with the wet form of age-related macular degeneration (AMD), a major health problem in the elderly population."

The company submitted the NDA to the FDA on March 31, 2004. Customarily, the FDA makes a determination to accept or refuse to file the NDA within 60 days of submission, and, if accepted, will designate its review status. In April 2004, SnET2 clinical investigators presented safety and efficacy results at the *Association for Research in Vision and Ophthalmology (ARVO)* meeting, Ft. Lauderdale FL. In two independent phase III clinical trials of patients with wet AMD, SnET2 demonstrated a visual acuity benefit and slowed the progression of problematic vascular lesions in the per protocol study population, the basis of the NDA submission.

Also in March, scientific results of the company's cardiovascular program were presented at the *American College of Cardiology (ACC)*, New Orleans LA. The development program focuses on the treatment of life-threatening coronary artery diseases, including atherosclerosis and atherosclerotic vulnerable plaque. In a series of preclinical studies conducted in atherosclerosis models, PhotoPoint PDT has been demonstrated to remove problematic inflammatory cells in atherosclerotic plaque, reduce plaque volume and induce healing and repair of vessel walls.

- 5/13 According to the *American Academy of Ophthalmology*, 47 new co-sponsors have signed on to support H.R. 3473, the "Veterans Eye Treatment Safety (VETS) Act," during the second legislative session. These new co-sponsors bring the total number to 71. More than one-third of House Veterans Affairs Committee members have signed on to become co-sponsors of the bill. The VETS issue was also featured during the opening session of the American Academy of Ophthalmology's annual Mid-Year Forum.

Representative John Sullivan (R-Okla.), who introduced the VETS Act to Congress in November of 2003, spoke about the importance of passing the VETS Act. Rep. Sullivan comes from the only state that allows non-physicians to perform limited laser eye surgery procedures. "I'm going to fight for you and do what's right," Representative Sullivan told the Mid-Year Forum audience. "I think it's pretty simple; If you want to perform surgery, go to medical school."

The Forum also included a presentation from Richard Weidman of *Vietnam Veterans of America*, who expressed his organization's support for the VETS Act. He ended his impassioned presentation by telling the audience of ophthalmologists that the veterans were with them, and that they were doing the "right thing" to fight for the eye safety of

America's veterans. The VETS Act would prevent non-surgeons from performing eye surgery on the nation's veterans in Department of Veterans Affairs (VA) healthcare facilities. It was introduced in response to outcry from the medical community over Oklahoma-licensed optometrists transferring their privileges to perform surgery to VA hospitals in other states, where it is strictly prohibited.

- 5/13 In the first six months of the current financial year (up to 30 September) **Carl Zeiss Meditec AG**, significantly increased its profitability. Consolidated net income of the global provider of systems for the diagnosis and treatment of eye ailments increased by 112% to E6.5m (previous year: E3.0m). Earnings per share almost doubled. The latter amounted to E0.23 (previous year: E0.12). The EBIT margin increased to 11.3% (previous year: 11.0%). At E13.1m, earnings before interest and tax (EBIT) remained almost at last year's level of E13.4m. At E115.9m, group sales were 3.8% down on the previous year's figure (E120.5m) as the result of the strong euro in the reporting period. On the basis of constant exchange rates sales would have risen by 5.1% to E126.6m.

The main reasons for the good results are the improvement of the product mix and the further optimization of manufacturing costs. The gross margin thus increased to 45.8% (previous year: 42.9%) in the first six months. Earnings were not affected by the currency fluctuations as the company also manufactures in the dollar region.

Ulrich Krauss, President and CEO of Carl Zeiss Meditec said: "We have reached our growth targets. Besides the USA, business has also been especially successful in Asia. Despite the currency fluctuations, sales in this region came in at €29.6m or 9.4% higher than in the previous year."

Sound financial structure: The significant improvement in earnings also had a positive impact on the operative cash flow. The latter rose by 29.1% to E8.0m (previous year: E6.2m). Despite the payment of an acquisition, cash and cash equivalents increased by 1.9% to E45.9m, net debt decreased from E24.2m (30 September 2003) by 32.6% to E16.3m, the equity ratio of Carl Zeiss Meditec on 31 March 2004 stood at 61.3% (30 September 2003: 59.0%).

"Considering our acquisition of **hiko medical communication GmbH** a few months ago, this growth shows just how strong the financial power of the company is," said the Carl Zeiss Meditec CFO, Bernd Hirsch. R&D activities increased The ophthalmic technology company continued to invest heavily in research and development in the first half of this year. Expenditure totalled E12.2m, up from E11.2m last year, with the R&D ratio increasing to 10.5% (previous year: 9.3%).

"In the last few months the R&D departments have been especially active as we are about to launch a raft of new products," explained CTO, Dr Walter Wrobel. For example, the ACMaster (for precise measurement of the anterior eye segment, based on the technology of the successful IOLMaster) and the Preview PHP (for early detection of age-related macular degeneration - AMD) are both about to be launched in the next few weeks.

As of 31 March 2004 the Carl Zeiss Meditec Group had 802 employees (previous year: 842) plus 23 trainees (previous year: 25).

Outlook: Further increase in profitability The President and CEO Krauss is confident about the company's performance in the financial year 2003/2004 as a whole: "If the dollar regains strength against the euro, this could see us post a slight increase in sales. We are aiming to continue to raise our profitability, and we are targeting a figure above that of last year."

5/14 **Survivision** issued a financial report for its fiscal fourth quarter.

Operating Highlights: Revenues - The revenues from equipment sales for the quarter ended March 31, 2004 (2004 Quarter) increased by 199% to \$980,000 from \$328,000 for the quarter ended March 31, 2003 (2003 Quarter). The 2004 Quarter increase in revenue is primarily due to increased international sales of the OptiVision Laser.

Salaries & Benefits - Expenses decreased 10% to \$115,339 for the 2004 Quarter as compared to \$128,637 for the 2003 Quarter due to a reduction in the cost of contractual temporary services. The reduction was offset by an increase in commissions due on revenue collections.

Advertising and Selling - Expenses decreased 94% to \$2,833 for the 2004 Quarter as compared to \$46,251 for the 2003 Quarter. It is anticipated that these expenses will increase as the company attends additional tradeshow and revises its trade literature to reflect results from the increased clinical activity as sales begin to recover, thus allowing more funding for these expenses.

Administrative and Other - Expenses decreased 1% to \$116,628 for the 2004 Quarter as compared to \$118,150 for the 2003 Quarter.

Professional Fees - Expenses increased 173% to \$219,828 for the 2004 Quarter as compared to \$80,428 for the 2003 Quarter. The increase is attributed to legal services for regulatory matters, patent legal billings, and international patent filing fees.

Research and development - Expenses remained the same at \$47,001 for the 2004 Quarter as compared to the 2003 Quarter as payroll and consultant expense allocations have remained unchanged over these periods.

Interest Expense - Interest expense increased 266% to \$46,520 for the 2004 Quarter as compared to \$12,711 for the 2003 Quarter due to the interest accruals for the GEM note payable that is in default and for convertible debenture that matured on December 31, 2002 that has not yet been redeemed.

Depreciation and Amortization - Expenses decreased 90% to \$3,477 for the 2004 Quarter as compared to \$35,887 for the 2003 Quarter. The decrease in depreciation resulted

primarily from the December 31, 2003 write-off of the company's laboratory equipment. In addition, \$315,000 of loans costs became fully amortized at December 31, 2003.

Total Operating Expenses - In summary, expenses increased 18% to \$551,626 for the 2004 Quarter as compared to \$469,063 for the 2003. The company has controlled its administrative, marketing, and payroll expenses as significant additional legal expenses were required for regulatory and patent matters.

Net Income (Loss) from Continuing Operations - The net income from continuing operations for the 2004 Quarter was \$234,046 (0.005 cents per share) as compared to a net loss of \$172,074 (0.005 cents per share) for the 2003 Quarter. The favorable turn around over the stated periods is a direct result of the increase in international sales and a decrease in most expense categories that was offset by increased legal fees.

Liquidity and Capital Resources: As of March 31, 2004, we had a bank balance of \$20,027 and a working capital deficit of \$(1,774,780) as compared to a cash balance of \$31,420 and a working capital deficit of \$(2,192,304) at December 31, 2003. Our ability to meet short-term obligations continues to improve, however we remain constrained by a very tight cash position which can be primarily attributed to the lower level of international sales than was expected, especially during the normally slow summer months.

The company's future capital requirements will depend on many factors, the scope and results of pre-clinical studies and pre-clinical trials, the cost and timing of regulatory approvals, research and development activities, establishment of manufacturing capacity, and the establishment of the marketing and sales organizations and other relationships, acquisitions or divestitures, which may either involve cash infusions or require additional cash. There is no guarantee that without additional revenue or financing, the company will be able to meet its future working capital needs. The company has severe liquidity problems which compromises its ability to pay principal and interest on debt and other current operating expenses in a timely manner. The company is seeking additional sources of financing, which may include short-term debt, long-term debt or equity. There is no assurance that the company will be successful in raising additional capital. In November 2002 the company received a commitment letter for a \$10 million line of credit secured by the company's inventory and accounts receivable. The terms require obtaining a bank guarantee at a cost of \$585,000, \$92,500 of processing fees to be paid prior to closing, and an additional \$153,000 to be paid at time of closing the transaction. The line of credit is for a term of ten years and accrues interest at a fixed rate of 4.75% for amounts utilized. The company has been negotiating the final agreement with the lender. However, there is no guarantee that the debt financing will be received or if received will be according to these terms.

The company's ability to meet its working capital needs will be dependent on the ability to sign additional distribution and licensing arrangements, achieve a positive cash flow

from operations, achieve and sustain profitable operations, and obtain additional debt and/or equity capital.

- 5/17 **LCA-Vision Inc.** reaffirmed its optimistic outlook for the current year at its annual meeting of stockholders, held today. The company also reported that stockholders elected all six members of the company's board of directors to one-year terms. "Our exceptional first quarter results have further increased our confidence that our performance will continue to be strong throughout the balance of the year," said Stephen Joffe, chairman and CEO of LCA-Vision. "We continue to benefit from, and further leverage, a number of key initiatives we executed during the past year that improved our top line revenues, while controlling costs in all parts of the company. The strength of our business model was evident in our first quarter results, which included annual revenue growth of approximately 58%, revenue growth in LasikPlus vision centers open at least 12 months of approximately 48%, and a 43% company-wide increase in procedure volume. With independent industry researchers estimating first quarter industry growth to be in the single digit range, our business clearly continues to hit on all cylinders.

"We are on track to meet or exceed our previously stated target of opening six to eight vision centers in 2004, and have already opened three vision centers so far this year, with a number of others in the pipeline," Joffe added.

At the annual meeting, management reiterated its 2004 full-year guidance for earnings per diluted share to be \$1.55 to \$1.65, which includes \$0.43 per diluted share for the partial reversal of the deferred tax valuation allowance recorded in the first quarter of 2004. Also at today's annual meeting, stockholders elected the following to the LCA-Vision board of directors:

-- William Coleman, formerly a senior executive with **The Procter & Gamble company** and currently a board member of **Touchtone Family of Funds** and **Millennium Bancorp**

-- John Gutfreund, senior managing director and executive committee member at the investment banking firm **C.E. Unterberg, Towbin**

-- John Hassan, president of **Champion Printing Company**

-- Craig Joffe, senior vice president and general counsel of LCA-Vision

-- Anthony Woods, chairman of **Deaconess Associations, Inc.**

-- Stephen Joffe, chairman and chief executive officer of LCA-Vision

- 5/19 **WaveLight Laser Technologie AG** announced the formation of a new subsidiary in Spain. The laser specialist has acquired a majority interest in the Spanish company **Tetramedic S.A.**, which will operate under the name of **WaveLight S.A.** and develop the extremely promising Spanish market. The company will be managed by Eckhard Rohr

who, as a founding member of Tetramedic, has many years' experience in the market for medical lasers as well as extensive contacts with physicians and ophthalmology clinics. Tetramedic and WaveLight can look back on a long-term distribution partnership in the field of ophthalmology applications. The formation of the new subsidiary represents a further step in WaveLight's full-service provider strategy, allowing it to boost its market presence in ophthalmology in Europe.

"Our new subsidiary will significantly strengthen our sales base in Spain, and so contribute to the dynamic growth of the WaveLight Group as a whole", noted Max Reindl, CEO of WaveLight Laser.

Founded in Madrid in 1986, Tetramedic sells medical technology applications in the field of ophthalmology. In the late 1980s, the company pioneered the launch of excimer lasers for refractive surgery on the Spanish market successfully establishing itself on the Iberian peninsula's medical laser market and becoming a major market player. However, the company also has a strong market presence outside of Spain, too, and can demonstrate extremely good sales volumes overall.

In the past few years, the Spanish market for medical lasers recorded relatively slow growth due to the difficult economic situation. However, a sharp recovery is expected in the near future, as many older models are due to be replaced by state of-the-art, user-friendly new systems.

5/20 **Regenera Limited** announced that it had successfully exceeded its target IPO raising of \$8 million and was continuing to receive over subscriptions. Regenera will now close the offer early next week. Chairman of Regenera, Tony Fitzgerald said he was delighted with the response to the IPO, particularly given the very difficult market conditions that have prevailed in the past four weeks. "We have a quality offering that has received strong endorsement from leading institutions, key ophthalmologists and high net worth investors familiar with the healthcare investor."

CEO Dr. William Ardrey said the response to Regenera's offer was indicative of the revenue-ready status of Visagen - the company's key treatment for back of the eye diseases. "The use of our proprietary drug Triamcinolone Acetonide (TA) is the key property of Visagen and is already approved for use in the treatment of inflammatory eye diseases, and is currently being used as a co-therapy. We are already in licensing discussions with a number of global players and have attracted investment interest from some of the world's leading opthamologists."

Regenera is an Australian health care company developing and delivering treatment for inflammatory diseases of the back of the eye, most often associated with Age-Related Macular Degeneration, and Diabetes-related diseases.

In Australia, an estimated 800,000 people suffer from Macular Degeneration, with 14% of sufferers exhibiting the late stages of the disease, which results in severe visual loss in one or both eyes.

Fitzgerald, said: "Regenera is offering Australians the chance to invest in a solid technology that will be managed by an experienced management team and international advisory board.

Visagen, is designed to address Age-related Macular Degeneration and Diabetes-related eye diseases and involves a proprietary formulation of the drug Triamcinolone Acetonide (TA). TA is an established and proven synthetic corticosteroid for the treatment of Age-related Macular Degeneration. Recent clinical studies have demonstrated the effectiveness of TA in treating these diseases either as a stand alone therapy or in conjunction with other treatments.

There is a large market for Visagen with the number of people with Age-Related Macular Degeneration and Diabetes-related diseases expected to double within the next three decades increasing the demand for effective treatments and co-treatments with other leading treatments.

Regenera is expected to list on the Australian stock exchange in early June.

5/25 Joanne Wuensch of **Harris Nesbitt** initiated coverage of **Advanced Medical Optics: AVO--Initiating Coverage with OUTPERFORM Rating and \$42 Price Target**

* **Event:** We are initiating coverage of Advanced Medical Optics with an OUTPERFORM rating.

* **Impact:** We believe Advanced Medical Optics has positioned itself for several years of growth, riding on the benefits of the spin-out from Allergan, a new focused R&D franchise and its successive product pipeline, and the integration and leverage of the Pfizer ophthalmology franchise.

* **Forecasts:** Our estimates include EPS growth of 48.1% in 2004 to \$1.18, 22.4% in 2005 to \$1.44, and 20.5% in 2006 to \$1.74. Our estimates include accretion from the Pfizer acquisition of about \$0.05-\$0.10 in 2004, \$0.10-\$0.15 in 2005, and \$0.15-\$0.20 in 2006.

* **Valuation:** Trading at 23.0x our 2005 EPS estimate of \$1.44, or at 1.0x its P/E to growth rate, AVO is trading above the P/E multiple of its ophthalmology peers (21.4x), yet it is below the group's P/E to growth ratio of 1.3x and below the small-cap medical technology peer group's multiple of 29.6x. Applying a 29x multiple to our 2005 EPS estimate of \$1.44 brings us to our 12-month price target of \$42.

*** Recommendation:** While the company and its stock have been successful since its spin, we believe that there is more to come, particularly given the acquisition of Pfizer's ophthalmology product line. We believe that in the current stock market turbulence, companies that have solid revenue and earnings with potential upside to estimates will outperform. We therefore are initiating coverage of AVO with an OUTPERFORM rating within a POSITIVE sector.

5/26 **www.Investorideas.com** announced that **Lasik America, Inc.** had retained its services to profile and feature the company on its global investor portal, **InvestorIdeas.com**. The medical technology company operates a medical facility in Albuquerque, New Mexico, providing laser vision correction surgery procedures and has now implemented a "growth through acquisition" strategy in the medical technology field. LSIK recently acquired **Salus Holdings**, a New York-based company that operates a kidney dialysis business near Rome, Italy, which will commence operations next month. The acquisition broadens LSIK's business model and offers a foothold in the European marketplace.

The acquisition of Salus also brings with it a new chairman and CEO, Ernest Remo, whose previous experience as chairman of one of the largest refractive providers in North America, with revenues of over \$60 million and the originators of the popular priced lasik model will enhance management's ability to roll out an expansion model.

In addition to expanding the lasik model, the company feels that the dynamic growth offered by the entry into the dialysis field through its acquisition and expansion strategy, first in Europe, and then in North America will make Lasik America a dynamic provider of medical services. The demand for dialysis service is expanding worldwide by almost 10% per year and the company and industry experts feel that this trend will continue.

The company's laser eye surgery center currently has the capacity to perform 100 procedures per week using excimer lasers to treat such common refractive vision disorders as myopia, hyperopia and astigmatism.

Lasik's founder and president, Dr. Howard Silverman has been actively involved in a private consulting business designed to address the capital and corporate structural needs of companies in the ophthalmic and vision correction industries. LSIK management also has extensive experience in financial management and investment banking. It is rare that a company of this size has expertise in both areas. Management believes that the company's core New Mexico facility provides an excellent foundation for future expansion. Fiscal year 2003 revenues for Lasik were in excess of \$1.4 million.

Industry consultant **MarketScope** estimates that approximately 50 million Americans (100 million procedures) are candidates for laser vision correction. The *American Academy of Ophthalmology* estimates that more than 63 million people in the U.S. are candidates for some type of refractive surgery.

- 5/26 **Norwood Abbey Limited** subsidiary **Norwood EyeCare**, the innovative ophthalmic devices company, has appointed a distributor for its Centurion SES System and EpiEdge (disposable separator) in Korea. Norwood EyeCare's exclusive distributor, **Damool Systec Corp. Ltd.**, is one of Korea's leading refractive surgery products suppliers in the country. Damool Systec is also the exclusive representative for complementary refractive surgical products companies in Korea such as Zeiss.

Korea is one of the top three priority markets for Norwood EyeCare and accounts for approximately 10% of the 3 million laser vision corrective procedures carried out each year worldwide. The other priority markets are the USA and key European countries. Damool Systec has placed an initial order for two Centurion SES Systems for immediate delivery for the purposes of evaluation and a further 20 systems for delivery during the second half of CY 2004.

Richard Walmsley, CEO of the Norwood Devices group, stated, "We are extremely pleased to have Damool Systec as our Korean distribution partner. The securing of such a high quality company in Korea is an integral component of our strategy to launch the Epi-LASIK product into key markets quickly."

Current vision correction surgery, called LASIK, uses a 'microkeratome' to create a stromal 'flap' on the surface of the eye, which is then peeled back. Industry statistics indicate that complications occur in up to 12% of patients as a result of cutting the eye. The next generation approach, Epi-LASIK treatment, uses the Centurion SES system and EpiEdge disposable separator, removing the need to cut the eye and hence eliminating associated complications. This unique instrument gently separates a thin layer, the epithelium along a natural cleavage plane. The clinician then moves the epithelial sheet to one side, the laser corrects the vision and the epithelial sheet is then moved back into place with minimal surgical manipulation.

OPHTHALMIC LASER UPDATE -- June 2004

- 6/1 **Miravant Medical Technologies** announced that the FDA had accepted for filing the company's New Drug Application (NDA) for SnET2 and has also granted a Priority Review designation. Acceptance of the filing means that the FDA has made a determination that the NDA meets the standard for substantive review, and the Priority Review designation expedites the review period. Miravant is seeking approval from the FDA for its proprietary new drug SnET2 as a treatment for patients with wet age-related macular degeneration (AMD), a leading cause of blindness in older adults.
- 6/1 **IntraLase Corp.** announced that it had filed a registration statement in connection with the initial public offering of its common stock. All of the shares are being offered by IntraLase. The shares will be quoted on the Nasdaq National Stock Market under the symbol "ILSE".

Banc of America Securities LLC, Wachovia Securities, First Albany Capital Inc. and ThinkEquity Partners LLC are the managing underwriters of the offering. The offering of common stock will be made only by means of a prospectus. When available, a copy of the preliminary prospectus relating to the offering may be obtained from Banc of America Securities LLC, 9 West 57th Street, New York, New York 10019, Wachovia Securities, 301 South College Street, 4th Floor, Charlotte, NC 28288-0735, First Albany Capital, Inc., One Penn Plaza, 42nd Floor, New York, New York 10119 or ThinkEquity Partners LLC, 28 West 44th Street, Suite 1200, New York, New York 10036.

6/2 **Advanced Medical Optics, Inc. and OPHTEC USA, Inc.**, a privately held medical device manufacturer and subsidiary of **OPHTEC B.V.** (Netherlands), announced an agreement to expand their strategic relationship to include the design and U.S. regulatory approval process for the Veriflex foldable phakic intraocular lens (IOL). Under terms of the agreement, AMO and OPHTEC USA will join forces to complete design work for the Veriflex, a foldable version of the Artisan/Verisyse phakic IOL, which is pending FDA approval. OPHTEC is currently engaged in clinical trials in Europe on a foldable silicone phakic IOL. AMO and OPHTEC will continue to improve on the foldable lens design and develop a compatible insertion system. AMO and OPHTEC will also share responsibility for submission of the FDA Pre-Market Approval (PMA) application and implementation of human clinical trials in the United States.

Similar to its distribution rights to the Verisyse lens, AMO will be the exclusive source for the Veriflex lens in the U.S. and Japan, and also plans to market the lens in Europe and other parts of the world.

"This agreement builds on the strong success of the Verisyse lens and demonstrates AMO's commitment to playing a leading role in the development of the entire refractive IOL marketplace," said James Mazzo, AMO president and CEO. "Through this agreement, we can combine our broad expertise in silicone optics, multifocal surfaces and IOL insertion systems with OPHTEC's extensive experience with phakic lens technologies. We believe this collaboration will result in new phakic IOL innovations that will expand our growing portfolio of refractive surgical products."

OPHTEC's phakic IOL technology was conceived by international award-winning ophthalmologist Professor Jan Worst, MD of Groningen, the Netherlands, and was first introduced in 1978 for the correction of aphakia following cataract surgery. The design was later modified and has been used in the phakic eye for the last 13 years. Marketed by OPHTEC under the Artisan brand name, this phakic IOL design has been implanted in more than 100,000 eyes worldwide.

"OPHTEC has long been considered a leader in phakic IOL technology and the expansion of our agreement with AMO will enhance our ability to continue to refine our innovations and make them available to surgeons and patients around the world," said Rick McCarley, president and CEO of OPHTEC USA.

6/2 **QLT Inc.** announced that it had entered into a Cooperative Research and Development Agreement (CRADA) with the National Eye Institute (NEI) to study the effects of preservative-free triamcinolone acetonide (PFTA) as an adjunct to Visudyne therapy in patients with wet age-related macular degeneration (AMD). The study will enroll approximately 300 patients in a multi-center, randomized, prospective Phase III clinical trial that will investigate the long-term safety and potential efficacy of PFTA in all wet AMD patients undergoing Visudyne therapy.

"This is a very exciting development for QLT and is a great fit with our efforts in identifying new opportunities for expanding Visudyne," said Paul Hastings, president and CEO of QLT Inc. "We hope the results of combination therapy will lead to improved vision for the many people with AMD."

Under the terms of the CRADA, QLT will provide funding for the combination clinical trial and assume responsibility for manufacturing of PFTA and in return will gain the option to an exclusive license for certain rights to PFTA in combination with Visudyne therapy. The NEI will be responsible for the clinical trial with scientific input from a joint committee representing both QLT and the NEI.

6/3 **Advanced Medical Optics, Inc.** announced that it expected to complete a series of transactions that will have the effect of increasing its stockholders' equity by approximately \$76 million. Under the terms of the privately negotiated transactions reached with a limited number of investors, the company has exchanged or has commitments to exchange on or prior to June 4, 2004, approximately \$83 million aggregate principal amount of its outstanding 3 1/2 percent convertible senior subordinated notes due 2023 for approximately 4.4 million shares of its common stock and approximately \$4.6 million in cash.

The company decided to exchange a portion of the convertible notes as a result of the increase in its share price since the announcement of its agreement to acquire the **Pfizer** ophthalmic surgical business and the company's need to increase equity in order to access the capital markets, if desired, to finance the acquisition. Because the notes are not currently convertible into equity, GAAP requires that AMO record an estimated \$76 million non-cash charge in the second quarter of 2004 equal to the fair market value of the common stock on the date of the exchange, less the \$20.54 conversion price for the notes, plus the premium paid to exchanging note holders.

In addition, the company announced that its Japan subsidiary had repaid a 2.5 billion yen-denominated (\$22.4 million equivalent) term loan facility, which was collateralized by the subsidiary's accounts receivable and inventory.

"These transactions represent initial steps in the overall financing relating to our acquisition of the Pfizer assets and help to position AMO for future growth," said Richard Meier, executive vice president of operations and finance and CFO. "Moreover, these transactions do not impact our previously stated 2004 pro forma diluted earnings per

share guidance, excluding the anticipated accretion of the Pfizer acquisition and non-cash charges associated with the financing."

AMO announced in April its agreement to acquire the Pfizer ophthalmic surgical business for \$450 million. The business, which generated approximately \$150 million in revenues in 2003, includes the Healon family of viscoelastics, the Tecnis and CeeOn lines of intraocular lenses and the Baerveldt glaucoma shunt, as well as related manufacturing and R&D facilities. AMO expects to complete the acquisition in early summer. The company expects to provide accretion guidance related to the Pfizer acquisition upon its completion.

6/4 **Advanced Medical Optics** held a meeting with analysts on June 3rd. Here are some of their reports of that meeting:

Joanne Wuensch of **Harris Nesbitt: AVO--Analyst Day; Technology Development and Pfizer Acquisition to Pave Growth Path**

* **Event:** Yesterday, AMO hosted an analyst day in NYC that was well attended and upbeat as much discussion centered on technology leadership, product development, positive demographics, and the potential for the Pfizer ophthalmic products acquisition to be additive to growth.

Impact: Positive. As we recently launched coverage on AMO, much of the information was a review (please refer to our May 25 report for an in-depth company discussion), yet it reaffirmed our optimism for the company's product line and ability to leverage the pending Pfizer acquisition. Meeting highlights included: 1) the announcement of AMO's extension of its Ophtec agreement to develop a next generation foldable phakic IOL; 2) recapitalization of its balance sheet, converting \$83 million of 3.5% convertible debt for 4.4 million shares and \$4.6 million in cash; and 3) potential Pfizer cost scenarios that could add \$0.30-\$0.40 of accretion in 2005 (our model includes a conservative \$0.10-\$0.15 of accretion).

* **Forecasts:** No change to our estimates. Our model has already factored in debt conversion and, until the Pfizer acquisition closes and management provides more specific transaction details, no change to our Pfizer accretion assumptions.

* **Valuation:** Our target price remains \$42 based on 29x our 2005 EPS estimate of \$1.44.

* **Recommendation:** AMO's execution since its spin from Allergan, has left us impressed with the company's ability to wring out cost savings and deliver market leading products, a pattern we anticipate will continue with the acquired Pfizer assets. We reiterate our OUTPERFORM rating.

Ted Huber of **Wachovia Securities: AVO: Analyst Day Highlights 2006 Earnings Power of \$2.00**

*** A WINNING PLAY IN OPHTHALMOLOGY:** Yesterday's investor meeting highlighted AVO's opportunities for multi-year revenue and margin acceleration. We are increasing our valuation range given improved visibility into AVO's growth potential and Pharmacia acquisition accretion. Though AVO shares carry near-term risk given their sharp recent acceleration and murky guidance picture, the long-term potential and modest fundamental valuation (1.6x proforma 2004 revenue) supports our Outperform rating.

*** A FRESH LOOK AT PCS DEAL ACCRETION:** With AVO's equity currency now more valuable, we calculate a 50/50 debt/stock financing could be \$0.33-\$0.59 accretive. Based on discussions with management yesterday, a \$0.35 addition to our current \$1.22 2005 model seems reasonable (management's scenario with upside potential). Should AVO choose to rely more on equity, the deal remains highly accretive (100% stock purchase yields \$0.27-0.51 EPS accretion) details will follow.

*** FOCUS ON THE PIPELINE:** The Verisyse phakic IOL was highlighted as a potential organic revenue growth driver. While management made the case for the Verisyse as mid and high myope product, we continue to view phakic IOLs as a niche opportunity (\$60-120MM) for high myopes (>-10D). The diffractive Tecnis IOL technology (acquired with PCS) has garnered 3-4% US market share with little Pfizer sales support and offers significant growth potential given AVO's stronger marketing.

Michael Lachman of **ThinkEquity Partners**: **AVO: No New Guidance, but Connecting the Dots to Higher Deal Accretion**

We maintain our Overweight-3 rating on shares of Advanced Medical Optics (AMO), and raise our 12-month price target from \$31-34 to \$40, following an upbeat analyst meeting. Although the company did not issue specific guidance on earnings accretion from the pending Pfizer deal, management did provide some guidelines that have led us to increase our accretion assumptions. For 2005, we now forecast 2005 accretion of \$0.27-0.32, versus our prior estimate of \$0.10-0.15. We have wrestled with the issue of valuation in recent weeks -- the stock has appreciated roughly 40% since the acquisition was announced six weeks ago. We have decided to stick with our Overweight-3 rating and raise our price target based on higher visibility on deal accretion, solid business fundamentals, expected positive news flow, potential top line synergies, a continued earnings boost from acquisition synergies in 2006, and management's track record of conservative guidance and outperformance.

Investment Highlights: At yesterday's AMO analyst meeting in New York, the focus was on the pending \$450 million acquisition of Pfizer's ophthalmic surgery business, as well as the company's technology and new product pipeline. Although AMO management did not provide specific guidance on 2005 earnings accretion from the acquisition, the company did provide some guidelines that have led us to increase our accretion assumptions.

* Incremental company revenues from the acquisition in 2005 (assuming zero growth and no top line synergies) will be approximately \$145 million. This assumes acquired revenues of \$150-155 million, less \$7-8 million of cannibalized viscoelastic sales.

* Management characterized acquired gross margins as comparable to current AMO company-wide gross margins, suggesting about 62%. We view this estimate as conservative, given that management has separately suggested acquired gross margins in the high 60%'s. With regard to SG&A, management stated that the acquired product lines could be supported with spending at roughly half the company's current percentage of sales, implying 22% (we are now assuming 22-24%). R&D spending at 8% of sales was suggested, above AMO's current 6.3% spending rate but in-line with the company's longer-term target. Taken together, these assumptions result in a 2005 operating margin of 30-32%. Applied to revenues of \$145 million, incremental operating profit would be \$43.5-46.4 million.

* We are modeling the cost of financing the \$450 million acquisition two different ways -- using all debt and using all equity -- and then averaging the calculated accretion results. Management suggested a 5% cost of capital, and we are using this rate to arrive at an incremental interest expense of \$22.5 million. In our all-equity calculation, we use a share price of \$35 to arrive at an incremental 12.9 million shares (on top of 40.5 million shares currently modeled for 2005). We also assume a tax rate of 35.5% for 2005, consistent with our current model, which is conservative relative to the 33% tax rate suggested by the company.

* Our all-debt scenario results in 2005 earnings accretion of \$0.33-0.38. Our all-equity scenario results in 2005 earnings accretion of \$0.22-0.25. Taking the average of these two scenarios suggests 2005 EPS accretion of \$0.27-0.32.

This updated 2005 EPS accretion range of \$0.27-0.32 exceeds our prior estimate of \$0.10-0.15 by \$0.17. We would characterize the sources of this \$0.17 increase as follows:

* Higher operating margins: We had previously assumed acquired company operating margins of 20-25%, and had further assumed that AMO could eliminate about 10% of total expenses (including COGS) by the end of the third year, implying ultimate operating margins of 28-33%. With half of the savings to be realized by 2005, our assumptions implied 2005 operating margins of 24-29% for the acquired business. Our updated 2005 operating margin assumption of 30-32%, which reflects an increase of roughly 400bp, accounts for about \$0.07 of the \$0.17 increase.

* Lower financing cost: Our earlier accretion estimate had assumed a 6% cost of debt instead of 5%, resulting in a \$0.07 difference in our all-debt scenario. We had also assumed a stock price of \$25, versus today's \$35 stock price, resulting in a \$0.13 difference in our all-equity scenario. Using the average of these two scenarios, the lower cost of financing accounts for about \$0.10 of the \$0.17 increase.

Other Highlights from the Analyst Meeting:

* Prior to the start of the meeting, AMO announced that it expects to complete a series of transactions in the coming weeks that will move approximately \$80 million from debt to equity on the balance sheet, in order to better position the company to finance the pending Pfizer deal. This will be accomplished by exchanging approximately \$83 million of the company's outstanding 3.5% convertible senior subordinated notes for approximately 4.4 million shares of common stock and about \$4.6 million in cash. GAAP requires the company to record an estimated \$76 million non-cash charge in Q2-04. Because our pro forma income statement model already assumed conversion of the notes beginning in H2-04, these transactions will have no impact on either our model or our EPS estimates. Later yesterday afternoon, Standard & Poor's Ratings Services affirmed its credit ratings on AMO's debt and removed the ratings from CreditWatch, characterizing the outlook as "stable."

* The primary focus of the analyst meeting was AMO's technology and new product pipeline. We believe that the company's pipeline features a good mix of incremental product improvements and line extensions (updates to phaco system features and software, IOL designs and materials, and lens care solutions), as well as completely new products representing longer-term opportunities (such as phakic and accommodating/multifocal IOLs).

* In our view, the products in the Pfizer ophthalmic surgery portfolio with the greatest upside potential are the Tecnis diffractive IOLs (both monofocal and multifocal). The monofocal version recently became the first IOL with FDA approved labeling for improved functional vision, including a safety benefit for elderly drivers at night. This should make for an interesting marketing battle, given the controversy surrounding potential night vision deficiencies associated with the AcrySof Natural blue-blocking IOL from Alcon (ACL - \$79.13 - Overweight-2 - Price Target \$80). A multifocal version of the Tecnis lens has received a CE Mark in Europe and is being launched in a controlled manner at present. This lens is being positioned as a refractive IOL instead of a cataract product, and as such will compete directly with the accommodating CrystaLens from eyeonics, inc. (private) and the multifocal AcrySof ReStor from Alcon. In the US, an IDE has been approved but a pivotal trial has not yet begun; this is likely a 2007-08 product in the US.

* The US FDA approval and launch of the Verisyse anterior chamber phakic IOL is slated for the fall of 2004, possibly in time for the American Academy of Ophthalmology (AAO) meeting in October. We still view this as a niche product for very high myopes (-10D and beyond) and have modest sales expectations, but recognize that this product is a source of revenue upside if our outlook proves to be too conservative.

* AMO is also acquiring along with the Pfizer assets a development project in the field of accommodating IOLs, based on the concept of a pliable biomaterial that is injected

into the capsular bag. This project will complement the company's internal development efforts, as well as a development partnership with QuestVision.

* AMO is clearly interested in entering the artificial tears market following the mid- 2005 expiration of the non-compete agreement with Allergan. As AMO is unable to even engage in development activities prior to this date, the company will have to acquire an existing business to obtain immediate access to this market, or will have to begin to develop its own products, a two-plus year process leading to US approval and launch.

* Randall Olson, MD, Chair of Ophthalmology at the University of Utah School of Medicine and a consultant to AMO, described the benefits of the company's White Star phaco technology. By delivering very short pulses of high levels of ultrasonic cavitation energy, significantly less heat may be generated during lens removal. This is especially beneficial during small incision bimanual micro-phaco. It seems clear from management's comments that the company plans to aggressively defend its intellectual property (against Alcon and possibly others) if and when patents are granted on this technology.

* On the manufacturing front, AMO in all likelihood will retain the viscoelastic manufacturing plant in Uppsala, Sweden, as this represents a new core competency for the company. Pfizer's IOL manufacturing plant in Groningen, Netherlands, will likely be retained for at least two years as well. AMO will probably look to sell the PMMA finishing plant in Bangalore, India.

6/4 The Japanese health authority has confirmed that patients can now claim back the costs for photodynamic therapy using the VISULAS 690s laser made by **Carl Zeiss Meditec AG**. Confirmation of the approval is crucial in ensuring that patients who suffer from age-related macular degeneration can be given photodynamic therapy (PDT) on a mass scale. The move means that doctors can now recoup the investment costs of purchasing a laser system.

Ulrich Krauss, president and CEO of Carl Zeiss Meditec AG, said, "For us, the announcement that the health ministry is willing to accept the costs is proof that our VISULAS 690s is a pioneering device which meets the market's needs. Systems produced by Carl Zeiss Meditec AG represent a secure investment for doctors while offering patients effective assistance for a widespread eye disorder."

Age-related macular degeneration (AMD) is the main cause of blindness in people over 50 in the industrialized countries. Doctors estimate that roughly 500,000 people contract AMD each year. The illness cannot be cured, but photodynamic therapy can help prevent blindness and halt its progress. The Carl Zeiss Meditec VISULAS 690s laser system was the only device to be granted approval for photodynamic therapy by the Japanese authorities in December 2003. The announcement that the costs will now be covered means that the quality of life can also now be significantly improved for large numbers of Japanese patients.

AMD is accompanied by the formation of abnormal blood vessels (choroidal neovascularisation) which grow into the central part of the retina, the macula. This destroys the central vision. Treatment (PDT) is possible using the VISULA 690s in combination with medication. In contrast to conventional laser treatment, the sensitive receptor layer of the retina is not damaged. During the treatment, the patient is first given an injection of light-sensitive dye (Visudyne from **Novartis**) which is deposited selectively only in the neovascularisation itself. The dye is activated in the subsequent laser treatment; it reacts with the oxygen in the tissues and destroys the diseased cells, thereby closing off abnormal vessels. The result of such treatment is the arrest of further loss of visual acuity.

6/7 *EyeWorld Week* reported that **ThinOptX** announced it had received approval from the FDA to begin U.S. clinical trials of its ultra-thin IOL, the 'Ultra Choice 1.0', cataract lens for cataract surgery. Upon receiving FDA approval of an investigational device exemption (IDE) to conduct clinical trials for the lens on a condensed schedule, ThinOptX announced plans to commence a multi-site clinical study involving 400 patients throughout the United States. Because of the FDA-granted IDE approval of an accelerated study, the company may be able to compress the time-to-market of the lens that will represent its entry into the U.S. cataract surgery marketplace. The lens involved in the clinical study is an ultra-thin lens and is capable of being implanted through microincisions of less than 1.5 mm. The Ultra Choice 1.0 cataract lens is already available internationally in Europe, South America, Asia, and the Middle East.

6/7 **STAAR Surgical company** announced that it had entered into a definitive agreement to sell 2.0 million shares of newly issued common stock at a purchase price of \$6.25 per share to certain institutional investors. The transaction is expected to close on June 10, 2004, subject to customary closing conditions. **Pacific Growth Equities, LLC** acted as the placement agent for the financing.

Following the announcement, John Calcagnini of **CIBC World Markets** issued an update report: **STAA: Updating Model To Reflect Dilution From Sales of 2M Shares**

We are updating our earnings forecast for STAA to reflect the sale of 2 million shares at \$6.25 announced this morning that will raise \$11-\$12 million after fees. We had been modeling a 1.5 million share deal already, so this adds another 500,000 shares.

We also included another 500,000 shares for options to employees, to be conservative, bringing our share count for 2005 to 21 million. This has caused us to reduce our earnings estimate for 2005 to \$0.08 from \$0.09 per share. We have no change to our sales and expense estimates.

STAA expects the FDA to Audit its Nidau, Switzerland ICL production facility on June 14, 2004, while Monrovia's audit is expected in mid-to-late July, 2004. STAA hopes to get ICL approval by the AAO meeting in New Orleans in October.

The latest financing is necessary to fund operations and the ICL launch as we estimate that STAA would have been down to \$2-\$4M in cash by the end of June without it. We believe the U.S. cataract business is weak this quarter due to the need for a new injector/cartridge in the U.S.

- 6/8 **VisiJet Inc.** announced that a 510(k) filing had been made with the FDA for approval of the Epi-Tome, a next-generation, ophthalmic surgical tool designed for cutting and separating corneal tissue. The company recently acquired worldwide distribution rights for the product from **Gebauer Medizintechnik GmbH** of Neuhausen, Germany. The Epi-Tome, which is already CE marked -- the European Union equivalent to FDA approval -- and being sold in Europe and Korea, joins a growing refractive surgery market estimated in excess of \$4 billion annually worldwide.

"While we are currently generating revenue with the Epi-Tome in Europe and the Far East, this filing is a significant step in our plan to generate significant sales in the United States," said Randy Bailey, president and CEO of VisiJet. "We also continue to finalize development of our stable of innovative ophthalmic applications utilizing our proprietary waterjet technology. Obviously, medical devices are much easier to gain approval for than pharmaceutical products, and since there is a 'predicate' product on the U.S. market already, we expect to be able to expedite FDA approval of the Epi-Tome within a short period of time, possibly as quickly as 90 days."

The Epi-LASIK procedure using the Epi-Tome solves many of the procedural problems associated with refractive corneal surgery using a lamellar flap (LASIK) as it better maintains the original structure of the cornea and eliminates the need for epithelial tissue removal through the use of alcohol, thereby possibly reducing problems such as postoperative pain, corneal ectasia and dry eye.

- 6/8 **Lasik America** announced the signing of a letter of intent (LOI) to acquire an initial 30% interest in five Italian Dialysis Centers. The Dialysis Centers operate private dialysis clinics in Italy and are fully licensed to provide treatments to patients. All treatments are reimbursed by the Italian National Health Service according to local tariffs. The dialysis centers have been operating for a number of years and have an established reputation for clinical quality. The agreement is part of Lasik's strategy to pursue acquisitions in the renal care field and complements the recently announced 100% acquisition of a newly constructed facility in Italy.

Lasik management feels this new agreement will compliment the company with experienced, established management and staff to help augment the aggressive growth strategy. Ernest Remo, CEO of Lasik commented, "We are moving forward with our growth through acquisition strategy in the medical technology field to build shareholder value."

- 6/9 Michael E. Lachman of **ThinkEquity Partners** resumed his coverage of **QLT, Inc.:** **QLTI: Underappreciated AMD Growth Story - Overweight**

We are resuming coverage of QLT, Inc. with an Overweight-3 rating and a 12-month price target of \$29. Growth in the AMD market will be driven by aging demographics, increasing awareness among patients and physicians leading to higher rates of diagnosis, and new treatment options. This should provide a positive backdrop for market leader QLT and its lead product, Visudyne. Revenue growth will be driven by new indications (occult and minimally classic lesions) and new geographies (Europe and Japan), supported by recent positive reimbursement decisions. We believe that the competitive threat from emerging new drugs is overstated; Visudyne will be used in combination with these and other agents, and usage could expand into indications where it is not effective alone. Our new 12-month price target of \$29 is based on a 26x P/E multiple applied to estimated 2005 EPS of \$1.10.

- 6/10 The June issue of *Ophthalmic Market Perspectives* from **Market Scope** focused on six innovative technologies that foreshadow medical advances in ophthalmology. The six are: the femtosecond microkeratome; wavefront diagnostics; CK for the treatment of presbyopia; accommodating IOLs for presbyopia; new low-energy phaco machines; and new AMD pharmaceuticals. "All of the technologies are in early market stages, or in the final stages of regulatory approvals. While long-term success may be uncertain, each is expected to lay the groundwork for dramatic expansion in ophthalmology during the next decade."

For more information about the six technologies, I suggest you obtain a copy of the June issue of the newsletter by contacting **Market Scope** at 314-835-0600 or via email at info@market-scope.com.

- 6/14 **QLT Inc.** and **Atrix Laboratories Inc.** announced that, after unanimous approval by the boards of directors of both companies, they had signed a definitive agreement, for QLT to acquire 100% of Atrix's common stock for approximately \$855 million in stock and cash, taking a significant step toward becoming a fully-integrated, biopharmaceutical company. In the transaction Atrix shareholders will receive one common share of QLT and \$14.61 in cash for each share of Atrix common stock. The transaction offer value is approximately \$855 million and the transaction value net of Atrix's cash is \$751 million. Atrix shareholders will own approximately 23% of the combined entity and QLT shareholders will own approximately 77%.

"This transaction will accelerate both companies' strategic initiatives and creates a world class biopharmaceutical company with multiple partnered commercial and near commercial products, a strong and diverse revenue base, a robust pipeline and the financial resources to grow faster and create sustainable shareholder value beyond what either company might have achieved independently," said Paul Hastings, president and CEO of QLT Inc. "Atrix is a recently profitable and rapidly growing specialty pharmaceutical company with a rich pipeline of excellent products and unique drug delivery platforms. The company has received FDA approvals for three New Drug Applications within the last two years, formed a growing topical dermatology products business, expanded and enhanced cGMP manufacturing capabilities and established

strategic alliances with such pharmaceutical companies as **Pfizer, Novartis, Sanofi-Synthelabo, Fujisawa and Aventis.**"

"We believe this merger brings together two complementary companies creating a growing revenue base of proprietary products, potential marketing opportunities, economies of scale, distribution synergies, complementary product portfolios and expanded manufacturing capabilities that ultimately should enhance shareholder value," said David Bethune, chairman and CEO of Atrix Laboratories. "With its fast growing product, Visudyne, QLT is a profitable biotechnology company with the financial and human resources necessary to accelerate the development of Atrix's pipeline. Together, we can maximize the combined company's core technologies to develop novel products and ultimately achieve our goal of becoming a fully-integrated leading biopharmaceutical company."

QLT has established a strong franchise in ocular disease and a growing focus in other therapeutic areas including dermatology, oncology and urology -- a strong complementary fit with Atrix's therapeutic focus. With this transaction, both QLT and Atrix take a significant step toward fulfilling their strategic objectives. The combined entity will:

- Diversify its revenue base and product portfolio with two lead marketed products, Visudyne for age-related macular degeneration (AMD) and Eligard for prostate cancer;
- Potentially have two additional products on the market by 2005, an improved 6-month, sustained release formulation of Eligard and Atrisone, a topical acne product;
- Deliver multiple clinical milestones near term from combined pipeline
- Further strengthen its revenue base with the expanding dermatology business;
- Strengthen the commitment to internal product/pipeline development and R&D initiatives with 300 dedicated R&D employees;
- Leverage Atrix's novel Atrigel sustained release technology to develop next-generation protein and peptide therapeutics for systemic and ocular delivery;
- Have the ability to develop a commercial organization over time to market its products; and
- Continue to license its unique patented technologies to pharmaceutical and biotechnology companies;

Transaction Terms:

The transaction is structured as a tax-free reorganization, and as such Atrix shareholders will generally recognize gain (but not loss) only to the extent of cash received in the transaction. The transaction is subject to approval by the shareholders of both companies, as well as customary regulatory approvals and satisfaction of other customary closing conditions and is expected to be completed in the second half of 2004.

Profile of the Combined company:

In addition to a strong balance sheet with approximately \$300M in cash, the combined company expects annual revenue growth of 15% to 20%. The company is targeting a 2006 Gross R&D spend of approximately \$75 to \$85 million and Net R&D (net of partner funding) of approximately \$60 to \$70 million. On a cash EPS basis, in other words, excluding the amortization of acquired intangibles, the transaction is expected to be accretive in 2006 and thereafter, based on the company's R&D plan. The company is targeting a long-term cash EPS compound annual growth rate of 20% to 25%.

QLT's Board of Directors will be expanded from 8 to 10 members. Atrix's Board of Directors will designate the additional two members, one of whom will be Atrix's current CEO, David Bethune, who will be appointed as non-executive Vice Chairman of the Board of Directors of QLT for a period of at least 3 months following consummation of the transaction.

QLT will welcome and maintain Atrix's operations in Fort Collins, CO housing the cGMP manufacturing facility, the dermatology business, and certain development programs currently underway by the Atrix team. Michael Duncan, presently Vice-President and General Manager of Atrix, will become Vice President and General Manager of QLT's Fort Collins facility.

Key Product Highlights:

The new QLT product portfolio will include two successfully marketed and partnered products, as well as growing revenues from the dermatology business in collaboration with **Sandoz**. Visudyne (QLT) is the only drug approved for the treatment of wet AMD and has been used in more than 250,000 patients worldwide. Visudyne is commercially available in more than 72 countries for the treatment of predominantly classic subfoveal CNV and in over 40 countries for occult subfoveal CNV caused by AMD. Visudyne is reimbursed in the U.S. by the Center for Medicare and Medicaid Services for certain patients with the occult and minimally classic forms of wet AMD. It is also approved in more than 55 countries, including the EU, U.S. and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In some countries Visudyne is also approved for presumed ocular histoplasmosis or other macular diseases. Visudyne is developed and commercialized through an alliance with **Novartis Ophthalmics**. Visudyne sales in 2004 are expected to reach \$430 to \$455 million.

Eligard (Atrix) is an extended release injectable depot for the treatment of prostate cancer. One, three and four month formulations were approved and launched in 2002/2003. Approval for the unique 6-month dosage formulation is anticipated in early 2005. This product could have a significant lead over competitive products such as **Takeda-Abbott's** Lupron (worldwide sales \$1.56 billion). Eligard is marketed in the U.S. and Canada through a partnership with Sanofi-Synthelabo. Additional partnerships with other leading pharmaceutical companies maximize the potential for Eligard in the rest of the world. Partnerships throughout the rest of the world include: Yamanouchi/Medigene

- Europe, Mayne Pharmaceuticals - Australia and New Zealand and Technofarma - South America/Mexico.

The Dermatology Portfolio is made up of both proprietary and generic products. The lead proprietary product is Atrisone. Atrisone has recently completed a Phase III trial and has a targeted NDA submission date in Q3 2004. Several other proprietary products are currently in development. The Generic business which is part of a 50/50 joint venture with Sandoz, a division of Novartis, leverages Atrix's expertise in manufacturing and formulation and provides near-term and long-term revenue growth potential. Atrix received 6 ANDA approvals from the FDA, has launched 5 generic dermatology products, and has an additional 4 ANDA's currently under review with multiple product candidates in the development pipeline.

6/15 Michael Lachman of **ThinkEquity Partners** issued an update report following the above announcement of **QLT, Inc.'s** acquisition of **Atrix Laboratories: QLT: Stock Oversold After Chilly Reception to Atrix Acquisition**

While we acknowledge the imperfect strategic fit between QLT and Atrix Laboratories, we believe that the stock is oversold at current levels. With this deal, QLT diversifies its revenue base by adding several currently marketed products, and bolsters its pipeline without straying too far from its own current areas of focus. We believe that the stock has sold off due to (1) valid concerns over the lack of real synergies between these two businesses, (2) near-term dilution (which we view as manageable), and (3) perceived signaling by QLT management that the Visudyne growth engine is running out of steam. We remain bullish with respect to near-term performance of the Visudyne franchise, and view this as the most important near-term catalyst for the stock. Our new price target of \$25 is based on a specialty pharma multiple of 25x applied to approximate 2005 cash EPS of \$1.00, which reflects dilution.

Investment Highlights: While we are not yet convinced of the real strategic fit between QLT and Atrix Laboratories, we remain cautiously optimistic and believe that the stock is oversold following a decidedly negative initial reaction to the deal. Yesterday, QLT announced a definitive agreement to acquire Atrix Laboratories for \$855 million in cash and stock (deal is currently valued at \$772 million following the decline in QLT's share price yesterday). Under the terms of the deal, each share of ATRX stock is transferable for a share of QLT stock plus \$14.61 in cash. Atrix shareholders will own approximately 23% of the combined entity and QLT shareholders will own approximately 77%. Net of Atrix's cash balance, the transaction value is approximately \$751 million, and the remaining cash balance for the combined company is approximately \$300 million. The deal is expected to close in H2-04.

QLT management has its work cut out in making its case for this deal to investors, and we do not expect the initial negative perceptions to turn around quickly. We believe that the stock has sold off due to three primary factors:

1. Concerns (which we view as valid) regarding the lack of real synergies between these two businesses. At this point, the primary arguments supporting the fit between these two companies are conceptual in nature: (1) the combination of a profitable and growing current product story (Visudyne/QLT) with a pipeline/platform story (Atrix); and (2) overlapping areas of clinical focus (ophthalmology, dermatology, oncology, and urology). There are no easy-to-quantify synergies, such as the funneling of two companies' products into a single sales channel or the immediate application of Atrix's drug delivery technology to current QLT compounds. While it is true that there is consistency among the four areas of clinical focus noted above, the fact remains that QLT is an ophthalmology company today, and that the Atrix ophthalmology pipeline is very early stage (pre-clinical). Atrix's currently marketed products are in the fields of urology, oncology, and dermatology; all of these are areas of interest for QLT, but all are at early stages of development.

2. Concerns over near-term dilution, which we view as manageable. There are always concerns that acquisitions that are initially dilutive can become more dilutive, over a longer period of time, than initially projected. Such concerns are heightened when they are coupled with questions of strategic fit. We view near-term dilution as manageable. Our first cut at the combined pro forma income statement for the QLT/ATRAX combination supports management's rough guidance of about 10% dilution in 2005 and modest accretion in 2006, without heroic expense reductions. (See detailed analysis below.) Unfortunately, we do have to rely on consensus estimates for Atrix Laboratories, absent our own independent forecast. A related concern among some investors is the lack of GAAP EPS guidance -- management has given no indication of either the total value of intangibles to be amortized or the time period over which they will be expensed. We are not overly concerned about this, as we already utilize cash EPS in modeling and valuing some of our companies under coverage.

3. Perception among some investors that this deal was driven by a concern on the part of QLT management that the Visudyne growth engine is running out of steam. While QLT management clearly acknowledges concerns over long-term growth as a single-product company and the need to bolster the R&D pipeline, we do not view the timing of the Atrix acquisition as a near-term warning signal regarding Visudyne sales growth. On the contrary, we remain bullish with respect to near-term performance of the Visudyne franchise, driven by newly reimbursed indications in all three major geographies (US, Europe, and Japan). We are also comfortable with the medium-term growth prospects for Visudyne in the 2005-2006 timeframe, based on expected use in combination with newly approved drugs such as Macugen (Eyetechnic Pharmaceuticals and Pfizer) and Retaane (Alcon - ACL - \$77.20 - Overweight-2 - Price Target \$80), and believe that the competitive threat posed by these new products is overstated. We believe that there is a positive bias to near-term estimates for Visudyne sales based on rapid uptake within the new indications, and view this as the most important near-term catalyst for the stock.

Having focused initially on the negative perceptions among investors, we turn our attention to the positive aspects of this deal.

1. With this acquisition, QLT diversifies its revenue base by adding several currently marketed products, and bolsters its pipeline without straying too far from current areas of focus. Atrix's lead product, Eligard for prostate cancer (partnered with Sanofi-Synthelabo in North America and with Yamanouchi in Europe), which has a current end-user sales run rate of \$60 million, has an opportunity to gain share in a current \$1.5 billion worldwide market dominated by Takeda/Abbott's Lupron. Potential near-term new product approvals include a six-month formulation of Eligard in Q1-05 (with a possible 6-9 month lead to market) and Atrisone, a topical acne medication which should be filed in Q3-04 with possible approval in 2005.

2. QLT will maintain a solid cash position post-acquisition (about \$300 million, with positive free cash flow). Although QLT will still have the financial capability to make additional small acquisitions, we view additional deals (other than opportunistic in-licensing) as unlikely until Atrix has been fully integrated.

3. Although QLT management has neither justified this acquisition nor based its accretion assumptions on aggressive cost reductions, there is always some level of cost synergy in a merger such as this. Prioritization (and elimination) of pipeline projects is expected, and has already been implied within 2006 R&D spending guidance. Additional savings from general and administrative expenses and manufacturing costs are not included in our initial pro forma model or in management guidance, and provide sources of accretion upside.

4. Atrix's Atrigel sustained release drug delivery technology has the potential to deliver small and large molecules into the eye using fewer injections than are required for current drugs under development, such as Macugen. QLT plans to partner with multiple companies that have proprietary molecules in development, and early research has shown little or no inflammatory response of the Atrigel material within the eye. As noted previously, this work is at a very early pre-clinical stage of development.

Additional Thoughts and Observations:

1. We believe that almost any major acquisition by QLT would have generated similar concerns regarding strategic fit. Because Visudyne is marketed through a partnership with Novartis, the opportunity to leverage an existing sales channel with any acquired product portfolio is extremely limited. Because QLT is currently a one product company, and because that product is in the field of ophthalmology, any acquired product portfolio outside of ophthalmology would be seen as "off the beaten path."

2. QLT management justifies the Atrix acquisition largely on the basis of product diversification, but we tend to place relatively little value on diversification for its own sake. Investors can achieve diversification within their portfolios without individual company managements doing it for them; as such, we believe that diversification must be accompanied by real operating synergies. In addition, integration risk and

management distraction resulting from a diversifying acquisition can negate the positive impacts of a deal.

3. We are not anticipating renegotiations of current marketing partnerships for Visudyne, Eligard, and dermatological products. Nor are we expecting the building of an internal company sales force over the near-term. Both companies have successfully marketed their products through partnerships with larger organizations, and potential self-marketed products are years away.

4. The QLT stock chart over the past month would suggest that word of a deal might have leaked out in advance of yesterday's announcement. However, if this had been the case, the Atrix chart would seem to indicate that it was not part of any such rumor.

6/15 **Advanced Medical Optics, Inc.** announced that it intended to offer, subject to market conditions and other factors, \$275 million aggregate principal amount of convertible senior subordinated notes due 2024 (\$330 million aggregate principal amount of notes if the initial purchasers exercise their option in full). The notes will be unsecured senior subordinated obligations of AMO. The offering will be made only to qualified institutional buyers.

The company also announced a preliminary 2005 guidance range reflecting the combined operations of AMO and its pending acquisition of the ophthalmic surgical business of **Pfizer Inc.** The company expects the combined 2005 revenue from its existing business and the acquired Pfizer ophthalmic surgical business to be between \$800 million and \$830 million. AMO expects combined pro forma diluted earnings per share for 2005 to be between \$1.50 and \$1.70. These estimates assume the successful completion of the acquisition in 2004, and the implementation of a successful global integration process, the transition of customers and maintaining market shares of the combined product lines.

"We are giving an estimated range of 2005 guidance in order to provide better visibility into the future operations of the combined businesses post-acquisition," said Richard Meier, executive vice president of operations and finance and CFO. "We intend to provide updated guidance for the second half of 2004 and for 2006 when we report second-quarter 2004 financial results in late July."

The company previously announced that it expected 2004 revenue and pro forma diluted earnings per share, excluding the benefits of the transaction, to be between \$635 million and \$645 million and \$1.02 and \$1.04, respectively. The company will report second-quarter 2004 financial results, review guidance and host a conference call with investors and analysts on Wednesday, July 28. The conference call will be available via a live Webcast on July 28, 2004.

Following the guidance and convertible debt announcements, several analysts provided updated reports.

Joanne Wuensch of **Harris Nesbitt** issued two update reports: **AVO Provides 2005 Guidance; Increasing Estimates**

* **Event:** This morning, Advanced Medical Optics announced 2005 guidance, which included the Pfizer ophthalmic surgical business (acquisition announced April 21 and expected to close summer 2004). Management guided for 2005 revenues in the range of \$800-\$830 million and diluted earnings per share in the range of \$1.50-\$1.70.

* **Impact:** Positive.

* **Forecasts:** We are increasing our EPS estimates for 2005 to \$1.58 (up 33.6%) from \$1.44 and for 2006 to \$1.87 (up 18.5%) from \$1.74. No change to our \$859 million (up 16.1%) and \$907 million (up 5.6%) revenue estimates, respectively. Our new 2005 EPS estimates are predicated on the assumption that the company funds its acquisition two-thirds by debt and one-third by equity - given the current stock price, the more funded by equity the higher the accretion would be.

* **Valuation:** Currently trading at 23.7x our 2005 EPS estimate of \$1.58, AVO is trading above its ophthalmology peer's 22.6x average, yet well below its PE/Growth rate. Believing that there is considerable upside to EPS estimates, we believe a higher multiple is warranted.

* **Recommendation:** We reiterate our OUTPERFORM rating on AVO and are increasing our price target to \$46 from \$42 based on 29x our new 2005 EPS estimate of \$1.58.

And the second report: **AVO--Convertible Debt Transaction Announced**

* **Event:** AMO has announced a private offering of convertible senior subordinated notes, offering \$275 million in aggregate notes due 2024 (\$330 million if exercised in full) with 2.5% to 3% coupon, at a 44%-45% conversion price. As part of its debt consolidation and clean-up strategy, the company will also be amending its existing credit facility (Term Loan B, also \$275 million). In addition, the company will issue a \$100 million five-year credit facility that will remain unfunded at the transaction closing.

* **Impact:** We anticipate a hit to the stock today as the market absorbs the convertible debt financing; longer term, we believe it positions the company for growth and future acquisitions.

* **Forecasts:** With the acquisition financing clarified and a sharpened pencil, our 2005-2006 EPS estimates are increased to \$1.67 (up 41.4%) from \$1.58 and to \$1.94 (up 16.1%) from \$1.87, respectively.

Ted Huber of **Wachovia Securities:** **AVO: Debt Financing Drives Larger Deal Accretion**

After the close, AVO announced plans for a \$275mm convertible bond and a \$275 million term loan to finance its Pfizer Cataract Surgery (PCS) acquisition. The convert strike (pricing tonight) should be near \$50 with a 2.75% coupon; the term loan costs less than 4%. With this low cost financing, our acquisition model generates deal accretion of \$0.50-0.82, \$0.20-0.30 higher than our prior estimates.

*** NEW GUIDANCE:** AVO issued new guidance yesterday that includes the impact of the PCS deal. Its 2005 revenue target is \$800-830 million and EPS target is \$1.50-1.70. This guidance, implying PCS accretion of \$0.30-0.45, is in line with street expectations, yet given the new low cost financing looks quite conservative to us. Though 2005 reinvestments might hold back some earnings, the EPS should flow through in 2006 and 2007.

*** RAISING ESTIMATES:** We are raising 2005 estimates to \$1.76 and inaugurating a \$2.13 2006 estimate, based on operating margin of 16.6% by 2006 and organic revenue growth doubling to 6%. Higher growth comes from better promotion of the neglected PCS franchise, the Vervise phakic IOL in 2005 and new dry eye solutions products in 2006.

6/15 **WaveLight Laser Technologie AG** reported revenues of E42,288 thousand for the first nine months of fiscal year 2003/2004 to April 30, 2004, a year-on-year increase of 32% (previous year: E32,029 thousand). Earnings before interest and taxes (EBIT) also improved again. At E3,314 thousand, EBIT was up 26% on the same period of the previous year (E2,632 thousand). WaveLight built on its successful first six months of 2003/2004 to increase its revenues in all four divisions in the third quarter. The Ophthalmology Division again made a decisive contribution to the strong overall results. This segment generated revenues of E28,806 thousand, up around 35% as against the prior-year period (E21,373 thousand). This accounted for 68% of consolidated revenues.

Distribution contracts between WaveLight Laser and **Lumenis, Inc.** in this division were radically revised. While the distribution partnership will continue for the markets in China, Taiwan, Hong Kong, and Japan, the partnerships for the European and U.S. markets and for the rest of the world have been reorganized. **WaveLight Laser, Inc.**, the Group's U.S. subsidiary, is now responsible for distribution, customer service and support, and product and patient marketing on the U.S. market, allowing it to develop the U.S. market even more intensively.

The Aesthetics Division also boosted revenues again as of April 30, 2004. In the first nine months of the current fiscal year, revenues climbed to E6,176 thousand, up 13% on the previous year (E5,467 thousand). The Surgery Division generated a clear increase in revenues to E3,144 thousand, a rise of 153% as against the same period of the previous year (E1,244 thousand). The Industrial Lasers Division also closed the first nine months of fiscal year 2003/2004 with positive revenue growth. The Division generated revenues of E4,162 thousand, an increase of almost 6% on the prior-year (E3,945 thousand).

"We can look back on a successful first nine months for fiscal year 2003/2004 during which we strategically consolidated our market presence," said Max Reindl, the CEO of WaveLight Laser. "We will systematically strengthen our international market position, encouraged by these excellent results and supported by our new distribution structure," he added.

- 6/17 **Refocus Group, Inc.** announced that it had completed the enrollment and surgeries of about one-third of the subjects in the FDA Phase II clinical trials of the Scleral Spacing Procedure for the treatment of presbyopia. While the results remain very preliminary, the company believes that the data continues to support its confidence in the clinical procedure. The Phase II trials, which began in Feb. 2004 as previously announced, are the first opportunity for U.S. clinicians to utilize the newly developed automated scleral incision handpiece and system designed to simplify and enhance the placement of the company's scleral implants, thereby providing greater reproducibility of the procedure. The company's scleral incision system, used to perform the Scleral Spacing Procedure, has received high marks to date from clinical investigators during the Phase II trials.

"Refocus Group's new automated scleral incision system has resulted in more accurate and precise placement of the implants," said Gene Zdenek, MD, head of the Zdenek Eye Institute in Reseda, Calif., and a Phase II clinical investigator. "I believe that this will translate into even better outcomes than experienced in Phase I of the study."

"The scleral incision system gives us the ability to place the scleral implants at the perfect incision depth virtually every time," said Barrie Soloway, MD, a Phase II clinical investigator who is Refocus Group's medical director as well as director of vision correction at New York Eye and Ear Infirmary in Manhattan. "The improvements that have been made in the system have resulted in greater consistency and standardization of the procedure."

The Phase II trials are being conducted as a multi-center, randomized study at five U.S. sites, with 100 subjects to receive the scleral implants and another 50 subjects designated as control. After the FDA's later review of a portion of the Phase II preliminary results, the company would expect to receive approval to expand the trial by enrolling a significant number of additional patients at up to five additional clinical sites.

- 6/17 **Advanced Medical Optics, Inc.** announced that it had priced a private offering of \$300 million aggregate principal amount of its 2.50% convertible senior subordinated notes due 2024 (\$350 million aggregate principal amount of notes if the initial purchasers exercise their option in full). The notes will be unsecured senior subordinated obligations of AMO. The notes were offered only to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933. The sale of the notes is expected to close on June 22, 2004, subject to customary closing conditions.

The notes will pay interest semi-annually in arrears at an annual rate of 2.50% and will be convertible under certain circumstances into shares of AMO's common stock at an

initial conversion price of approximately \$50.24 per share (an initial conversion rate of 19.9045 shares per \$1,000 principal amount of notes). The initial conversion price represents an approximately 34% premium to the \$37.49 per share closing price of AMO's common stock on The New York Stock Exchange on June 16, 2004.

AMO intends to use up to approximately \$84 million of the net proceeds of the offering to repurchase up to all of the \$70 million aggregate principal amount of its outstanding 9 1/4 percent senior subordinated notes due 2010 and to make the related consent payments pursuant to a cash tender offer and consent solicitation commenced on June 9, 2004 and the remainder to fund a portion of the purchase price for AMO's pending acquisition of the ophthalmic surgical business of Pfizer Inc. and for general corporate purposes. The actual amount used in the tender offer will depend on the number of tenders received by AMO and may vary from the above amount. The acquisition of Pfizer's ophthalmic surgical business is subject to customary closing conditions. The offering is not conditioned on completion of the tender offer and consent solicitation or the acquisition.

- 6/17 **NIDEK Inc.** announced that it had received FDA approval for commercial distribution in the United States of its advanced 200 Hz Eye Tracker for use with the NIDEK EC-5000 Excimer Laser System. The NIDEK EC-5000 Excimer Laser System is approved for commercial distribution in the U.S. for LASIK and PRK for myopia with or without astigmatism. The advanced infrared eye tracker is also a key element of NIDEK's future developments of the NAVEX (NIDEK Advanced Vision Excimer Laser) customized ablation platform for refractive surgery.

The 200 Hz Eye Tracker, which has been in use internationally for several years, enhances the functionality and utility of the current laser platform, and will continue to offer the refractive surgeon in the United States an exceptional tracking mechanism for use with the currently approved NIDEK EC-5000 Excimer Laser System.

"The powerful and extremely accurate 200 Hz Eye Tracker offers additional capabilities for the NIDEK EC-5000 Excimer Laser Platform in the US market and delivers on our commitment to work towards getting the overall NAVEX Platform approved for use in the United States," stated Ted Shimomura, executive vice president and General Manager, NIDEK, Inc. "The new 200 Hz CCD camera eye tracker system constantly monitors the position of the patient's undilated pupil and is not affected by instruments passing in and out of the surgical field. The tracker works by iris detection and multiple infrared beams. Some of the key features of the new eye tracking system include both active and passive tracking of the eye. The eye tracking system does not require dilation of the pupil, pre-tracking and pre-imaging of the patient's eyes, unlike other eye trackers available in the marketplace. A unique feature of the NIDEK 200 Hz Eye Tracker is that it enables the surgeon to choose where to center the tracker. The new tracker also works well with an open or lifted LASIK flap. With the approved system, surgeons can image the tracked eye and separately the treated eye. Future applications for this eye tracker include cyclotorsion detection and tracking. The eye tracker's accuracy is ideally suited

to NIDEK's unique scanning slit technology and will be integrated into the future investigational studies of the NIDEK NAVEX Platform."

- 6/22 **Miravant Medical Technologies** announced that the FDA had accepted for filing and granted Expedited Review status to the company's Premarket Application (PMA) for the **IRIS Medical** OcuLight 664 Ophthalmic PDT Laser used to activate SnET2, a proposed drug and light treatment for patients with wet age-related macular degeneration (AMD). The ophthalmic PDT laser was co-developed by Miravant and **Iridex Corporation**, a leading manufacturer of semi-conductor based diode lasers, and was tested with SnET2 in two independent phase III clinical trials. If approved, Iridex will be the exclusive provider of the PDT laser. Previously, on June 1, 2004, Miravant announced that its New Drug Application (NDA) for SnET2 was accepted for filing with the Priority Review designation.

The NDA and PMA were simultaneously submitted to the FDA on March 31, 2004, as the PDT treatment is classified by the FDA as a combination drug and device product. The filings are being concurrently reviewed by the respective FDA drug and device divisions. Acceptance for filing means that the FDA has made a determination that the NDA and PMA meet the standards for substantive review, and the Priority and Expedited Review designations accelerate the review period.

- 6/22 **NIDEK Co., Ltd.** held its 9th NIDEK International Refractive Surgery Symposium on June 18th & 19th, 2004 in Barcelona, Spain. Some 400 plus delegates from over 40 countries gathered in Barcelona, to review and share the latest advancements in surgical and diagnostic clinical applications using NIDEK's refractive surgery platform -- NAVEX and the NIDEK OPD-Scan. The NIDEK International Refractive Surgery Symposium is an event that NIDEK has hosted and sponsored over the last 10 years for surgeons and clinicians from around the world. This year's symposium included topics and sessions on Wavefront Analysis and Diagnostics, Presbyopia Treatments, NIDEK's Final Fit Software, NIDEK's proprietary softwares -- OATz (Optimized Aspheric Treatment Zone), CATz (Customized Aspheric Treatment Zone), and OPDCAT (Optimized Path Difference Customized Aspheric Treatment) for the treatments of myopia and hyperopia and special didactic courses and workshops on various advanced refractive surgery topics.

George Waring, MD served as the program chairman of the two-day event. "I know of no other ophthalmic company that supports such a unique educational program for its users and promotes and fosters an environment of sharing and collaboration on a global basis. New to this year's meeting was an emphasis on the last great refractive surgical problem: the treatment of presbyopia, with reports on creating multifocal corneas for distance and near vision using NIDEK's refractive surgery platform. One triumph that was celebrated at this year's meeting was the reduction of induced optical aberrations after excimer laser corneal surgery with NIDEK's new and proprietary software," commented Dr. Waring.

"Like in years passed, NIDEK has sponsored and supported the Journal of Refractive Surgery (JRS) supplement from this symposium. Proceedings will be printed in the October 2004 issue of JRS. This year we are excited that Alaa El-Danasoury, MD, FRCS from Jeddah, Saudi Arabia will be the guest editor for this supplement issue. The event was a great success with distinguished program faculty from some ten countries and participants from around Europe, Asia, the Middle East and Americas," reported Kuntal Joshi, Director of Global Marketing at NIDEK. "NIDEK continues to provide an excellent educational and networking forum for its product users and this year hundreds of surgeons and clinicians from around the world gathered to share their advancements and experiences with one another," added Joshi.

"This year we see that harmonizing a solid diagnostic instrument base with an advanced surgical platform holds much promise to the future advancements and greater clinical applications, along with outstanding clinical outcomes and results," commented Hideo Ozawa, founder and president of NIDEK. "The technological improvements continue year after year and NIDEK continued to advance refractive surgery in a strong and positive way. This year we heard about neural-networking algorithms for the analysis of corneal topography in the NIDEK OPD-Scan and Magellan Mapper. Surgeons and physicians have achieved excellent results using NIDEK's various software platforms. NIDEK looks forward to a strong focus on developing new surgical and diagnostic products, in its quest to advance the field of excimer laser technology and refractive surgery. We look forward to hosting another regional event in April 2005 in Dubai, UAE, as we continue our long-standing commitment to advancing the field of Refractive Surgery."

- 6/23 **Lasik America** announced an amendment to a letter of intent (LOI) which was previously announced on June 8, 2004. The revised letter of intent provides that Lasik America will acquire an initial 30% interest in a group of six Italian Dialysis Centers with revenues in excess of Euro 7 million \$US 8.5 million (the prior letter of intent provided for five Dialysis Centers). The Dialysis Companies operate private dialysis centers in Italy and are fully licensed to provide treatments to patients.
- 6/24 To mark the sale of the 100th ALLEGRETTO WAVE excimer laser in the People's Republic of China, **WaveLight Laser Technologie AG** held a formal celebration in Beijing to pay tribute to the entire Chinese sales team and the physician who bought the 100th ALLEGRETTO WAVE. Qi Ying Zhai, the president of **Lumenis APAC**, WaveLight's Chinese sales partner, was honored for his excellent work in front of 220 attending users and interested physicians. Professor Jialiang Zhao of Peking Union Medical College Hospital, who purchased the 100th ALLEGRETTO WAVE in China, was also honored by WaveLight Laser. Both gentlemen received an official WaveLight Laser certificate at the event.

Dr. Manfred Drax, member of the Executive Committee of WaveLight Laser (COO) and responsible for the Ophthalmology Division stressed the excellent collaboration with Zhai and his committed sales team in his speech. "We are very happy with the success to date

on the Chinese market and hope to continue the productive collaboration with our longstanding sales partner in future, too. The Chinese market represents a huge challenge for WaveLight -- and one we intend to meet successfully," commented Dr. Manfred Drax on site in China. The sale of the 100th ALLEGRETTO WAVE in China is impressive confirmation of WaveLight's undisputed market leadership in the field of ophthalmology lasers for refractive surgery in the world's most populous country.

"The Chinese market for medical lasers, in particular, offers enormous future growth opportunities. Together with our sales partner for the Asia region, Lumenis APAC, we will drive forward our activities on this promising market in the future, too," noted Max Reindl, CEO of WaveLight Laser, on the Ophthalmology Division's prospects on the Asian market for medical lasers. The ALLEGRETTO WAVE excimer laser system for refractive surgery is convincing a steadily growing user community of its global technology lead:

- Excellent treatment results in medical practice,
- an ergonomic design, and
- high reliability are the reasons for the global market success of the ALLEGRETTO product range.

The Asian markets are a particularly promising growth region in the field of medical lasers for ophthalmology applications due to the rapid growth in per capita income and many people's desire for an improved quality of life.

6/24 **Sight Resource Corporation**, a former refractive surgery provider, but now primarily providing primary eye care products and services, along with managed vision care programs, through its various eyecare stores (**Cambridge Eye Associates; Vision World; E.B. Brown Opticians; Vision Plaza; and Kent Optical**), has filed for Chapter 11 bankruptcy.

6/25 Michael Lachman of **ThinkEquity Partners**, issued an update report on **VISX: EYE: Strong Spring Season for LASIK: Raising Numbers and Price Target**

We are raising our estimates and price target for VISX based on very positive results from our latest channel check of LASIK surgeons and centers. The strong procedure growth trends seen in H2-03 and Q1-04 have continued through the spring season, driven by the improved economy and positive word-of-mouth from satisfied custom LASIK patients. We are raising our Q2 year-over-year procedure growth estimate for VISX from 14% to 18%. With patient bookings already appearing favorable into July and August, we are raising our Q3 procedure growth estimate from 9% to 12%. We are raising our Q2-04 EPS estimate from \$0.18 to \$0.19 and our full year 2004 estimate from \$0.79 to \$0.81, both a penny above the current guidance ranges. Our 2005 EPS estimate goes from \$0.99 to \$1.01. Our new 12-month price target of \$31 (versus a prior range of \$24-29) represents 31x our new 2005 EPS estimate.

6/28 **Advanced Medical Optics, Inc.** announced that it had completed its previously announced acquisition of **Pfizer's** ophthalmic surgical business. AMO announced on April 21, 2004 its agreement to acquire Pfizer's ophthalmic surgical business in a \$450 million all-cash transaction. The assets acquired from Pfizer include the Healon line of viscoelastic products used in ocular surgery, CeeOn and Tecnis intraocular lenses (IOLs) used in cataract surgery and the Baerveldt glaucoma shunt. These assets generated annual sales of approximately \$150 million in 2003. AMO also acquired related manufacturing and research and development facilities in Groningen, Netherlands; Uppsala, Sweden; and Bangalore, India.

"The addition of Pfizer's ophthalmic surgical assets, which include the industry's premier viscoelastic product line and patented IOL designs utilizing wavefront technology, is an excellent strategic fit for AMO, and complements our existing technological proficiencies," said James Mazzo, AMO president and CEO. "The transaction also allows us to enter the glaucoma medical device business and gain a greater understanding of the needs of glaucoma specialists and their patients. AMO has long respected the superior quality and technological advancements of the Pfizer ophthalmic surgical business, which served surgeons around the world for many years under the Pharmacia name. We are pleased and proud to welcome the Pharmacia employees and customers into our organization, and are confident that our combined organization will be an important contributor to the global ophthalmic community."

The company previously announced that it expects combined 2005 revenue from its existing business and the acquired Pfizer ophthalmic surgical business to be between \$800 million and \$830 million. Combined pro forma diluted earnings per share for 2005 are expected to be between \$1.50 and \$1.70. The company plans to provide revised guidance for 2004 and 2006, reflecting the impacts of the Pfizer transaction, when it reports second-quarter 2004 financial results on July 28.

To finance the transaction, AMO recently initiated a recapitalization of its balance sheet. The major components of the recapitalization included:

- * Exchange of approximately \$108.6 million aggregate principal amount of its outstanding 3.5 percent convertible senior subordinated notes due 2023 for approximately 5.8 million shares of its common stock and approximately \$4.6 million in cash.
- * Repayment by its Japan subsidiary of a 2.5 billion yen-denominated (\$22.4 million equivalent) term loan facility.
- * Purchase of debt under the tender offer to purchase for cash any and all of its \$70 million outstanding 9.25 percent senior subordinated notes due 2010.
- * Private offering of \$350 million aggregate principal amount of 2.5 percent convertible senior subordinated notes due 2024.
- * Amendment of its senior credit facility to provide for a \$100 million senior revolving credit facility and a \$250 million term loan B, both maturing on June 25, 2009.

"In addition to funding the transaction, this recapitalization was designed to reduce AMO's cost of capital and interest rate risk while increasing our stockholders' equity, and improving operational and financial flexibility for future growth," said Richard Meier, executive vice president, operations and finance and CFO.

OPHTHALMIC LASER UPDATE -- July 2004

6/16 **WaveLight Laser Technologie AG** held this year's European international annual user meeting from June 11 to 13 in Seville, Spain. All ophthalmologists who use the ALLEGRETTO product family in their practices were invited. The meeting offered an opportunity to exchange information and experiences in a relaxed atmosphere. More than 120 participants from over 20 countries attended specialist lectures demonstrating the technological features offered by the ALLEGRETTO WAVE excimer laser systems. In addition, symposiums and workshops offered interested users the chance to familiarize themselves with the WaveLight refractive product range, which uses efficient diagnostics to further optimize laser eye treatment.

The presentation of treatment results from medical practice was another key part of the program. Experienced specialists again confirmed the high reliability and excellent treatment results offered by the ALLEGRETTO WAVE lasers.

This year's user meeting on the Iberian peninsula was the first since the FDA approval of the ALLEGRETTO WAVE in October 2003. The treatment results produced during the FDA's approval process were impressive confirmation of the ALLEGRETTO WAVE's global technology leadership. Since then, WaveLight has systematically strengthened its global market activities. For instance, business activities in the U.S. market for medical lasers have been stepped up by WaveLight's U.S. subsidiary **WaveLight Laser, Inc.** In addition, WaveLight decisively expanded its market presence in Southern Europe with the formation of a new Spanish subsidiary, **WaveLight S.A.**

The annual international ALLEGRETTO WAVE user meeting offers the setting for a dialogue between manufacturer and users on issues relating to practical application. In addition, it promotes the exchange of experiences within the user community and thus offers the opportunity to establish an efficient communication network. This close contact with its customers, allows WaveLight Laser Technologie AG to further optimize its product range for refractive surgery in line with users' suggestions. Equally, attendees at the meeting have an excellent opportunity to receive detailed information about the treatment possibilities offered by the entire refractive product range and new developments.

"This year's meeting was another complete success. We will continue this relatively young but already established tradition of holding user meetings, in coming years, as well," commented Max Reindl, CEO of WaveLight Laser, with satisfaction. "We aim to further intensify dialogue with the international user community in future," added Reindl.

6/28 The FDA approved an expansion of the treatment range for **Alcon's** customized wavefront-guided LASIK procedure, CustomCornea. Performed with the LADARVision System, CustomCornea is now approved for treatment of myopia up to -8.0 diopters (up from -7.0) and astigmatism up to -4.0 diopters (up from -0.5). This approval gives Alcon the broadest wavefront-guided treatment range of any refractive laser system in the U.S. Eye surgeons can now use the LADARVision System to treat more than 90% of all myopic LASIK patients with the customized procedure.

"We are very pleased that our wavefront-guided LASIK procedure is now available for so many patients," said Bill Barton, vice president and general manager of Alcon's surgical division. "Since most vision correction patients suffer from some combination of nearsighted and astigmatism, the vast majority of vision care patients now have the potential to improve their quality of vision with CustomCornea."

Further clinical trials are ongoing to demonstrate the effectiveness of the LADARVision System for wavefront-guided treatment of hyperopia with and without astigmatism, and for the treatment of eyes with other symptoms, such as pre-existing night vision problems and post-LASIK complications.

Following the announcement of the expanded label for CustomCornea, Ted Huber of **Wachovia Securities** issued an update report on **Alcon: ACL: CustomCornea Receives Label Expansion**

*** CUSTOMCORNEA RECEIVES FDA LABEL EXPANSION:** The FDA approved a long-awaited label expansion for ACL's CustomCornea wavefront-guided LASIK procedure. The broader label allows surgeons to perform CustomCornea procedures with ACL's LADARvision laser for myopia up to -8.0 diopters (previously -7.0 diopters) and astigmatism up to -4.0 diopters (previously -0.5 diopters).

*** NOW THE BROADEST "CUSTOM" FDA LABEL:** While ACL was the first to receive FDA approval for its Custom LASIK procedure, it lost market share to Visx (EYE) and Bausch & Lomb (BOL) after the two companies received 2003 approvals that included astigmatism. ACL's new label enables surgeons to treat more than 90% of myopic patients (U.S. myopia population is around 36 million). BOL's laser is labeled to treat up to -7.0 diopters of myopia versus -6.0 diopters for Visx. Both BOL and EYE lasers are approved for up to -3.0 diopters of astigmatism in a Custom Lasik procedure.

*** A RETURN TO GROWTH:** Alcon's refractive business has declined for the past two years, despite a 2004 LASIK market rebound. This label expansion should help Alcon return to single-digit growth and halt recent share losses. Because refractive revenue is just 1.6% of Alcon's total revenue, the label expansion has a greater franchise value for the ophthalmology leader than a bottom-line impact.

6/29 **LaserSight Incorporated** announced that on June 30, 2004, the current holders of common stock would receive one share in the re-organized company for every 51.828

shares held. The corporate re-organization plan was approved by the creditors and shareholders of the company and confirmed by the U.S. Bankruptcy Court, Middle District of Florida, Orlando Division, on May 4, 2004. Under the re-organization plan, all common stock, preferred stock, stock options and warrants are canceled. New common stock was authorized for ten million shares. The new common shares will be issued as follows: 1,116,000 new shares issued to creditors of LaserSight Incorporated, 1,134,000 new shares issued to the creditors of LaserSight Technologies, a wholly owned subsidiary of the company, 360,000 new shares issued to the former preferred shareholders, 6,850,000 new shares issued to New Industries Investment, upon conversion of \$1,000,000 of debtor in possession financing, and 540,000 new shares issued to former common stockholders of the company. Previously there were 27,987,141 common shares issued.

6/30 Jen Ryan, of *DOW JONES NEWSWIRE*S, wrote about **LCA Vision** and the refractive surgery industry.

Employees at LCA Vision Inc. (LCAV) see its laser eye surgery as so effective and convenient that those who are eligible have undergone the procedure. That includes Chief Executive Steve Joffe, who had the surgery done last year. He said the LASIK, or Laser-Assisted In Situ Keratomileusis, procedure lasted less than an hour, caused no pain or discomfort and "the next day I had near-perfect vision."

Enthusiasm for shedding glasses and contact lenses has boosted the number of procedures done from 105,000 in the first year after it was approved in October 1995 to 6.9 million by the end of 2003, said David Harmon, editor of **MarketScope**, a magazine that follows the industry. Joffe sees the number of procedures increasing, noting the market has only reached about 3% of those Americans who had been wearing glasses or contacts. MarketScope expects the market, of which LCA has a 6.5% to 7% share, to grow by 8% to 12% over last year.

Market growth will be a boon to all companies in this industry, but Joffe believes LCA's more affordable, fixed-cost business model - and its opening of more facilities - will give it an edge over the competition. Most analysts favor LCA, but some say the good news is already reflected in the stock price. Shares of LCA have been hovering near their 52-week high of \$31.31, reached April 28. Shares recently traded around \$29.50.

Eyeing The Competition

Maxim Group analyst Andrew Scott is one of the analysts optimistic about the company's potential. "The timing in the market is just right," Scott said, adding that positive word of mouth has made people more confident about having the procedure, while a recovering economy has made it easier to afford. Scott does not own shares of LCA and Maxim Group does not have an investment banking relationship with the company. Scott said, LCA has built a number of facilities in response to the demand, which has pushed the volume of procedures done while eliminating some seasonal volatility. He added that

some of the new places have already generated profits. This year, the company plans to build six to eight more facilities. According to its 10(k) filing in March, LCA has 40 facilities.

While LCA expands, its primary competitor TLC Vision Corp. (TLCV) has closed facilities. It has about 70 facilities in the U.S., according to its March 10(k) filing. **ThinkEquity Partners** analyst Michael Lachman said TLC, which had first-quarter revenue of \$65.2 million compared to LCA's \$31.7 million, closed some unprofitable centers because of overcapacity in the market between 2000 and 2002. At that point, he said, the economy was weak and a number of companies began offering very inexpensive, lower-quality versions of the procedure. Those companies later went out of business, he said, but they created confusion about the quality and value of LASIK. Overall, LCA's growth is outpacing TLC's. In the recent first quarter, LCA's procedure volume rose 43% to 24,270, while the number of TLC procedures increased 6% to 56,800 from the year-ago period. Excluding new facilities or centers that are closed, LCA had same-store growth of 48% for the quarter while TLC's had growth of about 16%.

Differences in the companies' business model also benefit LCA, Maxim's Scott said. LCA employs a lower-cost marketing-based model through which it advertises directly to patients, as opposed to TLC's model, which advertises to physicians and pays them for patient referrals, the company said. As a result, TLC's model is more expensive, which is one reason why it charges patients \$1,900 per basic LASIK procedure compared with LCA's \$1,300 fee, ThinkEquity's Lachman said. Lachman does not own shares of TLC and ThinkEquity does not do investment banking with the company.

LCA also offers patients the option of financing the procedure, which is not an insured benefit, for as little as \$38 a month, an option TLC does not offer. While TLC doesn't offer its patients in-house financing, it will help patients negotiate lower interest rates for those who are eligible to pay with credit, through a relationship with MBNA Corp. (MBNA), the company said. A cost-effective advantage that both LCA and TLC offer are discounts for patients who participate in managed-care programs. LCAV currently has about 85 million lives under its managed-care agreements; TLC's agreements cover about 70 million lives.

Looking Pricey

While analysts say LCA is poised to benefit from its successful business model and from strength in the laser eye-surgery market, some say the positive outlook is already priced into the stock. "Clearly, LCAV is hitting on all cylinders right now, as evidenced by the solid results posted over the past few quarters and the heightened expectations for the remainder of 2004," Raymond James analyst John Ransom said in a research note.

For the first quarter, LCA had earnings of 50 cents a share, excluding items, vastly exceeding average analyst expectations of 29 cents, according to Thomson First Call. As a result, the company raised its 2004 earnings guidance to \$1.12 to \$1.22 a share,

excluding items, from 90 cents to 95 cents a share. However, Wall Street currently expects the company to earn \$1.24 a share for 2004. But Ransom added that despite LCA's strong results and positive outlook, the company's shares - which have been trading at almost 23 times Ransom's 2005 earnings per share estimates of \$1.32 - already reflect this past performance.

Ransom, who has a market perform rating on the stock, added that going into the second half of this year and into 2005, LCA's shares "may be range-bound as they grow into their lofty multiples." Ransom does not own shares of LCA. Raymond James expects to receive compensation for investment banking from the company in upcoming months.

Maxim Group's Scott, who has a strong buy rating on the stock, believes optimism regarding LCA's growth is likely to push its shares higher. However, he added that it would behoove the company to consider a 3-for-2 stock split to make shares more attractive to investors. Chief Financial Officer Alan Buckey declined to say whether the company plans to execute a stock split but said it could be attractive at some point, particularly because there has been strong growth in institutional stock ownership. Scott added that LCA is also sitting on about \$72 million in cash, which "could take the company to the next level" particularly if it invested in a company that made products such as eye drops, Scott said.

However, Chief Executive Joffe said LCA is not interested in expanding into peripheral markets but instead will focus on remaining a "pure play" in the laser correction field.

7/1 **NovaMed, Inc.** announced that it had acquired a majority interest in the **Altamonte Surgery Center** located in Altamonte Springs, Florida. This transaction represents NovaMed's first acquisition of a surgery center that is not primarily focused on ophthalmology. Terms of the transactions were not disclosed.

"This acquisition provides us with the opportunity to enter the very attractive greater Orlando market in partnership with a highly respected local orthopedic surgeon, Dr. George White," said NovaMed chairman, president, and CEO Stephen Winjum. "In the last 12 months over 1,000 orthopedic surgical procedures were performed at this surgery center and we expect this acquisition to be immediately accretive to our earnings. We are excited about the opportunity to attract new physicians to this surgery center and look forward to working with Dr. White to realize the center's full growth potential by expanding beyond orthopedics to other specialties," said Winjum.

"We look forward to our new partnership with NovaMed," said Dr. George White. "I believe that NovaMed's operational expertise and proven ability to execute a successful growth strategy will help us realize the full potential of this surgery center."

7/1 "Doctors, ophthalmic equipment producers and patients are now joining forces to secure the future of ophthalmology," said Dr. Markus Krämer, analyst at **Bankhaus Sal Oppenheim**, at the 2nd Ophthalmology Forum of **Carl Zeiss Meditec AG** in Nuremberg.

The forum focused on the contradictory requirements of innovation and cost-cutting in ophthalmology. Renowned specialists gave an insight into the current innovative techniques. At the same time, methods of reconciling high quality requirements with strict cost controls were discussed.

"Successful innovations will increasingly be judged in terms of efficiency gains in the future," said Dr. Krämer. A further key point examined at the Ophthalmology Forum was raising public awareness of the social significance of ophthalmology. "One of our top priorities must be to make people aware that early detection is the most important factor in treating serious eye disorders," explained Anselm Kampik, Professor of Ophthalmology at Munich University. "Decisions about regular preventive examinations should not be based primarily on costs as these are marginal in comparison to treatment costs and disability payments to the blind. This is why innovative techniques for early detection are of such immense importance."

Prof. Dr. Volker Klauss (LMU) was given a grant to the value of E10,000 by the **Carl Zeiss Foundation** in honor of his work in combating blindness in the Third World. The cheque was presented by the Carl Zeiss director Dr. Michael Kaschke. "This grant is our way of thanking Professor Klauss on behalf of countless people in the Third World for his outstanding commitment," said Dr. Kaschke. "Professor Klauss' practical work and research have played a significant role in combating blindness and therefore in making a major contribution towards improving the quality of life, especially in Africa."

Ulrich Krauss, President and CEO of Carl Zeiss Meditec AG, was most satisfied with the event. "The Ophthalmology Forum has been very well received. This represents a further step in ophthalmic development, taken together with doctors and patients and bringing us closer to the goal of granting every human being the possibility of perfect vision." In the field of early detection of eye diseases Carl Zeiss Meditec AG has already scored a number of major successes on the way to meeting this goal. Widespread and serious eye disorders such as glaucoma or age-related macular degeneration (AMD) can now be detected at a much earlier stage thanks to the company's highly innovative diagnostic units -- and be treated more efficiently as a result. The new ideas coming out of the Ophthalmology Forum will be used to prepare the ground for further innovations.

7/1 Ted Huber of **Wachovia Securities** issued an update report on the refractive surgery markets: **A Growing And More Competitive Refractive Market**

*** A GOOD YEAR FOR THE REFRACTIVE INDUSTRY:** Our field checks indicate that domestic LASIK volume growth should remain in the mid-teens for Q2 2004 and double digits for H2 2004 in spite of more difficult comps. Improving consumer confidence (currently 101.9) and volume stimulated by safer, better new technology (headlined by custom LASIK) are driving the growth. Alcon's new, expanded custom LASIK label, continued traction by new excimer laser entrant WaveLight (near 40 placements since H2 2003 launch), and the H2 2004 launch of phakic IOLs by AVO and STAA point to an increasingly competitive market. While phakic IOL share gains will

be very modest at first, they run the risk of extending the LASIK purchase decision time for some patients.

*** RAISING VISX ESTIMATES:** We are increasing VISX estimates by \$0.01 for both Q2 2004 and Q3 2004 to \$0.19 (equal to consensus), bringing our 2004 estimate to \$0.82 (consensus is \$0.79). Behind this change is an increase in our volume estimate to 13% for Q2 2004 with custom mix increasing to 38%. We expect VISX's growth to be just below the market rate given the steep ramp of smaller players BOL and WaveLight.

*** REFRACTIVE IS A 2004 DRIVER FOR BOL BUT GROWTH DECLINES IN 2005:** We expect continued mid-to-high teens revenue growth from BOL's refractive business in 2004, paced by share gains for its Zyoptics Custom LASIK system. Management reports BOL's share is now in the low teens and they are "guardedly optimistic" of hitting the 20% goal in 2005. We expect growth to go back down into the single digits for BOL in 2005 due to tougher comps and share losses for their leading Hansatome microkeratome franchise to laser based, bladeless LASIK flap makers.

*** EXPECT IMPROVED PERFORMANCE FROM ALCON:** Given Alcon's broader FDA label and 2005 launch of its ReStor accommodating IOL (which will be used by refractive surgeons despite being in the IOL category), we expect Alcon's refractive business to return to growth in H2 2004.

*** VERYSISE ON DECK FOR AVO:** We expect AVO to receive a H2 2004 FDA approval for its Verisyse phakic IOL and believe both hyperopia and high myopia approvals are a possibility. Our model estimates a \$5 million contribution in 2005 and a \$10 million contribution in 2006. Our conservative estimates leave room for upside.

7/6 **SurgiLight** reported that revenues from equipment sales for the quarter ended March 31, 2004 increased by 199% to \$980,000 from \$328,000 for the quarter ended March 31, 2003. The 2004 Quarter increase in revenue is primarily due to increased international sales of the OptiVision Laser.

Salaries & Benefits Expenses decreased 10% to \$115,339 for the 2004 Quarter as compared to \$128,637 for the 2003 Quarter due to a reduction in the cost of contractual temporary services. The reduction was offset by an increase in commissions due on revenue collections.

Advertising and Selling Expenses decreased 94% to \$2,833 for the 2004 Quarter as compared to \$46,251 for the 2003 Quarter. It is anticipated that these expenses will increase as the company attends additional tradeshow and revises its trade literature to reflect results from the increased clinical activity as sales begin to recover, thus allowing more funding for these expenses.

Administrative and Other Expenses increased 15% to \$135,575 for the 2004 Quarter as compared to \$118,150 for the 2003 Quarter.

Professional Fees Expenses increased 177% to \$222,969 for the 2004 Quarter as compared to \$80,428 for the 2003 Quarter. The increase is attributed to legal services for regulatory matters, patent legal billings, and international patent filing fees.

Research and development Expenses remained the same at \$47,001 for the 2004 Quarter as compared to the 2003 Quarter as payroll and consultant expense allocations have remained unchanged over these periods.

Interest Expense increased 266% to \$46,520 for the 2004 Quarter as compared to \$12,711 for the 2003 Quarter due to the interest accruals for the GEM note payable that is in default and for convertible debenture that matured on December 31, 2002 that has not yet been redeemed.

In summary, total operating expenses increased 18% to \$551,626 for the 2004 Quarter as compared to \$469,063 for the 2003. The company has controlled its administrative, marketing, and payroll expenses as significant additional legal expenses were required for regulatory and patent matters.

The net income from continuing operations for the 2004 Quarter was \$211,958 (.4 cents per share) as compared to a net loss of \$172,074 (.5 cents per share) for the 2003 Quarter. The favorable turn around over the stated periods is a direct result of the increase in international sales and a decrease in most expense categories that was offset by increased legal fees.

As of March 31, 2004, we had a bank balance of \$27,592 and a working capital deficit of \$1.8 million as compared to a cash balance of \$31,420 and a working capital deficit of \$2.2 million at December 31, 2003. Our ability to meet short-term obligations continues to improve, however we remain constrained by a very tight cash position which can be primarily attributed to the lower level of international sales than was expected, especially during the normally slow summer months.

The company's future capital requirements will depend on many factors, the scope and results of pre-clinical studies and pre-clinical trials, the cost and timing of regulatory approvals, research and development activities, establishment of manufacturing capacity, and the establishment of the marketing and sales organizations and other relationships, acquisitions or divestitures, which may either involve cash infusions or require additional cash. There is no guarantee that without additional revenue or financing, the company will be able to meet its future working capital needs.

The company has severe liquidity problems which compromises its ability to pay principal and interest on debt and other current operating expenses in a timely manner. The company is seeking additional sources of financing, which may include short-term debt, long-term debt or equity. There is no assurance that the company will be successful in raising additional capital. In November 2002 the company received a commitment letter for a \$10 million line of credit secured by the company's inventory and accounts

receivable. The terms require obtaining a bank guarantee at a cost of \$585,000, \$92,500 of processing fees to be paid prior to closing, and an additional \$153,000 to be paid at time of closing the transaction. The line of credit is for a term of ten years and accrues interest at a fixed rate of 4.75% for amounts utilized. The company has been negotiating the final agreement with the lender. However, there is no guarantee that the debt financing will be received or if received will be according to these terms.

7/7 **LCA-Vision Inc.** announced that it had been added to the Russell 3000 Index. Membership in Russell 3000 index is determined primarily by market capitalization rankings and style attributes. "We are delighted to receive added visibility from the wide base of institutional stock portfolios that use the Russell 3000 as a benchmark in their investment strategies," said Stephen Joffe, chairman and CEO of LCA-Vision. "We believe that inclusion in the Russell 3000 further affirms the robustness of our business model, which has supported our strong operational and financial performance, and led to enhanced shareholder value during the past year."

7/13 **Alcon** management announced that it expected second quarter earnings per share to be in the range of \$0.94 to \$0.96. This range includes an \$0.18 per share favorable impact related to tax items recorded in the second quarter that were previously announced in the company's first quarter conference call. Excluding this tax benefit, earnings per diluted share for the second quarter are expected to be in the range of \$0.76 to \$0.78. The projected earnings range reflects the expectation of a higher gross profit margin, due partly to favorable currency factors and product mix. In addition, the company has realized production efficiencies from the transfer of contact lens care manufacturing from Madrid, Spain to Fort Worth, Texas, which occurred in the second half of last year.

Joanne Wuensch of **Harris Nesbitt**, published an update report on Alcon, following the above quarterly pre-announcement: **ACL--They Did It Again! 2Q04 Pre-announcement Blows Away Estimates**

* **Event:** Alcon pre-announced earnings, significantly beating our and consensus estimates: 2Q04 EPS are now expected in a range of \$0.76-\$0.78 versus our and the First Call consensus for \$0.64. The better-than-expected results are attributable to manufacturing efficiencies, favorable product mix, and partly to foreign currency benefits. In addition, we believe that several new product launches in the 2H03 appear to be gaining traction faster than anticipated. During the quarter Alcon also benefitted from a \$0.18 tax benefit that resulted in reported EPS of \$0.94-\$0.96.

* **Impact:** Positive.

* **Forecasts:** We are increasing our 2Q04 revenue and EPS to \$1.09 billion from \$1.04 billion and to \$0.76 from \$0.64. In 2004 and 2005 our EPS estimates are increased to \$2.50 and \$2.90 from \$2.29 and \$2.68, respectively.

*** Valuation:** We are raising our price target to \$90 from \$83 based on 31x our 2005 EPS estimate \$2.90. Risks to our price target include competitive, regulatory, clinical, execution, and reimbursement.

*** Recommendation:** We believe that the 2Q04 performance is a testament to our investment thesis that Alcon is an ophthalmic leader, with key new product introductions (e.g., Retaane) that could create earnings upside. We reiterate our OUTPERFORM rating.

- 7/15 **IntraLase Corp.** announced results for the second quarter ended June 30, 2004 with 30 lasers placed for revenue, bringing the company's laser placements to 153 units globally. Procedures sold for the quarter exceeded 48,000, representing an increase of approximately 150% compared to the second quarter ended June 30, 2003. According to data from **MarketScope, LLC**, a market research firm reporting on the ophthalmic industry, IntraLase laser-created flaps were performed in approximately 14% of all LASIK procedures in the United States during the second quarter of 2004, up from 12% in the first quarter of 2004.

IntraLase laser sales included international placements in France, Switzerland, Turkey and Mexico during the second quarter. The existing installed base, in addition to the United States, includes units in Canada, Japan, Korea, Malaysia, Puerto Rico, Italy, Spain, Israel and Saudi Arabia.

"Our U.S. and international sales continue to show support for the IntraLase technology and its ability to attract patients to the LASIK vision correction procedure," said Robert Palmisano, president and CEO of IntraLase Corp. "As we continue to invest in our global infrastructure we anticipate continued international expansion. We believe our technology will become the new standard of care for the world's leading LASIK surgeons."

- 7/15 **Norwood Abbey Ltd.** subsidiary, **Norwood EyeCare** announced that the Centurion SES System and EpiEdge (disposable separator) had received Korean Food and Drug Administration (KFDA) approval. **DaMool Systec Corp. Ltd. (DaMool)**, Norwood EyeCare's exclusive distributor in South Korea, one of the leading refractive surgery products suppliers in that country and also the exclusive representative for complementary refractive surgical products companies in Korea such as **Zeiss**, said that the KFDA approval will now allow DaMool to actively market the Centurion SES system.

South Korea is one of the top three priority markets for Norwood EyeCare and accounts for several hundred thousand of the 3 million laser vision corrective procedures carried out each year worldwide. South Korea has been a strong market for many years with high rates of LASIK procedures and an estimated 300 laser centres.

As previously announced, DaMool placed an initial order for two Centurion SES Systems which were delivered in May for the purposes of evaluation and KFDA review and a

further 20 systems for delivery during the second half of CY 2004 to fill customer orders. The Centurion SES System was exhibited in mid-June at the *Korean Society for Cataract and Refractive Surgery (KSCRS)* meeting attended by approximately 500 eye surgeons. Norwood and DaMool conducted formal "wet lab" demonstration sessions for eye surgeons with more than 150 surgeons having an opportunity to use the system. Norwood and DaMool are extremely pleased with the response received from the market so far.

Richard Walmsley, CEO of the Norwood Devices group, stated, "The South Korean market is quite innovative and the surgeons seek to bring new technologies into their practice quickly when there is a clear patient benefit. KFDA approval is a significant milestone for Norwood EyeCare in growing our business."

7/16 Joanne Wuensch of **Harris Nesbitt**, issued an update report on **Bausch & Lomb: BOL--No Home Run Product, But Some Singles Could Aid Growth**

*** Event:** This week Harris Nesbitt hosted a lunch with Bausch and Lomb management and investors at our New York City offices. Representing the company was Stephen McCluski, CFO, who conducted a brief presentation on the company and then entertained various questions on its efforts to wring out cost savings and plans to accelerate growth. While we believe the company has done a commendable job in implementing its three-year restructuring plan, which began in 2002, we believe a focus for investors (and us) remains its ability to accelerate operational revenue growth from the mid-single-digit range excluding foreign exchange.

*** Impact:** Neutral.

*** Forecasts:** No change.

*** Valuation:** Currently trading at 20.2x our 2005 EPS estimate, BOL is trading below its ophthalmology peer group of 23.0x. However, on a PE/growth basis for 2005 the stock trades at 1.5x versus its peer's 1.2x.

*** Recommendation:** We believe the company has done a commendable job in turning the business around and once foreign currency wanes, we do believe that it has enough juice to maintain mid- to upper-single-digit top-line growth. Yet we are uncertain how much of the low-hanging fruit associated with the company's restructuring has already been garnered, making further operating margin expansion more difficult. Given the valuation, we maintain our NEUTRAL rating in a POSITIVE sector.

7/16 **Carl Zeiss Meditec AG**, Jena, is proposing to cooperate with **Calhoun Vision, Inc.** of Pasadena/USA in a new technology in the field of intraocular lenses (IOL). The contract between the two companies provides for the joint research, development and marketing of systems for customization of the refractive power of light-sensitive IOLs.

The new IOL distinguishes itself from conventional lenses in that it can be adjusted non-invasively after surgery, i.e. by means of light beams, to customize the lens power to meet the specific needs of the patient. This is a unique way of achieving individual, gentle and highly precise optimization of the refractive power for the patient. The digital light source for adjusting the final lens power will be produced by Carl Zeiss Meditec AG. Calhoun Vision, Inc. will supply the intraocular lenses.

Ulrich Krauss, president and CEO of Carl Zeiss Meditec AG, puts the joint venture into perspective: "Our goal is to give people better sight after surgery for cataracts or vision defects. The partnership with Calhoun Vision is in line with our strategy of leadership in ophthalmic innovations. We are convinced that immense potential lies in this technology."

Cary Reich, president of Calhoun Vision, Inc., adds: "We believe this technology will set a new paradigm for quality of vision for both cataract surgery and refractive surgery." Cataract surgery is performed almost 15 million times per year worldwide, making it one of the most common operations of all. The objective in implanting the artificial lens is to precisely adjust it to the eye in order to achieve the best possible visual acuity. The new technology enables the refractive power of the IOL to be adjusted much more precisely to the individual needs of the patient.

- 7/16 Stocks of companies involved in surgical products, LASIK, contact lenses and eye pharmaceuticals were among the top 10 best performers in the vision care industry in the first half of 2004 according to **OptiStock**, a provider of market intelligence for vision care investors. Leading the top 10 first-half gainers for 2004 were **Advanced Medical Optics (AVO)**, **TLC Vision (TLCV)** and **Akorn (AKRN)**, with gains ranging from 66% to 116%. Advanced Medical Optics, **VISX (EYE)** and **Ocular Sciences (OCLR)** led the second quarter with gains of 30% to 74%.

More of 2004's top 10 vision care stocks can be found at **www.optistock.com**. The site also lists the top performers by these categories:

- Eyewear/sunwear
- Contact lenses
- Pharmaceuticals
- Retail/PPMC/managed care
- Laser vision correction
- Eye surgery

OptiStock is a leading source of market intelligence for vision care investors. Publications include the OptiStock News weekly e-newsletter and OptiStock MarketWatch annual sector reports. OptiStock.com includes stock performance by sector, a vision care market index, research, and profiles of public vision care companies.

- 7/18 According to *OptiStock*, privately-held **Addition Technology** of Illinois announced that second quarter 2004 sales of Intacs prescription inserts in the U.S. increased 51% as compared to the same quarter of the prior year and 7% over the first quarter of 2004. International sales were up 47% versus the prior year and 6% as compared to the prior quarter. company officials said the double-digit quarterly sales increases that began in the first quarter of 2003 reflects Intacs growing acceptance as a problem-solver for corneal surgeons. Officials also hope to soon receive FDA approval to market Intacs in the U.S. for the treatment of keratoconus.
- 7/20 **QLT Inc.** reported that its alliance partner, **Novartis**, announced global Visudyne (verteporfin) sales of US\$109.3 million for the quarter ended June 30, 2004. This represents an increase of 22.6% over sales in the second quarter of 2003.

Following the announcement by QLT, Michael Lachman of **ThinkEquity Partners** released an update report on the company: **QLTI: Visudyne Q2 Sales In-Line, All Eyes Now on H2-04 Outlook**

Investment Highlights: Q2 worldwide Visudyne revenues of \$109.3 million (+22.6%) fell in-line with our estimate of \$109.6 million and what we believe to be the consensus number of \$108.7 million. Q2-04 was the first quarter following the positive CMS decision (effective April 1) to reimburse Visudyne use for Medicare patients with either minimally classic or occult lesions, a reimbursement expansion that has the potential to more than double the potential treatable patient population. In the absence of any formal or informal management guidance for Q2, we had perceived positive body language from management regarding Visudyne sales trends in the quarter, and had expected some upside to estimates based upon rapid adoption in the newly reimbursed lesion types. We believe that the weakness in QLT's share price this morning indicates that overall investor expectations ran somewhat higher than published estimates for Q2.

When QLT reports its full results on Thursday, July 22, we will be focused on the sales growth trajectory during Q2 and the outlook for the rest of 2004. The Q2 sales number will need to be interpreted in light of US/international mix, any stocking/de-stocking in the quarter, and sales growth trajectory from April through June. We believe that consensus Visudyne revenue estimates are at the high end of current full year guidance of \$430-455 million, so even with a Q2 Visudyne revenue number that was in-line with estimates, if the Q2 sales trajectory and Q3 visibility are both positive, management could choose to raise full year revenue guidance. We note that one quarter ago, based upon the positive CMS reimbursement decision, management brought up the lower end of 2004 Visudyne revenue guidance from \$420 million to \$430 million. However, there was disappointment that the top end of the guidance range was not increased, and we believe that investor sentiment will be similarly negative this quarter if management does not raise its outlook.

We remind investors that the Macugen FDA panel review is scheduled for August 27, and this could provide headline risk for QLT in the coming weeks. Macugen, from

Eyetech and Pfizer, is an anti-VEGF agent currently under FDA review for the treatment of wet AMD. Even though no one has seen enough pivotal clinical data for Macugen to have a truly informed opinion on the merits of the data, we perceive a positive FDA/regulatory climate in the area of AMD treatment at this time. We believe that it is highly likely that Macugen will receive a positive FDA panel recommendation for at least one lesion type (predominantly classic), and it is also likely that Macugen will be recommended for the other two lesion types as well (occult and minimally classic). If this is the panel outcome, Eyetech will probably trumpet its superior labeling, even though the newly expanded reimbursement for Visudyne would largely offset any labeling superiority for Macugen. It should also be noted that although we believe that combination therapy (Visudyne plus Macugen) will become the preferred treatment regimen for wet AMD beginning in 2005, the panel discussion (as well as post-panel PR from Eyetech) will focus on Macugen as monotherapy, not as combination therapy.

Valuation and Price Target: Our current 12-month price target of \$25 is based upon a specialty pharmaceutical peer group P/E multiple of 25x applied to approximate 2005 cash EPS of \$1.00, which reflects \$0.10 of dilution from the Atrix acquisition. We note that since we set our \$25 price target, the comp group P/E multiple on 2004 earnings has dropped from 25x to 22x. We are not adjusting our price target at this time, given the full Q2 financial report and updated 2004 outlook to come later this week.

7/21 **Refocus Group, Inc.** announced promising preliminary data from the company's ongoing U.S. Food and Drug Administration Phase II clinical trials for the treatment of presbyopia. "My first group of seven patients to reach the three-month exam milestone experienced an average of three lines of improvement in near vision, after undergoing Refocus Group's Scleral Spacing Procedure," said Gene Zdenek, MD, head of the Zdenek Eye Institute in Reseda, Calif., and one of Refocus Group's Phase II clinical investigators.

Refocus Group noted that the data also indicated that all patients in this initial group now have reading vision sufficient to read newspaper-size print without glasses. Further, in a survey completed by an early small group of the clinical trial patients, all responders indicated that they would recommend the Scleral Spacing Procedure to a friend. This preliminary data on a small group of the earliest patients has not yet been provided to the FDA, but will be included in the Phase II study report to be submitted later to the FDA for review and confirmation.

"I am very pleased with the outcomes my patients have experienced with the Scleral Spacing Procedure," added Dr. Zdenek. "Not only are all of my patients experiencing an improvement in near vision after the procedure, there were no complications and I am very pleased by the standardization of the procedure that is provided by Refocus Group's automated scleral incision system. I look forward to continued success as we proceed to the later stages of the FDA clinical trial process."

"These results, while preliminary, continue to support our belief that our Scleral Implant and Scleral Spacing Procedure is effective as a surgical treatment option for presbyopia,

without the inherent compromises or irreversibility of alternative approaches," said Terry Walts, president and CEO of Refocus Group.

Refocus Group remains on track to complete the enrollment of its remaining Phase II patients by the end of the year, subject to adequate financing. Subject to FDA review and approval, the company would expect to receive FDA approval to advance to the final, third phase of FDA clinical trials in early 2005.

7/21 In a pre-announcement before release of **VISX's** quarterly results, Jason Mills of **First Albany Capital** issued the following update report: **Expect Upside in 2Q; Guidance Will be Key**

* We are carrying 2Q:04 revenue and EPS estimates of \$40.8M and \$0.18, respectively, and believe both could be eclipsed.

* Our revenue estimate is predicated on: 1) 11.6% Y/Y growth in the LASIK procedural volume (194K procedures), 2) 37.4% conversion to CustomVue 3) 15 U.S. laser sales, 4) 5 OUS lasers, 5) 42 WaveScans system, and 6) other sales of \$4.8M.

* We anticipate gross margins of 74.5% versus 64.4% a year ago, reflecting a higher mix of CustomVue procedures and strong procedure volume.

* We are acutely interested in the forward guidance. Currently, guidance for FY04: 1) procedure volume up low to mid teens, 2) conversion to CustomVue in high 30s, 2) total revenue \$167-171 million, and (4) EPS \$0.76-\$0.80 range. For FY05, EPS growth guidance is 25%-30%.

* Several of our competitors have increased estimates in recent weeks, driving the consensus to high end of guidance. We believe upside potential in the quarter will not be enough to drive the stock higher; in addition, we think guidance needs to go up for this to happen. This puts the company in an precarious position, as we think current guidance is solid, fair, and, if met, should drive a \$28-\$30 stock price over the next 12 months; however, consensus estimate trends, through no fault of the company, have, in our minds, necessitated an upward revision to guidance.

7/21 **VISX, Incorporated** announced financial results for the second quarter and six months ended June 30, 2004. Second quarter revenues increased 34% to \$43.0 million from \$32.0 million for the comparable period of 2003. Net income increased 133% to \$9.5 million (19 cents per share) compared with net income of \$4.1 million (8 cents per share) in the second quarter of 2003.

Revenues for the six months ended June 30, 2004, increased to \$86.8 million compared with \$66.4 million for the comparable period of the prior year. Net income increased to \$21.3 million (42 cents per share) in the first six months of 2004 compared with net income of \$9.6 million (19 cents per share) in the first six months of 2003.

License revenue, which generated a 97% gross margin, grew 51% from the second quarter of 2003. This increase resulted from 18% growth in procedure volume compared to the second quarter of last year, as well as higher conversion to the company's new CustomVue procedure, which represented over 35% of total VISX U.S. procedure volume in the quarter.

"A healthy and growing laser vision correction market continues to drive our revenue and profit," stated Liz Davila, VISX chairman and CEO. "We believe that this growth is directly related to our CustomVue procedure as well as favorable economic conditions. We see further substantiation of the benefits of CustomVue. World-recognized refractive surgeons reported at the recent annual meeting of the *American Society of Cataract and Refractive Surgery* that customized laser vision correction offers superior results to the standard procedure and has the potential to provide vision better than that which can be achieved with glasses or contacts."

Davila continued, "Our doctors report routinely that patients are elated with their results and they are referring their friends for the procedure. We believe the scientific data and patient satisfaction will result in higher demand for the CustomVue procedure. A favorable economic environment should drive our procedure growth, yielding continued healthy financial performance."

VISX generated approximately \$8.5 million in cash from operations during the quarter, and now has over \$110 million in cash, cash equivalents, and short term investments. The company repurchased approximately 300 thousand shares of stock in the quarter under its board-approved stock repurchase program.

Financial Outlook: VISX believes that third quarter revenues will be in the range of \$40 to \$43 million. EPS is expected to grow 70% to 90% over the third quarter of the prior year and be in the range of \$0.17 to \$0.19 for the quarter. For the full year, VISX has increased its guidance and is now targeting revenue growth of 17% to 20% and EPS growth of 70% or greater compared with 2003, yielding revenue in the range of \$169 to \$173 million and earnings per diluted share of \$0.78 to \$0.81.

Following the earnings announcement, several analysts provided update reports:

Michael Lachman of **ThinkEquity Partners** upgraded **VISX: EYE: Story Intact, Valuation Now More Compelling - Upgrading to Buy**

With 40% upside from current levels to our 12-month price target of \$31, we are upgrading shares of VISX from Accumulate to Buy. For VISX, investor perceptions tend to change more rapidly than do fundamentals, and the best time to buy the stock is when sentiment turns negative while fundamentals remain sound. We believe that this describes the current situation. VISX reported a solid quarter, highlighted by robust 18% US procedure growth. The only metric that came in below expectations, which is likely driving this morning's sell-off, was CustomVue penetration of 35%, versus our 37%

estimate, up only modestly from 34% in Q1. Our field checks support our forecast of continued growth in CustomVue penetration, and view above-forecast Q2 hardware placement numbers (for both lasers and WaveScan diagnostic systems) as encouraging leading indicators for the business.

Investment Highlights: We are upgrading shares of VISX from Accumulate to Buy. For VISX, investor perceptions tend to change more rapidly than do fundamentals, and the best time to buy the stock is when sentiment turns negative while fundamentals remain sound. We believe that this describes the current situation. We believe that the stock has sold off following the company's overall solid Q2 report based on CustomVue penetration that came in below expectations (35%, versus our 37% estimate, up only modestly from 34% in Q1). Our field checks support our forecast of continued growth in CustomVue penetration, and we expect growth to resume in the second half of 2004.

Valuation has become more compelling at current levels. Our \$31 price target represents 31x our unchanged 2005 EPS estimate of \$1.01. At the recent price range of \$25-26, VISX was trading at about 31x estimated 2004 EPS of \$0.81 and 25x estimated 2005 EPS of \$1.01, in-line with the company's peer group of comparable small-mid-cap medical technology stocks. As such, we viewed the valuation as fair based on near-term P/E metrics, with upside driven by EPS growth. At \$22, VISX is trading at just 27x our 2004 EPS estimate of \$0.81 and just 22x our 2005 EPS estimate of \$1.01, representing meaningful discounts to current group average multiples.

The VISX growth story remains intact: Strong financial performance resulting from LASIK procedure growth, driven by the improved economy and positive word-of-mouth from satisfied custom LASIK patients.

Review of VISX Q2 Report: VISX reported Q2 results in-line with our Q2 preview on June 25, in which we raised our LASIK procedure growth forecast and EPS estimate to above-consensus levels. It was our perception that investor expectations for Q2 were mostly consistent with our latest forecasts, and that this quarter would be viewed as in-line. However, given the sell-off this morning, investors seem to be focusing heavily on the shortfall in CustomVue penetration. We expect growth in this metric to resume in H2-04, although we are adjusting CustomVue penetration estimates downward in-line with the Q2 shortfall. We are maintaining our procedure growth forecasts and EPS estimates for H2-04 and 2005, and note that the company did not change guidance for the second half of 2004 (but increased full year revenue and EPS guidance in accordance with the Q2 outperformance).

EPS of \$0.19, in-line with our estimate, beat guidance of \$0.16-0.18 and outperformed consensus by a penny. The strong procedure growth trends that characterized the second half of 2003 and Q1-04 continued through the spring season. US LASIK procedure growth came in at 18%, marking the fourth straight quarter of procedure growth in the 16-20% range for the company. We had increased our procedure growth estimate from

14% to 18%, based on very positive results from our Q2 channel check of LASIK surgeons and centers.

Very strong hardware placement numbers (for both excimer lasers and wavefront-diagnostic systems) are positive leading indicators for the business. VISX Star lasers and WaveScan diagnostic systems are sold at slim margins and have little impact on company profitability. But strong hardware placement numbers are indicative of confidence on the part of refractive surgeons and centers with regard to future procedure growth. VISX placed 35 lasers worldwide in Q2 (versus guidance of 20), the highest number since Q4-02. This number is a very encouraging sign that VISX will be able to maintain its market-leading share in the face of heightened competition for laser placements in recent quarters from Bausch & Lomb (BOL - \$60.33 - Accumulate - Price Target \$71) and WaveLight (private).

The only key metric that fell below expectations in Q2 was CustomVue conversion, but we expect growth to resume in H2-04. CustomVue conversion of just over 35% fell below our 37% forecast (we believe that consensus estimates fell within the 36-38% range), and grew only modestly from 34% in Q1. VISX management attributed the shortfall to a relatively high level of competitive account conversions in Q2, which brought to the company a number of surgeons and centers that had yet to begin their conversion to custom LASIK technology. Management reiterated its full-year 2004 guidance of high-30% CustomVue penetration. We have built additional conservatism into our model by reducing our Q3 and Q4 CustomVue penetration estimates, from 40% and 43% to 38% and 41%, respectively (our full-year forecast goes from 38.3% to 36.9%, still consistent with guidance). The placement of 57 WaveScan diagnostic units in Q2 (versus guidance of 40), mostly to new sites, is an encouraging leading indicator. Placements in Q2 increased the installed base of WaveScan systems by about 8% to just over 800.

Robust procedure growth trends continue to be driven by better economic conditions and strongly positive word-of-mouth based on the excellent clinical outcomes from custom LASIK. There is almost never direct visibility into LASIK procedure growth trends more than two months into the future, making Q4-04 and 2005 still difficult to forecast. As has been the case over the past few quarters, the longer-term outlook on the part of refractive surgeons and center operators remains one of "cautious optimism." However, given the strong and steady growth trends seen over the past four quarters, we feel that the 12-18 month outlook for the LASIK market is as good as could be expected. We maintain the procedure growth forecasts that we updated following our Q2 channel check. At that time, we raised our Q3 procedure growth estimate from 9% to 12%, based on positive indications of patient bookings into July and August. We also increased our Q4 procedure growth estimate modestly, from 9% to 10%, and maintained our 6.5% procedure growth estimate for 2005 off of our higher 2004 procedure forecast.

We believe that the bias to our procedure growth forecast over the next 12-18 months is to the upside, driven by (1) positive word-of-mouth from the large number of satisfied

LASIK patients treated over the past year; (2) potential FDA approvals for VISX's CustomVue technology for hyperopia in late 2004 and high myopia in H1-05, both of which appear promising based on initial clinical trial results; (3) updated wavefront-diagnostic software rolling out later in Q3-04 and a laser hardware upgrade (featuring iris registration) that could be launched by the end of 2004; and (4) potential for increased LASIK adoption among lower-level myopes based on the real and perceived reduction in risk offered by custom LASIK.

Ted Huber of Wachovia Securities: EYE: Q2 2004 In Line On Strong Volumes--Tougher Comps Lie Ahead

*** Q2 2004 IN LINE:** VISX reported EPS of \$0.19, in line with our model and a penny ahead of recently lowered consensus. Revenues (up 34%) beat our estimate by \$1.3mm on strong hardware sales and procedure volumes. Weaker gross margins (72.8%, down 470 b.p. sequentially) held back profit. Gross profit fell \$2.7mm sequentially on a seasonal license revenue decline of just \$2.3mm and \$1.4mm increase in hardware & maintenance revenue, indicating some modestly negative pricing.

*** STRONG VOLUME AND PAUSE IN MIX IMPROVEMENT:** U.S. procedure volume growth was 18%, a few points higher with pro forma adjustments for retreatment cards. But Custom mix rose just 1% point sequentially to 35%. We expect mix shift to accelerate in the back half (we model 2% point gains each quarter) as surgeons respond to the favorable clinical data and reviews of Custom at the May ASCRS trade show. Hardware sales were strong at 35 lasers and 57 wavefront units.

*** GUIDANCE RISES, NO CHANGE TO OUR FORECAST:** Guidance is now \$0.17-0.19 for Q3 and \$0.78-0.81 for FY2004 on double digit procedure volume growth and sequential gains in Custom mix. With tougher comps (Custom LASIK launch now anniversaried), and the seasonally slow LASIK period ahead, it should be more difficult for VISX to beat expectations. Our model remains essentially unchanged and is now positioned at the high end of guidance.

Joanne Wuensch of Harris Nesbitt: EYE--Quarter Tops Expectations; Tough Comps Ahead

*** Event:** VISX's 2Q04 beat expectations: revenue of \$43 million (up 34%) bested our \$40 million estimate and consensus's \$41.4 million. EPS of \$0.19 were higher than our \$0.17 estimate and consensus estimate of \$0.18. Customized ablation procedures were 35% of the mix, below our 36% estimate and up 1% sequentially. Although the company placed 35 systems, well above our 15-system estimate, a significant number were on operating lease contracts. Gross margins of 72.8% were well-below 1Q's 77.5%.

*** Impact:** Negative.

* **Forecasts:** Full-year 2004 guidance increased to \$0.78-\$0.81 (vs. \$0.76-\$0.80). Our financial estimates, which have been below consensus estimates, are being increased. Our EPS estimates are increased to \$0.79 from \$0.76 in 2004; to \$0.94 from \$0.90 in 2005; and we introduce \$1.08 in 2006. For a point of reference, the consensus is \$0.80, \$0.99, and \$1.05, respectively.

* **Valuation:** Currently trading at 26.0x our 2005 EPS estimate vs. the ophthalmology group's 22.3x and 1.4x its PE/Growth rate vs. the group's 1.2x.

* **Recommendation:** Our rating remains NEUTRAL on shares of EYE. While we believe that the company is executing its business plan, to maintain its premium multiple, we think that significant upside to current consensus estimates is needed. Management's tightening of the EPS range and increasing the top-end by a penny may not be enough to maintain that multiple.

Jason Mills of **First Albany: EYE/Buy : Upside Revenue & EPS; Business Tracking Well; Reiterate Buy**

* **Solid Quarter.** Revenue, operating margin, net margin, and EPS exceeded expectations. Revenue of \$43M beat our estimate by \$2M; EPS of \$0.19 eclipsed us by a penny.

* **Procedure Volume Robust; CTC Just Okay** - VISX posted robust procedure volume growth of 18% versus our 12% estimate. CTC was up 150 bps sequentially to 35%, yet lower than our 37.5% estimate. We point out 2Q CustomVue procedures approximated 72,300 – spot on with our estimate.

* **Strong System Placements Bode Well for Future Growth.** 2Q system placements indicate strong demand for CustomVue, as both laser placements (35 vs. 20 estimate) and WaveScan placements (57 vs. 40 estimate) exceeded our expectations. This bodes well for future CTC and procedure growth, in our view.

* **Plenty of Leverage Left in the Model** - We expect CTC to track upward sequentially and, along with strong procedure growth, should be a source of significant earnings leverage in 2H:04 and 2005. We increase our 2004 and 2005 procedure growth estimates materially and tweak down our CTC estimates, although we think upside in this area is likely.

* **Raising Estimates/Guidance Higher** - We raise our 2004 and 2005 EPS estimates modestly to \$0.81 and \$1.01, respectively. Management raised 2004 revenue and EPS guidance, which we think is achievable, possibly conservative and, if met, should drive a \$28-\$30 stock price within 12 months.

Q2 2004 Visudyne Sales: For the three months ended June 30, 2004, Visudyne sales were \$109.3 million. This represents an increase of 23% over sales in the second quarter of 2003, of which approximately four percentage points came from foreign exchange rate effects. Visudyne sales in the U.S. for the quarter were \$52.1 million, representing 48% of total sales for the quarter. This represents an increase of 15% over U.S. sales in the second quarter of 2003. The remaining \$57.2 million sales in the rest of the world are up 30% over the same period last year.

EPS in the second quarter of 2004 was \$0.20, up \$0.04 from the prior year's second quarter. The increase was mainly due to strong Visudyne performance. EPS for both the second quarter and first half of 2004 are reported using the "if converted" basis as the company's outstanding Convertible Notes met the test for conversion.

"We are pleased with the increase in Visudyne usage in the occult and minimally classic forms of the disease now that the reimbursement implementation has been effective for a full quarter," said Paul Hastings, president and CEO. "The expansion in Visudyne's market is clearly reflected in the U.S. sales growth this quarter and we expect to see this penetration into the occult and minimally classic segments continue for the balance of the year."

Q2 Results: The company's revenues reached \$44 million in the second quarter, growing by 23% from the second quarter of 2003. QLT's share of Visudyne net profit (excluding the recovery of manufacturing and other costs) from the QLT/Novartis alliance for the second quarter is on track with our annual guidance at 30.3% of Visudyne sales.

Michael Lachman of **ThinkEquity Partners** issued an update report on **QLT: QLTI: Company Reports In-line Q2 Results**

QLT's full Q2 report yielded few surprises, following the in-line Visudyne revenue result reported earlier in the week. Reported Visudyne revenues of \$109.3 million matched published estimates, but we believe fell a bit short real expectations, leading to weakness in the stock over the past few days. Although US revenue trends accelerated during Q2 and seemed to be driven by the newly reimbursed occult and minimally classic indications, both encouraging signs, management indicated that Visudyne sales did not "break out" enough to justify an increase to the current 2004 guidance range of \$430-455 million. We maintain our full year 2004 Visudyne sales estimate of \$453 million. We are lowering our 12-month price target on QLTI shares from \$25 to \$22, based solely on a reduction in comparable specialty pharmaceutical P/E metrics. We maintain our Buy rating.

Investment Highlights: Following an in-line Q2 report, QLT management did not revise its outlook for full year 2004. Q2 marked the first quarter following the positive decision by CMS to reimburse Visudyne in the US for small minimally classic and occult lesions - the decision took effect April 1. Worldwide Visudyne sales of \$109.3 million matched published estimates, but we believe fell a bit short of the expectations of most investors,

leading to weakness in the stock in the two days following the revenue announcement. On the call, management indicated that Visudyne sales met its own expectations for Q2, but did not "break out" enough to justify an increase to the current 2004 guidance range of \$430-455 million.

QLT management believes that the newly reimbursed indications drove revenue growth in the quarter, pointing out that (1) revenue growth accelerated during the months of Q2, although the level of acceleration was not quantified; (2) US sales drove the vast majority (86%) of sequential revenue growth; and (3) about 4,500-5,000 new patients eligible for reimbursement were treated in the quarter, weighted toward the newly reimbursed indications. While management did not raise full year guidance, there seemed to be little concern that numbers would flirt with the low end of the range, which would be the result if Visudyne sales were to stay at the Q2 run rate for the rest of 2004. We maintain our full year 2004 Visudyne sales estimate of \$453 million at this time.

On a geographic basis, Visudyne sales in the US delivered 15% y/y growth, which slightly trailed our 17% growth estimate, and international sales growth of 30% met our expectations. Overall growth drivers remained solid, with unit sales generating 18% of the 23% total y/y Visudyne sales growth in Q2. Foreign exchange rates remained advantageous to top-line performance, contributing 4%, and pricing contributed 1% to worldwide sales growth. US Visudyne revenues in Q2 were negatively impacted by about \$1 million due to distributor inventory de-stocking. Sales in Europe experienced a slight slow-down, likely due to strength in ordering patterns during Q1. The Japanese market continues to ramp in laser placements (currently at 37, on track to reach the end-of-year target of 50), and we continue to regard near-term sales in Japan as a modest incremental opportunity.

Reported revenues of \$44.4 million were in-line with our estimate of \$44.2 million, and diluted EPS of \$0.20 (on an as-converted basis) beat our \$0.17 estimate and met the consensus estimate. Driven by a reported Visudyne sales number that was in-line with our forecast, reported revenue closely tracked with our model as well. Diluted EPS of \$0.20 exceeded our estimate of \$0.17 as a result of lower-than-projected operating expenditures, which accounted for about half of the upside. The rest of the upside versus our model resulted from interest expense assumptions built into our "as-converted" diluted EPS calculation.

On the call, QLT management focused heavily on a recent survey, conducted among 106 retinal specialists in the US, which was designed to evaluate future Visudyne usage in various applications. The number of respondents was relatively large given the small population of 1,400+ US retinal specialists, and covered a variety of practice types: independent, group, academic and non-academic. The survey looked at Visudyne usage in the three wet AMD lesion types, alone and in combination with other agents (triamcinolone, Macugen, Retaane, and Lucentis). The survey was conducted in early May, shortly after Medicare reimbursement went into effect for small occult and

minimally classic lesions. Some of the findings from the survey, and our observations, are as follows:

- * Difficulty in interpreting survey results: It is difficult to interpret the top-line results of any survey given the results but not the survey methodology. Because this was an "attitude and usage" survey, it is not clear whether physician responses represented current clinical practice or future intentions. While the results were encouraging on a number of metrics (Visudyne usage in newly reimbursed indications, Visudyne usage in combination therapy with new agents), it is particularly difficult to draw quantifiable conclusions from the survey results discussed on the call. For example, respondents reported high rates of treatment for newly reimbursed occult and minimally classic indications, which is a bullish indicator if physicians were signaling their future intentions but makes little sense in the context of current market numbers if they were describing their current treatment patterns.

- * Occult lesions: 90% of the survey respondents supported Visudyne usage in the occult indication. Physicians report treating 50% of patients with eligible, small occult lesions with Visudyne alone, and an additional 25% report using combination therapy (with triamcinolone).

- * Minimally classic lesions: 75% of the survey respondents supported Visudyne usage in the minimally classic indication. Physicians report treating 40% of patients with eligible, small minimally classic lesions with Visudyne alone, and an additional 25% report using combination therapy (with triamcinolone). The lower treatment (or intent-to-treat) rate within the minimally classic lesion-type is consistent with the fact that there is less clinical data available supporting positive outcomes in this indication.

- * Predominantly classic lesions: Physicians report treating 55-60% of patients with predominantly classic lesions with Visudyne alone, and an additional 25-30% report using combination therapy (with triamcinolone).

- * Combination therapy with new agents: The case for combination usage was reinforced by an overwhelming 90% of surveyed retinal specialists stating that combination therapy will become the standard course of treatment. Among these positive respondents, 90% stated that the combination treatment regimen will involve Visudyne. There is a bias toward combination therapy for larger lesions and monotherapy for smaller lesions. Overall, survey respondents indicated a slight reduction in per-year treatment frequency with Visudyne when using it in combination with other drugs.

We remind investors that the Macugen FDA panel review is scheduled for August 27, and this could provide headline risk for QLT in the coming weeks. Macugen, from **Eyetech** and **Pfizer**, is an anti-VEGF agent currently under FDA review for the treatment of wet AMD. Even though no one has seen enough pivotal clinical data for Macugen to have a truly informed opinion on the merits of the data, we perceive a positive FDA/regulatory climate in the area of AMD treatment at this time. We believe that it is

highly likely that Macugen will receive a positive FDA panel recommendation for at least one lesion type (predominantly classic), and it is also likely that Macugen will be recommended for the other two lesion types as well (occult and minimally classic). If this is the panel outcome, Eyetech will probably trumpet its superior labeling, even though the newly expanded reimbursement for Visudyne would largely offset any labeling superiority for Macugen. It should also be noted that although we believe that combination therapy (Visudyne plus Macugen) will become the preferred treatment regimen for wet AMD beginning in 2005, the panel discussion (as well as post-panel PR from Eyetech) will focus on Macugen as monotherapy, not as combination therapy.

Valuation and Price Target: We are reducing our 12-month price target on QLTI shares from \$25 to \$22 based solely on a reduction in comparable specialty pharmaceutical P/E metrics. Our previous 12-month price target of \$25 was based upon a specialty pharmaceutical peer group P/E multiple of 25x applied to approximate 2005 cash EPS of \$1.00, which reflects \$0.10 of dilution from the Atrix acquisition. As we noted earlier this week in our note regarding Visudyne sales, since we set our previous price target, the comp group P/E multiple on 2004 earnings has dropped from 25x to 22x. As such, we are lowering our 12-month price target from \$25 to \$22. With 25% upside from current levels to our new price target, we maintain our Buy rating on shares of QLTI.

Changes to Estimates: Management did not revise its full year EPS and Visudyne sales guidance, and we are making only modest changes to our model. The company reiterated Visudyne worldwide sales guidance in the range of \$430-455 million for the full year 2004, and we maintain our estimate of \$453 million. EPS guidance for the full year remained in the range of \$0.81-0.91 on an as-converted basis and \$0.86-0.96 on a non-converted basis. Our full year 2004 revenue estimate remains at \$183 million. We are adjusting our EPS estimate slightly upward, from \$0.90 to \$0.91 on an as-converted basis (our non-converted estimate remains \$0.97). Changes within our model were minor: we pushed out some of the operating expense that did not materialize in Q2 into the second half of the year. We've made slightly more conservative assumptions with respect to interest income, which faces a more difficult interest rate environment, and amortization, which has increased. We had underestimated the interest payments associated with the convertible notes and have revised our conversion timing assumptions. We still expect Q3 to be reported under a non-converted basis, while Q4 should be reported as-converted.

OPHTHALMIC LASER UPDATE -- August 2004

7/26 Roger Mummert, a seasoned reporter of the contact lens scene, shared his notes for the recent *Global Symposium on Orthokeratology*:

I attended the Global Orthokeratology Symposium this past week in Toronto. GOS 2004 was an extremely well run meeting, which (though I don't have final numbers) attracted a reported 600 eyecare practitioners from 32 countries, about the same or higher than in their inaugural year in 2002. The international component was very much apparent, and

the meeting is emerging as a vital one that probably should remain free standing and not coalesce with CLES (a contact lens symposium). GOS has a very full agenda on a fascinating educational subject.

ORTHO K: As you may know, Ortho K has been around nearly a half-century and is based on the finding that rigid contact lens wear tends to retard creeping myopia in young wearers. In the past several years, patented "reverse geometry lenses" make it possible to effect a refractive change in the cornea, to reshape it to eliminate moderate amounts of myopia or hyperopia. The patient wears a corrective lens only at night and is free of contact lenses all day. The change begins in just 10 minutes and is stabilized after about a week of nighttime wear. A retainer lens then is worn nightly (and often every two or three nights is all that's required).

I went to the meeting believing that Ortho K was about the gas permeable lens industry reviving itself. Not so. This is a potentially huge practice building opportunity for ODs (MDs largely dismiss it). The biggest potential with Ortho K (or CRT [corneal refractive therapy]) lies with teens. Eyecare practitioners (ECPs) have the potential to keep teens from ever developing myopia at all! And lock in young patients for a lifetime of yearly checkups, replacement lenses and care! As one company ECP told me, "If I were still in private practice I'd be all over this — you can make a ton of money and help a lot of people!" Talk is that professional fees would be about \$1,000 — a lot cheaper than laser surgery and fully reversible. Those fees likely would erode.

Notably, there were many Chinese, Korean, Japanese and other Asian ECPs present. The Chinese, in particular, have high rates of myopia and consider it an affliction to be vanquished.

7/27 **LCA-Vision Inc.** reported record revenues and earnings per share for the three and six months ended June 30, 2004. Financial highlights included:

- * Earnings per share of \$0.78, or \$0.45 excluding an income tax benefit, up significantly from earnings per share of \$0.17 in the second quarter of 2003
- * Revenues up 56% to approximately \$31.6 million, compared with revenues of approximately \$20.2 million in the second quarter of 2003, marking the fourth consecutive quarter of revenue growth exceeding 50%
- * Revenue growth of 39% at our LasikPlus vision centers open at least 12 months, compared with the second quarter of 2003
- * Procedure volume up 47% to 24,093, from 16,432 procedures in the second quarter of 2003
- * Revenue per procedure up 6% to \$1,310, from \$1,231 in the second quarter of 2003
- * Operating margin of 19.9%, compared with 8.9% in the second quarter of 2003
- * Net cash provided by operations of approximately \$15.0 million for the first six months of 2004, up significantly from \$5.4 million in the first six months of 2003

Net income for the second quarter of 2004 rose to \$10.8 million from \$1.8 million for the second quarter of 2003. Earnings per share were \$0.78 for the second quarter of 2004, versus \$0.17 per share for the second quarter of 2003. Included in 2004 second quarter financial results was an income tax benefit of \$4.6 million to reverse the remainder of the valuation allowance on the company's deferred tax assets. Without the benefit of the reversal of this allowance, the company reported second quarter 2004 net income of \$6.3 million (45 cents per share). Management believes earnings per share excluding the benefit of the reversal of the reserve is a meaningful disclosure, facilitating year-over-year comparison on a consistent basis.

For the second quarter of 2004, revenues increased 56% to \$31.6 million, compared with \$20.2 million in the second quarter of 2003. The company reported that revenues at its vision centers open at least 12 months increased 39% during the quarter. Second quarter procedure volume rose 47% to 24,093, and average price per procedure increased 6% to \$1,310, both compared with the second quarter of 2003.

Net cash provided by operations in the first six months of 2004 was \$15.0 million. As a result, cash and short-term investments were \$79.6 million as of June 30, 2004, up from \$64.9 million as of December 31, 2003.

For the six months ended June 30, 2004, the company reported net income of \$23.6 million (\$1.71 per share) compared with net income of \$3.6 million (33 cents per share) for the six months ended June 30, 2003. Without the benefit of the reversal of the valuation allowance on the company's deferred tax assets totaling \$10.5 million for the six-month period, the company reported first half 2004 net income of \$13.1 million (95 cents per share). Revenue grew approximately 57% to \$63.2 million for the first half of 2004, compared with \$40.2 million for the first half of 2003.

Stephen Joffe, chairman and CEO of LCA-Vision, stated, "We continue to demonstrate exceptional financial performance and achieved several significant milestones during the quarter. We are pleased to report that our revenues for each of the past four quarters have increased by 50% or more versus the comparable quarter in the prior year. Additionally, trailing 12-month revenues exceeded \$100 million for the first time in our corporate history. Furthermore, same-store sales rose 39% year-over-year, substantially outpacing projected industry growth of approximately 13% and reflecting our continued ability to capture additional market share. Our earnings grew even more rapidly than revenues, demonstrating the operating leverage and efficiencies of our business model. While we are clearly benefiting from strong revenue and earnings growth to-date, we believe there remains tremendous upside going forward as we continue to achieve strong same-store sales growth and open new LasikPlus vision centers. Based on our confidence in continued strong performance, we are again raising our revenues and earnings guidance for the remainder of 2004, and are providing an initial outlook for growth in 2005."

2004 Guidance and 2005 Outlook: Based upon second quarter financial results and management's outlook for the remainder of the year, LCA-Vision increased full-year 2004 revenues and earnings guidance as follows:

- * Revenues in the range of \$121 million to \$123 million, up from prior guidance of \$115 million to \$117 million.

- * Earnings per share in the range of \$2.05 to \$2.15, including the \$0.76 per diluted share benefit recorded in the first half of 2004 for the reversal of the deferred tax valuation allowance and also reflecting a presumed 39% tax rate for the second half of 2004. This compares with prior earnings per diluted share guidance of \$1.55 to \$1.65.

For 2005, we expect revenues to increase 30-40% and income before taxes to increase 40-50%, both compared with management's current estimates for 2004 results.

LCA-Vision expects to add 10-12 laser vision correction centers during 2005.

7/27 **IRIDEX Corporation** reported improved operating performance for the quarter ended July 3, 2004. Revenue for the quarter increased 9.1% to \$8.1 million from \$7.4 million reported for the second quarter of 2003. (And up 9.5% from the \$7.4 million for the first quarter of this year.) The company recorded net income of \$133,000 (2 cents per share) for the second quarter of 2004 as compared with a net loss of \$299,000 (4 cents per share) for the second quarter of 2003.

Ophthalmology sales totaled \$6.7 million, an increase of 11.1% compared with the second quarter of 2003 and increased both internationally and domestically. Since international sales are denominated in US dollars, foreign currency fluctuations had no material impact on sales growth. Dermatology sales were \$1.4 million, an increase of \$7,000 compared with the corresponding quarter in 2003.

"We believe that our ongoing investment in product reliability combined with our asset management and cost reduction programs are continuing to generate positive returns," said Theodore Boutacoff, IRIDEX president and CEO. "As a result, gross margins and operating profits have continued to match our expectations, and we exited the quarter with our cash position at an all time high. More notably, particularly with the typical seasonality of our business, we were able to generate an operating profit in the second quarter for the first time in three years. We remain very excited about the progress of our Minimum Intensity Photocoagulation (MIP) treatment protocols. For example, for TTT alone there are now more than 100 published and presented studies; including 28 clinical studies with at least 6 months, and up to 28 months (mean) follow-up. The results of these studies indicate that the TTT approach to treating wet age-related macular degeneration (AMD) provides significant therapeutic benefits to patients compared to the natural history of the disease, which if left untreated might lead to profound vision loss or blindness. As reported last quarter, we still believe that results of the randomized TTT4CNV study for wet AMD will likely be released during the fourth quarter of this year."

Cash and cash equivalents at quarter-end was \$18.5 million as compared to \$16.9 million at the end of Q1 2004 and \$16.3 million at the end of Q4 2003. Inventories decreased to \$8.3 million at the end of Q2 2004, down from \$8.5 million at the end of Q1 2004 and \$8.7 million at the end of Q4 2003. Inventory turns at the end of Q2 2004 were slightly more than two. At the end of Q2 2004, accounts receivable was \$5.9 million, resulting in DSO of 66 days compared with 76 days at the end of Q1 2004 and 66 days at the end of Q4 2003.

7/28 **Alcon, Inc.** reported global sales of \$1.0 billion for the second quarter of 2004, an increase of 12.3% over global sales in the second quarter of 2003, or 9.9% excluding the impact of foreign exchange fluctuations. Net earnings for the second quarter of 2004 increased 67.9% to \$299.2 million (96 cents per share) compared to \$178.2 million (57 cents per share) for the second quarter of 2003.

Reported earnings per share in the second quarter of 2004 included an \$0.18 per share favorable impact related to the filing of amended federal income tax returns to claim research and experimentation tax credits for prior years and to the resolution of several significant tax audit issues. Excluding this tax benefit, earnings per diluted share for the second quarter of 2004 were \$0.78.

Tim Sear, Alcon's chairman, president and CEO commented, "This quarter represents a milestone for Alcon. It is the first quarter in Alcon's history that we have exceeded \$1 billion in sales. While this accomplishment is partly due to seasonality and currency factors, it also reflects the tremendous efforts of our entire team of employees at Alcon. Every region of the world and every major product line contributed to this performance. As previously announced, I will be turning over my roles as president and CEO to Cary Rayment this October. I have the utmost confidence that he will lead our company effectively and inspire our people to continued success in the years to come."

Selected Sales Highlights:

- * U.S. sales grew 7.6% to \$549.9 million, accounting for 52.9% of total sales.
- * International sales grew 18.1% to \$489.3 million, accounting for 47.1% of total sales. International sales growth was aided by a favorable currency environment, although constant currency growth was still 12.7%.
- * Surgical sales rose 14.2% to \$459.1 million, accounting for 44.2% of total sales.
- * The AcrySof Natural intraocular lens continued to gain physician acceptance, as sales of intraocular lenses increased 17.1% to \$148.1 million. AcrySof® Natural accounted for 33% of intraocular lenses sold in the U.S. in June, 2004.
- * Sales of cataract and vitrectomy products rose 15.1%, with shipments of the Infiniti vision system a key driver of growth in this sector.
- * Refractive revenue (of \$15.9 million) declined 16.8% because of a decline in global equipment sales. However, increased demand for LASIK procedures and a significant shift toward higher-priced custom procedures caused U.S. technology fees to rise.

(Refractive revenue, however, was up slightly over that for the first quarter, \$15.8 million.)

Financial Guidance:

- * Sales are expected to be between \$3,800 million and \$3,850 million.

- * Earnings per share are expected to be between \$2.43 and \$2.46. This range excludes the impact of the tax benefit realized in the second quarter of 2004. Diluted earnings per share including the impact of the tax benefits realized in the second quarter of 2004 are expected to be between \$2.62 and \$2.65.

Two analysts commented on Alcon's financial data:

Joanne Wuensch of **Harris Nesbitt** first commented prior to the analyst conference call:
ACL--Alcon: First Look

- * **Event:** Alcon's 2Q04 results were strong: revenues of \$1.04 billion (up 12.3%; up 9.9% ex-FX) were in line with the Street's \$1.04 billion. Operating EPS of \$0.78 were at the high-end of the company's pre-announced range of \$0.76-\$0.78 and above our \$0.76 and the Street's \$0.73. Excluded from operating EPS is a \$0.18 tax benefit. At the time of the company's pre-announcement for significantly higher EPS (we were at \$0.64), we raised our revenue estimate to \$1.09 billion from \$1.04 billion and adjusted our margin assumptions. It now appears that the EPS upside was almost entirely due to expense management: operating margin of 33.5% handily topped our revised estimate of 31.5% and our original 28.3% estimate. Pharmaceutical sales increased 12.3% to \$440.5 million; surgical sales increased 14.2% to \$459.1 million and consumer sales increased 6.3% to \$139.6 million. Weighing down the pharmaceutical franchise was a weak (up 0.3%) demand for allergy products, offset by demand for glaucoma (up 24%) and otic (up 24.5%).

- * **Impact:** Neutral. We deem management guidance conservative given the significant upside to the last two reported quarters.

- * **Forecasts:** Management provided a 2004 revenue guidance range of \$3.8- \$3.85 billion, tighter than the previous \$3.75-\$3.85 billion range and EPS between \$2.43-\$2.46, significantly higher than previous guidance of \$2.23-\$2.26. Current revenue consensus is for \$3.84 billion versus our \$3.89 billion and EPS consensus is for \$2.40 versus our \$2.50 estimate.

- * **Valuation:** Alcon is trading at 28.8x our 2005E EPS, above the peer group's 21x.

- * **Recommendation:** Maintain OUTPERFORM rating.

And then again following the call: **ACL--Expense Management Drove 2Q04 EPS Upside**

* **Event:** Alcon reported 2Q04 results that showed strength as healthy product demand and manufacturing efficiencies continued to flow through its income statement. Revenues of \$1.04 billion (up 12.3%; up 9.9% ex-FX) were in line with the Street's \$1.04-billion estimate, yet below our recently revised estimate for \$1.09 billion. EPS of \$0.78 was at the high end of the company's pre-announced range of \$0.76-\$0.78, above our \$0.76 estimate and the Street's \$0.73, and well above our original \$0.64 estimate. Lack of top-line information on the 2Q's pre-announcement led us to believe revenue was more robust; EPS upside in the quarter reflects expense management.

* **Impact:** Neutral.

* **Forecasts:** We have lowered our 3Q04 EPS estimate to \$0.56 from \$0.58. No change to full-year 2004 and 2005 EPS estimates, which remain at \$2.50 (up 30.5%) and \$2.90 (up 16.1%).

* **Valuation:** ACL trades at 26.3x our 2005E EPS vs. the group's 21.4x.

* **Recommendation:** While some of the punch of the blow-out second quarter was absorbed with the company's preannouncement, we believe the fundamentals of the company's underlying business and product pipeline are robust. However, we believe management is conservative in its 2H04 guidance, given the expectations for FX benefits to subside and additional operating expenses that were pushed from the 1H04 to 2H04. Maintain OUTPERFORM.

Michael Lachman of ThinkEquity Partners: ACL: Stock Down, Target Up - Maintain Accumulate Rating

We are raising our price target on Alcon shares from \$80 to \$86, and maintaining our Accumulate rating, following yesterday's 8% sell-off. We view this decline as a valuation "reality check" for a stock that had gotten a bit ahead of itself, and suspect that Alcon shares sold off yesterday because the pre-announced Q2 earnings outperformance was not accompanied by similar upside in revenues. Prior to the Q2 earnings release, Alcon shares had become a valuation "outlier," vulnerable to a correction. We still view a premium valuation as appropriate for Alcon, given the company's strong new product pipeline and opportunity for leveraged earnings growth beyond published estimates, and continue to use a 30x multiple applied to (higher) 2005 estimated earnings in calculating our price target. The most important upcoming milestone for Alcon is the reporting of pivotal trial data on Retaane (for wet AMD) at the AAO in late October.

Alcon's Q2 EPS of \$0.78 came in at the top end of the pre-announced range of \$0.76-0.78, and well above our prior estimate of \$0.65. Revenues of \$1.04 billion (+12.3%, +9.9% constant currency) fell right in line with our estimate, with the EPS upside of \$0.13 generated by positive variances in gross margin (\$0.06), SG&A (\$0.04) and R&D (\$0.03). Currency exchange rates boosted reported revenues by only 2.4% in Q2, well below the 6.4% seen in Q1-04 and the 5.9% seen in Q4-03.

7/28 **Advanced Medical Optics, Inc.** announced financial results for the second quarter of 2004. Net revenue rose 10.9% to \$168.7 million compared with last year's second quarter, reflecting strong growth in the company's core ophthalmic surgical and eye care businesses and across all geographic regions. Excluding the effect of currency, revenue grew 5.9% for the second quarter, compared to the same period in 2003. Pro forma net income for the second quarter of 2004 grew 28.3% to \$8.5 million (25 cents per share) compared to \$6.7 million (22 cents per share) in the year-ago quarter.

During the quarter, the company completed a series of transactions to restructure its balance sheet and fund the acquisition of the **Pfizer** ophthalmic surgical business, which was successfully closed on June 26, 2004. As a result of the recapitalization, AMO recorded a non-cash charge of approximately \$110.3 million and a cash charge of approximately \$16.0 million that caused a reported net loss in the quarter of \$112.5 million (\$3.67 per share). This compares to reported net income of \$4.4 million (15 cents per share) one year ago.

"With another quarter of solid performance across both businesses, AMO is demonstrating to shareholders its ability to deliver sustained growth by providing superior technologies that improve the productivity of practitioners and the well-being of patients," said James Mazzo, president and CEO. "This was a milestone quarter for AMO. We continued to improve our financial performance, recapitalized our balance sheet, prepared to close the strategic acquisition of the Pfizer surgical ophthalmic business and prepared to expand our eye care business in select markets with a technologically advanced contact lens. All of these steps are positioning AMO for future growth."

The acquisition of the Pfizer surgical ophthalmic business includes the Healon family of viscoelastics, the CeeOn and Tecnis lines of intraocular lenses (IOL) and the Baerveldt glaucoma shunt, as well as related manufacturing and R&D facilities. AMO acquired the business, which generated approximately \$150 million in revenue in 2003, for \$450 million in cash. The acquisition closed on the first day of the company's fiscal third quarter.

For the first six months of 2004, net revenue was \$319.0 million, compared to \$283.3 million for the first six months of 2003, an increase of 12.6%. Excluding the impact of currency, revenue grew 5.6%. Pro forma net income for the first six months of 2004 was \$13.1 million (40 cents per share) compared to \$6.8 million (23 cents per share) in the year-ago period. Including recapitalization-related charges in the second quarter, the company reported a net loss for the first six months of 2004 of \$107.8 million (\$3.59 per share) compared to reported net income of \$4.3 million (14 cents per share) in the first six months of 2003.

"With the acquisition completed and our integration efforts well underway, we now expect 2004 revenue to be between \$715 million and \$725 million, with pro forma diluted EPS to be between \$1.20 and \$1.25," said Richard Meier, executive vice president

of operations and finance and CFO. "In addition, we are increasing our post-acquisition guidance for 2005 revenue to a range of \$810 million to \$840 million, and narrowing the range of our 2005 pro forma diluted EPS guidance to \$1.60 to \$1.70."

AMO had previously set revenue and pro forma earnings-per-share guidance for 2004, excluding the Pfizer acquisition, at \$635 million to \$645 million and \$1.02 to \$1.04, respectively. Previous 2005 revenue and pro forma earnings-per-share guidance including the Pfizer acquisition was \$800 million to \$830 million and \$1.50 to \$1.70, respectively.

Ophthalmic Surgical: The company's ophthalmic surgical revenue grew 10.7% in the second quarter to \$86.7 million, compared to \$78.3 million in the year-ago quarter. Excluding the effect of currency, ophthalmic surgical revenue grew 6.3%. Total IOL revenue rose 7.3% to \$55.8 million, compared to revenue of \$52.0 million in the second quarter of 2003, reflecting sales increases of its proprietary Sensar acrylic and Clariflex silicone IOLs. Sales of phacoemulsification products grew 18.9% during the second quarter, to \$19.8 million, compared to \$16.6 million one year ago. This increase is attributable to continuing demand for the Sovereign and Sovereign Compact systems with WhiteStar technology and growth in recurring revenue from sales of the consumable surgical packs used during every phacoemulsification procedure performed with an AMO machine.

For the first six months of 2004, ophthalmic surgical revenue grew 13.1% to \$164.9 million, compared to \$145.8 million in the first six months of 2003. Excluding the effect of currency, growth was 6.6% for the period.

Financial Highlights: The company reported gross profit of \$104.7 million for the second quarter of 2004, up 9.7% from \$95.4 million a year ago. The gross margin for the period was 62.1%, compared to 62.7% in the second quarter of 2003. The modest decline is consistent with the company's previous guidance and is attributable to unabsorbed manufacturing overhead costs associated with bringing on line the company's recently acquired eye care manufacturing facility in Madrid, Spain, as well as expansion of its eye care manufacturing facility in Hangzhou, China. These actions are designed to allow AMO to transition away from its manufacturing arrangement with its former parent, **Allergan, Inc.**, by mid-2005.

Three analysts commented on AMO's quarterly results:

Joanne Wuensch of **Harris Nesbitt: AVO--Eyeing More Upside to Pfizer Acquisition**

* **Event:** AMO reported 2Q04 results that were essentially in line with expectations: revenues of \$168.7 million (up 10.9%, up 5.9% ex-FX) were in line with our \$168.1 million estimate, but higher than the Street's \$163.7 million. EPS from operations were \$0.25 (up 10.7%), in line with Street consensus and a penny below our \$0.26 estimate. The integration of Pfizer appears to be progressing well.

* **Impact:** Positive.

* **Forecasts:** For 2004 we have lowered our revenue estimate to \$734.2 million from \$740.2 million, closer to management's guidance, as foreign currency benefits begin to wane. However, we believe that management is taking a conservative stance in its view for revenue growth. Given the lower revenue base in 2004, our 2005, and 2006 revenue estimates have also been lowered to \$851.3 million and \$904.7 million from \$859.1 million and \$911.3 million, respectively. Despite the revenue decrease, our 2004, 2005 and 2006 EPS estimates are increased to \$1.23, \$1.70, and \$2.00 from \$1.18, \$1.67, and \$1.94, respectively.

* **Valuation:** AVO is trading at 21.1x our 2005E EPS, in line with ophthalmology peers.

* **Recommendation:** We believe AMO is undergoing a metamorphosis, integrating Pfizer's ophthalmic business, restructuring its balance sheet, transitioning to its own manufacturing facilities, and increasing R&D. Reiterate OUTPERFORM.

Ted Huber of Wachovia Securities: AVO: Results & Guidance As Advertised -- Raising 2004 Estimates

* **Q2 2004 RESULTS AS ADVERTISED:** AVO reported high quality EPS of \$0.25 for Q2 2004, equal to consensus. Surgical revenue grew 10.7% (6.3% cc), led by 18.9% phacoemulsification growth. Eyecare revenue growth of 11.2% (5.5% cc) was the best since AVO's spinout and was led by 30% growth of its COMPLETE brand of contact lens solutions in all regions. Excluding Pfizer deal costs (\$2.5mm) and higher than expected share count from AVO's convert, EPS would have been \$0.03 higher.

* **2004-05 GUIDANCE UPDATED:** Management offered updated 2004 revenue and EPS guidance of \$715-725 and \$1.20-1.25 to include the benefit of PCS (Pfizer Cataract Surgical) acquisition. Management added \$10mm to 2005 revenue targets (now \$810-840 million) and tightened the EPS range to \$1.60-1.70. Adjustments to these estimates for increased asset amortization are pending. Management characterized the targets as conservative.

* **WACHOVIA MODEL CHANGES:** We are increasing our 2004 EPS estimate to \$1.23 based on 3% organic cc revenue growth and \$80 million from PCS. We are maintaining our \$1.76 estimate for 2005 and are comfortable just above the guidance range given management's conservative asset step up assumptions, strength in AVO's underlying business, and upcoming product launches.

Michael Lachman of ThinkEquity Partners: AVO: Better Visibility on Margin Improvement, Investment Thesis Intact

We maintain our Accumulate rating on shares of Advanced Medical Optics (AMO), and lower our 12-month price target modestly, from \$43 to \$41, based solely on P/E multiple

contraction within the ophthalmic device sector. Reported pro forma EPS of \$0.25 met expectations, and would have beaten by a penny without the accounting for convertible notes on an as-converted basis. Revenue growth was solid across both business units (11% reported, 6% constant-currency). Continued margin expansion, driven by the highly accretive acquisition of the Pfizer ophthalmic surgery business and ongoing cost improvement initiatives, supports our 2005 and 2006 EPS estimates of \$1.70 (+37%) and \$2.15 (+26%). After a company-transforming acquisition and a doubling of the company's stock price over the past year, we reiterate our original investment thesis: solid execution, leveraged earnings growth, and a management team that will find ways to outperform in the slow-but-steady markets in which the company competes.

Investment Highlights: After a company-transforming acquisition and a doubling of the company's stock price over the past year, we think that the reasons to own AMO stock are much the same as they were when we initiated coverage nearly one year ago. Recall that our original AMO investment thesis was centered on (1) solid execution and mid-single digit revenue growth in the company's two slow-but-steady core markets, (2) leveraged earnings growth driven by margin expansion/operating leverage and debt reduction, (3) a management team that will find ways to participate in high growth opportunities within eye care, through internal development and partnering/M&A, and continue to under-promise/over-deliver, and (4) stock price appreciation driven by earnings growth, even in the absence multiple expansion, resulting in a relatively low risk profile.

What we didn't anticipate a year ago were the hugely accretive Pfizer ophthalmic surgery acquisition and the higher P/E valuations for ophthalmic device stocks.

* Our new 2005 EPS estimate of \$1.70 is 39% higher than our original estimate from late last year of \$1.22. Of the additional \$0.48 in 2005 EPS, about \$0.18 comes from revenue outperformance and margin improvement in the base business, and the additional \$0.30 comes from accretion from the Pfizer deal. Additional operating margin expansion in 2006 (another 200bp or more versus 2005) will be driven by the company's ongoing organizational realignment program and additional operating leverage from the acquired revenues.

* Over the past year, the average P/E multiple on current-year earnings for small-mid cap ophthalmic device stocks has expanded from 17x to 21x, driven by solid ophthalmic industry fundamentals and sound business execution by the leading companies. We note that the comparable group's P/E has moderated somewhat, from a recent peak of about 23-24x.

We reiterate our AMO investment thesis, with growth off of a higher base following the Pfizer deal. We note that AMO (along with its closest peers) is trading at a higher P/E multiple today than in recent quarters, suggesting greater valuation risk than before. However, we believe that any additional P/E valuation risk is offset by a longer track record of solid execution, tangible evidence that this management team can take

advantage of accretive opportunities, and greater visibility on margin expansion following the Pfizer ophthalmic surgery acquisition.

Valuation and Price Target: We are reducing our 12-month price target on AVO shares from \$43 to \$41, based solely on P/E compression within the ophthalmic device group and a modest reduction in our target multiple, and we maintain our Accumulate rating. Our previous 12-month price target of \$43 was based on a 25x P/E multiple applied to an anticipated 2005 EPS estimate of \$1.70. The premium P/E multiple (versus comparable company multiples in the 23-24x range at the time) was based on the expectation of another year of strong earnings growth in 2006, driven by additional operating leverage from the Pfizer deal.

Our new price target of \$41 is based on the same 2005 EPS estimate of \$1.70, and a slightly lower P/E multiple of 24x due to multiple compression within medical device stocks overall and ophthalmic device stocks in particular. We are still comfortable with a premium valuation versus the current 21-22x multiples of 2004 EPS for AMO's closest comps, based on (1) another year of above-trend earnings growth in 2006, (2) potential top line synergies from the Pfizer deal that are not yet reflected in our model, and (3) management's track record of issuing conservative guidance and outperforming expectations, which we expect to continue. We note that our new \$41 price target also equates to a more in-line group multiple of 22x applied to estimated 2006 EPS of \$2.15, discounted back one year at 15%.

Ophthalmic Surgical sales were \$86.7 million, slightly below our projection of \$87.3 million. The Clariflex silicone and Sensar acrylic IOLs and the Sovereign phaco platform were again key growth products in the quarter. In Q3, FDA approval of the Verisyse anterior chamber phakic IOL is expected (final labeling discussions are currently taking place), with a US product launch to follow. Also in H2-04, we expect the company to introduce enhancements to the Sovereign phaco platform and launch its Amadeus 2 microkeratome in the US and Europe. European launches of two new IOL products, the Resume multifocal IOL (second-generation acrylic/OptiEdge version of the Array) and the Tecnis diffractive multifocal IOL (acquired from Pfizer) are planned at the ESCRS conference this September. US product launches are planned in 2005 for the Resume (targeting the cataract market) and 2007 for Tecnis multifocal (following clinical trials, targeting the refractive market). In 2005, AMO plans to introduce the Sovereign 7.0 phaco platform with WhiteStar 2.0 technology.

7/29 **Bausch & Lomb** reported worldwide sales of \$566.5 million for the quarter ended June 26, 2004, an 11% increase (or growth of eight percent on a constant-currency basis) over the prior-year period. Each of the company's product categories reported solid sales growth. Earnings per share of \$0.76 grew 43% as compared to the \$0.53 per share reported in the prior-year period. Operating margins of 13.3% of sales increased from 11% of sales in the prior year, reflecting improved gross margins and lower operating expenses as a percentage of sales.

First-half 2004 net sales were \$1.1 billion, an increase of \$116.3 million or 12% over 2003, and a seven percent increase excluding the effect of currency. Earnings per share were \$1.19, an increase of 42% compared to the \$0.84 earnings per share before the cumulative effect of a change in accounting principle in the prior year. Including that item, net earnings per share were \$0.82 for the first half of 2003.

Commenting on second-quarter financial performance, Bausch & Lomb chairman and CEO Ronald Zarrella said, "We are pleased with the solid results we reported today, which demonstrate our continued progress toward our established financial goals. Just as important, we're starting to see the top-line contributions from recent product introductions. With more of those in the pipeline, we have good reason to be optimistic about our future growth prospects."

Bausch & Lomb indicated that it is now projecting full-year earnings per share to be in the range of \$2.80 to \$2.85. Previous guidance had been in the range of \$2.70 to \$2.75 per share. Zarrella commented, "The increased guidance reflects our current expectation for full-year constant-currency revenue growth of six to seven percent, with reported revenue growth in the low double digits if exchange rates remain where they are today. We expect the positive margin contribution from those higher sales to be somewhat offset in the back half of the year by higher R&D expenditures and investments to support new product launches like our new multi-purpose lens care solution."

Refractive: Growth in revenues from products used in refractive surgery was primarily driven by higher sales of per-procedure cards, microkeratome blades and upgrades to the Zyoptix brand platform for customized LASIK surgery. (Refractive revenues were \$35.6 million for the quarter, up 17% from the \$30.4 million in the same quarter a year ago, but down 8% from the \$38.9 million recorded for the first quarter this year.) The Americas region posted constant-currency growth of nearly 30%, with strong double-digit gains in Asia and essentially flat performance in Europe.

Several analysts commented on the second quarter results:

Jason Mills of **First Albany Capital: BOL/Strong Buy: Stellar 2Q Results - Beating Estimates & Raising Targets; Reiterate Strong Buy**

*** Revenue Upside** - \$567M sales beat our \$552M estimate; notably 8% organic growth accelerated from 5%-6%. Upside in every division, in-line refractive.

*** Significant EPS Upside** - \$0.76 vs. \$0.63 estimate (consensus: \$0.64). Estimate \$0.03 upside via timing - i.e., lens care solutions pulled \$3M of sales into 2Q from 3Q, and R&D project timing; \$0.05 upside from FX, which leaves \$0.05 upside from stronger operating earnings. There have been few mid- to large-cap med-tech companies to report \$0.05 upside in total EPS of late.

* **EPS Drivers** - Expect profitability will continue to be driven by three things: 1) favorable mix shift in all businesses to higher-margin products, 2) operating expense leverage - S&M infrastructure in place; G&A has more room for cost-cutting, partially offset by higher R&D expenses, which should actually help drive 3) modest acceleration in organic growth.

* **Guidance Raised to \$2.70-\$2.75 from \$2.60-\$2.65.** We are increasing our estimates for 2004 to \$2.86 from \$2.75 and for 2005 to \$3.29 from \$3.25. We suggest 14% 2005 operating margins (our estimate: 13.2%) would imply earnings power of \$3.50.

* **Reiterate Strong Buy Rating.** BOL is reaping the rewards of very sound operating changes made over the past few years in terms of product focus, strengthening product pipeline and cost cutting, and we think there remains significant leverage left to unlock, with decent visibility into doing it.

Ted Huber of **Wachovia Securities: BOL: Q2 EPS Upside \$0.12, 10th Beat In A Row--2005 Est. Inc.**

* **OPERATING MARGINS DRIVE UPSIDE:** EPS of \$0.76 was \$0.12 ahead of consensus. Key contributing factors were a 150 bps yr/yr gross margin expansion, modest R&D spend (7.4% of sales), and \$11MM upside to consensus revenue. Operating margins of 13.3% (130 bps yr/yr expansion) were driven by favorable mix shift, supply chain efficiencies, and cost reduction programs.

* **STRONG REVENUE GROWTH:** 10.5% reported revenue growth (3.1% currency contribution) was driven by 30% Americas refractive growth, 25% US PreserVision growth, and 8% Americas lens care growth. Bausch generated \$79 MM in operating cash flow (versus \$9 MM in Q203), reflects earnings growth and supply chain efficiencies.

* **INCREASING ESTIMATES:** Bausch increased 2004 EPS by \$0.10 (to \$2.80-2.85), \$0.02 less than the Q204 upside as some spending is pushed into the 2nd half. Our H204 EPS estimates remain unchanged. We are increasing our 2005 EPS estimate to \$3.25 (13% yr/yr) on 6% CC revenue growth. Based on management's targeted 15% operating margin, we believe our forecasts are conservative.

Michael Lachman of **ThinkEquity Partners: BOL: Another Quarter of Solid Execution and Earnings Outperformance**

We maintain our Accumulate rating and 12-month price target of \$71 on shares of Bausch & Lomb following another quarter of EPS upside driven by above-forecast margins. Top-line results were solid, with most business segments reporting in-line with our and consensus expectations, while the dime of earnings upside versus our estimate was driven by higher gross margins and below-forecast operating costs. We anticipate continued sound business execution on the part of management, with further margin improvement to come from the IT platform initiative, offset by pipeline challenges and

the potential for difficult comps through 2005 should the dollar strengthen relative to foreign currencies. Our unchanged 12-month price target of \$71 is based on a small-mid-cap group multiple of 21x applied to our new 2005 EPS estimate of \$3.36.

Investment Highlights: Q2-04 revenue of \$567 million (+10.5%, +8% constant currency) fell just below our projection of \$570 million but above the consensus expectation of \$562 million. Vision Care sales increased 10% (+7% constant currency) to \$302 million, based on continued strength in the lens care category that offset contact lens sales below our forecast. Pharmaceutical revenues were up 11% (+8% constant currency) to \$139 million, driven by Lotemax and the vitamins franchise in the Americas. Surgical sales grew 11% (+9% constant currency) overall to \$125 million, driven by worldwide refractive sales that benefitted from strong growth dynamics and demand trends in the Americas.

EPS of \$0.76 handily beat our estimate of \$0.66 and consensus estimate of \$0.65, driven primarily by higher gross margins and lower operating costs. The dime of earnings upside in the quarter can be attributed to: (1) Gross profits \$2.3 million above our expectation (EPS impact of \$0.03); (2) SG&A spending \$4.7 million below our forecast (EPS impact of \$0.06); and (3) R&D spending \$3.9 million below our forecast (EPS impact of \$0.05). Net below-the-line expenses \$3.4 million above our forecast had a negative EPS impact of \$0.04. Favorable mix shifts and cost savings drove gross margin upside, while the lower R&D expense in Q2 arose substantially from timing issues and should increase as clinical activities pick up in H2-04. Foreign currency contributed \$0.05 to year-over-year earnings growth, representing about 9 percentage points within the overall EPS growth of 43% in Q2 (FX impact on EPS growth is an important metric for many companies, including Bausch & Lomb, although few companies actually disclose this figure).

Valuation and Price Target: We are maintaining our 12-month price target of \$71 on Bausch & Lomb shares, which represents 17% upside from current price levels, consistent with our ongoing Accumulate rating. We previously arrived at our \$71 price target by applying a peer group average P/E multiple of 22x on 2004 earnings for small and mid-cap ophthalmic device stocks to our previous 2005 EPS estimate of \$3.23. While the comparable group P/E multiple on 2004 has declined over the past few months from 22x to 21x, our 2005 EPS estimate has increased from \$3.23 to \$3.36. We believe there is still an upward bias to earnings for Bausch & Lomb driven by the potential for continued margin expansion, but remain cognizant of the top-line growth challenges in this story.

Surgical: Within Surgical, cataract/vitreoretinal sales growth of 9% (+6% constant currency) to \$89.5 million was negatively impacted by declines in older IOL products. By geography, sales rebounded with 8% growth in the Americas, and increased 10% (+5% constant currency) in Europe and 10% (+6% constant currency) in Asia. Growth in SofPort and Akreos countered declines in older products. The refractive business, which came in at \$35.6 million (roughly +30%), was particularly strong in the US, with reported revenue growth of nearly 40%. The Asia business continued to recover with

exceptional growth of 24% (+22% constant currency), though against an easier 2003 comp. Sales in Europe were up 2% (flat on a constant currency basis) as higher revenues from Zyoptix upgrades were offset by lower equipment sales in the quarter.

Joanne Wuensch of **Harris Nesbitt: BOL--Expense Management Again Pulls Through**

* **Event:** Bausch & Lomb reported 2Q04 revenue of \$566.5 million (up 10.5%, 8% constant currency), better than our estimate of \$561.0 million. Once again, foreign exchange and rigorous expense management allowed it to pull through EPS of \$0.76 (up 43.6%), topping our \$0.62 and the Street's \$0.64 estimates. Positive foreign exchange tailwind contributed approximately \$0.05 to the bottom line. Better-than-expected Vision Care and Cataract results offset lower-than-expected pharmaceutical and refractive results.

* **Impact:** Neutral to positive.

* **Forecasts:** Our 2004 revenue and EPS are increased to \$2.22 billion (up 10%) and \$2.84 (up 27.4%) from \$2.21 billion and \$2.72, respectively. For 2005, our revenue and EPS are increased to \$2.4 billion (up 7.9%) and \$3.19 (up 14.3%) from \$2.38 billion and \$3.09. For 2006, our revenue and EPS are increased to \$2.58 billion (up 7.8%) and \$3.60 (up 14.8%) from \$2.57 billion and \$3.43.

* **Valuation:** Our \$63 price target is predicated on 20x our 2005 EPS estimate of \$3.19, or a premium to its long-term EPS growth rate of 15% (the ophthalmology group is currently trading at 1.2x 2005 PE/Growth).

* **Recommendation:** While we commend management on its cost control efforts and would like to be more constructive on the name, our stock picking criteria is conducted on a relative basis. We believe a few of the company's competitors have a more attractive risk-reward profile to drive accelerated growth; consequently, we maintain our NEUTRAL rating on BOL shares in a Positive rated sector.

7/29 **STAAR Surgical Company** announced financial results for its second quarter of 2004, which ended July 2, 2004. Total product sales for the second quarter were \$12.0 million compared with \$13.0 million reported for the same quarter last year and \$13.6 million reported for the first quarter of 2004. Excluding the impact of changes in currency, second quarter 2004 sales were \$11.7 million. Total revenues for the second quarter of 2003 were \$13.0 million and included royalties previously generated by technology licenses that terminated as of March 31, 2003.

Net loss for the quarter was \$3.4 million (18 cents per share) compared with a net loss of \$1.2 million (7 cents per share) for the same period one year ago and a net loss of \$1.3 million (7 cents per share) reported for the first quarter of 2004.

"While international sales of our Visian ICL (ICL) continue to grow and were up 22% during the quarter, the IOL market, particularly in the U.S., remains a challenge," said David Bailey, president and CEO of STAAR Surgical. "We believe that we will begin to see some positive momentum in U.S. IOL sales as we near the end of the year. On the very positive side, we were once again pleased to see that our preloaded silicone product continued to gain traction with cataract surgeons in international markets. Although we have yet to see the positive impact from the launch of the aspheric version of this lens in the Japanese market by our joint venture company **CANON-STAAR**, the lens debuted at the JSCRS conference in June and generated a considerable level of interest," said Bailey.

"We remain focused on the potential fourth quarter launch of the ICL in the United States," said Bailey. "Our recent private placement transaction has put us in a strong financial position to be able to make additional investments, wherever necessary, so that we will be well prepared to fully support the product in the U.S."

Update on FDA ICL Approval Process: On June 17, 2004, the FDA completed its pre-approval inspection of STAAR Surgical company's Nidau, Switzerland manufacturing facility, which was conducted June 14-17, 2004. The FDA issued no Form 483 observations at the conclusion of the audit. (A Form 483 is issued when violations of Quality System and Good Manufacturing Practices requirements are observed.)

In addition, the FDA began its re-inspection of the Monrovia, California facility on July 28, 2004. The company plans to file a report on Form 8-K when the audit is completed.

As previously disclosed, on April 26, 2004, the company received a second Warning Letter from the FDA relating to events that occurred from 1997 through 2001 concerning procedures of the company. The company has recently received notification from the FDA indicating that the agency is satisfied with the company's plan for response to the issues raised in the letter.

"We remain focused on working closely with the FDA to move the approval process for the ICL along as quickly as possible," continued Bailey. "The successful audit of our Nidau facility and the FDA's acceptance of our response plan to their April Warning Letter give us confidence that we are making steady progress. We are also pleased that the FDA has been able to begin the Monrovia re-audit within the timeframe that we had requested. We believe that we remain on track to officially launch the ICL in the U.S. during the fourth quarter of this year," said Bailey.

Looking ahead, Bailey offered this updated outlook for the remainder of 2004.

"While we continue to believe that we are in a strong position to be able to launch the ICL shortly after receiving approval from the FDA, we also believe that it is most prudent for us to provide conservative revenue guidance without any U.S. ICL contribution. Without U.S. ICL sales, we now believe that as a result of the second

quarter financial results our full year sales will be approximately flat compared with 2003. This estimate takes into account the continued challenges in the U.S. cataract market as well as the seasonality associated with our upcoming third quarter, particularly in international markets. Based on this expected revenue, a slightly improving gross profit and a gradual reduction of compliance expenditures we expect the net loss for the year to be approximately between \$0.52 and \$0.55 per share," concluded Bailey.

Two analysts offered their views on the Staar Surgical financial release:

John Calcagnini of CIBC World Markets: STAA: Reports Lackluster Quarter; Lowering Revenue and EPS Estimates

STAA reported 2Q04 revenues of \$12 million, down 7% from a year ago, which was below our and the Street estimate of \$14 million. Excluding the positive effect of foreign currency of \$276,000, revenues dropped 9%.

ICL sales were up 21.5% to \$1.1 million versus \$866,000 a year ago, but flat sequentially. The ICL has yet to be approved in the U.S., given the company had to have re-audits done by the FDA of its facilities following the FDA warning letter earlier this year.

Net loss for the quarter was a disappointing \$3.4 million, or \$0.18 per share. We were estimating a net loss of \$1 million, or \$0.05 per share. Gross margin was below expectations at 51.1% versus 54.5% last year and the 55% we were estimating.

The company lowered guidance for 2004 and now expects sales to be flat as compared to 2003's. The company also expects a net loss per share of \$0.52 to \$0.55. We are lowering our 2004-05 revenues and EPS estimates based on revised guidance and lower gross margins.

Joanne Wuensch of Harris Nesbitt: STAA--2Q04 Disappoints; Lean Times Until Visian Launch

* **Event:** STAAR reported 2Q results that disappointed, as resource constraints and a competitive environment held back financial performance. Revenue in the quarter was \$12.0 million (down 7.2%; down 9.3% on constant currency), which was below our and the Street's estimate for \$13.8 million. A reported loss per share of \$0.18 in the quarter was also much wider than our estimate for a loss of \$0.06 and the First Call consensus for a loss of \$0.07.

* **Impact:** Negative.

* **Forecasts:** In 2004, our revenue and EPS decreases to \$50.9 million (up 0.9%) and a loss of \$0.53 from \$56.1 million and a loss of \$0.18. In 2005, our revenue and EPS

decline to \$64 million (up 25.7%) and a gain of \$0.08 from \$69 million and \$0.14. We are introducing a 2006 revenue and EPS estimate of \$73 million (up 14.1%) and \$0.22.

* **Valuation:** STAA trades at 1.5x our 2005 revenue estimate.

* **Recommendation:** While we believe that the market opportunity for phakic IOLs might be small -- it should be profitable. However, the competitive landscape (e.g., the potential for Advanced Medical Optics to enter the market first with a competing phakic IOL), the ongoing stagnation of the company's core business, followed by commercialization risk once the Visian is approved leads us to maintain our NEUTRAL rating.

7/30 **Refractec Inc.** reported that during the first half of 2004, the company had experienced an increase of more than 131% in the number of NearVision CK procedures performed, totaling 12,778, as compared with the first half of 2003. Ninety-seven ViewPoint CK Systems were sold so far in 2004, a number that also reflects an increase from 2003. At present, approximately 55,000 CK procedures have been performed worldwide.

7/30 **Carl Zeiss Meditec AG**, announced that it would be equipping a modern ophthalmic practice, free of charge for the duration of the Olympic Games.

Optimum eyesight is indispensable for peak performance in most sports. To ensure proper medical care, both for the purposes of advance treatment and unforeseen problems, Dr Volker Rasch, Director of the Potsdamer Augenklinik (Ophthalmic Clinic) im Graefe-Haus GmbH, will be setting up an ophthalmic practice for the duration of the Summer Games in Athens. With this facility, the experienced eye specialist is ensuring that athletes and spectators receive comprehensive information and optimum treatment in emergencies, together with expert advice on advanced medical methods such as laser treatment. Ulrich Krauss, president and CEO of Carl Zeiss Meditec AG, puts the venture into perspective: "The athletes are expected to achieve peak performance; their eyesight should therefore receive the treatment afforded by top quality equipment. That is in line with our goal of giving everyone perfect eyesight. So we didn't hesitate for a moment in providing our most advanced equipment for the ophthalmic practice at the Deutsches Haus in Athens."

The Deutsches Haus, a facility provided by the German National Olympic Committee (NOC), has been in existence since 1988 and is the central meeting point for athletes, commercial partners and media representatives during the respective Olympic Games. The Deutsches Haus in Athens is located on the premises of the German School, midway between the Olympic sports complex and the International Media Centre.

7/31 According to *OptiStock*, **VisiJet** announced initial sales of more than \$600,000 from its worldwide distribution agreement rights to the Epi-Tome and LasiTome products from **Gebauer Medizintechnik GmbH** of Germany. company officials said they anticipate a rapid increase in international sales as distributors continue to open new accounts and also produce repeat purchases. The company expects to generate "significant sales" in the

U.S. shortly. The Epi-Tome and LasiTome products are considered the next generation technologies in the ophthalmic surgical market, entering a growing \$4 billion refractive surgery market.

- 8/2 **NovaMed, Inc.** announced that it had acquired a majority interest in both the Center for Reconstructive Surgery located in Oak Lawn, Illinois and the Palm Beach Outpatient Surgery Center located in Lake Worth, Florida. Terms of the transactions were not disclosed.

"The Center for Reconstructive Surgery is a large, multi-specialty surgery center with four operating rooms serving the Chicago market," said NovaMed chairman, president, and CEO Stephen Winjum. "With over 200 surgical procedures performed per month at this surgery center we expect this acquisition to be immediately accretive to our earnings and we believe there is significant capacity for growth. We are excited about the opportunity to work with our new partner, Dr. James Schlenker, to attract new physicians to this surgery center who will be able to utilize the available excess capacity," said Winjum.

"The Palm Beach Outpatient Surgery Center is a high volume ophthalmic surgery center serving the attractive and growing Palm Beach County market," said Winjum. "With over 500 ophthalmic surgical procedures performed per month at this surgery center we also expect this acquisition to be immediately accretive to earnings. We look forward to working with our new partner, Dr. Tom Coffman, to maximize the operating efficiency and continue the growth momentum of this surgery center."

"Counting these two acquisitions, we have now added five ambulatory surgery centers to our portfolio this year," commented Winjum. "I am excited about our progress and optimistic about us continuing to execute our external growth strategy with our capital resources and deal making ability."

- 8/2 **Refocus Group, Inc.** announced that the company and its Scleral Spacing Procedure are profiled in "**Trends In Ophthalmic Surgery: The Grey Population**," a newly released report from *Clinica Reports*, a leading publisher of business and market intelligence reports for the global medical device and diagnostic industries. The report provides insights into emerging and early-stage technologies and profiles nine "leading companies competing in the ophthalmic surgical arena."

In the report, Refocus Group's Scleral Implant and Scleral Spacing Procedure is discussed as a potential treatment for three critical eye disorders: presbyopia, primary open-angle glaucoma and ocular hypertension. These eye disorders are becoming far more prevalent as the world's "Baby Boomer" population ages. The report notes that "the potential market size for refractive surgical solutions aimed at correcting presbyopia is huge, considering that the risk of developing presbyopia in later life is virtually 100 percent." As a result, "it is believed that the surgical market for presbyopic correction will

gather momentum at a much faster speed than it originally did for LASIK," the report states.

"Advances in ophthalmic surgical technology have produced more efficient and less invasive procedures that minimize pain and result in improved patient outcomes, fewer post-surgical complications and faster recovery times," said Petula Coutinho, senior analyst for Clinica Reports. Clinica Reports is part of **PJB Publications**, a business unit of **Informa Group PLC** in the United Kingdom.

"Refractive surgeons have long viewed presbyopia as the 'Holy Grail,' the last frontier in eye care, while glaucoma remains a leading cause of blindness impacting between 100 and 150 million people worldwide as reported by Clinica Reports," said Terry Walts, president and CEO of Refocus Group. "This new report correctly notes the promising results for our technology to treat both presbyopia and glaucoma -- and potentially without the inherent limitations, complications and/or irreversibility of alternative approaches available or under development today."

As previously announced, Refocus Group is currently conducting U.S. Food and Drug Administration Phase II clinical trials of its Scleral Implant and Surgical Spacing Procedure for the treatment of presbyopia. The company's ability to continue the clinical trials is subject to obtaining adequate financing.

- 8/2 **The Lasik Vision Institute** announced that it was launching a patient education campaign as it opens new facilities in California and Texas. Live demonstrations of LASIK procedures and free seminars led by the surgeons performing them are among the activities planned for members of the public and other guests who attend The Lasik Vision Institute grand openings throughout August in San Diego, Houston and San Antonio. The campaign is designed to dispel the myths about LASIK.

"LASIK has grown in popularity in recent years, yet the procedure remains a mystery to many people who are considering giving up their use of eyeglasses," said Jim Usdan, The Lasik Vision Institute president and CEO. "As The Lasik Vision Institute expands to new markets, we want to showcase some of the world's most experienced surgeons by letting them demonstrate how simple, fast and effective LASIK is, thereby reducing the fear factor for many prospective patients."

"We encourage the public to meet our experienced surgeons and ask questions so they can better understand what LASIK involves and determine if it's right for them," said Amy White, The Lasik Vision Institute national operations director. "What better time than the celebration of our grand openings to provide that opportunity."

- 8/3 **LCA-Vision Inc.** announced the opening of two new LasikPlus vision centers in Jacksonville, Florida and St. Louis, Missouri. The new vision centers are equipped with technologically advanced lasers and diagnostic equipment, offering patients a wide choice of traditional laser vision correction and advanced custom procedures. Joseph

Faust, MD, leads the Jacksonville medical team, and Therese Alban, MD, heads the St. Louis medical team. Both Drs. Faust and Alban are board-certified ophthalmologists and have each performed thousands of refractive procedures.

"Expanding into new markets is integral to our strategy of capitalizing on the significant growth opportunity we see in laser vision correction services, as more customers learn about the benefits of laser vision correction and choose to have lasik," said Stephen Joffe, chairman and CEO of LCA-Vision. "Through our LasikPlus business model, we have the ability to offer patients in these two new markets a broad selection of advanced laser and diagnostic technology, a range of affordable prices and various payment programs. We select new locations for vision centers based on an analysis of various criteria that we believe will allow us to reach breakeven within six months of opening. We have now opened five vision centers in 2004 to-date, and are on track to meet our previously announced target of opening six to eight vision centers in 2004."

LCA-Vision currently operates 43 laser vision correction centers, including 39 wholly owned LasikPlus vision centers located in large metropolitan markets throughout the United States, three joint ventures in Canada and one joint venture in Europe.

8/4 *The Department of Veterans Affairs (VA)* has announced a new policy requiring optometric laser surgery to be performed only under the supervision of an ophthalmologist. This VA limitation follows months of debate on the issue and concerns raised by the VETS Coalition, led by the *American Academy of Ophthalmology*, congressional leaders and veteran service organizations.

The VETS Coalition has been fighting for nothing short of surgery by surgeons and remains dedicated to that principle and to the right of veterans to the highest quality of care. "This directive represents a significant step by the VA to resolve a serious patient safety issue; however, the VETS Coalition does not believe that optometrists, practitioners who do not attend medical school or fulfill surgical residencies, have the proper training and education to perform invasive eye surgery," said Michael Maves, MD, executive vice president for the *American Medical Association*.

The VETS Coalition has sought to work with VA leadership on resolving this veterans' safety issue, and will continue to do so in the weeks ahead. In light of VA's intention to proceed with this directive's approach despite VETS Coalition concerns, there remain several minimum level provisions that must be addressed before implementation to reduce the likelihood of a bad surgical outcome for veterans subject to optometric surgery. These include establishing minimum optometric education and training standards and requiring direct ophthalmic supervision. In its current form, the directive does not adequately define supervision, so it could range anywhere from "direct", in which a U.S. licensed ophthalmologist is in the operating room, to a mere reporting structure.

"We believe that an ophthalmologist-led team is the best way to ensure quality eye care for veterans, but allowing optometrists to perform invasive eye surgery—even with

ophthalmologic supervision—lowers the bar and goes against the standard of care in 49 out of 50 states and in the U.S. military," said Dunbar Hoskins Jr., MD, executive vice president of the Academy. "The directive also raises a number of questions about the implementation of this policy. For example, with multiple levels of supervision existing within the VA, this policy is vague on the extent of those requirements. It also establishes two standards of care. Some facilities will have properly qualified and trained ophthalmologists doing procedures, while others could allow less qualified optometrists to perform invasive procedures under a vague supervision requirement. We will closely monitor the developments as the VA works to further clarify and define these and other issues."

This controversy began when the ophthalmology, medical, and veterans' communities learned that in April 2003, contrary to state law, an Oklahoma-licensed optometrist in a Kansas VA facility had been privileged for and was performing laser eye surgery on veterans. The VA credentialing system permits facility directors to privilege practitioners up to their full license, despite the fact that Kansas law specifically prohibits optometrists from performing such invasive surgery. This immediately raised patient safety concerns within the medical community and among veterans.

"Along with the VETS Coalition, we will be examining the implications of this precedent-setting policy and its impact on veterans' safety," said Thomas Russell, MD, executive director of the *American College of Surgeons*. "We are not done in this process. We have many questions that need to be answered, and we will continue our efforts to assure the safety of our nation's veterans."

8/4 **NovaMed, Inc.** reported results for the second quarter and six months ended June 30, 2004. Net income from continuing operations in the second quarter of 2004 increased 5% to \$828,000 (4 cents per share) from \$790,000 (4 cents per share) in the prior year second quarter. The second quarter results for 2004 included a pre-tax loss on the sale of minority interests of \$27,000.

For the second quarter ended June 30, 2004, total net revenue increased 10% to \$15.5 million from \$14.0 million for the prior year second quarter. Net revenue from surgical facilities was \$11.1 million, up 20% from \$9.3 million in the prior year second quarter. This revenue increase was primarily due to a 25% increase in total surgical procedures performed in the second quarter of 2004 as compared to the same period in the prior year. On a same-facility basis, surgical facilities net revenue increased 8% over the prior year second quarter. Product sales and other revenue was \$4.3 million in the second quarter of 2004, down 9% over the prior year second quarter. Operating income in the second quarter of 2004 increased 28% to \$2.5 million, or 16% of net revenue, from \$2.0 million, or 14% of net revenue, in the same period last year. Minority interest in the second quarter of 2004 was \$1.2 million, up 74% over the prior year second quarter. This increase is due to the sale of minority interests in existing surgical facilities in 2003 and 2004 as well as surgical facilities acquired in 2004.

Net income from continuing operations for the six months ended June 30, 2004 increased 17% to \$1.6 million (7 cents per share) from \$1.3 million (6 cents per share) for the six months ended June 30, 2003. The results for the first six months of 2004 and 2003 included pre-tax net gains on the sale of minority interests of \$163,000 and \$115,000, respectively.

For the six months ended June 30, 2004, total net revenue increased 8% to \$29.7 million from \$27.5 million for the six months ended June 30, 2003. Net revenue from surgical facilities was \$20.5 million, up 15% from \$17.8 million in the first six months of the prior year. This revenue increase was primarily due to a 19% increase in total surgical procedures performed in the first six months of 2004 as compared to the same period in the prior year. On a same-facility basis, surgical facilities net revenue increased 8% over the first six months of the prior year. Product sales and other revenue was \$9.2 million in the first six months of 2004, down 5% over the same period in the prior year. Operating income in the first six months of 2004 increased 28% to \$4.3 million, or 15% of net revenue, from \$3.4 million, or 12% of net revenue, in the same period last year. Minority interest in the first six months of 2004 was \$1.9 million, up 54% from the same period last year.

"I am pleased with the progress we are making in our core surgical facilities business," commented Stephen Winjum, NovaMed chairman, president and CEO. "In the second quarter, our same-facility revenue growth of 8% and our overall facility revenue growth of 20% remains strong as we continue to pursue growth opportunities within our existing portfolio of 22 surgery centers. With our recent acquisition of two additional surgery centers, I am also pleased with the results of our acquisition efforts so far this year. As with the previous three acquisitions we closed in the second quarter, we expect these two acquisitions to be accretive to earnings immediately. We remain committed to finding attractive acquisition and development opportunities that will contribute to our growth momentum. We have the capital and deal pipeline required to continue to execute our external growth strategy."

8/5 **Lasik America, Inc.** announced that it had completed the merger of **Salus Holding, Inc. (Salus)** into a wholly owned subsidiary of Lasik America as detailed on Lasik America's Form 8K as filed with the Securities and Exchange Commission. Pursuant to the terms of the merger, Salus merged into a wholly owned subsidiary of Lasik America and in exchange the sole shareholder of Salus, **Homeland Security Technology, Inc.**, was issued shares of Lasik America's Common Stock that approximate 43.7 percent of the outstanding shares of Lasik America calculated on a fully diluted basis. In addition, Ernest Remo, former president and chairman of the Board of Directors of Salus, has assumed the position of CEO and chairman of the Board of Directors of Lasik America. Howard Silverman has assumed the position of president and member of the Board of Directors of Lasik America.

Salus is the sole shareholder in **Icon Salus Srl**, a company formed under the laws of Italy (Icon Salus). Icon Salus owns a dialysis clinic in Italy as well as the rights to acquire additional dialysis clinics.

"This is a very exciting time for Lasik America. With the consummation of the merger, we are now positioned to bring Lasik America to the next level with a diversified business model," said Ernest Remo.

As of the consummation of the merger, Lasik America has issued a total amount of stock in the amount of 4,260,000 shares of which in excess of 3,200,000 is held by affiliates and is subject to restriction.

8/6 **VisiJet Inc.** announced that **LibertyView Special Opportunities Fund, LP**, advised by **LibertyView Capital Management**, a division of **Neuberger Berman**, and other institutional investors, have provided a total of \$2 million in financing to the company in two separate transactions. The investments are in the form of convertible debentures with warrants. According to Randy Bailey, president and CEO of VisiJet, the financing will be used for working capital to assist in the development of the company's growth and infrastructure.

"The funds are being used to support the creation and training of a direct U.S. sales force as well as to increase our inventory of **Gebauer** Epi-LASIK products for sale," Bailey said. "We anticipate a similar positive reaction to the products here in the United States as we experienced internationally." VisiJet recently signed an agreement with Gebauer Medizintechnik GmbH of Neuhausen, Germany for the worldwide distribution rights of their Epi-LASIK products -- "next generation" LASIK surgical devices that are part of the \$4 billion refractive surgery market.

Bailey added that the capital will also aid in the continuing development of the Pulsatome and HydroKeratome, devices that use VisiJet's proprietary waterjet technology. "The financing will assist us to initiate animal studies shortly at the University of Utah in Salt Lake City for the Pulsatome, which is used to remove cataracts." He added that he expects the technology to enter the growing \$9 billion cataract market next year.

8/8 Privately-held **Refractec Inc.** reported record sales and procedures performed with its proprietary ViewPoint CK System, the first and only FDA-approved vision technology for those with near vision loss due to the age-related eye condition presbyopia. The Ophthalmic device manufacturer reported gross revenue increased by more than 64% to \$7.9 million in the first half of 2004, compared to \$4.8 million in the same time period 2003. The number of NearVision CK procedures performed increased than 131% to 12,778 for the time period providing a rise in annuity gross revenue of more than 175%. NearVision CK was approved by the FDA in March 2003.

8/8 *EyeWorld Week* reported that **BTG** (West Conshohocken, Pa.), an intellectual property and technology commercialization company, plans to commercialize fundamental patents

around conductive keratoplasty (CK) technology. BTG is licensing the CK patents from **RJF Holdings**, owned by Richard Fugo, MD, which is currently in litigation with **Refractec** (Irvine, Calif.) over alleged infringement of the CK patents. BTG is actively seeking to realize the value of these patents. RJF Holdings said Dr. Fugo received two patents in 1995 for methods of incising ocular tissue using radio frequency energy and for performing surgery on a corneal stroma layer using radio frequency energy.

8/9 **LCA-Vision Inc.** reported that it expected full-year 2005 fully taxed earnings per share growth of 40% to 50%, compared with full-year 2004 earnings per share at a pro forma fully taxed rate of 39% and excluding the benefit from the reversal of the deferred tax valuation allowance in the first half of 2004. The company confirmed expectations for revenue growth in 2005 of 30% to 40%, compared with anticipated revenue for the 2004 full year of \$121 million to \$123 million.

LCA-Vision also reiterated guidance of full-year 2004 reported earnings per share of \$2.05 to \$2.15, including \$0.76 per share recorded in the first half of 2004 for the reversal of the deferred tax valuation allowance and a first half 2004 tax rate of 7%, and reflecting a presumed 39% tax rate for the second half of 2004.

"Because 2004 reported bottom-line results will reflect a one-time tax benefit and a partial tax rate for the first six months of 2004 and a full tax rate for the balance of 2004, we want to clarify the basis of our projected earnings growth," said Stephen Joffe, chairman and CEO of LCA-Vision. "In comparing 2005 with 2004, we expect 30% to 40% revenue growth from our current projections of \$121 to \$123 million in 2004, and we expect 40% to 50% EPS growth from \$0.95 to \$1.05 pro forma 2004 results."

In reviewing LCA-Vision's reported and anticipated financial results for 2004, please note the following:

-- For the first quarter of 2004, LCA-Vision reported earnings per diluted share of \$0.93, or \$0.50 excluding the income tax benefit. Based on a pro forma 39% tax rate and excluding the income tax benefit, LCA-Vision would have reported first quarter earnings per share of \$0.31.

-- For the second quarter of 2004, the company reported earnings per share of \$0.78, or \$0.45 excluding the income tax benefit. Based on a pro forma 39% tax rate and excluding the income tax benefit, LCA-Vision would have reported second quarter earnings per share of \$0.30.

-- For the second half of 2004, LCA-Vision expects to report earnings per diluted share on a 39% tax rate of \$0.34 to \$0.44.

-- As such, in order to facilitate comparisons to financial results in 2005 and beyond, the company notes full-year EPS with a pro forma 2004 full-year 39% tax rate and excluding the income tax benefit are projected to be \$0.95 to \$1.05.

8/9 **TLC Vision Corporation** announced its financial results for the three month and six month periods ended June 30, 2004. Q2-04 total net revenues were \$64.7 million, up 36% from \$47.5 million in the second quarter of 2003. Second quarter total paid laser procedure volumes were over 51,600. Same-store year-over-year volume growth of 24% in the centers was partially offset by 9% year-over-year volume growth in the access business. The result was that Q2-04 total procedure volumes were up 16% from 44,500 for the same three month period a year ago. The procedure volume mix in Q2-04 was 59% centers versus 41% access. CustomLASIK procedures represented approximately 52% of center volumes in Q2-04.

TLCVision reported a Q2-04 net profit of \$6.2 million (9 cents per share) compared to a loss of \$3.5 million (5 cents per share) reported in last year's second quarter. The Q2-04 net profit included restructuring, severance and other charges totaling \$2.8 million (4 cents per share) primarily related to future severance payments associated with the planned retirements of Charles (Chuck) Bono III as CFO and Robert May as General Counsel. The effect of these charges was partially offset by a positive gain of \$1.2 million (2 cents per share) due to the reversal of a reserve for long-term receivables.

Second quarter 2004 adjusted EBITDA was \$13.1 million, up 272% from the \$3.5 million reported for the same three month period last year.

For the six months ended June 30, 2004 paid laser procedure volumes were over 108,500 and total net revenues were \$129.8 million. This compared to paid laser procedure volumes of 98,000 and total net revenues of \$101.1 million for the comparable period of the prior year. The net profit for the six months ended June 30, 2004 was \$14.3 million (20 cents per share) compared to a net loss of \$2.4 million (4 cents per share) for the same period last year.

Elias Vamvakas, TLCVision's chairman, commented "I am very pleased with what we have accomplished thus far in 2004. Adjusted EBITDA for the first six months of 2004 alone has already exceeded that achieved for the entire 2003 year by 48%, or \$8.6 million. Now into our third quarter, early indications are that year-over-year growth trends will continue. I remain confident that we will continue to build on TLCVision's world-leading position going forward."

The company also announced that **OccuLogix, Inc.** (formerly **Vascular Sciences Corporation**) and TLC Vision Corporation intend to file a registration statement with the U.S. Securities and Exchange Commission, whereby it proposes to offer and sell its common stock in an IPO. OccuLogix, Inc. is an ophthalmic therapeutic company founded in 1996 to commercialize innovative treatments for eye diseases.

8/10 According to the August issue of *Ophthalmic Market Perspectives*, refractive procedures soared in the second quarter of 2004. Improvements in consumer confidence, excitement over wavefront driven LASIK (WFL), and increased advertising helped boost refractive procedures to 341,300, up 21.6% over the same quarter last year. Including U.S. patients

traveling to Canada and Mexico, Q2 procedures were 348,100, up 21%. However, procedures declined 9.3% compared to the seasonally stronger first quarter.

While many low-volume surgeons stopped offering LASIK during 2001 and 2002, the improving economic conditions have reversed the trend and the number of U.S. laser centers (both private and corporate) climbed slightly to 1227, up six from the 1221 operating in Q1, and the 1192 in Q2 2003.

An estimated 34 new lasers were sold in the U.S. in Q2, compared to 24 for the same quarter a year ago.

Wavefront-driven LASIK continues to increase, with VISX reporting that 35% of procedure cards during the quarter were for CustomVue, while Alcon reported that 45% of procedures on its lasers were CustomCornea. The total number of WFL rose to 39.5% during the quarter, up from 37.7% during Q1. The average price of LASIK procedures decreased slightly to \$1785, reflecting the leveling off of higher priced WFLs and increased competition. Dave Harmon now forecasts that 1.35 million procedures will be done this year, for a growth of 17% over 2003.

8/12 In the first nine months of the current financial year ending 30 September, **Carl Zeiss Meditec AG** once again was profitable. The leading global provider of systems for the diagnosis and treatment of eye ailments doubled its consolidated net income to E 9.4 million (previous year: E 4.7 million). Consequently, there was also a significant increase in earnings per share. The latter amounted to E 0.33 (previous year: E 0.18). At E 18.9 million, earnings before interest and tax (EBIT) remained more or less at last year's level of E 19.3 million. However, the EBIT margin improved to 11.1% (previous year: 10.9%). The strong euro resulted in a 3.1% decline in group sales to E 170.4 million (previous year's figure E 175.9 million). Had exchange rates remained constant, sales would have increased by 3.7% to E 182.3 million. The positive results are mainly attributable to the increased gross margin due to innovative products and reduced manufacturing costs. In the first nine months of the current financial year the gross margin improved to 45.9% (previous year: 42.9%). This enabled investments to be increased in the R&D and Marketing & Sales sectors without having an adverse effect on profits.

According to Ulrich Krauss, president and CEO of Carl Zeiss Meditec: "We have significantly improved our profitability and at the same time invested more in the future. Sales successes in Asia and America demonstrate that our investments are already paying off. On top of that, we launched three new products on the market in the third quarter alone."

USA remains most important sales market - healthy growth in Asia: With a share of 47.7% in group sales the USA - the largest part of the Americas region - was once again the main focus of Carl Zeiss Meditec's sales. The 11.3% decline to E 80.8 million (previous year: E 91.1 million) was due to the adverse conversion rate from the weak US

dollar. Adjusted for the effects of exchange rates and OEM supplies in the previous year that were canceled by Carl Zeiss Meditec, this item would have shown a 13.6% growth in sales. Sales in Asia increased by 16.2% to E 45.2 million (previous year: E 38.9 million). European sales revenue of E 32.5 million remained at the previous year's level (E 32.7 million) and in Germany there was a 10.0% decrease that can be attributed primarily to the continued discussion on reforms in the health care system. Revenues in Germany stood at E 12.0 million (previous year: E 13.3 million).

Sound financial structure further improved: Thanks to operative cash flow amounting to E 17.3 million (previous year: E 19.2 million), cash and cash equivalents reached the record level of E 47.3 million (30 September 2003: E 45.0 million). Net debt decreased by more than two thirds to E 7.5 million (previous year: E 24.2 million). The equity ratio rose to 62.4% (30 September 2003: 59.0%).

R&D activities intensified: Numerous R&D projects have been stepped up since the start of the financial year in order to lay the foundations for proposed continued growth. This caused R&D expenses to increase to E 18.3 million (previous year: E 16.8 million) and the R&D ratio rose to 10.7% (previous year: 9.6%). Major projects have been brought to a successful close. For example, in the third quarter three new products VISUPAC 4.0 software, ACMaster and the PreviewPHP diagnostic system were launched on the market. Further progress was made with US approval of the MEL 80 refractive laser. The US health authority FDA gave the green light to an approval study in which the good treatment results of the MEL 80 were taken into account. For this reason the FDA requires, for example, only relatively short follow-up periods after the required treatments.

Together with the American company **Calhoun Vision, Inc.**, Carl Zeiss Meditec is working on the development of a new type of intraocular lens (IOL) whose refractive power can be adjusted after the cataract operation without the need for further surgical intervention. This could enable an additional customized treatment of vision defects.

Outlook - significant increase in profitability: Due to exchange rate trends, group sales for the year as a whole are expected to equal, at most, the previous year's level. On the basis of constant exchange rates, however, this item would show a net increase in group sales over the previous year. There will be a further enhancement in profitability and a distinct improvement in the return on sales.

8/16 Michael Eidam of *BusinessWeek Online* wrote about **VISX** and the refractive eye business in his story, **A Sharper Eye for Growth**.

Improvements in laser surgery and new treatments for other vision problems make outfits like VISX and **Alcon** worth watching. Lasik eye surgery suffered a black eye in recent years after deep discounters flooded the market, offering the procedure at cut-rate prices -- and with lower success rates. The press jumped on cases of unhappy patients dealing with unwanted side effects. To make matters worse, the economy soured and, since the

surgery is discretionary, Lasik-derived revenues tailed, dragging down the stocks of companies such as VISX (EYE) and **TLC Vision** (TLCV).

But in 2003, with the economy reviving and many deep discounters forced out of business by lawsuits and controversy, refractive eye surgery staged a comeback -- part of a surge in sales for the eye-care industry. The turnaround is driven in part by new, custom LASIK surgery, which has increased the number of patients eligible for treatment and raised the percentage who achieve 20/20 vision without those unpleasant side effects.

BRIGHTEST LIGHT. New technology allows doctors to create a three-dimensional map of the cornea and treat each patient's specific vision problem much more precisely than in the past. Custom LASIK -- laser-assisted in situ keratomileusis, to give it the medical name -- has "made people feel comfortable with the surgery," says Joanne Wuensch, an analyst with **Harris Nesbitt**.

Michael Lachman, an analyst with **ThinkEquity Partners**, forecasts about 10% to 12% growth in LASIK procedures in the second half of this year, and 6% to 7% next year -- perhaps more, if the economy regains steam.

With stabilized prices and greater demand, VISX (EYE) is one company getting a boost. The Santa Clara, Calif.-based manufacturer of the laser systems used in the procedure dominates the market with the largest installed base of lasers in the U.S. On July 21, VISX reported a 133% increase in net income, to \$9.5 million. This came on a 34% percent increase in revenues, to \$43 million, for second-quarter 2004. VISX collects a fee for each procedure performed, so its profits will rise in step with Lasik's popularity. The stock is trading at around \$19 per share -- near its 52-week low of \$17.

PUPILS OF PROFITS. TLC Vision (TLCV), the largest provider of LASIK surgery, is also poised to capitalize on the turnaround. On Aug. 9, the Mississauga, Ontario-based company revealed that second-quarter revenues jumped 36%, to \$67.4 million. In a conference call with analysts that day, CEO Elias Vamvakas said the 16% growth in procedures performed by TLC Vision led to a quarterly revenue gain of more than 30%. The custom LASIK approach continues to evolve, with new procedures representing approximately 52% of total second-quarter volume. Its stock is currently trading in the middle of its 52-week range at \$8 per share.

TLC Vision is causing a stir in the market, too, because of its joint venture with **OccuLogix** (formerly **Vascular Sciences Corp.**). The partnership is focused on developing a treatment for age-related macular degeneration (AMD), the leading cause of blindness in people over 50 and an estimated \$28 billion market.

On Aug. 9, the partners announced that a spinoff of OccuLogix in an initial public offering. Their treatment, called rheopheresis, is currently in clinical trials. If it's approved by the FDA, analysts estimate it could boost TLC Vision's value by another \$5 or \$6 a share. Paul Cohen of **Cohen Independent Research Group**, who has a buy rating

on TLC Vision, figures that at the stock's current price "you're buying the core business at a very reasonable multiple and the option [on rheophoresis] is virtually trading at nothing. I think the stock is extraordinarily undervalued." (Cohen doesn't own the stock or have any investment banking business with TLC Vision.)

EXPANDING MARGINS. Among large-cap stocks, a company worth a look is diversified eye-care giant Alcon (ACL), which does everything from selling contact-lens solution to developing pharmaceutical treatments and manufacturing surgical equipment.

On July 28, Alcon reported a 67.9% increase in net earnings, to \$299.2 million. This was on a 12.3% gain in global sales, to \$1 billion. The FDA recently approved Alcon's lasers to treat astigmatism (nearsightedness), which should halt its recent market-share losses to rival **Bausch & Lomb** (BOL). More importantly, Alcon's profit margins have been going up steadily, Lachman notes.

However, the really sexy story at Alcon's is its possible AMD treatment, known as Retaane. Alcon is expected to announce Retaane's Phase III data in late October. Meanwhile, expectations about the results have helped drive up the stock price.

READY TO RISE? Currently trading at \$74.64 "in the middle of its 52-week range" Alcon is up roughly 50% in the last year. Although that puts it at a premium, vs. its peers, Alcon has been a consistently pleasant surprise to Wall Street. The company's shareprice has fallen from \$87.51 on July 16 as markets generally have dropped. The dip could be a buying opportunity for investors who like Alcon's prospects.

Whether you like your companies big or small, the story's the same these days: The eye-care industry is a sector investors might want to keep an eye on.

8/17 **LCA-Vision Inc.** announced the opening of a new LasikPlus vision center in Kansas City, Kansas, its first facility serving the greater Kansas City area. The new vision center is equipped with technologically advanced lasers and diagnostic equipment, including **Bausch & Lomb**, **VISX** and **Alcon** lasers, offering patients a wide choice of traditional laser vision correction and advanced custom procedures. Stephen Wiles, MD, a board-certified ophthalmologist, leads the Kansas City medical team.

"We see tremendous upside opportunity within the laser vision correction market and are excited about now being able to offer consumers in the greater Kansas City metropolitan area the many benefits LasikPlus provides its patients," stated Stephen Joffe, LCA-Vision chairman and CEO. "To date, only 3 percent of the approximately 150 million Americans who wear eye glasses or contact lenses have elected to have laser vision correction. LCA Vision currently holds a fraction of this highly fragmented and growing market, and we expect to continue to gain market share with our ability to provide patients both a broad selection of advanced laser and diagnostic equipment and excellent clinical outcomes at an affordable price.

"With the opening of this new LasikPlus vision center as well as our recently announced Jacksonville, Florida and St. Louis, Missouri vision center openings, we have met our goal of opening six to eight new laser vision correction centers by the end of this year."

LCA-Vision currently operates 44 laser vision correction centers, including 40 wholly owned LasikPlus vision centers located in large metropolitan markets throughout the United States, three joint ventures in Canada and one joint venture in Europe.

- 8/17 **NIDEK Co., Ltd.** announced that it had shipped its 1,000th NIDEK EC-5000 CXII Excimer Laser System on August 6th, 2004. This milestone marked a very special day for NIDEK and its Refractive Surgery Business Unit. Having launched its first excimer laser some 8 years back, NIDEK has since established itself at the preeminent leader in refractive surgery excimer laser equipment on a global basis. This special milestone establishes NIDEK as the leader in install base and market share units on a global basis.

Hideo Ozawa, president and founder of NIDEK, Motoki Ozawa, R&D Director and General Manager as well as others from the NIDEK Excimer R&D and Manufacturing team presided over a special ceremony marking the official shipping of this special unit -- serial #51048. The unit was specially boxed and crated, Hideo Ozawa and Motoki Ozawa helped with fastening of the final bolts and screws as the unit shipment box as it was prepared for labeling and shipment.

The brand new NIDEK Excimer Laser with NIDEK's state-of-the-art eye tracker and advanced software algorithms -- part of the NAVEX Platform was shipped from Gamagori, Japan bound for Shanghai and then on to the Lin Yi Peoples Hospital in Shan Tong Province in China.

Hideo Ozawa and Motoki Ozawa collectively congratulated the hard work of the R&D and Manufacturing Teams and were quoted as saying, "We did it and we should be proud of our achievements ...this is a great milestone for NIDEK and all our employees and global distributor partners, as we continue to establish a strong and dominant position in terms of global install base, market share and laser placements around the world. China and the emerging markets represent a huge potential for NIDEK, as we continue to deliver advanced refractive surgery technologies with a proven track record for excellent surgical outcomes, outstanding reliability and durability, and a platform for future upgrades and advancements. It is the quality and reputation of our products that precede us and we should work towards that goal in the future."

- 8/19 **LCA-Vision Inc.** announced the Board of Directors voted to approve regular quarterly dividends beginning with a dividend of \$0.08 per share, declared payable on September 9, 2004 to shareholders of record as of September 2, 2004.

"This action on the part of our Board is in recognition of the company's strong financial performance, which has exceeded our projections for growth in revenue and EPS," stated Stephen Joffe, LCA-Vision chairman and CEO. "We are pleased to reward shareholders

with a portion of the cash flow we are generating from our proven business model while meeting our expansion goals and continuing to evaluate opportunistic transactions."

8/19 Kristen Gerencher of **CBS.MarketWatch.com** wrote about the refractive surgery marketplace: **Zooming in on vision correction -- How to weigh various surgery, spending options**

Consumers looking for the right medical and financial fit for vision correction surgery can go cross-eyed considering all the options. Lasik is by far the most popular procedure that surgically corrects most kinds of nearsightedness, farsightedness and astigmatism, with both traditional and "custom" Lasik accounting for 90 percent of vision-correction surgery. But it isn't cheap, is rarely covered by insurance and patients with certain visual characteristics aren't candidates for the procedure.

As workers with prescription eyewear take stock of the remaining balances in their pretax flexible-spending accounts, many are considering whether to have vision-correction surgery, what kind is right for them and whether it pays to delay taking action until next year. Americans pay \$3,570 on average to have Lasik surgery on both eyes and they dig up to \$800 deeper into their pockets to have the newer wavefront-guided Lasik procedure, said Dave Harmon, president of **Market Scope**, an ophthalmology industry research firm in St. Louis. Patients are typically in their late 30s and early 40s, he said. When Lasik first received approval in 1996, "complication rates, though still low, were much higher than they are now," Harmon said, noting that doctors have become better at screening patients.

Those considering pursuing Lasik or other vision-correction surgery are wise not to put it off in hope of seeing major advances just around the corner, he said. "I don't see dramatic improvements on the horizon. I see small, incremental improvements over time."

Weighing cost vs. benefit: Though the upfront fee can be substantial, surgery often drastically cuts spending on glasses and contacts over time, said Dr. Steven E. Wilson, corneal research director and staff refractive surgeon at the Cleveland Clinic's Cole Eye Institute. "There is a financial savings," Wilson said. "Usually people do this for quality of life [reasons,] but as a side benefit you do reduce the cost of taking care of your eyes."

Americans spend about \$2 billion a year on refractive surgery, according to Market Scope. They're expected to have 1.3 million procedures this year, up from 1.15 million last year, Harmon said. As more people consider having laser surgery to shed their glasses and contact lenses, many will find a host of new variations. Here's a look at the latest techniques on the market, their prices and how to tell which one's for you, according to vision-correction experts.

1. Lasik: Lasik surgery, short for laser-assisted-in-situ keratomileusis, begins by using a microkeratome blade to peel back the outer layers of the eye so the doctor can reshape

the cornea underneath with an excimer laser. This flap reattaches to the eye's surface. The procedure, known as "flap and zap" among ophthalmologists, generally takes three minutes for each eye and requires several hours to recover your vision, said Dr. Paul Dougherty, a clinical instructor at UCLA's Jule Stein Eye Institute. "It's not painful when it's happening, but some people can get some discomfort within the first four to six hours," he said.

2. IntraLase: Refers to Lasik surgery that uses a laser to make the flap that lifts the outer eye layers during the first part of the operation instead of the microkeratome blade used in traditional Lasik. There is some conflicting research on this option. Some studies suggest patients who opt for IntraLase have fewer complications and less need to have a follow-up enhancement, Harmon said. Still, some patients have a higher incidence of inflammation under the flap after surgery, Dougherty said.

Perhaps the biggest benefit is psychological for patients squeamish about using a blade, Wilson said. "In some cases, that's the major advantage of the procedure -- it gets by a block that some patients have about laser vision correction." Patients may prefer IntraLase, but they'll often pay a premium for it. "The major downside is it's more expensive," Wilson said. "We charge \$300 more an eye for it."

3. Wavefront-guided or Custom Lasik: A more precise form of Lasik that involves measuring how the eye bends to 200 points of light as opposed to one point in the middle of the eye in conventional Lasik, said Dr. Robert Maloney, spokesman for the American Academy of Ophthalmology. "The pattern of visual impairment in your eye is as different as your fingerprint," he said. "We can literally customize surgery and that makes it more accurate." Custom Lasik patients are less likely to need a touch-up and report better night vision than conventional Lasik patients, Maloney said. Custom treatment isn't yet available for farsighted patients but is expected to be approved by the end of the year, he said. People with thin corneas also may not be candidates.

The extra labor and equipment involved may drive up the price by an additional several hundred dollars per eye. Some doctors assure conventional Lasik patients concerned about having halos that custom treatment is available as a backup, Dougherty said. "I tell my patients we can use it as a safety net if you can only afford conventional."

VISX is the market leader in wavefront-guided Lasik surgery, accounting for 60 percent of lasers used compared with 20 percent provided by **Alcon**, Harmon said. The remaining 20 percent of custom lasers are supplied by **Nidek**, **Bausch & Lomb**, **WaveLight Laser AG** and **LaserSight**, he said.

4. Photorefractive Keratectomy or PRK: This procedure was available prior to Lasik and remains an alternative for many people, especially those with certain eye conditions or thinner corneas, Wilson said. A doctor removes the eye's surface skin with eye drops and performs the corneal reshaping with a laser, though without creating a flap. The downside is PRK causes more pain and is slower to heal. It typically costs the same as conventional

Lasik surgery. Another form of PRK is called Lasek, or laser-assisted subepithelial keratectomy.

5. Conductive Keratoplasty or CK: Those who are over 40 and are farsighted or have presbyopia can have this procedure that uses radio waves to change the shape of the cornea through heat. Designed to improve reading vision, CK is similar in price to Lasik or PRK, but the effect often disappears over time and some ophthalmologists don't offer it. Wilson and Dougherty said they had reservations about the procedure and don't offer it to patients.

New generation lenses: Patients with visual impairments outside the acceptable range for Lasik surgery or who have early cataracts may be candidates for implantable contacts lenses known as ICLs or intraocular contact lenses called IOLs, Dougherty said. The U.S. Food and Drug Administration is expected to approve the first of these implantable lenses at any time. One that's already been approved is Crystalens from **Eyegonic**, the first accommodating replacement lens to provide clear vision at all distances because it's flexible and works with the eye muscles, Dougherty said. To be sure, the Crystalens procedure is pricey -- Dougherty charges \$5,000 per eye -- and has to be done in a surgery center instead of in the doctor's office.

The Cleveland Clinic's Cole Eye Institute is taking a wait-and-see attitude toward the new generation lenses known as Phakic IOLs, Wilson said. While recent trials suggest the lenses now have fewer complications than they did earlier, "I think we need much longer follow-up to know how safe this is for someone who's 20 years old," Wilson said. "We plan on approaching this with caution."

Most accommodating and adjustable lenses, which will change shape by shining UV light on the lens, are still five to 10 years from becoming mainstream options, said Maloney of the American Academy of Ophthalmology. "The problem with any lens or surgery including Lasik is it's not perfectly accurate," Maloney said. "You're never sure you're going to get 20/20. You may still have a little nearsightedness or farsightedness or astigmatism."

Ultimately, patients need to consult with their doctors and take into account their prescriptions, the type of visual problem they have, their age and visual needs to determine which correction makes the most sense to pursue, Dougherty said.

Those shopping for a surgeon are wise to choose one who does the pre-operative and post-operative exams as well as performing the surgery, Wilson said.

8/19 Michael Lachman of **ThinkEquity Partners** issued the following update report on **QLT: QLTi: Downgrade - Stepping Out of the Way of a "Mac Truck"**

We are downgrading shares of QLT, Inc. from Buy to Source of Funds and lowering our price target from \$22 to \$15, in front of the **Eyetechnology**/Macugen FDA panel meeting and

early 2005 product launch, based on recent feedback from retinal specialists. Our change in outlook is driven by two primary factors: (1) the upside in US Visudyne sales from newly reimbursed indications is probably more limited than we previously believed, and (2) despite extensive use of combination therapy, the impact of newly approved drugs on Visudyne sales will likely be greater than previously forecast. We recognize that the sell-off in the stock over the past four months already reflects some of these concerns, and that the stock screens as inexpensive based on consensus estimates. However, we believe that estimates are too high and that revenue and EPS growth in the 2005-2006 period will be difficult to achieve.

Investment Highlights: We are downgrading shares of QLT, Inc. from Buy to Source of Funds and lowering our price target from \$22 to \$15, based on conversations we have had in recent days with retinal specialists from across the US . In our July 23 note following QLT's Q2-04 report, we noted the headline risk associated with the upcoming Eyetech/Macugen FDA advisory panel meeting to be held on August 27, and the anticipated approval and launch of this new product in early 2005. Based on the latest feedback we have received from the retinal community, our concerns regarding QLT run deeper than near-term headline risk and extend to the fundamental growth outlook for the company. We recognize that the sell-off in the stock over the past four months already reflects some of these fundamental concerns, and that the stock screens as inexpensive based on consensus estimates. However, we now believe that consensus estimates for 2005 and beyond are too high, and that revenue and EPS growth in the 2005-2006 period will be difficult to come by. As such, we expect little or no stock price appreciation for QLT as competitive developments play out over the next 12 months.

Our change in outlook is driven by two primary factors: (1) the upside in US Visudyne sales from newly reimbursed indications is probably less than we previously believed, and (2) despite extensive use of combination therapy, the impact of newly approved drugs on Visudyne sales will likely be greater than we had previously forecast. In this report, we discuss each of these factors in depth, and also provide our latest thoughts with respect to Macugen from Eyetech (EYET - \$34.00 - not rated) and **Pfizer** (PFE - \$31.85 - not rated) and Retaane from **Alcon** (ACL - \$77.94 - Accumulate - \$86 Price Target).

QLT Downgrade: Acknowledging a More Challenging Competitive Environment: Our change in outlook regarding the prospects for QLT (and Visudyne in particular) is based entirely on our most recent conversations with retinal specialists from across the US . Even with recently expanded Medicare reimbursement, most of the physicians with whom we have spoken expect little or no growth in Visudyne usage (many expect a decline) in the face of three new competitive products: Macugen in early 2005, Retaane in mid-2005, and Lucentis from Genentech (DNA - \$47.16 - not rated) in 2006. We believe that a number of factors will combine to make Visudyne revenue growth difficult to achieve during the 2005-2006 timeframe. Each of these factors is discussed in detail below.

The potential upside in US Visudyne sales driven by newly reimbursed indications is likely more modest than we had previously forecast. As of April 1, 2004, Medicare began to provide reimbursement for Visudyne use in small (< 4 disc area) minimally classic and occult wet AMD lesions. We have characterized this development as a major positive for the company, potentially doubling the US market opportunity for Visudyne. We had modeled incremental US Visudyne sales of nearly 40% by Q4-04 and over 80% by Q4-05 based on these newly reimbursed indications. However, the vast majority of the retinal specialists with whom we have recently spoken believe that the incremental Visudyne usage based on these newly reimbursed lesion types will be in the range of 20-40%. These more modest expectations for incremental Visudyne usage are based on (1) perceptions on the part of physicians that Visudyne was already being used off-label for many minimally classic and occult lesions, driven by "borderline" lesions that have been characterized as predominantly classic for reimbursement purposes, as well as some out-of-pocket payment by patients; (2) lesion size limitations; and (3) new competitive compounds that will be introduced over the next 12 months.

We now believe that the competitive impact of soon-to-be-approved drugs on US Visudyne sales will be greater than previously anticipated. We have highlighted the use of combination therapy (photodynamic therapy using Visudyne in combination with Macugen, Retaane, and steroids) as the savior for QLT in 2005 and beyond. We still believe that there will be extensive use of combination therapy in the treatment of wet AMD, a multi-factorial disease, but our most recent conversations with retinal specialists suggest that we have underestimated the competitive threat from the new compounds. We see a number of factors contributing to the competitive landscape:

* Despite our expectation of extensive use of combination therapy over time to treat wet AMD lesions, we expect a significant amount of Macugen monotherapy, at least initially. We expect FDA approval for Macugen in Q1-05, and we are expecting a Q2-05 product launch in the US. When approved, Macugen's label will not specifically address combination therapy with Visudyne. In addition, although Eyetech and Pfizer should have no motivation to discourage combination therapy with Visudyne, we expect the Macugen marketing message to be heavily focused on positioning the drug as first-line therapy. We suspect that many retinal specialists will initially want to see how Macugen performs on its own. Over time, less-than-ideal outcomes with Macugen should lead to an uptick in combination therapy, although by that time Retaane should be part of the mix. From a medical-legal standpoint, physicians that choose monotherapy over combination therapy should not be vulnerable to allegations that they have withheld the "standard of care" from their patients, given the lack of current data supporting combination therapy. Even though a number of patients in the Macugen clinical trials were treated with both PDT and Macugen, we doubt that there will be enough data available upon which to draw meaningful conclusions about the relative merits of combination treatment.

* Even if combination therapy becomes the standard of care sooner than expected, the number of Visudyne treatments per patient per year will very likely decline. Nearly every

retinal specialist with whom we have spoken believes that combination therapy with Macugen and/or Retaane will result in a meaningful reduction in the number of Visudyne/PDT re-treatments. In recent quarters, Visudyne has been used increasingly in combination with triamcinolone, a generic injectable steroid. The latest clinical data on this combination, which is consistently positive, indicates that fewer Visudyne/PDT treatments are required, suggesting that the PDT re-treatment rate could decline even in the absence of Macugen and/or Retaane.

* Visudyne is to Macugen as Palmaz-Schatz is to Multi-Link? For investors that remember the coronary stent wars of the late 1990s, we note that this analogy goes too far: we do not expect Visudyne to lose 70% of its market share within weeks following the Macugen launch. Unlike the original J&J/Cordis stent, Visudyne has a differentiated mode of administration and mechanism of action, along with the potential for combination therapy, to help defend against the Macugen competitive threat. However, we do see a parallel: in each case, the incumbent supplier (in this case, Novartis/QLT) built up a meaningful amount of customer ill will during a multi-year market-monopoly period, resulting in heightened interest in competitive product offerings. In our conversations with retinal specialists, we have detected an undercurrent of negative feelings toward QLT, and even stronger disdain for its marketing partner, Novartis.

* Latent ill will toward QLT and Novartis is based on customer perceptions of a flawed launch of Visudyne dating back to 2000, unattractive pricing/reimbursement and physician economics, a therapy that is disruptive from a patient flow/practice management standpoint, and clinical outcomes that have not lived up to expectations. Clearly, not all retinal specialists feel strongly enough to allow such perceptions to impact their usage of Visudyne, although there seems to be universal awareness of these issues within the retinal community. We have identified a "vocal minority" of physicians, however, that is eager to curtail Visudyne use once an alternative becomes available. Even if only 10-20% of retinal specialists feel strongly enough to reduce or eliminate their Visudyne usage, it could create a meaningful headwind to growth.

8/24 **American Laser Vision PA**, an association of LASIK eye surgeons, was awarded \$2.1 million from **The Laser Vision Institute, LLC**, a Lake Worth, Fla.-based national chain of laser vision correction centers. A commercial arbitrator from the American Arbitration Association handed down the award on Friday, August 20. "This case is a good example of how the law serves to fill the gap between the sometimes inconsistent goals of surgeons who want to practice excellent medicine and businesses that want to maximize profits," says Randy McClanahan, a partner at Houston's **McClanahan & Clearman** and counsel to American Laser. McClanahan & Clearman's Robert Espey also represented American Laser.

American Laser operated LASIK eye surgery centers in Houston, Plano, Oklahoma City, Lewisville and Fort Worth. In February 2002, American Laser entered into professional services agreements and sublease agreements with The Laser Vision Institute. According to those agreements, American Laser provided board-certified ophthalmologists to

perform laser surgeries and LVI generally managed the day-to-day, non-medical operations of the centers. The doctors were to be solely responsible for laser procedures and other services rendered by the surgeons at the centers.

In October 2003, American Laser sought arbitration of claims against LVI pursuant to an arbitration clause in the contracts. American Laser claimed that LVI interfered with the "care or treatment of patients" and the exercise of the surgeon's professional judgment. Specifically, American Laser contended that LVI employees understated the chance that a patient would need follow-up surgery to address problems and used non-refundable deposits in an effort to coerce patients into buying the laser surgery.

American Laser also claimed that LVI interfered with surgical protocol by changing surgical supplies without notifying the doctors, changing prescriptions without the doctors' permission or notification, altering post-operative care requirements, and interfering with sterile surgical techniques. American Laser claimed that LVI's interference ultimately reduced the number of surgeries American Laser surgeons were able to perform.

American Laser's damage claims included unpaid and lost surgical fees, and lost profits generated from the sale of ocular tear plugs -- which treat dry eye, a possible complication of the surgery -- at each of the centers involved in the arbitration. A separate lawsuit is pending regarding sale of ocular tear plugs at other LVI centers.

A hearing was held in Dallas from August 3-5, 2004. The arbitrator found that LVI breached its various Professional Services Agreements and Sublease Agreements with American Laser. LVI was ordered to pay to American Laser actual damages for breach of contract of \$1,842,220, attorneys' fees of \$148,940, and pre-judgment interest.

Last year, according to press reports, LVI agreed to settle federal charges that it made misleading promises of perfect vision and life without glasses. The Federal Trade Commission said Laser Vision Institute did not have scientific evidence to support claims that its LASIK procedures would eliminate the need for glasses and contact lenses. The settlement bars LVI, which did not admit breaking any law, from making such claims in the future without proof.

8/25 **WaveLight Laser Technologie AG** announced that it had successfully passed its inspection by the FDA in August. The FDA audits are performed at regular intervals to ensure that products approved for the U.S. market are of a consistently high quality. In the course of the comprehensive data examination, the FDA examined all processes, records, and procedures involved in the development, design, and manufacture of the ALLEGRETTO WAVE. No deviations from the FDA's strict legal requirements were found.

"FDA approval of our ALLEGRETTO WAVE in October 2003 was a key milestone in WaveLight Laser Technologie AG's history. This renewed confirmation of the outstanding quality, safety, and reliability of our excimer laser system by the FDA provides us with further confirmation on our path to dynamic, global growth," noted company founder and CEO Max Reindl, expressing his pleasure at the result of the FDA audit.

8/28 **Alcon** reported that the article, **Eye surgery fears as laser makers sued for millions**, appearing in the August 28th edition of *The Times of London* regarding Alcon and its LADARVision 4000 was based on allegations that are false and inaccurate. This article was based on the invalid contentions of parties who are attempting to avoid multi-million dollar debt owed to Alcon by raising claims that are completely unsupported by scientific or legitimate evidence.

The LADARVision system is safe and effective. It has been extensively tested in clinical trials, and was approved for its intended use by the U.S. Food and Drug Administration and other regulatory agencies around the world. In the five years it's been on the market, more than one million eyes worldwide have been treated successfully with LADARVision, and numerous peer-reviewed articles support the high quality patient results generated by the system.

Alcon has a long-standing commitment to patient safety and to providing the highest quality products to its customers and their patients. Alcon is the world's leading eye care company, and has been dedicated to the ophthalmic industry for more than 50 years.

Allegations and claims made in The Times article are completely without merit. The actual facts regarding these issues are well documented and include:

-- The objective, scientific and peer-reviewed evidence flatly refutes claims made in this article regarding retreatment rates for LADARVision. Peer-reviewed studies and physician data reported to a third-party organization demonstrate that retreatment rates for LADARVision and other leading excimer lasers are comparable. Claims made in this article regarding retreatment rates with LADARVision are false. They are based on a fundamental mischaracterization and incorrect analysis of an internal Alcon financial document that have lead to the article's invalid conclusion. The document referenced does not provide information that can be used to accurately calculate retreatment rates.

-- The voluntary 2001 field action taken by Alcon had absolutely nothing to do with the false claims made in this article concerning retreatment rates. Alcon voluntarily initiated this field action to prevent a potential malfunction, and ensure the continued safety of the laser. **Boots**, the U.K. laser center mentioned in The Times article, as well as all other existing LADARVision customers at the time, were notified by Alcon prior to the completion of the action on three separate occasions (by telephone, facsimile, and written letter). Alcon notified the FDA of this field action and the FDA reviewed the field action and deemed it closed.

There is no valid basis to the many erroneous and distorted claims made against Alcon or LADARVision in this article. Alcon conducts its business in an open and forthright manner. Although the potential exists for complications with any surgical procedure, the objective, truly scientific evidence supports the safety and efficacy of the LADARVision System. The contents of this article, based on the allegations of financially motivated parties, are refuted by the scientific evidence.

8/29 As reported by Kate Foster of *Scotland on Sunday*, HEALTH campaigners last night demanded a suspension of laser eye surgery after claims some machines have developed faults which could lead to damaged eyesight. The high street chain store **Boots the Chemist** was contacting patients after it discovered two lawsuits have been lodged in American courts claiming that a batch of machines have started malfunctioning, causing blurred vision and other serious eye problems. One laser machine used in a Boots clinic in London is said to be from the same batch.

The revelation is a serious blow to the growing eye laser industry which now treats around 100,000 patients in Britain every year to correct short and long sightedness and astigmatism.

Two lawsuits filed in America allege that some of the Autonomous Ladarvision Systems, which are used in Boots' nine eye treatment clinics across Britain including its Glasgow Sauchiehall Street branch, can develop faults leading to blurred vision. The Ladarvision machines are also used by a private clinic in Aberdeen. The machine used in Boots' London eye surgery clinic in Regent Street was said to be from a problem batch identified in 2001 by Swiss-owned health care company **Alcon** which makes them.

Boots, which has carried out around 30,000 eye procedures in the UK, said it is working to find out if there is any truth in the allegations as a "matter of urgency". Around 49 patients who were treated with the London laser before it was repaired by Alcon were being contacted by the company to discover if they have suffered any adverse effects. No complaints have been received by the company so far.

But Rebecca Petris, founder of patients' group LaserMyEye, said there were serious concerns about the quality of laser treatment. She said: "We have long been concerned about the absence of regulations to track outcomes and complications rates from laser eye surgery and have been campaigning for these standards to be implemented as this report reinforces the need. "We believe that the Ladarvision laser should be voluntarily withdrawn from service until these reports have been fully investigated, so as to ensure the safety and welfare of patients. The allegations underscore the risk inherent in failing to proactively monitor trends in laser eye surgery outcomes."

However, last night surgeons insisted they were already running stringent checks on their procedures. Nicholas Dash, an eye specialist from the **Accuvision** clinic in London, said: "All laser clinics have ongoing systems of internal and external audits. Most machines are maintained to some degree by the individual manufacturers as well as the clinic."

Around 10% of eye laser clinics in Britain use Ladarvision. Boots has carried out laser eye surgery on Scottish patients in its Glasgow Sauchiehall Street branch for the past two years.

Laser surgery, which was first introduced in the UK in 1989, costs £1,250 an eye at Boots' clinics. Last night, a Boots spokeswoman insisted there were no fears about the

safety of the equipment in its Glasgow clinic. She said: "We have no indications that there are any problems with the lasers there. They are performing normally. We do a lot of checks before each patient and our results are excellent. We would urge patients not to worry.

"We are in discussion with Alcon. Obviously we want to find out as much as we can about this accusation. If these ophthalmologists in America are voicing concerns, we would want Alcon to let us see that evidence as a matter of urgency."

(I tried to access The Times of London original story but was unsuccessful in obtaining a copy.)

8/30 Joanne Wuensch of **Harris Nesbitt** sent out an update on **Advanced Medical Optics: AVO--Fieldtrip to AMO Hits Home Outperform Potential**

*** Event:** Harris Nesbitt hosted a fieldtrip to AMO's corporate headquarters in Southern California. Key takeaways: 1) Pfizer acquisition could still be significantly accretive, even to current estimates; 2) In addition to "feeding" the potential of the current Pfizer assets, we believe that the pairing of its technology with AMO's could add another leg of growth (e.g., the Tecnis IOL); 3) The product pipeline should be driven by acquisitions and internal R&D (e.g., a product for dry eyes); 4) the company's agreement with the Cooper Companies to sell contact lenses is staged, and could expand; 5) there are transition agreements with Pfizer which should allow for a relatively smooth integration.

*** Impact:** Positive.

*** Forecasts:** We are shifting our 2H04 SG&A expense, moving some out of the fourth quarter and into the third, but keeping the full-year 2004 SG&A expense at \$323 million. The impact to our EPS estimates is to shift our 3Q04 EPS estimate to \$0.33 from \$0.38 and in the 4Q to \$0.50 from \$0.46. Our full year EPS estimate remains at \$1.23 - no other change to the components of our income statement.

*** Valuation:** AVO trades at 21.8x our 2005 EPS estimate, essentially in line with its ophthalmology peers (at 21.5x).

*** Recommendation:** Reiterate OUTPERFORM.

8/30 Michael Lachman of **ThinkEquity Partners** filed this report on the FDA review of Macugen: **QLTI: Macugen Panel - Whole Lotta Love, Early Flights Home**

Last Friday, August 27, the FDA's Dermatologic and Ophthalmic Drugs Advisory Committee conducted a very favorable review of Macugen (pegaptanib sodium injection) for the treatment of wet AMD, from Eyetech (EYET - \$37.46 - Not Rated) and Pfizer (PFE - \$32.65 - Not Rated). In its own presentation to the panel, the FDA concluded that Macugen is effective and safe based on the trial data. The advisory committee meeting

did not conclude with a formal vote for or against approvability of Macugen. In fact, the final question from the briefing documents, which asked the panel to weigh the benefits of Macugen against the risks, was dropped prior to the meeting. However, the panelists were informally polled on each question, and each poll was unanimously positive by our count. If there had been a final vote for approvability, it clearly would have been favorable.

The panel meeting outcome supports our view that Macugen will receive a broad FDA approval for all three wet AMD lesion types and a wide range of lesion sizes. In our QLT model, we assume a Q2-05 US launch of Macugen. After the meeting, the question was raised as to whether the FDA would consider delaying approval until the availability of two-year clinical data, expected in early 2005. While more data is always better, the FDA's position on this issue is that the one-year endpoint is meaningful in wet AMD, and the agency has made a conscious decision to make one-year data sufficient for approval. Approval timing could now be dictated by other non-clinical NDA modules, such as chemistry, manufacturing, and controls (CMC). During the panel meeting, a senior FDA official remarked, "We're still very early in the review of this application," which could be interpreted to mean that there are outstanding manufacturing issues that will delay approval beyond the mid-December PDUFA date. This could just as likely be "FDA-speak" reminding people that a favorable advisory committee meeting is not the final step toward full FDA approval. While Eyetech and Pfizer filed the CMC module of the NDA in mid-June, we do not know how to handicap potential Macugen manufacturing issues and their effect on approval timing.

More than any single topic that was discussed by the panel, what stood out to us was what was not discussed during one of the least contentious advisory committee meetings we have observed. On a number of questions and issues, we had expected lively debate that just did not materialize. The sponsors were extremely well prepared in terms of their formal presentation, effective use of backup materials, and ability to address questions from the panel. The meeting actually concluded three hours ahead of schedule.

Concerns expressed by the panel focused on the need for longer-term follow-up in order to determine the appropriate dosing and to assess efficacy beyond the first year of treatment, and to assure the long-term systemic safety of anti-VEGF injections.

Important implications for QLT (highlighted here and discussed in greater detail below):

* The clinical data and the panel deliberations support the view that there are no meaningful safety concerns regarding Macugen/Visudyne combination therapy. However, the data sheds little light on any synergistic efficacy benefit, due to small numbers and biases in the study design. While it appears that Macugen does provide an incremental benefit over photodynamic therapy (PDT) using Visudyne alone, the trial design makes it nearly impossible to assess the incremental benefit of Visudyne over Macugen monotherapy.

* Importantly, a detailed review of the FDA briefing documents supports our thesis that there is likely already a significant amount of off label use of Visudyne in occult and minimally classic lesions, limiting the potential upside from recently established Medicare reimbursement for these indications.

* The Macugen trial data also suggests that Visudyne could be used in fewer patients once Macugen is available, and that combination therapy will involve fewer Visudyne treatments per patient.

On the margin, the relatively benign panel review of Macugen is an encouraging data point as Alcon (ACL - \$75.86 - Accumulate - \$86 Price Target) prepares for its own panel review of Retaane in H1-05. However, as we've pointed out previously, we suspect that there may be more questions with regard to study design, dropout rates, dose response, and data analysis for the Retaane trials than for the Macugen trials. In addition, we have seen no data yet from the second pivotal study for Retaane, making it difficult to assess the prospects for approval.

Where Was the Much Anticipated Debate? A Review of What Was Not Discussed:

There were a number of questions and issues that we expected to be the subject of heated debate (or at least interesting discussion), but received little or no attention during the Macugen panel meeting. After the meeting, we asked a senior FDA official if he was surprised by fact that these issues had not been raised; he reminded us that there was plenty of time for additional discussion and that the panelists were free to raise any and all of these issues had they wished to do so.

* There was little discussion of secondary efficacy endpoints, in terms of either their relative importance or the weight of evidence behind them.

* There was no mention of lesion subtypes (predominantly classic, minimally classic, and occult) or the fact that efficacy results were inconsistent by subtype within each of the two pivotal trials. While the protocol did not require efficacy to reach statistical significance when broken down to this level, we were surprised that no one even raised this as a topic of discussion. In the international study (EOP1003), efficacy for the 0.3 mg dose appeared to be driven primarily by occult and minimally classic lesions, with little or no treatment effect seen in predominantly classic lesions. In the North American study (EOP1004), the efficacy results for the 0.3 mg dose appeared to be driven by both predominantly and minimally classic lesions, with little or no benefit seen in occult lesions.

* There was no discussion of efficacy stratification according to lesion size. A broad range of lesion sizes (0-12 DA) was included in the studies. In the briefing documents, efficacy was stratified based only on ≥ 4 DA and < 4 DA groupings. The fact that the relative treatment benefit appears to be lower in the larger lesion subgroup suggests that

there may be a lesion size beyond which there is little or no benefit, and we would have liked to see a more detailed stratification.

- * There was no mention of the pooling of data from the two separate trials to address secondary endpoints, and very little discussion in general regarding study design or statistical issues.

- * There was little or no concern expressed regarding the relatively low (albeit statistically significant) treatment benefit overall, or the very low incidence of visual improvement.

- * There was just one brief question regarding the fact that the smallest study dose (0.3 mg) turned out to be the most efficacious from a statistical standpoint.

- * The panel appeared to be satisfied with inclusion/exclusion criteria, with little or no discussion on this issue.

- * In its introduction to the meeting, the FDA raised a general concern regarding the use of sham injections versus vehicle controls (actual injections of a placebo), given the belief that shams can introduce bias into a study. There was no subsequent discussion of this issue by the panel. The FDA also raised a concern regarding the use of visual acuity testing (ETDRS) at a distance of two meters versus four meters. The panelists did discuss this issue, and concluded that the robustness of the data, training/certification of trial sites, and randomization and masking of patients were sufficient to dismiss this as a concern.

A Consistent Theme of the Panel Discussion: the Need for Longer-term Follow-up

The panelists consistently expressed the view that longer-term follow-up is necessary in order to develop a more complete picture of the safety and efficacy of Macugen, and to provide clues regarding proper dosing beyond the first year. However, no one suggested that the need for longer-term follow-up should impact the approvability of Macugen, and the panel fell short of recommending formal Phase IV clinical studies.

- * With 97% of patients having reached the two-year safety-reporting milestone, no new safety concerns have been raised. Endophthalmitis is clearly the adverse event of greatest concern, and the endophthalmitis rate has improved significantly over time. Prior to a protocol change in June 2003, the endophthalmitis rate was 0.18% per injection, and this dropped to 0.03% following the change. It was also noted that retinal specialists have been performing an increasing number of intravitreal injections over the past year for the treatment of diabetic macular edema (DME) as well as AMD (in combination with Visudyne), and this could be contributing to improving safety outcomes as well. One panelist argued that the risk of endophthalmitis with Macugen, at 1.3% per patient per year, is far lower than the risk of severe vision loss without Macugen (22%, versus 9.5% with the drug). One panelist noted that if the risks and adverse events associated with Macugen injections begin to outweigh the benefits, "patients will vote with their feet."

The fact that compliance was 90%-plus in the trials, and that only one-third of patients reported mild or moderate pain (in only about one-fourth of their injections) suggests that patients will largely tolerate the discomfort, given the potential benefits of Macugen.

* It is not yet known over how many years patients will still receive an efficacy benefit from continued Macugen administration. Two-year data that will be available early next year should provide the first clues on this subject, but long-term dosing will likely come down to physician judgment (trial and error) following approval. The uncertainty surrounding long-term dosing will not get in the way of initial FDA approval, and the Macugen label will likely be amended as more data becomes available.

* While the administration of an anti-VEGF agent did not appear to present any short-term safety issues, the panel expressed a need to assure that there are no long-term systemic effects. Of particular concern is the risk of losing some of the neuroprotective effect of VEGF over years of cumulative dosing; it was suggested that long-term electroretinogram (ERG) and visual field studies be conducted in a subgroup of patients.

Combination Therapy: Macugen Clinical Trial Data Supports Our Concerns Regarding Visudyne Growth

Our review of the FDA and sponsor briefing documents suggests that no major safety concerns have been raised with regard to Macugen/Visudyne combination use. The advisory committee came to the same conclusion, but of course expressed a desire for larger numbers of patients and possibly additional clinical trials to better evaluate combination therapy.

The number of patients that received combination therapy during the Macugen studies was too small to support any statistically-based conclusions that could find their way into an FDA-approved label. However, we analysts have the artistic license to extrapolate the data and draw all of the conclusions we like.

A detailed review of the FDA briefing documents supports our thesis that there is already a significant amount of off label use of Visudyne in occult and minimally classic lesions, limiting the potential upside from recently established Medicare reimbursement for these indications.

* In the North American study (EOP1004), 30% of all patients in the sham arm were treated with PDT "on-study" during the course of the trial. Because this sham group of patients was not receiving Macugen, it is most like the current "real world" North American treatment population. While 68% of sham patients with predominantly classic lesions received Visudyne treatment, 27% of minimally classic and 9% of occult lesions were also treated, even though Visudyne is not indicated for these lesion types. We note that the study populations among the three wet AMD lesion types were consistent with the real world AMD population.

* Of all of these sham arm patients treated with Visudyne during the study, 42% had minimally classic or occult lesions instead of predominantly classic lesions. If this is at all indicative of current "real world" Visudyne use in North America, it supports our view that there is already a significant amount of off label use in minimally classic and occult lesions, suggesting limited upside from newly reimbursed indications. We note that in the international study (EOP1003), 32% of sham patients receiving on-study PDT had either minimally classic or occult lesions, suggesting that a large number of patients are being treated off label outside of North America as well.

The Macugen trial data also suggests that Visudyne could be used in fewer patients once Macugen is available, and that combination therapy will involve fewer Visudyne treatments per patient.

* Physicians administered PDT treatment on a discretionary basis during the trial to patients that, in their judgment, would benefit from it. In the North American study, while 30% of sham patients were treated on-study with PDT, only 24% of patients in all Macugen-treated groups (and 22% in the 0.3 mg group) received PDT treatment with Visudyne. This suggests that Macugen treatment may lead to a smaller number of patients receiving PDT.

* In the North American study, Macugen-treated patients also received fewer PDT treatments on average (1.9 treatments overall, 1.8 treatments in the 0.3 mg group) than did sham patients (2.2 treatments).

* We note that the international study did not show decreased levels of Visudyne use in Macugen-treated patients, although the baseline rate of Visudyne use in sham group was significantly lower than in the North American study (13% versus 30%).

The Macugen trial data suggests that Macugen does provide an incremental efficacy benefit over PDT alone. However, the data sheds no light at all on the incremental benefit of PDT over Macugen monotherapy, as the discretionary use (rather than randomized use) of PDT during the study makes efficacy comparisons meaningless.

* Looking at both studies on a combined basis, a higher percentage of patients that had never received any treatment at all (neither Visudyne nor Macugen) showed a higher response rate than those patients that had received on-study PDT and no Macugen (60% versus 46%). This counterintuitive outcome clearly reflects the fact that Visudyne was used on a discretionary basis in a less responsive subgroup of patients. This "channeling bias" makes it impossible to draw conclusions with regard to the efficacy benefit of PDT over and above Macugen monotherapy.

* The data does suggest, however, that Macugen provided an incremental benefit over PDT alone. Looking at both studies on a combined basis, for patients that received on-study PDT, Macugen increased the percentage of responders from 46% in the sham group to 61% for all Macugen-treated patients (71% in the 0.3 mg group). Among

patients that received no PDT either before or during the study, Macugen increased the percentage of responders from 60% in the sham group to 71% for all Macugen-treated patients (70% in the 0.3 mg group).

* It could also be argued that discretionary use of PDT during the study, which occurred at a higher rate in the sham groups than in the Macugen-treated groups, biased the study modestly against Macugen, making the achievement of a statistically significant improvement over the sham groups more challenging.

OPHTHALMIC LASER UPDATE -- September 2004

8/28 Laura Scott of *PA News*, writing in *Scotsman.UK*, brought another point of view on the article published about Alcon's LadarVision in *The Times of London*: **Fears over Safety of Eye Laser**

Patients who had laser eye surgery at a clinic run by high street healthcare chain Boots are being contacted by the company amid fears that the equipment used could lead to damaged eyesight, it was revealed today. The company is investigating claims that one of their machines was part of a problem batch of lasers that could malfunction.

Two lawsuits filed in America allege that some of the Autonomous Ladarvision Systems, which are used in Boots' nine eye treatment clinics across Britain, can develop faults leading to blurred vision. The laser machine used in Boots' London eye surgery clinic in Regent Street was said to be from a problem batch identified in 2001 by Swiss-owned health care company Alcon who make them. Boots said it is working to find out if there is any truth in the allegations as a "matter of urgency".

Around 49 patients who were treated with the London laser before it was mended by Alcon were being contacted by the company to discover if they have suffered any adverse effects. No complaints have been received by the company so far.

A Boots spokeswoman said: "We are in discussion with Alcon. Obviously we want to find out as much as we can about this accusation. It is a concern to us going forward if there are reports of older lasers degenerating. If these ophthalmologists in America are voicing concerns, we would want Alcon to let us see that evidence as a matter of urgency. Now we have been made aware of these concerns we are demanding from Alcon to see any evidence they have relating to this. So far we have not been presented with any evidence but we are pushing Alcon as much as we can. We are going to get in touch with the customers that we know have had the laser eye treatment with this piece of equipment. We are not aware of anybody suffering any adverse reaction but we will be getting in touch with people to make sure they are still completely satisfied with their treatment."

She added that the company was certain no errors had occurred with the suspect laser which had always had good retreatment rates and that lasers in their clinics are safe,

giving 99.7% of patients "driving standard" vision. "We would like to reassure patients our lasers are operated under stringent controlled conditions and we calibrate them before each and every patient. We have absolutely no reason to suspect there is any problem with our lasers."

Alcon, who make lasers based on NASA technology, denied there was a problem with its lasers and said the lawsuits are financial disputes and that any problems were the result of surgeon error, The Times reported today. The company is being sued in North Carolina District Court by **EBW Laser**, which acquired 10 of its lasers to lease to US clinics, and alleges that two of the machines were "badly malfunctioning", the newspaper said.

A Washington State eye surgeon, who was sued by Alcon for failing to pay fees on the machines, has also filed a lawsuit against the company, according to the newspaper. Documents from Alcon support allegations that some machines operated erratically between 2000 and 2002 and that in 2002 more than a third of patients had to be retreated at more than a dozen surgeries, The Times said.

Laser surgery, which was first introduced in the UK in 1989 in the form of PRK (Photo Refractive Keratectomy) costs £1,250 an eye at Boots' clinics, and is performed on around 100,000 people each year in Britain. LASIK is the most popular procedure, where a flap about one third of the thickness of the cornea is cut, the bed underneath reshaped using the laser and then the flap is replaced.

Experts at Moorfields Eye Hospital in London say most people will have their sight vastly improved but in around 2%-4% of patients there will be a measurable loss of "best corrected vision".

8/30 **QLT Inc.** reiterated its confidence in Visudyne's potential in the treatment of age-related macular degeneration (AMD). The company also reiterated its 2004 guidance of Visudyne sales of US\$430 to \$455 million and its post-integration guidance for the combined **QLT-Atrix** company of a cash EPS compound annual growth rate of 20-25%. This statement was made following the FDA advisory panel for the anti-VEGF aptamer which was held on Friday, August 27th. At this panel, Phase II/III results were presented for the anti-VEGF aptamer, confirming QLT's earlier view of the top-line aptamer data, that those data appear to provide no advantage over Visudyne therapy for patients with AMD, the leading cause of blindness in patients over 50. In the United States, Visudyne is reimbursed by the Centers for Medicare and Medicaid Services (CMS) for certain patients with all three forms of wet AMD, predominantly classic, occult and minimally classic.

"While there are no head-to-head comparative clinical trials of Visudyne vs. the anti-VEGF aptamer, the data presented at the panel did not appear to provide any advantage over Visudyne and requires nine repeated intravitreal injections yearly, directly into the eye," said Paul Hastings, president and CEO of QLT Inc. "Given the

discrepancies in efficacy across all subtypes that was evident in the FDA briefing document, we believe that retinal specialists who now for the first time have access to this more detailed data, will take this into consideration in their treatment decisions."

9/1 Ted Huber of **Wachovia Securities** issued an update report on **VISX: EYE: Rolling Out 2006 Estimates**

* **NEW 2006 ESTIMATES:** We are initiating our 2006 revenue and EPS estimates of \$208.1 million and \$1.20, growth of 7.9% and 16.8% over our 2005 forecast. Our estimates assume VISX hits 54% custom mix by the end of 2006 and procedure growth of 7%, in a market growing near 9%. We expect VISX's custom mix (currently 35%) to increase in quarters following hyperopia (end of 2004) and high myopia (mid-2005) FDA approvals. With few new lasers being sold, we expect high margin procedure revenue to account for near 80% of the total by end of 2006.

* **MAINTAINING 2005 EPS ESTIMATES:** We are maintaining our 2005 EPS estimate of \$1.03, within management's guidance range of 25-30% yr/yr EPS growth over their 2004 \$0.78-0.81 forecast. Our model assumes VISX will reach 48% custom mix by Q4 2005 as physicians become more acquainted with custom LASIK data and FDA label expansions for hyperopia and high myopia increase the prospective patient pool. Industry consultant Market Scope forecasts total refractive surgery procedures will grow 18.9% yr/yr in 2004. We note that refractive surgery procedures will continue to track very closely to economic conditions and consumer confidence (dropped to 98.2 in August from 105.7 in July).

* **ON THE ROAD:** Management is on the road this week (September 1-2) at Wachovia-sponsored investor meetings. We will post management comments in a note later this week.

9/1 Implantable contact lenses (ICLs) to correct myopia, are safe, effective and have predictable results for correcting moderate to high myopia or nearsightedness. These are the conclusions discussed in an article published in the September issue of *Ophthalmology*, the clinical journal of the *American Academy of Ophthalmology*.

The article provided an update to the U.S. Food and Drug Administration's long-term, follow-up multi-center **STAAR** Myopic Implantable Contact Lens (ICL) clinical investigation. The STAAR ICL is one of the lenses expected to receive FDA approval. A competing ICL, the Verisyse lens, to be sold by **AMO Inc.**, has received approval by the FDA's device panel and is also expected to receive FDA approval at about the same time.

For the study, the STAAR myopic ICL was implanted in 526 eyes of nearly 294 patients whose myopia ranged from -3.0 to -20.0 diopters. The lens was inserted through a tiny incision and placed in front of the eye's natural lens. The study found that at three years, nearly 60% of the patients had 20/20 or better visual acuity and nearly 95% had 20/40 or

better. Reports of symptoms such as glare halos, double vision, night vision and difficulty driving at night either decreased or remained unchanged. Ninety seven percent of the patients said they would chose ICL implantation again. Less than 1% of the patients said they were dissatisfied.

When compared with the refractive surgical procedure, LASIK, the ICL was found to be more effective for those with higher degrees of myopia. The study states, "These data suggest that the ICL should be given serious consideration for use in eyes with -7 diopters of myopia or more."

"While LASIK is the best surgical option for many patients, there can be more complications for patients with a higher range of myopia. Implantable contact lenses may be a good option for those patients," said Academy Spokesperson Peter Kastl, MD, professor of ophthalmology and adjunct professor of biochemistry at Tulane University in New Orleans.

The study was funded by STAAR Surgical of Monrovia, Calif.

- 9/6 **Wavelight Laser Technologie AG** was granted an investigational device exemption (IDE) by the FDA, allowing it to carry out further clinical studies in the USA for its ALLEGRETTO WAVE excimer laser system. In October 2003, the FDA approved the ALLEGRETTO WAVE for the treatment of astigmatism, myopia, and hyperopia in the USA. The clinical studies, expected to begin in the fall of 2004, are intended to substantially expand the range of treatments approved in the USA. Thus they will include the correction of mixed astigmatism and wavefront-guided LASIK treatment.

"The FDA approval for our ALLEGRETTO WAVE in October 2003 was a crucial step in our international expansion. The upcoming studies will help to further expand the ALLEGRETTO WAVE's treatment range and hence its international market success," said Max Reindl, founder and CEO of WaveLight.

- 9/9 Ted Huber of **Wachovia Securities** reported on two ophthalmic companies that met with Wachovia clients at a sponsored investor event — **Alcon Laboratories** and **VISX**.

ACL: Management Exudes Confidence In Meetings With Investors

* **WACHOVIA SPONSORED INVESTOR MEETINGS:** Alcon's Investor Relation's chief Doug Machatton met with investors in Wachovia sponsored meetings this week. Highlights included a reaffirmation of 2004 guidance and long term growth targets, firm confidence in the approvability of AMD drug RETAANE, and an emphasis on developing market growth prospects.

* **RETAANE 12 MONTH DATA COLLECTION NOW COMPLETE:** Alcon reported that 12 month follow up data on the final patient in its pivotal RETAANE trial was collected last Friday. Investors' first look at the 12 month results will be on 10/23 at the

AAO meeting. Alcon remains confident of a Q404 FDA filing and H105 launch. With this note, we also include our assessment of the FDA Ophthalmic Panel's recent review of competing AMD drug MACUGEN. The drug looks approvable but consistent with our view from last fall's AAO, not significantly more attractive than incumbent treatment VISUDYNE.

*** REAFFIRMATION OF ESTIMATES:** Alcon remains confident in current 2004 revenue (\$3.8-3.85B and EPS (\$2.43-2.46) guidance. Based on these meetings and ACL's continue competitive dominance in demographic driven ophthalmology markets, we remain confident in their ability to exceed these targets.

EYE: Management Meets With Investors

*** WACHOVIA-SPONSORED INVESTOR MEETINGS:** A central theme during meetings last week was VISX's continued leadership of growing refractive surgery markets that enjoy significant untapped potential. FDA label expansions and upgrades to the Star S4 platform were central to VISX's plans for holding share. Management also emphasized VISX's strong cash flow position and openness to investing in opportunities within the broader ophthalmology industry.

*** LABEL EXPANSIONS DRIVE MIX AND GROWTH:** While VISX does not quantify the expected impact on custom mix, they indicate the label expansions will help drive 25-30% EPS growth in 2005. VISX expects to receive a FDA label expansion for CustomVue for hyperopia by the end of 2004 and for high myopia in mid-2005. Having just begun clinical trials in the U.S., VISX does not expect an approval for presbyopia until late 2006 at the earliest. Two new upgrades in 2004 include new software for CustomVue and VISX's iris recognition technology hardware.

*** REAFFIRMING GUIDANCE:** Management reaffirmed Q3 2004 revenue and EPS guidance of \$40-43 million and EPS of \$0.17-0.19. For 2004, VISX still expects EPS of \$0.77-0.81 and 2005 guidance of 25-30% yr/yr EPS growth. No change to VISX's custom mix estimates which call for custom mix percentage ending in the high-thirties by the end of 2004.

9/10 **Advanced Medical Optics, Inc.** announced that it had filed a registration statement on Form S-3 with the Securities and Exchange Commission (SEC). The registration statement relates to the resale by holders of AMO's 2.50% Convertible Senior Subordinated Notes due 2024, and the shares of AMO's common stock issuable upon conversion of the notes. AMO's initial issuance of the notes, in an aggregate principal amount of \$350 million, was completed on June 22, 2004. A written prospectus, when available, meeting the requirements of Section 10 of the Securities Act may be obtained from AMO at 1700 E. St. Andrew Place, Santa Ana, California 92705.

9/13 **Advanced Medical Optics, Inc.** and **OPHTEC USA, Inc.**, a subsidiary of **OPHTEC B.V.**, announced that the FDA had approved the Verisyse/ARTISAN phakic intraocular lens

for use in patients with myopia, or nearsightedness. The Verisyse/ARTISAN phakic IOL is the first lens of its kind to receive FDA approval. The unique, patented lens design was introduced by OPHTEC in Europe more than 17 years ago and has been safely implanted in more than 150,000 eyes worldwide. OPHTEC BV manufactures and distributes the lens under the trade name ARTISAN in all markets except North America and Japan. In 2002, AMO acquired global distribution rights to the phakic IOL, which it markets under the Verisyse brand. AMO is the exclusive source for the product in North America and Japan.

The FDA-approved product labeling indicates that the Verisyse/ARTISAN lens is suitable for the reduction or elimination of myopia in adults with myopia ranging from -5.0 to -20.0 diopters and in patients aged 21 and over. The FDA approval followed OPHTEC USA's submission of a Pre-Market Approval (PMA) application, which received expedited review status in August 2003.

"AMO is committed to playing a leadership role in the development of the global refractive IOL marketplace," said James Mazzo, AMO president and CEO. "Approval of the lens in the U.S. marks an important step forward in our goal to build a comprehensive product portfolio that can provide a full range of options to ophthalmic surgeons and their patients."

AMO is currently coordinating surgeon training and certification for the Verisyse(TM) lens in the U.S. and expects to begin releasing the product to trained surgeons by October.

"This technology provides an excellent alternative for surgeons whose myopic patients may not be good candidates for laser surgery and want to eliminate their dependence on glasses or contact lenses," said Jane Rady, corporate vice president of strategy and technology for AMO. "The progressive design of the lens and its placement in the eye's anterior chamber provide high levels of safety and stability, and optimal visual outcomes."

"This approval represents a significant development in refractive surgery technology," said Rick McCarley, president and CEO of OPHTEC USA, who conducted the U.S. study over the past seven years. "The Verisyse/ARTISAN lens provides superior quality of vision, especially for individuals with high myopia. Unlike laser surgery, implantation of phakic lenses involves no removal of tissue, and the lens can be easily removed at any time in the future. In addition, the Verisyse/ARTISAN lens design has the longest human experience of any phakic IOL and accounts for the largest percentage of phakic lens implantations worldwide."

AMO and OPHTEC announced in May that the two firms signed an agreement to collaborate on the design, development and U.S. regulatory approval process for the Veriflex, a foldable version of the Verisyse/ARTISAN phakic IOL. OPHTEC is currently engaged in clinical trials in Europe on a foldable phakic IOL. AMO and OPHTEC plan

to continue to improve the foldable lens design and develop a compatible insertion system. AMO and OPHTEC also plan to share responsibility for submission to the FDA of the PMA application for the Veriflex lens and implementation of U.S. human clinical trials. Once approved, AMO will be the exclusive worldwide source for the Veriflex lens. OPHTEC will market the foldable ARTISAN as the ARTIFLEX in all markets except North America and Japan.

One analyst provided her comments: Joanne Wuensch, of **Harris Nesbitt: AVO--FDA Approves First Phakic IOL**

* **Event:** The FDA approved AMO's Verisyse lens, the company's phakic IOL lens. A polymethylmethacrylate (PMMA) lens, the Verisyse is inserted through minimally invasive surgical techniques, similar to the placement of an IOL in a cataract procedure. The lens was approved in patients over 21 years of age with myopia in the range of -5 to -20 diopters. Although we expect the phakic IOL market to be a niche market, we do believe it will benefit patients who search for vision correction yet are not good candidates for LASIK (laser in situ keratomileusis) procedures. We believe that the Verisyse will hold several attractions for both the physician and patient: 1) the procedure is additive to the eye, allowing the Verisyse to be removed at any time in the future should the need arise; 2) it provides an option for patients who would normally not be good LASIK candidates, particularly individuals who have high myopia; and 3) no capital equipment purchase is required with the implantation of the phakic IOL, just the cost of the phakic IOL itself.

* **Impact:** Neutral to positive.

* **Forecasts:** Based on conversations with management, we are shifting some SG&A spend into the 3Q04 and out of the 4Q04 to account for the timing of certain transition agreements related to the Pfizer acquisition. No change to full-year EPS of \$1.23, but 3Q will decline to \$0.29 from \$0.33 and an increase in 4Q to \$0.54 from \$0.50.

* **Valuation:** AVO trades at 23.1x our CY05 EPS estimate of \$1.70, slightly above its ophthalmology peer's 22.4x multiple.

* **Recommendation:** Reiterate OUTPERFORM rating.

9/13 According to *Optistock News*, **Schwind eye-tech-solutions**, a privately-held German maker of excimer laser systems, received FDA clearance to market the Cariazzo Pendular Microkeratome in the U.S. This new microkeratome, developed by Dr. Ceasar Cariazzo, has a unique pendular cutting motion allowing a no-tension automated smooth cut and a full view of the cutting surface.

9/14 Writing in the September issue of *Ophthalmic Market Perspectives*, Dave Harmon comments on VISX's "sweeping CustomVue upgrade planned for this fall." Changes include updating the mathematical underpinnings of its wavefront analyzer, transitioning

from Zernike polynomials to a Fourier algorithm for calculation of wavefront error. The company's scientists claim that the new mathematical model produces a more precise measurement of the cornea that translates into a more accurate ablation pattern and better results. Other improvements in the system include better wavefront capture and expanding the treatment diameter out to 7mm. In addition, the ablation process has been enhanced to optimize spot placements to minimize thermal changes in the cornea, allowing for significantly faster treatment times without increasing the maximum corneal temperature during treatment. Regulatory approval has already been received for the planned enhancements and more than a dozen sites have already received the upgraded software. The new enhancements will be provided free of charge to VISX users with active maintenance contracts.

- 9/15 **VisiJet Inc.** announced that it had opened 14 markets to date with its EpiLift and LasiTome Systems -- next-generation, ophthalmic surgical products used for refractive surgery. "The growth and market penetration demonstrated by our EpiLift and LasiTome products have been substantial," said Randy Bailey, president and CEO of VisiJet. "This acceleration demonstrates an acceptance of our technologies that will create and sustain successful product lines."

Bailey indicated that the company now ships products to Hong Kong, Germany, Czechoslovakia, Korea, Cyprus, Italy, Russia, Malaysia, Jordan, Romania, the Benelux countries, the United Kingdom, Spain, Greece and Israel. He anticipates expanding distribution even further by the end of this year.

Bailey believes the growth is due to the many advances and benefits offered by the systems. The products solve many of the procedural problems associated with certain refractive surgeries today.

VisiJet signed an agreement earlier this year with **Gebauer Medizintechnik GmbH** of Neuhausen, Germany, for the worldwide distribution rights to its Epi-LASIK products and has experienced continued revenue increases with the product lines.

- 9/19 *Contact Lenses Today* reported that **Wavefront-Guided CLs in Store for Future. Ophthonix and Optical Connection** have announced a strategic alliance that will produce wavefront-guided contact lenses. The Ophthonix Z-View aberrometer captures low- and high-order aberration measurements, which can be used to create Ophthonix iZon spectacle lenses. Under the new alliance, these wavefront measurements can also be used to produce iZon by Definition contact lenses, made by Optical Connection. The iZon contact lenses will be available no later than the first quarter of 2005 through Ophthonix and Optical Connection.

- 9/20 **VisiJet Inc.** announced that it had received FDA approval for its EpiLift System. The EpiLift System is the cornerstone of a new improvement in LASIK surgery called

Epi-LASIK. Epi-LASIK combines the best of today's most popular refractive techniques - LASIK and PRK. It produces virtually instant visual results like LASIK but with the stable long-term visual outcomes of PRK.

"The EpiLift System provides a revolutionary new method to perform refractive surgery," said Randy Bailey, president and CEO of VisiJet. "The EpiLift System will make Epi-LASIK a mainstay procedure for the correction of myopia, hyperopia and astigmatism. It provides the safety, control and better visual outcomes vital to both physician and consumer acceptance."

During the Epi-LASIK procedure the top layer of the cornea (the epithelium) is separated into an intact sheet of viable tissue. This tissue, the Epi sheet, is temporarily lifted away from the cornea so that a laser can be applied to reshape the corneal bed. Once this is completed, the epithelial sheet is returned to its natural position on the eye. A key attribute the EpiLift System provides to this new surgical procedure is precision. It cleanly and safely separates the epithelium from the next layer of corneal tissue, Bowman's membrane. In traditional LASIK, a microkeratome creates a permanent flap onto the center layer of the cornea (stromal layer). By eliminating the cutting of stromal flaps, the EpiLift System eliminates the primary cause of LASIK complications.

VisiJet Inc. received the CE Mark (European approval) for the EpiLift System earlier this year. Since that time, there has been a growing interest in the technology in Europe and key Asian markets. Now, with FDA approval, the company expects domestic sales to be significant due to the strong interest shown in the technology by leading U.S. refractive surgeons.

"The EpiLift System provides us with another entry into the \$4 billion worldwide refractive surgery market," said Bailey. He noted that the new EpiLift technology joins the company's proprietary waterjet technologies which are in final development stages.

9/21 **WaveLight Laser Technologie AG** confirmed its revenue projections published in October 2003. As of the year-end on July 31, 2004, WaveLight generated revenues of E62,041 thousand. This represents an increase in revenues of around 30% year-over year (previous year: E47,810 thousand). The EBIT margin for fiscal year 2003/2004 will also be in double digits, at around 10%. This figure is in line with WaveLight Laser Technologie AG's expectations.

"We have again proved that WaveLight is a dynamic, high-growth company. Our systematic corporate policy, our high-quality laser applications, and our extensive customer service have proved themselves on the global market for medical lasers," commented Max Reindl, CEO of WaveLight Laser. The effective tax rate is expected to be slightly over 50%, compared to 66.9% the previous year. Without the extraordinary tax effects from the previous year, which arose in connection with the first-time consolidation of the US subsidiary **WaveLight, Inc.** as of July 31, 2003, the tax rate would have been around 40%. The new sales structure, which has the medium- to long-

term aim of pursuing market development even more vigorously than before, allows the Ophthalmology Division to grow at an above-average pace. While the distribution partnership with **Lumenis** will continue in China and Japan, WaveLight is now organizing its distribution activities in Europe, the USA, and the rest of the world directly, thus proving once again that it can successfully restructure its distribution activities quickly.

The US subsidiary, WaveLight, Inc. is already successfully organizing and managing all sales activities in the Ophthalmology Division. "Following the reorganization of our distribution activities, we made optimal use of existing contacts from the very beginning. The flying start to our new sales structure and market acceptance have allowed us to meet our revenue projections," Reindl continued.

- 9/22 The first clinical trial subjects in the USA have been treated with **Carl Zeiss Meditec AG's** MEL 80 Excimer Laser. The FDA recently granted the Jena-based provider of ophthalmic solutions permission to carry out the study.

Ulrich Krauss, president and CEO of Carl Zeiss Meditec AG said, "The launch of this approval study for our MEL 80 Excimer Laser constitutes a major step for us as we increase our worldwide market presence yet further. Our staff in Jena and in our subsidiary in Dublin have put a lot of time and effort into the preparation of this study. We are well equipped to meet the FDA's high quality criteria with our innovative laser system."

The study encompasses all aspects of the treatment of myopia, hyperopia and astigmatism. Five centers will participate in the clinical trial. The ophthalmic surgeons who will be conducting operations with the laser are Dr. Mark Packer, Dr. Howard Fine, and Dr. Richard Hoffman (Eugene, Oregon), Dr. John Doane (Leawood, Kansas), Dr. Steven Dell (Austin, Texas), Dr. Steve Schallhorn (San Diego, California), and Dr. Roger Steinert (Irvine, California).

The IDE study is the precondition for market entry in the USA. It is internationally regarded as the most stringent and extensive of studies which have to be conducted in order to obtain device approval.

- 9/23 Ted Huber of **Wachovia Securities** reported on new developments at **Advanced Medical Optics** from the ESCRS: **AVO: New Products At ESCRS Plus Model Maintenance**

*** NEW PRODUCTS AND CHALLENGES AT ESCRS:** AVO unveiled two products this week at ESCRS: the Amadeus II microkeratome and the Tecnis diffractive multifocal IOL. We expect both to be minor contributors in 2005. Recent conversations with surgeons still using a microkeratome reveal considerable enthusiasm for the Amadeus vs. BOL's Hansatome. Presentation of new data on Alcon's viscoelastic DiscoVisc (Q105 launch) highlights new competition for AVO's Healon franchise.

* **INTEGRATION AND BUSINESS PLANS REMAIN ON TRACK:** Integration of Pharmacia's cataract surgical (PCS) business is on track, according to management. IMS data show a Healon share dip in the U.S. during July (August data not yet available). However, management indicates Healon sales are ramping nicely in Europe and Japan. These regions, according to our estimates, accounted for near 73% of PCS's 2003 revenue.

* **TRUING UP MODEL:** We are raising our 2004 EPS estimate by a penny to \$1.24 (equal to consensus) and shifting \$0.03 from Q3 into Q4. Guidance (from July cc) calls for 2004 EPS of \$1.20-1.25 with 65% of H2 2004 EPS concentrated in Q4. Our model had weighted EPS too heavily in Q3. We have loaded additional SG&A expense, related to the Pfizer Cataract acquisition, into Q304.

9/23 **Carl Zeiss Meditec AG** announced that it intends to buy its own shares on the stock exchange. The number of shares to be purchased is limited and will be a number midway between one and ten thousand. The Management Board of the company was authorised at the annual general meeting on 19 March 2004 to buy back its own shares so as to offer these for purchase to employees of Carl Zeiss Meditec AG or its subsidiaries.

The authorisation granted to the Management Board to buy back its own shares is limited until 18 September 2005. In accordance with the shareholders' resolution, the purchase price may not be more than 10% above or below the closing rate of Carl Zeiss Meditec shares in XETRA trading at Frankfurt Stock Exchange on the respective previous day of business.

The Management Board considers an investment in the company's own shares at the current market price to be beneficial.

9/26 As reported in *OptiStock*, privately-held **Ophthonix** received a fourth patent for a system to provide customized eyeglasses and contact lenses. The patent is for iZon Wavefront-Guided Lenses, the first ever fully customized and optimized lenses. The Ophthonix system begins with a wavefront instrument, the Z-View Aberrometer, which objectively measures the traditional sphere, cylinder and axis captured in today's refraction. It also separately measures and corrects high order aberrations including coma, trefoil, spherical aberration, tetrafoil, distortion and increasing levels of astigmatism. After this measurement, the Eye Care Practitioner can prescribe the iZon Wavefront. This new process was first introduced Sept. 10.

9/26 As printed in the *Boston Globe*, Kimberly Hefling of the *Associated Press* filed the following story: **US soldiers flock to laser eye clinic**

Command Sergeant Major Kurt Pinero looked up from the operating table after laser eye surgery, and made out the pictures on the television screen across the room. "It was amazing," said the 45-year-old Iraq war veteran. "It was the first time I could see that far since I was a child."

After months in the Iraqi desert fumbling with dusty contacts, smudged eyeglasses, and prescription goggles, soldiers by the thousands are flocking to get refractive eye surgery. And the Army is picking up the tab.

"Our workload and number of patients has gone through the roof," said Major Glenn Sanford of the two-year-old Warfighter Refractive Eye Surgery Clinic at Fort Campbell's Blanchfield Army Hospital. About 26,000 soldiers have undergone the surgery at Army clinics nationwide since it was first made available four years ago at Fort Bragg, N.C.

More than 9,000 of the operations have been done at Fort Bragg, and 8,000 other soldiers at the post are on a waiting list to have the procedure between now and January, when many are scheduled to be deployed.

The military sees this surgery as a way to help soldiers see better on the battlefield, where split-second decisions can save lives. Soldiers without glasses can also use instruments such as night-vision goggles with less trouble. In combat, soldiers who lose their glasses are not only a danger to themselves, but also to others.

Priority for the surgery is typically given to the soldiers most likely to be in combat. It is offered at eight Army medical centers, and at least 10 Navy and Air Force medical facilities. The surgery costs the Army about \$1,000 per soldier, compared with an average \$1,785 per eye in the civilian sector.

In 1993, the military's first refractive surgery program started at Naval Medical Center San Diego. The surgery was done on Navy SEALs; many had problems with losing contacts or glasses while parachuting or in the water.

Of 450,000 active Army soldiers, an estimated one-third are potentially eligible for surgery, said Colonel Kraig Bowers, refractive surgery consultant for the Army surgeon general. But with its current funding, the Army can treat only about 10,000 to 12,000 soldiers a year.

Lieutenant Colonel Mark Torres, an optometrist who has analyzed surveys of soldiers who have been deployed with and without the surgery, said they say overwhelmingly that it was a benefit. "We look at this surgery as a performance-enhancing procedure that gives us a soldier that's better able to function," said Torres, chief of refractive surgery at the Madigan Army Medical Center at Fort Lewis, Wash.

The two procedures commonly done by the military are photorefractive keratectomy, or PRK, and laser keratomileusis, or LASIK. In PRK surgery, a laser is used to reshape the surface of the cornea. LASIK involves cutting a flap in the cornea and using a laser to reshape exposed tissue before the flap is put back.

9/27 Joanne Wuensch of **Harris Nesbitt** published her overview of the ophthalmic market ahead of the upcoming AAO meeting: **MedTech--Ophthalmology Overview: The Underpinnings Of The Market Are Strong**

* Ahead of AAO, we are publishing our 80-page ophthalmology overview (please contact your Harris Nesbitt sales person for a copy).

* Ophthalmology stocks' outperformance since the beginning of 2003 has been driven by solid industry underpinnings. In addition to industry fundamentals, the investment landscape has changed dramatically with spin-outs and pending acquisitions. The result is a group of stocks that has outperformed since the beginning of 2003, increasing 119% versus the S&P 500's 22% rise and the MedTech 100 Index's 27% increase.

* We believe continued technology innovation, industry consolidation, demographics, and geo-graphic expansion bode well for the group.

* Our report reviews four corners of the estimated \$18-billion ophthalmology industry: 1) consumer eye care (contact lenses and lens care); 2) cataract; 3) refractive; and 4) pharmaceutical, with a focus on back-of-the-eye treatments. It is designed to serve as a primer on the individual ophthalmology markets, its participants, and the new emerging technologies.

* Our stock picks are based on technology cycles and potential market share gains. Within our POSITIVE rating on the medical technology sector, our OUTPERFORM-rated ophthalmology stocks are **Advanced Medical Optics, Alcon, and The Cooper Companies**. Our NEUTRAL-rated ophthalmology stocks are **Bausch & Lomb, STAAR Surgical, and VISX**.

OPHTHALMIC LASER UPDATE -- October 2004

9/28 Joanne Wuensch of **Harris Nesbitt** reported on **Staar Surgical**, just before the company filed an 8K about the results of an FDA inspection of its manufacturing plant: **STAA--Another Day Another Delay**

* **Event:** A representative from STAAR Surgical has notified us that the company has released that it received 36 observations from the FDA regarding the review of its facilities related to an FDA warning letter that it received in January. In addition, the company has confirmed what we have suspected (and wrote in our Ophthalmology Overview on 9/27/04), that it will not be launching its phakic IOL at the upcoming *American Academy of Ophthalmology* meeting, and has not scheduled a time frame for its launch.

* **Impact:** Negative.

* **Forecasts:** At this time there is no change to our forecasts, as our financial model does not assume US market entry until 1Q05. In 2005, US phakic IOL contribution is estimated at \$10.7 million, increasing to \$17.2 million in 2006.

* **Valuation:** Our \$7 price target is a sum-of-the-parts analysis: 1x 2006 cataract sales or \$2.40 plus 4-5x 2006 refractive sales or \$4.60.

* **Recommendation:** It is our understanding that an 8K will be filed shortly - management was not available for commentary on the length of time it will take to resolve FDA issues. We anticipate this news will not be received well by investors. Our NEUTRAL rating is predicated on a 1Q05 market entry in the US of its phakic IOL, a continued delay in the product launch would put our sum-of-the-parts analysis at risk.

9/29 As previously announced, **Staar Surgical** received a warning letter from the FDA on December 29, 2003, following the FDA's inspection of the Company's facility in Monrovia, California. The company engaged the services of **Quintiles Consulting**, a well regarded consulting organization that specializes in FDA related compliance matters, to assist it in correcting the issues raised in the Warning Letter. The company, with Quintiles' help, has assessed the state of its quality system in light of the FDA's concerns and has developed an improvement plan. This plan was submitted to the FDA. It provided details of a systematic approach for reviewing and improving all of the company's quality system procedures. The following are some of the actions that the company has taken in consultation with Quintiles:

- conducted a retrospective review of complaint files from the last three years and conducted root cause analysis;
- implemented more rigorous quality processes for complaint investigation, root cause analysis, trend analysis and reporting;
- submitted a quality system improvement plan to the FDA that details a systematic approach for reviewing and improving all of the company's quality systems procedures;
- strengthened the expertise in several critical business functions, including quality, clinical, regulatory, manufacturing and research and development. Specifically, the company expanded the Complaint Handling staff, hiring an M.D. to manage the department, and hired a Vice President of Research and Development, a Vice President of Regulatory Affairs/Quality Assurance, and various quality and manufacturing engineering employees;
- successfully completed the FDA's pre-approval inspection of the company's Nidau, Switzerland manufacturing facility with no observations; and

- re-engineered several key quality systems including failure investigation, root cause analysis, complaint handling and medical device reporting, clinical systems, management review, corrective and preventive action, trending and analysis practices, and validation.

On July 28, 2004, the FDA commenced an inspection of the Monrovia facility to determine the progress of the company's corrective actions. On September 23, 2004, the FDA completed the inspection and issued a form "FDA 483 Inspectional Observations". The FDA 483 contains observations that, in the opinion of the FDA investigators, represent deviations from the FDA's regulatory requirements. Observations listed on the FDA 483 do not necessarily represent a final FDA determination as to the state of the company's compliance. The FDA 483 contains 36 observations addressing the following areas:

Production and process controls, corrective and preventative action, quality system requirements, statistical techniques, complaint handling system, medical device reporting, design controls, acceptance criteria, and document controls and records.

During the meeting with the FDA at the conclusion of the inspection, the company provided an initial response to each of the observations. In response to some of the observations, the company provided evidence, and the FDA verified, that corrective action had been taken. With respect to other observations, the company provided evidence of corrective action which requires verification by the FDA. In addition, the company promised to undertake corrective action with respect to some of the observations, and gave no response to other observations pending further evaluation.

The company is preparing a written response to the FDA 483 to be submitted as soon as practicable. Until the FDA is satisfied with the adequacy of the company's corrective action, it may take further actions which could include conducting another inspection, seizure of the company's products, injunction of the Monrovia facility to compel compliance (which may include suspension of production operations and/or recall of products), or other actions. Such actions could have a material adverse effect on the company's established lines of business, results of operations and liquidity. Furthermore, until the FDA is satisfied with the company's response, it is unlikely to grant the company approval to market the ICL in the United States.

The company is not able to predict whether the FDA will conclude that the company's corrective actions to date or those to be included in its response to the FDA 483 satisfactorily resolve its concerns. Nor can the company predict the likelihood, nature of, or timing of any additional action by the FDA or the impact of the FDA 483 or any other FDA action on the company's established lines of business, results of the operations or liquidity or the approval of the ICL for the United States market. The company does not believe that it will receive approval of the ICL before the October 22, 2004 meeting of the American Academy of Ophthalmologists.

Reuters reported that shares of **Staar Surgical Co.** lost more than 40 percent of their value following the news that the medical device maker had received a warning letter from U.S. regulators following an inspection of its facility in Monrovia, California. Staar, whose shares tumbled to a two-year low, disclosed the warning letter in a filing with the U.S. Securities and Exchange Commission.

In January, the FDA said it sent the company a letter following an inspection of the Monrovia facility. In March, the company said the FDA said plans to correct quality-control problems were adequate.

The FDA completed its latest inspection on Sept. 23, according to the filing.

10/1 Scott Reeves, writing the *IPO Outlook* in Forbes.com, offered some commentary on the upcoming public offering by **IntraLase: An Eye To The Future; IntraLase offers investors a deft technology in the growing field of eye surgery.**

The company's planned initial public offering represents the best of the new issues market--leading-edge technology in an emerging field. But IntraLase's market, while growing, is small and unlikely to offer the robust growth IPO investors seek. Expect the IPO to deliver a modest opening and a quiet first day.

IntraLase designs, develops and markets a laser, software and disposable equipment used to cut tissue across the cornea of a patient's eye. Creating the "corneal flap" is the first step in Lasik surgery. The company says its technology is designed to improve the safety, precision and final result of the eye surgery by providing a computer-controlled procedure. The traditional technique of creating the corneal flap uses a hand-held mechanical device with a metal blade called a microkeratome. IntraLase says its patent-protected laser generates 10,000 pulses per second to create a precise surgical incision. The company's proprietary software controls the laser as it creates the corneal flap based on the shape of each patient's eye.

MarketScope, a market research firm that tracks the surgical vision correction market, said the procedure represents one of the largest potential medical markets in the U.S. It estimated that 156.5 million Americans require vision correction and about 55.5 million could benefit from surgery but haven't been treated. Lasik surgery represents about 88% of all surgical vision correction procedures performed in the U.S. The market is currently estimated at \$2.4 billion a year.

Lasik surgery was introduced to the public in 1997, but it has been used by less than 7% of the U.S. population. MarketScope expects the total to grow to 12% in the U.S. and to 10% internationally, with most growth in Europe and Asia. Complications from the procedure include postsurgery discomfort, over- or undercorrections, disorders in corneal healing and unusual visual sensations caused by bright lights including glare, halos or dry eye. Insurance generally doesn't cover Lasik surgery and patients pay for the procedure

out of their own pockets. Many patients pay with pretax dollars, but a change in the tax code could reduce demand for the surgery and erode the company's revenue.

IntraLase's laser costs about \$350,000 compared with \$40,000 to \$60,000 for microkeratome devices. Disposable blades in the standard procedure cost \$25 to \$50 per operation compared with \$150 for disposable equipment used in the laser procedure. IntraLase said surgeons typically receive an average of \$334 more per eye when using its equipment than when using the traditional microkeratome technique. Surgeons report that the number of consultations resulting in surgery increases to about 77% from 64% when using the company's equipment, but it's impossible to say if the trend will continue.

The number of doctors using the company's equipment is still small. MarketScope said there are about 4,100 Lasik surgery practices worldwide. IntraLase targets the 1,400 most active practices in the U.S. and selected international markets, or those that perform more than 50 procedures per month. On June 30, about 14% of all surgeries used the company's equipment.

For the six months ended June 30, IntraLase reported a net loss of \$4 million on revenue of \$25.3 million compared with a net loss of \$7 million on revenue of \$8.55 million for the same period a year ago. On June 30, the company had an accumulated deficit of about \$57.1 million. IntraLase Corp. of Irvine, Calif., plans to offer 6,636,314 shares, including 336,314 by current shareholders, at \$11 to \$13 each through underwriters led by **Banc of America Securities**. The company plans to use net proceeds to pay for equipment, to make the second payment on the purchase of a license from the University of Michigan and for working capital. The proposed Nasdaq symbol is ILSE. The deal is expected to be priced the week of Oct. 4.

As part of the licensing agreement with the University of Michigan, the company agreed to permit the school's venture fund to sell all its IntraLase shares as part of the IPO. The company will receive nothing from the sale of these shares.

Competitors include **Bausch & Lomb**, **Moria/Microtech**, **Advanced Medical Optics**, **Alcon**, **Visx** and **Nidek**. IntraLase also competes against other vision correction technologies that don't require the creation of a corneal flap, including contact lenses and makers of eyeglasses such as **Lens Crafters**, a subsidiary of **Luxottica Group**, and **Pearle Vision**, a subsidiary of **Cole National**.

IntraLase is a small company in a highly competitive field. It could be a sleeper, but expect its IPO to slumber in early trading. Keep--ahem--an eye on this company because it has great potential.

9/30 **Miravant Medical Technologies** announced that the FDA had issued an approvable letter for its proprietary drug SnET2. The letter outlines the conditions for final marketing approval, which includes a request for an additional confirmatory clinical trial. SnET2

PDT is a drug-and-light procedure that is being developed to slow the progression of wet age-related macular degeneration (AMD), the leading cause of blindness in older adults.

Gary Kledzik, chairman and CEO, stated, "We are pleased with the approvable designation, which reflects positively on the results achieved in phase III clinical trials. The company will work with the FDA to address the issues needed for final approval. We expect that this guidance, coupled with the knowledge we have gained about wet AMD through the phase III studies, should enable us to efficiently fulfill the requirements. We remain committed to serve the large elderly population with wet AMD, and we again thank the investigators and patients who participated in these important clinical trials."

SnET2 intended to stabilize vision loss: It is estimated that over the next five years, 1.35 million people within the U.S. will develop wet AMD, with similar numbers outside the U.S. A debilitating eye disease, wet AMD is characterized by the growth of abnormal blood vessels (choroidal neovascularization, or CNV) at the back of the eye. The lesions leak fluid and blood that can lead to severe loss of central vision. SnET2 PDT uses a light-activated drug designed to selectively destroy the leaking vessels and stabilize vision loss.

CNV lesions are made up of classic and/or occult components, and it is important that new treatments address both of these components. In the phase III clinical trials, SnET2 showed benefit in a range of CNV lesions, regardless of the percent classic component or presence of occult component.

10/4 Kirk Teska, writing in *MassHiTech* in his Close-Up column: **Front Lines in the Life Sciences: Keep an eye on medical technique infringement**

Profitable technologies often breed patent litigation, and there is probably no better example than corrective laser eye surgery. In late 2002, **Summit Technology**, then in Waltham, convinced a Boston jury that **Nidek Co.** of Japan willfully infringed Summit's patents. The jury assessed damages at \$17.2 million, and Summit was poised to win an injunction preventing Nidek from selling its competing EC-5000 Lasik machine as well as perhaps treble damages and even attorney fees. The 11-day trial pitted several well-known Lasik doctors against one another, including doctors Roger Steinert of Harvard Medical School and Ophthalmic Consultants on behalf of Summit and Peter Rapoza of Harvard Medical School and the Lasik Eye Center on behalf of Nidek.

At issue was the technique of differential ablation, whether Nidek's EC-5000 machine ablated the same depth of corneal material at each pulse of the laser, and the size of the light spot produced by the laser. Summit's victory, however, was short-lived. Boston Federal District Court Judge Edward Harrington overturned the jury's verdict after reviewing the evidence and found that Summit failed to prove patent infringement. In April of this year, the patent appellate court in Washington, D.C., agreed.

Nidek is now cleared to compete in the Lasik market, where Summit and Santa Clara, Calif.-based **Visx** dominate. Nidek's business model is different from most Lasik players in that Nidek doesn't charge a per-procedure fee collected by most other manufacturers and instead prefers to build a traditional capital equipment business.

Analysts of the refractive surgery market deem it "challenging" because although Summit was the first to win FDA approval for the Lasik procedure, there are now many competitors each touting its own set of patents. The only certainty is probably more litigation, as none of the Lasik players are strangers to the courtroom. Summit and Visx, for example, once sued each other and then settled by pooling their patents and jointly profiting each time a Summit or Visx laser was used to correct a patient's vision. A number of class-action lawsuits were filed in response to the patent pool on behalf of both doctors and patients and the Federal Trade Commission ruled in 1998 that the patent pooling partnership was anticompetitive. The partnership was ultimately dissolved, and Visx and Summit then cross-licensed their respective patents.

Visx, however, has also sued and ultimately settled with **LaserSight, Inc., Bausch & Lomb** and even Nidek — resulting in a \$9 million payment to Nidek. Summit and Visx both sued individual surgeons who were using custom-made or gray-market laser systems. Nidek, for its part, has sued both Summit and Visx.

The next technological improvement in the Lasik procedure is the use of a laser instead of a blade or microkeratome to create the flap, which is folded back to provide access to the corneal tissue during the laser surgery. The company that holds the patents on that technique is **Interlase Corp.** in Irvine, Calif. Interlase's management team consists largely of ex-Summit executives who left Summit after or shortly after it was sold for almost \$1 billion to **Alcon**, a **Nestle SA** subsidiary. Interlase has secured FDA approval and now has 120 machines in use.

Interlase has not sued or been sued for patent infringement, but vice president of business development Bernard Haffey, a resident of Dover, said there is a competitor in Germany attempting to establish its own IP position for the new flap-creation technique. Given his previous experience at Summit, he said he wants to "avoid litigation at all costs."

10/5 **Advanced Medical Optics, Inc.** announced that its registration statement on Form S-3 relating to resales by security holders of the company's issued and outstanding 2.50% Convertible Senior Subordinated Notes due 2024, and the shares of its common stock issuable upon conversion of the Notes, was declared effective by the Securities and Exchange Commission.

10/5 **PRK Study Finds Vision Stable after 12 Years**

Refractive outcomes of photorefractive keratectomy (PRK) for correction of mild to moderate nearsightedness remain stable from one to 12 years after the procedure. This is the conclusion of a British study appearing in the October 2004 issue of *Ophthalmology*

, the clinical journal of the *American Academy of Ophthalmology*. This is the first study to follow up with refractive surgery patients for more than 10 years after the procedure.

In this study, 68 of the original group of 120 patients in the first excimer laser clinical trials in the United Kingdom in 1990 underwent clinical assessment 12 years after having the PRK procedure. Though some refractive regression occurred in the first year after the procedure, refractive stability was maintained when checked at six and 12 years. At 12 years, 64 eyes (94%) had best corrected visual acuity better than or equal to best corrected visual acuity before the surgery.

Academy spokesperson Roger Steinert, MD, said, "This study represents a major body of work addressing an area of vital concern to refractive surgeons and refractive surgery candidates. Attention to the long-term results of these procedures is an obligation to our patients and provides an opportunity to maximize the quality of the outcomes with which our patients will live for the rest of their lives."

In the original trial, patients were treated with an early broad-beam ultraviolet laser, which was used to make a four-millimeter corneal treatment zone, called an ablation zone. Some patients developed night vision disturbances because the ablation zone was smaller than their pupils. Because the pupil becomes larger at night so the eye can receive more light, the patients could see the untreated and still myopic circular area of the cornea that lay beyond the ablation zone. However, all reported improvement in their night vision over the 12-year period. Today, small optical zones are no longer used, and most lasers are scanning-spot lasers, which produce a more uniform removal of corneal tissue.

Dr. Madhavan Rajan, MRCOphth, lead author of the study, said, "This study highlights the importance of ablation zone size in improving night vision problems and refractive predictability after PRK. Given that PRK has proven long-term stability, newer developments such as wavefront-guided customized ablations at the corneal surface are likely to yield better results than LASIK, while preserving the biomechanical integrity of the cornea."

In the current study, 51% of patients were very happy with their PRK outcomes. Ten patients (15%) were dissatisfied. No corneal thinning and no late regression or complications were found.

10/6 **Miravant Medical Technologies** announced PHOTREX as the new brand name for SnET2, a proposed PDT drug for the treatment of wet age-related macular degeneration (AMD). The company also announced that the United States Adopted Name Council (USAN) has designated "rostoporfin" as the drug's unique generic name. USAN is the agency that assigns generic names to pharmaceuticals.

"We believe that PHOTREX is a powerful and distinctive brand name for SnET2 photodynamic therapy," stated Gary Kledzik, chairman and CEO. On September 30,

2004, the FDA issued an approvable letter for PHOTREX outlining the conditions for final marketing approval, which included a request for an additional confirmatory clinical trial.

Wet AMD is a degenerative eye disease that can cause severe loss of central vision. It is estimated that over the next five years, 1.35 million people within the U.S. will develop wet AMD, with similar numbers outside the U.S.

- 10/7 **IntraLase Corp.** announced the initial public offering of 6,636,314 shares of its common stock at a price of \$13 per share. The 6,636,314 shares include 336,314 shares which are to be sold on behalf of certain selling stockholders of IntraLase. The company will not receive any of the proceeds from the sale of common stock held by the selling stockholders. In addition, IntraLase has granted the underwriters an option to purchase up to an additional 995,447 shares of common stock to cover over-allotments, if any. The shares have been listed on the Nasdaq National Market under the symbol "ILSE".

Banc of America Securities LLC is acting as sole book-running manager, **Wachovia Securities** is acting as senior co-manager, and **First Albany Capital** and **ThinkEquity Partners LLC** are acting as co-managers for the offering.

- 10/11 **Refocus Group, Inc.** announced the successful closing of an interim financing. This closing enables the company to continue its U.S. Food and Drug Administration Phase II clinical trial evaluating Refocus Group's Scleral Spacing Procedure for the surgical treatment of presbyopia, as well as fund its other operations for a period of time. The interim financing is designed to bridge the company's operations until the close of a subsequent private placement, strategic alliance or other financing alternative. Those financing efforts are currently being pursued by the company. The interim financing included the issuance of convertible debt and warrants and is described in a Form 8-K being filed with the U.S. Securities and Exchange Commission.

- 10/11 Michael Lachman of **ThinkEquity Partners** published an update report on **VISX: EYE: VISX Q3 Looks Fine, Q4 Looks Better**

We maintain our Buy rating on shares of VISX and keep our earnings estimates through 2005 unchanged, but lower our 12-month price target from \$31 to \$26 based on a target P/E multiple that is more in line with the company's ophthalmic device peers. Our new price target represents 26x our 2005 EPS estimate of \$1.01. We are also introducing a new 2006 EPS estimate of \$1.21, which reflects 20% growth over 2005. Based on our most recent LASIK channel check, we are maintaining our Q3 estimates of \$41.7 million in revenue and EPS of \$0.19, although we are increasing our procedure growth estimate and decreasing our CustomVue penetration estimate slightly. Our survey of LASIK providers suggested a high degree of practice-to-practice variability in procedure growth trends for Q3, which is common for the summer season, but the outlook for the fall and winter seasons was consistently positive.

Investment Highlights: Based on our most recent LASIK market channel check, we are maintaining our Q3 revenue estimate of \$41.7 million and EPS estimate of \$0.19, which is at the upper end of the management guidance range of \$0.17-0.19. While our Q3 revenue and EPS estimates remain unchanged, we are assuming a slightly different mix of procedure growth and CustomVue conversion. We are increasing our Q3 y/y procedure growth estimate from 12.0% to 13.4%, and decreasing our CustomVue penetration estimate from 38.0% to 36.5%. We are making directionally similar changes to both of these metrics in our model going forward as well, with no resulting change in our quarterly EPS estimates and minimal impact on our revenue estimates through 2005. We are also introducing new 2006 revenue and EPS estimates of \$208 million (+9%) and \$1.21 (+20%) respectively. Our modeling changes are discussed in greater detail below.

We are lowering our 12-month price target from \$31 to \$26 based on a target P/E multiple that is more in line with the company's ophthalmic device peers. We have previously based our 12-month target price for VISX shares on the average P/E multiple for a group of small and mid-cap medical device stocks (see attached tables). When we set our previous price target, that group of stocks was trading at an average P/E of 31x on 2004 EPS, which applied to our 2005 EPS estimate of \$1.01 resulted in our \$31 price target. That same group of stocks is still trading just over 31x 2004 EPS. However, our peer group of ophthalmic device stocks normally trades at a somewhat lower P/E multiple, currently 26x 2004 EPS. In recent months, VISX has been trading more in line with its ophthalmic device peers than with the broader group of small and mid-cap medical device stocks, and we base our new 12-month price target of \$26 on a 26x P/E applied to our 2005 EPS estimate of \$1.01. Our new price target represents 26% appreciation from current levels, consistent with our ongoing Buy rating. With forecast EPS growth of 25% in 2005 and 20% in 2006, we believe that VISX shares should continue to be valued in-line with their ophthalmic device peers, and that earnings growth should drive appreciation in the stock.

LASIK Channel Check: Q3 On Track, Q4 Off to a Strong Start: Over the past two weeks, we surveyed over two dozen LASIK surgeons and practice managers from over 15 states across the US, and checked in with corporate providers as well. The highlights of our latest field check are summarized below.

* The summer season is always the most variable across the industry in terms of procedure growth trends, and this year was no exception. Variability increased from July through mid-September, and we uncovered individual practices that experienced y/y procedure growth in September of over 30%, as well as individual centers that saw y/y declines of over 20%. Summer vacations for surgeons and patients, and the focus by the optometric community on back-to-school exams during August, contribute to this variability. Overall, we believe that y/y procedure growth trends were stronger in July and August than they were in September, although volume seems to have picked up in the final days of the quarter even in centers that lagged through most of September. We don't believe that the impact of the hurricanes that hit Florida and surrounding areas during September will have a meaningful impact on overall Q3 procedure numbers.

* Feedback from providers was consistently positive with regard to the outlook for the upcoming fall and winter seasons. LASIK patients have become increasingly aware of flexible medical spending plan benefits, which allow people to set aside pre-tax dollars from their paychecks to pay for non-reimbursed medical expenses (such as LASIK). This factor was cited repeatedly as the impetus behind increasing patient traffic heading into October, as patients prepare to spend remaining account balances prior to the end of 2004 and plan for new payroll deductions and LASIK procedures in 2005. Providers expect volumes to pick up throughout Q4, beginning in October, and January surgery schedules are already filling up.

* CustomVue adoption is still increasing, but at a slower rate. It is difficult to peg an overall average CustomVue penetration level based on input from individual centers, as penetration rates vary significantly across providers. But the sequential rate of increase has clearly slowed, consistent with VISX's Q2 report in which the CustomVue adoption rate increased to just 35% from 34% in Q1. The next significant drivers of faster CustomVue penetration will be new indications: hyperopia by the end of 2004, and higher levels of myopia by mid-2005.

* We do not expect the recent approval of **Advanced Medical Optics'** (AVO - \$38.70 - Accumulate - \$41 Price Target) Verisyse phakic IOL and the upcoming approval of the **STAAR Surgical** (STAA - \$3.99 - Not Rated) Visian ICL to have a noticeable impact on LASIK procedure volumes. We believe that these lenses will be utilized primarily in patients that are not good candidates for LASIK, particularly high myopes, that make up a small portion of the LASIK patient base.

VISX Modeling Updates: Following our latest channel check, we are updating our model to reflect a stronger procedure growth outlook and more modest CustomVue conversion forecasts. There are no resulting impacts on our quarterly EPS estimates through 2005, and the impacts on revenues are minimal. We are also introducing new estimates for 2006.

Procedure growth forecasts: For Q3, we are increasing our y/y procedure growth estimate for VISX from 12.0% to 13.4%. Based on the positive outlook for Q4-04, we are increasing our y/y procedure growth forecast from 9.9% to 12.7%, and suspect there could be further upside. For 2005, we are increasing our procedure growth outlook modestly, from 6.6% to 7.0%, and introducing a new 2006 procedure growth forecast of 6.5%.

CustomVue conversion forecasts: For Q3 and Q4-04, we are lowering our sequential growth forecasts from 300 incremental basis points per quarter (from 35% in Q2 to 38% in Q3 and 41% in Q4) to a more modest 150 basis point progression (from 35% in Q2 to 36.5% in Q3 and 38% in Q4). In the first half of 2005, the new hyperopia indication for CustomVue should drive faster penetration. Assuming that half of all hyperopia procedures, which represent 10-15% of the LASIK market, transition to CustomVue over a 2-3 quarter period, we forecast sequential growth to re-accelerate to 300 basis points

in H1-05, to 41% in Q1 and 44% in Q2. With CustomVue for high myopia coming online in H2-05, we expect sequential growth in CustomVue penetration to outpace the rate of increase in H2-04; we forecast 200bp of sequential growth per quarter, to 46% in Q3 and 48% in Q4. We forecast just over 50% overall CustomVue penetration in our new 2006 forecast.

Hardware forecasts: We are not changing any of our laser hardware modeling assumptions, except for the introduction of the next wave of hardware upgrades that could be launched by the end of this year. The next upgrade cycle will feature iris registration and cyclotorsional tracking, which should incrementally improve the precision of LASIK procedures performed on VISX Star lasers. We have not received any guidance from the company on pricing or anticipated volumes for these upgrades. Our initial forecasts include 100 upgrades in 2005 and 200 in 2006, at an estimated price of \$40,000 each. We expect to update these forecasts as the actual product launch approaches.

We are introducing new estimates for 2006. We forecast revenues of \$208 million (+9%) and EPS of \$1.21 (+20%). These numbers are based on procedure growth of 6.5%, CustomVue penetration of 50.5%, total laser placements of 100 (consistent with 2003 actual volume and our estimates for 2004 and 2005), and operating expense growth of 5%.

- 10/11 **Miravant Medical Technologies** announced that it had entered into a non-binding letter of intent with a group of existing Miravant investors to provide the company a convertible debt line-of-credit up to \$15 million. Upon execution of definitive agreements, the funds will be available at the company's discretion in increments of up to \$1.0 million per month, with convertible debentures for the principal borrowed amounts and associated warrants for shares of common stock to be issued and priced at the time of each borrowing. The transaction is subject to the negotiation and execution of definitive documents. In addition to this line of credit, the company had cash of approximately \$8.0 million as of September 30, 2004.

Gary Kledzik, chairman and CEO, stated, "We are very pleased to enter into this letter of intent with investors who have held an interest in Miravant for many years. The additional funding that the completed transaction will provide will enable us to focus on our business plan to complete our New Drug Application (NDA) process for PHOTREX."

- 10/12 Steve Gelsi of *CBS.MarketWatch.com*, reported on how a student-based VC fund cashed out on the IPO of **IntraLase: Student VCs cash out on IntraLase; Wolverine Venture Fund invested \$250,000**

When IntraLase went public on Oct. 8, the little-known **Wolverine Venture Fund** made \$1 million on its initial investment of \$250,000 in 1998. While not particularly large in

the world of venture capital, the IPO payday marked the first exit by the Wolverine Venture Fund, the only student-run venture fund in the United States.

Housed at the University of Michigan's Samuel Zell & Robert H. Lurie Institute for Entrepreneurial Studies at the Ross School of Business, the Wolverine Fund requires a two-thirds vote from its student-run board to take a stake in a startup. Students research all the companies, evaluate the business proposals and make the final investment decisions. With stakes ranging from \$50,000 to \$250,000, the Wolverine Venture Fund has made 20 investments in 11 companies in the past six years. Including the \$1 million made from IntraLase (ILSE: news, chart, profile), the fund now manages about \$2.5 million.

IntraLase, which licensed some of its technology from the University of Michigan, was the first investment made by the fund when it kicked off about six years ago, according to University of Michigan Professor Tim Faley, who serves as managing director of the fund. The fund first heard about IntraLase from a student who did a summer internship at venture firm **EDF Ventures**, an early investor in the company, he said.

In the wake of the dot-com boom and bust, the MBA students taking part in the fund are extremely selective. "The students are very tough," Faley added. University officials were "nervous" at first about turning over the initial \$3 million for the fund, a small part of the university's overall endowment. "We never invest alone. We always invest with a [venture] syndicate; there are advisers on the fund," he said. "The students have been, if anything, conservative."

IntraLase raised \$86 million in the IPO, which priced atop its \$11 to \$13 price range. The shares are now trading near \$17 per share. Jason Miller, 25, an MBA student at the University of Michigan who serves on the fund, said he's thinking about starting his own company and considering a move into venture capital.

Miller added IntraLase earned the Wolverine Fund's interest because of its "unique technology" in the laser eye-surgery market, which is poised for further growth. The company sells an eye surgery laser, related software and disposable devices for use in Lasik, the most common vision correction process in use today.

"Either way, this gives you experience to do all kind of things," Miller said. "We were pleased to see it go well." Faley said the Wolverine Venture Fund names eight new students per year out of a pool of 425 applications for the 16 to 20 member spots on the fund. "Some want to be venture capitalists, and half want to get the VC insight to start their own firm," he elaborated. "They don't see long, stable careers in large companies, so starting their own firm doesn't seem too risky."

10/12 **WaveLight Laser Technologie AG** announced that it had an increase in revenues in fiscal year 2003/2004. The company generated revenues of E62,041 thousand for the fiscal year, ending July 31, 2004. This represented an increase of 30% compared to the prior

year (E47,810 thousand). Earnings before interest and taxes (EBIT) also improved in fiscal year 2003/2004, rising by 40% to E6,204 thousand compared with the previous year (E4,419 thousand).

All four divisions on growth path: Once again, WaveLight Laser's core business areas of ophthalmology and aesthetics played a key role in its dynamic growth path. In the field of refractive surgery in particular, WaveLight was able to further extend its technology lead. After becoming the first European manufacturer to receive FDA approval for an excimer laser, the ALLEGRETTO WAVE, in October 2003, WaveLight is continuing to set new standards in the treatment of vision correction with its completely revamped ALLEGRETTO product family, which was launched at the beginning of fiscal year 2003/2004.

The high-end ALLEGRETTO WAVE Concerto laser, which is a further development for series production of the concept laser introduced in 2002, impressively demonstrates the current state of the art in the field of refractive surgery. Technical highlights including a repetition rate of 500 Hz and an outstanding design clearly put the laser system at the top of the range. In addition to technical innovations, the company's dynamic growth path depends on an intelligent sales structure. WaveLight therefore reorganized the distribution structures in its Ophthalmology Division at the end of April 2004. While sales in China and Japan continue to be organized by the company's long-standing sales partner, **Lumenis**, WaveLight sells its laser systems in Europe, the U.S.A., and other regions of the world directly.

The extremely successful Ophthalmology Division recorded revenues of E43,313 thousand in fiscal year 2003/2004 and contributed 70% of consolidated revenues. This represents an increase of around 34% compared to the prior year (E32,300 thousand). The Aesthetics Division also successfully continued its growth, generating revenues of E8,759 thousand in fiscal year 2003/2004. This represents an increase of 20% compared with the prior year (E7,311 thousand). The Division contributes 14% of the WaveLight Group's total revenues. As a full-service provider, WaveLight's Aesthetics Division develops, manufactures, and sells laser systems for applications ranging from lifestyle-oriented dermatological treatments to vascular surgery. As a result, the Aesthetics Division has also developed into a highly promising growth segment in the relatively short history of the company .

At the end of fiscal year 2003/2004, the MYDON and SINON aesthetics laser systems were successfully tested under 510(k) pre-market notification in line with the Food, Drug, and Cosmetic Act by the Food and Drug Administration (FDA) and approved for use in the U.S.A. In the coming weeks, WaveLight Laser Technologie AG expects to receive approval for two further aesthetics laser systems.

The Urology and Industrial Lasers Divisions also ended the fiscal year with highly positive results. The Urology Division reported total revenues of E3,552 thousand, an increase of 39% year-on year (prior year: E2,559 thousand). The Industrial Lasers

Division recorded revenues of E6,417 thousand. This represents an increase of 14% compared with the prior year (E5,640 thousand) for this segment.

"Once again we were able to improve on our strong past performance and demonstrate our technology lead. In the new fiscal year we will exploit our international market opportunities and gain increased market share," said Max Reindl, WaveLight Laser Technologie AG's founder and CEO.

- 10/12 The Executive Board of **WaveLight Laser Technologie AG** resolved, with the approval of the Supervisory Board, to implement a capital increase while applying shareholders' pre-emptive rights. To this end, the Executive Board is utilizing the authorized capital resolved by a large majority at the Annual General Meeting on January 14, 2004. The medical technology company, which is listed in Deutsche Börse AG's Prime Standard, will increase its share capital from the current figure of E4,242,078.00 to E6,342,486.00 by issuing up to 2,100,408 new shares. The new shares will be entitled to full dividend rights as from the current fiscal year, 2004/2005.

The banking syndicate led by **NORD/LB Norddeutsche Landesbank**, Hanover, is scheduled to offer the new shares to existing shareholders at a ratio of 2:1 in the period from October 30, 2004 to November 12, 2004. The announcement of the take-up price is provisionally set for November 9, 2004. In addition to NORD/LB, **HSBC Trinkaus & Burkhardt KGaA**, Düsseldorf, will be involved in implementing the increase in share capital.

WaveLight Laser will use the majority of the issue proceeds to expand one of its core business areas, ophthalmology. Within the Ophthalmology Division a new business area, intraocular surgery, will be established. In addition, the laser-based and diagnostic applications in the field of refractive surgery will be rounded off and sales activities intensified to expand the company's worldwide market presence.

The Aesthetics Division will also be further extended to meet future market needs. The expansion of the current range to include lightwave based systems will underscore WaveLight's full-service provider strategy and improve its national and international market presence in this business area as well.

"Our stronger equity base will allow us to invest more, and in a more focused manner, in the future. The expansion of our core competencies and strengthening of our sales structure will allow WaveLight to continue to participate in the global growth of the international medical lasers markets," commented Max Reindl, CEO and founder of WaveLight Laser Technologie AG on the positive effects of the capital increase.

- 10/13 **WaveLight Laser Technologie AG** announced its revenues forecast for fiscal year 2004/2005. The Executive Committee of the Erlangen-based laser producers expects revenues of E78 million for fiscal 2004/2005, which began on August 1, 2004. The EBIT

margin is also set to improve in the current fiscal year. WaveLight expects an EBIT margin of around 11% at the close of the fiscal year on July 31, 2005.

The forecasts for fiscal 2004/2005 are based on three success factors: Firstly, FDA approval of the ALLEGRETTO WAVE for the US market has brought WaveLight Laser Technologie AG much closer to becoming a global player. Secondly, the new ALLEGRETTO product range for refractive surgery was launched at the beginning of fiscal year 2003/2004, and finally, distribution structures in the Ophthalmology Division have been radically reorganized. These three factors will lead to a further increase in revenues in the current fiscal year. WaveLight Laser Technologie AG has also laid the foundations for worldwide growth in the aesthetics field. Following FDA approval in the U.S. market for the aesthetics lasers MYDON and SINON, WaveLight is now in a position to achieve sales success on the key world market for medical lasers.

"Based on the extremely encouraging results of previous years, we are expecting growth in revenues of around 25% in fiscal year 2004/2005. We are also planning to further expand our international market presence," said Max Reindl, CEO of WaveLight Laser Technologie AG, commenting on the forecasts for fiscal 2004/2005. The effects of the capital increase are not included in the forecast revenues for fiscal 2004/2005.

- 10/13 **IRIDEX Corporation** announced 510(k) clearance from the FDA for the new solid-state IRIS Medical IQ 810 infrared diode laser photocoagulator for the treatment of retinal disorders and glaucoma. The company's top-of-the-line, solid-state system represents its latest technological innovation and is designed to perform traditional and Minimum Intensity Photocoagulation (MIP) procedures in the office and operating room settings. In addition, the IQ 810 increases the clinical versatility available to ophthalmologists today with its SmartWare interactive software with customizable settings, advanced waveform capability, and unique FiberCheck Slit Lamp Adapter delivery device.

Theodore Boutacoff, president and CEO commented, "IRIDEX has been a pioneer and leader in the ophthalmic semiconductor-based laser industry since 1989 when the OcuLight product line was first introduced. Now, we are pleased to introduce the IQ 810, an intelligently engineered laser system designed to expand treatment capability to ophthalmologists while also simplifying use for MIP procedures."

The IQ 810 features SmartWare interactive software for intuitive set up and operation of the laser, customization of laser output and settings, and integrated system diagnostics. SmartWare enables quick access to CW-Pulse (continuous wave), MicroPulse, and LongPulse operating modes as well as advanced pulse modalities, Group and PowerStep, for precise control and laser energy output customization with developing protocols.

The IQ 810 is lightweight and portable, facilitating easy transport of the device from room-to-room or clinic-to-clinic. The intelligently designed internal circuitry results in precise pulse timing, power stability and consistent laser mode quality. The IQ 810 is compatible with a variety of IRIS Medical delivery devices including the FiberCheck Slit

Lamp Adapter (SLA), Laser Indirect Ophthalmoscope, G-Probe, DioPexy Probe and family of EndoProbe handpieces to maximize clinical versatility. The FiberCheck feature for the SLA is unique and new to the IQ 810 and allows the doctor to quickly and easily verify the integrity of the fiber before treatment which is increasingly important with the adoption of MIP procedures where endpoints are not visible.

The IQ 810 will be featured at the IRIDEX exhibit during the 2004 annual meeting of the *American Academy of Ophthalmology (AAO)* being held in New Orleans, October 22-26, 2004. The IQ 810 has been released to the market and is currently available to ship.

- 10/13 **IntraLase Corp.** announced that the underwriters of IntraLase's initial public offering have exercised their over-allotment option in full to purchase an additional 995,447 shares of common stock from IntraLase.

Including the over-allotment shares, IntraLase has issued and sold a total of 7,295,447 shares in the offering. An additional 336,314 shares were sold on behalf of certain selling stockholders of IntraLase. All of the shares, including the over-allotment shares, were sold to the public initially at a price of \$13 per share. Net proceeds to IntraLase from the sale, including the over-allotment shares, will be approximately \$86.8 million. IntraLase will not receive any of the proceeds from the sale of common stock by the selling stockholders. The shares have been listed on the Nasdaq National Market under the symbol "ILSE."

Banc of America Securities LLC is acting as sole book-running manager, **Wachovia Securities** is acting as senior co-manager, and **First Albany Capital** and **ThinkEquity Partners LLC** are acting as co-managers for the offering.

- 10/13 **Alcon, Inc.** completed an initial analysis of the one-year data from its comparative study of anecortave acetate (15 mg for depot suspension) versus Visudyne photodynamic therapy (PDT) in the treatment of wet age-related macular degeneration (AMD). In the study, the percentage of patients who maintained vision (defined as less than a three line loss in logMAR visual acuity) when treated per protocol with anecortave acetate was 45 percent, compared to 49 percent for PDT. Although anecortave acetate did not meet the primary non-inferiority endpoint of the clinical study, these overall results indicate that the two therapies are not statistically different from each other.

After analyzing the data, Alcon believes there were controllable factors that negatively impacted the overall results of the study, including drug reflux and treatment interval. Reflux occurs when a portion of the medication leaks out through the small incision in the conjunctiva during or immediately after application of the drug. The treatment interval refers to the medically reasonable timeframe during which re-administration of the drug should occur.

A preliminary analysis of the clinical data indicates that controlling for drug reflux during re-administration of anecortave acetate may provide a moderate improvement in patient outcomes.

To control reflux during administration, Alcon has initiated changes in the procedure, expanded training measures and developed a simple counter pressure device (CPD). This device has been evaluated in pre-clinical models where it was determined to be effective in controlling reflux. Based upon discussions with the FDA, the company has initiated a clinical pharmacokinetic study to evaluate the device. It plans to submit the results of this study to the FDA during its review of Alcon's new drug application (NDA). Furthermore, the company is incorporating this device into all current and future studies of anecortave acetate worldwide.

10/14 As reported by *Reuters*, shares of **Alcon Inc.** fell as much as 15% on Thursday after a clinical trial of its experimental drug to treat age-related blindness failed to show it was any better than the current leading therapy. Shares of **QLT Inc.**, which makes Visudyne, against which Alcon's experimental Retaane was tested, rose 7% on the Nasdaq, while shares of **Eyetechnical Pharmaceuticals Inc.**, which is developing a rival product with **Pfizer Inc.**, rose 14%.

QLT's Visudyne, Eyetechnical's Macugen and Alcon's Retaane are all designed to treat the worst form of age-related macular degeneration, the so-called "wet" form, which is the leading cause of blindness in the elderly.

An estimated 1.2 million Americans have wet AMD, which occurs when abnormal blood vessels in the eye leak and damage the part responsible for central vision. Macugen in August received a positive review from a U.S. advisory panel. A decision could come in January.

Alcon, meanwhile, said it still plans to file for U.S. Food and Drug Administration approval for its drug and said it plans to complete its application by the end of 2004. However, **Wachovia Securities** analyst Theodore Huber on Thursday cut the \$40 million in sales he had expected for Retaane from his 2005 model, saying he does not believe the drug will be approved. **JP Morgan** analyst Michael Weinstein in a research note said even with a 2005 approval, Alcon's ability to market Retaane has taken a "not insignificant hit." He also said Macugen "should have a notable efficacy claim supporting its launch, which is now likely coming well ahead of Retaane."

Alcon's shares fell \$10.65, or 13.9%, to \$65.75 in Thursday morning trade on the New York Stock Exchange, after touching a low of \$64.44. Shares of Eyetechnical gained \$5.08 to \$40.98 on the Nasdaq, while shares of QLT gained \$1.16 to \$16.61 on the Nasdaq.

10/14 **QLT Inc.** announced that it would continue the Visudyne (verteporfin for injection) in Occult (VIO) trial to the 24-month endpoint. This announcement is made following an analysis of the 12-month data which included an independent analysis by the Data and

Safety Monitoring Committee (DSMC) and their recommendation that the trial should continue unchanged to its conclusion at 24 months.

The VIO trial is an ongoing Phase III, multicenter double-masked randomized trial to determine if photodynamic therapy with Visudyne can reduce the risk of vision loss in age-related macular degeneration (AMD) patients with subfoveal occult with no classic choroidal neovascularization (CNV). The trial was designed to confirm the results of a previous Phase III trial, known as the VIP (Verteporfin In Photodynamic Therapy) trial, in patients with similar lesion type. While some benefit was seen in year one in the VIP trial, the trial did not achieve statistical significance in the primary outcome until year two. Similarly, the VIO trial did not achieve statistical significance at the 12-month time point. However, the VIO trial prospectively designated both 12 and 24 months as primary endpoints, therefore, statistical significance in either time point would be sufficient to conclude that the VIO trial is positive. Assuming the trial is positive, QLT plans to file for regulatory approval in the U.S. when the trial concludes, Visudyne is marketed by **Novartis Ophthalmics**, a division of **Novartis AG**.

There were no new safety concerns identified in the VIO trial to date.

The DSMC is an independent panel of experts who are not participating in the studies. The primary responsibility of the DSMC is to oversee the studies and safeguard the interests of current and future participants in these trials.

- 10/14 **QLT Inc.** and **Atrix Laboratories, Inc.** announced that QLT's registration statement on Form S-4 filed in connection with their proposed merger had been declared effective by the United States Securities and Exchange Commission (SEC). The registration statement includes a joint proxy statement/prospectus that will be sent to the stockholders of both companies.

The proposed merger remains subject to various closing conditions, including the approval of stockholders of QLT and Atrix. QLT has scheduled a shareholder meeting to vote on the issuance of QLT common shares in connection with the proposed merger. This stockholder meeting will be held at 9:00 a.m. (Pacific time) on November 19, 2004 at QLT's head office at 887 Great Northern Way, Vancouver, British Columbia. Atrix has scheduled a stockholder meeting at 10 a.m. (Mountain time) on November 19, 2004 to vote on the proposed merger, to be held at The Fort Collins Marriott, 350 East Horsetooth Road, Fort Collins, Colorado.

- 10/18 Ophthalmic devices company **Norwood EyeCare**, a subsidiary of **Norwood Abbey Limited**, announced it had opened its North American headquarters in the Atlanta area. The new facility at 6455 East Johns Crossing in Duluth, Georgia will house the sales, marketing and operations staff for Norwood EyeCare's North American business.

"Along with Europe and Asia, the U.S. is a pivotal market for us," commented Richard Walmsley, CEO of Norwood Devices (and head of EyeCare worldwide). "Up to 50

million Americans are candidates for laser vision correction. In 2003, more than three million laser corrective surgery procedures were performed worldwide, and recent surveys of ophthalmologists indicate that surgery volume has increased markedly in the past year."

Norwood EyeCare is the manufacturer of the Centurion SES Epikeratome for Epi-LASIK, the next generation in laser vision corrective surgery. Instead of using a sharp blade to make an incision in the cornea, the Epikeratome employs a non-sharp plastic edge that oscillates as it sweeps across the cornea to gently separate a hinged sheet of epithelium along a natural cleavage plane.

Norwood's bladeless Epi-LASIK technology provides the benefits of LASIK but is designed to reduce trauma to the eye and the risk of LASIK-induced dry eye, facilitating faster recovery and less postoperative pain. Patients for whom LASIK is not advised -- such as those with thin corneas or dry eye -- or who have had concerns about potential LASIK side effects are strong candidates for Epi-LASIK.

"Epi-LASIK is a huge step forward in laser vision corrective surgery," explained Marguerite McDonald, MD, Professor of Ophthalmology at Tulane University, a pioneer in laser surgery and former president of the *American Society of Cataract and Refractive Surgery*. Dr. McDonald is the medical monitor and a principal investigator for the U.S. prospective study of Epi-LASIK, a 3-month study to evaluate visual recovery, pain and post-operative regimen.

Dr. McDonald continued, "My patients are relieved when I tell them their laser surgery can be done without using a cutting blade. I feel the risk/benefit ratio gives Epi-LASIK advantages over LASIK."

The inventor of the Epi-LASIK technology, Professor Ioannis Pallikaris, MD, and president of the University of Crete, will act as a consultant to Norwood and as a foundation member of its clinical advisory board. Lamar Chandler, who heads Norwood EyeCare's marketing in the U.S. and Europe, has more than 12 years of senior management and product development and marketing experience in the ophthalmic surgical devices sector. Norwood's management brings more than 50 years of cumulative in-house expertise in the field of ophthalmology and a worldwide network of professional industry contacts.

Norwood EyeCare's new Atlanta headquarters will enable it to access the tremendous local pool of technology-savvy workers, and the area's extensive transportation resources will make it easy to reach customers throughout the U.S. and internationally. The facility is located in Johns Creek, a 1,900 acre master-planned, mixed-used development situated in the fast-growing North Fulton/South Forsyth area.

10/18 Ahead of **VISX** reporting its third quarter results, Jason Mills of **First Albany Capital** issued an update report: **Downgrade to Neutral - Survey Results Solid, but Other Cautionary Factors**

- * We are downgrading on rating on VISX to Neutral from Buy.
- * Our latest on-line LASIK survey included 36 LASIK surgeons, more than 90% of who utilize the VISX S4 laser.
- * Our analysis of these results suggests VISX' 3Q procedure growth is tracking to roughly 10% and Conversion to Custom (CTC) is in the 35%-40% range
- * All things being equal, these data suggest in-line procedure growth and CTC relative to our original 3Q targets for VISX of 10.9% and 38.9%, respectively.
- * However, several factors taken together make us cautious that all things in 3Q are NOT equal to prior periods, including: 1) survey results good but not great - suggest only in-line results, 2) Consumer sentiment data are deteriorating, 3) inclement weather may have impacted 3Q, 4) Year-over-year comps are difficult, and 5) increasing competitive activity.
- * We are modestly lowering our 3Q, 2004, and 2005 revenue and EPS targets. The drivers are more conservative procedure volume and CTC targets.
- * Downgrade to Neutral. The combination of factors mentioned above makes us cautious. We move to the sidelines for now (downgrading our rating on VISX to Neutral from Buy).
- * While we do not believe EYE is overvalued; the next few quarters may not show the upside necessary to drive multiple expansion, in which case EYE would likely perform in line with the overall market.
- * We reduce our price target to \$23 from \$29.

10/19 Jason Mills of **First Albany Capital** also published a preview of **Bausch & Lomb**, prior to its earnings report: **3Q:04 Preview: Expect Fundamentals to Continue Improving - Reiterate Strong Buy**

- * Expect Another Solid Quarter with Potential for EPS Upside. BOL will report 3Q:04 financial results Wednesday, October 20, before the open.
- * We expect BOL to meet or exceed expectations, with potential upside to our 3Q:04 and 2004 EPS estimates of \$0.72 and \$2.86, respectively.

* Our model estimates 3Q and 2004 revenue of \$549.7M (8.0% Y/Y growth) and \$2,222.5M (10.1% Y/Y), respectively.

* Focus on Key Catalysts. Recent launch of One-Day Medalist in Japan, strong worldwide growth trends in contact lenses, Zyoptix market share gains, ocular vitamins growth trends, and an update on launch timing of Zylet (4Q:04E) and Retisert for Posterior Uveitis (mid-2005E) are all areas we will be listening for on the conference call.

* Look for Commentary on Possible Uses of \$453M Cash Held Offshore, but Potentially Repatriated Soon. Moreover, we estimate the company has an additional \$370M in permanently invested profits overseas.

* Reiterate Strong Buy Rating. BOL is reaping the rewards of very sound operating changes made over the past few years in terms of product focus, strengthening product pipeline and cost cutting, and we think there remains significant leverage in the P&L left to unlock, with decent visibility into doing it.

Refractive Surgery: \$33.5M estimate (17.4% growth Y/Y). The comps for the LASIK business are relatively easy in 3Q, but more difficult in 4Q, when Zyoptix (its custom LASIK system) was launched in 2003, both of which are reflected in our estimates. Importantly, we think the profitability of this business is beginning to be unlocked, and will be a contributor to (rather than a detractor from) earnings growth leverage going forward.

10/19 **NovaMed, Inc.** announced that it had entered into an amendment to its credit facility that increases the size of the facility from \$30 million to \$50 million and extends the term by two years to June 30, 2008. **National City Bank** remains as agent, with **LaSalle Bank** and **The Northern Trust company** as the other participating banks. NovaMed intends to use the expanded credit facility for the acquisition and development of ambulatory surgery centers as well as for general corporate purposes.

"With five ambulatory surgery center acquisitions closed so far this year representing over \$21 million in total purchase price and a strong acquisition pipeline, we believed it was prudent to expand the size of our credit facility at this time," said Stephen Winjum, NovaMed chairman, president and CEO. "We are very pleased with the terms of our amended credit facility and greatly appreciate the confidence expressed by our banks in NovaMed's management team and growth strategy." As of September 30, 2004, NovaMed had \$7,000,000 in outstanding borrowings from its credit facility.

10/19 **IRIDEX Corporation** reported results for the quarter ended October 2, 2004. Revenue for the quarter decreased 1.1% to \$8.2 million from \$8.3 million reported for the third quarter a year ago. The company recorded a net loss of \$720,000 (10 cents per share) as compared with a net profit of \$261,000 (4 cents per share) for the third quarter of 2003. Included in the third quarter 2004 net loss was a one-time charge of \$1.2 million to

establish a reserve for historical adjustments of state sales taxes. Additionally during the third quarter of 2004, the company reserved approximately \$300,000 for saleable, but aging and potentially excess inventory partially associated with the company's recent introduction of new products.

Ophthalmology sales totaled \$7.2 million, an increase of 4.3% compared with the third quarter of 2003. Dermatology sales were \$1.0 million, a decrease of 28% compared with the third quarter in 2003. Total Domestic and International sales were down slightly compared to the third quarter in 2003. Since international sales are denominated in US dollars, foreign currency fluctuations had no material impact.

Year-to-date 2004 ophthalmology sales totaled \$20.1 million, an increase of 7.9% compared with the first three quarters of 2003. Dermatology sales year-to-date were \$3.6 million, a decrease of 17% compared with the first three quarters of 2003. Year-to-date International sales were up 12.1% while Domestic sales were down 1.9% compared to the first three quarters of 2003.

Cash and cash equivalents at quarter-end were \$18.1 million as compared to \$16.3 million at the end of the fourth quarter in 2003, January 3, 2004. Inventories were \$8.4 million at the end of third quarter 2004, down from \$8.7 million at the end of fourth quarter in 2003. Inventory turns continued to show improvement and were 2.2 at the end of Q3 2004 compared to 1.9 at the end of Q3 2003 and 1.8 for the 2003 fiscal year. Accounts receivable in Q3 2004 was \$6.5 million, resulting in DSO of 69 days which was the same DSO reported in Q3 2003 as compared to the 66 days reported at the end of the fourth quarter in 2003.

"We are pleased with our two recent new product introductions, the IQ 810 in ophthalmology and the VariLite 532/940 in dermatology and we are encouraged by the year-over-year as well as the year to date growth in the ophthalmology business despite the typical seasonality of the third quarter," said Theodore Boutacoff, IRIDEX president and CEO. "Had it not been for the sales tax and inventory charges adjustments, we would have been profitable for the quarter."

"The introduction of the VariLite in dermatology provides a cost effective alternative for treating 19 different dermatology indications and the dual wavelength expands on our existing platform to allow treatment of deeper larger vessels such as leg veins. The IQ 810, our top-of-the-line infrared laser system in ophthalmology, is designed to perform traditional and minimum intensity photocoagulation (MIP) retinal and glaucoma procedures. We will feature the IQ 810 at the 2004 annual meeting of the *American Academy of Ophthalmology (AAO)* in New Orleans. We have been notified by Dr. Elias Reichel, TTT4CNV Study Chairman and Associate Professor of Ophthalmology at Tufts University School of Medicine, that he intends to present updated information on the TTT4CNV Clinical Trial for treating occult wet age-related macular degeneration (AMD) at the AAO Retina Subspecialty Day Program on Friday this week," continued Boutacoff.

Sales Tax and Inventory Write Downs: During the third Quarter 2004 the company completed a comprehensive review of its sales tax collection practices. Historically the company had been collecting and remitting sales tax in only those states where it believed it had nexus. Based on this independent review, the company will now begin to collect and remit sales taxes from customers in additional states and will attempt to enter into voluntary settlement agreements with certain states for the payment of prior period sales taxes and associated interest. As a result the company has recorded a one-time charge of \$1.2 million to establish a reserve for unpaid sales taxes and interest. The \$1.2 million, which represents the current estimate of the amounts to be remitted to these states, could differ materially from the actual amount recorded.

Boutacoff explained the one-time charges. "IRIDEX has proactively adopted this sales tax collection policy to reflect current best corporate practices across the United States. We believe that the \$1.2 million charge will cover the company's potential sales tax obligations. We will not pursue historical sales tax collection from our customers, but plan to collect sales taxes on all future sales. Additionally, in light of our new product introductions, the company believes that it is prudent at this time to reserve \$300,000, for saleable, but aging and potentially excess inventory."

10/20 **Bausch & Lomb** reported worldwide sales of \$548.9 million for the quarter ended September 25, 2004, an 8% increase (or growth of 4% on a constant-currency basis) over the prior-year period. Sales gains were reported in each of the company's geographic business segments and in all product categories except lens care.

Earnings per share of \$0.79 grew 32% as compared to the \$0.60 per share reported a year ago. Operating margins were 14% of sales in the third quarter, compared to 12% in the prior year. Lower-than-planned research and development expenditures combined with operating expense management more than offset a decline in the company's gross margin ratio. Gross margins were 57.8% of sales in the third quarter compared to 58.8% in 2003, due to unfavorable sales mix shifts as compared to the prior-year period, as well as charges taken in the current quarter for manufacturing asset and inventory obsolescence write-downs that will not recur.

The company indicated that it now expects full-year 2004 constant-currency revenue growth of approximately 6%, translating to reported growth of between nine and 10%, should exchange rates remain where they are today. Earnings per share are now forecast at between \$2.85 and \$2.90 per share, up from previous expectations of between \$2.80 and \$2.85 per share. For 2005, the company projects constant-currency revenue growth of between 6 and 7%, yielding earnings per share between \$3.30 and \$3.40.

Bausch & Lomb chairman and CEO Ronald Zarrella said of today's announcement, "Our third-quarter results demonstrate the opportunities within our leaner organization to leverage sales growth into even higher earnings growth on an ongoing basis. Some of the quarter's upside was due to lower R&D spending, reflecting the timing of certain in-licensing opportunities as compared to our original projections, and not a change in

our commitment to accelerate R&D investment to fuel long-term growth. Given the leverage opportunities within our current structure, we are confident in our ability to achieve the 2005 earnings targets we set forth today."

Refractive revenues were up 22% for the quarter, reaching \$34.7 million, compared to \$28.5 million for the third quarter of last year. But, revenues were down 3% from the \$35.6 million for this year's second quarter, and down 11% from this year's first quarter.

Several analysts provided their comments on BOL's results:

Jason Mills of **First Albany Capital: Mixed Results in 3Q; Remain Bullish Overall, But It's a "Show Me" Stock Again**

- * **Mixed Results in 3Q** - EPS upside of \$0.07, to \$0.79 vs. our \$0.72 estimate (consensus \$0.73), did not excite us, given the mechanics of the upside (essentially all driven by lower R&D spending).

- * **Sales of \$549M were in line with our estimate of \$550M.** Pharma, cataract, and refractive divisions outperformed, while contact lenses and lens care solutions fell modestly short. We expect contact lens growth to reaccelerate markedly in 4Q and expect this area to be the fastest-growing division for BOL in 2005, due primarily to new product launches.

- * **Margin Picture Mixed** - Gross margins came in light (58% vs. 59% estimate), while operating margins were strong (14% vs. 13% estimate). SG&A leverage is indisputable, but lower R&D spending made the OM result less sterling.

- * We are taking our rating on the stock down one notch, to Buy from Strong Buy. While we believe there is more upside potential than downside risk from yesterday's lower close, we see less upside over the next 12 months (10%-15% vs. 20%+).

- * We think multiple expansion is limited to 20x forward EPS until the company proves it can expand operating margins and grow R&D as a percentage of sales simultaneously. We believe it can, but realistically, BOL is a "show-me" stock again.

Joanne Wuensch of **Harris Nesbitt: BOL--3Q Reflects BOL's Balancing Act**

- * **Event:** Bausch & Lomb reported 3Q04 results that were mixed: revenues of \$549 million (up 8%; up 4% excluding foreign exchange) were lighter than our \$555 million estimate, yet a lower-than anticipated R&D and SG&A spend led to EPS of \$0.79, topping our \$0.74 and the consensus \$0.73 estimates.

- * **Impact:** While the EPS beat is a positive, showing strength in leveraging the franchise, the source of the beat is not likely to warm investors' hearts. R&D expenses were lower than expected, as several licensing partnerships did not materialize: BOL remains

committed to increasing its R&D spend and its product pipeline -- leading to the question of how do revenues accelerate? Which is not answered with a 4% ex-fx revenue growth rate.

* **Forecasts:** Our 4Q04 EPS estimates remains \$0.91, leading to a full-year 2004 EPS estimate of \$2.90, at the top-end of management guidance. For 2005, our revenue estimate declines to \$2.39 billion (up 7.7%) from \$2.40 billion, but EPS increases to \$3.32 (up 16.4%) from \$3.19. For 2006, our revenue estimate declines to \$2.57 billion (up 7.7%) from \$2.58 billion and, again, our EPS increases to \$3.71 (up 13.9%) from \$3.60.

* **Valuation:** BOL trades at 17.4x our 2006 EPS estimate, just below the group's 17.9x.

* **Recommendation:** We maintain our NEUTRAL rating.

Ted Huber of **Wachovia Securities: BOL: R&D Discipline Drives Upside--Raising Estimates Again**

* **R&D DISCIPLINE DRIVES 11TH QUARTER OF EPS UPSIDE:** With just 4% cc revenue growth (vs. 6.5% H1 2004) and weak gross margins (57.8% vs. 58.8% Q3 2003), BOL delivered 31.4% EPS growth, beating consensus by \$0.06. OpEx increased just 1% in part due to lower R&D spend. Gross margins were weak in equal parts due to mix and one time obsolescence/asset write down charges. The lower R&D spending reflects appropriate discipline on license deals not lack of opportunity, in our view.

* **WEAK TOP LINE NO CAUSE FOR WORRY:** BOL revenue was \$4.9 million below our target as 13.5% surgical growth did not fully offset weak consumer growth (up 4.9%). Management cited several anomalous issues that held back growth, including product launch timing and distributor changes. We fully expect cc revenue growth to accelerate back the 6% range Q404 and 2005. BOL's H2 2004 and 2005 pipeline is rich with lens (Medalist 1-day in Japan and PureVision in U.S.), lens care (ReNu with Moistureloc) and pharma (Zylet and Retisert for Uveitis) launches that support this acceleration.

* **INCREASING ESTIMATES:** Our new \$2.90 2004 estimate is at the high end of guidance. Our \$0.92 Q404 EPS estimate is down \$0.03 from prior due to more conservative GMs and higher R&D spending. We are increasing 2005 to \$3.37 on lower OpEx growth (new guidance is \$3.30-3.40). Excluding Yen impacts, our model forecasts 16% EPS growth for 2005.

10/20 Two analysts provided a preview of the AAO meeting being held in New Orleans October 22 through October 26th:

Michael Lachman, **ThinkEquity Partners: AAO Preview and Meeting Planner for Ophthalmology Investors.**

In this report, we provide a preview along with a comprehensive planner for this weekend's *American Academy of Ophthalmology (AAO)* meeting, focused on our universe of ophthalmic device and pharmaceutical companies. As was the case last year, this year's AAO is less about headline clinical data than it is an opportunity to gauge physician attitudes within our core areas of focus in ophthalmology: refractive surgery and emerging retinal therapeutics. Of particular interest are: (1) LASIK procedure growth and conversion to custom/wavefront technology; (2) the growing interest and advancing technology in the field of presbyopia correction; and (3) physician attitudes toward and expected utilization of current and new AMD therapeutics, including Visudyne from QLT/Novartis, Macugen from Eyetech/Pfizer, and Retaane from Alcon. With the "pre-announcement" of the one-year Retaane pivotal trial data, the most important new clinical data will be two-year results for Macugen in AMD.

Investment Highlights: The American Academy of Ophthalmology (AAO) 2004 Annual Meeting will be held in New Orleans, Louisiana on October 22-26, beginning with the Subspecialty Day this Friday. The AAO provides us with the opportunity to challenge our existing views of the ophthalmic industry and to spot new and emerging trends. In this report, we provide a preview along with a comprehensive planner for the AAO meeting, focused on technologies and clinical developments relevant to our universe of ophthalmic device and pharmaceutical companies. Our primary areas of focus within the ophthalmic industry are (1) refractive surgery, including LASIK and other energy-based vision correction technologies, along with implantable lens-based approaches, and (2) retinal disease therapeutics, particularly for the treatment of age-related macular degeneration (AMD). Our AAO preview and detailed meeting planner reflect these areas of focus.

Companies Highlighted in this Report:

Advanced Medical Optics (AVO - \$36.58 - Accumulate - \$41 Price Target)
Alcon, Inc. (ACL - \$66.44 - Accumulate - \$72 Price Target)
Bausch & Lomb (BOL - \$61.20 - Accumulate - \$71 Price Target)
Eyetech Pharmaceuticals (EYET - \$41.86 - Not Rated)
QLT, Inc. (QLTI - \$15.67 - Accumulate - \$15 Price Target)
VISX, Inc. (EYE - \$19.50 - Buy - \$26 Price Target)

Refractive Surgery: Focus on LASIK Market Dynamics and Emerging Presbyopia Treatments

At half-year intervals, the AAO and ASCRS conferences provide an opportunity to gauge growth prospects within the dynamic LASIK market, from the point of view of the refractive surgeon.

* Over the past year, conversion to custom/wavefront technology has also been a major focus. Late last year at the 2003 AAO, the evidence of clinical superiority of custom LASIK over standard LASIK was limited. By the spring ASCRS meeting, the evidence

had grown stronger, and we expect even more data in support of custom LASIK at this year's AAO.

* However, with sequential growth in custom LASIK penetration beginning to plateau in recent months, surgeon (and patient) attitudes toward the cost/benefit of custom LASIK have become even more important than the supporting clinical data. At the AAO, we will measure physician attitudes against our latest custom LASIK market forecast, which calls for only modest incremental penetration during H2-04, with somewhat faster growth in 2005 driven by new indications for VISX's CustomVue for hyperopia and high myopia.

Last year's AAO introduced custom/wavefront excimer laser systems from both VISX and Bausch & Lomb; this year's new product launches will be more incremental.

* VISX is planning to launch its new iris registration and cyclotorsional tracking system in the US by the end of this year, and will be previewing these new technologies. VISX is also launching its new Fourier-based wavefront software. Importantly, we should get a look at updated CustomVue clinical data for both hyperopia (expected approval end of 2004) and high myopia (expected approval mid-2005).

* On the competitive front, we will be looking to gauge competitive inroads against VISX, particularly from WaveLight and Bausch & Lomb, which have both had some success in placing lasers over the past year. This is also the first major conference since Alcon received approval to treat astigmatism with its CustomCornea system, and we will be looking to see if this approval has reinvigorated the refractive surgery business at the company. New clinical data for hyperopia and mixed astigmatism indications for Alcon's CustomCornea system is expected. We believe that custom/wavefront systems from all three major suppliers (VISX, Alcon, and Bausch & Lomb) provide satisfactory clinical outcomes, and we will be on the lookout for any credible clinical data that differentiates any of them.

The growing emphasis on the treatment of presbyopia will be a trend for years to come, driven by a number of diverse technologies. There will be numerous sessions and symposia focused on emerging approaches to correcting presbyopia, involving products that are already available on the market and others that are under development.

* We believe that accommodating IOLs are the presbyopia products with the highest potential. The crystalens from eyeonics (private), the first approved accommodating IOL, has been on the US market for nearly one year. We hope to get an update on adoption rates for this lens, as well as progress in the area of reimbursement for a product that is, for now, unavailable to Medicare-aged cataract patients. At the AAO, we expect to see clinical updates on Alcon's ReStor pseudo-accommodating/multifocal IOL. We also expect status updates for second-generation accommodating IOLs.

* VISX is in the process of launching its LASIK-based treatment for hyperopic presbyopia internationally, and is beginning a US clinical trial. We expect to see more descriptive information on this procedure than actual clinical data. We will also be gauging the commercial prospects for conductive keratoplasty (CK), an RF-energy-based treatment for presbyopia that was approved by the FDA in March of this year and is being marketed by Refractec (private).

This year's AAO will be the first following FDA approval of a phakic intraocular lens. Following the recent FDA approval of the Verisyse anterior chamber phakic IOL, Advanced Medical Optics (AMO) will be officially launching the product at this meeting.

* We continue to view this as a niche market for the foreseeable future, addressing a small base of highly myopic patients (-8D to -12D and above). Now that there is an approved product on the market, cataract/refractive surgeons will be able to discuss their intentions with these lenses from a new perspective. Although we believe there is likely a backlog of interested patients, we expect AMO to roll out the Verisyse in a measured fashion.

* Staar Surgical (STAA - \$3.84 - Not Rated) is still awaiting US approval of its Visian ICL posterior chamber phakic IOL, pending resolution of manufacturing/quality issues with the FDA. Because this lens involves a more familiar implantation technique, we believe that it is more likely than the Verisyse lens to ramp quickly in response to the patient backlog.

Retinal Therapeutics: Sizing Up the Market with Macugen in the Wings

Some of the expected suspense leading into this year's AAO was eliminated when Alcon released top line results of the Retaane Phase III trial last week. Alcon has already announced that the trial failed to meet its non-inferiority primary endpoint, and we are now expecting a delayed approval until additional efficacy data can be submitted to the FDA. We expect to see additional color on the trial results presented and discussed on Friday morning at the Subspecialty Day program, on Friday afternoon at Alcon's investor/analyst meeting, and on Monday morning during the scientific program.

* We will be trying to assess the attitudes of retinal specialists toward Retaane given the latest clinical trial data: whether they would still like this drug approved and available despite inconsistent efficacy results from the trials, given its favorable safety and administration profiles, or whether a "show-me" attitude prevails. It has been our view that Retaane, if approved next year, was to be used mostly in combination with Visudyne and Macugen and not as first-line monotherapy; we will be gauging the impact of a delayed Retaane approval on future usage of these other two products.

* With the Retaane data disclosure largely out of the way, the two-year Macugen data moves center stage. Data will be presented in two sessions on Friday morning at the

Subspecialty Day. Given improvements made in the administration protocol during the course of the trial, a lower infection rate in the second year of the trial is a distinct possibility. Although the infection rate seen in the first year is largely viewed as acceptable, this has been the highest profile complication so far. We will be consulting with retinal specialists at the meeting to test our view that uptake will be rapid following FDA approval, which could come as early as the end of this year.

* We don't expect any meaningful new data for Lucentis from Genentech (DNA - \$48.93 - Not Rated). We will, however, have our ears to the ground to see if the buzz on this drug is still as positive as it has been in recent months.

We don't expect any headline data from any of the key Visudyne clinical trials (such as VIO), but the steady flow of incremental data and discussion regarding combination therapy with injected triamcinolone should continue. This combination, which has seen significant adoption by the retinal community, has been the subject of a number of independent studies of late and will be reflected in numerous posters and podium presentations. The AAO will also provide an opportunity for us to reevaluate the assumptions that led to our downgrade of QLT shares two months ago: that upside from newly reimbursed occult and minimally classic indications is more limited than we had previously expected, and that the approval of Macugen will have a greater impact than we had previously forecast.

We expect to see a continued and growing focus on AMD prevention and risk reduction. Despite advances in the treatment of wet AMD, there seems to be a strong underlying feeling within the ophthalmic community that all of these new wet AMD therapies are "too little too late." Bausch & Lomb has a stake in the growing interest in AMD prevention (OcuVite PreserVision vitamin supplement), as does Alcon (Retaane for risk reduction).

Ted Huber of Wachovia Securities: Retina Drugs And IOLs Highlight 2004 AAO Meeting

* **AAO ANNUAL MEETING BEGINS FRIDAY 10/22:** The 2004 AAO (American Academy of Ophthalmology) meeting begins Friday, 10/22 and ends Tuesday, 10/26. The conference begins on 10/22 with two-day subspecialty programs on refractive surgery, retinal disease, and glaucoma. We expect no critical new clinical data to be presented. Of most value should be surgeon reaction to recently released data and assessment of commercial activities by industry participants.

* **THE THREE MOST CRITICAL ISSUES TO WATCH:** We focus on three product areas as most important to our ophthalmology coverage stocks: 1) physicians' reactions to ACL's RETAANE data which has fallen short of primary endpoints in its pivotal trial, 2) surgeon reactions and commercialization traction/plans for ACL's Restor multifocal IOL and AVO's Tecnis diffractive IOL, 3) physicians' impressions of BOL's recently-released RETISERT for Uveitis data (met efficacy endpoints with comparable

safety to prior trials). We continue to view RETISERT as an approvable product that is positioned to be a positive catalyst for BOL shares in the year ahead.

*** OTHER IMPORTANT ISSUES:** Other issues important to our stocks include surgeon buzz on LASIK procedure volume and custom mix (EYE), competitive viscoelastic data (AVO), new phakic IOLs (AVO), and LASIK vs. IOLs for treating presbyopia (AVO, ACL, BOL, EYE).

*** WACHOVIA-SPONSORED EVENT ON RETISERT DATA:** On Saturday, 10/23 we will discuss BOL's recently released data on RETISERT for Uveitis with retinal specialist and lead Phase III investigator Dr. Robert Devenyi.

10/20 **Alcon, Inc.** reported global sales of \$958.1 million for the third quarter of 2004, an increase of 16.5% over global sales in the third quarter of 2003, or 13.3% excluding the impact of foreign exchange fluctuations. Net earnings for the third quarter of 2004 increased 26.9% to \$194.3 million, or \$0.62 per share on a diluted basis, compared to \$153.1 million, or \$0.49 per share, for the third quarter of 2003.

Cary Rayment, Alcon's president and CEO commented, "This quarter reinforced our market leadership and the value of the many sales drivers we have in our portfolio. We are early into a new product cycle for many of these important products and expect to see healthy growth from them for many years to come. As this quarter also demonstrated, with our established manufacturing, distribution and sales infrastructure in place around the world, we expect to consistently translate this growth to faster profit growth."

Refractive Sales Highlights: Refractive revenue declined 1.2% to \$16.5 million, compared to \$16.7 million in the same quarter a year ago, but higher than the \$15.9 million reported in the second quarter, as growth in procedures and conversion to higher-priced custom procedures almost overcame lower sales of equipment.

Financial guidance for the full year 2004:

- * Sales are expected to be between \$3,850 million and \$3,900 million.
- * Diluted earnings per share are expected to be between \$2.52 and \$2.55. This range excludes \$0.18 per share in tax benefits realized in the second quarter of 2004. Diluted earnings per share, including the impact of these tax benefits, are expected to be between \$2.70 and \$2.73.

Two analysts provided their inputs on Alcon's results:

Ted Huber of Wachovia Securities: ACL: Who Needs Retaane -- Another Exceptional Quarter

- * Alcon delivered its highest ever constant currency revenue growth (13.3%) and gross margins (74.1%) as a public company in Q304 results that significantly exceeded

guidance and consensus (EPS of \$0.62 vs. \$0.57). Earnings quality was high (tax rate and OpEx were above targets).

* **BROAD TOP LINE STRENGTH:** Pharma was up 20.1% (paced by surprisingly strong anti-infective, allergy, and otic growth). Surgical was up 15.1%, paced by a 17.7% rise in IOLs. Consumer revenue grew 11.4%. All divisions beat our targets and guidance handily. While ophthalmic market growth is robust, at these growth rates, Alcon appears to be taking share in most all businesses.

* **MORE CONSERVATIVE GUIDANCE:** Full year 2004 targets imply just 4.3% to 10.2% reported Q4 2004 revenue growth (currency should contribute near 1%) and EPS of \$0.46-0.49, up just 9% to 17%.

Joanne Wuensch of **Harris Nesbitt: ACL--3Q04 First Look; Earnings Power Retained**

* **Event:** Once again Alcon posted superb financial results with 3Q revenues of \$958 mil (up 16.5%; up 13.3% ex-fx) and EPS of \$0.62, which easily beat our estimate for \$0.56 and the Street's \$0.58. Revenue strength was witnessed across all business units: pharmaceutical sales were \$376.4 mil (up 20.1% vs. our 9.9% estimate), surgical sales were \$438.5 mil (up 15.2% vs. our 9.3% estimate) and consumer eye care sales registered \$143.2 mil (up 11.4% vs. our 6.7% estimate). Gross margin of 74.1% vs. 72.2% in 3Q03 was aided by product mix and manufacturing efficiencies.

* **Impact:** Positive. Despite the recent pullback in ACL shares owing to disappointing Retaane results, we believe the third quarter's performance will be viewed positively as the financial upside continues to reinforce the strength of a broad portfolio of market-leading ophthalmology products.

* **Forecasts:** Management issued guidance for 2004 revenues in a range of \$3.85-\$3.90 billion (vs. both our and consensus \$3.84-billion estimate) and EPS between \$2.52 and \$2.55 (prior guidance was \$2.43-\$2.46)

* **Valuation:** Trading at 20.5x our 2006 EPS est. vs. two-year historical average of 27x.

* **Recommendation:** We reiterate our OUTPERFORM rating on ACL shares.

10/21 **Advanced Medical Optics, Inc.** announced financial results for the third quarter of 2004. Net revenue rose 31.2% to \$198.4 million compared with last year's third quarter, reflecting continued growth in the company's core ophthalmic surgical and eye care businesses, and the benefits of the **Pfizer** acquisition. Excluding the effect of currency, revenue grew 25.3% for the third quarter, compared to the same period in 2003. Pro forma net income for the third quarter of 2004 grew 64.7% to \$11.3 million (29 cents per share) compared to \$6.9 million (23 cents per share) in the year-ago quarter. The company reported a net loss of \$31.7 million (89 cents per share) compared to a net loss of \$3.7 million (13 cents per share) in the same period one year ago. The loss in the third

quarter of 2004 was attributed to a \$49.2 million charge. The charge included purchase-accounting adjustments, which included \$28.1 million for in-process R&D and \$14.1 million for the step-up in inventory and other charges related to the June 2004 acquisition of the Pfizer surgical ophthalmic business, as well as costs associated with the early retirement of debt. The loss in the third quarter of 2003 is attributed primarily to costs associated with the company's mid-2003 recapitalization.

The Pfizer acquisition fortified AMO's surgical franchise through the addition of the Healon family of viscoelastics, the CeeOn and Tecnis lines of intraocular lenses (IOL) and the Baerveldt glaucoma shunt, as well as related manufacturing and R&D facilities. Excluding the \$32.3 million in revenue related to the acquisition during the quarter, the company's net revenue rose 9.9% to \$166.1 million, compared to the same period last year, or 4.9% on a constant-currency basis.

"We continue to transform AMO into an increasingly strong global enterprise capable of delivering sustained growth and profitability to shareholders," said James Mazzo, president and chief executive officer. "During the quarter, we achieved strong performance across all geographic regions while moving aggressively to integrate the Pfizer acquisition. We have leading positions in the markets we serve, a host of scientifically significant products to meet the needs of practitioners and patients, the technological expertise to seize new market opportunities and a scala global infrastructure and distribution network."

For the first nine months of 2004, net revenue was \$517.4 million, compared to \$434.5 million for the first nine months of 2003, an increase of 19.1%. Excluding the impact of currency, net revenue grew 12.5%. Excluding the \$32.3 million in revenue related to the Pfizer acquisition in the third quarter, revenue for the first nine months grew 11.7%, or 5.4% on a constant-currency basis.

Pro forma net income for the first nine months of 2004 was \$24.4 million (70 cents per share) compared to \$13.6 million (46 cents per share) in the year-ago period. The company reported a net loss for the first nine months of 2004 of \$139.5 million (\$4.36 per share) compared to reported net income of \$612,000 (2 cents per share) in the first nine months of 2003. The loss in the first nine months of 2004 is attributed to purchase-accounting adjustments and other charges related to the June 2004 acquisition of the Pfizer surgical ophthalmic business, as well as costs associated with the early retirement of debt. Reported net income for the first nine months of 2003 included charges associated with the 2003 recapitalization.

"With the Pfizer acquisition completed, the integration process well ahead of schedule and our global reorganization beginning to yield benefits, we are on track to achieve our previous 2004 revenue guidance in the range of \$715 million to \$725 million, with pro forma diluted EPS for 2004 in the range of \$1.20 to \$1.25," said Richard Meier, executive vice president of operations and finance and chief financial officer. "In light of our rapid integration success, the greater visibility we now have into the near-term

potential of the Pfizer assets and the productivity and efficiency gains of our reorganization, we are adjusting our previous guidance for 2005 revenue to a range of \$820 million to \$840 million, and increasing our pro forma diluted EPS estimate for 2005 by \$0.05 to a range of \$1.65 to \$1.75."

Ophthalmic Surgical: Ophthalmic surgical revenue grew 53.0% in the third quarter to \$113.5 million, compared to \$74.2 million in the year-ago quarter. Excluding the effect of currency, ophthalmic surgical revenue grew 46.7%. Growth in the third quarter included \$32.3 million in revenue associated with the Pfizer acquisition. Excluding this revenue, the company's base ophthalmic surgical business grew 9.5% in the third quarter, or 5.1% on a constant-currency basis. Other quarterly ophthalmic surgical highlights included:

- * Total IOL revenue rose 16.5% to \$58.8 million, compared to \$50.4 million in the third quarter of 2003. The increase reflected strong performance of the proprietary OptiEdge series of acrylic and silicone IOLs, and addition of the Tecnis and CeeOn family of IOLs acquired from Pfizer. Excluding sales related to the Pfizer acquisition, the company's total IOL revenue rose 3.0%, compared to the same period last year. As part of a new global product positioning strategy, AMO has begun to discontinue some of its older IOL and viscoelastic products and transition customers to newer, more technologically advanced offerings. This planned transition and repositioning is reflected in the quarterly growth rates of the base IOL and viscoelastic categories.

- * Sales of viscoelastics rose dramatically during the quarter to \$28.4 million, compared to \$3.6 million one year ago. This rise reflected the addition of the Healon family of viscoelastics.

- * Sales of phacoemulsification products demonstrated continued gains during the quarter, climbing 11.0% to \$16.9 million, compared to \$15.2 million one year ago. The increase reflects continued penetration of the company's Sovereign and Sovereign Compact systems with WhiteStar technology, as well as recurring revenue from the consumable surgical packs used during every phacoemulsification procedure performed with an AMO machine.

For the first nine months of 2004, ophthalmic surgical revenue grew 26.6% to \$278.4 million, compared to \$220.0 million in the first nine months of 2003. Excluding the effect of currency, growth was 20.2%. Excluding the revenue related to the Pfizer acquisition in the third quarter, ophthalmic surgical sales for the first nine months of 2004 were \$246.1 million, up 11.9% versus the year-ago period, or up 6.1% on a constant currency basis.

Joanne Wuensch of **Harris Nesbitt** provide her commentary on AMO's results:
AVO--Integration of PFE Assets Ahead of Schedule

* **Event:** AVO reported solid 3Q04 results that were essentially in line with our expectations: revenues of \$198.4 million (up 31.2%, up 25.3% excluding foreign exchange) were slightly lighter than our \$199.7 million estimate. EPS of \$0.29 (up 26.7%) were in-line with our estimate and a penny above consensus. The surgical ophthalmic business acquired from Pfizer contributed \$32.3 million; organic growth from core AVO products would have been 9.9%, or 4.9% constant currency.

* **Impact:** Neutral; results in line with expectations.

* **Forecasts:** Though our 4Q04 and FY2004 EPS estimates remain unchanged (at \$0.54 and \$1.23, respectively), we are lowering our revenue estimates slightly to \$214.3 million (up 28.4%) from \$215.5 million in the 4Q04 and to \$731.8 million (up 21.7%) from \$734.2 million in 2004. In 2005, we are increasing revenues to \$853.4 million (up 16.6%) from \$851.3 million and EPS to \$1.74 (up 42.2%) from \$1.70. In 2006, we are increasing revenue to \$906.7 million (up 6.2%) from \$904.7 million and EPS to \$2.16 from \$2.00.

* **Valuation:** AVO trades at 17.3x our 2006 estimate versus the group's 17.4x.

* **Recommendation:** We reiterate our OUTPERFORM rating. Our valuation range is based on 20x-23x our new 2006 EPS estimate of \$2.16 or in a range of \$43-\$50.

10/21 The first laser to replace the hand-held blade historically used in LASIK is giving thousands of consumers each month the confidence to finally undergo this vision correction procedure. Many say they've been waiting years for LASIK technologies to improve and, specifically, for the blade to go away. Market data show growing consumer demand for the IntraLase(r) technology (**IntraLase Corp.**) is helping contribute to an increase in LASIK volume. According to research firm **Market Scope's** data, the U.S. LASIK market is up 16% this year, representing a rebound to its 2000 peak.

IntraLase, which gained nationwide distribution of its INTRALASE(r) FS laser in mid-2004, offers the first laser technology for the initial step of the LASIK procedure. To date, ophthalmologists have performed more than 200,000 IntraLase-initiated LASIK procedures, with almost 90,000 laser flaps completed in the first half of 2004 alone, representing one of every seven LASIK procedures performed in the United States. While LASIK has proven to be a successful and relatively safe procedure, it is the first step that has caused the majority of LASIK complications. Traditionally, the corneal flap was made using a hand-held device with an oscillating metal razor blade, called a microkeratome. This device has been a source of anxiety for patients and physicians alike.

"A blade is the last thing most people want near their eye, which is why many of the 55 million Americans estimated to be eligible for LASIK are still wearing glasses or contacts," said Michael Gordon, MD, assistant clinical professor of ophthalmology, University of California, San Diego and medical director of the Gordon Binder Vision

Institute. "IntraLase removes the LASIK fear factor by replacing the hand-held blade with the precision of a computer-guided laser."

With accuracy more than 100 times greater than the microkeratome, the IntraLase laser makes every LASIK procedure safer, and virtually eliminates the severe, sight-threatening complications sometimes seen with the hand-held blade. According to **SM2 Consulting**, when given a choice, 78% of patients choose IntraLase-initiated LASIK rather than the blade.

The IntraLase laser is the first LASIK advancement to improve upon the first-step of the nation's number-one elective procedure by eliminating the blade. Wavefront-guided and Custom LASIK technologies (which provide for three-dimensional measurements of the eye to allow for customized vision correction) focus on improving the second step: vision correction by an excimer laser. "New technology, including the IntraLase laser and wavefront-guided LASIK, has helped reinvigorate the U.S. LASIK market," said David Harmon, Market Scope. "Lower LASIK complication rates reported by surgeons using the IntraLase technology are playing an important role in reducing patient fears about LASIK."

Clinical studies report that the IntraLase laser significantly decreases the occurrence of blade-related complications, including invasive corneal incisions, corneal abrasions, "button-hole" cuts and improperly formed flaps; and is dramatically less likely to produce overly thin flaps or extremely thick flaps, events which could lead to serious complications.

Better Vision with IntraLase: In addition to making LASIK safer, clinical studies confirm that patients see better with IntraLase-initiated LASIK than with bladed LASIK. Data from the largest prospective randomized study comparing the visual acuity achieved by IntraLase-initiated LASIK to that of a mechanical blade will be presented at the *American Academy of Ophthalmology (AAO)* joint meeting on Saturday, Oct. 23. The study, "Randomized Prospective Clinical Study of LASIK Performed with Mechanical vs IntraLase FS Laser Keratome," followed 88 patients undergoing bilateral LASIK, each eye randomized for flap creation with IntraLase or the leading microkeratome. Patients in the first arm underwent Custom LASIK while those in the second received standard LASIK. The study concludes significant visual acuity improvements were demonstrated in the IntraLase-treated eyes. Additionally, results for eyes receiving standard LASIK with IntraLase outperformed those for eyes receiving Custom LASIK with a microkeratome.

Additional data show:

- * More patients achieved 20/20 or better vision with IntraLase-initiated LASIK.
- * Patients who stated a preference preferred the post-operative vision of their IntraLase-treated eye 3-to-1 over their blade-treated eye.

* The IntraLase laser created fewer high- and low-order aberrations, which can affect quality of vision and be associated with night glare and halos.

Clinical data previously presented and published show:

* In several studies, standard tests performed to diagnose post-operative dry eye indicated lower rates of this side-effect among IntraLase-treated patients.

* IntraLase patients required fewer enhancement procedures (re-operations) following LASIK.

* The precise IntraLase flap significantly reduces the incidence of post-operative induced astigmatism as compared with microkeratome-created flaps.

"These outcomes are the clinically proven results of better corneal flap technology," said Daniel Durrie, MD, associate clinical professor, University of Kansas, lead investigator and presenter at Saturday's joint session of the AAO. "The ability to create corneal flaps with consistent dimensions, specifically thickness, is critical to a successful LASIK outcome, and are factors unachievable with the blade."

10/21 **QLT Inc.** reported financial results for the third quarter ended September 30, 2004.

Q3 2004 Visudyne Sales: For the three months ended September 30, 2004, Visudyne sales were \$114.0 million, an increase of 27% over the third quarter of 2003 of which 5 percentage points were attributable to positive foreign exchange effects. Visudyne sales in the U.S. for the quarter were \$56.5 million, up 22% over the same period last year. Visudyne sales in the rest of the world were \$57.5 million, an increase of 32% over the same period last year.

Q3 2004 Earnings per Share (EPS): EPS in the third quarter of 2004 was \$0.24, up \$0.05 from the prior year's third quarter. The increase was mainly due to strong Visudyne performance in the quarter. GAAP EPS is reported using the "not converted" basis as the company's outstanding convertible notes did not meet the test for conversion.

2004 Annual Guidance: Based on recent events and current trends in Visudyne sales, QLT is narrowing its Visudyne sales range from \$430-\$455 million to a new range of \$435-\$455 million, which represents top-line growth of 22% to 27% over 2003. The company has also updated EPS guidance for 2004 to \$0.92 to \$0.97 treating the convertible notes on a "not converted" basis or \$0.87 to \$0.92 on an "if-converted" basis. This represents an increase from the previous guidance of \$0.86 to \$0.96 on a "not converted" basis or \$0.81 to \$0.91 on an "if-converted" basis. The annual EPS guidance is on a stand alone basis and excludes potential effects of our pending transaction with **Atrix Laboratories**.

"Once again this quarter we are seeing a significant contribution to sales growth in the U.S. due to continued Visudyne utilization by retinal specialists for certain patients with the occult and minimally classic forms of age-related macular degeneration (AMD)," said

Paul Hastings, president and CEO. "Not only has the Centers for Medicare and Medicaid Services (CMS) reimbursement contributed to further positive growth, but also, despite the seasonality typically seen in the third quarter, we are pleased to see continued growth globally."

10/21 **VISX, Incorporated** announced financial results for the third quarter and nine months ended September 30, 2004. Third quarter revenues were \$38.7 million compared with \$39.3 million for the comparable period of 2003, and \$43.0 million for the second quarter. Operating income increased 89%, due to a favorable product mix shift to higher margin license revenue in the quarter. Net income rose to \$0.22 per diluted share from \$0.10 in last year's third quarter, reflecting higher operating income as well as an effective tax rate of 24.5%.

License revenue, which generated a 97% gross margin, grew 16% from the comparable period of 2003. This increase resulted from 4% growth in U.S. procedure volume compared to the third quarter of last year, as well as higher CustomVue procedure sales in both domestic and international markets.

"Our highly profitable license revenue drove operating profit sharply higher this quarter," stated Liz Davila, VISX chairman and CEO. "In the eastern United States, in particular in the southeast where business was repeatedly disrupted by the impacts of the hurricanes, we experienced weaker than anticipated procedure volume. However, in the rest of the country, we saw healthy procedure volume growth of 8%. In the international market, CustomVue procedures were three times last year's level."

Davila continued, "In the U.S., we are awaiting approval of our CustomVue hyperopia procedure which will expand our market opportunity for CustomVue. Our total CustomVue conversion in the quarter was just over 35%. More than 200 U.S. accounts are now at 50% or greater conversion to CustomVue. We are expanding our marketing and training programs to target the low volume accounts that are lagging behind the average."

VISX results for the third quarter of 2004 included tax-related items that increased earnings per diluted share by approximately \$0.04. VISX cash and equivalents at the end of the third quarter were \$121.0 million. Cash flow from operations was \$6.2 million reflecting higher net income offset by increased inventory for anticipated laser and new product shipments and higher receivables.

Revenues for the nine months ended September 30, 2004, increased to \$125.5 million compared with \$105.7 million for the comparable period of the prior year. Net income more than doubled to \$32.6 million, or \$0.64 per diluted share, in the first nine months of 2004 compared with net income of \$14.4 million, or \$0.28 per diluted share, in the first nine months of 2003.

Financial Outlook: VISX believes that fourth quarter revenues will be in the range of \$39 to \$42 million. EPS is expected to be in the range of \$0.17 to \$0.20 for the quarter. The tax rate in the fourth quarter is anticipated to be 40%.

For 2004, the company expects revenue growth of 14% to 16% compared to 2003 and earnings per diluted share of \$0.81 to \$0.84, an increase of over 75% compared with last year's earnings per diluted share. VISX is targeting 25% to 30% operating profit growth in 2005.

New Product Introductions:

CustomVue Presbyopia: In the third quarter, VISX launched internationally its CustomVue presbyopia treatment for far sighted individuals that require reading glasses. This is the first commercially available laser treatment of presbyopia that corrects the eye for simultaneous near and distance vision.

Fourier Wavefront Upgrade: During the quarter, VISX introduced worldwide its Fourier Wavefront Upgrade, a new software that fully utilizes the wavefront data to assess visual error. This provides a new level of precision and unprecedented resolution for individualized CustomVue treatments.

Iris Registration: In international markets, VISX introduced its Iris registration product. It is the first fully automated method of adjusting for the differences between the eye's position when sitting for a WaveScan measurement versus lying down for the laser treatment.

Several analyst provided their thoughts on VISX's third quarter results:

Joanne Wuensch of **Harris Nesbitt: EYE--EPS Beats, but Quarter Lacks Quality**

* **Event:** VISX reported 3Q04 results that showed improved profitability, but which lacked quality. Revenues of \$38.7 million (down 1.5%) were lighter than our \$40.6 million estimate and while EPS of \$0.22 (up 77.0%) were higher than our \$0.18 and the Street's \$0.19 estimates, it included a \$0.04 one-time tax benefit. Negatively affected by the hurricanes in the southeastern US, the procedural growth rate was an anemic 4% and conversion to custom ablation was sequentially flat at 35% (pending approvals of hyperopia and high myopia should shore-up future adoption of customized ablation technology).

* **Impact:** Negative.

* **Forecasts:** Our full year 2004 EPS estimate increases to \$0.83 from \$0.79, to account for the \$0.04 upside in the 3Q. Our 2005 and 2006 EPS estimates of \$0.94 and \$1.08, respectively, remain unchanged. While our procedural growth rate expectations remain 10% in each of the next two years, our conversion to customized ablation is tempered and

is balanced by software upgrades of the company's Iris registry technology (which should be FDA approved by year end), leaving revenue estimates essentially unchanged.

* **Valuation:** EYE trades at 17.8x our 2006E EPS vs. the group's 17.4x.

* **Recommendation:** We maintain our NEUTRAL rating.

Jason Mill of **First Albany Capital:** **EYE/Neutral: Procedure Volume & CustomVue Conversion Miss; Reiterate Neutral**

* **Procedure Volume & CTC Miss** - VISX posted low procedure volume growth of 4% versus our 9% estimate. CTC was flat sequentially, at 35%, which is concerning this early in the launch (about 1 year in).

* **What happened with procedure volume and CTC?** The company blamed inclement weather in the Southeast (one of the cautionary factors we pointed out in our 10/18 downgrade note) for the procedure volume shortfall, but even outside of the SE, volume grew only 8%. We think increased competition may have resulted in modest share loss in 3Q. As for CTC, we think conversion has slowed at these levels owing to price sensitivity on the part of patients.

* **P&L Noise** - Top-line Miss; EPS in line with recently lowered \$0.18 estimate. Revenue of \$38.7M missed our \$40.8M target, owing to lower procedure fees. Excluding a convoluted tax benefit, EPS were in line with our recently lowered \$0.18 estimate. Gross margins were higher than expected; operating margins a tad lower, owing to higher R&D spending.

* **Lowering Estimates** - We lower our 2004 and 2005 EPS estimates to \$0.78 and \$0.96 from \$0.79 and \$0.98, respectively. We advise investors to stay on the sidelines until we get better visibility into volume growth (company guidance: 8%-10%; FAC 6%) and CTC (no guidance; FAC: 38.5%).

* We lowered our price target to \$22 from \$23.

Ted Huber of **Wachovia Securities:** **EYE: LASIK Growth Slows, Custom Flatlines -- Lowering Val. Range**

* **WEAK REVENUE AND STRONG MARGINS DRIVE EPS IN-LINE:** Excluding a one time \$0.03 tax savings, VISX EPS was \$0.19, in line with consensus. Revenue at \$38.7mm were down 2% y/y and below management's \$40mm to \$43mm range. Stronger than expected gross margins at 76%, made up the shortfall. Management estimates that volume lost from the hurricanes cost \$0.02 this quarter.

* **VOLUME GROWTH AND CUSTOM DISAPPOINT:** U.S. LASIK procedure volumes were up 4%, 8% excluding hurricanes. Implied guidance was 10%+ growth.

With Alcon reporting 19% U.S. LASIK volume growth and BOL reporting 60%+ "Americas" growth, VISX clearly lost share (estimated at 59%, down 5 points since Q303, lost mostly to BOL). Custom mix remains stuck at 35%; many high volume surgeons have peaked near 50% but VISX is struggling to drive mix at lower volume practices.

* **GUIDANCE LOWERED:** Q404 implied guidance was revenue of \$42mm to \$43mm and EPS of \$0.19 to \$0.20. VISX is now targeting revenue of \$39mm to \$42mm and EPS of \$0.17 to \$0.20. Our prior model had forecasted EPS of \$0.20 on revenue of \$43.7mm; we'll updated it next week.

* **WAITING FOR 2005:** Off this 2H04 deceleration, we expect an acceleration in volume and mix with VISX's expected label expansions (hyperopia Q404, high myopia mid 2005). A new Iris recognition system that boasts improved outcomes should also drive incremental revenue and profit in 2005.

10/22 **IRIDEX Corporation** announced that Dr. Elias Reichel presented preliminary two-year results from the TTT4CNV Clinical Trial for occult neovascular (wet) age-related macular degeneration (AMD) at the *Retina Subspecialty Day Program* during the annual meeting of the *American Academy of Ophthalmology*. A total of 303 patients were enrolled in the study. Patients who were treated in the study with the Transpupillary Thermotherapy (TTT) laser protocol were compared to sham treatment. Results showed that TTT, as applied in this trial, did not result in a significant beneficial effect relative to sham.

Dr. Elias Reichel, Study Chairman of the TTT4CNV Clinical Trial and Associate Professor of Ophthalmology at the New England Eye Center, Tufts University School of Medicine, presented the data. At two years 47% of eyes avoided modest or severe vision loss compared to 43% of sham eyes, which was not statistically significant. Follow-up at 18 and 24 months showed an advantage of approximately 4 letters in TTT treated eyes; though this trend was not significant.

Additionally, it was reported that 11% of patients who were treated with TTT compared to 3% of patients who received sham showed improvement (greater or equal to 2 lines increase) from baseline when evaluated at one year. This secondary outcome was statistically significant.

Dr. Reichel stated, "Further analysis of this subgroup of patients who improved vision may yield information regarding those patients who respond to TTT. Specifically this subgroup of patients may have certain characteristics that result in a high likelihood of improvement or stabilization over time."

Safety results were also presented. Some patients, both in the treatment and sham groups, showed severe loss of vision at the one-month follow-up visit. This occurred in 5% of

TTT treated eyes compared to 1% of sham eyes. This finding was not statistically significant.

Dr. Reichel concluded, "Given the fact that the Executive Committee was unmasked to the outcome data only recently, there are a number of questions for which analyses remain to be done. Specifically, careful inspection of baseline characteristics between groups and a per protocol analysis that evaluates the subset of enrolled patients who met all key eligibility criteria needs to be done."

Theodore Boutacoff, president and CEO of IRIDEX said, "We are disappointed that these preliminary results did not demonstrate a significant difference compared to sham when these patients were treated following the TTT4CNV dosing protocol. We are encouraged that a number of patients experienced a significant improvement in vision and look forward to the comprehensive analysis of the study data that may provide clarity into the patients who responded well to TTT. We remain optimistic about this therapy in light of the difficulties and inconsistencies in treating this devastating condition and the economic burden given the large numbers of newly affected patients."

10/22 **NIDEK, Inc.** announced 9-month clinical data from its US FDA Hyperopia Clinical Study for the treatment of hyperopia and hyperopic astigmatism. This marks an important milestone in the study protocol, as a total of 248 eyes have been treated, with a total number approved in the study at 300 eyes. Over the last 12 months, NIDEK has worked closely with the FDA on the design, data-collection and evaluation of the clinical study.

"We are extremely excited and very pleased with these results and the 9-month follow-up data that we are getting from our 7 clinical sites for the new hyperopia software for the US EC-5000 platform. The results we have generated to date all exceed and surpass FDA criteria for hyperopia approval and we look forward to collecting all the 9-month data and thereafter working with the FDA to evaluate our submission process. With the expanded study, we look forward to completing the actual treatments in short order and doing the follow-ups necessary for submission and approval with the FDA," commented George Waring, MD, Medical Monitor for the NIDEK US Hyperopia Study and Chairman of NIDEK's Medical Advisory Group.

Ted Shimomura, executive vice president and General Manager of NIDEK, Inc. stated, "These are excellent and outstanding results and we look forward to expediting collection and review over the coming months and thereafter submitting our data to the FDA for approval in short order. NIDEK is truly dedicated to providing the highest quality solutions and treatment therapies for quality patient care and surgical outcomes in refractive surgery. The NIDEK EC-5000 provides expanded treatment options, parameters and an innovative, technologically advanced platform for Refractive Surgery. The NIDEK EC-5000 platform is designed for surgeons' present use as well as future needs, as the field of Refractive Surgery continues to advance and grow. NIDEK is actively working on developing and launching its own custom ablation and wavefront technology platform with the NIDEK EC-5000 Excimer Laser System. Currently this

technology is available internationally and will soon be introduced in the U.S. once clinical studies and regulatory processes are done."

NIDEK plans to begin custom ablation clinical trials in the United States in the next few months, using its proprietary CATz (Customized Aspheric Treatment Zone) software algorithm and advanced laser hardware. The company has been in detailed discussions with the FDA for the initiation of additional studies to evaluate hardware and software for the NIDEK EC-5000 Excimer Laser System. Additionally, NIDEK and the FDA will review and perform analysis of international clinical experiences with new technologies, including CATz, OATz and OPDCAT software algorithms.

- 10/23 **Tracey Technologies** announced that it had submitted all physical object, human clinical, and software verification and validation testing data required under its agreement with **VISX, Inc.** as of September 10, 2004. "This represents the completion of a huge effort on our part to re-engineer our iTrace VFA to meet the compatibility standards outlined by VISX in our March 11, 2003 License Agreement," stated Joe Wakil, MD, and chairman of Tracey. "We are pleased to have VISX moving forward with software linking and FDA Equivalency filings as is called for under the agreement. It is anticipated that the software and engineering required will take a minimum of six months to complete. After completion of the engineering and software link, the parties will initiate the USA FDA approval process."

Tracey Technologies, LLC is a developer and manufacturer of advance technology refractive diagnostic devices and systems. The company's newest offering, the Tracey iTrace Visual Function Analyzer, combines ray-tracing aberrometry wavefront analysis with advanced corneal topography measurement and analysis. Tracey's patented technology is viewed as the next generation of refractive diagnostics.

- 10/23 Michael Lachman of **ThinkEquity Partners** provided an overview of the ophthalmology sector that he covers: **Q3 Ophthalmology Roundup: ACL, AVO, BOL, EYE, QLT**

Greetings from the AAO in New Orleans. Attached are our Q3-04 earnings recaps for our covered ophthalmology companies: Alcon, Advanced Medical Optics, Bausch & Lomb, VISX, and QLT, with summaries below.

ACL: Increasing Price Target Following Strong Revenue Driven Quarter

We are raising our 12-month price target on Alcon shares from \$72 to \$75 following a strong, top-line driven quarter. Q3 revenue featured constant currency revenue growth of 13.3%, the highest in company's history as a public company, and robust performance across all major business segments. Despite the recent setback in the second Retaane pivotal trial, we continue to believe that the other components of Alcon's broad ophthalmic product line, combined with cost reductions, favorable product mix shifts and a high degree of operating leverage, suggests an upward bias to estimates. In an analyst/investor meeting today at the *American Academy of Ophthalmology* conference,

Alcon intends to discuss in greater depth the results of the Retaane pivotal trials, and we hope to come away with greater clarity regarding the regulatory pathway. At current stock price levels, our 12-month price target of \$75 represents 6% upside, consistent with our Accumulate rating.

AVO: Pfizer Cataract Integration Right on Track

We maintain our Accumulate rating and raise our 12-month price target from \$41 to \$44 following a solid earnings report in a transition quarter following the acquisition of Pfizer's ophthalmic surgical business. AMO reported pro forma Q3 EPS of \$0.29 (+27%), beating both our and consensus EPS estimates by a penny, and revenue of \$198.4 million exceeded our forecast of \$196.5 million. Opportunities in product bundling and cross-selling, as well as positive pricing and volume from new product launches, suggest to us that revenue momentum should persist over the next year. We also believe that there continues to be a positive bias to earnings, as the company works through acquisition-related charges early next year and begins reaping the benefits of an in-house lens care manufacturing platform in mid-2005.

BOL: EPS Upside but Lower Quality - No Change to 2005 Outlook

We maintain our Accumulate rating and 12-month price target of \$71 on Bausch & Lomb shares following a lower quality quarter that still delivered EPS outperformance. EPS of \$0.79 beat our estimate of \$0.72 and consensus of \$0.73, with upside again boosted by lower than projected operating expenditures, particularly R&D. Revenue of \$549 million came in \$8 million below Street consensus (and in-line with our estimate), and the company under-delivered on the gross profit line as well. Issues relating to timing of cooperative marketing programs and product line transitions impacted the top line, and the gross margin miss in the quarter was at least partially due to non-recurring expenses. With our 2005 EPS estimate of \$3.36 already in the middle of the new guidance range, we maintain our 2005 and 2006 EPS estimates, our target 21x P/E multiple, our \$71 price target, and our Accumulate rating.

EYE: Reducing Price Target Following a Lackluster Q3

VISX reported a disappointing Q3 on the three metrics that matter most: EPS, LASIK procedure growth, and CustomVue penetration. Without a \$0.04 one-time tax benefit, EPS of \$0.18 fell a penny shy of our estimate and consensus (but within \$0.17-0.19 guidance). Even though severe weather in the southeast contributed to procedure growth of only 4% (and according to management impacted EPS by \$0.02), underlying growth of 8% in the rest of the US was still below our 13% forecast. CustomVue penetration of 35%-plus was within roundoff error of the Q2 rate and below our 36.5% estimate. We raise our 2004 EPS estimate by a penny to \$0.82, although net of the tax gain this represents a real reduction of \$0.03. We lower our 2005 estimate by a penny to \$1.00. We reduce our 12-month price target from \$26 to \$23, based on a lower target multiple of 23x 2005 EPS.

QLTI: In-Line Quarter, No Change to Overall Cautious Stance

We maintain our overall cautious outlook on QLTI's business prospects and stock performance following a mostly in-line quarter. Visudyne sales missed our expectations by 3% in both the US and internationally, which translated into a 1.5% shortfall on the reported revenue line. Visudyne worldwide sales growth of 27%, to \$114 million, was boosted by 5% due to positive currency. GAAP EPS (non-converted) of \$0.24 beat our and consensus estimates of \$0.20, with half of the upside coming from lower than expected operating expenses and the other half resulting from a one-time gain from a milestone payment received from Axcan Pharma. Our cautious stance is based on our below-consensus view of the upside resulting from newly reimbursed indications for Visudyne in the US, and from the near-term competitive threat from Macugen, which awaits FDA approval.

10/25 **Miravant Medical Technologies** announced additional results from analyses of the Photrex (rostatporfin, SnET2) phase III clinical trials, presented at the *American Academy of Ophthalmology (AAO)* meeting, New Orleans. Based on data from two randomized, placebo controlled two-year trials, clinical investigators reported on:

- * Significant visual acuity benefits in Photrex-treated (0.5mg/kg) patients with occult choroidal neovascularization (CNV) lesions;
- * Angiographic evidence that Photrex treatments slowed the progression of both classic and occult CNV leakage and fluid accumulation;
- * Treatment benefit in Photrex patients regardless of visual acuities (VA) at commencement of treatment, with a greater benefit noted with higher baseline VA;
- * Photrex clinical retreatment guidelines based on vessel leakage.

Edgar Thomas, MD, Retina-Vitreous Associates, Los Angeles, presented favorable visual acuity (VA) results based on subgroup analyses of lesions with predominantly (greater than or equal to 50%) occult CNV, including pure occult lesions. Statistically significant vision benefits were observed in occult CNV lesions treated per protocol in both the primary and secondary efficacy endpoints. Currently there are no FDA-approved therapies for occult CNV lesions.

The occult VA outcomes were supported by secondary angiographic assessments reported by Ronald Danis, MD, University of Wisconsin Fundus Photograph Reading Center, Madison. Photrex-treated lesions (both classic and occult CNV) had statistically significant reductions in vessel leakage and fluid accumulation, factors that are considered to be indicative of AMD disease activity.

Baruch Kuppermann, MD, University of California, Irvine, presented data on the effect of baseline visual acuity on efficacy at the study endpoint. Analysis of results showed a statistically significant treatment benefit for all baseline VA strata. The greatest relative gain over placebo was noted in patients at highest risk of vision loss, i.e., those with higher VA at the commencement of treatment. Irrespective of baseline VA, patients

receiving placebo were approximately 2 times more likely to lose 3 or more lines of vision than treated patients.

Carl Regillo, MD, Wills Eye Hospital, Philadelphia, provided data suggesting Photrex retreatment guidance. During the trials, patients were eligible for retreatment at 3-month intervals. Primary efficacy was assessed in patients who received retreatment when there was evidence of ongoing or increased vessel leakage and compared to patients who did not receive retreatment under those conditions. At two years, patients treated according to the leakage criteria had a statistically significant primary VA benefit. Supporting this finding, angiographic outcomes were statistically significant for these patients at all analysis timepoints over two years.

The phase III clinical trials of patients with CNV associated with wet AMD were conducted at 60 U.S. ophthalmology centers. The primary efficacy endpoint for the two-year studies was the proportion of patients losing less than 15 letters (3 lines) of vision on a standard eye chart. The secondary efficacy endpoints were mean change in letters loss and patients losing greater than or equal to 30 letters (severe vision loss). Secondary endpoints assessed by fluorescein angiography were areas of overall lesion, choroidal neovascularization, fluorescein leakage and subretinal fluid accumulation.

On September 30, 2004, the company announced that it had received an FDA Approvable Letter for Photrex, which included a request for a confirmatory clinical trial.

10/25 **WaveLight, Inc.** announced that during the last 12 months, its ALLEGRETTO WAVE laser attained 20% share of all new refractive laser sales in the U.S., according to **Market Scope**, an independent market research company. Internationally, WaveLight has an installed base of 411 ALLEGRETTO WAVE excimer systems and has been the leader in new refractive laser sales for two years running. "Despite a late start in the U.S. market, WaveLight has captured a significant share of new laser sales during the past year," said David Harmon, president of Market Scope.

In addition to acquiring a considerable presence within ophthalmology, WaveLight recently announced that its revenues have increased 30% or EUR 62 million for the fiscal year ending July 31, 2004. WaveLight attributes much of its financial performance to refractive laser sales and forecasts revenues of EUR 78 million in fiscal year 2004/2005.

"We consider our success in the U.S. market to be our greatest accomplishment to date," said Max Reindl, CEO of WaveLight Laser. "Ophthalmologists and patients alike benefit from the ALLEGRETTO WAVE's shorter treatment times, safety features and unique ablation profile designed to minimize the induction of spherical aberrations during surgery. Strong demand for the ALLEGRETTO WAVE validates our commitment to develop and introduce the most innovative technology in the marketplace."

WaveLight has achieved several other milestones within the last three months, including:

-- Investigational device exemption (IDE) granted by the FDA in September 2004. The IDE permits WaveLight to conduct further U.S. clinical studies with the ALLEGRETTO WAVE excimer laser system to expand its treatment ranges (including mixed astigmatism and wavefront-guided LASIK).

-- Completion of a successful FDA audit in August 2004.

-- Five-year renewal of contract for Max Reindl, founder of WaveLight, as Supervisory Board member in August 2004.

-- Sale of 100th ALLEGRETTO WAVE laser in People's Republic of China, announced in July 2004.

The ALLEGRETTO WAVE was the first refractive laser to receive concurrent approvals for the treatment of myopia up to -12 diopters with astigmatism of up to -6 diopters and hyperopia up to +6 diopters with astigmatism of up to +5 diopters, not exceeding a mean spherical equivalent of +6 diopters.

OPHTHALMIC LASER UPDATE -- November 2004

10/24 **Refractec** announced that NearVision CK (Conductive Keratoplasty) has become the nation's leading non-laser refractive procedure according to new data published by research firm **Market Scope**. The 2004 Annual Survey of Refractive Surgeons found that the non-laser refractive procedure market, as a whole, grew 54.7% over 2003 fueled in part by the expanded indication for NearVision CK. The CK procedure leads the segment with a 73.3% market share, leaving refractive intraocular lens (IOL) implantation at 23.3%. In April of this year, Refractec's proprietary ViewPoint CK System, used to perform the NearVision CK procedure, became the first and only vision technology approved by the FDA for the millions of baby boomers with presbyopia. It is being used by more than 500 physicians around the country, who collectively performed over 50,000 procedures since approval.

Also, The FDA granted Refractec approval for a Phase III clinical trial to study the procedure's ability to improve near vision in patients who previously had LASIK surgery. Refractec will begin enrollment of CK post-LASIK patients by the end of the year. Investigators for the multi-center study include: Daniel Durrie, MD (Overland Park, KS); Marguerite McDonald, MD (New Orleans, LA); Louis Nichamin, MD (Brookville, PA); and Ralph Chu, MD (Edina, MN).

10/26 **LCA-Vision Inc.** reported financial results for the third quarter of 2004. Highlights of the three months ended September 30, 2004 include:

* Earnings per share up 86% to \$0.26 with a 41% effective tax rate, compared with earnings per share of \$0.14 with a 5% effective tax rate in the third quarter of 2003

* Revenues up 53% to approximately \$31.2 million, compared with revenues of approximately \$20.5 million in the third quarter of 2003, marking the fifth consecutive quarter of revenue growth exceeding 50%

* Revenue growth of 38% at vision centers open at least 12 months, compared with the third quarter of 2003, marking the fifth consecutive quarter of strong same-store revenue growth of at least 38%

* Procedure volume up 46% to 23,248, from 15,965 procedures in the third quarter of 2003

* Revenue per procedure up 5% to \$1,342, from \$1,281 in the third quarter of 2003

* Operating margin of 17.7%, compared with 7.2% in the third quarter of 2003

* For the first nine months of 2004, net cash provided by operations of approximately \$20.6 million, up significantly from approximately \$8.4 million in the first nine months of 2003

Net income for the third quarter of 2004 rose 137% to approximately \$3.6 million with a 41% effective tax rate, compared with net income for the third quarter of 2003 of approximately \$1.5 million with a 5% effective tax rate. Earnings per share for the third quarter of 2004 rose 86% to \$0.26, compared with earnings per share of \$0.14 for the third quarter of 2003.

Revenues for the 2004 third quarter increased 53% to approximately \$31.2 million, compared with revenues of approximately \$20.5 million for the 2003 third quarter. The company reported that revenues at vision centers open at least 12 months increased 38% during the third quarter of 2004. Third quarter 2004 procedure volume rose 46% to 23,248, and average price per procedure increased 5% to \$1,342, both compared with the third quarter of 2003.

Net cash provided by operations in the first nine months of 2004 was approximately \$20.6 million. As a result, cash and short-term investments were approximately \$82.8 million as of September 30, 2004, up 28% from approximately \$64.9 million as of December 31, 2003.

For the nine months ended September 30, 2004, the company reported net income of approximately \$27.2 million (\$1.96 per share) compared with net income of approximately \$5.1 million (47 cents per share) for the nine months ended September 30, 2003. Revenues grew approximately 56% to approximately \$94.4 million for the first nine months of 2004, compared with revenues of approximately \$60.7 million for the comparable prior-year period.

"We generated exceptional financial performance during the quarter and achieved several significant milestones," said Stephen Joffe, chairman and CEO of LCA-Vision. "Third quarter results featured strong growth in revenues and net income, an increase in revenue per procedure and excellent procedure volume growth. With the opening of LasikPlus vision centers during the quarter in Jacksonville, Florida, St. Louis, Missouri and Kansas City, Kansas, we have already achieved our previously announced target for new laser vision center openings in 2004. Furthermore, same-store sales rose 38% year-over-year during the quarter, substantially outpacing projected industry growth and reflecting our continued ability to gain market share. Once again, net income grew even more rapidly than revenues, demonstrating the operating leverage and scalability of our business model."

Joffe added, "We believe there remains tremendous opportunity going forward for LCA-Vision as we post robust same-store sales growth at a multiple of industry growth rates and open new LasikPlus vision centers, including plans to open 10-12 vision centers during 2005. Based on our confidence in continued strong performance, we are again raising our revenues and earnings guidance for 2004, and are reaffirming our projected 2005 revenues and income before taxes growth rates based upon these higher 2004 numbers."

Company Raises 2004 Guidance, Reaffirms 2005 Growth Rates: Based upon third quarter financial results and management's outlook for the remainder of the year, LCA-Vision increased full-year 2004 revenues and earnings guidance as follows:

* Revenues in the range of \$124 million to \$125 million, up from prior guidance of \$121 million to \$123 million

* Earnings per share in the range of \$2.12 to \$2.17, up from prior guidance of \$2.05 to \$2.15. Both the new and previous guidance include a \$0.76 per share benefit recorded in the first half of 2004 for the reversal of the deferred tax valuation allowance and also reflect a presumed 41% tax rate for the fourth quarter of 2004

For 2005, LCA-Vision reaffirmed expectations for revenues to increase 30-40% and income before taxes to increase 40-50%, resulting in EPS of \$1.45 to \$1.55 for 2005. If the company had recorded an effective tax rate of 41% for all of 2004, we project EPS for 2004 to be \$1.01 to \$1.06. Management feels that this proforma calculation for 2004 is a meaningful disclosure as it facilitates investors comparing 2004 and 2005 projected results on a consistent basis.

10/26 LARRY HAIMOVITCH, writing in *Medical Device Daily*, posted his take on AMD from the AAO: **AMD clinical trials capture spotlight at AAO conference**

The annual meeting of the *American Academy of Ophthalmology (AAO)*, the largest gathering of eye physicians in the world, took place here this weekend at the Morial Convention Center. The AAO meeting typically covers a broad range of topics of interest

to the ophthalmic community, including cataract and refractive surgery, glaucoma diagnosis and management and major retinal disorders such as diabetic retinopathy and age-related macular degeneration (AMD).

AMD is a chronic and progressive disease of the macula, or central part of the retina, and is the leading cause of severe vision loss and blindness in patients over the age of 50 in the developed world. According to an article in the April issue of *Archives of Ophthalmology*, the Eye Diseases Prevalence Research Group estimates that about 1.8 million Americans have AMD. Moreover, owing to the rapidly aging population, the number of persons having AMD will increase by 50% to nearly 3 million by 2020.

Prior to 2000, there was only one AMD treatment option – thermal laser photocoagulation, which is fraught with numerous disadvantages and therefore is not widely used. In April 2000, the FDA approval of the pharmaceutical agent Visudyne, developed by QLT (Vancouver, British Columbia) and marketed worldwide by Novartis Ophthalmics (Basel, Switzerland), sparked a surge in interest in AMD. This heightened interest has continued in the past four years.

Visudyne is the first new pharmaceutical agent designed for AMD therapy and also is the first drug using photodynamic therapy, which uses light-activated drugs, called photosensitizers, to treat diseases that exhibit rapid tissue proliferation, e.g., the growth of tumors or abnormal blood vessels. Visudyne is expected to register worldwide sales in 2004 of about \$430 million. This is testimony more to the desperate need for new treatment options rather than the efficacy of this drug, which typically does not improve the course of the disease, but rather prevents severe vision loss from progressing in about half the patients.

The promise of other agents with greater efficacy reaching the market soon has fueled tremendous interest in both the retinal and financial communities. A week before the AAO meeting, Alcon Laboratories (Fort Worth, Texas), reported disappointing clinical results for its flagship AMD agent Retaane, as initial analysis of the one-year data of Retaane, compared to Visudyne, showed that it did not meet its primary “non-inferiority” endpoint. Specifically, the percentage of patients who maintained vision, as defined by less than three lines of visual acuity, was 45% for Retaane, vs. 49% for Visudyne.

At an analysts’ meeting held here last Friday, Alcon’s management team reiterated statements made in its press release that in analyzing the data, there were two controllable factors – drug reflux and treatment timing – that contributed to the poor results. Thus, the company indicated that these issues could be readily overcome and said it plans to submit a New Drug Application (NDA) before year-end. Gerry Cagle, PhD, senior vice president, research and development, told the analysts that “we have looked very carefully at that data, have met with the FDA and have decided to move forward with an NDA filing.” There was considerable skepticism by most of the analysts attending the meeting, with some noting that the results of the company’s earlier Retaane trial had not been robust, due to a high patient dropout rate.

Several retinal specialists interviewed by Medical Device Daily after the Alcon meeting indicated that failing to meet its primary endpoint could mean a rejection by the FDA, in spite of Alcon's ability to rationalize the clearly disappointing results. The ongoing challenge in effectively treating AMD is to attack the disease earlier in its progression. To that end, Alcon is in the midst of a clinical study called the Risk Reduction Trial, which aims to assess the efficacy of treating patients with advanced dry (earlier stage) AMD who appear to be at risk of progressing to wet AMD. This trial uses a novel transscleral drug delivery device that implants a tablet behind the eye, enabling even longer-term delivery of Retaane.

Enrollment for this trial began early this year and patient follow-up will occur over a period of four years. A total of some 2,500 patients ultimately will be enrolled at 100 sites worldwide. The FDA has given a "fast track" designation to this trial, because it represents a significant unmet medical need for a serious condition. According to Jason Slakter, MD, clinical professor of medicine at New York University School of Medicine (New York), who discussed Retaane at the Alcon analysts' gathering, "more than ever, we need to reduce the risk of getting full-blown AMD by treating it earlier." Slakter, well known in the retinal world, also reminded the analysts that "AMD is a very nasty disease that thus far has not benefitted [from] any magic bullets."

There was considerable interest at the AAO in two other compounds – Macugen, being developed by Eyetech Pharmaceuticals (New York), and Lucentis, being developed by Genentech (South San Francisco, California). Both work by inhibiting the effect of ocular vascular endothelial growth factor (VEGF), which the retinal community believes may thwart the development of choroidal neovascularization (CNV), or the formation of new blood vessels. Left untreated, CNV can cause bleeding and scarring in the macula, destroying central vision.

Just prior to the AAO meeting, Eyetech, which has partnered with the pharmaceutical giant Pfizer (New York) to market Macugen worldwide, reported that the treatment effect of Macugen extends for two years. This treatment benefit, which required an additional eight to nine injections in year two, was also seen for patients who received Macugen for two years compared to those only receiving one year of therapy. Macugen was positively reviewed on Aug. 27 by the FDA's Dermatologic and Ophthalmic Drugs Advisory Committee and final approval is expected within the next few months. Market analysts have very high expectations for Macugen, with several recent investment banks projecting peak global sales in excess of \$1 billion.

While Macugen clearly has the best near-term prospects, based on its likely near-term FDA approval and solid clinical results, Genentech's agent may be the most promising drug for wet AMD therapy. Importantly, although Lucentis also is a VEGF inhibitor, it binds to all four forms of VEGF, whereas Macugen binds to just one. Some retinal specialists believe that this is a very important distinction and will make a marked difference in clinical outcomes.

Genentech is in the midst of four key Phase III AMD trials and has completed patient enrollment in three of them. The first, called MARINA, compared two different doses of Lucentis to a placebo treatment and completed enrollment of about 700 patients at year-end 2003. The second trial, called FOCUS, completed its 170-patient enrollment in early 2004 and compared Lucentis and a sham injection to Visudyne and a sham injection. The third trial, called ANCHOR, compares Lucentis and a sham Visudyne treatment to Visudyne and a sham injection and completed enrollment of more than 400 patients within the last few weeks. Finally, the PIER trial, currently enrolling up to about 180 patients, will compare two different doses of Lucentis to a sham injection.

Although Genentech has not released any pivotal Phase III data as of yet, the positive buzz in the retinal community, based on the Phase I/II data and anecdotal reports, is enormous. For example, Philip Rosenfield, MD, from the Bascom Palmer Eye Institute of the University of Miami School of Medicine (Miami), speaking at a Genentech-sponsored evening seminar, noted that there was a “dramatic” improvement in visual acuity (VA) patients treated with Lucentis in the Phase I/II trial. Moreover, this gain in VA was corroborated by optical coherence tomography imaging, a relatively new non-contact, non-invasive imaging technique used to obtain high-resolution, cross-sectional images of the retina. It is increasingly being relied on to assess the benefits of AMD drug therapy and may someday supplant the current gold standard, fluorescein angiography.

Rosenfield, one of the best-known retinal specialists in the U.S., said that he is “spectacularly impressed with the Lucentis results” and believes that enough patients have been treated with a known mechanism of action that the Phase III results should be equally impressive. Peter Kaiser, MD, of the Cleveland Clinic Foundation (Cleveland), speaking at a Sunday morning symposium, expressed similar sentiments, telling MDD: “I think that Lucentis is the real deal and if I were a betting man, that is where I’d put my money.”

Given that the Phase III trials are still in the follow-up period, final FDA approval for Lucentis could take up to two years. However, it appears at this juncture that it will be the winner in this high-stakes market opportunity.

10/26 Taken from the *OSN Supersite*: **Crystalens 3-year data show movement, near vision are maintained**

Even after 3 years in the eye, an accommodative IOL still demonstrated movement upon pharmacological manipulation, according to one study. A separate study of the same lens found good near and distance vision and high patient satisfaction 3 years after implantation. Steven Dell, MD, discussed his study of movement of the eyeonics **Crystalens** accommodative IOL here at the refractive surgery subspecialty day at the *American Academy of Ophthalmology* meeting. He said the degree of movement observed using immersion ultrasound was consistent with the near visual acuity demonstrated by the patients in the study. Dr. Dell said he had observed that patients with the Crystalens

were demonstrating near visual acuity about as good at 3 years postop as they had at 1 year, "and the question we had was, Is the IOL still moving?"

The study was performed in 10 eyes at least 3 years after Crystalens implantation. All patients had "excellent distance vision," Dr. Dell said, with a mean uncorrected distance acuity slightly better than 20/20. Their distance-corrected near visual acuity was also good, with a mean of J 2.1. Immersion ultrasound was performed in each eye under the influence of cyclopentolate and under the influence of pilocarpine to determine the maximum range of movement of the IOL. He found that the lenses moved anteriorly a mean of 0.84 mm under cyclopentolate compared to their position under pilocarpine. Taking into account the IOL powers implanted, this movement would correspond to a mean accommodative change of 1.79 D, Dr. Dell said, which he said was consistent with patients' near visual performance with distance correction in place.

At a separate presentation, George Papastergiou, MD, said patients implanted with the Crystalens had excellent distance and near visual acuity without glasses at 36-month follow-up. "Patients who received Crystalens were very satisfied even 36 months after the operation," he said. Dr. Papastergiou and colleagues measured near and distance visual acuity with and without correction, as well as accommodative range, in 84 pseudophakic eyes at least 3 years after the Crystalens was implanted. All eyes achieved uncorrected distance visual acuity of 20/40 or better, and 93% had uncorrected near acuity of J 3 or better, Dr. Papastergiou said. The pseudoaccommodative amplitude ranged from 0.75 D to 2 D, he added.

Dr. Papastergiou cautioned that the lens should not be implanted in eyes with pupils smaller than 6 mm and that the long-term incidence of fibrosis still must be studied.

These results were similar to those attained in the study submitted for FDA approval of the Crystalens, according to Howard Fine, MD, the discussant of Dr. Papastergiou's presentation. Dr. Fine, who participated in the FDA study, said one aspect of the Crystalens that has always troubled him is that investigators have never been able to consistently demonstrate the lens' exact mechanism of action in the eye. Despite this, he said, the data have conclusively shown that "the lens works," and furthermore it has scored well among patients who were asked pointed questions about their quality of life following surgery.

10/27 **Lasik America, Inc.** announced that it had changed its name to **Critical Care, Inc.** In addition, effective today, the company's common stock will be traded on the OTCBB under the new ticker symbol "CTCC."

Ernest Remo, CEO and chairman of the Board of Directors of Critical Care, Inc., remarked, "The name change better reflects our business plans to focus on the development and operations of dialysis clinics worldwide." Critical Care, Inc. currently operates a dialysis clinic in Italy and a medical facility in Albuquerque, New Mexico, providing laser vision correction surgery procedures.

10/28 **IntraLase Corp.** reported consolidated revenues for the third quarter ended September 30, 2004 more than doubled over the comparable prior-year period to \$15.5 million. Revenues benefitted from continued growth in demand for INTRALASE FS lasers, with the company placing for sale or lease 27 lasers in the quarter compared to 14 sales or leases in the third quarter of 2003. Laser revenues were \$8.6 million versus \$3.4 million in the comparable quarter a year ago. The company's expanding base of installed lasers resulted in an increase in per-procedure disposable patient interface revenues, which also more than doubled to \$5.7 million in the third quarter of 2004 versus \$2.6 million in the prior-year period. Per-procedure revenues stem from disposable patient interfaces used to create corneal flaps in the first step of each LASIK procedure. Revenues from laser maintenance contracts totaled \$1.2 million for the third quarter versus \$0.5 million for the prior-year quarter.

Robert Palmisano, president and CEO of IntraLase, said, "The growing acceptance among refractive surgeons that IntraLase lasers enable superior clinical and visual outcomes for patients is at the heart of our success. We estimate that over 15% of all LASIK procedures performed in the U.S. during the third quarter of 2004 relied on one of our lasers for the creation of a corneal flap, a rate that is almost 70% greater than a year ago. All indications point towards a continuation of this trend."

Palmisano went on to say, "The annuity nature of our business model is apparent in the rapid growth of our per-procedure disposable patient interface unit volume, which exceeded 49,000 in the third quarter of 2004 as compared to approximately 22,000 procedures sold in the third quarter of 2003. Our installed base of lasers reached 180 at the end of the quarter, and our current experience suggests that each of these could be used in approximately 1,200 corneal flap procedures on an annualized basis."

For the first nine months of 2004, consolidated revenues totaled \$40.8 million versus \$15.1 million in 2003. Laser revenues of \$21.7 million increased substantially from the 2003 nine-month revenue amount of \$7.9 million, while per-procedure disposable patient interface revenues increased to \$16.1 million, a gain of 155% from the \$6.3 million attained in the first nine months of 2003. Maintenance revenues amounted to \$3.0 million for the first nine months of 2004 compared to \$0.9 million the previous year.

The company's increasing revenues and procedure volumes led to a substantial rise in the gross margin, which climbed to 45.1% in the 2004 third quarter, an increase of 26% from the comparable period a year ago. The net loss for the third quarter amounted to \$3.2 million (\$1.37 per share) versus the prior-year loss of \$2.7 million (\$1.27 per share). The higher loss in the most recent quarter stemmed from an increase in stock-based compensation and continuing discretionary investments in research and development, clinical support, marketing and other programs designed to strongly position IntraLase technology in new markets in North America, Europe and Asia. For the first nine months of 2004, the net loss declined to \$7.1 million (\$3.15 per share) compared to the prior-year loss of \$9.7 million (\$4.66 per share).

Nine of the 27 lasers sold or leased in the third quarter were placed in markets outside the U.S., including the company's first installations in Hong Kong, Germany, and the United Kingdom. Also during the quarter, regulatory approval was received to begin marketing IntraLase lasers in Australia.

On October 6, 2004, IntraLase completed its initial public offering of 7.3 million shares of common stock through which it received proceeds of \$84.3 million, inclusive of the October 13, 2004 exercise of the underwriters' over-allotment option. The proceeds from this offering significantly strengthened the company's capital resources, resulting in a pro forma cash balance of approximately \$91.4 million (assuming the offering was completed on September 30, 2004.) Also in October, Charline Gauthier, previously vice president, Research, Development and Corporate Affairs was named executive vice president and COO, and Shelley Thunen, previously vice president and CFO was promoted to executive vice president and CFO.

Robert Palmisano commented on these most recent developments by saying, "We now have substantial additional resources to pursue our business strategies and to establish IntraLase lasers as the new standard of care for the creation of the corneal flap in the first step of LASIK surgery throughout the world." He concluded by stating, "We are very pleased by our continued commercial momentum during the third quarter and by the further development of our senior management team. The company's strong sales momentum should enable us to reach profitability in the fourth quarter of this year."

11/1 **Ted Huber of Wachovia Securities: Spotlight On Retina And IOLs At AAO -- Detailed Review**

*** WHO EXCEEDED EXPECTATIONS AND WHO FELL SHORT:** Among our coverage companies, we rate BOL and EYE as modest winners at this year's AAO. BOL is progressing in cataracts and appears poised to launch RETISERT for posterior Uveitis (PU) in H2 2005. EYE should inch ahead in the excimer laser technology race in early 2005 with software and hardware upgrades and two U.S. label expansions. AVO came in as expected and appears poised for accelerating organic revenue growth in 2005-06. Though Alcon's near term pipeline looks less robust than prior years, we found evidence of ACL's sales & marketing power in recent contract wins (VA hospital system for TRAVATAN). Alcon's Restor IOL could be a 2006-07 driver, but competition looks marginally stronger. Alcon's Systane is emerging as an important dry eye product. With its recent sell off, BOL is our top pick in ophthalmology.

*** IN RETINA, A STEP FORWARD FOR BOL, A STEP BACK FOR ACL:** We are now confident FDA will approve BOL's RETISERT for PU. MDs reported a desire to implant RETISERT in 33-50% of chronic PU patients and to use it off label to treat DME. With a Q205 U.S. approval likely, RETISERT could be a meaningful driver in 2006-07. By our math, each 250 RETISERT implants should drive a penny of EPS. Investigators and other MDs remain confident in RETAANE's efficacy, but by most accounts, Alcon will have a marginal safety/efficacy case in its RETAANE NDA (Q404

filing). We place the likelihood for approval around 25%. Company and investigator enthusiasm for the AART trial (AMD risk reduction) remains high; enrollment could be falling behind schedule as investigators made a strong pitch for more patients while presenting on the trial at AAO.

*** NTIOL DECISIONS KEY IN CATARACT - AVO & BOL POISED FOR BETTER GROWTH:** NTIOL decisions (extra \$50 reimbursement in ASCs) are due for AVO's Tecnis and Alcon's Natural in late November, and we expect the Tecnis will gain it but the Natural won't. AVO & BOL appear poised for marginally better performance in 2005 due to stronger new product cycles (silicon aspheric IOLs); ACL faces tougher comps having lapped AcrySof Natural and Infiniti launches. ACL should again lead the industry's growth in 2005 but we do not expect it to grow 1.5x faster than AVO and 3x faster BOL as we saw in 2003-04.

*** OTHER INTERESTING TOPICS:** There was significant interest in Phakic IOLs among cataract and refractive surgeons, more than 600 attended a Staar-sponsored viewing of live procedures. AVO's earlier approval and anterior position give it a slight edge at this point. We spoke with some surgeons who are waiting for Staar's Visian ICL; advantages include an easier implant procedure and slightly better clinical safety/efficacy data. Presbyopia was again a hot topic with data on multifocal & accommodating IOLs.

11/2 **Jason Mills of First Albany Capital: BOL/Buy: Positive Takeaways from Our Meeting with Management at AAO; Reiterate Buy**

*** Meeting with Management Augments Bullish Thesis.** We garnered positive incremental data points from our meeting with management at the AAO meeting in New Orleans that give us confidence BOL can achieve, if not eclipse its 13%-14% operating margin target in 2005 (our estimate is 13.4%).

*** R&D Spending Clearly a Focus Area.** We are optimistic BOL will increase spending on R&D (we model > 8% sales in 2005) simultaneous to increasing margins.

*** We see several drivers to operating margin expansion:** 1) Potential accelerating constant currency sales growth in 2005 (6%7% E) vis-a-vis a solid pipeline including launches in contact lenses, lens care solutions, pharma, cataract and refractive; 2) gross margin expansion via favorable mix shift; and 3) SG&A expense reductions.

*** Trend of Upside Results Still in the Cards.** Continuing to execute on the metrics of its operating profit improvement plan, coupled with incremental top-line drivers (PureVision, Retisert for PU, Medalist One Day Japan, SofPort aspheric IOL, and Millennium ActiveFlow), could portend upside to our 2005 sales and EPS estimates of \$2.4B and \$3.41.

*** Reiterate Buy.** We would be buyers of this stock at current levels. Not only do we expect a strong 4Q, but we also believe BOL shares offer more upside potential than

downside risk. Our price target of \$68 offers nearly 10%-15% upside potential vs. our downside risk valuation of \$56.50 (6% downside).

Refractive: Driven by approval for Zyoptix in October 2003, Bausch's worldwide refractive revenue grew over 20% over the last twelve months. We think BOL took share in the domestic LASIK procedure market in 3Q, and we look for the company to continue to take share in the U.S. market, augmented by its penetration of the LVI business (LVI is the third largest corporate provider of LASIK procedures in the U.S.) in late 2003. We estimate LVI centers perform roughly 100K procedures annually. We believe the company's commitment to the refractive business is intact, and expect Bausch's share of domestic LASIK volume to continue tracking higher, toward the 20% level. The company is currently upgrading its Zylink software that should improve Zyoptix treatment times by up to 40% (in field testing at present). Finally, the company expects to launch the latest iteration of its mechanical microkeratome (the XP) in 1H:05. We estimate the refractive business will grow 8.5% Y/Y in 2005, although we again think this estimate is conservative, given recent trends in the company's procedural volume growth, namely in the U.S. market.

11/2 **STAAR Surgical company** announced financial results for its third quarter of 2004, which ended October 1, 2004. Total product sales for the third quarter were \$12.1 million compared with \$11.9 million reported for the same quarter last year and \$12.0 million reported for the second quarter of 2004. Excluding the impact of changes in currency, third quarter 2004 total product sales were \$11.7 million.

Total product sales for the nine-month period ended October 1, 2004 were \$37.7 million compared with \$37.7 million reported for the comparable nine-month period of 2003. Total revenue for the nine-month period ended October 3, 2003 was \$37.7 million, which included royalties previously generated by technology licenses that terminated as of March 31, 2003. Excluding the impact of changes in currency, total product sales for the nine-month period ended October 1, 2004 were \$36.1 million.

Net loss for the quarter was \$2.3 million (11 cents per share) compared with a net loss of \$2.7 million (15 cents per share) for the same period one year ago and a net loss of \$3.4 million (18 cents per share) for the second quarter of 2004.

STAAR exited the third quarter with approximately \$11.8 million in cash and cash equivalents on its balance sheet compared with \$14.9 million at July 2, 2004 and \$7.3 million at January 2, 2004. STAAR's bank debt at the end of the third quarter of 2004 was reduced slightly compared with the second quarter of 2004 and was approximately \$2.8 million.

"Clearly the focus this quarter remained on new product development and compliance issues," said David Bailey, president and CEO of STAAR Surgical. "We generated another quarter of increased international Visian ICL (ICL) sales with third quarter growth of more than 65% over the prior year period. At the same time, we realize we

have yet to reach the two most critical near-term milestones -- FDA approval of the Visian ICL in the U.S. and the launch of our new three piece collamer lens and injector. As we have previously disclosed, the FDA completed its re-audit of our Monrovia facility on September 26, 2004, and we are currently preparing our response to their observations. We plan to submit our response to the FDA on November 4, 2004, and our entire organization is committed to correcting, to the FDA's satisfaction, all unresolved observations. Regarding the three-piece Collamer lens, we are currently developing a new injector and lens that we believe will allow us to competitively re-enter this market. Based upon the progress to date, we are planning for a full launch in the first quarter of 2005."

"In addition, at the recent *American Academy of Ophthalmology (AAO)* meeting, we reported that the first results from our Toric ICL trial have been very encouraging," continued Bailey. "Enrollment in the trial is now complete and follow up is underway. The results we reported were exceptional. When examined, 73 percent of the patients achieved an improvement in best corrected visual acuity versus pre-op levels."

"We remain keenly focused on managing our core cataract business through this challenging period," continued Bailey. "We are committed to energizing U.S. sales of our cataract products and believe that with the strengthening of our collamer IOL line we will soon have the tools necessary to accomplish this goal. Once again this quarter we were encouraged by the performances of our ICL line and preloaded silicone in the international markets and Cruise control product in the U.S. market," said Mr. Bailey.

Looking ahead, Bailey reiterated the outlook for the remainder of 2004. "Without U.S. ICL sales, we continue to expect that full year sales will be approximately flat compared with 2003. This estimate takes into account the continued challenges in the U.S. cataract market. Based on this expected revenue, we expect the net loss for the year to be between \$0.52 and \$0.55 per share," concluded Bailey.

Two analysts provided their take on Staar's performance:

Joanne Wuensch of **Harris Nesbitt: STAA--It's Not the Numbers, It's the FDA OK**

* **Event:** STAAR Surgical reported 3Q04 results that were essentially in line with expectations. Revenue of \$12.1 million (up 1.8%; down 2% ex-fx) and an EPS loss of \$0.11 compared with our estimates for \$11.9 million and loss of \$0.16. Total intraocular lens (IOL) sales declined 10.7%, as STAAR awaits the launch of its three-piece Collamer IOL (now anticipated 1Q05). OUS phakic IOL sales increased 65%. Despite much questioning, the company remained vague regarding the potential FDA approval of its phakic IOL. This Thursday (11/4) STAAR will submit a response to the FDA regarding the 36 #483 complaints. On a positive note: encouraging Toric ICL data were presented at AAO, indicating 73% of patients had improved visual acuity.

* **Impact:** Neutral.

* **Forecasts:** 4Q04E EPS declines to a loss of \$0.16 from a loss of \$0.12. We are delaying our US phakic IOL launch expectations to 2Q05 from 1Q05 in our model and reviewing expense assumptions. Our EPS estimates decline to a gain of \$0.06 from \$0.08 in 2005 and to \$0.19 from \$0.22 in 2006.

* **Valuation:** STAA trades at 1x our 2006 revenue estimate.

* **Recommendation:** NEUTRAL; uncertainty regarding FDA approval provides overhang to stock.

John Calcagnini of **CIBC World Markets: STAAR: Revenues In-Line With Consensus; Unclear When FDA Observations Will Be Resolved**

STAAR reported 3Q revenues of \$12.1M, up 2% from a year ago, slightly above our \$11.7M estimate and in line with consensus of \$12M. Excluding a foreign-exchange effect of \$430,000, revenues fell 2%. The net loss per share was \$0.11, vs. our loss est. of \$0.16, due to sharp cuts in SG&A.

ICL sales grew 65.5% to \$1.1 million from \$635,000 a year ago, but were flat sequentially, and we note that this represents very little adoption in Europe. We estimate the company's cataract business dipped about 2% to \$10.9 million vs. \$11.1 million a year ago.

The IOL business has continued to struggle over the past few quarters, and we estimate sales were \$7 million for 3Q04. We estimate Collamer and Silicone IOLs sales dropped 13% and 23%, respectively. Glaucoma products sales fell slightly vs. year-ago levels at roughly \$220,000.

We reiterate our Sector Underperformer-Speculative rating on STAAR, given the continued delay for an ACL approval, the outstanding FDA observations and the company's cash burn, which could become a problem if the ACL is not approved.

11/3 As reported by *CRSToday*, from the *AAO* meeting:

Trends in Refractive Surgery: According to the results of the 2003 *ISRS/AAO* survey, which is in its 7th year, LASIK continues to be the procedure of choice for patients with refractive errors between -8.00 and 3.00D. For high myopes, refractive lens exchange remains the preferred procedure, and phakic IOLs were favored for highly myopic patients, said presenter Richard Duffey, MD. The preferred procedure for presbyopia is LASIK, although the Crystalens (**Eyeonics Inc.**, Aliso Viejo, CA) accommodating IOL is showing strong market growth. The Hansatome (**Bausch & Lomb**, Rochester, NY) remains the most commonly used microkeratome, a consistent track record for this device since 1998. In terms of wavefront analyzers, **Visx Inc.'s** (Santa Clara, CA) platform is the most frequently used among the survey responders. Dr. Duffey claimed that he found

it interesting that 8% of survey respondents consider bilateral phakic IOL implantation to be acceptable.

A major drop in comanagement occurred, with 38% of survey responders comanaging patients versus 80% in 2002. Also, comanagement with an optometrist inside or outside of a surgeon's practice decreased by approximately 50%.

Fourth-generation fluoroquinolones are monopolizing the postoperative refractive surgery market. Postoperative use of Zymar (**Allergan, Inc.**, Irvine, CA; 25%) and Vigamox (**Alcon Laboratories, Inc.**, Fort Worth, TX; 25%) tied, followed by Ocuflox (Allergan, Inc.; 10%), Quixin (**Santen, Inc.**, Napa Valley, CA; 3%), Ciloxan (Alcon Laboratories, Inc.; 3%), tobramycin (3%), and gentamicin (1%). The remaining 25% of responders use "other" antibiotics.

According to Dr. Duffey, of approximately 1,500 surveys mailed to members of the newly combined ISRS/AAO, 135 responses were analyzed by October 15 for this presentation; they constitute slightly more than 12% of the ISRS/AAO membership. For the full survey results, visit **www.duffeylaser.com**.

Norwood Eyecare's Epi-LASIK Device: Marguerite McDonald, MD, joined Ioannis Pallikaris, MD, in presenting customized surface ablation as a superior alternative to wavefront-based LASIK at the annual AAO/SOE Joint Meeting. Dr. Pallikaris is the inventor of Epi-LASIK and co-developer of the Centurion SES Epikeratome (**Norwood Eyecare**, Duluth, GA). The instrument, which was FDA 510(k)-approved in October 2003, was designed according to the premise that it is unnecessary to cut any tissue. By incorporating a PMMA separator, the Epiedge, in lieu of a blade, the epikeratome eliminates the creation of LASIK stromal flaps and reportedly reduces the occurrence of higher-order aberrations as well as other complications. In addition, according to Drs. McDonald and Pallikaris, the Epi-LASIK procedure allows for the repositioning of the epithelial layer with ease, minimal pain, and an increased probability for reattachment.

Dr. McDonald serves as Global Medical Advisor for Norwood Eyecare. Although the Centurion SES is already FDA-approved, she announced that a US prospective study is being conducted to enable the company to provide the ophthalmic field with the additional positive results that are anticipated.

Automated Screening for Refractive Surgeons: Stephen Klyce, PhD, and Michael Smolek, PhD, are developing an automatic screening method to analyze and classify corneal topography from most available topographers without the use of a device.¹ They collected 1,825 topographic examinations that were performed with the OPD-Scan corneal topographer/aberrometer (**Nidek Inc.**, Fremont, CA) and classified as (1) normal, (2) astigmatic, (3) keratoconus suspect, (4) clinical keratoconus, (5) pellucid marginal degeneration, (6) penetrating keratoplasty, (7) myopic refractive surgery, and (8) hyperopic refractive surgery. Drs. Klyce and Smolek then used a 2-D Fourier filter to determine a common spatial resolution compatible with both fine- and wide-mire

topographers. Using the common resolution, they interpolated a new mire set from which they extracted up to 18 topographic indices. They used these indices in parallel neural networks that they manipulated to automatically recognize each of the categories. The researchers categorized any maps that did not fall into a defined category as "unknown."

In initial testing, the method correctly classified 91% of the examinations in the independent test set with a single category. Three percent of the maps generated two responses, and the researchers judged both responses to be correct for mixed corneal conditions. The rest were classified as unknown. Drs. Klyce and Smolek are continuing to refine the method to perform postprocessing and include contact lens-molded corneas as a ninth category.

New Accommodating IOL: At a press conference during the AAO/SOE joint meeting, executives from **Nulens Ltd.**, based in Herzliya, Israel, discussed their development of an accommodating IOL that operates on the same principles as the accommodative powers in the eye. The lens features an anterior reference plane and a posterior aperture near the nodal point. After cataract removal, the surgeon sclerally fixates the Nulens IOL into the ciliary sulcus without sutures. The lens capsule is allowed to collapse, thus creating a "capsular diaphragm" that incorporates the ciliary process, the zonules, and the collapsed lens capsule. A patented haptic system angles the lens toward the capsular diaphragm. The Nulens contains a small chamber with a soft silicone gel and a posterior piston with an aperture at its center. The aperture allows this silicone material to bulge in response to forces in the capsular diaphragm generated by the ciliary muscles' reacting to a naturally occurring blur stimulus for accommodation in the brain.

Although the Nulens IOL is still in development, the company intends for it to provide more accommodative amplitude than any other accommodative lens currently available. A study conducted by Jorge Alió, MD, and colleagues in Alicante, Spain, confirmed an accommodative effect of more than 30.00D in primates implanted with the lens.

Intralase for High Myopic Treatments--Excellent Safety and Results: Nancy A. Tanchel, MD, presented the safety and efficacy results of treating high myopes with the Intralase FS femtosecond laser (**Intralase Corp**, Irvine, CA). In a study of 64 eyes from -8.00 to -19.25D, 70% had achieved 20/20 UCVA at 6 months. Fifteen eyes had been followed for more than 1 year; 60% of these had achieved 20/20 visual acuity, and all of them had attained better than 20/40 visual acuity. Furthermore, six of the 15 eyes gained one line of BCVA at 1 year, and none of the 15 eyes lost lines of BCVA. By 1 month, all patients reported having night vision that was better than or equal to their preoperative status. No patient developed DLK postoperatively. In addition, Dr. Tanchel showed images of FS-laser flaps taken by Richard Foulkes, MD, with the Artemis 2 VHF Digital Ultrasound Arcscan (**Ultralink LLC**, St. Petersburg, FL). The images show the smoothness of the corneal bed created by the FS laser.

Dual-Optic Accommodating IOL: The goal of the first dual-optic accommodating IOL developed (**Synchrony; Visiogen, Inc.**, Irvine, CA) is to provide every individual eye

with a moving 34.00-D lens by varying the minus power of the coupled posterior optic, according to presenter David Chang, MD. The single-piece, foldable lens is made of a silicone material and has a 5.5-mm, high-powered anterior optic (34.00D) coupled with a 6.00-D, minus-powered posterior optic. The amount of minus power fluctuates in order to correct each individual eye to emmetropia. Silicone struts that exert a specific amount of spring-like tension connect the two optics. The uncompressed device is 9.5mm long axially and 9.8mm wide. When compressed, the dual optic achieves 2.2mm of accommodation. The IOL is sized with the goal of filling and distending the capsular bag, where it should be confined by a small-diameter capsulorhexis. The Synchrony IOL is designed to utilize natural accommodation based on the Helmholtz theory of accommodation, Dr. Chang said.

To implant this lens, the surgeon must create a temporal incision that is astigmatically neutral but can be enlarged to between 4.5 and 5.0mm for forceps implantation. The capsulorhexis must be 4.5 to 5.0mm. According to Dr. Chang, a preloaded, disposable, injector prototype for the lens is under development. Dr. Chang explained that capsular fibrosis is the obvious enemy of IOLs, but he said that the design of the Synchrony minimizes anterior capsule contact and the dual optics expand and fill the capsular bag.

According to Dr. Chang, Visiogen expects to begin a US FDA trial next year.

In a separate discussion, Ivan Ossma, MD, presented 1-year results with the Synchrony IOL. The lens was implanted in patients who were older than 40 years and had cataracts. Dr. Ossma's presentation focused on 25 eyes that had received the latest version of the lens. Enrollment ended in April 2004. Dr. Ossma reported that, in three patients, uncorrected distance visual acuity improved with time to a mean of 20/30 at 12 months. Spherical equivalent was -0.50D at 1 year, and near UCVA was better than J1 at 6 months. Best-corrected distance vision was better than 20/40. Dr. Ossma reported that only one IOL had to be explanted.

The dual-optic design of the Synchrony capitalizes more dioptric change per unit of lens displacement, Dr. Ossma said, and he added that this IOL is a viable option for the correction of pseudophakic presbyopia.

11/3 **NovaMed, Inc.** reported results for the third quarter and nine months ended September 30, 2004. Net income from continuing operations in the third quarter of 2004 increased 34% to \$1.1 million (5 cents per share) from \$799,000 (4 cents per share) in the prior year third quarter. The third quarter results for 2004 and 2003 included pre-tax net losses on the sale of minority interests of \$64,000 and \$188,000, respectively.

For the third quarter, total net revenue increased 21% to \$17.4 million from \$14.4 million for the prior year third quarter. Net revenue from surgical facilities was \$12.9 million, up 38% from \$9.4 million in the prior year third quarter. This revenue increase was primarily due to a 36% increase in total surgical procedures performed in the third quarter of 2004 as compared to the same period in the prior year. On a same-facility

basis, surgical facilities net revenue increased 8% over the prior year third quarter. Product sales and other revenue was \$4.5 million in the third quarter of 2004, down 10% from the prior year third quarter. Operating income in the third quarter of 2004 increased 56% to \$3.4 million, or 20% of net revenue, from \$2.2 million, or 15% of net revenue, in the same period last year. Minority interest in the third quarter of 2004 was \$1.5 million, up 112% over the prior year third quarter. This increase is due to the sale of minority interests in existing surgical facilities in 2003 and 2004 as well as surgical facilities acquired in 2004.

"I believe our third quarter results are beginning to show that both our internal and external growth strategies are working. The positive contribution from our five 2004 surgery center acquisitions plus our strong same-facility revenue growth of 8% produced total surgical facilities revenue growth of 38%," commented Stephen Winjum, NovaMed chairman, president and CEO. "I am pleased with this revenue growth which contributed to our operating income growth of 56%, net income growth of 34% and operating income margin improvement of five percentage points over the prior year," said Winjum. We will continue to focus on growth opportunities within our existing portfolio of 22 surgery centers as well as pursue attractive acquisition and development opportunities. Our acquisition pipeline remains strong and the recently announced increase in our credit facility to \$50 million further enhances our ability to execute our growth strategy and continue our growth momentum."

NovaMed acquires, develops and operates ambulatory surgery centers in partnership with physicians. NovaMed currently owns a majority interest in 22 centers located in 12 states. NovaMed's executive offices are located in Chicago, Illinois.

- 11/6 As reported by *CRSToday*, **Nidek Co., Ltd.** (Gamagori, Japan), presented 9-month clinical data from its US FDA Hyperopia Clinical Study, which incorporates the utilization of new hyperopia software for the US NIDEK EC-5000 Excimer Laser System. Currently, 248 eyes out of a total 300 eyes approved for the study protocol have been treated for hyperopia and hyperopic astigmatism.

Nidek executive vice president and General Manager Ted Shimomura was pleased with the findings: "These are outstanding results and we look forward to expediting collection and review over the coming months and thereafter submitting our data to the FDA for approval in short order and the NIDEK EC-5000 provides expanded treatment options, parameters, and an innovative, technologically advanced platform for refractive surgery."

- 11/6 *CRSToday* also reported that in a surprise turn of events in the LASIK lawsuit filed back on April 19, 2001 by United Airlines pilot Steven Post against **University Physicians Inc. (UPI)**, the Honorable Kenneth Lee, of the Arizona Superior Court of Pima County, by Order dated October 28, 2004, reinstated the record \$4 million jury verdict previously entered against Defendant UPI on May 9, 2002.

Cataract & Refractive Surgery Today provided detailed coverage in its July/August 2002 issue of the 10-day trial and record \$4 million verdict, which was returned in favor of the Plaintiff in his lawsuit against UPI, relating to his LASIK surgery. CRSToday also reported on the unusual events that occurred after the trial, which include Judge Lee granting Defendant UPI a new trial in November, 2002, and setting aside the record \$4 million jury verdict. Judge Lee's decision was based on newly discovered evidence presented by the Plaintiff's expert witness, Jeffrey Machat, MD, at a post-trial evidentiary hearing during which he changed his standard-of-care opinion.

Plaintiff Post subsequently appealed that decision to the Arizona Court of Appeals, which, more than a year later, rendered its decision in an unpublished Memorandum Decision on February 1, 2004, overturning Judge Lee's decision which threw out Plaintiff Post's \$4 million verdict. Nevertheless, the record \$4 million verdict was not automatically reinstated as a result of the Appellate Court's reversal. Rather, the case was remanded by the Appellate Court back to the state superior court where the Plaintiff filed a Motion to Reinstate the Judgment, the Defendant UPI filed a Renewed Motion for a New Trial, and Plaintiff filed a Motion to Correct a Mathematical Error.

On October 28, 2004, Judge Lee ruled on these pending motions, denying the Defendant's Renewed Motion for a New Trial, and granting Plaintiff's Motion to Reinstate the May 14, 2002 judgment in favor of the Plaintiff, as well as granting Plaintiff's Motion to Correct a Mathematical Error, awarding the Plaintiff taxable costs against the Defendant in the amount of \$44,569.71.

Ted Schmidt and Bob Beal, attorneys for the Plaintiff Steven Post commented on the Order, stating that "this ruling demonstrates the importance of a jury's final decision and how very inappropriate it is that influences outside the courtroom be allowed to undo what they have done, or that witnesses, who have sworn to tell the truth in an open court of law be allowed to change their testimony based upon such inappropriate outside influences and pressures. This was a victory for the sanctity of the jury system."

Jeff Campbell, attorney for the Defendant UPI, declined to comment on the ruling at this time.

Although the jury originally awarded \$4 million against the Defendant, it apportioned fault of 85% to the Defendant and 15% to the Plaintiff, however, today, with back interest, the judgment against Defendant UPI totals \$4,306,738.06.

- 11/8 **TLC Vision Corporation** announced its financial results for the three and nine month periods ended September 30, 2004. Q3-04 total net revenues were \$56.6 million, up 23% from \$46 million in the third quarter of 2003. Third quarter total paid laser procedure volumes were over 45,600. Year-over-year volume increased 21% in the centers and 9% in the access business. The result was Q3-04 total procedure volumes were up 16% from 39,400 for the same three month period a year ago. The procedure volume mix in Q3-04

was 60% centers versus 40% access. CustomLASIK procedures represented approximately 55% of center volumes in Q3-04.

TLCVision reported a Q3-04 net profit of \$3.3 million (5 cents per share) compared to a loss of \$4.1 million (6 cents per share) reported in last year's third quarter. Third quarter 2004 adjusted EBITDA was \$8.0 million, up 143% from the \$3.3 million for the same period last year.

Jim Wachtman, TLCVision's CEO, commented "Our premium model continues to demonstrate superior financial leverage even during a slow seasonal period. During our second quarter conference call, we said that growth trends were continuing, and they obviously have. Based on preliminary analysis, we now expect these trends to continue through the remainder of 2004 and into 2005. Additionally, we continue to improve our financial position, and are poised to capitalize on new growth opportunities."

- 11/9 Michael Lachman of **ThinkEquity Partners** sent along his report from the recent AAO meeting: **Ophthalmology Market Update: Retinal Treatments and Refractive Surgery** (See our note at the end of this brief.)

Our comprehensive review of the ophthalmology market focuses on emerging retinal therapeutics and refractive surgery. On the retinal front, we provide a deeper look into the latest clinical data for **Alcon's** Retaane, which we still believe will fail to win FDA approval in 2005. Initial two year data for **Eyeteck's** Macugen looks positive, and we still expect a timely approval (possibly before year-end) and a strong launch, which will create a difficult growth backdrop in 2005 for **QLT's** Visudyne. The publication of pivotal trial data in Q2-05 for **Genentech's** Lucentis remains a highly anticipated event. In refractive, we have re-worked our LASIK market model to better understand recent procedure share shifts, and why **VISX** reported below-market procedure growth in Q3. We also review the outlook for new technologies and indications for LASIK, phakic IOLs for high myopia, and accommodating/multifocal IOLs and CK for the potentially huge presbyopia market.

Investment Highlights and Report Contents:

I. Retinal Therapeutic Update:

Retaane: A Deeper Look into the Data - We Still Doubt Near-Term FDA Approval

At the recent *American Academy of Ophthalmology (AAO)* meeting, Alcon provided a deeper look into the Retaane pivotal trial results, and addressed some of the issues and questions regarding the higher-than-expected dropout rate, low overall response rates to treatment with both Retaane and Visudyne, and the identified "controllable factors" of drug reflux and dosing interval. While the additional data analysis adds some clarity and in most cases provides reasonable explanations for some of the most puzzling questions, we doubt that the existing data will be enough to support FDA approval in 2005, relying

too heavily on retrospective data analysis. Alcon's stock has rebounded sharply from the initial sell-off following the release of the disappointing Retaane data.

Macugen: First Cut of Two Year Data Looks Favorable

At this year's AAO, Eyetech Pharmaceuticals announced that the treatment effect with Macugen extends for two years in patients with wet AMD. In those patients who continued on therapy for two years, the positive effect of Macugen (0.3mg dose) was statistically significant at two years, with a 45% treatment benefit compared to usual care controls. A treatment benefit was also seen for patients who received Macugen for two years compared to those only receiving one year of therapy: a statistically significant 67% more three-line-loss was noted in patients who were limited to one year of Macugen versus those who were treated for two years. The rate of compliance remained high (92%) during the second year of the trial, and the safety profile of Macugen remained similar to that of the first year as well. After a May 2003 protocol amendment to reinforce aseptic technique, the endophthalmitis rate declined significantly, from 0.18% to 0.03% per injection. We could hear of a Macugen FDA approval decision by the December 17 PDUFA date, and we still expect a strong launch following approval. However, investors must keep an eye on Genentech's Lucentis, for which expectations remain high (see below).

Visudyne: Growing Interest in Combination Therapy, but Growth Outlook Remains Challenging

Although there is mounting evidence that Visudyne combined with intravitreal triamcinolone acetonide (IVTA) injections has become the standard of care for the treatment of wet AMD, we remain concerned about revenue growth prospects going forward for Visudyne. While we expect PDT/IVTA combination therapy and the broader range of Medicare-reimbursed indications to support relatively stable Visudyne sales over the next 1-2 years, we still believe that growth will remain a challenge. We maintain our cautious stance regarding QLT and its stock for the following reasons: (1) Although combination therapy should support Visudyne usage across a broader range of patients, we believe this will be offset by less frequent dosing. (2) We expect the FDA approval of Macugen to have an impact on Visudyne sales, at least over the near-term. (3) We still forecast less upside in Visudyne usage resulting from newly Medicare-reimbursed indications than most people expect. (4) We continue to detect an underlying negative sentiment regarding Novartis, and the way it has priced and marketed Visudyne over the past several years, which could have an impact on the growth prospects for Visudyne once an alternative is available.

Lucentis: The Buzz Remains Positive - ARVO 2005 Could Bring High Fives or Broken Hearts

Although there was no significant new Lucentis clinical data presented at this year's AAO, the level of excitement surrounding this Genentech product remains high. A new

Lucentis Phase IIIb clinical study (the PIER Trial) was announced at the AAO, which will evaluate a less frequent dosing regimen. This new study follows from observations made in an open-label extension study of Lucentis that showed a sustained benefit of up to six months. Results from the Phase III MARINA Trial and the Phase I/II FOCUS Trial will be presented in Q2-05, possibly at the ARVO meeting. Results from the Phase III ANCHOR Trial should be available in late 2005 or early 2006. Lucentis represents a real threat to Macugen in the 2006-2007 period, with relatively low barriers to switching. Eyetech is already promoting the potential safety benefits of its selective isoform approach over Genentech's less targeted approach, although we expect the retinal community to focus more heavily on safety outcomes from the Lucentis clinical trials than on theoretical safety arguments.

II. Refractive Surgery Update:

LASIK Market: Sorting Out Procedure Growth and Market Share Dynamics

After VISX reported a y/y LASIK procedure growth rate in Q3 of only 4%, well below the market-wide growth rate that we now estimate at 14%, many questions were raised regarding market share shifts in recent quarters. Our updated industry model suggests that VISX's procedure share jumped from 60-61% prior to CustomVue approval in mid-2003 to 65-66% in H2-03. However, with both **Bausch & Lomb** and Alcon having caught up with VISX's custom-approved indications over the past year, VISX's share has "round-tripped" to a more sustainable 60-61% level. We believe that VISX's H2-03 share spike created difficult procedure growth and market share comps that the company is currently working through, resulting in a period of below-market growth rates that are already factored into our estimates. We like VISX's stock at current levels, trading at a depressed valuation due to the recent underwhelming quarter and the unsatisfying management explanation for it. At the same time, LASIK industry fundamentals remain solid (mid-teens growth forecast for H2-04 and 9% forecast for 2005), and these industry fundamentals will ultimately benefit the market leader. The next two major custom LASIK approvals will likely go to VISX, which should support further custom penetration and possibly boost market share as well.

LASIK Technology: Continued Improvement in Clinical Outcomes, New Indications Coming

With mounting evidence that custom/wavefront guided LASIK is superior to standard LASIK, attention is turning to new indications (hyperopia, mixed astigmatism, and high myopia) and new technologies (particularly iris registration and tracking). Based on the clinical data we have seen so far from both VISX and Alcon, we believe that the relative benefit of custom versus standard LASIK for the new indications of hyperopia and high myopia will be greater than the benefits seen in the currently approved low-to-moderate myopia population. Approval is expected for VISX's CustomVue to treat hyperopia by the end of 2004 and approval for high myopia is expected by mid-2005. These two indications address 20-25% of the LASIK market, and thus should drive an additional

10% or more CustomVue penetration during 2005, as well as contribute positively on the margin to procedure growth and market share for VISX.

Phakic IOLs: The Bell for Round One Has Sounded, but One of the Fighters is Still in the Corner

Phakic IOLs are lenses implanted electively into eyes that still contain the natural crystalline lens, for the purpose of refractive vision correction (similar to LASIK). At the recent AAO, the debate over the relative merits of **AMO's** Verisyse phakic IOL and **STAAR Surgical's** Visian ICL (formerly "Implantable Contact Lens") raged on. Absent the obvious advantage of first-to-market status in the US for the Verisyse, which was approved in September, the debate seems to us to be pretty evenly balanced, with a possible edge going to the Visian ICL based on a more familiar implantation technique. We still expect phakic IOLs to represent a niche market for the foreseeable future, addressing a low-to-mid-single digit percentage of the vision correction population consisting of very high myopes (-8D to -12D and beyond). Below this level, we believe that most patients and surgeons will view the risk/reward vis-à-vis custom LASIK to be unfavorable. Commercially, STAAR Surgical is suffering the effects of a delayed US launch of the Visian ICL due to FDA quality/compliance issues not related to the product, and has clearly lost some early sales and yielded surgeon training momentum to AMO. According to AMO management, the Verisyse launch is progressing better than expected, but the company is moving ahead in a staged fashion to assure proper surgeon training and good initial clinical outcomes.

Presbyopia: An Opportunity Large Enough for a Diverse Set of Approaches

Presbyopia, the loss of near (reading) vision, affects everyone by the age of 40-50, making the potential patient population enormous: 90-100 million people in the US, or about 200 million presbyopic eyes. Presbyopia, which results from the loss of the eye's "dynamic" ability to adjust its focus from far to near, is a fundamentally more complex problem to solve surgically than are the "static" conditions of myopia and hyperopia. The surgical correction of presbyopia requires either (1) a dynamic solution that provides active accommodation to different focal lengths, or (2) a "multifocal" solution that provides two or more different focal lengths and thus multiple images for the brain to process. In this report, we review a number of products and procedures that have either recently become available or are under development for correction of presbyopia. We are most excited about accommodating IOLs, such as the crystalens from eyeonics, and also expect Alcon's multifocal AcrySof ReSTOR IOL to become a popular alternative following potential FDA approval next year. Both of these premium-priced lenses could see broad use if, as we expect, CMS reimbursement policy is updated to allow use in Medicare cataract patients. LASIK can potentially address presbyopia with multifocal ablations, and VISX hopes to gain FDA approval for such a multifocal approach (applicable to hyperopic presbyopes) by early 2007. Early clinical outcomes appear encouraging, but we are not yet convinced that this will ultimately pan out as a preferred approach. Finally, we review Conductive Keratoplasty (CK), an RF-based procedure

combining monovision with the concept of "blended" near and distance vision that has been gaining traction since FDA approval to treat presbyopia in March 2004.

(The full report -- what is shown above is just the highlights -- is quite comprehensive. Anyone wishing to obtain a copy of the full report should send me an email requesting it.)

11/9 **Advanced Medical Optics, Inc. and VISX, Incorporated** announced the acquisition of VISX by AMO. The strategic combination, which was unanimously approved by both company's boards, will bring together two highly complementary companies with a broad range of superior technologies and a singular focus on serving the vision care needs of practitioners and patients around the world.

Under the terms of the definitive merger agreement, VISX stockholders will receive 0.552 shares of AMO stock and \$3.50 in cash for every share of VISX common stock they own, or a total value of \$26.52 per share of VISX common stock, based on the closing price of AMO's common stock on November 8, 2004. The total consideration will be approximately 29.0 million shares of AMO stock and \$184 million in cash.

AMO expects the exchange of shares to be tax-free to VISX stockholders. Upon completion of the transaction, AMO's stockholders will own approximately 58.5% of the combined company and VISX's stockholders will own approximately 41.5%.

The combination of AMO and VISX provides numerous strategic and financial benefits, including:

- * Creates the world's leading refractive surgical business focused on fast-growing segments of the ophthalmic medical device market.
- * Provides surgeons and patients with a comprehensive portfolio of leading technologies, including some of the market's most visible brands such as VISX's STAR Laser System and CustomVue custom ablation technology, and AMO's Amadeus microkeratome, Verisyse phakic IOL, and ReZoom, Array and Tecnis multifocal IOL.
- * Creates a \$1 billion global enterprise with a strong track record of growth, higher operating margins and increased free cash flow, and broad exposure to growing, global ophthalmic device markets.
- * Fortifies the company's commitment to innovation through combined R&D expertise and technical competencies.
- * Provides substantial cost synergies and operating efficiencies by building upon the size and scope of the combined organization's infrastructure, distribution network, service capability and manufacturing expertise.

* Improves the company's financial flexibility and deleverages the balance sheet, allowing for continued investment in the future.

"AMO and VISX represent an exciting combination of talent, technology, customer knowledge and growth potential," said Jim Mazzo, AMO president and CEO. "With its proprietary laser systems and custom ablation technologies, skilled service organization and long-standing reputation for reliability, VISX is the manufacturer of choice in laser vision correction. Adding their robust product platform to our existing refractive business represents a bold step forward to achieve one of AMO's core strategic goals to build a leading refractive surgical business. Joining forces will enable us to better serve practitioners and patients with a full range of surgical technologies while continuing to deliver improving returns to shareholders."

"This merger is a compelling strategic, financial and cultural fit," said Liz Davila, VISX chairman and CEO. "Our two organizations share a rich heritage of innovation, a commitment to exceptional customer service and a track record of creating value for shareholders. By taking advantage of AMO's global distribution network, we can expand our laser vision correction business into new markets. At the same time, we can enhance surgeon understanding and adoption of AMO's new refractive IOL technologies. The result will be an expanded opportunity to give ophthalmic surgeons an increasingly broad set of options for treating myopia, hyperopia and presbyopia."

The combined company will retain the Advanced Medical Optics name and be headquartered in Santa Ana, CA. Upon close of the transaction, Ms. Davila will join AMO's board of directors, increasing to eight the number of directors for the combined company. Following completion of the transaction, Doug Post, VISX president and COO will become president of AMO's Americas region, joining the existing AMO officers, who will continue to serve in their current management positions.

"In less than two-and-a-half years since our spin-off, AMO has made remarkable progress to strengthen our core businesses, improve global efficiency and create a platform for sustained growth," said Richard Meier, executive vice president of operations and finance and CFO. "We have accomplished this by executing against a clearly defined strategic plan, including our reorganization under a centralized operating model, and the acquisition and rapid integration of the Pfizer surgical ophthalmic business earlier this year. The acquisition of VISX builds on this strong foundation and, together with the benefits of our **Pfizer** acquisition and our improved operating model, we expect the transaction will be neutral to earnings in 2005 and to be meaningfully accretive to our pro forma earnings per share in 2006 and beyond."

Assuming closing of the transaction in the first quarter of 2005, AMO expects to realize cost synergies of \$10 million to \$15 million in 2005, resulting principally from eliminating certain redundant G&A expenses and leveraging VISX's equipment manufacturing operations. In addition, AMO expects modest revenue synergies in 2005. AMO expects these opportunities to grow in future years as it fully integrates VISX and

capitalizes on each company's strong products, brands, technologies and teams, and leverages further the complementary markets that each company addresses today. Based on this, AMO expects the transaction to be neutral to its 2005 pro forma earnings per share guidance of \$1.65 to \$1.75, excluding transaction-related costs. AMO expects to achieve 2006 pro forma earnings per share of \$2.20 to \$2.30.

Upon closing, AMO expects to provide more detailed guidance regarding certain transactional costs. The transaction requires the approval of both AMO and VISX stockholders, and is subject to clearance under the Hart-Scott-Rodino Antitrust Improvement Act, as well as other customary closing conditions.

Morgan Stanley & Co. Incorporated acted as exclusive financial advisor and **Skadden, Arps, Slate, Meagher and Flom LLP** acted as legal advisor to AMO in this transaction. AMO has received a commitment from Morgan Stanley to provide for the cash consideration of the transaction. **Goldman, Sachs & Co.** acted as exclusive financial advisor and **Wilson Sonsini Goodrich & Rosati** acted as legal advisor to VISX.

Several analysts provided their take on the proposed merger:

Jason Mills of **First Albany Capital: AMO to Acquire EYE; Good for VISX; Suggested Synergies Questionable**

* **Advanced Medical Optics** (AVO-\$42.44-Not Rated) announced yesterday after the market close that the company plans to acquire **VISX** in a cash-and-stock deal valuing EYE at a market capitalization of \$1.27 billion, or \$26.52 per share.

* Eighty-seven percent of the acquisition price will be AVO common stock (based on yesterday's close of \$42.44), and 13% of the purchase price will be cash (representing \$3.50/share in cash).

* AVO positioned the acquisition announcement as an "industry transforming event," but we are cautious to acquiesce to such a bullish characterization.

* In our view, the acquisition should be viewed positively by VISX shareholders, who, in our view, faced an uncertain business environment wherein we see unpredictable conversion to CustomVue ramp and slowing procedure volume growth, even with CustomVue Hyperopia, CustomVue High Myopia/Astigmatism and Iris Registration technology coming down the pike.

* The two companies - AVO and EYE - put forth an impressive presentation, laying out proposed synergies on the top line, expected margin expansion and EPS accretion (for AVO in 2006). Honestly, we have a lot of work to do to get comfortable with these suggested synergies, from AVO's perspective.

* We recommend holders of EYE common to sell into strength this morning near the proposed offer price for the equity of \$26.52.

Joanne Wuensch of **Harris Nesbitt: AVO--Shock and Awe, AVO Acquires VISX**

* **Event: Advanced Medical Optics** announced its intention to acquire **VISX**, the leader in the laser vision correction (LVC) market, for \$1.27 billion (roughly 7.7x 2004 revenues), creating a broader and larger medical technology ophthalmology franchise. The transaction values VISX at \$26.52 per share (a 46.5% premium to the stock's closing price on November 9 and is payable as 87% AMO stock and 13% cash in a tax-free exchange. The combined entity should generate revenues of approximately \$1 billion and provide a full slate of ophthalmology medical technology products.

* **Impact:** Positive in the long run, but increased integration risk near term.

* **Forecasts:** No change. The transaction, expected to close 1Q05, is anticipated to be neutral to earnings in 2005 (AMO reiterated its \$1.65-\$1.75 EPS guidance) and accretive in 2006 (guidance of \$2.20-\$2.30 is above consensus's \$2.15 estimate).

* **Valuation:** AVO is trading at 24x our 2005 EPS estimate of \$1.74, ahead of the ophthalmology group's 22x multiple.

* **Recommendation:** AVO's stock price is within spitting distance of our \$46 price target (based on 21-22x our 2006 EPS estimate of \$2.16). As we are currently not ready to increase our 2006 EPS estimate and, given the increased integration risk, we are not comfortable increasing our price target multiple, we are stepping to the side and lowering our rating to NEUTRAL from OUTPERFORM.

Ted Huber of **Wachovia Securities: AVO: Creates Refractive Powerhouse, At A Price**

* **BOTTOM LINE:** This combination is another bold, strategically sound move from AVO, but at a steep price. The risk is increased volatility and near term EPS dilution. We maintain our outperform rating based on the strategic value of this deal and faith that AVO can generate upside to its forecasts.

* **THE DEAL:** AVO plans to acquire VISX for \$26.52 per share, cash of \$3.50 .552 shares of AVO stock, valuing VISX at 1.27B, a 46% premium to last night's close. AVO hopes to close the deal early Q105.

* **SOURCES OF VALUE:** AVO sees year 1 cost synergies of \$15-20mm, 23-30% of VISX OpEx. Direct revenue synergies include cross selling AVO's microkeratome to VISX surgeons and selling VISX lasers through AVO's direct international sales force. The deal creates an ophthalmic surgery power house, combining the No. 1 refractive surgery offering and No. 2 cataract line. The combination is accretive to margins and growth, delevers AVO's balance sheet, and bolsters cash flow.

***ACCRETION/DILUTION:** Our preliminary math says the deal is dilutive (GAAP EPS) in year 1 by \$0.06 -0.15, closer to neutral year 2. Amortization accounting and the extent of revenue synergies are key to the final number. On a cash EPS basis, the deal looks \$0.15-0.20 accretive in year 1.

*** GUIDANCE AND MODEL CHANGES:** AVO reaffirmed 2005 guidance and initiated 2006 at \$2.20-2.30. AVO is using untapped upside from its Pharmacia purchase to cover this deal's modest dilution.

Michael Lachman of **ThinkEquity Partners**: **AVO: Would You Like Some CustomVue With That?**

We view **AMO's** acquisition of **VISX** favorably, and upgrade the stock from Accumulate to Buy following the initial sell-off in AMO shares. We see this as another sound strategic move for AMO, providing the company with the leading platform in the high potential refractive surgery market. AMO has executed extremely well in its core businesses and in the integration of the Pfizer cataract line, and we have a high degree of confidence in the company's ability to successfully integrate VISX, achieve targeted operating synergies, and make the deal accretive to earnings in 2006 and beyond. We remain optimistic regarding fundamentals within the refractive surgery market. Our new 12-month price target of \$47 is based on a P/E of 25x applied to approximate 2006 pro forma EPS of \$2.25, discounted back one year at 20%. With over 20% upside to our new price target, a Buy rating is warranted.

Investment Highlights: Last night after the close, AMO announced that it will acquire VISX for \$1.27 billion, or \$26.52 per share of VISX. At yesterday's closing price for AMO, the deal values VISX (EYE - \$23.69 - Accumulate - \$25 Price Target) shares at closer to \$27, although with this morning's sell-off in AMO shares, the valuation is closer to \$24. Expected to close in Q1-05, the transaction is structured using 13% cash and 87% stock, representing exchange of 0.552 shares of AMO stock and \$3.50 of cash for each VISX share. After the closing, AMO shareholders will own approximately 58.5% of the combined company and VISX shareholders will control about 41.5%.

We see this as another sound strategic move for AMO, combining the company's #2 worldwide cataract surgery franchise with the #1 player in refractive surgery. This deal moves AMO past **Bausch & Lomb** (BOL - \$61.99 - Accumulate - \$71 Price Target) into the #2 position in worldwide sales of ophthalmic surgical products (2005 surgical revenues of about \$700 million, up from about \$510 million previously, versus about \$550 million for Bausch). This acquisition also moves AMO into a worldwide leadership position in refractive surgery, combining VISX's #1 position with AMO's emerging refractive surgery product line. Prior to the VISX acquisition, AMO had already taken a number of smaller steps into the refractive surgery arena, with its Verisyse phakic IOL (the first such product approved by the FDA), the Amadeus microkeratome, the Tecnis multifocal IOL (acquired along with the **Pfizer** business), and accommodating IOL technology in early development. We tend not to overrate the value of size and market

leadership for their own sake, but this business combination clearly provides AMO with an attractive platform from which to grow its refractive surgery presence.

Criticisms of this deal will likely focus on the price AMO is paying for VISX, on the high level of cost savings required to make the deal accretive, and on the acquisition of a more volatile/less predictable business.

* The announced acquisition price represents a 47% premium to VISX's closing share price yesterday. This is, indeed, a large takeout premium, although we have been more bullish than most on the business prospects for VISX and believe that VISX has been trading of late at a depressed valuation. We note that the acquisition price represents a more modest 25% premium over the low \$20's price range that VISX stock has averaged over the past several months, and the 26.5x P/E multiple on 2005 EPS represents a similar 25% premium to the average 21x P/E on 2005 EPS for a comparable group of ophthalmic device companies. The 26.5x P/E multiple on 2005 EPS is in-line with the average for small and mid-cap medical device stocks. The valuation results in a deal that is accretive to pro forma EPS in 2005 only after an additional \$0.05-0.10 of upside from the base business is factored in, although the picture is much brighter on a "cash EPS" basis, given the high level of intangibles amortization.

* Projected cost savings of \$10-15 million in the first year represent a significant proportion of VISX's total cost base. We note that these cost-saving targets seem aggressive on the surface, amounting to 15-23% of VISX operating expenses (SG&A plus R&D) and 11-14% of VISX total expenses (including COGS) for 2005. However, these cost-saving opportunities should be highly visible to the management of both companies: VISX is a very centralized company, with a single headquarters and manufacturing site, and management knows where every penny resides on the income statement. Cost-saving opportunities should be easier to identify for this business than they were for the Pfizer cataract business, which was buried within a much larger corporate entity.

* The VISX business is by its nature a less steady, predictable franchise than the core AMO cataract surgery and lens care businesses, but with it comes greater growth potential as well. The addition of VISX to the AMO platform increases the underlying revenue growth rate of the company, and positions AMO for additional revenue upside, particularly as presbyopia treatments become a potential growth driver later in the decade.

Integration should be straightforward, and we expect AMO to manage the process well. Over the past two years, AMO management has proven its ability to "disintegrate" in its spinout from Allergan, and is ahead of schedule in the integration of the Pfizer cataract surgery business. This integration process is largely complete, and we don't expect it to distract from the effective integration of VISX.

Finally an answer to that age-old question: what's VISX going to do with all that cash? As it turns out, the answer does not involve acquisition of new technology by VISX, but instead, VISX's cash is helping to finance its own acquisition by another party. We have always maintained that there are few natural, synergistic potential acquirers of VISX, given the fact that the two largest diversified ophthalmology companies (**Alcon** and Bausch & Lomb) already have laser vision correction platforms. AMO is clearly the best strategic fit for VISX.

Doug will remain at his Post. VISX has distinguished itself over the years from its competition in basic business execution: product quality, service and responsiveness to customer needs, and first-to-market approval of new indications. In our view, this has been largely the result of a single-minded focus on the company's core laser vision correction business. In contrast, the laser businesses of VISX's two leading competitors have been relatively low priorities within the much larger and more diversified Alcon (ACL - \$74.44 - Accumulate - \$75 Price Target) and Bausch & Lomb organizations. It sounds to us like AMO's management is aware of this critical success factor, and will do its best to not "mess it up." VISX president and chief operating officer, Doug Post, will remain at VISX headquarters in Santa Clara and become president of AMO's Americas region, which should contribute to continuity. At the same time, making Post responsible for Americas region sales across all AMO product lines could help integrate the new parent company into the VISX culture. If AMO can maintain the historically high level of focus and execution within its VISX business segment, this could have a negative impact on the refractive surgery businesses of Alcon and Bausch & Lomb. Previously, these two companies had a superior ability versus VISX to cross-sell and bundle products for the cataract/refractive surgeon, given their strong presence in the cataract market. If, however, VISX loses its edge in this area, these and other competitors could benefit from missteps by the market leader.

Financial Impacts of the Acquisition: We think this deal makes good financial sense for AMO. The acquisition creates a much larger company (\$1 billion revenue base in 2005, versus only \$600 million in 2003). This deal will also increase the company's underlying revenue growth rate, operating margins, and percentage of revenues from the US (reducing the impact of foreign currency exchange fluctuations). Strong cash generation will allow more rapid debt reduction. The company has increased its 2006 financial targets for revenue growth to 6-8% (up from 4-6% previously), gross margin to 66-67% (up from 64-65%), operating margin to 19-21% (up from 17-18%), and earnings growth to 20-22% (up from 15-17%).

Excluding acquisition costs, AMO expects the transaction to be neutral to 2005 pro forma EPS, and the company is maintaining its previous 2005 pro forma EPS guidance of \$1.65 to \$1.75. On a pro forma basis, amortization of intangibles alone will impact EBIT by \$28-32 million, and EPS by \$0.26-0.30. Pro forma EPS guidance gets back to the original level of \$1.65-1.75 by adding (1) base business upside of \$5-10 million in EBIT, or \$0.05-0.10 in EPS, driven by cost savings and productivity improvement in the existing AMO business, including additional synergies from the Pfizer acquisition; and (2) cost

savings and revenue synergies from the VISX deal of \$20-25 million in EBIT, or \$0.19-0.24 in EPS. One takeaway from this is that the deal itself, including synergies, is dilutive to 2005 pro forma EPS by \$0.05-0.10, which is offset by upside in the base business. However, we note that the picture is much brighter on a cash EPS basis, given the significant \$0.26-0.30 non-cash amortization expense.

The company expects the deal to be accretive by 2006, and is providing initial pro forma EPS guidance of \$2.20 to \$2.30. Our 2006 EPS estimate stood at \$2.15 prior to this announcement. According to our modeling of the deal, this guidance implies \$44 million in deal-related cost and revenue synergies plus base business upside in 2006 (versus \$25-35 million in 2005), worth \$0.41 in pro forma EPS (versus \$0.24-0.34 in 2005).

We note that AMO's management has established a solid track record of conservative financial guidance, and we suspect that a degree of conservatism has been built into current numbers as well. From comments made on yesterday's call, it appears that the company is modeling LASIK procedure growth of about 7% next year and CustomVue penetration of 40%-plus, which we believe leaves room for upside.

AMO management expects cost synergies of \$10-15 million in 2005 from this acquisition and modest revenue synergies as well. Cost savings result primarily from elimination of redundant G&A expenses and leveraging of VISX's equipment manufacturing operations. AMO expects to realize these savings quickly, with \$10 million to be achieved in the first 90 days post-closing through reduction of administrative costs. G&A savings result from operating one public company instead of two, and from the sharing of other administrative expenses. Other cost savings arise from distribution, a combined service organization, and leveraging VISX's equipment manufacturing operations. Revenue synergies result from cross-selling within the cataract/refractive surgery business, and the ability for VISX to go direct internationally and benefit from AMO's strong sales presence in many parts of the world. VISX has not historically performed well outside the US, taking a backseat to **Bausch & Lomb**, and in many markets lagging even smaller players such as **Nidek**, **Schwind**, and **WaveLight**.

Valuation and Price Target: We are raising our 12-month price target on AMO shares from \$44 to \$47 following announcement of the VISX acquisition. We had based our previous \$44 price target on a P/E of 25x applied to our 2005 pro forma EPS estimate of \$1.76. As we move closer to 2005, and with improving visibility on 2006 EPS and preliminary guidance now in place, we move our valuation basis forward to 2006 pro forma EPS. Using the same 25x P/E multiple and approximate EPS of \$2.25, which corresponds to the midpoint of the new 2006 EPS guidance range, and discounting back one year at 20%, we arrive at our new 12-month price target of \$47. With over 20% upside to our new price target, a Buy rating is warranted.

We are adjusting our VISX price target to \$25, based upon the proposed acquisition terms, and lowering our rating from Buy to Accumulate. With a fixed exchange rate now set between the two stocks, there is little incentive to own VISX shares instead of AVO

shares. However, we fully expect this deal to close, so if the arbitrage spread becomes too great we would recommend purchase of VISX shares.

Positive Outlook for the VISX Business: We have been more bullish than most on the VISX story, particularly after the company reported an underwhelming Q3 result last month. We refer investors to a comprehensive ophthalmology market update that we published yesterday, featuring a detailed discussion of procedure growth and share dynamics within the LASIK market, and a preview of some of the new technologies and clinical indications coming soon for VISX. Some of the key points are summarized below:

- * After VISX reported a y/y LASIK procedure growth rate in Q3 of only 4%, well below the market-wide growth rate that we now estimate at 14%, many questions were raised regarding market share shifts in recent quarters. Our updated industry model suggests that VISX's procedure share jumped from 60-61% prior to CustomVue approval in mid-2003 to 65-66% in H2-03. However, with both Bausch & Lomb and Alcon having caught up with VISX's custom-approved indications over the past year, VISX's share has "round-tripped" to a more sustainable 60-61% level. We believe that VISX's H2-03 share spike created difficult procedure growth and market share comps that the company is currently working through, resulting in a period of below-market growth rates that are already factored into our estimates.

- * We believe that VISX's stock has been trading at a depressed valuation due to the recent underwhelming quarter and the unsatisfying management explanation for it. At the same time, LASIK industry fundamentals remain solid (mid-teens growth forecast for H2-04 and 9% forecast for 2005), and these industry fundamentals will ultimately benefit the market leader. The next two major custom LASIK approvals will likely go to VISX, which should support further custom penetration and possibly boost market share as well.

- * With mounting evidence that custom/wavefront guided LASIK is superior to standard LASIK, attention is turning to new indications (hyperopia, mixed astigmatism, and high myopia) and new technologies (particularly iris registration and tracking). Based on the clinical data we have seen so far from both VISX and Alcon, we believe that the relative benefit of custom versus standard LASIK for the new indications of hyperopia and high myopia will be greater than the benefits seen in the currently approved low-to-moderate myopia population. Approval is expected for VISX's CustomVue to treat hyperopia by the end of 2004 and approval for high myopia is expected by mid-2005. These two indications address 20-25% of the LASIK market, and thus should drive an additional 10% or more CustomVue penetration during 2005, as well as contribute positively on the margin to procedure growth and market share for VISX.

- * VISX is currently entering the presbyopia market internationally with its CustomVue LASIK multifocal treatment, targeting hyperopic presbyopes. A clinical trial is getting underway in the US, and FDA approval is targeted for late 2006 or early 2007. The VISX multifocal aspheric ablation profile features a central zone that is steepened to provide

near vision and a peripheral zone targeted for distance vision. Early clinical outcomes appear encouraging, and patient interest in this procedure so far has been high in the Canadian centers where it is offered, but we are not yet true believers that this will ultimately pan out as a preferred approach for hyperopic presbyopes.

- 11/9 The November issue of *Ophthalmic Market Perspectives* highlighted two events: the third quarter refractive procedure estimates and the highlights of the 2004 AAO meeting.

As noted by Dave Harmon of **Market Scope**, improvements in consumer confidence, excitement over new technologies, and increased advertising, all helped boost Q3 procedures significantly over the same period last year. Encouraged by higher average procedure prices, due to wavefront-guided LASIK (WFL) and higher procedure volumes, refractive surgery centers and surgeons have increased advertising in an effort to capitalize on the market upturn. In addition, PR campaigns for WFL, **IntraLase**, Crystalens, and CK treatment of presbyopia continue to stimulate interest in refractive surgery.

The total estimated U.S. refractive procedures for Q3 were 308,100, up 16.1% over the 265,300 procedures done in the same quarter last year. When U.S. patients treated in Mexico and Canada are included, Q3 procedures reached 314,300, up 15.5% over Q3 2003. The average price of LASIK increased \$71 during Q3, to reach \$1856, reflecting the higher priced WFL and IntraLase market shares. Surgeons reported charging an average of \$379 per eye premium for WFL during the quarter.

Surgeons reported that their percentage of WFL procedures increased to 42.2%, up from 39.5% during the second quarter. Wavefront-guided LASIK capability continues to expand, and according to Market Scope's Q3 survey, was available at more than 83% of all U.S. laser centers.

Market Scope's current forecast for U.S. refractive procedures indicates that 1.35 million procedures will be done this year, up 17% over 2003. (For more details of Market Scope's survey results, either see their November newsletter or contact the company directly.)

- 11/10 **IntraLase Corp.** announced that it had released preliminary clinical guidelines extending the use of its laser to new therapeutic applications, specifically, the treatment of diseased corneas. In a related development, a global team of corneal surgeons, expert in the field of therapeutic lamellar keratoplasty, has formed the IntraLase Lamellar Study Group specifically chartered to advance the use of the INTRALASE FS laser for therapeutic procedures.

The new guidelines will assist ophthalmic surgeons performing anterior lamellar keratoplasties, a procedure involving the replacement of patient corneal tissue that has become severely scarred or diseased. Up until this time, surgeons have relied upon hand-held scalpels to dissect diseased tissue with replacement segments obtained from donor corneas. INTRALASE FS lasers bring unsurpassed precision to this procedure by

using computer software to match the exact shape of the removed and donated tissue segments.

A second therapeutic procedure, the use of intrastromal rings to treat a condition known as keratoconus, is also being addressed in the new guidelines which the company released to surgeons attending the IntraLase laser user meeting at the recent *American Academy of Ophthalmology* meeting in New Orleans. Keratoconus is a disorder characterized by an extreme steepening of the cornea. The INTRALASE FS laser enables surgeons to precisely create a pocket into which an intrastromal ring segment is inserted to correct for the steepness and flatten the cornea.

Both therapeutic indications have been granted regulatory clearance in the United States and the European Union. IntraLase is providing reimbursement information to surgeons electing to use the company's lasers for therapeutic purposes.

Robert Palmisano, IntraLase president and CEO, stated, "While the markets for anterior lamellar keratoplasty and intrastromal ring implants are small in comparison to the market for creating corneal flaps, the added indications are significant because they demonstrate the broad potential for the company's femtosecond laser technology." He went on to say, "Both therapeutic indications incorporate the use of IntraLase's patented disposable patient interface and could therefore result in additional per-procedure revenue opportunities for the company."

11/15 Kathy Kincade, writing in *Optoelectronics Report* on the acquisition of **VISX** by **Advanced Medical Optics (AMO): AMO to acquire VISX for \$1.3 billion**

Shares of VISX jumped nearly 35% on Nov. 10 following the announcement that Advanced Medical Optics (AMO), a global provider of ophthalmic surgical devices and eye care products, has acquired VISX, the leading provider of laser vision correction services, for \$1.27 billion (29.0 million shares of AMO stock and \$184 million in cash). VISX stock rose \$6.26 to \$24.36, while shares of Advanced Medical Optics fell \$3.64 to \$38.80, an 8.6% drop.

Under terms of the definitive merger agreement, VISX stockholders will receive 0.552 shares of AMO stock and \$3.50 in cash for every share of VISX common stock they own, or a total value of \$26.52 per share of VISX common stock, based on the closing price of AMO's common stock on November 8, 2004. The combined company will retain the Advanced Medical Optics name and be headquartered in Santa Ana. The VISX facility in Santa Clara will remain intact, with the laser group's R&D, sales, service, and manufacturing activities continuing to operate there.

Upon close of the transaction, Liz Davila, VISX chairman and CEO, will join AMO's board of directors, increasing to eight the number of directors for the combined company. Doug Post, VISX president and chief operating officer, will become president of AMO's Americas region.

According to Post, who came to VISX in 1992 with the acquisition of **Questek**, which was then providing excimer lasers to VISX (Questek's nonmedical division was sold to **Lambda Physik** in 1993), the merger makes strategic sense on a number of levels. "When you look at field of ophthalmology, the two companies are so well aligned. There is no overlap of products," he said. "AMO offers the lifecycle of vision care, with the exception of the laser. And VISX, while successful, is really a one-product type of company. For example, if you look at presbyopia, a market with so much potential, and you look at the solutions available, we have a laser-based solution, but companies like AMO are developing intraocular lenses and other types of solutions. And in the shorter term, AMO has the Amadeus microkeratome for LASIK, which is something we are not participating in. We have the laser, but now we can bundle the entire procedure."

In addition, AMO has a very large international presence, while VISX derives about 85% of its revenue from the US market, which accounts for about 50% of the world market for vision correction.

VISX was founded in the mid-1980s by Charles Munnerlyn, Terry Clapham, and ophthalmologist Steven Trokel. Munnerlyn and Clapham had previously worked at **Coherent Medical** and **Cooper Lasersonics**, where they developed ophthalmic lasers and diagnostic instruments. But it was Trokel who first theorized that shaping the surface of the eye with the excimer laser might have the same effect as corrective lenses. Munnerlyn derived a mathematical formula for removing corneal tissue to form the desired refractive corneal surface; it took another 10 years, however, for the company to gain its first FDA clearance. Today VISX holds more than 200 patents world-wide and has licensed its vision-correction technology to **Alcon**, **Bausch & Lomb**, **LaserSight**, **Nidek**, **Schwind**, **Zeiss-Meditec**, and **WaveLight Technologies**.

AMO focuses on developing a broad suite of innovative technologies and devices to address a wide range of eye disorders. Products in the ophthalmic surgical line include foldable intraocular lenses, phacoemulsification systems, viscoelastics and related products used in cataract and refractive surgery, and microkeratomes used in LASIK procedures for refractive error correction. "With its proprietary laser systems and custom ablation technologies, skilled service organization and long-standing reputation for reliability, VISX is the manufacturer of choice in laser vision correction," said Jim Mazzo, AMO president and CEO. "Adding their robust product platform to our existing refractive business represents a bold step forward to achieve one of AMO's core strategic goals to build a leading refractive surgical business." —Kathy Kincade

- 11/15 **Norwood Abbey Limited**, subsidiary **Norwood EyeCare**, announced it had begun a 3-month study of post-operative comfort, visual recovery and wave-front guided custom ablation with its Centurion SES Epikeratome with EpiEdge for Epi-LASIK in surgical treatment of myopia. Marguerite McDonald, MD is the principal investigator and medical monitor for the study. Daniel Durrie, MD, and Lee Shahinian, MD, are clinical investigators.

"Epi-LASIK and wavefront diagnostics address two key complications such as stromal flap complications and higher order aberrations associated with current refractive laser procedures," explained Dr. McDonald. "In this exciting study, we will examine how the coupling of the two technologies may impact visual outcomes."

Unlike conventional LASIK, in which a sharp blade is used to make a stromal flap in the cornea, the Epikeratome employs a non-sharp plastic separator to gently lift a hinged sheet of intact epithelium from the cornea. Norwood's bladeless Epi-LASIK technology provides the benefits of LASIK but is designed to reduce or eliminate stromal flap complications as well as the risk of LASIK-induced dry eye, potentially facilitating faster recovery and less postoperative pain. Patients for whom LASIK is not advised -- such as those with thin corneas or dry eye -- or who have had concerns about potential LASIK side effects are strong candidates for Epi-LASIK.

A maximum of 35 patients (up to 70 procedures) will be enrolled at each of the three U.S. study sites. The treatments will be either bilateral or single eye, and if bilateral, both eyes will be treated at the same time. Only patients who have not previously had ocular surgery will be included.

In addition to a comprehensive preoperative evaluation, patients will be examined one day postoperative until re-epithelialization occurs; at 3 to 6 weeks postoperative; and at 10 to 15 weeks postoperative. Measures of post-operative comfort and visual recovery will be taken and wavefront measurement will be performed.

11/15-

11/16 Two analysts initiated coverage of **IntraLase** and shared their thoughts with us:

Michael Lachman of ThinkEquity Partners: ILSE: What the Flap Is All About - Initiating Coverage of IntraLase

We are initiating coverage of IntraLase, a fast-growing technology leader in the large laser vision correction market, with an Accumulate rating and a 12-month price target of \$20. The company's technology improves the safety and efficacy of LASIK, and addresses the "fear factor" associated with the procedure for both surgeons and patients. IntraLase presents an attractive value proposition for refractive surgeons and centers, resulting in rapid uptake and positive word-of-mouth among satisfied users. Management has executed extremely well and is a key component of our investment thesis. Key risks include the fundamental unpredictability of LASIK market growth, and the difficulty in forecasting the company's ultimate market penetration at this early stage of the adoption curve. Our sense is that stock has gotten a bit ahead of itself, most likely driven by strong business momentum and high near-term visibility. We would be more aggressive buyers of the stock in the mid-teens.

Investment Highlights: Our IntraLase investment thesis is based on the following key drivers:

* New and differentiated technology that addresses the large and growing LASIK market. The company's technology addresses the safety and efficacy of LASIK, as well as the "fear factor" associated with the procedure for both surgeons and patients. We forecast over 1.3 million LASIK procedures in the US this year, expected to grow to 1.5 million next year and 1.6 million in 2006.

* IntraLase is three years into a steep growth ramp that we believe still has a lot of room to run. The IntraLase story combines a large long-term opportunity with high near-term visibility.

* The company's "Better Medicine" and "Better Business" model has resonated with refractive surgeons, as this group of physicians is driven to do what is best for their patients while also maximizing practice profitability. Surgeons and patients have been motivated to adopt the IntraLase technology based on evidence of improved safety and efficacy outcomes. Surgeons have also been motivated by the opportunity to improve procedure volumes and practice profitability.

* IntraLase users exhibit a high level of customer satisfaction, evidenced by rapid uptake and high rates of penetration within existing accounts. The company's business has been driven largely by positive word-of-mouth among users, and technology uptake within new accounts has been rapid.

* IntraLase is a classic razor/blade business model... without the blade, of course. The model involves high margin annuity revenues driven by sales of lower margin capital equipment. The ongoing mix shift from capital equipment sales to per-procedure revenues will lead to higher profitability and greater predictability going forward.

* IntraLase is developing its business on a global scale, which significantly increases the overall opportunity. We forecast roughly one-third of laser unit sales to be placed outside the US over the next three years. We expect international procedures to exceed 15% of the company's total volume over the same time period.

* We view the direct competitive threat as relatively low. IntraLase has a meaningful lead to market advantage over its closest direct competitor, and significant blocking intellectual property.

* IntraLase is led by an experienced management team that has executed exceptionally well. Strong company leadership is clearly one of the key components of our IntraLase investment thesis. Management brings many years of experience in the laser vision correction market, at the senior executive level and in key functional areas.

Key investment issues and risks are as follows:

* Industry-wide LASIK procedure growth has been, and will continue to be, relatively difficult to predict. As an elective, out-of-pocket (unreimbursed) procedure, LASIK is

more dependent upon the overall health of the economy and on consumer confidence than are most medical technology markets.

* It is too early to know what the company's ultimate "peak" market share will be. Every new medical technology eventually finds penetration rates at which growth begins to slow, and eventually plateaus. While in the midst of the initial adoption curve, where IntraLase resides at present, it is difficult to predict where these "resistance levels" will be. In addition, international markets have not supported per-procedure LASIK models in the past and are difficult to forecast.

* The LASIK industry involves headline risk: negative publicity can result from unfavorable clinical outcomes and/or questionable business practices, particularly on the part of service providers. Importantly, any and all of the market players can suffer the consequences of negative PR, whether or not they are directly involved in any controversy.

* As is the case with many medical device companies, the IntraLase story involves few actionable catalysts (such as new product introductions and FDA approvals). At this point in the company's life cycle, success for IntraLase will be defined by continued progress in placing lasers and converting procedures, and by reporting strong revenue and earnings results on a quarterly basis.

* Pricing risk results from competition with custom LASIK for premium procedure fees, and from penetration beyond the early adopters and into more price-sensitive segments of the market. As adoption grows to the next level and IntraLase begins to address a broader slice of the market, more patients may have to choose between custom LASIK and IntraLase.

* Although we view the threat of direct competition as relatively low, competition cannot be dismissed completely. Competitive threats can result from other femtosecond lasers for LASIK flap creation, improvements in microkeratome technology, and alternatives to LASIK within the laser vision correction field.

* There is no compelling "second act" in our IntraLase forecast. There are other uses for the company's platform technology beyond LASIK, but none of these additional applications has yet risen to the level of a compelling follow-on growth driver for IntraLase.

* As is the case with any emerging medical technology, there are naysayers, and there is a bear case. Not all refractive surgeons are positive on the IntraLase story. We have spoken to surgeons that have not yet adopted IntraLase technology, and have also consulted with a small number of high-volume surgeons that are now IntraLase users but have not yet converted a majority of their practices. Some of the issues holding back further adoption include price sensitivity among potential patients, economic barriers at the surgeon/center level, and complications associated with IntraLase.

Valuation, Price Target, and Rating: We are initiating coverage of IntraLase with an Accumulate rating and a 12-month price target of \$20. We base our valuation analysis on both price/earnings and price/sales metrics, driven primarily by revenue and EPS estimates for 2006 and 2007. We would characterize our model as neither overly optimistic nor overly conservative, with both upside opportunity and downside risk dependent upon company execution and growth dynamics within the overall LASIK market.

* Our sense is that stock has gotten a bit ahead of itself, most likely driven by strong business momentum and high near-term visibility. We would be more aggressive buyers of the stock in the mid-teens.

* Our 12-month price target of \$20 equates to 40x estimated 2006 fully-taxed EPS of \$0.50, and 30x estimated 2007 fully-taxed EPS of \$0.82 discounted back one year at 20%.

* Our 12-month price target of \$20 equates to 4.3x estimated 2006 revenues, and 4.0x estimated 2007 revenues discounted back one year at 20%.

Financial Highlights: We expect IntraLase to break even in Q4-04, on revenues of \$17.2 million. We forecast the bottom-line impact of non-cash stock based compensation expense to be about \$0.7 million, or about \$0.02 per share on a pre-tax basis.

For 2005, our revenue and fully-taxed EPS forecasts are \$99.6 million and \$0.16, respectively. We note that our EPS estimate of \$0.16 is a fully-taxed number based on a 42% tax rate; our untaxed/reported estimate for 2005 stands at \$0.28. We are modeling EPS on a fully-taxed basis in order to make year-to-year comparisons more straightforward, and because we are basing our valuation on EPS estimates for 2006 and 2007. We also note that our EPS estimate for 2005 is impacted by approximately \$0.08 pre-tax (\$0.05 fully taxed), or about \$0.02 per quarter pre-tax, due to non-cash stock based compensation expense.

For 2006, we forecast revenues of \$144 million and fully-taxed EPS of \$0.50. By 2006, we estimate that the impact of non-cash stock option expense will decline to approximately \$0.01 per quarter on a pre-tax basis. Our revenue and fully-taxed EPS estimates for 2007 are \$187 million and \$0.82, respectively.

Risks to Target Price and Investment Thesis: Key risk factors include: (1) Fundamental unpredictability of industry-wide LASIK procedure growth, due at least in part to dependence upon the overall health of the economy and on consumer confidence. (2) Uncertain peak market penetration of the company's product and technology. (3) Headline risk within the LASIK industry: negative publicity that could impact IntraLase even if the company is not directly involved in any controversy. (4) Competitive threats resulting from competition with custom LASIK for premium procedure fees, directly competitive laser products, improvements in microkeratome technology, and alternatives

to LASIK for laser vision correction. (5) Lack of a compelling follow-on product or application: although there are other uses for the company's platform technology beyond LASIK, none has yet achieved high visibility as a potential long-term growth driver. (6) Negative sentiment among some potential physician customers: concerns include price sensitivity among potential patients, economic barriers at the surgeon/center level, and complications associated with IntraLase.

company Description: IntraLase Corp., based in Irvine, CA, develops and markets products for laser vision correction, specifically for the LASIK procedure. The company's INTRALASE FS laser brings precision to the first step of LASIK surgery, the creation of the corneal flap, as an alternative to mechanical, metal-bladed microkeratomes. Revenues are expected to exceed \$55 million in 2004.

Ted Huber of **Wachovia Securities** also initiated coverage of **IntraLase: ILSE: A Better Flap-- Patient Peace of Mind, Surgeon Profit**

* **A BETTER FLAP:** The IntraLase femtosecond laser offers surgeons safety, better visual outcomes, and a more profitable (for early adopters) method for creating the corneal flap needed for LASIK vision correction surgery. Claims of a superior safety profile are well supported by the research and preliminary studies hint at better visual outcomes than blade based (microkeratome) LASIK.

* **STANDARD OF CARE IN TIME:** Since its 2001 launch, IntraLase has taken nearly 14% of U.S. LASIK procedure share and is gaining 1-2% share points per quarter. International procedure share is less than 5% with sequential share growth of 1% point per quarter. We expect IntraLase domestic procedure share to top 50% by 2008 and 15% international. High volume LASIK surgeons have driven most IntraLase adoption to date. The technology's compelling safety and efficacy profiles are beginning to attract corporate centers and lower volume surgeons.

* **BUSINESS MODEL DRIVES SUSTAINABLE PROFIT GROWTH:** IntraLase is successfully pursuing a premium pricing strategy (more than \$300 thousand for the laser and \$125 per procedure). The technology is patent protected and has no direct competition nor comparable substitutes. IntraLase should turn its first profit Q4 2004 (excluding stock compensation expense) and generate 20.4% operating margins in 2006 driven by its high margin consumable revenue stream.

11/17 **LCA-Vision Inc.** announced that the Board of Directors voted to approve a 3-for-2 stock split, in the form of a stock dividend, payable on December 15, 2004 to shareholders of record as of December 6, 2004. The stock split will increase the number of outstanding shares from approximately 13.45 million to approximately 20.2 million shares outstanding. In addition to the stock split, the Board of Directors approved a quarterly cash dividend of \$0.08 per share, post stock split, payable on December 23, 2004 to shareholders of record as of December 16, 2004.

"This Board action recognizes the company's continued strong financial performance, which has exceeded our projections for growth in revenue and earnings per share," stated Stephen Joffe, LCA-Vision chairman and CEO. "We are again pleased to reward our shareholders with some of the cash flow we are generating from our solid financial performance, while continuing to meet our expansion goals. By maintaining the same per-share quarterly cash dividend following the stock split, we have effectively raised the cash payout by 50% over the prior quarter."

11/17 **VisiJet, Inc.** reported revenues for the third quarter ended September 30, 2004 of \$982,567 compared to nil reported in the same quarter of last year. The increase in revenue is attributed to the sales of the company's new EpiLift System in international markets. The company received FDA approval to sell the EpiLift system in the United States in the middle of September 2004.

For the third quarter of 2004, VisiJet reported a net loss of \$1.5 million (5 cents per share) based on the weighted average of 29.4 million shares outstanding compared to a net loss of \$1.2 million (6 cents per share) reported in the third quarter of 2003 based on the weighted average shares outstanding of 20.4 million. The increase in net loss is primarily a result of non-cash expenses recorded in connection with debt transactions and the increase in sales and marketing expenses due to the U.S. launch of the EpiLift System.

The EpiLift System is a next-generation corrective eye surgery procedure combining the best aspects of today's most popular refractive surgeries, PRK and LASIK. In May 2003, VisiJet purchased the worldwide rights to distribute and sell the EpiLift System from German ophthalmic equipment developer, **Gebauer Medizintechnik GmbH**. The product, which had previously acquired the CE mark for European approval, received FDA approval in September 2004. VisiJet has started marketing the EpiLift system in the United States and worldwide. In September, the company announced that it had opened 14 markets around the world in which to sell the EpiLift System, and anticipates expanding distribution even further by the end of this year.

According to Randy Bailey, CEO of VisiJet, "This quarter marks an important transition for VisiJet as the company moved from a research and development organization to one that is focused on the marketing and sales of our revolutionary products. We brought the EpiLift System to market, and so far, early sales numbers have surpassed initial expectations. In October, we had the opportunity to present the EpiLift System to industry professionals attending the *American Academy of Ophthalmology* Meeting in New Orleans. The VisiJet management team was enormously encouraged by the interest shown in the EpiLift System by ophthalmologists and other professionals in attendance, and we are extremely excited about the launch of our product."

The company is presently marketing and selling the EpiLift system in the United States and internationally. It has already begun shipping units in the United States, and over

twenty foreign countries including Japan, Korea and all the major European market countries. The company anticipates availability in additional countries by Q1 2005.

"The EpiLift System undoubtedly represents the next generation of corrective vision surgery," says Dr. Terry O'Brien, lead corneal researcher at the Wilmer Eye Institute at Johns Hopkins. "Nearly all of the possible side effects of refractive surgery, such as dry eye, loss of corneal sensation and change in structural strength of the eye, stem from the creation of a non-healing corneal flap. In bypassing the need for that procedure, EpiLift offers patients a safer method of refractive surgery without any compromise in terms of immediacy or quality of results."

- 11/22 Thanks to an increase in sales and earnings in the fourth quarter, the revenues of the medical technology provider **Carl Zeiss Meditec AG** for the financial year 2003/2004 will be at about the same level seen in the previous year despite the negative effects from the development of currency exchange rates. The adjusted organic growth in sales is based above all on innovative products. In total the company expects revenues of just under EUR 235 million (previous year: EUR 235.7 million).

In comparison to the previous year an improvement in the earnings before interest and taxes (EBIT) to over EUR 26 million is expected (previous year: EUR 24.7 million). The EBIT margin will thus increase to just above 11% (previous year: 10.5%).

Thanks to the excellent development in the operating result, Carl Zeiss Meditec expects its net income for the year to almost double (previous year: EUR 6.6 million). The operative cash flow will probably improve by more than 12% over the excellent financial year 2002/2003 to a figure of more than EUR 31 million. The net cash and cash equivalents will thus increase to a record level of over EUR 75 million. This provides Carl Zeiss Meditec with an excellent basis to achieve its growth targets in the new financial year. For the financial year 2004/2005, which has just begun, Carl Zeiss Meditec is planning on increasing its revenues by more than 20% and further improving its profitability.

- 11/29 **NovaMed, Inc.** announced that it had added another surgery center to its portfolio. NovaMed now has ownership interests in 23 surgery centers, six of which have been added in 2004. NovaMed acquired a 25% interest in the **Eye Care and Surgery Center of Fort Lauderdale** located in Fort Lauderdale, Florida. NovaMed has an option to acquire an additional 26% from its new partner, Dr. Tom Coffman, starting in November 2005. Dr. Coffman is also NovaMed's partner in the **Palm Beach Outpatient Surgery Center** in which NovaMed acquired a majority interest in late July 2004. "This acquisition provides NovaMed with an expanded presence in the attractive and growing south Florida market," said NovaMed Chairman, president, and CEO Stephen Winjum. "In the last 12 months approximately 2,000 ophthalmic surgical procedures were performed at this surgery center and we expect this acquisition to be immediately accretive to our earnings," said Winjum.

OPHTHALMIC LASER UPDATE -- December 2004

- 11/18 As reported by **VISX** in a Form 8 filing, on or about November 12, 2004, two putative class action lawsuits were filed in the Superior Court of the State of California in the County of Santa Clara against VISX and the VISX board of directors. The cases are captioned William Kinchy vs. VISX, Inc., et seq., Case No. 104CV030447 and Douglas Shearer vs. VISX, Inc., et seq., Case No. 104CV030452.

The complaints allege that, among other things, the VISX board of directors breached their fiduciary duties of loyalty and due care by deciding to sell VISX to **AMO** without undertaking sufficient effort to obtain the best offer possible for stockholders. The complaints further allege that the consideration to be paid in the merger is unfair and inadequate, and that VISX's board of directors breached their fiduciary duties of care, loyalty, and candor to VISX's public stockholders in connection with the merger. The complaints seek, among other things, an injunction prohibiting VISX from consummating the merger and rescission against the merger and any of the terms of the merger agreement, as well as attorneys' fees and costs. VISX believes the complaints are without merit and intends to vigorously defend itself against these actions.

- 12/2 Michael Lachman of **ThinkEquity Partners** on **QLT: Model Updates to Incorporate Atrix Labs Acquisition**

We are formally updating our QLT income statement model to reflect the financial impact of the **Atrix Laboratories** acquisition. Compared to our prior post-acquisition EPS forecasts, which we had discussed in our reports but not incorporated into our published model, we now expect \$0.03-0.04 in additional dilution per year through 2006 due to higher levels of amortization in the model. We expect additional financial guidance and a more in-depth look at the Atrix product portfolio and R&D pipeline at the company's upcoming analyst/investor meeting, which will be held in New York on Thursday, December 9. We remain cautious regarding the upside potential from the newly reimbursed minimally classic and occult indications in the US and from the near-term competitive threat posed by Macugen, which is nearing its December 17th PDUFA date. As such, we maintain our 12-month price target of \$15 and Source of Funds rating on QLT shares.

Investment Highlights: We are formally updating our QLT income statement model to reflect the financial impact of the Atrix Laboratories acquisition. At the close of the transaction, QLT issued approximately 23.2 million common shares (excluding issuable shares relating to Atrix options) and \$339 million in cash to Atrix shareholders. We incorporate slightly less than half a quarter's impact of Atrix financials into our Q4-04 estimates for QLT. With no change to our underlying Visudyne sales model and base QLT business forecasts, our revenue estimate goes from \$46.8 million to \$54.6 million, and our new EPS forecast of \$0.15 reflects acquisition related dilution of \$0.02 versus our prior estimate of \$0.17.

For 2005, our revenue and EPS estimates go from \$206.9 million to \$288.6 million and from \$0.90 to \$0.77, respectively. The total acquisition-related dilution of \$0.13 for 2005 is higher than our preliminary assumption of approximately \$0.10, due to the additional dilutive effect of \$8.1 million in annual amortization related to acquired intangible assets, which reduces EPS by approximately \$0.04. Slight upside in interest income due to higher than expected cash flow in the past couple of quarters adds back about \$0.01.

For 2006, our revenue estimate goes from \$190.4 million to \$295.7 million and our EPS estimate remains unchanged at \$0.83. Our prior analysis, which again did not include the dilutive impact of additional amortization, suggested \$0.04 in EPS accretion, or 2006 EPS of \$0.87. We now view the acquisition as earnings-neutral in 2006 with upside from synergies offset by higher levels of amortization. Revenue outperformance and cost savings notwithstanding, higher-than-expected levels of cash flow versus our comparatively conservative estimates may generate incremental interest income and provide modest upside to our earnings estimates in 2006.

Valuation and Price Target: We maintain our 12-month price target of \$15 and Source of Funds rating on QLT shares. We previously arrived at our \$15 price target by applying a specialty pharmaceuticals peer group average P/E multiple of 20x on 2004 earnings to our previous 2006 EPS estimate (post-acquisition) of \$0.87, and discounted the valuation back one year at 20%. While we are lowering our 2006 EPS estimate to \$0.83, the comparable group P/E multiple on 2004 has increased over the past couple of months from 20x to 21x. Discounting the implied 2006 valuation back one year at 20% results in the same \$15 price target, consistent with our Source of Funds rating.

- 12/4 According to *Cataract & Refractive Surgery Today*, **Lumenis, Inc.**, was issued a warning letter from the FDA on June 14, 2004, pertaining to multiple inspections conducted at the 3959 West 1820 South, Salt Lake City, Utah, location. The investigators found various aspects of the company's operations inadequate and not in accordance with current FDA regulations at this establishment. Among the inefficiencies of the indicated branch were: improper methods of manufacturing, packaging and storing; an unsatisfactory management system for implementing quality assurance standards; and improper establishment of corrective and preventive action procedures.

This is not the first offense for the Salt Lake City branch, according to the FDA warning letter. Prior FDA concerns issued in 2003 have been insufficiently addressed. The current letter alerted the company to the specific deviations and expressed that failure to comply with the terms set forth could result in more serious penalties, such as seizure, injunction, and/or civil penalties. Lumenis is required to take corrective action and present the adjustments and alterations to the FDA within a designated period of time.

- 12/8 **Norwood Abbey Limited** subsidiary, **Norwood EyeCare**, advised that as part of the global expansion of its ophthalmic product line it has appointed distributors for its Centurion SES System with EpiEdge (disposable separator) in Spain, Austria, Czech Republic, Slovakia and Taiwan. Ophthalmic surgeons from many of these territories

attended recent tradeshows at which Norwood EyeCare exhibited the Epi-LASIK system. Norwood's distributor has placed an initial order for the Centurion SES System for immediate delivery for the purposes of customer evaluation and sales.

The European distributors appointed are responsible for territories within Europe that account for in excess of 200,000 procedures annually. Spain is the largest market in Europe with an average of 180,000 vision correction procedures annually. Taiwan is a smaller market with approximately 35,000 procedures annually.

As previously stated, Norwood EyeCare utilized very strict selection criteria for the ideal distributor profile including:

- Existing portfolio of complimentary refractive surgery products
- "Best in class" in sales, marketing and technical support
- Well-established, strong reputation within the clinical community
- Breadth of market coverage in the specific country/region

In 2003 the worldwide ophthalmology market was US\$17.8 billion of which laser vision correction (LVC) is a key subset. As stated in an ophthalmic industry report, in recent years LVC has witnessed a resurgence based on an improved economy and the introduction of wavefront-guided technology procedures that have allowed physicians to customize or individualize a patient's treatment.

The Centurion SES system has an end-user price of between US\$65,000 and US\$100,000 and the EpiEdge disposable separator has a recommended price of US\$75 per patient.

12/8 The December issue of *Ophthalmic Market Perspectives* features two articles of interest: one on EpiLASIK products reaching the market; and the second about new multifocal phakic IOLs that offer promise.

As author Dave Harmon points out, a return to surface ablation techniques has been the subject of much discussion over the past several years. Theoretically, surface ablation would improve results of wavefront-driven techniques by reducing higher order aberrations. Also, the technique is less invasive, penetrating less of the cornea. In general, however, surgeons have been reluctant to return to surface ablation because of the pain and slow vision recovery. In addition, evidence to date of improved results -- the underlying theoretical reason for using the technique -- has not been compelling.

The latest twist on surface ablation is EpiLASIK, a procedure similar to LASIK, but that involves the use of a microkeratome-like device to create a thin epithelium flap (about 50 microns), in place of a conventional LASIK flap of about 200 microns. Like with other surface techniques, patients wear a contact lens and use some drops for pain for a

few days following the procedure. First results of the technique are promising, with the pain and visual recovery being manageable. Pain was judged low and all pain gone by day five, while 80% of patients were able to return to work by day three.

Four new devices were introduced to create epithelial flaps at the recent AAO meeting, including devices from **Norwood Abbey** (the Centurion ES -- the original pioneering device invented by Ioannis Palikaris), **VisiJet** (Epitome from **Gebauer**), **Moria** (EpiK), and **AMO** (Amadeus II). Relatively few EpiLASIK procedures have been done to date -- roughly less than 5000 worldwide -- mostly because of limited availability of the devices. However, with equipment now available, this is expected to change quickly. (For more on this subject, see the December issue of OMP from **Market Scope**.)

As for the multifocal IOLs, they include the Acrysof from **Alcon**; the Verisyse/Artiflex from AMO; the New Life Presbyopic from **IOLTECH**; the Kelman Duet from **Tekia**; and the Vision Membrane from **Vision Membrane Technology**. Again, for the complete story, see the Market Scope newsletter.

12/8 **IntraLase Corp.** announced that Prof. Dr. med Thomas Neuhann, an international cataract and refractive surgery pioneer, has purchased an INTRALASE FS Laser for use in his Munich ophthalmic practice, the alz eye clinic munich. This sale further establishes the INTRALASE FS laser in the very technologically advanced European market, extending the technology's global reputation for improved safety, precision and visual outcomes over blade-based microkeratomes historically used in LASIK surgery.

"Clearly the INTRALASE FS laser plays an important role in advancing the science of refractive surgery, improving the first step of LASIK as well as therapeutic surgical treatments for the rehabilitation of diseased corneas," stated Prof. Neuhann.

"Prof. Neuhann is one of the most influential scientists in the field of ophthalmology. Adding such a prominent thought leader to the growing base of surgeons who utilize the INTRALASE FS laser amplifies the compelling endorsement of our technology solution," stated Robert Palmisano, president and CEO of IntraLase Corp. Prof. Neuhann is the current Director of the Eye Bank in Munich and active head of the *German Society of Refractive Surgery (KRC)*. He is a former president of the *European Society of Cataract and Refractive Surgeons* as well as a founding member of the *Organization of German Specialty Clinics for Eye Laser and Refractive Surgery*.

As of September 30, 2004, 180 INTRALASE FS lasers were installed in ophthalmic practices worldwide, resulting in a 15% market share of all corneal flap procedures in the United States for the quarter. Prof. Neuhann's adoption of the technology compliments the company's 35 existing international laser placements throughout Europe, Asia, Canada and Mexico. The INTRALASE FS laser was granted CE mark in March 2004. As the first laser technology designed to replace the bladed mechanical microkeratome in the first step of LASIK, to date more than 250,000 IntraLase initiated procedures have been sold.

Current data suggests that the INTRALASE FS laser may be as much as 100 times more accurate than the microkeratome, making every LASIK procedure safer, and virtually eliminating the severe, sight-threatening complications sometimes caused by the hand-held microkeratome blade. Clinical studies report that the INTRALASE FS Laser significantly decreases the occurrence of microkeratome related complications, including invasive corneal incisions, corneal abrasions, "button-hole" cuts and improperly formed flaps; and is less likely to produce overly thin flaps or extremely thick flaps, events which could lead to serious complications.

12/8 **Paradigm Medical Industries, Inc.** announced that verbal agreements had been made to settle certain lawsuits brought against the company and its former executive officers, Thomas Motter, Mark Miehle and John Hemmer. The following are the lawsuits that have been verbally settled:

* The class action lawsuit filed on May 14, 2003 by Richard Meyer, individually and on behalf of all others similarly situated, against Paradigm Medical and certain former executive officers in the United States District Court for the District of Utah, which was consolidated into a single action on June 28, 2004 with two other class action lawsuits -- the class action lawsuit filed by Michael Marone on June 2, 2003 and the class action lawsuit filed by Lidia Milian on July 21, 2003 against the company and its former executive officers in the same court. The consolidated action is captioned In re Paradigm Medical Industries Securities Litigation, with lead plaintiffs **Rock Solid Investments of Miami, Inc., Brito & Brito Accounting, Inc.** and Joseph Savanjo.

* The class action lawsuit filed on October 14, 2003 by Albert Kinzinger, Jr., individually and on behalf of all others similarly situated, in the Third District Court for the State of Utah against Paradigm Medical and certain former executive officers.

* The lawsuit filed on July 10, 2003 by **Innovative Optics, Inc.** against Paradigm Medical and certain former executive officers.

"We are extremely pleased to have reached verbal agreements on these lawsuits. This settlement represents a major milestone for the new Paradigm Medical and will better enable the company to focus its energy and resources to further reduce costs, introduce new products, drive growth and enhance shareholder value," said Paradigm Medical's CEO, John Yoon.

12/9 **Lumenis Ltd.** announced the introduction of the new Novus 3000 photocoagulator, which debuted at the 2004 *American Academy of Ophthalmology (AAO)* conference in New Orleans. As a successor to the Novus 2000, the new Novus 3000 offers state-of-the-art laser delivery in an integrated design for use in operating rooms for the treatment of retinal diseases. The Novus 3000 is a solid-state, diode-pumped laser providing 532nm (nanometer) laser light with a dual-fiber delivery output and a color touch screen user interface.

Avner Raz, president and CEO, noted, "The Novus 3000 is ideally suited for both operating rooms and office environments due to an illuminated interface, a fully functional remote control, and an innovative design that allows for the storage and integration of all required accessories such as the laser indirect ophthalmoscope."

The Novus 3000 has been designed with increased power, delivering up to 3.0 watts of laser energy to meet the increasing demand for a comprehensive and integrated laser system. As the most powerful 532nm laser on the market, the Novus 3000 has expanded the number of indications for the laser to include ophthalmic, surgical, aesthetic and dental applications. A full line of new laser delivery devices and accessories will be available as well.

Also at the AAO conference, in addition to the Novus 3000, Lumenis introduced to the ophthalmic community its new dual port Spectra 532nm laser system. The new Spectra is the world's most powerful portable 532nm laser. The new dual port version will allow the physician the same convenience of an operating room laser in a portable model. Lumenis continued its tradition of innovation by also introducing a number of improvements in laser delivery devices and integrated slit lamp systems. All of these products are pending FDA approval.

At the conference, Selective Laser Trabeculoplasty (SLT) was highlighted as a leading technology in the treatment of glaucoma. The Selecta II and Selecta Duet, which utilize Lumenis' patented SLT technology, received FDA approval in 2001 and have since grown nearly 1000 systems installed worldwide. Lumenis, the leader in ophthalmic laser technology, is celebrating 39 years of innovation.

- 12/9 **TLC Vision Corporation** announced that it had entered into an underwriting agreement to sell 2.3 million shares of common stock in the initial public offering of **OccuLogix, Inc.** TLCVision will receive \$27.9 million in gross proceeds from the sale of the stock. TLCVision will continue to be a major shareholder with a 51.4% interest in OccuLogix. TLCVision and the other selling stockholders in the offering have granted the underwriters an option, exercisable for 30 days from this date, to purchase up to 1.26 million shares of common stock of OccuLogix at the public offering price. Should the underwriters exercise their over-allotment option fully, TLCVision will sell an additional 1.05 million shares of common stock of OccuLogix for additional gross proceeds of \$12.6 million and its ownership in OccuLogix will be reduced to 48.9%.
- 12/10 **NovaMed, Inc.** announced that it had acquired a 51% interest in the **Madison Laser Eye Center**, an ambulatory surgery center located in Madison, Wisconsin. This acquisition represents NovaMed's first acquisition in Wisconsin and seventh surgery center acquisition in 2004. "This acquisition provides us with the opportunity to enter the attractive and growing Madison market in partnership with two highly respected local ophthalmologists, Dr. Joseph Anderson and Dr. Michael Shapiro," said NovaMed chairman, president, and CEO Stephen Winjum. "In the last 12 months over 2,700 ophthalmic surgical procedures were performed at this surgery center and we expect this

acquisition to be immediately accretive to our earnings. In addition, we believe there are opportunities to attract new physicians to this surgery center and look forward to working with our new partners to realize the center's full growth potential in ophthalmology and by expanding into other specialties, " said Winjum.

- 12/13 Ted Huber of **Wachovia Securities** reported that the LASIK market growth continues to track with U.S. consumer confidence (CC) trends -- following four consecutive monthly declines in CC, preliminary December data is positive. As reported Friday, December 10, the University of Michigan's preliminary consumer sentiment index for December rose to 95.7, up from 92.8 in November but down from the three-year high of 103.8 recorded in January 2004. Data tracking U.S. consumer confidence and refractive surgery volume growth is attached. (More on his thoughts on the LASIK market are presented below.)

Wavelight reported ophthalmology revenue growth of 28% for the quarter ended October 2004, again outstripping growth posted by refractive market leaders **VISX** and **B&L**.

- 12/15 An international patient advocacy organization said that the *National Institute for Clinical Excellence (NICE)* interventional procedure guidance report of the popular laser eye surgery LASIK is more likely to cause confusion than to help advise patients and clinicians. "The NICE report does not give the public information they need, indicates problems where they are not necessarily a concern, ignores areas of true concern, and does not reflect the current outcomes with new advanced technology", stated Glenn Hagele, executive director of the California based Council for Refractive Surgery Quality Assurance (www.USAEyes.org). "NICE has really performed a disservice to those wanting to use LASIK to reduce their need for glasses or contacts."

Approximately 8 million LASIK or similar laser eye surgery procedures have been performed since introduction in the late 1980s, with about 100,000 performed in the UK each year. LASIK is the most often performed elective surgery in the world. Based upon concerns raised during the yearlong investigation culminating with the NICE report, The *National Health System (NHS)* has declined to provide LASIK to UK citizens. Although the NHS has declined to provide LASIK under its nationalized healthcare program, the procedure is available through private clinics throughout the UK. "It would be surprising for a federal or private health insurer to provide expensive elective surgery like LASIK. LASIK treats a problem that can normally be corrected with spectacles or contacts, which are significantly less expensive and certainly less invasive than laser eye surgery", said Hagele.

"One of the problems with the NICE report is that it does not reflect current patient outcomes", said Hagele, whose organization evaluates and certifies LASIK surgeons and provides patient information through its Internet website. "They didn't include wavefront technology lasers, which take a detailed and unique fingerprint of the patient's eye and customize the laser treatment to maximize the probability of a good outcome. By not

including the outcomes of wavefront-guided lasers, the NICE report was outdated before it was published."

The type and rate of complications from LASIK is an area where Hagele believes the report causes substantial confusion. "Imprecise language is used that does not provide a comprehensive answer to import questions, such is the probability of having a permanent complication. The report quotes rates of a few individual complications without giving the big picture. Our organization has evaluated many medical studies and reviewed thousands of LASIK patient outcomes. About three percent of patients have some sort of unresolved complication at the end of the normal six month healing period, with less than one-half of one percent having a serious complication that requires extensive maintenance or invasive intervention."

Even what constitutes a complication is unclear. "The NICE report specifies incidents such as when cells get under the flap and multiply, but this cell ingrowth is a problem can be readily resolved with no long-term negative effect by lifting the flap and removing the cells", reported Hagele. "There is a big difference between a problem that is fully resolved, and a true long-term complication. Refractive surgery is often more of a six month process than a 20 minute miracle. There are occasions when patients are slightly over or undercorrected and this may require enhancement surgery to 'fine tune' the result. Some patients may have a significant improvement in vision, but not perfection and will require glasses on occasion. Patients may experience dry eye, fluctuation in vision, or similar temporary problems. In all but a relatively small, but important, minority of cases, these issues are resolved with healing or treatment. If to be considered a 'success' LASIK must provide instantly perfect vision with no healing time, then somebody has unreasonable expectations. This is surgery, after all, and surgery requires time for healing."

12/15 **VISX, Incorporated** announced that it had received approval from the FDA to treat hyperopia with the VISX CustomVue laser vision correction procedure. The CustomVue procedure is the first U.S. approved wavefront-guided laser treatment for hyperopia. It employs the VISX WaveScan System, a diagnostic system that captures a comprehensive "fingerprint" of each eye and generates an individualized treatment for each CustomVue procedure. As shown in a clinical study, CustomVue has the potential to deliver better vision than contacts or glasses.

Colman Kraff, MD, principal investigator at the Kraff Eye Institute, participated in the VISX multi-center clinical study. Dr. Kraff stated, "VISX's new CustomVue Hyperopia procedure is a significant step forward in the treatment of farsightedness. The overall quality of vision with this new procedure is so superior that I plan to treat all of my qualified patients with CustomVue Hyperopia."

The VISX clinical study results exceeded all of the FDA required measurements for safety and effectiveness. A six-month evaluation of clinical study participants showed that more than four times as many people were very satisfied with their night vision after

the VISX CustomVue Hyperopia procedure, compared to their night vision before with glasses or contacts.

Liz Davila, VISX chairman and CEO stated, "With this approval, VISX now offers our U.S. doctors the broadest range of wavefront guided treatments. We believe this further advancement of laser vision correction technology will enhance our market leadership position, drive CustomVue conversions, and increase future revenue and profit opportunities."

- 12/15 For the financial year 2003/2004 **Carl Zeiss Meditec AG** almost doubled its net income for the year to E12.6 million from E6.6 million in the previous year. This was disclosed in the annual financial statements for the year ending 30 September 2004. Earnings before interest and tax increased to E26.3 million (prev. year: E24.7 million) and the EBIT margin rose to 11.2% (prev. year: 10.5%). Sales remained almost constant at E234.9 million (E235.7 million). Thus, the company managed to compensate for the slump in the dollar price of about 11% by organic growth. "This is a very good result, considering that we realize about three-quarters of our sales in the USA and Asia," said Ulrich Krauss, president and CEO.

Operative cash flow reached E31.6 million and was thus 12.6% above the previous year's level of E28.1 million. Net cash and cash equivalents increased by 35.1% to E77.1 million (prev. year: E57.1 million). Ulrich Krauss: "On this basis we will be able to continue our organic growth also by acquisitions. This could boost our efforts to expand our market position and become a solution provider for the ophthalmic sector." Today Carl Zeiss Meditec already offers a broad product portfolio of innovative systems and devices for the ophthalmic market. These range from early detection and diagnosis to the treatment of eye diseases. The most important of these diseases are cataracts, vision defects, glaucoma and retinal disorders.

The largest share of overall sales were generated by the Diagnostic business unit at E169.8 million (72%). Carl Zeiss Meditec achieved sales of E44.1 million with therapeutic systems (lasers), equal to almost 20% of its total turnover. The remaining E21 million are attributable to service business. Carl Zeiss Meditec recorded the strongest growth in laser business with an increase of approx. 28%. A breakdown by region illustrates the dominance of the American continent with E109.8 million, or 46.8% of total sales. E65.5 million or 27.9% were attributable to the Asian/Pacific region, where the strongest rate of growth (+17.4%) was recorded. Sales in Europe excluding Germany amounted to E41.9 million, corresponding to a share of 17.8%. In Germany, Carl Zeiss Meditec generated 7.6% of its sales (E17.7 million). Compared to the previous year this represents an increase of 8.2%. The first signs of an easing off in the reluctance to invest in replacements are recognizable here. As of 30 September 2004 the Carl Zeiss Meditec Group employed a workforce of 796 (previous year: 752).

President and CEO Ulrich Krauss announced that besides the growth in terms of sales, the company would also increase its profitability. The target is a doubling of last year's

sales (E235.7 million) by the financial year 2007/2008. By then Carl Zeiss Meditec aims to generate an EBIT margin of about 15%. In the current financial year 2004/2005 total sales are to increase by about 20%.

12/16 **TLC Vision Corporation** announced the completion of the initial public offering of **OccuLogix, Inc.** and the previously announced sale of 2.3 million shares of OccuLogix, Inc. common stock. The common shares were sold in the United States and Canada at a price of \$12.00 per share and TLCVision will receive \$27.9 million in gross proceeds from the sale of the stock. TLCVision will continue to be a major shareholder with a 51.4% interest in OccuLogix (48.2% on a fully diluted basis).

12/17 Ted Huber of **Wachovia Securities** issued an update on the LASIK market: **LASIK Market Tracking To Expectations**

*** LASIK MARKET ON TRACK Q404:** Our recent field checks support our forecast for low teens LASIK volume growth for Q404 (our VISX volume growth forecast calls for 10% Q404 growth). While some surgeons reported weak results earlier in the quarter, December looks strong by most accounts and this year's Saturday Christmas and New Years adds surgery days. The December approval of VISX's Custom hyperopia label may have been too late to drive mix this quarter (most surgeons view it as a modest 2005 mix driver) but the VISX's practice level marketing specialists focused on Custom Mix should help Custom Mix. We model VISX's Q404 Custom Mix at 35%, consistent with Q304.

*** EXPECT LOW DOUBLE DIGIT GROWTH FOR 2005:** Current market conditions and surgeon opinion continues to support our 11% LASIK market growth forecast for 2005. The 2005 forecast assumes consumer confidence rebounds from its somewhat depressed level now, following 4 consecutive monthly declines. We note the preliminary measures for December are up over November. Surgeons generally believe 2005 volumes will grow over 2004 but at a slower pace than this year.

*** KEY DRIVER REFRACTIVE PROFITS:** VISX profit performance is derived almost exclusively from U.S. LASIK volume growth and Custom mix. If its acquisition of VISX is completed, over one third of AVO's EBIT will derive from the U.S. refractive surgery business. While Intralase profit is more dependant on its share gains against microkeratomes (incumbent method for LASIK flap creation), LASIK market growth paces surgeon capital spending and should have a significant effect on the slope of the Intralase adoption curve.

12/17 **Carl Zeiss Meditec** will acquire about 63% of the shares in the ophthalmic surgery specialist **IOLTECH**. This company, listed on the Second Marché at the Paris Stock Exchange, specializes in the production and distribution of intra-ocular lenses (IOL). IOLTECH sales for the last financial year amounted to E44.7 million. The price offered to the majority shareholder values 100% of IOLTECH's shares at E110 million, which represents E91.80 per IOLTECH share and corresponds to a premium of 15.6% on the

IOLTECH average weighted share price of the last three months. Carl Zeiss Meditec will pay for 80% of the bloc shares in cash and for 20% by issuing new Carl Zeiss Meditec AG shares.

These terms are the subject of an agreement signed by the majority shareholder of IOLTECH and Carl Zeiss Meditec AG. The transaction is also subject to the approval of the German anti-trust authority. Subsequent to getting all these approvals the bloc acquisition is expected to be finalized by February 2005. After acquiring the majority of the shares, Carl Zeiss Meditec AG is aiming at a complete takeover of IOLTECH. Accordingly, in a second step Carl Zeiss Meditec will submit a take-over bid at the same amount of E91.80 per share in cash to the remaining shareholders of IOLTECH.

This acquisition will put Carl Zeiss Meditec in a position to combine its globally recognized competence in the field of diagnostics and post-treatment of eye diseases with the implants (IOL) used in the surgical treatment of cataracts. Doctors and patients alike will profit in the long term from the development of innovative products and solutions. Cataract is the most widespread vision defect worldwide and its treatment represents the most common surgery performed on human.

In the field of intraocular lenses and related products IOLTECH has a comprehensive and competitive product portfolio and holds a strong market position in Europe.

The merger of Carl Zeiss Meditec and IOLTECH will enable considerable advantages to be exploited by both parties:

- Due to the expansion of the product portfolio, all clinical areas from diagnosis to treatment and follow-up treatment are now covered.
- The combination of the existing pools of expertise of the two companies will enable potential to be exploited for the development of innovative products.
- Both companies have an efficient sales organization which will profit from integration in future. In this way the presence of the products, particularly in Europe, can be selectively expanded.

"This step is one of the most important milestones in our company's history to date," says Ulrich Krauss, president and CEO of Carl Zeiss Meditec AG. "In IOLTECH we have found a partner who, like ourselves, stands for innovative strength and sustainable earning power. The expertises of the two companies in the field of diagnosis and treatment of cataracts are a perfect complement for another."

"We are looking forward to this cooperation and are convinced that the transaction will open up very positive perspectives for the company's continued growth and for our employees," said Philippe Tourrette, majority shareholder and CEO of IOLTECH.

The new shares necessary for payment of the acquisition price to the IOLTECH majority shareholder will be issued in compliance with the existing authorization approved by the Carl Zeiss Meditec General Meeting in March 2004 and within the scope of about 4.5 percent capital increase (approx. 1.3 million shares) with the exclusion of shareholders' subscription rights.

12/20 **TLC Vision Corporation** announced that its subsidiary, **OR Partners**, has become the single largest shareholder in **Summit Ambulatory Surgery Center**, a 12-partner facility located in Houston, Texas. This is the fifth ambulatory surgery center (ASC) OR Partners and TLCVision have acquired in the last 16 months, with several ASC deals in development. OR Partners acquires, develops, and manages ambulatory surgery centers in partnership with physicians. These centers provide out-patient surgery services in a less institutional atmosphere than can be achieved in a hospital setting and appeal to doctors seeking improved efficiencies and the highest degree in patient satisfaction.

Led by John Garrett, MD, a cataract surgeon with more than 30 years experience, the Summit Ambulatory Surgery Center is a highly successful facility featuring two operating rooms and performing nearly 5000 ophthalmic and pain management procedures annually. Dr. Garrett said, "OR Partners is well capitalized, managed by a team of experienced professionals and committed to achieve results. Most importantly, from a physician's perspective, they understand that patients are the number one priority. I am very excited about being associated with OR Partners, improving operational efficiencies and growing the center."

Mary Green, MD, one of 12 partners in Summit Ambulatory Surgery Center, has also worked with the laser refractive division of TLCVision for 3 years. Dr. Green said, "I know the quality of service this company provides and the commitment to their doctor customers. When I heard about the OR Partners subsidiary, and the great work they were doing in ASCs, it just made sense to continue the relationships already built with TLCVision."

"Through our current network of over 1100 ophthalmologists, we will continue to acquire or develop similar centers in association with some of the country's most prominent surgeons," commented Jim Wachtman, TLCVision's CEO. "This approach will broaden our eye care services strategy and be immediately accretive to TLCVision's cash flow and profitability."

TLC Vision Corporation also announced that it intends, subject to regulatory approval, to purchase up to 2 million shares (or up to 3%) of its 68.153 million common shares currently outstanding. Upon approval of the buy-back from the Toronto Stock Exchange, the purchases may take place from time to time, depending on market conditions, through the facilities of the NASDAQ National Market and the Toronto Stock Exchange. The prices which TLCVision will pay for any common shares will be the market price of the shares at the time of acquisition.

Jim Wachtman, TLCVision's CEO, stated "With a healthy balance sheet and strong cash flows, we are well positioned to invest for growth as well as continue our commitment to enhancing shareholder value. The Executive Team and the Board of Directors believes that TLCVision shares are undervalued, and that this stock buy-back represents a good use of the corporation's funds and will benefit its shareholders."

12/20 **Refocus Group, Inc.** reported preliminary data on surgical patients at the important three- and six-month follow-up exam milestones and announced the completion of the first half of its FDA Phase II clinical trial surgeries for the treatment of presbyopia.

To date, 50 of a planned total of 100 Phase II study participants have undergone the company's Scleral Spacing Procedure (SSP) for the surgical treatment of presbyopia (the loss of near or reading vision impacting virtually 100% of the population after age 40). In addition, 26 of a planned 50 control participants have been enrolled for comparative monitoring. Of the 50 SSP surgical participants, 45 have now completed three- or six-month follow-up exams. Preliminary data on these surgical patients indicates:

- 80% of these surgical patients experienced sufficient improvement to result in 20/40 or better reading vision (roughly equivalent to Jaeger 3 or better), which is the vision generally needed to read a phone number in a typical telephone book without reading glasses.

- Surgical patients have experienced an improvement in their Snellen near vision acuity averaging nearly 3 lines of improvement. Near vision acuity is the common measure of a patient's ability to distinguish letters or words at a normal reading distance. Lines of improvement refer to the progressively smaller lines of print on the near vision acuity chart.

- 15 (one-third) of these patients experienced an improvement of 4 lines or better, with some patients experiencing up to 6 to 7 lines of improvement in near vision acuity.

- About 90% of these surgical patients answering a survey describe the change in their reading vision as "better" or "significantly better."

- Importantly, there has been virtually no change in any patient's best-corrected distance vision as a result of SSP.

- Finally, these preliminary Phase II results were also favorable when compared to the non-surgical control group and when compared to the company's FDA Phase I results, which used an earlier surgical protocol without the new automated incisional handpiece.

The company stressed that while this data remains preliminary, it continues to support the company's belief in its presbyopia treatment and clinical approach. The company expects to submit the clinical data to the FDA in a Phase II study report during 2005.

"Refocus Group's clinical results, while still preliminary, suggest that for the first time, there appears to be a mainstay surgical alternative for treating presbyopia that does not have the inherent compromises of other more invasive or irreversible surgical approaches," said Barrie Soloway, MD, Refocus Group's medical director and director of vision correction at New York Eye and Ear Infirmary in Manhattan.

"In order to improve near vision, other existing surgical treatments often result in an undesired compromise of distance vision such as glare or halos, loss of depth perception or loss of contrast sensitivity."

"We are very pleased by the continued progress in our clinical study," said Terry Walts, president and CEO of Refocus Group. "Achievement of the halfway point in our Phase II FDA surgeries with these promising preliminary results represents a significant milestone for the company. Based on these results to date, we would expect to receive FDA approval in 2005 to advance to the final, or third, phase of the clinical trial."

The company also reported that it does not currently have sufficient cash on hand to continue its operations for the full first quarter of 2005, unless additional funds are obtained. Refocus Group has retained a placement agent to arrange the sale of the company's Series A Preferred Stock in a private offering to accredited investors. The company is also separately in discussions with potential strategic partners and investors. No assurance can be given that the company will be able to obtain financing on acceptable terms. See the company's most recent Form 10-QSB filing for a full discussion of the company's financial condition. The inability of the company to obtain additional financing would have a material adverse effect on the company.

- 12/21 The author of a medial study cited by the *National Institute for Clinical Excellence (NICE)* as indicating that LASIK is not safe enough to be included in the *National Health Service (NHS)* has sent a letter to NICE stating that he is "appalled" by the use of the decade old study, stating it is out of date and "has essentially no bearing on conditions of safety in 2004." Atlanta ophthalmologist George Waring, directed a comprehensive study of LASIK surgery performed on patients between 1995 and 1996. The study included reports on the safety and efficacy of LASIK using techniques and technology of the time. "The laser used in 1996 is no longer manufactured and the company is out of business", said Waring, who is also the editor of the respected *Journal of Refractive Surgery*. "The lasers used in LASIK today have been superseded by many improved generations of succeeding technology."

"The inappropriate and inaccurate conclusions drawn by NICE ignore ongoing laser eye surgery development", added Waring. "That the British National Institute for Clinical Excellence would cite these data in an attempt to guide patients and physicians in their evaluation of LASIK in 2004 belies apparent ignorance of the enormous progress that has been made in both the technology and the clinical application of LASIK in the 9-10 years since our study was done. "

