OPHTHALMIC LASER UPDATE -- JANUARY 1999

12/29 Summit Technology, as expected, filed suit against Nidek, alleging that the Nidek EC 5000 excimer laser infringed certain of Summit's issued patents covering methods and apparatus for laser ablation of the cornea. Specifically, the patents alleged infringed are the Azema patent (4,973,330 -- Surgical Apparatus for Modifying the Curvature of the Eye Cornea) and the Marshall patent (4,941,093 -- Surface Erosion Using Laser). The company seeks treble damages for willful infringement.

In checking with VISX, I learned that they too had filed against Nidek, on December 18th, several days prior to the announcement of Nidek's FDA approval on December 22nd. The VISX suit alleges infringement of three of Francis L'Esperance's patents assigned to VISX via Taunton Technologies. These are 4,729,372 -- Apparatus for Ophthalmic Surgery; 4,718,418 -- Apparatus for Performing Ophthalmic Surgery; and 4,732,148 -- Method for Performing Ophthalmic Surgery.

(I have copies of both complaints, if anyone is interested in seeing them.)

12/30 Iridex Corporation announced that its board of directors had authorized it to institute a stock repurchase program of up to 150,000 shares of common stock. President and CEO, Theodore A. Boutacoff stated, "Our board of directors felt that an investment in our own stock would be beneficial to the company and its stockholders." He noted that the corporation will utilize all of the reacquired shares for reissuance in connection with employee stock programs.

1/4 Sterling Vision announced plans to launch a fully interactive, optical goods web-site. The company has formed a special task force to create what it believes will be the most advanced E-commerce site marketing optical products and services online. Dr. Robert Cohen, chairman, said "We will use Sterling's 85 years of professionalism, retail experience, product and technical knowledge to enter the 21st century as the country's first true optical E-tailer".

1/4 According to NewsPage, Aichi Prefecture medical equipment maker Nidek Co. and other firms will form a company in February to culture and market human skin for transplant procedures. This represents the first such commercial project in Japan.

1/4 Ann Sundius of CNBC interviewed Mark Logan, CEO of VISX at the BancBoston Robertson Stephens medical conference held in New York City. Logan commented on how the company had done in the two years since the previous interview, making note of the fact that even though its competitor (Summit Technology) had 100% market share due to its earlier approval for PRK, that VISX now "is generally given between 70% and 80% of the market". He also discussed the dissolution of Pillar Point, and the company gaining back the right to operate independently. Looking at the analyst's predictions for procedures in the United States, Logan noted that they were talking about 400,000 in 1998, 100% growth over 1997, and that 1999 could have 600,000 or more. (Probably

more.)

Commenting on equipment sales, Logan said that he was surprised by the growth of laser sales. "We thought that the market was beginning to be saturated towards the end of last year (1997). And the introduction of our Star S2 Smooth Scan...really invigorated the equipment sales, both in the U.S. and worldwide. And that continues quite strong into this quarter." Looking overseas, Logan noted that Korea was a good market for his company, with Japan being the last major market with a regulatory hurdle to overcome, with the hope that it might come in the not to distance future. He went on to note that no one had yet been approved in Japan, so that VISX would certainly be either the first or among the first to gain approval.

Logan also discussed the possibility of correcting presbyopia. He said that VISX was looking at it in their laboratories, but that it is probably a few years off. He also mentioned that they were looking at a "new generation" product, but that it wouldn't be introduced until 2001 or 2002.

Sundius also interviewed BancBoston's healthcare analyst Wayne King, who said that VISX had a 73% share of the U.S. procedures market with, as he put it, "what we think is the best technology and certainly most extensive customer support and service network". He also said that laser vision correction represents a "huge market opportunity". As with cataract procedures, an ophthalmologist can conceivably do 10 or more procedures in a morning. His final comments on VISX were, "...this is an example once again of doing your homework...looking for large market opportunities, great companies...looking once again to take a stand there and make a lot of money for our clients, VISX is an example of that."

1/5 QLT PhotoTherapeutics and CIBA Vision Corporation -- the eye care unit of Novartis AG -- announced that Visudyne (verteporfin) therapy has been shown to preserve vision in a significant number of patients with the "wet" form of age-related macular degeneration (AMD), the leading cause of blindness among people over the age of 50. These findings are based on an initial 12-month analysis of 24-month pivotal Phase III studies using verteporfin, now referred to by the brand name Visudyne. The treatment is being co-developed by QLT and CIBA Vision. Results of the TAP (Treatment of AMD with Photodynamic therapy) Investigation, which comprises two randomized, double-masked, placebo-controlled trials involving 609 patients at 22 centers in North America and Europe, showed that patients treated with Visudyne therapy were more likely to have stable vision (defined as a loss of less than 3 lines of vision on a standard eye chart) or improved vision compared to placebo-treated patients at 12-month follow-up. These results were found to be statistically significant for each of the two studies, as well as for the combined data ($p=0.0002$).

Based on these positive 12-month results, QLT and CIBA Vision anticipate filing for regulatory approval of Visudyne therapy in the U.S., Canada, and Europe in 1999. The study remains ongoing in order to determine longer-term efficacy and safety. As this

therapy is still investigational, only patients who are currently enrolled in these clinical trials are eligible for treatment at this time.

"Today's announcement is a significant breakthrough in the efforts to find a treatment for a widespread disease that has grown into a major public health concern," said Dr. Neil M. Bressler, Chair of the TAP Study Advisory Group, and a retinal specialist and Professor of Ophthalmology at the Wilmer Eye Institute of the Johns Hopkins University School of Medicine in Baltimore, Maryland. "We are indebted to the hundreds of patients who are continuing to participate in these trials and to all the investigators for their efforts in carrying out such a landmark study. Visudyne therapy offers new hope for potentially preserving the vision and independence of the hundreds of thousands of individuals who will be diagnosed with wet AMD each year," said Dr. Bressler.

Based on the release of the study results, shares of QLT jumped 23% following the announcement according to Dow Jones Business News. Analysts have been excited about the prospects of the drug, because the incidence of the disease is expected to grow as baby boomers age, and because there are no other treatments for the condition. They have speculated that those two factors could make Visudyne and other eye drugs under development by other pharmaceutical firms into billion-dollar blockbusters. Duncan Stewart, portfolio manager at Tera Capital Corp., said the study results warrant the run-up in QLT's stock price. "We're talking about a drug here that could be a billion dollars a year, three or four years out," he said.

While the study still has another year to run, Dr. Neil Bressler, of the Wilmer Eye Institute, said that even if the benefits in the first year aren't sustainable in the second year, he expects people will still want the treatment. "If you go to a 75-year-old patient and say if I do this to you at least for a year, you'll have a better chance of being able to see your grandchild's face...they'll say I'll take that year, as long as you're not going to harm me, and the bottom line was there wasn't harm seen by the treatment," Bressler said. After the drug is approved, QLT plans to manufacture Visudyne and CIBA will market the product worldwide. Other companies targeting eye diseases as possible growth drivers include Pharmacia & Upjohn Inc. and Alcon Laboratories Inc. unit of Nestle SA.

Later in the week, Canada's Financial Post carried a major story about QLT's potentially blockbuster drug therapy, which could bring the company into "billion-dollar sales territory". As told by reporter John Greenwood, "Nearly two decades after the biotechnology industry was born, only a handful of companies have succeeded in fulfilling their early dreams of fabulous wealth. Vancouver-based drug developer QLT PhotoTherapeutics Inc. appears set to join that exclusive group. Although, to a layman the findings reported were hardly dramatic... industry analysts and the medical community were overjoyed, describing the event in terms rarely heard in this country."

"Certainly Visudyne is being tossed around as a potential blockbuster, the numbers are there," said Michael Lorimer, an analyst at ScotiaMcleod Inc. (A blockbuster in industry

parlance is a drug with more than $1-billion in annual sales.) "This is a huge success story," said Ezra Lwowski, a normally low-key analyst at Yorkton Securities Inc. One reason for the optimism is that QLT is likely to be the first company to come out with an effective therapy for what is a devastating disease that has stubbornly resisted attempts to find a cure. AMD is a disease of the elderly; most sufferers are in their sixties and seventies. It starts off as a thinning of one of the layers of the retina. That phase is called dry AMD. Eventually, about 10% to 15% of those cases develop into what's called wet AMD, where the bottom retinal layer becomes so atrophied it cracks, allowing the growth of abnormal blood vessels. Within five years (usually less) nearly all people who develop the wet form of the disease are legally blind. Most of the time "there is really nothing you can do," says Patricia Harvey, a doctor at The Toronto Hospital and a leading retinal specialist who took part in the Visudyne trial. "We provide them with visual aids like magnifiers and software programs that allow them to read text on a computer screen, but that doesn't change visual acuity, it just helps them to use what they've got a little better." QLT's drug is good only against the wet form of the disease. But that's still a potentially huge market with about 500,000 new cases worldwide every year, 200,000 of them in North America, according to the company. Even though it appears Visudyne is effective in a fraction of cases, it represents the only option available.

1/5 IRVision announced that following excellent results from its animal studies, the company had received IRB approval to begin to treat Phase I feasibility patients in Canada. The first three legally blind patients were treated with a -4.0 diopter, 6 mm diameter myopic procedure by Dr. Raymond Stein on December 18th in Toronto. Dr. Stein said, "The AccuScan 2000 was wonderful. It produced the smoothest ablations I've ever seen! And the tracker worked great -– even on these blind eyes, which don't fixate at all well. Tracking was never lost throughout all three procedures. The epithelium healed by the fourth day on all three eyes with no adverse effects. Only one patient complained of a little discomfort during the first night."

"We are very pleased with these preliminary results," said William Telfair, CEO of IRVision. "These eyes so far demonstrate safety and healing characteristics identical to the excimer. The next few months will answer questions about the haze level, refractive change, and healing stability characteristics of this new ablation mechanism." IRVision plans to treat the rest of the phase I patients in January and February and follow their progress for at least a year. Meanwhile, it will build more prototypes and partner with additional ophthalmologists in 1999 to treat sighted patients as soon as possible with appropriate approvals.

IRVision, of San Jose, CA, is developing a low-cost, solid-state, mid-infrared (MIR -- an OPO converted YAG laser operating at the erbium wavelength) laser system for the refractive surgery market. The system differs from other MIR systems by employing photospallation rather than photovaporization as the ablation mechanism. Photospallation is a mechanical ablation mechanism that can remove a thin layer of tissue from the front surface of the eye through the shearing forces of a bipolar thermo-

elastic stress wave. When highly absorbed short pulse radiation is employed, ablation proceeds without heating the water in the tissue to the boiling point, thus avoiding significant thermal damage to surrounding tissue. The U.S. Patent Office issued patent 5,782,822 to IRVision last July covering a mid-infrared laser to perform refractive surgery using this photospallation process.

This process produces ablations with submicron collateral damage, which is comparable to that of the excimer, as shown in previous results from studies on Eye Bank and in-vivo cat eyes using its novel Optical Parametric Oscillator (OPO) laser at 2.94 microns. (See Laser Insight, April '97 EYEWORLD, page 20, and an article published in SPIE, Vol. 3246, pp. 97-108, 1998.) The IRVision AccuScan 2000 Laser system directs a "flying spot" scanning OPO laser as part of the surgical system. The OPO laser consists of a Q-switched Nd:YAG laser frequency down-converted to 2.94 micron wavelength, using a non-linear crystal. The system also incorporates an eye tracker to stabilize the ablation pattern over the pupil during the procedure, even when the patient's eye moves.

1/6 Not to be outdone by the QLT/CIBA announcement (see above), Miravant Medical Technologies announced that it also was enrolling and treating patients in its Phase III clinical trials to treat the advanced ("wet") form of age-related macular degeneration (AMD) with the PhotoPoint drug SnET2. Ophthalmologists at select academic and medical centers are participating in the nationwide studies, which were initiated during fourth quarter 1998. The study is investigating the effects of the PhotoPoint drug/light procedure on patients' vision. Miravant is conducting the phase III study in collaboration with Pharmacia & Upjohn, which holds the exclusive, worldwide license to SnET2. The PhotoPoint light source for the clinical studies was jointly developed by Miravant and Iris Medical Instruments, Inc., a subsidiary of Iridex Corporation. As noted in a story published by Medical Industry Today, QLT is further along with its Phase III study of Visudyne. Miravant plans to start a Phase III study in Europe later this year, which would be managed by its partner, Pharmacia & Upjohn. A spokesperson for Miravant also noted that the drug was undergoing a name change, which "would be more ophthalmic-oriented", but which has not yet been disclosed.

1/6 TLC The Laser Center announced that it had expanded its presence in the Mid-Atlantic region of the United States, by partnering with Dr. Anthony Kameen, the leading refractive surgeon in the Baltimore/ Annapolis area. TLC and Dr. Kameen plan to open two new laser vision correction centers. TLC has also entered into a long-term contract with Dr. Kameen under which he will serve as medical director at the new TLC Baltimore and Annapolis Centers. In that capacity, he will work with other refractive surgeons and optometrists to build centers that incorporate the TLC approach to laser vision correction. Dr. Kameen currently performs more than 750 laser vision correction procedures per quarter. He was recently selected by VISX as one of the top 50 refractive surgeons in the United States. Dr. Kameen's practice is exclusively devoted to refractive surgery. Elias Vamvakas, TLC's President and CEO, noted that "the signing of this agreement typifies TLC's ongoing expansion strategy of partnering with the best doctors in every market."

1/7 LCA-Vision reported another sharp increase in quarterly procedure volume. System-wide procedures in the fourth quarter nearly doubled to a record 6,791, up from 3,400 procedures for the same period a year ago. For all of 1998, system-wide procedures performed at LCA-Vision centers rose 138% to a record 23,080, up from 9,715 procedures in 1997. Growth was even more dramatic for LCA-Vision's wholly owned U.S. centers, where 1998 procedure volume grew 171% to 18,479, versus 6,832 procedures in 1997. (Annual growth rates reflect, in part, the addition of centers acquired from Summit Technologies in August 1997.)

On a same-center basis, LCA-Vision's wholly owned centers in the U.S recorded the strongest growth. Fourth-quarter procedures for this segment of the business rose 135% to 5,224, ending the full year with 17,549 procedures, a year-over-year increase of 219%. Dr. Stephen Joffe, LCA-Vision chairman and CEO, commented, "Fourth-quarter procedure volume was the highest in the company's history. That healthy trend should continue unabated in 1999, and with it a steady, sustainable improvement in profitability. Cash flow continues to be strong and positive, and financially we have never been in a better position to capitalize on the robust growth we see ahead. We remain confident we will achieve positive earnings per share in 1999 -- our breakout year.

1/7 Bausch & Lomb Surgical announced that B&L had acquired Hansa Research & Development. Hansa is the designer and manufacturer of the Hansatome and Automatic Corneal Shaper microkeratomes used in the majority of refractive surgery procedures worldwide for vision correction. The company purchased the Miami-based Hansa Research & Development firm from Johann, Irma, and Birgitta Hellenkamp. The Hellenkamps have manufactured the keratomes and distributed them under an exclusive agreement with Chiron Vision, now Bausch & Lomb Surgical, since 1992. All assets used in connection with the Hansatome microkeratome business were included in the sale. The financial details of the transaction were not disclosed. The Hellenkamps will continue to work as consultants with Bausch & Lomb Surgical.

"Our purchase of the company will allow us to expand manufacturing capabilities and quickly ramp up for the exceptional demand for this excellent product," said Bausch & Lomb Surgical president Hakan Edstrom. "The Hellenkamps have been partners with us in the development and refinement of this technology," Edstrom continued, "and the purchase will allow them to concentrate on expanded research and development."

1/7 IntraLase Corp., a developer of femtosecond lasers for vision correction and therapeutic eye surgery, announced the closing of a $3 million round of venture capital financing. The funding was led by Brentwood Venture Capital and by Enterprise Development Fund of Ann Arbor, Michigan. Additionally, the financing round was supported by IntraLase's major original investors, including the founders. The new funds will be used to fund European clinical studies and for commercialization and scale-up of the IntraLase laser vision correction system.

As part of the financing, William Link Ph.D., general partner of Brentwood Venture

Capital, was elected to the board of directors. Before joining Brentwood, Dr. Link was chairman and CEO of Chiron Corporation, leading Chiron Vision's sales to over $210 million annually, before selling the company to Bausch & Lomb in December of 1997.

"Laser vision correction is a very hot market right now," said Dr. Link. "I believe the IntraLase laser technology can become the next generation refractive laser. I think it's a wonderful opportunity for Brentwood to invest in this venture and to help move this technology towards commercialization."

Founded in December of 1997, IntraLase is a privately held company which combines licenses and technology from the University of Michigan (home of the Center for Ultrafast Optical Science), Escalon Medical Corp., and its own in house research in order to develop the next generation refractive laser. The company's all solid-state femtosecond systems represent a significant advance in vision correction technology, providing micron range surgical precision, without the need for a knife incision. In addition to the safety and performance benefits this affords, technical advantages make these systems significantly less expensive to own and operate, compared to current excimer lasers. IntraLase has offices in Irvine, California and Ann Arbor, Michigan.

1/7 NewsPage noted that a U.S. patent had issued to Autonomous Technologies. The patent, 5,849,006, Laser Sculpting Method and System, describes a method and system for eroding or ablating a shaped volume of an eye's corneal tissue in accordance with the treatment of a specified eye condition, by applying a plurality of laser shots of uniform density.

1/9 The Montreal Gazette ran a feature story reporting that competition in the Montreal area had resulted in a newly opened laser vision center, LASIK Vision, to offer laser surgery for about half the going rate, at $999. In response, local doctors were cutting their prices by as much as 60%, but they questioned how long they could maintain those prices. In the body of the story, LASIK Vision's vice president of sales and marketing, James Watson, said that its usual price for the surgery would be $1950, but an advertising campaign offerred to do 1000 patients for $999. Since the first 1000 surgeries quickly sold out, the company was offerring another 2000 patients the same price. LASIK Vision is expanding its Canadian operations. It currently runs offices in Vancouver, Calgary, and Toronto, and will open offices in Montreal and Ottawa at the same time. It plans to add six additional Canadian locations this year before heading into the U.S.

With the competition, the charges for LASIK in Quebec have dropped from $2000 to $2400 per eye, to $1000 to $1400, with some doctors charging $1000 to match LASIK Vision's prices.

1/11 Sunrise Technologies International announced the completion of a $10 million private placement that will position the company for its expected 1999 launch of the Sunrise LTK System for treating hyperopia in the United States. The funding will allow the company to build its production inventory and capacity and increase sales and marketing

infrastructure prior to approval by the FDA. The company also recently completed an $11.8 million private placement of common stock. The company raised all funds from both of these offerings exclusively through its own efforts and without a placement agent.
The $10 million private placement was received in return for a convertible note with warrant from a single investor. The note bears interest at 5% and will convert into common stock when the company achieves two milestone events; $5 million in common stock priced at $4 per share must be converted from debt when the FDA's Ophthalmic Devices Panel recommends conditional approval of the Sunrise LTK System, and an additional $5 million in common stock priced at $8.00 per share must be converted when the company receives final approval to market the Sunrise LTK System in the United States.

According to Russ Trenary, president and CEO, "We feel this shows how sophisticated investors view the Sunrise opportunity and it is a significant step toward our anticipated product launch in 1999. Additionally, we plan to expand ongoing clinical trials for higher levels of hyperopia, presbyopia, and treatment for unsuccessful excimer laser procedures for myopia."

1/11 According to Optistock, Bausch & Lomb was profiled in the Jan. 11 issue of Forbes. Writer Stephane Fitch related the company's recent turnaround efforts that include renewed focus on core vision care businesses.

1/11 According to OpticalBuyer.Com, well-known optometrist Jack W. Melton is taking delivery of a VISX Star excimer laser, which will make him the first OD to own and operate an excimer laser for refractive correction. An expanded scope of practice allowing optometrists to PRK took effect in Oklahoma Nov. 1st. Melton does not intend to perform LASIK because "it is illegal to do so in Oklahoma," he said.

Melton is founder and chief executive officer of the LExES (Laser Excimer Eye Surgery) network and senior partner of Omni Eye and Laser Center in Edmond, near Oklahoma City.

1/12 TLC The Laser Center announced results for the fiscal second quarter. Results were characterized by continuing record revenues and profitability. All were driven primarily by a strong growth in the number of refractive laser procedures performed. Second quarter gross revenues more than doubled to $43.5 million from the same period a year ago. Net revenues grew to $30 million (of which refractive represented $26.8 million), which was more than double last year's second quarter total. Over 18,000 paid refractive procedures were performed at TLC refractive clinics in the second quarter, compared to 6,420 from the same quarter a year ago.

TLC's net profit for the fiscal quarter was $0.7 million (2 cents per share), versus a net loss of $1.9 million (7 cents per share) for the corresponding period a year ago. Income from operations was $1.7 million (5 cents per share). This figure compared to a loss from

operations of $0.9 million (3 cents per share) for the fiscal 1998 comparative quarter. Elias Vamvakas, TLC's president and CEO, commented that the company "was very pleased with its second quarter results. This good performance of TLC is despite the traditional weakness of this quarter. For the first 6 months of fiscal 1999, net revenues from our core business, refractive surgery, are already higher than all last year. We continue to expand our leadership position in the laser vision correction industry, carefully managing our resources and our expenses as we grow."

1/12 Laser Vision Centers announced today that same U.S. laser revenue for the month of December increased over 68% compared to the same month a year ago. Same U.S. laser revenue compares the revenue generated on 23 lasers that were in operation in December 1997 to the revenue generated by those same lasers in December 1998 and is not equal to total company growth which would be a higher percentage. The company operated a total of 33 lasers in the U.S. during December 1998. In addition, LaserVision said that December was its best month to date for U.S. case volume increasing 17% over its previous best month and 134% over last December.

1/12 CBS MarketWatch posted a brief report on Bausch & Lomb. The report said that B&L would increase earnings by 15% annually over the the coming two years as the "eyecare giant" extended its three-year turnaround. After his presentation at the Hambrecht & Quist Healthcare conference, Bill Carpenter, CEO said that he expects revenues to increase "in the high single digits" from 1999 to 2001, and that he was comfortable with H&Q's projections of earnings of $2.73 per share in 1999.

1/12 I received a call from Mitch Campbell, the new president and CEO of Refractec, to bring me up to date about his company's developments. As reported in both the November and December issues of this newsletter, in-depth articles about the company have been published in both EyeWorld and Ocular Surgery News. Campbell told me that enrollment for Phase III hyperopia trials was underway, with the first treatments scheduled for this month. With both ISO and EN/CE Mark clearance, international marketing would begin shortly. One correction from the OSN article, Campbell said that the RF device would sell for $48,000 in the U.S., not the $35,000 noted in the OSN piece, while disposable tips would sell for $125.

1/12 VISX announced preliminary fourth quarter results in advance of chairman and CEO Mark Logan's presentation to the Hambrecht & Quist Healthcare Conference. The projected results for the quarter would exceed current consensus of analyst's estimates of $0.66 per share earnings, assuming an effective tax rate of 40%. Based upon preliminary analysis of 1998 fiscal fourth quarter results, which included record unit shipments and record license fee revenue, VISX expects to show total revenues of approximately $41 million. The company's earnings per share on a pre-split basis (shares will be split 2:1 on January 17th) is expected to be in the range of $0.71 to $0.73. The company expects to announce actual results for the quarter and fiscal year on January 20th. In an accompanying release about the presentation, the company noted that it had licensed and receives royalties from six of its major competitors outside of the U.S.

Following the announcement, Matthew Dodds, an analyst with Warburg Dillon Read, attributed the improved sales to an increase in the fees the company charges for the use of its equipment and an increase in the number of laser-vision correction surgeries performed. Based on VISX's preannouncement, Dodds said he had raised his 12- to 18-month share price target to 130 from 110 a share and raised his 1999 earnings estimate to $2.95 a share from $2.75 and his 2000 estimates to $3.70 from $3.45. He also believes VISX can hold on to its 70% share of the market in laser-vision procedures even though Japan's Nidek Co. recently got approval from the FDA to market its own laser system. He expects that Nidek will sell about 45 laser in the U.S. market in 1999, while VISX should place about 55, Dodds said. The number of procedures in 1999 is expected to rise to 680,000, from Dodds' initial estimate of 630,000, and most of those new procedures should go to VISX, he said.

1/12-
1/13 The FDA's Ophthalmic Device Panel recommended approval of KeraVision's intracorneal rings (ICR) for the treatment of myopia for -1.0 to -3.5 diopters. The renamed product, now called Intacs, was recommended with conditions that the company do a two-year post-market surveillance study of the thickest rings, used for the higher degree of correction. Also, the device labeling will allow for reversibility in most, but not all cases. The outpatient procedure takes about 15 minutes and is done under local (eye) anesthesia. Channels are created in the periphery of the cornea and two arcs of PMMA between 0.25 and 0.35 mm in thickness are placed into the channels, causing a flattening of the central cornea for correcting myopia.

The cost to the patient of the implants should be similar to laser surgery, running between $2000 to $2500 per eye. Data presented at the panel hearing on about 400 eyes showed that 74% were corrected to 20/20 and 97% achieved unaided 20/40 vision. After 12 months, 9.7% of the people treated reported that they often or always suffered from glare, 11.9% had halos, and 17.3% had problems with night vision. Altogether, 34 implants were removed during the study, there was no clinically significant harm to any subject, showing the reversibility of the device. The implants are available in Europe, with slow sales, and in Canada where the company claims they are doing well. About 1000 patients have been treated internationally to date.

1/13 This month's issue of Refractive Market Perspectives contains several articles of interest. Author David Harmon reports that despite the number of laser vision procedures doubling last year, the number of refractive laser centers grew only slightly compared to 1997. Refractive procedures per installed laser grew from 63 per month in 1997 to over 95 per month by the end of 1998. Laser center growth occurred primarily in the surgeon and institution segment, together adding a net of 68 lasers, while corporate centers only added a few systems. According to Harmon, at year's end, corporate centers had 34% of the lasers, 31% were held by institutions, and 34% were owned by physicians. At year-end, 160 corporate owned laser centers (with an additional 199 mobile sites) were operated by 18 companies, with only 4 companies having more than ten centers. During the year, TLC The Laser Center acquired the ten centers formerly operated by

BeaconEye, LCA-Vision sold, closed, or disposed of 13 laser centers, and Laser Vision Centers acquired nine new lasers for its mobile fleet.

Again, according to Harmon, surgeons, either alone or in partnership operated 148 excimer lasers, while institution had 134 systems in use. (The newsletter shows a total of 442 laser centers in operation, with the additional 199 mobile sites operated by three center companies.) For 1999, Harmon expects the number of laser centers to grow significantly based on continued growth in demand for surgeries and the innovative and competitive pricing of possible new laser entrants.

The newsletter also commented on the recent Nidek approval, which, according to a Nidek spokesperson, will be offered without a per procedure fee -- unless and until the company is forced to license the U.S. patents from either or both VISX or Summit Technology. Nidek claims its laser does not infringe key VISX or Summit patents and intends to fight the lawsuits that both have filed against it.

Finally, the newsletter notes that a patent has recently been issued to Dr. Henry McDonald of Pasadena, CA for an accommodative IOL. Apparently, the IOL is made of an undisclosed compliant material with haptics that extend into and adhere to the ciliary muscles, such that as these muscles contract it causes an optical change in the lens to produce accommodation. (Another potential solution to the riddle of finding a truly accommodative device.)

1/13 I received a copy of the American Academy of Ophthalmology's "Y2K Alert for Ophthalmic Practices". This excellent guide to the potential problem was put together by the Academy's Practice Management Department and sponsored in part by Ophthalmic Mutual Insurance Company. The booklet does a commendable job in defining the problem, describing how it might impact both you and your business, and describes steps you can take to test your systems and ensure that your vendor's systems are in compliance. Contact the Academy if you would like to obtain a copy of this excellent guide.

1/15 This week's issue of Ocular Surgery News contains information about the current trial underway at the FTC over its alleged claim that VISX obtained one or more patents illegally. Apparently, the FTC Administrative law judge Stuart Levin has ruled in favor of VISX and dismissed charges of fraud that had been brought by the FTC staff, but still at issue is whether VISX had made the necessary disclosure of "prior art" in the application that resulted in U.S. Patent 5,108,388, awarded to Stephen Trokel and assigned to VISX. VISX's attorney argued that the prior art was cited correctly, along with numerous detailed discussions with the Patent examiner. Patent author, Stephen Trokel testified about his efforts, relating his own texts, peer reviewed articles and scientific diaries, as well as the role of Air Force researcher John Taboada, and researchers at IBM. (Taboada has a separate lawsuit underway to add his name to the patent as a co-inventor, and to collect royalties.)

Final filings in the case are due in February, along with final arguments. The judge is expected to make his ruling in May.

1/18 This month's edition of EyeNet (from the AAO) contains a feature article about "Custom Cuts for Better Vision". Linda Roach Monroe delves into the phenomenon of custom cornea with interviews of leading ophthalmologists about their views, including several who are currently working on projects that will hopefully lead us there. Dr. Michael Knorz in Germany is testing a topographic-assist module with the Technolas 217 laser. Also, Monroe interviewed Dr. Marguerite McDonald about the Autonomous Technologies approach, using the Hartmann-Shack wave-front sensor to obtain an optical snapshot of what is happening in terms of light reaching the retina. Apparently, this technology is an output of adaptive optics in the eye, first promulgated by Dr. Junzhong Liang as his doctoral thesis in Germany, and later at the University of Rochester, before joining Autonomous. (My interpretation of the article is that the implementation of this type of approach is still several years off and, even when developed, will it work with LASIK? Or will it be confined to PRK?)

1/18 Gimbel Vision International reported that the number of paid refractive procedures performed at its centres rose to 4,376 for the three month period ended December 31, 1998. This is an increase of 49% from the 2,935 procedures performed during the same period last year. During 1998, a total of 16,182 paid refractive procedures were performed, which is a 74% increase over the 9,322 procedures performed during 1997. Glenn Gimbel, GVI's President and CEO commented, "1998's procedure volumes set another record for Gimbel Vision. Our commitment to quality and patient satisfaction is the reason for our success in the marketplace, and we look forward to continued growth in our procedure volumes."

1/18 Miravant Medical Technologies and Pharmacia & Upjohn jointly announced an agreement for P&U to make an infusion of up to $41.5 million in Miravant. The additional funding consists of an immediate equity investment of $19 million and a $22.5 million line of credit to support Miravant's ophthalmology program as well as for general corporate purposes. In conjunction with the loan, Pharmacia & Upjohn will receive a total of up to 360,000 warrants to purchase common stock of Miravant. Pursuant to this investment, Pharmacia & Upjohn will assume control of the clinical and regulatory aspects of the joint ophthalmic programs, including the PhotoPoint drug SnET2 (tin ethyl etiopurpurin) which is in Phase III clinical trials for age-related macular degeneration (AMD). Pharmacia & Upjohn will also assume responsibility for the manufacturing scale-up of SnET2 to commercial levels. The new agreement amends the agreement executed in July 1995 and subsequent amendments, where Pharmacia & Upjohn and Miravant agreed to co-develop, market and distribute SnET2 for indications in ophthalmology and oncology.

"This substantial investment accelerates the funding provisions of our earlier ophthalmology and oncology agreements and shows Pharmacia & Upjohn's confidence in PhotoPoint technology in ophthalmology," said Gary Kledzik, Miravant chairman and

CEO. "We are very pleased to allocate more clinical, regulatory and manufacturing responsibilities for the AMD program to Pharmacia & Upjohn, with its global capabilities. Pharmacia & Upjohn is in the best position to facilitate AMD development, approvals and market launch; and Miravant is now able to focus its resources and significant expertise in photodynamic therapy on the remainder of the PhotoPoint pipeline."

1/19 According to a study in the January 1999 issue of Ophthalmology, the journal of the American Academy of Ophthalmology, complications are rare in the use of LASIK for the correction of nearsightedness. Doyle Stulting, M.D., lead author of the study, said, "Complications occur in about 5 percent of cases, but these rarely lead to substantial loss of vision or to visual acuity below 20/40." The authors of this prospective, observational clinic study of 1,062 eyes of 574 nearsighted patients found that the incidence of complications during surgery decreased from 3.1 percent in the first three months to 0.7 percent during the last nine months of the study, indicating that complication rates decrease as the surgical team gains experience. They also found that a flap buttonhole (a small hole in the center of the corneal flap) is more likely to cause loss of vision than either of the two other complications -- flaps that have been cut off completely and those that have not been cut far enough. The flap buttonhole complication may be more likely in eyes that have undergone previous surgery.

1/20 **Iridex Corporation** announced that it had started shipping the new **Iris Medical** OcuLight GLx semiconductor-based green laser photocoagulator. This laser further expands the market opportunities of the OcuLight product family by increasing the clinical and delivery device versatility currently available to ophthalmologists. The OcuLight GLx has increased power and delivery device capability compared to the OcuLight GL laser. The OcuLight GLx can adapt to a completely integrated Laser/Slit Lamp Workstation providing uncompromised diagnostic and treatment capabilities.

The workstation provides a laser delivery device with a 50-1000 micron zoom spot size, electronically actuated eye safety filter and a micromanipulator for precise targeting. The OcuLight GLx also attaches to Iris Medical's complete line of visible delivery devices including portable UltraView Slit Lamp Adapters, TruFocus Laser Indirect Ophthalmoscope and EndoProbe devices.

"We believe the new OcuLight GLx is an exceptional value to the ophthalmologist who prefers green laser light. It offers the versatility of multiple delivery devices with the convenience of portability," commented Theodore Boutacoff, president and CEO. "We also believe this product will successfully meet the increasing demand for photocoagulators that are portable and durable enough to be carried between offices and can be used in an office or hospital setting."

1/20 **VISX** announced financial results for the fourth quarter and year ended December 31, 1998. Revenues for the quarter were $41.9 million compared to $19.3 million for the comparable period of the prior year. Net income was $17.2 million (52 cents per

share), compared to net income of $7.0 million (22 cents per share) in the comparable period of the prior year. Mark Logan, chairman, president, and CEO, commented, "The strong fourth quarter represents a fitting conclusion to a year of great achievement in financial results, regulatory approvals, product development and marketing. This success was not limited to VISX, but was also enjoyed by our customers, all of whom have shown strong procedure growth and increasing levels of profitability." Mr. Logan continued, "As we enter 1999, there is a strong sense that the laser vision correction market is poised to move to a new level of consumer acceptance."

Revenues for the year were $133.8 million, compared to $68.6 million for the prior year. Income from operations was $59.2 million compared to $15.5 million for the prior year. Net income was $25.6 million (78 cents per share), compared to net income of $14.1 million (45 cents per share) for the prior year.

In a teleconference following release of the results, Logan noted that VISX now believes that more than 400,000 laser vision procedures were performed during 1998, and that he has revised his estimate, along with analysts following the industry, to 650,000 for 1999. VISX sold 41 laser systems during the quarter, 75% to U.S. customers, compared to 39 systems in the third quarter. (Assuming an average ASP of $285,000 during the year, because of tradeins and discounts, we believe that the company sold about 143 new laser systems during 1998, compared to about 98 units in 1997, when its ASP was about $350,000.) Logan commented that system sales should remain strong during the company's first quarter, but that he expected them to tail off for the remainder of the year, closer to 1997's levels. Discussing the ongoing FTC trial, the judges decision could be on hand in either May or June this year, but if VISX loses, it will appeal, which could stretch the time frame out until the year 2002! He wouldn't comment on the ongoing **Nidek** litigation, except to say that developments would be forthcoming over the next few weeks.

During the Q&A session, Logan said that he anticipates marketing approval in Japan by mid-year, and once achieved, sales would commence right away. Neither he nor Liz Davila would comment on progress on "next generation" systems, except to say that they hoped to "leap-frog" current technology. Also, Liz said to look for more on their ongoing work to link topography to custom ablations at the upcoming ASCRS meeting in the spring. Also, both Davila and Logan said they anticipated no change in procedure fees, although they admitted they were under heavy pressure from some of their largest accounts.

1/21 **LaserSight** announced that it had entered into an agreement with **Humphrey Systems**, a division of **Carl Zeiss**, in which Humphrey will manufacture the control console for LaserSight's keratome product line. The keratomes, blades and other related disposable products offer LaserSight an opportunity to participate in the rapidly growing refractive laser procedure market. Based upon the Humphrey agreement and high demand in the marketplace, LaserSight expects to generate approximately

$8-$10 million in revenues in 1999 from keratome hardware sales. In addition, the company will have the opportunity to generate recurring revenues on a per-procedure basis through LaserSight's single-use disposable keratomes and the blades necessary to perform each procedure. Forecasts estimate that laser refractive procedure volumes may grow to 1 million in the United States during the year 2000, with greater numbers of procedures performed in the rest of the world.

LaserSight's keratome console is designed to operate interchangeably with its high precision single-use keratome as well as the company's new durable model. The console has been commercially released for manufacturing and the first units are scheduled for delivery to LaserSight in February. Shipments to customers will follow during the 1999 first quarter in limited supply, with a ramp up to full production quantities in subsequent quarters. Michael Farris, CEO LaserSight, commented, "Our selection of Humphrey as OEM manufacturer for our keratome console reflects LaserSight's commitment to providing high quality products and solutions that exceed the expectations of our customers and their patients. Humphrey will manufacture our control console to meet international and U.S. quality standards for medical devices. We look forward to the market introduction of our control console as it provides drive power and intelligent control for LaserSight's full line of keratomes, offering a number of advantages over existing products."

1/21 **Nidek** issued a statement in response to the **VISX** lawsuit filed against it on December 18th, following obtaining FDA marketing approval for its EC-5000 excimer laser system on December 17th. According to Mr. Hiroshi Okada, vice president and general manager of Nidek, North America, VISX representatives began disseminating inaccurate information in an attempt to divert physicians away from purchasing the Nidek system. Nidek views this intrusion to ophthalmologists as unacceptable. Refractive surgeons looking to purchase the Nidek EC-5000 system report that VISX representatives are informing customers that Nidek has been enjoined from selling this system. According to Mr. Okada, this is incorrect and misleading as no injunction has (yet) been filed. Further, physicians have reported that VISX has threatened legal action should they purchase and use the EC-5000. According to Nidek this is also incorrect as the company fully supports its customers and offers a standard indemnification on its products to customers. (We understand that this indemnification, however, does not cover any "per procedure fees" that might be claimed.)

Mr. Okada went on to say that Nidek has already prevailed in a similar suit against VISX in Great Britain where VISX patents were found to be either invalid or non-infringed. Nidek fully expects that its position will be vindicated here in the United States as well, and is preparing a vigorous defense of this suit. He also said, Nidek views the threats from VISX as desperate, particularly since they are still under investigation by the U.S. Federal Trade Commission for unfair trade practices pertaining to royalties and user fees. (This is not true, that portion of the suit was settled with the breakup of Pillar Point Partners. Only the matter of one patent that

might have been fraudulently obtained is still at issue.) The Nidek EC-5000 is sold free from any fee-per-procedure charges. "With the issues of royalty income and sales revenue from product, the stakes are high. However, we at Nidek don't feel that this is at all acceptable," stated Mr. Okada. Given the demand for alternative laser systems with lower operating costs, Nidek will vigorously defend its position both in the marketplace and in the legal arena. The company believes that this dispute is between the manufacturers, and therefore should not involve or implicate customers.

1/25 According to *EyeWorld Week*, the patent infringement case **Bausch & Lomb** brought against **Moria** in France has been decided in a way that encourages both sides. The Paris court said that Moria's Carriazo Barraquer microkeratome did not show sufficient evidence of infringing B&L's Ruiz-Lenchig patent (European patent 0442156), but it did order Moria to deposit a security of 3.5 million francs to continue manufacturing the microkeratome (? No explanation provided.). B&L filed the injunction in September requesting that Moria be prohibited from manufacturing the device.

1/25 *Optistock* noted that **Robertson Stephens** had downgraded **VISX** from "Buy" to "Long Term Accumulate".

1/25 **TLC The Laser Center** announced that this Wednesday, the company will perform its 100,000th vision correction procedure. TLC is the first company worldwide to achieve this number. "This is a very proud moment for us," said Elias Vamvakas, TLC's president and CEO. More than half of our 100,000 procedures have been done in the last 8 months alone. The current trend could well put us into the 200,000 range this year."

1/25 **Sight Resource** announced that it had acquired **Shawnee Optical**, a privately-held primary eye care chain with operations in central Ohio and western Pennsylvania. This is the sixth retail optical chain that Sight Resource has acquired and the second chain in Ohio and western Pennsylvania. Terms of the transaction were not disclosed.

Established in 1977, Shawnee Optical operates nine eye care centers with total annualized revenues of approximately $4 million. Robert Leonardi, one of the previous owners of Shawnee Optical, will assume the position of Vice President and General Manager of both Shawnee Optical and **E.B. Brown Opticians**, the other Sight Resource chain located in Ohio and western Pennsylvania. The company's wholly-owned subsidiaries include **Cambridge Eye Doctors** in Massachusetts and New Hampshire, E.B. Brown Opticians in Ohio and Pennsylvania, **Eyeglass Emporium** in Indiana, **Vision Plaza** in Louisiana and Mississippi, **Vision World** in Rhode Island, and now Shawnee Optical in Ohio and Pennsylvania. (Apparently, the company is giving up on its original objectives, to operate laser vision correction centers in conjunction with its retail optical business, as it only currently operates three lasers, according to the latest available information.

1/25 *NewsPage* reports that U.S. Patent 5,861,486 was issued last week covering the use of collagen modulators as a means of smoothing irregular corneal surfaces and removing protuberances from the corneal surface during photoablative excimer laser keratectomy. The patent covers the method of using these modulators for the smoothing process. No assignee is mentioned.

OPHTHALMIC LASER UPDATE -- FEBRUARY 1999

1/25 Optical Buyers Guide reported that Humphrey Systems had introduced two new lasers: the Zeiss VISULAS YAG IIplus and Zeiss VISULAS 532 Laser. The VISULAS YAG IIplus laser includes a super gaussian mode that enables optical breakdown at lower energy levels -- 2.5 mJ in air. The system also incorporates a patented four-point aiming beam that merges into a single spot to assist in the determination of astigmatic distortion. The frequency-doubled Nd:YAG VISULAS 532 laser is designed to improve the clinical results of standard photocoagulation treatments. Its diode-on-demand technology activates the laser diode only when the laser is fired, which gives it a useful lifetime as much as five times longer than that of a conventional pumped laser system.

1/26 I received a copy of Pacific Growth Equities Fred Toney and Al Kildani's January 20th research report on TLC The Laser Center. For the report, the authors conducted a survey of PRK and LASIK pricing at laser vision center providers across the U.S. The highest prices were in the mid-Atlantic region ($1990 for PRK and $2470 for LASIK), while the lowest were in the Southwest ($1900 for both). The National averages were $1975 for PRK and $2180 for LASIK. Their conclusions: pricing for PRK is trending down while LASIK prices continue to hold steady. They believe this trend will continue as LASIK approaches 90% of procedures and PRK fades in popularity.

Commenting on the panel approval for the KeraVision Intacs corneal rings, they believe because of the limited range of approved indications it is unlikely that the rings will make significant inroads into the LVC market, but that they may carve out their own niche. (This is similar to my thinking.)

As for TLC, they note that TLC continues to charge $2000 for PRK and $2500 for LASIK, with some former Beacon Eye Centers getting as high as $2750. Of these charges, TLC retains over $1300 on average as its net revenues, while the rest goes to the doctors. Other chain providers of LVC access or services maintain similar pricing structures. Toney and Kildani's model for TLC assumes only modest decreases in revenue per procedure through May of this year.

Geoffrey Harris and Rebecca Irwin of Salomon Smith Barney also put out a report on TLC, initiating coverage of the company. Their extensive report goes into detail about both the co-management model utilized by TLC and the size of the laser vision correction market. They note that TLC, currently operating 50 refractive centers, anticipates acquiring or developing approximately three new centers per quarter over the

next several years. They comment that the major risk facing the company is if procedure prices come down, as they currently pay referring optometrists a $400 fee for pre- and post-op care, while the surgeon collects $350 per procedure. With the $250 royalty payment to the laser company, TLC keeps the remainder, between $1100 to $1300 on average.

The authors are a little behind the times with their believe that only 350,000 procedures were performed in 1998, and only double that number will be done in 2000. Although their accompanying graphic shows 400,000 procedure in 1998, about 650,000 in 1999, and over 800,000 in 20000. Some of the risks noted, in addition to downward pricing pressure, were the need to comply with onerous government regulations, state anti-kickback laws concerning the division of global fees, and the advent of changing technology -- with no imminent danger seen on the horizon.

The one risk faced by the company that they left out, that of doctors deciding that their share of the global fees may not be adequate and strike out on their own in competition with TLC, especially as several laser companies bring lower-cost systems to market, was not addressed, but could become a reality as some surgeons begin to build up experience and referral clientele.

1/26 I also received two research reports on KeraVision, prepared following the FDA panel's recommendation for approval. One report was by the medical device team at SG Cowen, led by Daniel Lemaitre, while the other was written by Lawrence Keusch of Goldman Sachs. In the January 14th Cowen report, the authors reiterated their "buy" rating in the belief that FDA marketing approval would be forthcoming during the second quarter of this year and, even though sales in Europe of the corneal rings have been disappointing, they expect that U.S. sales will be more favorable. Their market model for KeraVision calls for just under 5% penetration of refractive surgery procedures by 2001, from a 0.5% penetration this year. The only problem with their model is, as with other conservative analysts, they only show 480,000 total refractive procedures in 1999, 576,000 in 2000, and 691,000 in 2001! These are well below most knowledgeable analysts' projections.

The Cowen people don't even mention the Canadian marketing effort underway which, I have been told, is resulting in a lot of laser procedures and only a few ring implants!

The Goldman Sachs report, issued on January 13th, calls for an unreasonable 10%-20% penetration of refractive procedures, 5%-7% by 2000 as, apparently, Larry has bought into the company's story that Intacs will become a significant device for correcting vision. He is looking for FDA approval by mid-year, but notes that it could come sooner.

I also received a copy of Keusch's initial coverage of KeraVision from last October. In this report he notes the Canadian market blitz and states that it could be a "good proxy" for what will happen in the U.S. If he is right, then, as I believe, the publicity generated over the rings will lead to more laser procedures, and only 1% to 2% of the procedures done with the rings.

1/26 And finally, I also received a copy of John Kinnard's Richard Leza's report on Staar Surgical. This January 20th report starts Staar with a "strong buy" recommendation. The report places Staar as a leading player in the cataract surgery market with about a 17% share of IOLs, and future products including AquaFlow, a wick-like device made of collagen to control glaucoma through allowing outflow of the built-up fluids within the eye, and the implantable contact lens (ICL) for refractive correction, especially of higher myopia and hyperopia. (The correctable range in current Phase III clinical trials runs from -3.00 to -20.00 diopters for myopia, and from +3.00 to +20.00 diopters for the Phase II hyperopia trials, the widest range of correction of any surgical procedure.)

Apparently, Richard Leza is planning to cover other refractive surgery companies, with, as he told me, several reports to be issued over the next few months. Based on his positive comments about KeraVision in the Staar report, I would anticipate that that company will be next.

1/26 According to a study in the January 1999 issue of Ophthalmology, the journal of the American Academy of Ophthalmology, the use of polyacrylic intraocular lenses during cataract surgery significantly reduces the need for subsequent laser surgery to clear opacity from the posterior capsule. In this randomized prospective trial at a British teaching hospital, a study group of 90 eyes received PMMA, silicone, or polyacrylic IOLs. At the three-year follow-up exam, there was a significant difference in rates of laser surgery (posterior capsulotomies) among the lens types. Polyacrylic lenses were associated with less opacities (10%) than silicone (40%) and PMMA lenses (56%). The capsulotomy rate was zero for polyacrylic, 14% for silicone, and 26% for PMMA.

The authors discussed three possible theories for these results. First is the "no space, no cells" theory, meaning the convex IOL implant reduces migration of cells from the peripheral capsule onto the rear of the capsule, thus preventing opacification. They further suggested that the squarer edge of the polyacrylic lens may act as a mechanical barrier to such cell migration, thus contributing to the prevention of lens opacity. Second, the polymer from which the lens is made provides a tacky surface, which makes the lens more adhesive. This tight adhesion may keep the IOL away from migrating cells as well as nutrients in the inner eye which promote cell growth. Third, as the capsule and the IOL become adherent, physical compression may squeeze out cells, causing atrophy of the outer cells already in the capsule.

Posterior capsule opacification is one of the last obstacles to truly perfecting cataract surgery, already the most successful of ophthalmic procedures. Approximately 10% to 15% of the 1.5 million annual cataract surgery patients subsequently need the posterior capsulotomy procedure, at substantial cost to Medicare and themselves. (These numbers, both for laser capsulotomies and for cataracts seem to be very low. It is my understanding that closer to 40% of the 2.3 million cataract procedures performed in the U.S. result in the need for posterior capsulotomies.) If the results of this study are corroborated by further study using larger populations over longer periods of time, the use of polyacrylic IOLs may have major medical, social and economic consequences.

1/28 Bausch & Lomb announced that revenues from ongoing product lines for the fourth quarter were $599.1 million, up 32% from the $454.8 million reported in the fourth quarter of 1997. This comparison excludes $14.6 million in 1997 fourth-quarter revenues from the skin care business, which was divested in May of 1998, as well as $3.6 million in 1997 fourth-quarter revenues from the thin film technology business, which was divested in December 1997. The comparison includes $113.6 million in 1998 fourth-quarter revenues generated by the pharmaceuticals and surgical product lines of the former Chiron Vision Corporation and Storz Instrument Company, which were acquired by Bausch & Lomb at the beginning of fiscal year 1998.

Full year 1998 revenues from ongoing product lines were $2,343.6 million, up 27% from the $1,851.5 million reported in 1997. This comparison excludes $19.2 million in 1998 revenues from the divested skin care business, and $64.2 million in 1997 revenues from the divested skin care and thin film businesses. Full year net earnings, excluding previously announced charges and the gain from the sale of the skin care business, were $129.7 million ($2.30 per share) in 1998 and $115.8 million ($2.08 per share) in 1997. Non-recurring items reduced 1998 and 1997 reported net earnings by $104.5 million, or $1.85 per share, and $66.4 million, or $1.19 per share, respectively.

Broken down by business segments, fourth quarter revenues in the pharmaceuticals/surgical segment were $173.2 million, compared to $44.5 million reported in the fourth quarter of 1997, reflecting the addition of the former Chiron Vision and Storz product lines.

1/28 NewsPage reported that an unassigned U.S. Patent had issued on January 19th, describing a method and device for mapping the cornea for use in effecting vision by removal of corneal tissue. The abstract reads: A method and device for highly accurate corneal topographical mapping and a device for effecting the mapping for use in effecting vision correction by removal of corneal tissue. The method and device involve use of a modified optical interferometer with directing of a coherent light beam, such as from a laser, to the anterior surface of a cornea; splitting the beam so that half the beam is directed to a reference object having a predetermined shape; capturing the reflected light from the cornea and the reference object so as to form an interference pattern; and using the interference pattern to determine deviations or displacements of the corneal surface from the known reference shape. The deviations are then utilized in corneal tissue removing procedures, such as RK, PRK and RLK, by determination of the extent and position of tissue removal. With a modified RLK procedure, the deviations are used in preparing an appropriate corneal template for use with a keratome using a high speed water jet as the cutting means.

1/29 Iridex Corporation announced that sales increased 30% to $23.6 million in 1998 from $18.1 million in 1997. Net income for 1998 was $1.7 million (26 cents/share) as compared to $2.1 million (31 cents/share) in 1997, a decrease of 17%. For the fourth quarter, sales increased 13% to $6.5 million from $5.8 million in the corresponding 1997 quarter. Net income for the quarter was $525,000 (8 cents/share) as compared to

$803,000 (12 cents/share) in the corresponding 1997 quarter, a decrease of 35%.

Net income decreased for the fourth quarter and for 1998 as compared to corresponding prior year periods, primarily as a result of accelerated investments in developing new sales channels and product development programs in response to lower sales activity from the economically weakened Asian region. During the fourth quarter, the company experienced strong dermatology sales growth world wide. Strong ophthalmology sales growth continued in Europe and in the U.S. These results reflect a shift to separate direct sales forces for dermatology and ophthalmology products and addition of specialized distribution channels for dermatology products internationally.

President and CEO, Ted Boutacoff commented, "We finished the year in strong form in both ophthalmology and dermatology. We sold more ophthalmology products in the U.S. in the fourth quarter than any other quarter on record. This occurred on the strength of our existing products, the OcuLight GL green laser photocoagulator and OcuLight SLx and SL infrared laser photocoagulators. This strong performance was assisted by the introduction of new products like our new generation of portable Slit Lamp Adapters with a micromanipulator and UltraView optics. Dermatology sales for the quarter were also a record. We had strong international dermatology sales activity and orders, and an increase in domestic sales activity for the DioLite 532 laser system. Our new domestic dermatology sales personnel made significant contributions in the fourth quarter. In addition, our new international sales personnel helped step up sales activity for both ophthalmology and dermatology products."

1/29 Eyemakers, Inc. announced that its board of directors has approved its entry into the laser vision correction business through a joint venture with Icon of the Southwest, a division of Icon of North America. Eyemakers previously announced its intention to acquire Icon Of North America, a transaction which is still underway. However, because of the speed with which the U.S. market is developing, both companies deemed it important to proceed immediately with this unique opportunity for EYEM to enter the laser surgery field through joint ownership of an existing laser vision center located in Scottsdale, Arizona.

Relating to this event, and in anticipation of the merger of the two companies, Eyemakers has elected to its board three representatives of Icon North America. They are Charles Casebeer, M.D.; Michael Addley; and Ghassan Barazi. Each is an expert in laser vision correction and is associated with Icon as a consultant or executive. Dr. Casebeer is chairman and president of CRS Clinical Research, Inc. and is generally recognized as the leading clinical authority in the world on the new LASIK laser vision correction procedure. John Edwards, president of Eyemakers said, "We believe that the combined experience in the laser refractive field of these three gentlemen will greatly enhance the ability of the joint venture's success, and pave the way for a smooth transition once merger of the two companies is completed."

2/1 According to EyeWorld Week, VISX filed its second legal motion against Nidek.

Apparently, VISX has asked the U.S. International Trade Commission (ITC) to initiate an investigation under Section 337 of the Tariff Act of 1930 regarding Nidek's importation of its EC-5000 excimer laser system and to prohibit the importation, sale, and servicing of the system in the United States by Nidek or its affiliates. The complaint, filed Jan. 22, alleges that the EC-5000 system infringes upon Visx's U.S. Patents 4,718,418; 4,732,148; and 5,711,762. The ITC is expected to deliver its decision within the next 30 days. For its part, Nidek has reiterated to potential consumers that no legal injunction blocking sales of the EC-5000 system exists in the United States.

2/1 Contact Lenses Today carried a story about the recent CLAO meeting held in Los Vegas. Alan Dozier, Bausch & Lomb Corporate VP, in his "State of the Contact Lens Industry" presentation, indicated that the rate of contact lens wearer growth in the U.S. may have slowed, and that there are only about 600,000 daily disposable contact lens wearers in the US. Yet, he indicated optimism with new products on the horizon, "A well-educated patient willing to try new technology is your best patient."

The "State of the Refractive Surgery Industry" was delivered to CLAO by Thomas Loarie, CEO of KeraVision. In 1999, said Loarie, 600,000 refractive surgeries will take place in the U.S., up from about 450-500,000 in 1998. Also, 1999 will mark the first time that $1 billion will be spent on refractive surgery (one-third that of contact lens industry sales in the U.S.).

2/1 Sunrise Technologies International announced that the FDA had determined that the company's premarket approval application (PMA) is suitable for filing. The company submitted its application on Dec. 14, 1998 to the FDA for review of its Sunrise LTK System for the treatment of hyperopia ranging from +.75 to +2.50 diopters. The next milestone for the PMA will be a review by the FDA's Ophthalmic Devices Panel, the timing of which is solely determined by the FDA.

"We are very pleased that our application is sufficient for filing. Three hundred forty-five (345) cases are included in the company's PMA cohort, which is the population of cases that underwent the greatest degree of statistical analysis. As stated in the PMA, clinical results meet or exceed target endpoints set forth by the FDA draft guidance document for the treatment of hyperopia by refractive surgery lasers," said Jeannie Cecka, vice president of clinical & regulatory affairs for Sunrise. Russ Trenary, president and CEO stated, "We estimate, based upon peer reviewed studies, that 200 million persons in the Americas and Europe are over 40 years old and hyperopic between +.75 to +2.50 diopters, which is the range treated in our first study. This patient population is extremely large and is characterized by an inability to see well near or far."

2/1 OptiStock's Analyst Forum contained two new presentations; an analysis of VISX by analysts Parice Halbert, and Dave Therkelsen of Dain Rauscher Wessels and Arnie Ursaner of CJS Securities' coverage of Staar Surgical. Halbert and Therkelsen said, "We expect the strength seen recently in many vision care stocks to continue throughout 1999, particularly for companies participating in the fast-growing refractive vision correction

segment. Driving this trend is growing consumer adoption of laser vision correction, evidenced by accelerating growth in procedure volumes during the second half of 1998. We expect this trend to continue in 1999 and beyond. In fact, we have just raised our laser vision correction procedure volume forecast to 655,000, up over 57% from 1998 levels. Therefore, we expect companies that participate in the rapid growth of refractive vision correction, such as VISX, to perform particularly well in 1999 relative to the overall stock market.

According to Ursaner, "Staar Surgical has a strong market position in foldable intraocular lenses (IOLs) used to restore sight for patients suffering from glaucoma. The company is currently undergoing FDA testing of a new product, implantable contact lenses (ICLs), which offers significant improvement versus current therapy choices. We believe that Staar may take longer to get to market (in the U.S.) with this product, and may only end up with a small niche market versus PRK treatments. In the high-diopter market, it appears to provide superior results versus any other current therapy, with outstanding safety. While we are currently neutral on the stock, we are looking for an attractive entry point during the first half of this year. (The newsletter also contains comments made by analyst Richard Leza of John G. Kinnard & Co. on his initial coverage of Staar -- see my comments above.)

2/2 According to Optical Buyers Guide, a lawsuit was filed in U.S. District court for the Middle District of Florida on behalf of purchasers of Vision Twenty-One Inc. securities which asks the court for class-action status. Named as defendants are Vision Twenty-One and executives Theodore Gillette and Richard Welch. The plaintiff firm Berger & Montague, of Philadelphia, asks the court to designate the class period as Dec. 5, 1997, through Nov. 5, 1998. The complaint alleges that Vision Twenty-One misrepresented its ability to integrate the acquisitions that the company had made during the class period and misstated its revenues, net income and expenses for the first and second quarters of fiscal 1998. On Nov. 6, 1998, Vision Twenty-One reported a $0.03 per share loss for the third quarter of 1998, and admitted that revenues for the first and second quarters were overstated and expenses were under reported, the complaint states. The company was forced to make adjustments to the third-quarter financials resulting in a charge of $700,000, or just under $0.05 per share, for the accounting irregularities in the first and second quarters. During the class period, Vision Twenty-One common stock traded as high as $11.75 per share. In the days following the Nov. 6, 1998 announcement, the stock price plunged to $4 per share, losing over 60% of its value from its high during the period. The company released no statement on the litigation. (Other law firms that jumped on the class action lawsuit bandwagon included; Milberg Weiss, Weiss & Yourman, Pomerantz, Hudek, Block, Grossman, and Gross, and Burt & Pucillo.)

Finally, on February 4th, the company responded with a statement from CEO and President Ted Gillette, "We strongly disagree with and deny the allegations contained in the lawsuits and we will vigorously defend our position." Consistent with company policy, Mr. Gillette was unable to comment further on the proceedings.

2/2 Dow Jones News Service reported that Iridex Corp.'s Iris Medical Instruments received a warning from the FDA about the operation manual for its OcuLight GL Laser System. The Jan. 20 letter said the company didn't provide adequate instructions in the manual to instruct doctors on how to adjust the laser's computer. Ted Boutacoff, Iris's president and CEO, said the company refuted the agency's contention. "We felt we were fully compliant," Boutacoff said. "There was confusion about the wording in the operation manual. They felt we needed more instruction on how the user should calibrate the computer. We explained that the computer self-adjusts and the FDA agreed with us." Boutacoff said Iris should soon receive a written notice from the FDA saying the agency agrees with the company's position. "We've heard it verbally already," he said. No confirmation was immediately available from the FDA.

2/3 Premier Laser Systems announced that it had been granted a U.S. patent covering a multi-camera corneal analysis system, an imaging technology used in the EyeSys.Premier System 2000 corneal topography system. The patent covers EyeSys' three-camera method for capturing a true image of the cornea for mapping purposes. According to the announcement by Premier Laser chairman, president and CEO Colette Cozean, the three-camera technology is a simple solution to the complex problem of precisely measuring and mapping the cornea, enabling practitioners to perform limbus to limbus mapping. This patented technology provides information that is useful to refractive surgeons as a prelude to eye surgery and to optometrists in the fitting of contact lenses. The company has an additional U.S. patent pending on the technology and has filed foreign applications as well.

2/3 Nidek's corporate offices in Japan announced that another legal victory had been won in the company's ongoing efforts to assert its right to manufacture and market the EC-5000 excimer laser on a worldwide basis. Summit Technology, claiming infringement of its Japanese patent No. 2,125,313, (the so-called Azema patent), filed a lawsuit against Nidek in Japan on April 15, 1996. The case was heard by the Civil Affairs 29th Section of the Tokyo District Court, and the court found in favor of Nidek -- a ruling that once again supported the company's basic position that their technology does not infringe on that of other excimer lasers.

Kazumi Suzuki, manager of the Legal Affairs Section at Nidek, commented on the latest ruling: "While we understand that the patent laws of various countries may differ, it is clear that the scope of the U.S. version of the Azema patent is much more narrow that its Japanese counterpart. Therefore, our recent victories in Japan and the United Kingdom are positive indications that we will prevail in the U.S. as well."

On the following day, Summit responded, confirming that the Tokyo District Court had issued a judgment in favor of Nidek Co., Ltd. of Japan, but that it planned to appeal the decision. Commenting on the Tokyo Court decision, Robert Palmisano, Summit's CEO stated, "We cannot comment specifically until we receive an English translation of the Japanese Court's decision. However, Summit believes it presented a strong infringement case to the Tokyo District Court and intends to appeal the decision to a higher court with

more experience deciding patent matters. Summit's U.S. patents, and the U.S. court system, differ from those in Japan. Moreover, Summit's U.S. infringement action includes an additional patent which we also believe the Nidek system infringes...We look forward to having this matter adjudicated in the United States courts."

2/4 Escalon Medical reported record results for its second fiscal quarter, including revenues of $75,000 related to its licensing of its laser technology to IntraLase. Commenting on IntraLase Corp., in which Escalon has an equity stake, Richard DePiano, chairman and CEO said, "The progress at IntraLase, which was created through the combination of our ultrafast laser business with that of the University of Michigan, has been very exciting. In January, IntraLase received $3.0 million of additional financing led by Brentwood Venture Capital and Enterprise Development Fund. These funds are earmarked for European clinical studies and the commercialization and scale-up of the IntraLase laser vision correction system. In addition, IntraLase appointed Randy Alexander as its president and CEO...These milestones reflect the significant progress being made at IntraLase as it continues its steps toward commercialization in this rapidly growing market."

2/4 KeraVision reported financial results for the fourth quarter and year. Revenues totaled $332,000 for the quarter and consisted largely of sales to Canadian surgeons of surgical instruments and start-up inventories of Intacs for treating myopia, which followed the product's Canadian launch in October. This compares to revenues of $94,000 for the fourth quarter the year before. Net loss for the quarter was $7.2 million (59 cents/share) versus $5.4 million (43 cents/share) for the fourth quarter in 1997. The increase in losses was primarily due to market development investments in North America.

KeraVision chairman and CEO Tom Loarie said, "During the fourth quarter KeraVision advanced to the final stage of U.S. regulatory review with our initial product, Intacs for myopia. In Canada, we began our professional training and marketing effort with a core group of the country's leading vision correction surgeons. We also continued our work on a consumer marketing program that the company intends to test in a regional Canadian market in the second quarter... We are now expanding the hyperopia study beyond the initial clinical site in Mexico to three new sites in Europe, with a goal of eventual commercial review and approval in the European Union."

The company also announced that it had begun clinical studies in Europe for Intacs for hyperopia. Since Jan. 7th, a total of eight patients have been treated for +1.0 to +3.5 diopters of hyperopic correction at the Hospital of Neubrandenburg in Neubrandenburg, Germany. This follows a Mexican study in which 85% of farsighted patients achieved 20/20 vision or better and 100% achieved 20/40 or better, based on preliminary data for 13 Intacs patients who were monitored for one month.

2/5 Lauran Neergaard filed a story for the Associated Press about the use of Visudyne in the fight against ARMD. The story, entitled, "Ray of Light in Blindness Fight", goes on to relate the National Eye Institute's fight against age-related macular degeneration,

including the QLT PhotoTherapuetics/Ciba Vision study of using PDT to stabilize vision in patients with the "wet" form of ARMD.

2/5 Another new analyst and firm checked in with a report on LCA-Vision. Analyst Bob Wasserman of Southeast Research Partners issued a "buy" rating on this service firm, based on the company's about to be reported first quarterly profit (see announcement below). According to Wasserman, the growing acceptance of refractive laser correction has spurred center growth of nearly 100% at LCA's 17 wholly-owned U.S. centers. He estimates that LCA's growth for the year will approach 60%, which, along with tight cost controls, are expected to keep the company profitable for this year and beyond. Wasserman also commented on improved marketing techniques undertaken by the firm that have aided growth. These include an advanced call-in center, a new web site, direct mail, and other techniques borrowed from mature eyecare providers such as contact lens marketers.

And analyst Steve Hart of Commonwealth Associates checked in with his report, initiating coverage of LCA Vision. Hart rates the company a "strong buy", as he is optomistic about management's ability to capitalize on the growing opportunity in LVC. He expects LCA to increase revenues at an annual rate of 35% over the next several years. Hart's model shows procedure growth for the industry at 605,000 in 1999, and reaching 1 million annual procedures in the year 2000. Apparently, this analyst is a little behind the times, as he still lists Sight Resource as a major competitor to LCA, along with Laser Vision Centers and TLC The Laser Center.

2/8 Omega Health Systems announced a change in strategic focus that will include a major new initiative to expand its laser vision correction capabilities. During the first half of 1999, the company plans to have excimer laser technology available on-site in all of its 22 markets across the country. Through either fixed-site or shared-site lasers, patients will have on-site access to laser vision correction services by surgeons affiliated with Omega. Fixed-site lasers will be placed in Omega's highest volume locations, and a mobile program utilizing shared-site lasers will service its lower volume locations. Omega has over three years experience in operating similar mobile surgical programs in a number of its markets. In connection with this new initiative, Omega has agreed to acquire 12 VISX Star S2 excimer lasers.

Laser vision correction procedures accounted for over 13% of the total surgical procedures performed in 1998 by surgeons affiliated with Omega. These procedures represent one of the fastest growing areas in eye care in the nation and at Omega. Surgeons affiliated with Omega performed 4,925 refractive procedures in 1998, compared with 2,453 procedures in 1997. This significant growth is continuing, with a current run-rate of over 7,000 procedures for 1999 based on the volume from the two previous months. The company believes that this new initiative, including improved laser access and a coordinated marketing program, will cause this growth to accelerate.

"This new initiative will eliminate facility fees paid to outside third parties and allow us

to customize and market our own on-site laser program," commented Thomas Lewis, president and CEO of Omega Health Systems. "Approximately two-thirds of patients who are candidates for this surgical procedure are currently in the care of optometrists, making laser vision correction an ideal application for Omega's co-management model. In addition, we believe that there are significant advantages to launching this initiative through our established national network of eye care centers. We can efficiently leverage our resources with the collective purchasing power of multiple markets, providing the company access to laser technology on a more cost-effective basis. There are also clinical benefits to collaboration, as it creates opportunities for Omega doctors around the country to share case information with their peers. Our model for this initiative also includes continuing education programs for our affiliated doctors and their patients."

2/8 LCA-Vision reported results for the fourth quarter and year, making good on its forecast to shareholders to deliver "break-even or better" financial performance by the end of 1998. In the fourth quarter, the company generated net income of $247,000 (1 cent/share) on record revenues of $9.9 million. A year ago, the company reported a net loss of $2.6 million (7 cents/share), on revenues of $6 million. Fourth-quarter procedure volume doubled to 6,791, up from 3,400 procedures during the same quarter last year.

For all of 1998, LCA-Vision performed a record-breaking 23,080 procedures, up 137% from a year ago. Revenues for the year doubled to a record $35.2 million, up from $17.6 million in 1997. Excluding the impact of restructuring charges, the company's full-year net loss was $3.2 million (9 cents/share), compared with a loss of $6.9 million (26 cents/share) a year ago. Dr. Stephen Joffe, LCA-Vision chairman and CEO, commented, "LCA-Vision had a better than break-even quarter, a clear sign, we believe, that our business has turned the corner. The sharp increase in procedure volume that marked the closing weeks of 1998 has continued in the new year. Looking ahead, we see continued strong growth and sustained profitability in 1999...Based on our ability, today, to treat nearsightedness, farsightedness and astigmatism, more than 99 percent of the potential U.S. market remains untapped. LCA-Vision's current streamlined, more efficient operational structure will allow us to take full advantage of the rapidly accelerating pace of patient acceptance."

2/8 The Business Standard of India carried a story about Bausch & Lomb India, the 44% subsidiary of the U.S.-based eyecare multinational. Commenting on the area of surgery, the article notes the company was now marketing excimer laser devices directly into India from Singapore, and that they would soon be integrated into the Indian operations.

2/8 EyeWorld Week reports that Vision Correction Centers has changed its name to Aris Vision Inc. The refractive surgery management company oversees 15 vision institutes and 24 doctors in California, Utah, Massachusetts, and Mexico.

2/8 Gimbel Eye Centre announced a new fee structure that will make its services more accessible to potential vision correction patients across Canada. Dr. Howard Gimbel, founder and senior medical director, said "Doing what is best for our patients includes

not only focusing on their visual outcomes, but also constantly striving for efficiencies. With five centres across Canada, and vast surgical knowledge we have from our years of experience, we are very happy to be able to provide our quality of service at a more affordable level". The new fee structure for laser vision correction surgery, LASIK or PRK, at the Calgary, Edmonton, and Saskatoon centres is $1500 per eye. In the two newer centres, Vancouver and Toronto, the fee is $1200 per eye. The change is effective February 1, 1999.

2/9 According to Newspage, a U.S. Patent has been issued and assigned to Premier Laser Systems, covering laser surgical procedures for treatment of glaucoma. The abstract reads: A laser is used to reopen the natural drainage passageways in the eye or to form new passageways to enable the drainage of the aqueous humor from the eye.

2/10 Laser Vision Centers announced that over 14,950 cases were performed on its U.S. laser systems during the fiscal third quarter ended January 31, 1999, a 122% increase over the same quarter a year ago and a 29% increase over the previous quarter. The company said that in January it performed over 6,200 surgical cases in the United States, the best month ever for U.S. case volume. In addition, the company said that over 480 surgeons used its services during the quarter compared to 408 the previous quarter.

Same U.S. laser revenue for its fiscal third quarter, was up 45% over the same quarter last year. Same U.S. laser revenue compares the revenue generated on 23 lasers that were in operation in January 1998 to the revenue generated by those same lasers in January 1999 and is not equal to total company growth which would be a higher percentage. The company operated a total of 35 lasers in the U.S. during all or part of the quarter.

Following the announcement above, Pacific Growth Equities analysts Fred Toney and Al Kildani issued an update report, rating the company a "long term buy". They noted that including international procedures, they believe that over 15,700 LVC procedures were performed on the company's lasers worldwide during the quarter, compared to their estimates of 13,400. At the end of the quarter, the company operated 43 lasers, 35 of which were in the U.S.

2/10 According to NewsPage, a U.S. Patent was assigned to VISX covering a system for detecting, measuring and compensating for lateral movements of a target. The abstract reads: A method, apparatus and system for a transverse tracker is described that can greatly improve the accuracy, speed, range, reliability, versatility, safety, and efficacy of interventions such as laser microsurgery.

2/10 I received a copy of PaineWebbers' Charles Olziewski's latest research note on VISX. He remains bullish on the company, which remains on track to meet his quarterly estimates. He also notes that the recently approved Nidek laser does not appear to be making inroads in the domestic marketplace, partly because of the limited clearances it has received. (And partly because of the threatened lawsuits against purchasers!) He is holding with a forecast of 650,000 domestic procedures for 1999 for the industry.

Charles also believes that VISX's domestic installed base of laser systems will surpass 300 lasers by quarter's end.

2/12 TLC's Windsor Laser Center became the first refractive center in Ontario to implant the Implantable Contact Lens (ICL) for the severely nearsighted and farsighted. Dr. Lou Probst, Medical Director for the TLC Windsor Laser Center, performed the new procedure as part of a nationwide clinical study to correct the vision of patients so severely nearsighted that they could not be treated with other forms of laser eye surgery. It is the first procedure of its kind to be performed in Ontario. "This is another indication of TLC's position at the leading edge of technology for vision correction," said Dr. Probst. The patients who had their first eye treated today will return in one month for treatment of their other eye. The ICL is a contact lens which is custom-made for each patient and surgically implanted in front of an individual's own natural lens. The procedure involves minimal discomfort and takes only minutes to perform, with recovery time usually in one day.

2/12 This month's issue of Refractive Market Perspectives contains David Harmon's latest estimates for the number of refractive procedures performed in 1998, and his first projection for 1999. According to David, 480,000 procedures were done in the U.S. on 478 lasers, with 53 systems added during the fourth quarter alone. This is up from over 215,000 procedures done in 1997 on 372 laser systems. He states that an additional 350 ophthalmologists offered laser refractive surgery last year. Of the 53 new lasers put into service during the fourth quarter, 11 were added to corporate centers, while the remaining 42 were split between private surgeons and institutions.

Based on the surprising growth both in new lasers and in surgeons, plus preliminary results for January, he suggests that volume for 1999 could reach 750,000 procedures, well above even the most optimistic analysts projections. He bases his projection on additional new treatment ranges, an ever growing referral base, expanding market awareness, and patient demand for refractive procedures. As a result of this anticipated growth, he forecasts 125 new laser centers to open for operation in 1999, with an ever increasing number of procedures performed per installed laser system.

David also discusses LCA Vision's first quarter results, noting that the company operated 32 laser centers at year's end 1997, but after merging, closing or selling 13 centers, the company now operates only 19 centers, having placed some of the surplus VISX lasers in each of the remaining centers, either replacing a Summit system or adding to it. He notes that LCA has also divorced itself from the university-based hub and spoke model used to build the Summit refractive laser center network.

The newsletter also notes that Vision Correction Centers has changed its name to Aris Vision Institute, as part of a broader marketing and growth plan. The company now operates 12 laser centers and serves an additional six sites with two mobile lasers, along with operating three of the twelve in international areas (including Japan, which, according to a letter I received from the company, is expected to account for 30% of the

company's revenues by 2002). The company operates in Northern California, Utah, and Massachusetts in the States, and expects to open at least three more centers shortly, and as many as ten new centers this year. (The letter I got claims projected revenues of $17.5 million in 1998, rising to $44.1 million in 1999, and then $71 million in 2000. The letter notes that the company is seeking $20 million in financing for center expansion, capital equipment, and working capital.)

David also writes about the Nidek/VISX/Summit situation. He says that Nidek has offered to indemnify prospective purchasers of their lasers, with limited protection against legal costs, provided that Nidek has the sole right to control conduct of the suit, including choice of counsel and terms of settlement. The indemnification, however, does not include any per procedure license fees that might be assessed -- with VISX possibly seeking treble per procedure fees because of the alleged willful infringement by Nidek.

2/14-
2/15 Jacques Frehner of MFC Merchant Bank S.A. sent me a copy of his new research report on Sunrise Technologies International. I was quite surprised by the negative nature of the report. Based on his analysis of the past history of both the company and its reliance on LTK, and his believe that the company's LTK laser for hyperopia and presbyopia "will never be used on a(n) economical scale by practitioners due to regression, non-predictability, non-stability, limited market, limited diagnosis, less effective than alternative treatment (hyperopic PRK and LASIK), and coming technology (IOL)", he recommends "sell and short sell" ratings.

I disagree with his analysis. It is based on outmoded historical studies of laser and non-laser thermal keratoplasty, and has no reference to recent or current clinical studies that show reasonable stability on patients over 40 and using the company's newer protocols. As readers of this newsletter know, I have disagreed with the company's estimates of the potential population likely to be treated with this technology, but although the population might be somewhat smaller than most people think, I do believe that the technology works, at least under the company's current guidelines of use, and that the company will be successful in placing systems in doctors offices for correcting hyperopia, for over corrected PRK/LASIK patients, and potentially for the treatment of presbyopia.

Part of Jacques' report digs into the financial aspects of the company, both historical and current. As I don't pretend to be a financial analyst, I will not comment on that. One disturbing element, however, notes that the company has been unsuccessful in penetrating the European market, with only a little over a dozen systems sold in that area. In a conversation with Russ Trenary, president and CEO, he pointed out that because of the company's limited resources, they decided as long as two years ago, to concentrate their efforts on obtaining U.S. FDA marketing approval and on product development of the new Hyperion system, before spending the money necessary to obtain and support European sales. Trenary assured me that once U.S. marketing approval is obtained, and the product launched, the company would then address the European and Asian markets, where over 40 systems have found their way. Further, because Sunrise intends to market

the LTK laser on several levels, surgeons who don't want to purchase the system outright, or spend a lot of money upfront, will be able to obtain a system either for nothing, or for a minimum amount, and then pay off the remainder of the sales price on a per procedure basis.

2/15 EyeWorld Week reported that the Refractec Corneal Shaping (RCS) system for the treatment of hyperopia was used on its first U.S. patient last week. Edward Manche, MD, director of cornea and refractive surgery at Stanford University School of Medicine, performed the operation. The technology uses a ring of radio-frequency applications around the cornea's periphery to create two to three intrastromal collagen bands at 6, 7, and 8 mm, resulting in shrinkage of collagen and steepening of the cornea. The patient's refraction was brought from +1.83 D to -0.75 D immediately postoperatively, a deliberate overshoot to allow for the slight regression that typically occurs 6 to 18 weeks after the procedure. "In the hands of an experienced surgeon, the operation takes only 2 to 5 minutes," Manche said. "The patient experienced no pain and was able to read a newspaper straight out of the operating chair." In other news, the device received approval from the FDA to begin Phase III trials for hyperopia up to 4 D. Ten sites are expected to be included in the study.

2/15 According to Optical Buyers Guide, 24 Washington, D.C.-area police officers received LASIK at TLC laser centers in Rockville, Md., and Fairfax, Va., as part of "Law Enforcement Appreciation Day." The centers offered LASIK at about half the normal rate of $2,750 an eye. The Washington Post quoted Roy Rubinfeld, MD, of the Fairfax center, who said the discount was offered because police "are underappreciated, and it's just a way of giving something back to the community." The Rockville surgeon was Mark Whitten, MD. Clinic officials said similar discounts have been offered to teachers and firefighters, and that no endorsements are expected from those receiving the discount.

2/16 KeraVision said that its PMA application to sell Intacs, a non-laser alternative for treating myopia, has been deemed "approvable" by the FDA. The FDA action comes a month after the FDA's Ophthalmic Devices Panel unanimously recommended approval, with conditions, of Intacs for myopia. KeraVision chairman and CEO Tom Loarie said, "KeraVision is gratified by the FDA's prompt action. We very much look forward to competing in the U.S. market with what is potentially the first approved non-laser approach for treating mild to moderate myopia."

2/17 Innovative Optics announced that it had received recommendation for certification to the ISO 9001 Quality Standard. Final approval will take about six weeks to complete. This certification will allow Innovative to market its Innovatome surgical microkeratome in the European Community.

The following day, the company chairman and CEO, Mario Barton announced that the rapid increase in orders due to demand for the Innovatome "makes it clear that we should draw upon additional resources to capitalize on this market opportunity and continue

capturing major market share. We must take advantage of the overwhelming acceptance of this instrument in a continually expanding marketplace." Barton announced that the company had engaged the Hankin investment banking firm of Los Angeles as a strategic and financial adviser. This firm will explore strategic alternatives for maximizing investor value and building on the Company's initial marketing success with Innovatome.

2/17 Nidek issued a statement to clarify some issues with the professional ophthalmic community regarding its commitment to providing quality instrumentation to American surgeons; its position on patents and per-procedure fees; and the introduction of competition into an anti-competitive environment.

"Nidek is committed to providing American surgeons with quality instrumentation. Presently, there are over 25 Nidek products available in the United States ophthalmic industry, including high-caliber surgical, diagnostic, and laser equipment. Nidek has nearly 30 years experience in this highly specialized field. We attribute a large measure of our success to working closely with physicians to design products to their specifications, employing high quality components, ease-of-use, and effective customer support. We have invested much time, effort and money in the FDA Market Approval process of the Nidek EC-5000 Excimer Laser System since 1994. The EC-5000 is now FDA Approved for PRK and available for sale in the United States. Our excimer laser is proven, state-of-the-art, scanning technology, with hundreds of systems placed worldwide. We are committed to continuing our efforts to allow your patients to benefit from this next generation laser.

Nidek believes in the rights of a company to protect its technology with patents. We believe that we do not infringe the technology of competing excimer laser companies. Recent lawsuits have strengthened our position with victories in the United Kingdom and Japan. These cases have demonstrated that our technology has not infringed that of others. In the United Kingdom, one of the asserted patents was, in fact, found to be invalid. We also believe that licensing of patents should be settled company-to-company, and not result in per-procedure costs that burden the end user. Nidek has not, and does not intend to, charge a per-procedure fee for any of our technology. We hold our own patents, and in addition, have purchased the rights to the IBM patents on excimer technology internationally. In the United States, we have pre-paid licensing fees for these patents. These patents were purchased for a price of $7.5 million. We will not charge the end user of our laser to recover that cost.

Nidek believes in fair competition and offering today's refractive surgeons a choice in the instrumentation that they use to treat their patients. Current trade practices of our competitors are under review by the Federal Trade Commission. We do not believe in companies involving end users in litigation to force them into buying a product. Nidek is a privately held company and is not driven by the value of it's stock on the public market. Our goal is to provide a high-quality excimer laser to American physicians at a reasonable cost."

2/17 Summit Technology and Autonomous Technologies announced that they had tentatively

scheduled special meetings of their stockholders for March 30, 1999 for a vote on the proposed merger of the two companies. The record date of February 17, 1999 has been set. Stockholders of record on that date will be entitled to vote on the transaction.

2/18 The January issue of Optometric Management contains an interesting article on co-managing of laser vision correction, entitled, "Refractive Surgery: Breaking Free of Misconceptions". In the piece, author Charles Aldridge, OD, makes the case for co-managing, rather than dispensing contacts or eyeglasses, as with both the co-management fee ($800 for both eyes) and ongoing yearly examination fees (from outcome guarantee programs), more than make up for the $100 per year an OD might get from a contact lens patient, or the $300 over two years for eyeglasses. In a comparison of the fees collected from 30 patients that underwent LVC, his office collected net income of $23,105 in the year following only $2789 from those same patients. An interesting article.

2/20 Optistock reports that Nidek Ltd. said in a U.S. District court filing that its EC-5000 excimer laser does not infringe "valid and enforceable" patents that VISX holds and added that the U.S. patents under which VISX filed its lawsuit are not valid or enforceable. Nidek said that patent applicant Stephen Trokel "made materially false representations that he solely invented the subject matter" of one of the patents.

2/20 As reported in the February issue of The BBI Newsletter, Bob Palmisano, president of Summit Technology, noted in his presentation at the recent Hambrech & Quist Healthcare Conference, that, in the second quarter of 1999, his company would be introducing "a very exciting and vastly superior technology that will produce vastly superior outcomes" and would have broader labeling than its competitors. (Was he refering to the Autonomous Technologies' laser, or something else?)

OPHTHALMIC LASER UPDATE -- MARCH 1999

2/5 As previously reported in January, Nidek Co., Ltd. has joined forces with Toyama Chemical Co., Ltd. and INAX Corporation, to form Japan Tissue Engineering Co., Ltd. (J-TEC), a new venture for the engineering and production of human graft tissue. In collaboration with Professor Minoru Ueda (Department of Oral Surgery, Nagoya University School of Medicine), J-TEC will research and develop technology to cultivate human skin, cartilage and bone cells, which may be used in their pure state or combined with artificial materials for specific applications. The new company, located in Gamagori, Japan, will provide graft tissues to local clients first, gradually expanding to nationwide distribution. Sales projections anticipate dramatic growth, from 300 million yen in 2004 to 4 billion yen by 2009. Tissue engineering is an emerging new technology, with huge potential markets being created by the world's aging populations.

2/12 The Memphis Business Journal picked up on Omega Health System's announcement last month (see our February 8th brief) about their new strategic initiative to expand further into laser vision correction by publishing a story about the event. As noted in the writeup,

Tom Lewis, president and CEO of Omega said that the company would hire a national marketing director for the project, and a marketing director in each of the 20 markets the company serves. Of the 20 markets, four will be served by fixed laser installations, while the remainder will be served with 8 mobile laser systems. He went on to say that the potential profit is significant, as it costs Omega about $900 to perform a procedure with its own laser, compared to $1000 when it rents a system and, as volumes increase, the company's cost per procedure could drop to as low as $500 to $600.

2/20 As noted in the February 20th brief in last month's newsletter, Nidek filed its response in U.S. District Court to the patent infringement allegations made by VISX, declaring that the Nidek EC-5000 excimer laser does not infringe any valid and enforceable patent held by VISX. The response also contended that each of the U.S. patents under which VISX brought suit against Nidek (U.S. Patents 4,718,418, 5,711,762 and 4,732,148) are invalid and unenforceable for several reasons, including VISX's misuse of their patents and a failure to meet requirements for patentability. The response claimed that patent applicant Stephen Trokel made materially false representations that he solely invented the subject matter of the '762 patent, and violated a duty of candor by not disclosing relevant prior art.

In October of last year, NIDEK successfully defended itself against another patent infringement lawsuit brought by VISX in the United Kingdom. In that case, VISX's European patents 0,151,869 and 0,207,648 were found either invalid, or Nidek was found not to infringe.

2/22 Sunrise Technologies International reported financial results for the fourth quarter and year. For the quarter, revenues were $90,000 compared to $300,000 for the comparable period in 1997. Operating expenses were $3.7 million compared to $2.1 million for the same period of 1997. The net loss was $4.9 million (14 cents per share) compared to a net loss of $2.5 million (8 cents per share) in the comparable period of 1997.

Revenues for the year were $594,000 compared to $2.9 million for the same period in 1997. Operating expenses were $12.7 million compared to $7.4 million for 1997. The net loss for the year was $17.8 million (52 cents per share) compared to a net loss of $6.6 million (23 cents per share) in the comparable period last year. According to Timothy Marcotte, vice president and CFO, "Approximately 33% of the $17.8 million of the 1998 net loss (17 cents per share) was attributable to non-cash expenses associated with the company's 1997 and 1998 convertible debt financings, warrants issued in connection with these financings and warrants issued to consultants in lieu of cash." Approximately $2 million of 1997 revenues, $2 million of 1997 operating expenses and $1.8 million of the 1997 net loss was attributable to the company's dental business that was sold in June 1997.

"The company raised over $31 million in the last fourteen months, without the services of a placement agent, saving it approximately $2 million in placement and legal fees," added Marcotte. Sunrise closed the year with a cash and cash equivalents balance of $9.9

million and $6.8 million in working capital as compared to $2 million in cash and cash equivalents and $1.4 in working capital at the end of 1997."

2/22 The law firm of Pomerantz Haudek Block Grossman & Gross said that since filing its complaint against Vision 21 on January 22nd, it has received numerous telephone calls and e-mails from investors interested in the action.

2/22 NewsPage reported that a leading eye surgeon has developed a new sterilization protocol that has eliminated Diffuse Lamellar Keratitis (DLK) at TLC The Laser Center in Vancouver. Dr. Simon Holland, Medical Director at TLC launched a study with University of Calgary microbiologist Dr. Doug Morck and UBC epidemiologist Dr. Rick Mathias after doctors observed the condition in a small cluster of LASIK refractive patients. "The new sterilization protocol has subsequently eliminated the occurrence of DLK at our center," said Dr. Michael Melenchuk TLC Regional General Manager. "Dr. Holland is in the process of presenting his study for scientific and academic review and validation."

2/24 According to Medical Industry Today, Anamed Inc., a privately-held medical device company located in Irvine, CA, is developing the PermaVision intracorneal stent, which it said can overcome one of the shortcomings of laser vision correction which is irreversibility, while also providing a variety of other benefits. PermaVision stents are made of a clear version of a material called Nutrapore that can be formed into meniscus-shaped discs. Anamed's proprietary Nutrapore material (biocompatible, micro-porous hydrogels) manages nutrient and fluid transfer, and regulates cell attachment and tissue growth, according to the company. Although the stent potentially could have several applications, the company is pursuing hyperopia (farsightedness) as its initial indication.

Company CEO Alok Nigam believes that PermaVision occupies a unique niche, as the only surgical technology being developed for reversible correction of farsightedness. And the market opportunity is large, because an estimated 1.3 billion people worldwide have hyperopia. When the stent is inserted, under a corneal flap, the technology reshapes the outer surface of the eye to correct farsighted refractive errors, in which the central thickness determines the amount of vision correction. Because the Nutrapore material enables nutrient and fluid transfer, deterioration of the surrounding corneal tissue is prevented, according to the company.

To insert the device, the surgeon uses a keratome to cut a thin layer of the cornea, but leaves the cornea attached on one side. (Apparently, similar to the flap created for LASIK.) The surgeon then places the stent on the center of the cornea and closes the flap. The entire procedure is short, lasting about 5 minutes, and is allegedly painless. The patient can resume normal activities within about three days, with full recovery expected after about a week. The expected cost to the patient would be about $2,000 per eye -- roughly comparable to the cost for the LASIK procedure, according to Nigam.

2/25 VISX announced that the U.S. International Trade Commission (ITC) had instituted an investigation of the activities of Nidek Co. Ltd. of Japan, and its U.S. subsidiaries, related to the importation and sale of the Nidek excimer laser system used for laser vision correction. The ITC's investigation will determine whether Nidek and its subsidiaries have violated Section 337 of the Tariff Act of 1930, as amended, by importing into the U.S. and selling laser vision correction systems that infringe VISX-owned U.S. Patent Nos. 4,718,418, 4,732,148 and 5,711,762. The investigation was initiated by the ITC in response to a complaint filed by VISX. (The official announcement appears in the March 1st issue of The Federal Register.)

If the ITC determines that violations have occurred, it may issue an order permanently excluding the entry into and sale within the United States of the infringing laser vision correction systems and all subassemblies and component parts thereof. The ITC may also issue a cease and desist order against Nidek and its subsidiaries, as well as certain others, prohibiting the sale, service, maintenance and repair of the Nidek laser system and its subassemblies and component parts in the U.S.. The ITC is expected to announce by mid-April a target date for completion of the investigation against Nidek. An initial determination by the administrative law judge could be issued as early as November 1999. Either party can seek review of the initial determination by the full Commission. Final determination by the full ITC could occur as early as February 2000.

2/25 The New York Times on the Web published a lengthy article about implanted eye lenses, written by David Morrow. The thrust of the article was about the upcoming clearance for marketing of Intacs, the plastic arcs made by Keravision, along with developments underway at several other companies, including Presby Corporation of Dallas, TX, developers of the scleral band, and Staar Surgical, developers of the implanted contact lens.

2/25 Laser Vision Centers announced that revenue for its third quarter ended January 31, 1999, were $14.1 million compared to $6.3 million for the same quarter last year, a 122% increase. Revenue for the nine month period were $33.6 million compared to $15.7 million last year, an increase of 114% Net income for the quarter was $2.2 million (22 cents per share) compared to a net loss of $969,000 (10 cents per share) for the same quarter in 1998. For the nine month period, net income was $3.4 million (34 cents per share) compared to a net loss of $3.8 million (42 cents per share) for the same period last year.

The company reported that it performed more than 14,950 surgical cases in the U.S. during the quarter and over 15,840 worldwide. Over 480 U.S. surgeons accessed LaserVision's services during the quarter. The company noted that it was the seventh consecutive quarter of both increased revenue and improved operating results and the fourth consecutive quarter of profitability.

The company also announced that it had filed a registration statement with the SEC relating to the proposed public offering of 1.72 million of the company's common stock.

The offering includes 720,000 shares being sold by stockholders of the company. The company intends to use the proceeds of this secondary offering to make future payments relating to recent strategic acquisitions, to purchase additional equipment, to fund possible future strategic acquisitions, to expand patient financing programs and for working capital and general corporate purposes. The managing underwriters for the proposed offering are A.G. Edwards & Sons, Inc. and Prudential Securities.

The following day, Fred Toney and Al Kildani of Pacific Growth Equities issued an updated report, maintaining the company as a "long term buy". The analysts were bulllish on the company, noting the growth in revenues and procedures, both of which were ahead of their projections. However, because of the secondary offering and its accompanying "quiet" period, they could not garner any comments from management about future projections.

According to Federal Filings Newswires, Laser Vision Centers established a limited liability partnership to own and operate one transportable refractive laser and related equipment and services in Minnesota beginning Jan. 1. Laser Vision is the general partner and owns 60% of the partnership. Minnesota Eye Consultants P.A. (MEC) is a limited partner and owns 40% of the partnership. Richard Lindstrom M.D., is president of MEC. Laser Vision contributed equipment valued at $650,000 to the partnership and will receive $260,000 from MEC for this minority interest.

2/26 In response to the patent infringement claims brought by VISX, Nidek Co., Ltd. and Nidek Technologies Inc. (collectively, Nidek), have filed counterclaims alleging fraud, misrepresentation, and nondisclosure of material prior art by VISX. In its response filed on February 20th, Nidek accuses VISX of asserting patents obtained through misrepresentations and fraudulent acts. Nidek requests that three VISX patents be declared invalid and unenforceable. Nidek asks for recovery of its own attorneys fees and costs and the matter be deemed "exceptional" such that Nidek is awarded treble damages. (Case No. C98-04842 CRB, pending in the U.S. District Court for the Northern District of California, San Francisco division).

According to Nidek, the origins of the controversy date back to excimer laser patent applications filed by Francis L'Esperance, Charles Munnerlyn, and Stephen Trokel more than a decade ago. Their competing patents and patent applications provoked several interference actions which exposed the existence of forged documents, material misrepresentations to the U.S. Patent and Trademark Office (PTO), and disputed dates of invention. Nidek alleges, as an example, that a meeting of the parties involved was held in December 1990 to resolve the interference proceedings. As a result, they requested a suspension of the proceedings, in consideration of a contemplated merger of the two companies to whom the patents had been assigned (Tauton Technologies, Inc. and the predecessor of VISX, Inc). Nidek asserts that the PTO was not informed of the basis for resolving the interferences, and contends that the fraudulent settlement of these activities render all of the involved patents unenforceable.

Nidek also claims that VISX has intentionally withheld material prior art from the PTO examiners, including the IBM patent (No. 4,784,135) which teaches the use of an excimer laser to ablate biological tissue without causing damage to surrounding tissue. Failure to disclose this and other prior art references in itself renders at least the Trokel patent unenforceable, according to Nidek. It is also contended by Nidek that Trokel was not the sole inventor having derived the technology from an IBM researcher in the field.

3/1 TLC The Laser Center announced that over 25,600 paid laser procedures were performed at the company's refractive centers in the three-month period ending February 28, 1999. This is a 173% increase from the 9,381 procedures performed in the same period a year ago. The over 25,600 procedures performed in Q3-99 represents a 42% increase from the 18,017 procedures last quarter. The company noted that Q3-99 volumes do NOT include any of the more than 1,800 procedures performed by Dr. Tooma's California practice that is part of a joint venture expected to close within the next six months. The increase this quarter was primarily driven by an 111% annual same-store procedure growth. In the same 34 centers that TLC operated in both Q3-98 and Q3-99, paid procedures more than doubled from 9,381 to 19,815 respectively. This is the 12th consecutive quarter of record procedure volumes since the company's March 1996 IPO. Elias Vamvakas, TLC's president and CEO, commented that, "pricing for the procedure remains strong and we continue to increase our share of this rapidly growing market."

Fred Toney and Al Kildani of Pacific Growth Equities immediately issued an update report on TLC. They reiterated their "buy" rating, noting the increase in procedure volumes and the "booming" LVC market. Although still holding -- at least for now -- with 650,000 procedures for 1999, they say that they would not be surprised to see the number surpassed by 50,000 to 100,000 procedures.

NOTE: In line with recent developments, including VISX's announcement below, and discussions with several analysts, I have raised my estimates for U.S. procedures, for both 1999 and 2000 -- sent along with this issue of the newsletter -- as well as revising my estimate for 1998 to 450,000 procedures. I now believe that 850,000 procedures will be performed in 1999 and 1.2 million in 2000. Using the Dain Rauscher model of 35% of the vision correction market as the potential target population for LVC, 2% penetration of the target population will occur in 1999, and over 3% penetration in 2000!

3/1 This week's issue of Business Week contains an article entitled, "Surgery to Scrap Those Specs", in the Personal Business section. Kate Murphy writes about the Keravision Intacs implanted into a patient as part of the clinical trials. The article also discusses the possibility of the use of the holmium laser from Sunrise Technologies for the treatment of hyperopia, overlooking the fact that the VISX laser already has approval for that condition. The story also notes that the accuracy of LVC may soon be improved by the use of tracking systems, such as that provided by Autonomous Technologies, which won FDA marketing approval last November. Also mentioned is the possibility in the future of treating severe vision problems with either the phakic IOL from Ophtec USA, or the implantable contact lens from Staar Surgical. Mention is also made of the scleral bands

under investigation for the treatment of presbyopia (for believers of this theory) by Presby Corporation, which will begin clinical trials in March.

3/1 VISX announced that it was experiencing continued strong demand for its VISX STAR S2 Excimer Laser System and a stronger than expected increase in license fee revenue. The company expects to report record revenue and earnings for the first quarter ending March 31, 1999. Projected results are expected to exceed the current consensus of analysts' estimates of $0.36 per share, assuming an effective tax rate of 40%. Based upon a preliminary analysis of performance during the first two months of the quarter, the company's earnings per share are expected to be in the range of $0.51 to $0.55. Actual results for the first quarter are expected to be announced after the close of market on Wednesday, April 14, 1999.

Mark B. Logan, chairman and CEO, remarked, "We are extremely pleased with the continued growth of laser vision correction procedures. Plans are underway to strengthen our commitment to this industry by making additional investments in the areas of Marketing and R&D."

Following the announcement, BancBoston Robertson Stephens senior medical devices analyst Wade King upgraded VISX to a "buy" rating from "long-term attractive". He commented, "VISX announced late yesterday that preliminary earnings per share for first quarter fiscal 1999 would likely fall in the range of $0.51 to $0.55 on a fully taxed basis, well ahead of our estimates. Consequently, we are upgrading VISX to a buy rating from long-term attractive, with a price target of $81, and increasing our revenue and earnings estimates. For fiscal 1999, we are raising our revenue estimate from $165 million to $218 million and our earnings per share estimate from $1.54 to $2.10. For 2000, we are increasing our revenue projection from $187 million to $248 million and our earnings per share estimate from $1.88 to $2.70."

"By the end of 1999, we look for shares of VISX to trade at $81, which is 30 times our new 2000 earnings estimate of $2.70 per share. VISX management indicated that procedural growth is significantly higher than expected and that doctors will likely perform more than 600,000 LVC procedures using VISX lasers in 1999. In our opinion, the overall domestic LVC market could exceed 850,000 procedures in 1999, and 1.2 million procedures in 2000. In 2000, we expect doctors to perform more than 800,000 LVC procedures using VISX lasers," said King.

Following the announcements above, Dow Jones Business News reported that VISX shares "leapt to a new 52-week high". The stock rose $19.25, or 32%, to close at $79.75. It reached a mid-day high of $82.25, surpassing the old 52-week high of $66.125, set on February 24th.

3/2 Iridex announced that results reported at the annual meeting of the Macula Society demonstrated that the accumulated deposits associated with the early stages of dry Age-related Macular Degeneration (ARMD) can be significantly reduced or eliminated

after only one treatment with the company's IRIS Medical OcuLight Infrared Laser Photocoagulator, the OcuLight SLx diode (810 nm) laser. (Recall that "dry" ARMD represents about 85% - 90% of total ARMD!)

In addition, it was also determined that visual acuity was significantly improved by this treatment -- an improvement of two or more lines -- in 24% of selected eyes. Given that ARMD affects about 15 million Americans and that there is no effective treatment for preventing visual disability in the large majority of these people, the company believes these pilot study findings have important implications. The pilot study was conducted at four clinical centers in the U.S. Two hundred twenty-nine eyes of 152 patients with dry ARMD were randomized to either treatment with the company's Iris Medical OcuLight SLx infrared laser photocoagulator, or observation. Dr. Joseph Olk, director of The Retina Center, St. Louis, Mo., directed the study and reported the results at the Macula Society Meeting.

Age-related macular degeneration (ARMD) is a progressive condition that damages the macula, the part of the retina in the back of the eye which provides central vision, and currently affects approximately 15 million people in the U.S. Loss of central vision robs the ability to perform tasks which require fine focus, such as reading, watching TV, or seeing faces. ARMD can occur in two forms, the dry form and the wet form, and both can coexist in the same patient. The dry form affects an estimated 13.5 million people in the U.S. and is typically characterized by a build-up of deposits (i.e., drusen) underneath the retina in the macula and initially results in minimal visual symptoms. With time, vision may deteriorate, more or less gradually, depending upon drusen type, size, quantity, and location. More importantly, presence of drusen constitutes a risk factor to develop severe vision loss due to development of geographic atrophy or development of the exudative (wet) form of ARMD.

The subsequent wet form is typically characterized by a proliferation of new vessels (i.e., choroidal neovascularization) underneath the retina in the macula and results in a more rapid and profound loss of central vision. While only approximately 10% to 15% of all ARMD cases, about 1.5 million to 2.3 million people in the U.S. are of the wet form, this form accounts for the vast majority of ARMD patients who are legally blind. ARMD is the leading cause of blindness in the U.S. for all age groups. For persons 65 to 74 years of age, the prevalence approaches 30%. In the U.S., the current annual incidence of ARMD is approximately 2 million people, 200,000 to 300,000 of whom have the wet form. It is expected that both the incidence and prevalence of ARMD will increase substantially with the aging of the population.

Currently, there is no clinically proven interventional therapy for dry ARMD while about 15% of patients with the wet form of ARMD are currently effectively treated using laser photocoagulation. Thus, currently proven effective treatments are routinely used in less than 2% of eyes with ARMD. Dr. Olk commented further, "To our knowledge, no other published research study has used the infrared (810 nm) diode laser in the treatment of non-exudative (dry) ARMD. We feel the positive results in this study may be

significantly related to this laser manufactured by Iridex Corporation. "The Iris Medical OcuLight SLx diode (810 nm) laser was selected for use in this pilot study for the following reasons: (1) the longer infrared wavelength allows the thermal effects to be absorbed in the deeper tissues (i.e., the retinal pigment epithelium), thus sparing damage to the sensitive overlying retinal layers such as occurs with other visible wavelength lasers; (2) experimental studies have shown that infrared diode (810 nm) laser treatment produces increased pre-retinal oxygen levels compared to argon lasers, which may in turn be more efficacious in reducing the progression to the exudative (wet) form of ARMD; and (3), additional experimental studies have demonstrated that infrared diode (810 nm) laser may be effective in restoring normal transport mechanisms to and from the outer retinal layers/retinal pigment epithelium and choriocapillaris."

One purpose of the pilot study was to determine the appropriate dose to be used in a subsequent larger multi-center randomized clinical trial called the Prophylactic Treatment of Age-related Macular Degeneration (PTAMD) Trial. The PTAMD Trial, also sponsored by IRIDEX, was designed to answer the question of whether reduction of drusen using prophylactic laser treatment would halt or delay the progression of the ARMD from the dry form to the wet form. Dr. Thomas R. Friberg, Professor of Ophthalmology, University of Pittsburgh, is the Director of the PTAMD Trial which is currently enrolling patients at 13 U.S. centers. "One of the purposes of the Pilot Study was to determine whether a one-time gentle treatment of the eye using an infrared diode laser wavelength (810 nm) would cause drusen to disappear yet not harm the patient. This is particularly important in that another similar study, the Choroidal Neovascularization Prevention Trial (CNVPT), using a laser wavelength substantially different from the infrared, reported that their chosen treatment was associated with a high complication rate. That study had to be halted and reorganized. From a standpoint of the large national collaborative PTAMD Trial, we are especially encouraged by the safety, the drusen resorption effectiveness and improvement of vision enjoyed by a substantial portion of patients from the pilot study who had dry macular degeneration. We are continuing to enroll patients and hope that we will also establish the merit of using the infrared (810 nm) diode laser as a simple prophylactic treatment for patients with dry ARMD."

Ted Boutacoff, president and CEO of Iridex, commented, "ARMD is the largest under-treated disease in ophthalmology. Iridex is investigating a number of approaches to treat ARMD using lasers; all focussed on reducing the extent of vision loss caused by ARMD. One of these approaches is being tested by the follow-on PTAMD Trial, which is investigating whether prophylactic laser treatment during the dry stage can halt or delay the progression of the disease to the wet form before vision loss is severe. The potential benefits of a prophylactic approach are substantial. Researchers at the University of Pennsylvania have modeled that just a 33% effective prophylaxis could more than halve the proportion of patients with dry ARMD developing legal blindness within 10 years."

3/3 PhotoVision Pharmaceuticals Inc. announced that it had signed an exclusive license agreement with Johns Hopkins University for the PhotoTarget family of drug delivery

systems and intellectual property potentially useful in the treatment of Age-related Macular Degeneration (ARMD). PhotoVision has also obtained the services of Dr. Ran Zeimer, the lead inventor of the licensed technology. Dr Zeimer is a Professor of Ophthalmology and Director of the Ophthalmic Physics Laboratory at the Wilmer Eye Institute, Johns Hopkins University. According to Frank O'Donnell, Jr., M.D., co-founder and chairman of the board of PhotoVision, "We believe that this technology can be effective in treatment of age-related vision loss. The Hopkins technology will permit further development of a method of photo-selective drug delivery that can be applied to diagnose, treat, and reduce occurrence of new blood vessels in the eye."

Terry Fuller, Ph.D., co-founder, president and CEO of PhotoVision, stated, "The method being developed by PhotoVision consists of encapsulating a drug in a microscopic, heat-sensitive shell or liposome. The liposome is injected intravenously and its contents released at the site of choice by non-invasively and non-traumatically warming the target tissue with a pulse of light. The PhotoVision drug then affects the target tissue while leaving the surrounding tissue and body virtually unaffected. The studies performed on several animal species including primates has demonstrated that we are able to selectively destroy abnormal blood vessels in the eye while avoiding exposure of the drug to unintended organs or tissues. We believe this technology will be able to preserve optimum visual acuity. This is in contrast to the natural history of the disease and therapies presently in use."

In a separate conversation with Dr. O'Donnell, I learned that he is also working on "curing" snoring with the same laser that is the basis for his Laser SkinToner development (collagen shrinking), that was sold to BioLase last year. The new application gives immediate relief, no pain or bleeding, and restores the patient to normal activities the same day. He has named the device the SilentNite laser. More on this development as it becomes available.

3/3 According to Inter@ctive Week, a commercal Web site dedicated to bringing together buyers and sellers of ophthalmic equipment and supplies is set to go live later this month. The operation is co-headed by Jim Barney, president of Hunter Delatour, a manufacturer of optical tinting supplies and equipment. The site (www.opticalauctions.com) will involve the sale of items such as glass lenses, ophthalmic lasers, optometrist chairs, and testing equipment.

3/3 Autonomous Technologies reported results for the fourth quarter and fiscal year. For the quarter, the company reported a net loss of $4.9 million (42 cents per share) on revenues of $86,625, compared with a net loss of $3.3 million (33 cents per share) on revenues of $26,065 for the same quarter a year ago. For the year, the company reported a net loss of $17.5 million ($1.59 per share) on revenues of $221,955, compared with a net loss of $11.6 million ($1.43 per share) on revenues of $37,065 for the same period a year ago. The company's losses increased during the quarter and full year as the company prepared for the commercialization of its LADARVision System. A special shareholder's meeting to vote on the proposed merger of the company with or into a wholly-owned subsidiary

of Summit Technology is tentatively scheduled for March 30, 1999. Summit has also tentatively scheduled a special shareholder's meeting for the same day to vote on the issuance of stock in conjunction with the proposed merger transaction. Autonomous expects to begin product shipments at the closing of the proposed merger transaction. (However, a glitch has developed in the merger -- see the 3/16 brief below.)

3/4 Medjet announced two developments in its litigation with the New Jersey Institute Of Technology (NJIT) over ownership of a patent for shaping the cornea for vision correction with a waterjet. NJIT's lawsuit disputing the validity and ownership of Medjet's patent in the U.S. District Court of New Jersey was previously dismissed by the court for lack of subject matter jurisdiction. In addition, on October 6, 1998, the U.S. District Court of New Jersey ruled that NJIT's attempt to remove Medjet's lawsuit from the New Jersey Superior Court of Middlesex County was improper and remanded the lawsuit back to that court. Medjet's lawsuit is to obtain a declaratory judgment against NJIT ending their claims of co-ownership of the Medjet patent. Medjet seeks $5 million in damages from NJIT. The lawsuit includes counterclaims by NJIT.

Eugene Gordon, Ph.D., chairman, CEO and founder of Medjet, pointed out that the invention underlying the patent dispute (U.S. Patent 5,556,406) had been improved to a great extent by Medjet. Additional proprietary information and patents, including international patents, which have issued or are about to issue to Medjet, now surround it. Dr. Gordon said, "Whatever the outcome of this lawsuit, we expect that Medjet's improvements will remain proprietary and its product plans will not be compromised."

3/4 VISX sent a "dear customer" letter to explain its position in the dispute between it and Nidek. In the letter, Liz Davila, the new president and CEO stated, "Unfortunately, property rights are not always respected. When they are not, I think you would agree that it is necessary and reasonable for owners to defend them...We believe this is true for intellectual property rights as well...We regret that this situation has come to pass. However, we believe we must act to protect what is ours. While we are defending our patented technology, VISX will continue to invest throughout our company to provide you with the product and service support you need to achieve excellent refractive outcomes on as broad a range of indications as possible. Our sole business is laser vision correction. We know that our success depends completely on your success."

For more on this litigation, see both the 3/15 and 3/24 briefs below.

3/8 According to OptiStock, PaineWebber has upgraded TLC The Laser Center from "attractive" to "buy". Salomon Smith Barney also upgraded the company from "neutral" to "outperform". In other analyst action, BancBoston Robertson Stephens upgraded VISX from "long-term attractive" to "buy", while Dain Rauscher Wessels re-initiated coverage at "strong buy-aggressive". The latter analyst firm also re-initiated coverage of Bausch & Lomb at "strong buy", with a six-month price target price of $75. (A new Dain Rauscher extensive update report on the LVC industry is in preparation -- probably for publication in April.)

OptiStock also noted that VISX will introduce the Contoured Ablation Pattern (CAP) Method, a Star S2 excimer laser system feature, that lets surgeons perform a sequence of precise ablations to treat irregularly shaped corneas, at next month's American Society of Cataract and Refractive Surgeons (ASCRS) meeting in Seattle. The CAP Method upgrade will be available gratis to VISX customers outside the U.S. after its debut, and available to U.S. customers following FDA approval.

3/9 OneSource Services, a national medical equipment service provider headquartered in Cleveland, announced that it had completed a merger with Field Service Engineering of Boston, a leading laser service provider. Ray Dalton, president and CEO of OneSource said, "By rolling our already successful national laser business into Field Service Engineering's national laser business, we are taking advantage of the technical and management strengths of the two largest and highest quality laser service organizations in the nation." Kent Williams, president of FSE, will become president of the combined operations.

3/9 Reuters announced that Merrill Lynch had raised its rating for QLT PhotoTherapeutics to "long-term buy" from "accumulate".

3/9 The American Academy of Ophthalmology reports that the current issue of its journal, "Ophthalmology" contains two articles reporting refractive surgery patients prefer LASIK to PRK for correction of low to moderate nearsightedness. In these prospective, randomized, paired clinical trials, 59 patients in the Middle East received photorefractive keratectomy (PRK) on one eye and laser in situ keratomileusis (LASIK) on the other eye. All patients described their PRK surgical experience as painless, but reported severe postoperative pain from one hour up to four days following the procedure. In contrast, 92% of patients described the first six hours after LASIK as uncomfortable because the eye was scratchy, burning, and tearing, but not painful.

On the first day after surgery, over 80% of LASIK eyes were painless. At two weeks, visual acuity was significantly better in the LASIK eyes, indicating a faster visual recovery. Throughout the two years of the study, uncorrected visual acuity of 20/20 or better was achieved by 25% more LASIK eyes than PRK eyes. At 2 years, 63% of LASIK eyes and 37% of PRK eyes achieved 20/20 or better and 100% of LASIK eyes and 96% of PRK eyes achieved 20/40 or better. Twice as many patients preferred LASIK at one year, but showed no preference at two years. This may be due to patients' adapting to the function of the two eyes together.

The Academy also reported that results of another recent study showed phakic anterior chamber intraocular lenses may offer advantages over laser surgery for correcting refractive errors, especially for higher levels of nearsightedness. The IOLs were implanted into the anterior chamber between the iris and the innermost corneal surface, of 263 phakic eyes -- eyes with their natural lenses intact. The 160 patients who participated in the study from Spain were monitored for up to seven years following the surgery for complications. The study was published in the March 1999 issue of

Ophthalmology. According to the study's authors, although controversial, this procedure "offers well-defined advantages as a refractive surgical technique due to its simplicity, potential reversibility, and the precision and stability of the refractive correction." The procedure provides an option for people with high levels of nearsightedness who tend to experience problems with night vision, regression of refractive correction and poor optical quality following refractive laser surgery.

According to Douglas Koch, M.D., professor of ophthalmology at the Cullen Eye Institute, Baylor College of Medicine, this study is important because a large number of people were involved and the follow-up period was significant. "The results are positive," Dr. Koch said, "but some of the complications need further monitoring. Complications included: Elevations in intraocular pressure, requiring the administration of anti-glaucoma drugs in 7.2% of the cases. Cataract formation resulted in nine of the IOLs being removed. Pupil ovalization in 5.9% of the cases with another 10.3% experiencing smaller degrees of the complication. Extreme glare associated with pupil ovalization was reported two cases, and detached retina in three cases."

In addition to the anterior chamber IOL, there are two other phakic IOL designs currently under investigation, the iris-fixated IOL and the posterior-chamber IOL. "Each phakic lens shows promise, although important issues need to be resolved before they gain wide acceptance," Dr. Koch said. He expects it will be at least two to three years before the lenses become widely available in the United States.

3/10 LCA-Vision announced that the company had reached an agreement with certain majority holders of its 6% Series B-1 convertible preferred stock. Under the agreement, the company will issue 165,076 shares of its common stock in exchange for these holders waiving their option to purchase an additional $5 million of convertible preferred shares under the same terms and conditions as the original $10 million convertible preferred private placement, which was announced on May 11, 1998.

"With this agreement we are reducing potential future dilution while simplifying our capital structure," said Stephen N. Joffe, M.D., LCA-Vision chairman and CEO. The agreement will result in a non-cash charge of $325,000 or less than $0.01 per share to the first quarter 1999 statement of operations. Of the original $10 million of convertible preferred issued in 1998, $2 million remains outstanding as of March 9, 1999.

3/12 Coronado Industries announced that Leo Bores, M.D., Medical Director of the Arizona Glaucoma Institute has been brought into its corporate offices. His function will be to take Coronado Industries through the final stages of the FDA approval process and to participate in a world wide speaking tour regarding PNT (pneumatic trabeculoplasty), starting with an Innovators meeting at the ASCRS meeting in April. Under Dr. Bores' direction as Medical Director of the Arizona Glaucoma Institute, Coronado Industries had managed to establish the safety and efficacy of PNT and also established third party insurance coverage, including Medicare, for the treatment. The closing of the Arizona Glaucoma Institute will allow Coronado Industries to better use the abilities of Dr. Bores

in the promotion of PNT and the sales of PNT equipment.

3/15 Refractec, Inc. released clinical data from Phase II studies with their non-laser Refractec Corneal Shaping System. This patented device, which uses radio-frequency energy to reshape the cornea for vision correction, produced very favorable results on 65 human eyes. Patients enrolled in this study had from +1 to +4.5 diopters of hyperopia. After treatment with the Corneal Shaping System, researchers performed followup studies on the patients for up to two years. At 12 months post-op, 100% of the treated eyes were within 1 diopter of the attempted correction, and achieved uncorrected visual acuity of 20/40 or better. Best corrected visual acuity was 20/25 or better for the entire cohort. Results at 24 months after treatment were very similar.

Based on this data, the FDA granted Refractec permission to begin Phase III clinical studies in February of this year. After a designated followup period, this final round of clinical data will be submitted to the FDA as part of a PMA application. The Refractec Corneal Shaping System has already been approved for sale in Canada, and received the necessary CE Mark in Europe.

3/15 This week's Business Week contains an item about the surge in VISX share price. According to the note, VISX share price advanced 32% on March 2nd, after the announcement that demand would push quarterly earnings to 51 to 55 cents/share, well above Wall Street estimates of 36 cents. Shares in the top three surgery centers using the VISX lasers -- TLC The Laser Center, Laser Vision Centers, and LCA-Vision -- also rose with the news.

3/15 According to this week's OptiStock and EyeWorld Week, VISX filed complaints in court against three laser vision correction providers and one physician using the Nidek laser. The complaints allege that OR Providers, Inc. and Refractive Support, Inc. in Ohio, two mobile laser providers (Refractive Support is a mobile excimer laser company and OR Providers specializes in mobile and fixed-site placement of cataract surgery equipment), and the Farmington Laser Eye Center PLLC and Donald Fiander, M.D. in Michigan have infringed VISX's U.S. Patent 4,665,913 by using the Nidek EC-5000 laser system. VISX said it would seek treble damages and legal costs. This is a continuation of the company's battle against laser importer, Nidek.

3/16 Laser Vision Centers announced that same U.S. laser revenue for the month of February increased 40% compared to the same month a year ago. Same U.S. laser revenue compares the revenue generated on 24 lasers that were in operation in February 1998 to the revenue generated by those same lasers in February 1999, and is not equal to total company growth, which would be a higher percentage. The company operated a total of 36 lasers during February 1999. The company noted that surgical case volume increased 56% for the 24 lasers that were in operation in both February 1998 and February 1999. These 24 lasers accounted for 69% of the total U.S. case volume for the month of February 1999.

3/16 I received a copy of an undated report on Eyemakers, LTD., written by John Rooney of Hornblower & Weeks. The report describes the company's strategy, including the acquisition of ICON Laser Centers. (According to Rooney, the report was written in February.) The report is primarily a promotional piece for Eyemakers, describing how, once the ICON acquisition is completed, Eyemakers will begin to establish Eyemakers Laser Vision Stores. (The potential acquisition was reported in our newsletter last November.) The company will employ a retail hub of optical shops, feeding the laser vision center, and will charge about half the normal fee of surrounding centers (about $999 per eye) to encourage procedure volume. Part of the strategy is to use the Nidek laser and thus avoid paying the added $250 royalty fee. The company has taken delivery of the first of 50 Nidek lasers which it has committed to purchasing over the next three years. The Nidek laser was set up in the ICON Scottsdale center and is being used for correction of nearsightedness, while the center's VISX laser is used for all other corrections (astigmatism and hyperopia) at a higher fee of $1450. The HornBlower report states that once the Scottsdale center began advertising refractive surgery at $999 last December, procedures volumes tripled.

Eyemakers/ICON plans to acquire up to 50 refractive centers and/or high volume retail stores necessary to build a $250 million revenue-based company over the course of the next three years. That assumes that all 50 centers can generate $5 million in revenues, based on 5000 procedures per year at an average of $1000 per procedure. The company intends to employ the strategy of "Quality at an affordable price". As the Hornblower report concludes, no center company has yet introduced this strategy into the U.S. market, and Eyemakers/ICON plans to be the first.

3/16 I received an email from Randy Frey, chairman and CEO of Autonomous Technologies letting me know that its merger with Summit Technology was still on track, but delayed until the end of April, due to further SEC review of "truly minor items from Summit and Lens Express three years ago". The following day, the official press release announcement came through stating that both companies had agreed to extend the closing of their proposed merger to a date no later than April 30, 1999. Autonomous and Summit had planned to hold their stockholder meetings on March 30, 1999, but a longer than anticipated SEC review of the S-4 registration statement and joint proxy statement/prospectus has resulted in the delay. Autonomous understands that Summit will file a final amendment to the S-4 within the next few days, with an anticipated effective date and mailing next week. The Boards of Directors of Autonomous and Summit have reset the record dates for the meetings to March 19, 1999 and have rescheduled the actual shareholder meetings for April 29, 1999.

3/16 This month's issue of Refractive Market Perspectives notes that surgeon and institution-owned laser centers have gained market share due to phenomenal growth exceeding 40% over the previous quarter for those segments. Corporate-owned centers reported more modest growth of 10.6% over the previous quarter. The differences in growth rates were attributed primarily to increases in capacity within the surgeon-owned segment, as surgeons purchased new lasers at an unexpectedly high rate during both the third and

fourth quarters of 1998. Although all market segments reported healthy growth, differences in the growth rates led to shifts in market share. Corporate centers now account for 42% of procedures, declining 5% in overall share as compared to the third quarter. Institution owned centers now hold a 19% share -- down from 21% last quarter, while surgeon-owned centers account for 39% -- up from 32% last quarter.

Dave Harmon also notes that the growth in laser centers has expanded capacity over the past six months, with demand for procedures growing to match the expansion -- with signs of excess capacity difficult to find. He notes that corporate centers continue to out-perform the other segments in terms of procedures per laser, but the gap is closing. Of the top ten U.S. procedure per laser centers, five are surgeon-owned. The top five corporate centers in terms of market share are TLC The Laser Center (28%); Laser Vision Centers (20%); Clear Vision (14%); LCA-Vision (11%); and Aris (formerly Vision Correction Centers, Inc.) (7%). The physician practice management companies, including Omega, NovaMed, and Vision 21, have all announced plans for aggressive expansion in this area.

Dave states that the combination of a larger installed base of lasers and indications of strong first quarter procedure volumes point to between 750,000 to 850,000 procedures for this year, compared to 480,000 for 1998.

The newsletter also contains an explanation of VISX's contoured ablation pattern feature for the Star S2 laser. Apparently, the procedure enables surgeons to perform a sequence of ablations precisely controlled by size, depth, and location. The enhancements include an improved interface to adjust the size and shape of the ablation zone, and new controls to offset the center of ablation based on 1-mm grids, corresponding to those printed on most corneal topography elevation maps, which are used to plan the ablation. The process begins with a topography map which apparently can be used to feed the appropriate information to the laser's computer to specify the location, size, shape, and depth of the contoured ablation. The upgrade will be available via KeyCard at no additional charge to VISX international customers following its debut at ASCRS, with use limited to clinical studies in the U.S. pending FDA approval.

Another piece in the newsletter discusses how price discounting of refractive surgery has reached new lows in some parts of the country and Canada. Both LASIK-Vision in Canada and the ICON Laser Center in Phoenix (really in Scottsdale) have recently run price promotions causing a turmoil in the local markets. LASIK-Vision has been promoting LASIK for US$675 into New York and Washington state, although the company's efforts have been somewhat thwarted by a recent expose on local Vancouver TV, with Hugo Sutton, MD, a major stockholder and primary surgeon alleged to have a higher than normal rate of complications, based on several unhappy patients. (Apparently, the problems stems from Sutton's work on high-risk high myopes.) The company has plans to bring its low-cost surgery into the U.S., with centers scheduled to open in Seattle and Anaheim during the second half of 1999.

ICON Vision of Phoenix has also attracted attention, with its $499 per eye advertisements running in local papers (also note the Eyemakers brief above). Apparently, the offer was limited to patients undergoing the procedure prior to April 30th, and to procedures performed on the centers new license/royalty-free Nidek EC-5000 laser. Patients with astigmatism or hyperopia, who need to be treated on the center's VISX laser, are charged $995 per eye. (According to the Hornblower Weeks report, noted above, the real price being charged is $1450!) Harmon notes that to date, these new low-priced competitors have had only a minor impact on the market price and little if any impact on the number of procedures taking place in the local areas.

3/16 Dow Jones News Service reports that Mark Logan, chairman of VISX told CNBC that he now expects about 800,000 procedures will be performed in 1999, up from his earlier estimate of 600,000. He noted that he was surprised at the higher than expected growth in procedures that his company was seeing. The news service also noted that PaineWebber had downgraded its investment rating on VISX to "neutral" from "attractive", due to "valuation concerns" (no explanation given).

3/16 This months issue of Review of Ophthalmology contains an interesting article on new emulsification techniques for removal of cataracts. Included is a description of the new Catarex system, developed by Optex Ophthalmologies, and licensed to Bausch & Lomb Surgical. Basically, Catarex is a tiny propeller system that creates a vortex which emulsifies and removes the cortex without the need to move the probe around within the capsule. There are also descriptions of the various laser techniques being used or under development -- the erbium:YAG system from Premier Laser Systems, the Dodick Photolysis YAG system from ARC Laser, and the Photon Phacolysis YAG system under development by Paradigm Medical. (Not mentioned, were the erbium:YAG laser systems from Aesculap Meditec and from Wavelight.)

3/18 Photogen Technologies announced that it was working with the laser group of Coherent, Inc., to develop and build what is believed to be the first medical ultrafast laser device for treating ocular melanoma (a cancer of the eye) and advanced macular degeneration (the most common cause of vision loss in people over 55 years of age). The new laser device utilizes Photogen's proprietary multi-photon activation technology, and makes use of special laser beam focusing and scanning capabilities. Pre-clinical trials for ocular melanoma and advanced macular degeneration, using this ultrafast laser device with various photoactive agents, have already begun at Massachusetts Eye and Ear Infirmary (MEEI), with which Photogen has a research agreement. The trials are expected to be completed in the near future.

"We have assembled our first prototype ultrafast laser treatment system utilizing our technology that we believe provides more focused laser beam penetration, better spatial control and greater depth of penetration," said John Smolik, Photogen's president and CEO. "The trials at MEEI are the first step toward developing a variety of applications for treating diseases or disorders of the eye using this new ultrafast laser." Photogen's multi-photon activation system is different from conventional photodynamic therapy in

that it uses pulsed, longer wavelength light to more effectively stimulate photoactive agents. This results in defined eradication of the affected area, more precise execution and deeper penetration of therapeutic light into diseased tissue. In contrast, competitors are using a single photon-activation system based on continuous wave, shorter wavelength light, which results in shallower penetration and less precise targeting of the treatment site.

The ocular melanoma study, a joint Photogen/MEEI research project, is already in progress using this new ultrafast laser system under the supervision of Dr. Lucy Young, M.D. According to Dr. Young, Photogen's technology could lead to enhanced survival rates and better visual outcome for patients suffering from ocular melanoma. About 2,000 cases of the disease are diagnosed in the U.S. each year. Dr. Young's pre-clinical trial is expected to be completed by early summer, at which time the study is expected to move into human clinical trials.

The trial for macular degeneration, also a joint Photogen/MEEI project, is being conducted by Dr. Joan Miller, M.D., a renowned researcher in this field. This study will evaluate the effectiveness of a variety of drugs using two different wavelengths. Macular degeneration is a form of vision deterioration that is caused by blood-vessel leakage behind the eye. One form of macular degeneration is characterized by abnormal new blood vessels growing under the retina, leading to severe vision loss. Currently, treatment is limited thermal laser photocoagulation. Conventional photodynamic therapy utilizes a photoactive drug delivered systematically to the new blood vessels followed by light application to seal the abnormal blood vessels. Unfortunately, while relatively selective, there is some damage to collateral tissue with this method.

Photogen believes that it will be able to restrict the area of activation to the new abnormal blood vessels without risk of damaging other areas of the eye. This initial study is intended to provide evidence that Photogen's process is safe and effective and to generate the data needed in designing and gaining approval to begin human studies. Pending results of this study, it is anticipated that a human trial would be the next phase toward commercialization.

3/18 Reuters reported via NewsEdge, that a slew of good news in the past few months, along with increased analyst coverage, had pushed the shares of QLT PhotoTherapeutics past its 52-week high. Prompting the excitement were test results earlier this year that showed its Visudyne, coupled with QLT's unique light therapy, preserves vision in a significant number of patients with a form of AMD. The findings were based on a 12-month analysis of Phase 3 studies using Visudyne. Tests showed vision was stable or improved in 61.4% of patients treated with the therapy compared with 45.9% of patients administered a placebo.

Shares of the biotechnology company have jumped an impressive 110 percent since early January on the strength of the results of this anti-blindness treatment. "It's just the excitement surrounding Visudyne," said Lennox Gibbs, an analyst at CIBC Wood Gundy,

in Toronto. Gibbs added there were no new developments in the past few weeks to fuel the further climb.

The positive results saw a number of new investment houses initiate coverage of the company and prompted others to raise their targets. One such analyst boosting his expectations was Duncan Stewart, a portfolio manager at Tera Capital, in Toronto. "The QLT data was so strong that people are assuming that further data could justify greater numbers," Stewart told Reuters.

3/19 Premier Laser Systems announced that its EyeSys Vision Group had received a response from the FDA regarding its submission for its cataract surgical laser. The FDA reviewed the Phase II controlled clinical trial cases and has requested the documentation necessary for the agency to begin its review for final approval of the Centauri Er:YAG laser. While the FDA has not cleared the system to be marketed for cataract procedures, it has given its approval for ophthalmologists to continue and expand the treatment of patients using the system in the clinical environment. Dr. John Hunkeler, chief clinical investigator for the Centauri and head of the Hunkeler Eye Institute in Kansas City, Mo., said, "If the Centauri receives final clearance to market from the FDA, it will be a significant entry into the cataract surgery market. Unlike conventional ultrasound phaco surgical systems, cataract lasers produce significantly less heat and allow for smaller incisions, resulting in less trauma to the eye." Premier initially submitted clinical data of the Centauri for cataract emulsification to the FDA in December 1997.

Cataract surgical lasers will be the topic of a special laser cataract course hosted by Dr. Hunkeler and representatives of ARC Laser and Paradigm Medical Industries at ASCRS.

3/19 Goldman, Sachs & Co. initiated coverage of VISX, with a two-part report issued by analyst Lawrence Keusch. Goldman started the company off with an "outperform" rating, looking for earnings per share of $2.09 in 1999 and $2.61 in 2000. Further, Keusch forecasts revenues of $215 million for this year and $252 million for next. Sales of lasers are expected to be $51 million in 1999, while royalty income should top $164 million. Larry is looking for 791,000 procedures in 1999 and about 1 million in 2000.

According to the reports, VISX is the market leader, with a 74% share of the U.S. market and an installed base of approximately 300 laser systems, vs. just over 200 for Summit Technology, with over 70 of those traded in for VISX systems. Keusch believes that the U.S. market can tolerate 700 to 1000 lasers over the next couple of years, with VISX likely to place the majority. He believes that the most significant risk to the company relates to the continuing U.S. economy, and the sensitivity of the growth in procedure volume to disposable income. If the market tanks, or slows, it could have an impact on VISX revenues.

3/22 According to Contact Lenses Today, Michael Lachman of Hambrecht & Quist has raised his estimates for laser vision correction procedures in the U.S. to 800,000 procedures for 1999, and 1.1 million in 2000.

3/23 Staar Surgical reported its year-end results, with revenues of $55.1 million for the year, a 21% increase over the $45.5 million of the previous year. John Wolf, chairman and president said, "We saw the beginning of a turnaround in Staar's domestic IOL business during the fourth quarter, spurred both by initial excitement over our Toric IOL and waning enthusiasm for competitive products...During the fourth quarter we achieved two very significant clinical milestones. The FDA approved Phase III clinical trials of the Implantable Contact Lens (ICL) for treatment of myopia and significantly expanded our hyperopia trial, based on the very positive results of the Phase I and Phase II clinical trials. In clinical trials the ICL has delivered the most dramatic and predictable vision improvements of any ophthalmic surgery product, including lasers and other implantable devices. More significantly in the near-term, we received FDA marketing clearance of the STAAR Toric IOL, the only intraocular lens designed to reduce pre-existing astigmatism in cataract patients. Because roughly one of every five cataract patients has pre-existing astigmatism, this is a sizable market that STAAR is now uniquely positioned to address."

3/24 The March 15th issue of Ophthalmology Times contains an excellent overview of the current Nidek vs. Summit and VISX controversy. Headlined, "Will Nidek Prevail in the U.S.?", author Lynda Charters takes a look at all of the lawsuits, including the foreign suits, except for the latest filings where VISX took action against several laser centers and a doctor using Nidek lasers, although the article discusses such a consequence. It concludes with commentary from an intellectual property lawyer, Evan Katz, of the firm Kane Kessler PC, discussing the significance of the actions taken by the foreign courts. He said that generally the standards of law are applied similarly in most countries, but can differ significantly in how strictly various country courts enforce them, and how broad or narrow they allow or require their patents to be. Katz said, "So, if a company's patent is granted or invalidated in a particular country, it generally makes it slightly more likely that the same may occur in another country, but not a certainty."

3/24 Summit Technology finally released its fourth quarter and year-end results. Release was delayed by questions raised by the SEC during its review of the acquisition of Autonomous Technologies by Summit. For the quarter, revenues were $22.4 million, an increase of 13% over revenues of $19.9 million for the same period last year. Revenues for the laser vision correction business increased by 32% in the fourth quarter of 1998, with procedure volume up 64% compared to the fourth quarter of 1997. Income from continuing operations for the quarter was $3.6 million (12 cents per share) as compared to a loss from continuing operations of $400,000 (1 cent per share) in the fourth quarter of 1997. Income from continuing operations in the fourth quarter was favorably impacted by a gain of $2.0 million from the sale of assets related to a cardiovascular laser technology that Summit was previously developing. (The company would not say to whom these assets were sold, but acknowledged that it was either U.S. Surgical or Laser Photonics (AccuLase). Net income in the quarter was $4.5 million, (15 cents per share) which included a gain of $0.9 million on the sale of the company's vision correction centers, compared to a net loss of $400,000 (1 cent per share) in the prior year.

Revenues for the full year were $91.6 million, a 15% increase over revenues of $79.7 million in 1997. Laser vision correction revenues were $44.9 million versus $33.1 million in 1997, a 36% increase. System sales increased by 86% compared to 1997. (Including the sale of 52 new systems and 65 upgrades to the Apex Plus model -- almost all sales and upgrades being done in the U.S.) The number of procedures performed on Summit equipment in the U.S. rose by 25% in 1998 over the prior year, paced by the 64% gain in the fourth quarter of 1998 compared to the fourth quarter of 1997.

Excluding revenues for Lens Express, Summit had laser-related revenues of $10.7 million for the quarter, down from $11.2 million and $12.9 million for the previous two quarters, and total revenues for the year of $44.9 million, up from the restated $33.1 million for 1997, but down from our forecast of $47 million for 1998.

During the accompanying teleconference, Robert Palmisano noted that procedure growth continues strong in the first quarter, building on the strong increase in last year's final two quarters -- following the company's receipt of astigmatism approval. He also said that he expects the Autonomous acquisition will close in late April, which will allow the company to sell both its Apex Plus system and the LadarVision small spot scanning system developed by Autonomous. That company is building systems for inventory until the closing is completed, whereupon it will begin sales to meet a pent-up demand. Commenting on the ongoing litigation between Summit and Nidek, Palmisano said that the court battle was ongoing, unless Nidek decided to settle. He also said that Summit had no intention to file against Nidek laser users, except as a last resort.

As for procedure growth, Palmisano said he was as surprised as everyone else at the number of procedures being done and forecast. He now believes that 800,000 to 850,000 procedures are possible in the U.S. for 1999. He said that Summit's share is now holding steady in the mid-20s, and will likely increase once they get hyperopia approval, expected at any time, and begin to sell the Autonomous system. He also noted that he anticipated that Summit's microkeratome revenues could reach $4 to $5 million in 1999.

3/26 LCA-Vision announced that the holders of the remaining $2 million of the company's 6% Series B-1 convertible preferred stock have converted their shares to 1.2 million shares of LCA-Vision common stock. With the announcement, all Series B-1 convertible preferred shares and dividends have been converted to shares of LCA-Vision common stock.

3/26 Sterling Vision announced a record 90% increase in the number of laser surgery procedures performed on the six excimer lasers owned by its wholly owned subsidiary, Insight Laser Centers, Inc., including those performed at Insight's premier facility located in Trump Tower, New York City. Dr. Robert Cohen, chairman, stated, "I believe that the laser surgery procedure continues to gain widespread acceptance by the general public, all as evidenced by such increases; and we believe that this huge rise in laser procedures will have a positive impact on Sterling's 1999 financial performance."

3/29 LaserSight released its fourth quarter and year-end results. Revenues for the quarter were $3.3 million, compared with approximately $4.0 million in the same period of 1997 adjusted for the sale of LaserSight's two health care subsidiaries sold in December 1997. Excluding these adjustments, revenues for the fourth quarter of 1997 were $6.3 million. Revenues in the quarter were lower relative to prior quarters in 1998 and the fourth quarter in 1997 due to the fact that the company obtained CE Mark approval on the LaserScan LSX excimer laser system on September 30, 1998, which resulted in manufacturing and shipping delays to Europe (because of long lead times on some engineering components), one of the Company's key markets since it currently only sells lasers internationally. As a result, the company sold 8 lasers in the fourth quarter compared with an average of 14 lasers in prior quarters in 1998, because it was unable to ship as many units to Europe as expected. For the year the company sold 50 laser systems compared to 46 systems in 1997. The company expects that during the first quarter of 1999, unit sales levels in the international markets should return to levels similar to that of the first three quarters of 1998.

For the fourth quarter, the company reported a net loss of $6.0 million (46 cents per share) compared to a net loss of $5.0 million (53 cents per share) in the same period of 1997, reflecting adjustments for the gain on the sale of the two health care subsidiaries sold in December 1997. Excluding these adjustments, the net loss in the fourth quarter of 1997 was $1.8 million (20 cents per share).

For the year the company's revenues were $17.8 million, compared to $13.3 million in 1997, including adjustments for the sale of the two health care subsidiaries sold in December 1997. Excluding these adjustments, total revenues for 1997 were $24.4 million. The company incurred a net loss for 1998 of $11.9 million ($1.26 per share) as compared with a net loss of $10.5 million ($1.14 per share) in 1997, adjusting for the gain on the sale of the two health care subsidiaries sold in December 1997. Excluding these adjustments, the net loss was $7.3 million (80 cents per share). The company's increased loss in the fourth quarter of 1998 was the result of lower revenues combined with higher expense in preparation for the launch in 1999 of its MicroShape family of keratome products and the anticipated introduction of its excimer laser system in the U.S. LaserSight will launch its MicroShape family of keratome products and blades for sale in the U.S. and internationally this year. The company expects to start shipping its ADK UniShaper single use (disposable) keratome in April to international markets with shipments in the U.S. to follow shortly thereafter, while expecting to start shipping its UltraShaper reusable (stainless steel) keratome in the second quarter internationally and in the U.S. following anticipated clearance of its 510K filing for the product shortly thereafter. The company also expects to enter the market with its high quality UltraEdge blades used in keratomes during the summer of this year. The company has established a new blade manufacturing facility with production scheduled to begin in May 1999 and ramp up to 10,000 blades per month per shift, over the ensuing months. Indications of customer demand for the company's keratome and blade products have exceeded management's expectations due to the strong growth in refractive surgery procedures in 1998 and anticipated in 1999. The company already has a significant order backlog.

With the recent $ 9 million in financing and added infrastructure, the company is confident that it will successfully meet demand for its products and achieve significantly higher revenues in 1999 than in 1998. (I have raised my forecast for company revenues to $30 million for 1999, up from $28 million last fall.)

The company's PMA application for its scanning excimer laser system, which was filed in the second quarter of 1998, is under final review by the FDA, and hopefully, will be approved for sale into the U.S. market by this summer. The company has completed the biomonitoring audits with the FDA and awaits the final stages of review and inspection, including GMP and labeling issues as required by the FDA. The LaserScan LSX excimer laser system has been received positively in the international market by some of the world's leading refractive surgeons.

On March 23, 1999, the company completed a $9 million equity private placement with certain existing (Pequoit Industries and TLC The Laser Center) and new institutional investors. In connection with this financing, the Company issued 2,250,000 common shares and warrants to purchase 225,000 common shares at a price of $5.125 per share.

Michael R. Farris, CEO, commented, "1998 was an important year for LaserSight as we created a number of key strategic alliances and prepared several products for launch into the U.S. market. These strategic alliances include an equity investment made by TLC The Laser Center, the largest vision correction corporate centers company in North America, and a joint venture arrangement with Humphrey Systems to develop topography planned laser vision correction." Mr. Farris added, "We believe that the launch in 1999 of our products is very timely given that the refractive eye care industry is experiencing tremendous growth with U.S. procedure volumes projected to reach 800,000 in 1999 and 1,200,000 in the year 2000. We expect to be a significant player in this industry."

3/29 According to EyeWorld Week, Presby Corp. won FDA approval to begin Phase I clinical trials for its scleral expansion band for the surgical reversal of presbyopia. The initial study will take place at six sites: Barnes Hospital of Washington University in St. Louis, Dean A. McGee Eye Institute in Oklahoma, Jules Stein Eye Institute in Los Angeles, New York Eye and Ear Infirmary, Stanford University, and the Storm Eye Institute of Charleston. Five eyes from each center will be treated, for a total of 30 eyes.

3/29 BancBoston Robertson Stephens senior medical devices and medical technologies analyst Wade King, M.D., today reiterated his "Buy" rating and raised estimates on VISX, Inc. "We are raising our estimates on VISX to reflect both the phenomenal growth in the domestic LVC market and VISX's dominant market share and successful execution," said King. "For 1999, we are raising our revenue estimate from $218 million to $227 million and increasing our earnings per share estimate from $2.10 to $2.25. For 2000, we are raising our revenue estimate from $248 million to $271 million and increasing our earnings per share estimate from $2.70 to $3.00."

OPHTHALMIC LASER UPDATE -- APRIL 1999

3/29 **Bausch & Lomb** announced that it had signed an agreement to purchase **Orbtek, Inc.**, a privately held ophthalmic diagnostic technology company based in Salt Lake City, Utah. This is the second acquisition in 1999 for the global technology-based eye-care company's growing surgical business, the first being the acquisition of **Hansa Research & Development**, the developer and manufacturer of the Hansatome. Orbtek is known for its unique diagnostic instrument, Orbscan II, which is designed to take and integrate multiple measurements of the anatomical interior and surface topography of the eye. The measurements form a "map" by which ophthalmic surgeons perform various procedures, including LASIK to correct myopia, hyperopia, and astigmatism. This new technology can give the surgeon the ability to do truly "customized" ablation according to the patient's individual ocular physiology. It will be a significant enhancement to Bausch & Lomb's Technolas 217 excimer system which is currently awaiting approval for the U.S. market.

"This unique technology is a natural addition to the platform of refractive solutions we have in our portfolio," said Hakan Edstrom, senior vice president and president of **Bausch & Lomb's Surgical and Pharmaceuticals** businesses. "We believe enhanced diagnostics can take refractive surgery to the next level of performance in terms of patient outcomes. This device has the potential to generate improvements in any of the emerging vision correction procedures." In addition to its application in laser refractive surgery, Bausch & Lomb expects the Orbscan unit to be utilized in a variety of other ophthalmic surgery applications including phakic intraocular lens implantation for patients with higher levels of myopia and hyperopia, and cataract surgery.

3/30 **Sight Resource** reported operating results for its fourth quarter and year. For the year the company reported revenue of $55 million, up 23% from last year's $44.6 million. The gains in revenue reflect the April 1, 1998 acquisition of **Eyeglass Emporium** and the July 1, 1997 acquisition of **Vision Plaza**. The company reported a net loss of $985,000 (11 cents per share) compared to a net loss of $4 million (46 cents per share) for the prior year. The $985,000 net loss for the year included charges of $276,000 associated with changes in senior management occurring in 1998, a $417,000 provision for charges associated with inefficiencies in prior accounts receivable systems and procedures and an increase of $270,000 for accounts receivable allowances. The $4 million net loss for the prior year included a $2 million dividend to holders of Series B Convertible Preferred Stock, a $400,000 charge for the write-off of software associated with the company's point-of-sale system and a provision of $110,000 for store closings.

For the fourth quarter, the company reported revenues of $12.6 million, an increase of 10% over revenue of $11.4 million for the prior year period. The company reported a net loss of $1.2 million (14 cents per share) compared to a net loss of $3.4 million (40 cents per share), including the $2 million dividend to holders of Series B convertible

preferred stock, for the prior year period.

3/30 **Nidek Co. Ltd.** of Japan and its U.S. subsidiary **Nidek Incorporated**, announced that it had filed an antitrust lawsuit in Federal Court in the Northern District of California against **VISX**. The suit alleges that VISX has violated federal and state antitrust laws and federal false advertising law with the intent to monopolize the market for excimer laser refractive surgery systems to the harm of U.S. consumers. Nidek requested that VISX be permanently enjoined from engaging in these activities and that VISX's patents be declared unenforceable. If successful, Nidek would receive monetary damages, including treble and punitive damages, and its attorneys' fees and costs.

Nidek claims that VISX has engaged in an integrated series of exclusionary and anti-competitive acts and strategies which are designed to increase the costs of its rivals and raise barriers to entry and expansion, which ultimately harm consumers. These acts and strategies include: (1) acquiring competitors and forming a joint venture with its principal competitor in the U.S. to eliminate challenges to its unenforceable patents, with which it could attempt to exclude Nidek as well as other potential competitors from the market; (2) maintaining and attempting to enforce patents obtained by fraud or otherwise known by VISX to be unenforceable; (3) entering into anti-competitive and exclusionary agreements with providers of laser refractive surgery that prohibit and hinder those providers from using excimer lasers manufactured by competitors of VISX; and (4) making false statements about Nidek to potential customers of Nidek's laser surgery systems in the U.S.

Nidek alleges that although VISX claims to permit other manufactures to acquire licenses for producing excimer lasers, their licensing conditions are so onerous that other manufactures are effectively precluded from entering the market. One particularly onerous condition opposed by Nidek is the requirement to impose and collect a per-procedure fee of $250 from its customers. As stated by Hiroshi Okada, vice president and general manager of Nidek Inc., "Nidek intends to open the refractive market to cutting edge technology and will vigorously defend the refractive surgeon's right to freely choose the latest refractive technology to benefit their patients and advance the refractive market. It is inherently wrong for a company to control access to a medical procedure, which in effect is what VISX is attempting to do through the use of fraudulent patents. The patent laws of most countries recognize that public good and advancement of technology suffers when medical science is held hostage." A recent change in U.S. patent law now prohibits the patenting of a medical procedure. (But the VISX patents in question were issued prior to the new law being enacted.)

Nidek alleges that fraud and inequitable conduct during activities before the U.S. Patent and Trademark Office (PTO) render VISX's patents unenforceable. Many of VISX's patents are based on excimer laser patent applications filed by Francis L'Esperance, Charles Munnerlyn, and Stephen Trokel more than a decade ago. Their competing patents and patent applications provoked several interference actions which

exposed the existence of forged documents, material misrepresentations to the PTO, and disputed dates of invention. In addition, Nidek claims that VISX has intentionally withheld material prior art from PTO examiners, and that Trokel was not the sole inventor of U.S. Patent No. 5,711,762, having derived the technology from an IBM researcher in the field, Dr. Rangaswamy "Srini" Srinivasan.

3/30 **Autonomous Technologies** and **Summit Technology** announced that the Joint Proxy/Prospectus for the proposed merger of Autonomous into a subsidiary of Summit had been made effective by the Securities and Exchange Commission and that copies of the document had been mailed to stockholders of both companies. On October 1, 1998, Autonomous and Summit announced the agreement to merge Autonomous with or into a subsidiary of Summit Technology, subject to a vote by the stockholders of both companies. The board of directors of both companies had unanimously approved the merger.

The agreement calls for Summit to acquire all of Autonomous' outstanding shares for cash and stock. The actual value of the transaction will not be determined until closing. Autonomous stockholders will receive 11,650,400 shares of Summit stock and an equal amount of value in cash, not to exceed $50 million. The per share consideration will be a function of the average closing Summit stock price for the five days before the closing of the merger and is more fully described in the Joint Proxy/Prospectus. A special meeting of stockholders and closing date is scheduled for April 29, 1999. (For some interesting news about both companies, see my read of the prospectus below.)

3/30 Chicago area ophthalmologist Mitchell Jackson, M.D., successfully performed LASIK on Chicago Bears kicker Jeff Jaeger. Dr. Jackson says Jaeger was able to see 20/20 with both eyes on day one after the procedure without relying on corrective lenses. Jaeger said he was thrilled with the outcome and just after the completion of the procedure exclaimed, "I can see the clock on the wall!" Jaeger joins several other athletes like Dallas Cowboys quarterback Troy Aikman, Arizona Diamondback outfielder Bernard Gilkey, San Diego's Wally Joyner and Tampa Bay's Wade Boggs who have had the LASIK procedure to correct nearsightedness or myopia. Jaeger, a 12-year NFL veteran, said he selected Dr. Jackson to perform the procedure after talking with a friend who underwent LASIK and was extremely pleased with the outcome. "Jeff is a good candidate for the LASIK procedure," according to Dr. Jackson. "As a professional football player, wearing a helmet makes wearing glasses impossible, and there is a high risk of getting something under your contact lens and not being able to see the action on the field." Jackson says Jaeger's prescription made him a perfect candidate for LASIK.

3/30 **VISX** announced the launch of its Contoured Ablation Pattern (CAP) method which enables physicians to perform specific ablations for the treatment of irregular corneas. With the CAP method, doctors can perform a sequence of ablations precisely controlled by size, depth, and location, making it possible to reshape the cornea into

the most optically desirable surface. This is combined with the smoothing effect of the Star S2's seven-beam scanning technology to treat irregularities that tend to distort visual acuity or affect the quality of vision. The upgrade will be available via VISX's VisionKey Card for international customers, following its debut at the 1999 ASCRS meeting, and for U.S. customers, following FDA approval.

According to VISX, the CAP method can work in tandem with corneal topography, allowing surgeons to plan ablation patterns over the pre-operative topography, to design the best possible ablation sequence for an individual cornea. Topography planning modules are currently being developed by leading topography companies with cooperation from VISX. (For more about one such system, see the **EyeSys** announcement below.)

3/31 **Omega Health Systems** announced that it had expanded its web site, www.omegahealth.com, in line with its new strategic focus and major initiative to expand Omega's laser vision correction capabilities. The new site features information about laser vision correction, patient education links, and new developments at Omega. The site also includes search engines to direct patients to Omega surgeons across the country who are performing this procedure and to optometrists in their area for primary eye care. Omega recently agreed to acquire 12 **VISX** STAR S2 excimer lasers from VISX. The Omega web site will include a link to the VISX site to enable potential surgical candidates to understand more about the procedure and laser technology.

3/31 **Varilux**, the progressive addition lens company, a subsidiary of **Essilor of America, Inc.**, which in turn is a subsidiary of **Essilor International**, posted a news release about presbyopia, stating that the condition currently affected more than 100 million Americans. "As the baby boomer generation continues to age, the number of people with presbyopia will increase dramatically," said Dr. Rodney Tahran, vice president of professional relations and clinical affairs for Varilux. "Although the eye condition is irreversible, there are better solutions available now than ever before to treat presbyopia."

Presbyopia occurs when the cells in the crystalline lens of the eye keep growing and multiplying, but the capsule that encloses the lens loses its elasticity. Eventually the cells become so densely packed that the lens can't change shape when trying to focus on near objects. Progressive addition lenses allow for different prescriptions in one lens, thus eliminating the "old age" line and "vision jumps" (due to sharp breaks in prescriptions) associated with bifocals and the hassles of taking reading glasses on and off. (Of course, bifocal contacts and monovision, either with contact lenses or by laser vision correction, are yet other options.)

3/31 **VisiJet** announced that it had filed for FDA approval of its HydroKeratome device, to be used with LASIK surgery. The HydroKeratome would replace the microkeratome for creating the LASIK flap. VisiJet's HydroKeratome uses a supersonic beam of

water to make the corneal cuts, instead of a metal blade. The thickness of the water jet beam is less than the size of a human hair, and provides a cleaner, smoother cut than the blade can provide. The company holds the rights to 9 issued patents and 4 patents pending in the waterjet area, including one specifically describing the device and its use as a corneal cutting instrument.

4/5 *ContactLens Today* reported that legislation seeking to enable optometrists to use lasers had been introduced in Florida. The bill would allow optometrists to use lasers to treat glaucoma, secondary-cataract surgery conditions, and retinal disease; and to perform refractive correction. A separate bill would allow ODs to prescribe systemic medications.

4/5 *Optistock* reported that US Bancorp Piper Jaffray initiated coverage of **Bausch & Lomb** with a "buy" rating, citing future divestitures of its Eyewear and Miracle Ear divisions as positives. The newsletter also reported that a suit had been filed by **Laser Vision Centers** against **Nidek**, **Custom Trailerwerks**, and a former LVCI employee charging that the three used proprietary information about LVCI's mobile refractive laser surgery services to compete unfairly with the company in that business. Among other things, LVCI alleged patent infringement and breach of agreement.

4/5 According to *Optical Buyers Guide*, the FDA has accepted two premarket approval applications (PMAs) for LASIK studies sponsored by **CRS Clinical Research**, and promised to expedite the reviews. CRS submitted the two PMAs to cover LASIK as performed with the **Summit** Apex Plus laser and **VISX** Star laser. Treatment under the PMAs is for myopia up to -14 D with up to 6 D of astigmatism. CRS says that approval of the PMAs would lessen the liability risk of surgeons who are currently performing LASIK as an off-label procedure on an approved device. The PMAs will be considered by the FDA's Ophthalmic Devices Advisory Panel in July. CRS is a not-for-profit California corporation whose LASIK studies are funded by participating surgeons.

4/5 I received a news release concerning a paper to be presented at ASCRS, entitled, "Wavefront-Guided Customized Ablations-Beyond Topography-Assisted Refractive Surgery". The paper will be presented by Drs. Marguerite Mcdonald, Ronald Krueger, George Pettit, and Raymond Applegate, O.D., who will review the platform needed to utilize wavefront sensing in the application of customized ablations. A review of current technology, visual function modeling and refractive map clinical measurements will illustrate how this technology can be applied for customized ablations. The wavefront sensing platform will be contrasted with topography-assisted ablations to show its utility, limitations and opportunities in refractive surgery. (This is a "favorite" subject of mine. The named doctors will be discussing the **Autonomous Technologies'** system, which is still under development.)

4/5 I received copies of two updated analyst reports on **VISX**, one from analyst Matthew Dodds of **Warburg Dillon Read**, raising his estimates for procedures, revenues and

target share price; and the second from Wade King of **BancBoston Robertson Stephens**, commenting on the business momentum remaining very strong, and expanding on his last report at the end of March.

Highlights of Mathew Dodds' report: He now believes that 840,000 LVC procedures will be done in 1999, up from his previous estimate of 795,000, and that VISX would capture 77.5%, or 650,000 of those. His revenue model now shows $239 million in 1999 for VISX (my $180 million estimate now looks puny!), and $294 million for 2000. Dodds thinks that there will now be 225 lasers placed in 1999, to support his 840,000 procedures, while an additional 110 lasers will be sold in 2000, in support of his 1.39 million procedure estimate. He notes that **Nidek** has not had much success placing systems, even though their laser is priced below VISX's, nor does he believe that the **Autonomous** acquisition by **Summit** will provide much assistance to Summit's current market position.

Of the 225 lasers to be placed this year, he believes that 180 will be sold by VISX, to maintain their 80% share of systems in place, while 77.5% of procedures will be done on VISX systems. He also has decided that the per procedure price will hold at $250 (actually $260 for the VISX VisionKey Card) and not decline in 1999.

Highlights of Wade King's update report: "VISX continues to dominate the domestic LVC market and to execute successfully in this rapidly growing marketplace. Going forward, we believe that VISX will continue to both dominate the domestic LVC market and exceed street expectations."

His model assumes that doctors will use VISX lasers to perform over 655,000 procedures in 1999, and approximately 915,000 procedures in 2000, with the totals for the two years to be 910,000 for '99 and over 1.32 million in '00! (The estimates keep going higher and higher -- and will soon meet my projections made in 1992!)

King believes that the domestic market for laser systems is now over 50% penetrated, although VISX reports a significant backlog of orders for its Star S2 system, making his system sales estimates somewhat conservative. His VISX revenue model still calls for $227 million for '99, and $271 million for '00 (much more conservative than Mathew Dodds' estimates above).

4/6 **LCA-Vision** reported that same-center procedure volume for the first quarter of 1999 increased significantly. For the three months ended March 31, 1999, volume at the company's U.S. wholly owned centers increased 119% to 7,326 procedures, compared with 3,348 procedures for the comparable 1998 period excluding 178 procedures performed at centers subsequently closed. On a sequential quarterly basis, first quarter procedure volume was up 36%, compared with 5,396 procedures performed during the 1998 fourth quarter.

"This quarter's U.S. same-center procedure volume was the highest in the company's

history, and we fully expect this healthy growth trend to continue," commented Stephen Joffe, M.D., chairman and CEO of LCA-Vision. "The accelerating rate of patient acceptance fueled by positive word of mouth, coupled with media visibility within the U.S. market has helped to drive overall industry growth. Indeed, several securities analysts have recently raised their estimates for total U.S. laser vision correction procedures to around 800,000 during 1999, and more than 1.1 million in 2000."

System-wide procedure volume, which includes U.S. and Canada wholly owned centers, increased 105% in the first quarter of this year to 7,591 procedures, compared with first quarter 1998 procedure volume of 3,699 excluding 178 procedures performed at centers subsequently closed. Wholly owned system-wide sequential quarter procedure volume rose 34%. "During the 1999 first quarter, we saw slowing growth in Canada, where we have been performing procedures since 1991, due to general market maturity and procedure pricing competition," added Dr. Joffe.

4/6 In conjunction with the **VISX** CAP method announcement above, **Premier Laser Systems** announced that its **EyeSys Vision Group** would demonstrate Foresight for VISX, a new software package that simulates the PRK/LASIK procedure for the VISX STAR S2 excimer laser system, at the ASCRS meeting in Seattle. The software allows the refractive surgeon the ability to better plan and execute vision correction procedures. According to the announcement by Premier Laser chairman, president and CEO Colette Cozean, Foresight for VISX is the result of a joint development program between EyeSys and VISX Inc. Foresight applies the planned ablation data to the pre-operative corneal image and then generates a topographical map of the most likely post-operative results. The software provides a tool that allows surgeons to visually customize refractive ablation procedures, which may optimize these surgical outcomes. The software package is expected to be available for shipping in May, and is priced at $985.

4/6 I received a copy of **Summit Technology/Autonomous Technologies** joint proxy/prospectus for their merger scheduled for the end of April. Perusal of the prospectus found several interesting items that I was not aware of previously, mostly for Summit. In the "risk factors" section, "Summit believes that some users of its Apex excimer system in the United States have tampered with the software configuration of their systems to defeat the card reading system that facilitates the collection of per procedure license fees." (Later in the "recent development" section, one of the items notes that the company entered into a settlement agreement with **Field Service Engineering Associates** in December 1998, resolving their outstanding litigation. Summit had filed a suit against Field Services alleging that it had serviced unapproved laser systems, including tampering with the lasers to disable the cardreaders.)

Summit also acknowledged that since August 2, 1996 there were 16 separate shareholder legal actions taken against the company, and multiple state and federal

antitrust lawsuits pending against both Summit and **VISX**, related to the **Pillar Point Partners** arrangement, now dissolved.

Other items under the legal section in "recent development": On February 23, 1999, the U.S. District Court for the Western District of Texas, granted summary judgement in favor of Summit, **Summit Partner**, and Pillar Point, in the action taken by John Taboada vs. VISX claiming he was the sole inventor of certain VISX patents. Summit is no longer a defendant in the case. The other surprise potential legal action was a letter that Bob Palmisano received from Olivia Serdarevic, MD, claiming that she had inventorship rights in both the Marshall and Azema patents! (Yes, she was around in the early days at Columbia Presbytarian with Fran L'Esperance and Steve Trokel, but the Marshall work was done in the UK, and the Azema patent covers work done in France by **Biophysique Medicale**! How she was involved in the invention of those patents is beyond me. Although, she does appear to travel extensively -- based on her columns that appear in *Ophthalmology Times*.)

The other interesting information involves work underway at Autonomous on its both its LadarVision system and the Custom Cornea device. Noted are that Autonomous has filed for a U.S. patent for the Custom Cornea diagnostic device and that certain claims have been allowed by the Patent Office. A working model of the device has been built and used to measure the visual acuity of 100 patients. As for the LadarVision system, 13 patent applications have been filed in the U.S., with five resulting in patents issued to date. The patents and applications cover the following:

- A cartridge excimer laser device for high serviceability (Apparently, the excimer laser portion of the system can be easily removed for servicing or replacement.);
- Fast response eye tracking;
- Fast and accurate optical narrow beam delivery system with tracking;
- Ablation with shot pattern, with minimal sensitivity to ablation debris;
- The algorithm for reshaping with arbitrary combinations of plus and minus sphere and cylinder;
- Custom Cornea; and,
- Measuring vision defects of a human eye.

One other interesting note, that I was aware of but had forgotten, the Autonomous license of the IBM patent is still owned by IBM -- not **LaserSight**, and Autonomous has an automatic right of renewal for another four year term upon expiration in 2000, subject to a fixed limit increase in royalty rates thereafter. (Upon expiration of the

second term, the applicable patent will have expired.)

4/6 **VISX** announced that it was initiating a multimedia national consumer advertising campaign, designed to increase awareness and consumer demand for VISX doctors and centers. The campaign is scheduled to begin this summer and continue throughout the year. It is expected to increase demand and guide consumers interested in laser vision correction to seek out a VISX-certified physician. The campaign will begin with national radio flights and insertions in widely read print publications. The campaign is designed to work as an umbrella for local practice or center-specific advertisements. VISX customers can expect to receive the campaign kit in early June.

4/7 **TLC The Laser Center** announced that it had formed **TLC USA, LLC ("TLC USA")**, a nationwide venture in laser vision correction services with **The Permanente Federation, LLC ("Federation")**, **Kaiser Permanente's** national association of **Permanente Medical Groups**. TLC USA was established to develop quality laser facilities in which Permanente physicians and community eye care professionals can serve the vision correction needs of Kaiser Permanente's membership and other "self-pay" patients. Initially, TLC USA will concentrate on providing laser vision correction services in California, with plans to also develop centers in other states.

Francis Crosson, MD, executive director of the Federation, stated, "We are enthusiastic about participation in this venture with TLC. TLC has a dedication to quality and service similar to that of the Permanente physicians, and the joint venture promises an excellent strategic and cultural fit in the service of our members." Elias Vamvakas, TLC's president and CEO, stated, "The signing of this agreement exemplifies TLC's ongoing strategy of partnering with the best doctors in every market. It also expands our focus in some of the most significant markets for laser vision correction in the country."

TLC USA will be owned by TLC and The Permanente Federation, LLC.

The following day, Fred Toney and Al Kildani of **Pacific Growth Equities** released their update report on the TLC/Kaiser Permanente announcement. They note that TLC currently operates 3 centers in California, and they expected the joint venture to open an additional 4 centers in that state over the next six months, with a total of 10-12 centers in operation in California within a year.

Their read on the agreement: Kaiser will market LVC services to its member base with procedures to be performed by Kaiser surgeons. These surgeons will use TLC USA's centers exclusively, and Kaiser will pay an access fee, somewhere near $1000 per procedure. In return, TLC will provide the necessary technical support staff. Kaiser will set its own pricing policy, and the analysts expect that it will be premium priced similar to that employed by TLC centers. Until the new centers are built, Kaiser will use a pre-existing TLC center unless there is not one nearby. In any area where Kaiser has a presence, the joint venture will not develop a new center until

capacity at any nearby center is exhausted. In addition to Kaiser business, TLC will operate its own separate LVC practice at these centers using its standard co-management model. Toney and Kildani believe that the joint venture structure will significantly reduce the time it takes a center to achieve profitability -- usually 12-14 months -- by providing a more immediate flow of patients.

4/9 *NewsEdge* reported that U.S. Patent 5,888,243 had issued on March 30th to **KeraVision**, entitled, "Hybrid Intrastromal Corneal Ring". The abstract reads: This invention is an intrastromal corneal ring housing comprising at least one outer layer of a physiologically compatible polymer having a low modulus of elasticity, which polymer may be hydratable and may be hydrophilic. The inner portion of the hybrid intrastromal corneal ring may be hollow or may contain one or more physiologically compatible polymers.

4/9-
4/13 The FDA announced that it had approved the **KeraVision** Intacs (intrastromal corneal rings) for the correction of mild myopia (-1 to -3 diopters) and no more than 1 diopter of astigmatism. This approval was slightly less than suggested by the FDA's Ophthalmic Devices Panel (who had said the rings were approvable for up to -3.5 diopters of myopia), and without the label claim for reversibility, although the FDA, in its "Talk Paper" about the approval, did say that although the Intacs are considered to be permanent implants, they can be removed if necessary, and in most cases, vision returns to its pre-surgery level, but some patients may have visual symptoms of glare, halos, etc. after removal.

Dow Jones Business News reported that KeraVision had asked the FDA to approve Intacs for the 22 million adults in the U.S. with **mild to moderate** nearsightedness. However, the FDA only granted approval for people who are mildly nearsighted because the agency said the product's safety and effectiveness hadn't been proven for moderate or severe cases. Also, Ira Loss, an analyst who follows KeraVision for **HSBC Washington Analysis**, said because the FDA denied KeraVision's request to label Intacs as reversible, the market would probably view it as a negative. Soon after the FDA's ruling was announced KeraVision's stock price rose to an interday high of 17 1/2; however it soon fell below opening level and finished the day off 1 3/4 at 13 5/16 in heavy trading.

Loss said the Intacs' approval wasn't as broad as the approval for laser surgeries, which use laser beams to remove small amounts of tissue to change the cornea's shape. "They're not going to overtake and surpass lasers," Loss said. "They're not going to get the bulk of the procedures, but they can get a nice percentage of the procedures and do quite well."

A KeraVision spokesman said the Intacs will cost between $2,000 to $2,500 per eye and will be available immediately. The company is studying a version of Intacs for the treatment of hyperopia, as well as thicker versions for treating higher degrees of

myopia.

A flurry of announcements followed the approval: Dr. Robert Maloney released a statement that he would perform one of the first surgeries following the approval at his Vision Institute on April 26th. KeraVision announced that the product had been developed over 13 years at an investment of nearly $100 million, and that it was developing the Intacs technology to possibly treat hyperopia and astigmatism -- the two most common vision problems after myopia. The company plans to commence commercialization upon receipt of pending 510K clearance for a few selected instruments. KeraVision has taken the following steps to prepare for the U.S. launch of Intacs for myopia:

-- *Surgeon training.* Six sites have been established to train U.S. surgeons in the Intacs treatment: Atlanta, Houston, Kansas City, San Diego, Santa Monica, Calif., and St. Louis. Each site is headed by a prominent ophthalmic surgeon who will lead the training. To promote optimum clinical results, the company will proctor surgeons once they return home and begin performing the Intacs treatment.

-- *Sales team.* The company has hired 11 direct sales representatives and four manufacturers' representatives, all considered leaders in the ophthalmic sales field. Their initial focus will be on what the company believes to be the fastest growing vision correction surgery markets where excimer laser procedures have already gained acceptance. As a value-added service, the sales team will work with individual surgeons to help build their overall vision correction surgery business.

-- *Market development.* A multi-media advertising campaign is being tested in a major Canadian market and is intended for use in the U.S. As surgeons are trained in the Intacs treatment, the company intends to help create consumer awareness with locally-oriented advertising and publicity activities.

-- *Initial revenue base.* Intacs are expected to be commercially available immediately in 13 markets consisting mainly of cities where the Intacs clinical studies were conducted, including: Atlanta, Fayetteville, Ark., Houston, Kansas City, Los Angeles, Minneapolis, New York, Portland, Ore., San Diego, San Francisco, St. Louis, Tampa and Washington, D.C. The company expects to enter other U.S. markets as it trains additional surgeons.

On April 12th, KeraVision announced two agreements to make its Intacs product more widely available. The agreements were with **ARIS Vision**, a privately-held refractive surgery management company (formerly **Vision Correction, Inc.**), to make Intacs available at Aris's 12 vision correction surgery centers in metropolitan Boston, Northern and Southern California, and Salt Lake City. The second agreement was with **NovaMed Eye Care**, a second privately-held eye care services company specializing in vision correction. NovaMed also has 12 surgical sites, in metropolitan Chicago, Kansas City, St. Louis, Louisville, and Richmond, Va.

On the 13th, **LCA-Vision** also got into the act, announcing that it was already performing the implant procedure in its Toronto center and would make Intacs available at its U.S. centers once the product is readily available.

4/12 According to *Optical Buyers Guide*, the Florida OD laser access bill reported on in last month's newsletter, has been withdrawn. The bill, which would have eliminated Florida's prohibition against optometrists performing laser surgery, was introduced in the state House in early March, but didn't live through the month. House bill 843, written by state Rep. Everett Kelly (R), was withdrawn from further consideration on March 24th. According to Sherry Cooper of the *American Optometric Association*, many such bills have been introduced in various state legislatures over the past few years. Only Oklahoma currently allows optometrists to perform ophthalmic laser procedures.

The newsletter also reported that **AmSurg** was negotiating to buy **Physicians Resource Group's (PRG)** interest in its ambulatory surgery centers. The company had entered a letter of intent with PRG to purchase a portion of its ownership interests in its practice-based ophthalmic ambulatory surgery centers (ASCs). AmSurg is not acquiring interest in PRG physician practices, according to a joint company press release. The deal is subject to stockholder approval and the outcome of negotiations AmSurg must conduct with each individual ASC. AmSurg develops, acquires and operates physician practice-based ASCs and specialty physician networks in partnership with surgical and
other group practices. AmSurg owns a majority interest in 52 centers and has three centers under development.

4/12 **Omega Health Systems**, following up on the announcement to expand its role in laser vision correction made in February (see our February 8th brief), announced that it had accepted delivery of two **VISX** STAR S2 Excimer Laser Systems and had established laser centers at the company's eye care centers located in Memphis, Tennessee and Omaha, Nebraska. The Memphis location is known as **Southern Eye Associates** and the Omaha location is known as **Omaha Eye Institute**. The first laser vision correction procedures utilizing the new lasers were performed on April 8, 1999. In connection with this new initiative, Omega had agreed to acquire a total of 12 VISX STAR S2 excimer lasers from VISX. Fixed-site lasers will be placed in Omega's high volume locations and a mobile program utilizing shared-site lasers will service its lower volume locations.

4/12 According to *OptiStock*, **First Venture Capital** finished its acquisition of **Lasik Vision Canada** shares, completing a private placement of special warrants, and implementing a stock option plan. The company is also changing its name to **Lasik Vision Corporation**.

The newsletter also reported that **VisiJet**, of California, filed for FDA approval of its HydroKeratome device, a waterjet cutting tool used in LASIK. The company says its

device provides a cleaner, smoother cut than currently used metal blades and has a disposable component that ensures sterility for each patient. VisiJet may consider issuing an IPO in a few months.

4/13 **TLC The Laser Center** announced its results for the three months ended February 28, 1999. Results were characterized by continuing record revenues and profitability. All were driven primarily by strong growth in the number of refractive laser procedures performed. Fiscal 1999 third quarter gross revenues more than doubled to $56.5 million from $25.4 million for the same period a year ago. Net revenues grew to $41.3 million, up 177% from the fiscal 1998 third quarter total of $14.9 million. Over 25,600 laser procedures were performed at TLC refractive clinics in the third quarter which is a 173% increase from 9,381 for the same period a year ago and represents a 42% increase from the 18,017 procedures last quarter. TLC's net profit for the quarter was $3.6 million (11 cents per share), versus a net loss of $2.3 million (8 cents per share) for the corresponding period a year ago.

Included in the 11 cents per share third quarter net profit was a loss of 3 cents per share from **Partner Provider Health (PPH)**, TLC's managed care subsidiary. Managed care expenses consisted of costs associated with developing PPH. As previously disclosed, the company plans to restructure its secondary care and PPH businesses and make no further investments in those areas. In connection with the restructurings, TLC intends to incur a non-recurring charge in an as yet undetermined amount in the fourth quarter of fiscal 1999. More than 90% of third quarter net revenues, and 100% of income from operations, were generated by the company's core business, refractive laser surgery.

In the accompanying teleconference, Elias Vamvakis noted that same store growth for the quarter was 111%. He also said that the company planned to pursue alliances with major companies to provide their vision care needs, mentioning the recent agreement with Kaiser Pemenante and several others such as Ernst & Young and Prudential as examples. The **VISX** patent problem was mentioned, but Vamvakes thinks its premature to say whether it will mean any reduction in per procedure fees. He also said that pricing at his centers was holding up, even in the face of price competition. He said that 90% of the procedures being done by TLC are at its U.S. centers.

The company also announced the filing of a multi-jurisdictional disclosure system registration statement containing a preliminary prospectus with the securities regulatory authorities in Canada and the U.S. SEC relating to a proposed public offering of 4 million common shares and up to an additional 600,000 shares to cover underwriter over-allotments. 1.4 million shares are being offered and sold by certain selling shareholders of the company (Vamvakes and Machat, selling about 10% and 25% of their holdings respectively), and the remainder of the shares are to be issued by TLC. The company will not receive any proceeds from the sale of the shares from the selling shareholders. The offering will be lead-managed by **PaineWebber** with **RBC Dominion Securities**, **Hambrecht & Quist LLC** and **Warburg Dillon Read LLC**

acting as co-managers.

4/14 **VISX** reported record revenues and earnings for its first quarter. Revenues were $53.9 million, up from $24.3 million for the same quarter last year, and up from the $41.9 million from last year's fourth quarter. Net income was $19.7 million (58 cents per share), compared to $9 million (29 cents per share) in last year's first quarter. The company also announced that its board of directors had approved a two for one stock split payable to shareholders on April 27th. Upon completion, the number of shares outstanding would be approximately 63 million.

For the quarter, system sales of $11.9 million increased 58% over last year's first quarter, with the sale of 50 systems. Pricing was consistent with those achieved during the fourth quarter. Of the 50 units, 38 were sold in the U.S., and the remainder overseas. Licensing revenues increased 158% over Q4 '98, and service revenues were up 100% over Q1 '98. The total for licensing and service was $42 million, or 78% of total revenues. During the Q&A session of the teleconference following the announcement, it was revealed that procedure volume on VISX systems was up 42% over Q4, and seemed to be continuing strong into April. Although the company had been increasing manufacturing production, it remained backlogged with many orders still unfulfilled. Liz Davilla commented that the company was now able to produce about 300 systems over 12 months, if the need was there. The backlog was attributable to the long lead time for some items used in the systems.

The question of the patent litigation came up and Mark Logan addressed it in full. Explaining the recent PTO office action, he said it was a result of the lawsuit originally filed against John Dishler, MD by **Pillar Point** back in 1996 regarding his use of a "black box" laser. As part of his defense strategy, Dishler asked the PTO to reexamine two of the VISX patents, and as usual in such cases, the PTO has asked VISX to explain why the references cited by Dishler are not relevant to the validity of the Trokel (5,108,388) and Warner (4,903,695) patents. (According to this month's edition of *Refractive Market Perspectives*, the prior art cited against the first five claims of Trokel included the use of a CO_2 laser to ablate rabbit corneas by Beckman, and the work of Blum, using 193 nm UV energy to remove organic tissue [the **IBM** patent]. The examiner also cited the work by Keates in modifying the refractive powers of the eye, also using a CO_2 laser. The patent office examiner also rejected the first 11 claims of the Warner (LASIK) patent stating obviousness in light of prior art by Krwawicz and Peyman.) As Logan put it, this is usual in a reexamination case, and just the first step in a long process that could take years to play out. The VISX patents remain in force and have not been disallowed or invalidated. Logan said that it could take until 2006 to resolve. He also noted that this action was separate from the FTC action, although, he hoped that the FTC judge would understand about the separate PTO reexamination action, and drop the FTC action.

Regarding the **Nidek** lawsuit in California, Logan said that separate patents were at issue and that action would proceed, but was delayed pending resolution of the ITC

action, which had been accepted for trial and had a twelve month timeline. A decision is expected in March 2000. It affects the importation of lasers, parts and service.

A question was asked about the range of patients being treated on VISX lasers and Logan or Davilla remarked that between 10% to 15% of the procedures being done were for the treatment of hyperopes, but the majority were done on myopes. The company would not say exactly how many lasers were in place in the U.S., but suggested in was in excess of 300, with Wade King of **BancBoston Robertson Stephens** suggesting it could be about 335. Logan still holds that U. S. capacity is between 750 to 1000 systems.

The company also announced that it was starting a direct to the consumer brand advertising campaign, which would concentrate on print and radio ads, beginning in June and expected to cost about $10 million for the remainder of this year. The tag line will be "insist on VISX". The hope is that the campaign will reinforce local advertising by both VISX doctors and centers.

4/14 The *American Academy of Ophthalmology* announced that it had a membership of 25,000. In a recent survey of its membership, ophthalmologists estimated a 20% decrease in cataract surgery, but expected to be performing more LASIK -- by 75% -- in three years. They also said to leave refractive surgery to the surgeons -- 98% said optometrists should not do it. In keeping with their role as comprehensive eye care providers, ophthalmologists also expected a 30% increase in eyeglass dispensing over the next three years.

4/14 **Sterling Vision** announced continued record increases in the number of laser surgery procedures performed in the first quarter of 1999, as compared to 1998, on the six excimer lasers owned by its wholly owned subsidiary, **Insight Laser Centers, Inc.**, including those performed at Insight's premier facility located in Trump Tower, New York City. Dr. Robert Cohen, chairman, stated "I believe that the laser surgery procedure continues to gain widespread acceptance by the general public, as evidenced by such increases; and we believe that this huge rise in laser procedures will have a positive impact on Sterling's 1999 financial performance".

4/14 **KeraVision** said that a possible new non-laser option for surgically treating hyperopia resulted in 20/25 vision or better for 91% of patients in a small clinical study. The results were announced at the ASCRS meeting in Seattle. Intacs for hyperopia -- an investigational product under development outside the U.S. by KeraVision -- are based on the same patented technology as Intacs for myopia, which became the first FDA-approved non-laser surgical option for treating mild nearsightedness on April 9. In the Mexico study, 55% of patients achieved 20/20 vision or better, 91% saw 20/25 or better, and 100% saw 20/40 or better. Clinical data was from 11 patients who were treated for mild farsightedness (+1.0 to +3.5 diopters of correction) and monitored for one year. The company also announced that it had expanded its clinical trial sites into Europe in January at Neubrandenburg, Germany, and two more sites are expected to

be added in April, at Munich and Fuerth in Wald. If positive clinical results continue, KeraVision plans to apply for European Union regulatory approval within two years. The company also plans to initiate an FDA-regulated hyperopia clinical study in the U.S.

4/14 I received an email message from a company called **BioShape AG** of Berlin, Germany, introducing a device, called the EyeShape system. It apparently is capable of measuring the topology of the cornea online during refractive surgery. The company claims to be working with several unnamed laser companies on the implementation of the new technology into their lasers. The company's topographer is not a stand alone device as are others. It is intended to be integrated into the laser system for refractive surgery. The aim is to measure the corneal surface during the laser procedure in order to monitor the ongoing treatment continuously. This is achieved by projecting a pattern of parallel lines at low fluence with the excimer laser onto the cornea. The fluorescence pattern of the corneal tissue is captured with a camera at a tilted angle compared to the projection direction. Thus the originally parallel lines appear bent. The amount of bending is directly related to the height information, as is usually obtained as fringe projection. The main advantage over existing systems is the capability to measure the corneal tissue without using the tear film, especially during refractive procedures as an online control. This will be vital for individual (custom cornea) laser corrections.

The company's technical director, Stephan Schruender will be in the U.S. attending ARVO starting on May 7th. Its president, Daniel Kluting, will be here the following week. Some additional information is available on the company's website at **www.bioshape.com**.

4/15 **KeraVision** announced the first two post-approval Intac procedures would take place as part of a worldwide internet webcast, on chairman and CEO Tom Loaries' son, Thomas Loarie II, 27, a certified athletic trainer in San Diego, and Michael Billig, 49, vice president for regulatory quality and clinical research at a Silicon Valley cardiac equipment developer and husband of KeraVision vice president Darlene Crockett-Billig. The procedures will be performed by David Schanzlin, MD, chief investigator for the Intacs clinical studies since 1986 and professor of ophthalmology and director of vision correction surgery at UCSD.

The company also announced that it had signed a distribution agreement with **Laser Vision Centers** to make KeraVision's Intacs for myopia available to 480 surgeons at more than 180 locations in 40 states throughout the U.S. that are served by Laser Vision.

4/15 **TLC The Laser Center** announced that it had expanded its presence in the state of Wisconsin through a venture with Dr. David King Aymond of **Vision Correction Technology LLC**. The venture with Dr. Aymond will add two new refractive centers to TLC's portfolio. The venture incorporates Dr. Aymond's existing clinic in Green

Bay and a new facility currently being developed in Milwaukee. "This agreement is characteristic of TLC's ongoing expansion strategy to partner with the best doctors in every market," said Elias Vamvakas, TLC's president and CEO.

4/15 **Laser Vision Centers** announced that same U.S. laser revenue for the month of March increased 60% compared to the same month a year ago. Same U.S. laser revenue compares the revenue generated on 26 lasers that were in operation in March 1998 to the revenue generated by those same lasers in March 1999 and is not equal to total company growth which would be a higher percentage. The company operated a total of 36 lasers during March 1999. The company noted that March was the company's best month to date for U.S. surgical case volume and that surgical case volume increased 66% for the 26 lasers that were in operation in both March 1998 and March 1999. These 26 lasers accounted for 70% of the total U.S. case volume for the month of March 1999.

4/15 **Bausch & Lomb** announced that revenues from ongoing product lines for the first quarter were $574.8 million, up 7% from the $539.4 million reported in the first quarter of 1998. This comparison excludes $13.6 million in 1998 first-quarter revenues from the skin care business, which was divested in May of 1998. The company reported net earnings for the first quarter of 1999 of $22.4 million (39 cents per share) compared to a loss reported in the same period last year of $23.2 million (42 cents per share). Earnings in the first quarter of 1998 were reduced by $37.2 million after taxes (67 cents per share) as a result of restructuring charges and purchase accounting adjustments recorded in the period. Excluding the impact of these charges and adjustments, net earnings in the first quarter of 1999 were up 60% from the $14.0 million (25 cents per share) earned in first quarter of 1998.

Sales of surgical products grew 10% over last year, reflecting exceptionally strong sales of Hansatome microkeratomes, disposable blades, and the Technolas 217 lasers, all used in refractive surgery. Sales of the combined pharmaceuticals/surgical division were $160.2 million, up from the $138.8 million reported for the same quarter a year ago.

4/15 **Gimbel Vision International** reported that 1998 revenues rose to $20.8 million from $14.9 million in 1997; net income was $2,345 ($.00/share) vs. $1.0 million 5 cents/share) the year before. Low earnings resulted from the write-off of the company's investment in Australia and the loss from discontinued operations of a non-core business. The company also reported record procedure volumes of 16,182 for the year, compared to only 9,322 in 1997. New laser surgery alliances were formed in Eugene, OR, Rio de Janeiro in Brazil, and a wholly-owned center was established in Toronto. At year's end, Gimbel's continuing operations included 5 centers in Canada, 3 in the U.S., and 4 centers based outside of North America. Eighty-two percent of revenue was generated from North American operations, compared to 72% in the previous year.

During the third quarter of 1998, the company completed the closure and write off of its investment in two Australian laser eye surgery centres. This investment was not a value-added operation for the company in either the short or long term. The write off resulted in a charge of $212,478 to the statement of earnings in 1998. The company also completed the divestiture of its ophthalmic medical equipment distribution business unit, formerly know as **IC Medical**, resulting in an after tax loss from discontinued operations of $896,959. With a high percentage of the North American population diagnosed with some type of refractive vision problem and their increasing awareness of the benefits that laser eye surgery offers, the North American refractive laser eye surgery market is moving into a strong growth phase. Accordingly, although other international opportunities that arise in the field of laser eye surgery will be investigated if they appear to offer profitable growth and acceptable investment returns, the company's strategic focus will be on the North American market where growth projections are strongest.

4/15 **BancBoston Robertson Stephens** analyst Wade King reiterated his "Buy" rating and raised estimates on VISX following their first quarter report. "We are reiterating our Buy rating on VISX. After the market close yesterday, VISX reported excellent financial results for first quarter 1999. Revenues for the period were $53.9 million, slightly ahead of our $53.1 million estimate. The company reported earnings per share for the quarter of $0.58, ahead of our $0.54 estimate. In addition, it announced yesterday a two-for-one stock split to shareholders of record on April 27, 1999," said King. "Going forward, we are revising our model on VISX to reflect the continued strength of the company's core business, dominant market share and successful execution," said King. "We are raising our 1999 revenue estimates from $227 million to $231 million and 2000 estimates from $271 million to $286 million. We also are raising our 1999 earnings per share estimates from $2.25 to $2.33 and 2000 estimates from $3.00 to $3.15. Looking ahead, we continue to believe that our procedure estimates have the potential for upward revision. Additionally, VISX is currently reporting backlog for laser systems, suggesting potential upside to our system sales estimates. We believe VISX represents an excellent long-term investment opportunity and should be a core holding for investors in medical device and medical technology companies."

4/16 **Sterling Vision** reported that it incurred a net loss, for 1998, of approximately $17.8 million ($1.22 per share), of which approximately $15.6 million represented charges to earnings (which management believes to be non-recurring in nature) as a result of certain financing obtained by the company, management's decision to increase certain of its reserves, and the write-down of certain of the company's assets. System wide sales (sales for both company operated and franchised stores) increased by approximately 2.5%, to $150 million for 1998, as compared to approximately $146 million for 1997.

4/16 **OptionInvestor.com** updated its research and commentary on several companies, including **VISX**. The company makes a laser-vision correction system (LVC)

designed to recontour the surface of the cornea. More complex pathological vision disorders can also be corrected. VISX markets their product through 20 distributors and has the system installed in 45 countries. The VISX system is the only excimer laser currently approved by the FDA (not true -- what about the three other approved systems!). The momentum for its earnings run has been unstoppable, gaining over $41 in the last two weeks and showing no signs of slowing down. VISX does have strong fundamentals, but, most importantly, the dominant market share.

4/19 *NewsEdge* reports that a U.S. Patent, 5,891,132 has issued on a "Distribute Excimer Laser Surgery System", and assigned to **Chiron Technolas GmbH**. The abstract reads: A distributed system is provided for controlling excimer laser eye surgery. A topography system, a computer system, and an excimer laser eye surgery system are provided, with the topography system providing profile data to the computer system, and the computer system calculating and providing an ablation shot pattern to the excimer laser eye surgery system. At least the computer system and the excimer laser eye surgery system are located remotely, and the excimer laser eye surgery system can receive data from more than one computer system and more than one topography system. This allows for better utilization of resources.

4/19 According to **Sunrise Technologies International**, a press release issued earlier in the day, touting the company's results of its LTK procedure for correcting hyperopia, was unauthorized. The company said that the release was issued by a source outside of the company, although the release carries the name of the company's corporate communications director. The release said that more than 1000 ophthalmologists had attended a company function during the recent ASCRS meeting, and learned about Sunrise's LTK process, with several attendees expressing their enthusiasm for the system. The release noted that the Sunrise LTK system was currently marketed in 15 countries with over 4000 eyes successfully treated, while still awaiting FDA approval for marketing in the U.S. The FDA is expected to review the company's application sometime this summer.

4/19 According to *OptiStock*, the **LASIK Institute** launched a website to educate both patients and surgeons about the LASIK procedure. Patient topics include how to select a surgeon, risks and complications, and eligibility. Surgeon information covers practice management, research grants, and more. Headquartered at the **New England Eye Center**, the LASIK Institute is funded by a three-year unrestricted educational grant from **Summit Technology**. The web site can be seen at **www.lasikinstitute.org**.

The newsletter also noted that **Goldman Sachs** initiated coverage of **VISX** at "Market Outperform", while downgrading **KeraVision** from "Recommended List" to "Market Outperform". **US Bancorp Piper Jaffrey** upgraded **Summit Technology** from "Neutral" to "Buy". Also, several analyst firms began coverage of **Pharmacia & Upjohn** (which has an agreement with **Miravant** for developing a PDT treatment for ARMD). **Credit Suisse First Boston** initiated coverage at "Buy" and set a $77 price target, while **Morgan Stanley Dean Witter** initiated at "Outperform". **Gruntal & Co.**

upgraded from "Hold" to "Buy" and set a new 12-month price target of $76.

4/19 *Refractive Market Perspectives* reports that **Aris Vision Institute** plans to raise $17 million to fund aggressive expansion plans, including development of five additional centers in Japan. The planned offering will be through a private placement managed by **Piper Jaffray**. Aris has recently undergone expansion into several new markets including Northern California, Salt Lake City, and Boston. The company now operates 17 laser centers including 1 in Japan and 2 in Mexico. Their business plan includes aggressive marketing of both the Aris Vision name and the local affiliated surgeon. Company management is excited about the expected regulatory approvals in Japan, which has an affluent population of 120 million with a high incidence of myopia, and is considered the last untapped large market for laser vision correction. Aris presently operates a laser center in Tokyo, under a regulatory loophole allowing the operation, without marketing, of imported lasers until approved. An estimated 20 laser centers are currently operating under these import provisions, despite the marketing limitations.

Dave Harmon also reports that he believes that **Nidek** has at least a dozen lasers operating in the U.S., and possibly as many as 20, including the original investigational devices. Several recent placements have been secondary machines positioned in large practices that operate under the guise of an investigational laser in order to avoid **VISX** legal action.

David also provided some insight into the recent ASCRS meeting in Seattle. He said that over 5000 were in attendance, including over 3000 physicians. Papers were presented on a variety of subjects, including the use of all of the excimer laser types, studies of phakic IOLs, several studies on the intracorneal rings, and more than a dozen reports on the use of the holmium laser for LTK for hyperopia and presbyopia from **Sunrise Technologies International**, and one paper on the use of **Rodenstock's** CW diode laser for LTK. The **Refractec** RTK (radio frequency thermokeratoplasty) system was also presented, as an alternative to LTK. In addition, there were several papers on microkeratomes, comparing the various types, providing both the advantages and disadvantages. It appears that just about all of the newer models produce better results than the older Automated Corneal Shaper from **Chiron** (now **Bausch & Lomb Surgical**). As Dave put it, comparisons of results using the different designs were limited and inconclusive. There were over 200 exhibitors registered for the meeting. (I have a copy of the program and abstracts if anybody needs any information from either source.)

4/20 **Refractec, Inc.** announced that it had begun clinical trials in the U.S. for Radio Frequency Keratoplasty (RFK), a minimally invasive non-laser approach for correcting mild to moderate hyperopia using the Refractec Corneal Shaping (RCS) System. Since February 10th, a total of 21 patients have been treated for +1.00 to +4.00 diopters of hyperopic correction at 3 sites in the United States. Of the 21 patients treated who have completed their one month follow-up, 100% are within 0.5

diopter of intended correction, and 100% have achieved 20/25 or better visual acuity. This follows the completion of Phase II studies last year, where 100% of the patients achieved UVCA of 20/40 or better and were within 1 diopter of the attempted correction. The Phase II clinical study data was presented at the ASCRS meeting in Seattle earlier this month.

4/21 **TLC The Laser Center** announced that a wholly owned subsidiary will hold TLC's strategic investments ancillary to its core business, laser vision correction, and will be known as **TLC Capital Corporation**. TLC secondary care practices are being restructured to remove operating responsibility and potential losses. TLC will maintain an ongoing portfolio investment interest in these clinics through this subsidiary. TLC is also in the process of negotiating the sale of its managed care division, **Partner Provider Health (PPH)**. As previously reported, operating profits in the 9 months ended Feb. 28, 1999, were negatively impacted by $3 million (9 cents per share) by the continuing start-up and development costs associated with PPH. This restructuring is expected to eliminate any future losses from PPH. As a result of these restructurings, TLC intends to take a one-time charge in its fiscal 4th quarter that is expected to be no more than $13 million. The company expects that approximately half of this charge will reduce goodwill. Although exact amounts cannot yet be determined, the company expects the remainder of this charge will be attributable to impairment of assets, cash, and forgiveness of debt.

4/21 As promised last month, David Therkelsen of **Dain Rauscher** released his updated "U.S. Refractive Vision Correction Industry: 1999 Update and Outlook" report. As usual a superb job on capturing the essence of what's happening in this dynamic industry. The report also includes initiation of his coverage of **KeraVision**, although the report was put together just prior to that company's receiving FDA marketing approval for its Intacs intrastromal corneal rings. In the report David has revised and updated his estimates for the size of the refractive market and its growth potential. His revised estimate of excimer refractive procedures for 1999 now stands at 842,000, with 838,000 of those to be done by laser, and the remainder possibly rings, LTK, or other implants (phakic IOLs or intrastromal contacts). One interesting table, to which I contributed, presents a breakdown of the vision correction population, and how many people fall into the various categories of mild, moderate, and high myopia; the same for hyperopia, and within those categories, the number with astigmatism. (I think we lost the pure astigmats with emmetropia somewhere.) But, at least we are now accounting for at least 60% of the total population needing some vision correction (other than presbyopia).

David also comments on the microkeratome market, noting that the B&L Hansatome and ACS models probably having a combined 80% plus share of the worldwide market. He notes that surgeon demand for high quality microkeratomes (and especially reliable blades) is rising rapidly, in tandem with the growth in procedure volumes.

In summary, even with the phenomenal procedural growth to date, by the end of 1999 only 0.8% of the target market will have been penetrated, and with over 1 million procedures next year, only 1.2% penetration will have occurred.

4/21 *The Wall Street Journal*, in its "Heard in California" section (only published in California), contained an article on **KeraVision**. Author Brenda Moore wrote that the prospects for KeraVision's Intacs were a "little blurry", based on quotes from such luminaries as myself, Dave Harmon of **Market Scope**, David Therkelsen of **Dain Rauscher**, and Larry Haimovitch of **Haimovitch Medical Technologies**, all of whom believe that the Intacs will only achieve a "niche" market of 3%-6%. The only "bullish" analyst was Larry Keusch of **Goldman Sachs**, who believes that they could achieve a 10% to 15% share of the refractive market. I guess we'll just have to wait and see who's right.

4/21 **Omega Health Systems** announced that surgeons affiliated with Omega performed 2,071 laser vision correction procedures in the first quarter of 1999, more than triple the 683 procedures performed in the first quarter of 1998. The company also announced that it had accepted delivery of a **VISX** STAR S2 Excimer Laser System and had established a laser center at the company's eye care center located in Tampa, Florida. The Tampa location, known as **Omega Eye Associates**, has a satellite center located in Clearwater that will also have access to the laser. The first laser vision correction procedures utilizing the new laser were performed on April 21, 1999. The Tampa/Clearwater market represents the third Omega center to participate in the Company's previously announced new initiative to expand its laser vision correction capabilities. Fixed-site lasers will be placed in Omega's high volume locations and a mobile program utilizing shared-site lasers will service its lower volume locations. The company had already established lasers in Omega centers in Memphis, Tennessee and Omaha, Nebraska.

4/22 **IRIDEX Corporation** announced that sales for the first quarter were $5.7 million, a decrease of 3% from $5.9 million in the corresponding 1998 quarter. Net income for the quarter was $185,000 as compared to $655,000 in the corresponding 1998 quarter, a decrease of 72%. Earnings per common share for the quarter were in line with analyst expectations at 3 cents per share as compared to 10 cents per share for the corresponding 1998 quarter.

President and CEO, Theodore A. Boutacoff commented, "Sales growth was positive in our core ophthalmology and dermatology markets for the first quarter of 1999 compared to the first quarter of 1998. Lower overall sales were due primarily to an intended reduction of external contract research not directly related to our core business. Net income decreased for the first quarter as compared to the corresponding prior year period, primarily as a result of accelerated investments in research and development and in developing new sales channels. Specifically, R&D expenses increased 77% to $968,000 in the first quarter of 1999 as compared to $546,000 in the first quarter of 1998. We expect R&D expenses to continue at least at this level for the

next few quarters to support new product development and to fund clinical studies primarily in treatments of age-related macular degeneration (AMD)."

The company expanded its dermatology product line with the introduction of the IRIDERM 810, a new hair removal laser system. IRIDEX believes the IRIDERM 810 will offer treatment specifications comparable to the most effective competitive systems in the market, but in a more portable package, with a lightweight handpiece, and a lower selling price. The company expects to begin shipping the IRIDERM 810 in the fourth quarter, pending FDA 510(k) clearance, which will allow it to compete in the $150 million/year laser hair removal market.

4/22 **KeraVision** reported revenues of $472,000 for the first quarter -- up 40% from the $332,000 in revenues for the previous quarter and up 220% from the $152,000 in revenues for the first quarter a year ago. The increase was based mostly on Canadian sales of Intacs and of related surgical instruments and surgeon training in connection with the launch of Intacs in Canada. The net loss for the period was $7.3 million (60 cents per share) vs. $7.2 million for the previous quarter and $5.5 million (44 cents per share) for the first quarter in 1998.

4/22 **Laser Vision Centers** announced that it had restated its financial statements for the quarter ended July 31, 1997 and the fiscal year ended April 30, 1998 to reflect a $1.7 million deemed dividend on its Series B Convertible Preferred Stock upon its issuance in July 1997. This deemed dividend resulted in a one-time 19 cents increase in the loss per share for both the quarter ended July 31, 1997 and the year ended April 30, 1998. The company also has reclassified the Series B Stock as temporary equity in order to reflect the possibility of mandatory redemption in certain circumstances that the company considers unlikely. This restatement did not affect net income, net loss, total assets, total liabilities or cash flow for any period. Laser Vision will amend the applicable sections of its fiscal 1998 Form 10-K and fiscal 1998 and 1999 Form 10-Q's previously filed with the SEC to reflect the impact of this one-time non-cash restatement and equity reclassification. The reclassification was deemed necessary because the events that trigger mandatory redemption, although highly unlikely, were not within the sole control of the company.

4/23 **Pharmacyclics, Inc.** announced that **Alcon Pharmaceuticals, Ltd.** (an affiliate of **Alcon Laboratories, Inc.**) had committed to further evaluation and clinical development of lutetium texaphyrin (Lu-Tex/OPTRIN) in the field of ophthalmology. Pharmacyclics and Alcon entered into an evaluation and license agreement in December 1997 for the use of Lu-Tex for ophthalmology indications including age-related macular degeneration (ARMD), the leading cause of blindness in adults in the U.S. Under the terms of the agreement, Alcon conducts and bears all costs for the worldwide development and drug registration for ophthalmology indications of Lu-Tex. Alcon has been conducting preclinical and clinical development of Lu-Tex. Pharmacyclics has received an additional payment from Alcon and may receive further payments based upon successful completion of milestones, as well as a royalty

on product sales. The payment received by Pharmacyclics comes as a result of Alcon's ongoing phase I/II clinical study evaluating safety, optimum drug and light dosing, and efficacy. Additional clinical trials are expected to begin later this year.

4/23 **Sight Resource** announced that it had acquired **Kent Optical Company**, a privately-held primary eye care chain with 28 retail operations in central and southwest Michigan. Terms of the acquisition were not disclosed. The company's seventh acquisition, Kent Optical is the second completed by Sight Resource in 1999 and its fourth acquisition in the Mid-West. Sight Resource now operates 130 retail eye care centers with annualized revenues of approximately $70 million, placing it among the top fifteen chains in the United States in sales and number of locations.

The company also announced that it had obtained a new $20 million credit facility from **Fleet National Bank** of Boston. The credit facility will be used to finance future acquisitions, refinance existing debt, provide working capital and for other general corporate purposes.

4/26 According to *Contact Lenses Today*, the **Surgical Eyes Foundation** has been established "by patients who have experienced poor, life-altering results from refractive surgeries," according to the group. The organization's goals are to focus medical attention on its members' problems and to provide support, information and guidance to corrective options for post-refractive surgery patients. Their website, **www.surgicaleyes.org**, will be an open forum of exchange among members discussing practitioners, procedures and products which have helped to overcome their difficulties, says the organization.

4/26 *OptiStock* reported that **Lasik Vision** and **MedNet International** will form an alliance to expand into the U.S. and other markets. Each Lasik Vision share will represent 1 common share, with each MedNet share, 0.7. Lasik Vision has seven refractive surgery centers in Canada while MedNet operates eyecare centers in China in joint ventures with government hospitals.

4/26 **STAAR Surgical** reported revenue of $14.8 million for its first quarter. This reflects record product sales of $14.7 million, which compares with $14.0 million a year ago and $13.4 million in the fourth quarter of 1998. Net income for the quarter was $673,000 (5 cents per share), compared with $1.7 million (12 cents per share) for the first quarter last year. In refractive surgery, the STAAR Toric IOL, the company's first refractive product cleared for marketing in the U.S., has completed the 1,000 implants required by the FDA post marketing surveillance, which will allow STAAR to satisfy physician interest through a broader product release. STAAR's Implantable Contact Lens(ICL) is now in Phase III clinical trials for treatment of myopia, and has completed enrollment for the Phase II hyperopia study.

OPHTHALMIC LASER UPDATE -- MAY 1999

4/26 *The Orlando Sentinel* noted that the **Autonomous Technologies** acquisition by **Summit Technology**, originally valued at $87 million, was now worth $180 million because of the rise in Summit's stock, which has quadrupled in value since the deal was first announced.

4/27 **Sight Resource** reported financial results for the first quarter of fiscal 1999. Revenues were $15.8 million, an increase of 16% from revenues of $13.6 million for the first quarter of 1998. Net income was $173,000 (2 cents per share) compared with net income of $13,000 (0 cents per share) a year ago. First quarter results for 1999 include the operations of the **Eyeglass Emporium** chain acquired effective April 1, 1998, and the **Shawnee Optical** chain acquired effective January 1, 1999.

4/27 **Bausch & Lomb** conducted its annual meeting in St. Louis. Chairman and CEO William Carpenter told shareholders that the company had moved beyond its restructuring phase to emerge as the preeminent technology-based healthcare company for the eye, with innovative products and capabilities that will allow it to lead the way in how the world sees. "Our future lies in capitalizing on the tremendous synergies that exist across our eye-care businesses of vision care, pharmaceuticals and ophthalmic surgery," said Carpenter. "Individually, each of these businesses has a remarkably strong position in today's most attractive eye-care categories. Together, they give Bausch & Lomb unique advantages in leading the global eye-care market." Carpenter also told the assembled group that it planned to sell its sunglass company, its **Miracle Ear** hearing aid business, and **Charles River Laboratories**, a supplier of laboratory rats.

4/27 **Lasik Vision** announced today that it had begun booking procedures at its two new Lasik Vision centres in Windsor and Winnipeg, scheduled to open in May 1999. With these two latest additions to its Canadian operations, Lasik Vision has a total of nine clinics and is now the largest operator of laser eye surgery clinics in Canada.

"Lasik Vision's operations are increasing dramatically, paralleling the rapid growth of the laser eye surgery industry, which is growing at an annual rate of more than 100%. Our strategy to provide the highest quality laser refractive care at the most affordable, everyday price is proving to be successful with a wide range of consumers," said Michael Henderson, President and CEO. He continued, "Lasik Vision is the first major laser eye surgery company to market its services directly to the public. Successful patient results and the cost savings we have been able to pass on to consumers have led to positive word-of-mouth patient referrals and great demand for our laser refractive services from Canadian and U.S. consumers. Our plan is to continue to remain a leader and increase market share in Canada; at the same time, we expect to begin aggressively expanding into the U.S. market in the second half of 1999."

4/27 **U.S. Bancorp Piper Jaffray** senior health care analyst David Gruber issued a new report that said that ocular technology exploded in the U.S. in 1998. This was led by **VISX**, up 295%, **QLT PhotoTherapeutics**, up 104%, **Allergan**, up 95%, and **Bausch & Lomb**, up 51%. The boom was lead by companies with LASIK and age-related macular degeneration (ARMD) technologies, as well as new drugs for glaucoma. "LASIK has essentially replaced other refractive surgical techniques as the procedure of choice; it is relatively painless and provides one-day visual recuperation," said Gruber.

The report, "Ophthalmology in the Millennium," is a comprehensive overview of the $9 billion ophthalmology market including the $4.8 billion visual correction market, the $3.4 billion pharmaceuticals market and the $1.1 billion cataract surgery market. Ocular technology companies that comprise the unweighted U.S. Bancorp Piper Jaffray ocular technology index had underperformed the S&P 500 and NASDAQ between 1995 to 1997.
Highlights of the report include:

-- The visual correction market will approximate $5.6 billion in 2001. Contact lens prices are forecast to stabilize somewhat and lead to mid- to high-single-digit growth. The contact lens solution market remains relatively flat.

–- Worldwide, the number of LASIK procedures is projected to grow from 695,000 in 1998 to 2.1 million in 2001.

–- The worldwide cataract surgery market was $1.2 billion in 1998, up 4.7% from 1997. Physician reimbursement for the procedures has declined from $2,700 to $900 per case in the last 15 years.

–- The worldwide ophthalmic pharmaceutical market was $3.31 billion in 1998. Merck is the largest ophthalmic pharmaceutical company in the world followed by Alcon and Allergan.

–- Bausch & Lomb has emerged as the only multi-national company solely dedicated to the treatment of eye disorders.

The report also includes detailed modeling of the contact lens, lens care solutions, LASIK and refractive surgery, cataract, and ophthalmic pharmaceuticals markets. (I have a downloaded electronic copy of the 66 page report.)

4/27 *The Wall Street Transcript* published an in-depth interview with Mark Logan, chairman and CEO of **VISX**, in which he talked at length about his company's future. He commented that the company, founded in 1986, was the world leader in the manufacture and service of excimer laser systems for laser vision correction. They held very basic patents in the field, having been founded on the inventions of Dr.

Stephen Trokel and Dr. Francis L'Esperance back in 1983. It was those inventions which have led to this entire industry. He went on to discuss that VISX got its first FDA approval in 1995, for the therapeutic use of the laser to correct various diseases of, or injuries to, the eye. That was followed by commercial approval for myopia in late March 1996. VISX was the second company to get approval. Its competitor, in fact, had 100% of the market and was very well established by the time VISX received its approval. Notwithstanding that, VISX today, has approximately a 75% share of the market in the U.S., being the leader of a market that has been growing tremendously. VISX has been clearly both feeding and riding that wave.

Looking forward, he stated, "We've announced publicly that our goal is to grow between 25 and 35% on an annual basis. We think that's sustainable. That's earnings per share, the only kind of growth I really consider. We've been profitable, by the way, since we were approved for PRK in 1996. That was the first quarter of 1996. We became profitable and have been profitable every quarter since, and have had good growth in our profits." (I was able to download a complete copy of the interview from the site, **www.twst.com/ceos.htm**, and will make it available to anyone who requests it.)

4/28 **Bausch & Lomb** and **Luxottica Group S.p.A** announced that a definitive agreement had been signed for B&L to sell its Sunglass Business to Luxottica for $640 million. (Luxottica owns and operates **LensCrafters**.)

4/29 **LCA-Vision** reported results for the first quarter. Total revenues were $13.9 million, compared with revenues of $7.2 million for the same period last year, an increase of 92%. Net income was $1.6 million (4 cents per share) compared with a net loss of $1.6 million (4 cents per share) in the comparable period last year. On a sequential basis, first quarter 1999 net income increased $1.4 million from $247,000 (1 cent per share) which was reported in the fourth quarter of 1998. In addition, first quarter 1999 revenues increased over 40% from tje $9.9 million reported in the fourth quarter of 1998.

4/29 **Summit Technology** said that it completed its acquisition of **Autonomous Technologies**, and reported strong first quarter results, led by record procedure volume growth. The total value of cash and stock issued to Autonomous stockholders, based on the average Summit closing price of the five days prior to the closing was approximately $224 million. Shareholders of Autonomous will receive .727 shares of Summit common stock and $3.04 in cash for each share of Autonomous common stock. The total consideration paid by Summit will be approximately 11.2 million shares of Summit common stock and $46.8 million in cash.

Revenues for the quarter were $25.7 million, an increase of 17% over revenues of $22.0 million for the same quarter a year ago. Laser vision correction revenues were $13.5 million compared to $10.1 million in the first quarter of 1998, a 34% increase. In the quarter, revenues from contact lens and related products increased 2% to $12.2

million from $11.9 million. Net income in the quarter was $2.4 million, (8 cents per share) compared to a net loss of $9.7 million (31 cents per share) in the first quarter of 1998. The 1998 first quarter results include a one-time non-cash charge of $10.1 million (32 cents per share) representing the cumulative effect of adopting a new accounting principle as of January 1, 1998.

According to Robert Palmisano, Summit's CEO, momentum has continued to build at Summit during the first quarter. "Since obtaining FDA approval to market our Apex Plus system to correct astigmatism in March 1998, the number of procedures performed on our systems has climbed dramatically. In the first quarter procedure volume in the U.S. increased 31% over the fourth quarter of 1998 and 81% over the first quarter of 1998. We are confident this trend will continue and be strengthened by the acquisition concluded today."

In accordance with the merger agreement, Randy Frey, founder, chairman and CEO of Autonomous, and Dr. Glen Bradley, president and CEO of **CIBA Vision Corporation**, will join the Summit board of directors effective immediately. CIBA owned approximately 13% of the Autonomous common stock. Post-acquisition, Autonomous will continue to operate as a wholly-owned subsidiary of Summit with Mr. Frey as its president. Mr. Frey will also serve as an executive vice president of Summit.

"We are delighted to combine these two pathfinding organizations," said Palmisano, "With this acquisition, Summit is now the only company to offer refractive surgeons a choice in laser vision correction platforms. With procedure volume growing, and more refractive surgeons entering the field, doctors may choose between our superb Apex Plus system, currently being used by thousands of clinicians worldwide, and the Autonomous LADARVision system which will provide surgeons the latest in precise tracking and small beam technology. We believe that our effort to `mean more to our customers', of which this acquisition is just one reflection, will increasingly pay off in subsequent quarters."

During the teleconference accompanying release of the financials, Palmisano said that Summit's hyperopia approval was on track, with approval expected before year-end, as well as for high myopia and hyperopic astigmatism. During the quarter, the company sold 16 laser systems, 12 new (at an average ASP of between $275,000 to $300,000) and 4 upgrades. Of those, 14 were sold in the U.S., and 2 internationally. He also said that the new microkeratomes were also selling well, with 15 systems sold in the first quarter, 8 in the U.S., and 7 internationally, and the company is still in a backorder situation. As for Autonomous, Summit will help them scale up production to 100 units per year. Five systems in clinical trials are now being used for surgery, with an additional 4 units ready to be shipped. Palmisano expects that Autonomous will sell and ship between 60 to 80 systems by the end of the year. He also noted that procedure volume into the second quarter continued to look strong.

In a separate matter, both *Federal Filings* and *The Boston Globe* reported that two California ophthalmologists who operate **The Laser Eye Center**, have filed an anti-trust suit against Summit to stop its acquisition of Autonomous. The doctors claim that the deal will significantly reduce competition in the prices of laser devices. The suit was filed in the U.S. District Court in Los Angeles on April 29th. Palmisano told the Boston Globe that the lawsuit was "bizarre", noting that **VISX** held 80% of the laser vision correction market, while Summit and Autonomous combined had only about 20%. Apparently, the legal action came after Summit sued the two ophthalmologists in February, claiming they repeatedly failed to pay the $250 royalty fee for each procedure conducted on the Summit equipment. *The Orlando Sentinel* identified one of the ophthalmologists as Antoine Garabet.

A few days later, on May 5th, *The Boston Globe* ran a feature on Summit in its "Boston Capital" section, with authors Steven Syre and Charles Stein commenting that Summit's recovery was a "welcome sight" for its investors. They attributed the company's improvement to improved performance benefiting from a hot market and a promising turnaround plan, including completion of the acquisition of Autonomous, and a broader following by investors. They go on to note that although Summit's main competitor, VISX, may be ahead for now, that the outlook for Summit is considerably brighter than it was two years ago, when the company's business practices, finances, and even technology came under fire as Summit's shares plunged. Co-founder and chairman David Muller was ousted, as the company's strategy of competing with its customers was questioned. As Robert Palmisano was quoted, "The company had a very bad reputation with doctors. There were a variety of reasons, least of which was going into competition with them". Summit has since ditched the vision centers, organized a sales force that emphasizes medical support and practice building help for physicians, he added.

4/30 I received a copy of the **LaserVision Centers** "red herring"/prospectus. It reiterates that the company runs 10 U.S. fixed site centers and 25 mobile lasers, with 15 fixed sites [ten in the U.S., 1 in Canada, and the rest in Europe] worldwide, and 28 mobile lasers (25 of which are roll on/roll off and 3 MobileExcimers [excimer surgeries mounted on trucks]) serving 490 physicians in over 180 locations as of January 31st. (All of the company's excimers are **VISX** systems.) The company also owns 43 **Bausch & Lomb/Chiron** microkeratomes that are used by its surgeons. In addition, the company owns 23 mobile cataract units serving 140 surgeons in over 220 locations. Nearly all of the revenues and income is from U.S. operations, in fact, the company expects "further declines in the significance of our international operations both relative to our U.S. business and in terms of total revenue". (In the nine months ending January 31st, only about 6% of total revenues were generated by international operations.) The company intends to increase penetration in new and existing markets, by adding six new mobile lasers and twelve fixed site operations in its fiscal year 2000. Approximately 91% of all procedures done in company facilities/on company lasers in the U.S. are LASIK, 8% were PRK, and about 1% were PTKs.

The only legal proceedings reported were the subpoena served in March 1988 by the U.S. Department of Justice as part of its industry-wide investigation into the so-called "international card" (Bermuda Cards) software purportedly allowing VISX keycards to perform higher degrees of myopia prior to its approval by the FDA, done by a Bermuda company; and the suit filed on March 12, 1999 in U.S. District Court for the Eastern Region of Missouri against **Nidek**, **Custom Trailerwerks, Inc.**, and a former Laser Vision employee, Bradley Hiyama, alleging infringements of Laser Vision patents (U.S. 5,398,986 [mobile laser surgical center] and U.S. 5,845,914 [portable suspension system]), breaches of a confidentiality and non-compete agreements, unfair competition, and misappropriation of Laser Vision's trade secrets and confidential information relative to the development of a mobile laser system by Nidek and Custom Trailerwerks.

As reported by *Ocular Surgery News Business News*, LVCI is damaged by such infringement in an amount not yet determined but in excess of $75,000. When hired, according to LVCI, the former employee signed a Confidentiality and Non-Competition Agreement. Under these agreements, the employee stated that during his employment at LVCI he would not participate in any competitive business or would not be employed by a competitor at the time of his termination. Additionally, the agreement covered issues including not interfering with any of LVCI's suppliers and not disclosing trade secrets and technology while employed and after termination. Three days after his resignation in 1998, according to the formal complaint filed by LVCI, the employee became an employee of Nidek. Additionally, LVCI alleges that Nidek and Trailerwerks, through unauthorized use of LVCI's confidential information, have unlawfully benefitted from LVCI's proprietary data. According to LVCI, at the beginning of this year, LVCI visited Trailerwerks and inspected the transporter units manufactured and sold by Trailerwerks. The plaintiff noted a number of similarities between LVCI's units and ones being manufactured by Trailerwerks, according to the court document. (I have a copy of the complaint if anyone is interested in seeing it.)

4/30 **Sunrise Technologies International** released its first quarter results, with revenues of $13,000 and operating expenses of $5.2 million. The net loss for the quarter was $8.5 million (21 cents per share), with approximately $4 million, or 47% of the net loss (10 cents per share) primarily attributable to non-cash expenses associated with the January 1999 debt financing costs and warrants issued to consultants in lieu of cash. Approximately $2 million or 53% of the net loss (6 cents per share) was attributable to non-cash expenses. According to Russ Trenary, president and CEO, "Our first quarter results were in line with our expectations. We are obviously in a much stronger cash position which was primary among our goals. This was achieved by simultaneously continuing to be efficient and frugal regarding expenditures while raising $10 million through a private placement of a convertible note in January 1999...As we prepare for our prospective meeting with the FDA Ophthalmic Devices Panel regarding our study for treatment of hyperopia from +.75 to +2.50 diopters, we will continue to engage in studies for the treatment of mid-hyperopia from +2.75 to +4.0 diopters, presbyopia, and treatment of myopia patients that resulted in hyperopia

from inadequate excimer laser treatments."

4/30 **TLC The Laser Center** announced that its common stock had been selected for inclusion in the new S&P/TSE Canadian MidCap Index, which is comprised of sixty stocks, with an emphasis on liquidity, and investability. The S&P/TSE Canadian MidCap Index provides investors and fund managers with an effective benchmark for mid-cap equity performance.

5/3 According to **NewsEdge**, a U.S. Patent, 5,895,384, titled, "Device for Shaping the Cornea" has issued and been assigned to **Rodenstock Instrumente GmbH**. The abstract reads: A device for shaping the cornea of an eye, including a laser (1), the laser beam of which has a circular mode of distribution, and a beam-shaping device and a beam-guiding device, which direct the laser beam onto the cornea. To homogenize the energy density over the cross section of the beam, the beam-shaping device is provided with a focusing optic which focuses the laser beam, a diffraction element which is disposed at a short distance from the focus plane of the focusing optic and the diffraction maxima of which interfere with the minima of the mode of distribution, and an image-field diaphragm which is disposed at a site which is optically conjugate to the cornea.

5/4 I received a copy of the **TLC The Laser Center** prospectus. According to the document, TLC currently operates 49 refractive centers in 25 states and provinces throughout the U.S. and Canada, with an additional 19 centers currently in various stages of development, and plans to open 10 to 15 centers within the next 12 months. More than 90% of laser procedures performed at TLC's refractive centers are LASIK. The company plans to use the proceeds from the 2.6 million shares being offered (expected to raise approximately $99 million) to 1) fund planned and future strategic alliances ($25 to $30 million); 2) fund the expansion of the business through the development or acquisition of new refractive centers (approximately $15 to $20 million). The remainder will be used for working capital and general corporate uses. The prospectus contains an interesting chart showing the approved and pending approval stages of myopia, astigmatism, and hyperopia for all of the major laser suppliers who have announced intentions to market in the U.S. However, the chart is incorrect. It shows that **Chiron** and **Nidek** only have applications into the FDA for myopia (with Nidek having that approval). According to my information, Chiron has also filed for high myopia and astigmatism, while Nidek has done likewise, and for hyperopia as well.

5/4-
5/5 **Sunrise Technologies International** announced that it had received approval from the FDA to expand its study for the treatment of hyperopia from +2.75 to +4.0 diopters. The study will be expanded to 80 patients at up to 6 clinical sites in the U.S. Twenty patients at two sites have already been treated under a study outside the U.S., begun in April 1998. "The U.S. clinicals and other studies that have been performed outside the U.S. using the same algorithm indicate that the Sunrise LTK procedure can achieve

correction for higher levels of hyperopia. This expanded study provides us an opportunity to further investigate the versatility of the LTK technique for the treatment of mid-hyperopia," said Donald Sanders, MD, from the Center for Clinical Research in Elmhurst, IL. The company estimates that the population over 40 years old with hyperopia is over 50 million in the U.S., and that the number of people who have up to 4 diopters includes approximately 90% of all hyperopes in that age category.

The company also announced that it will convert its 12% Convertible Subordinated Pay-In-Kind Notes Due 2001 into common stock effective April 22, 1999. In addition, the company will pay its final interest payment to the noteholders pro-rata in cash, instead of in common stock. The 12% Convertible Subordinated Pay-In-Kind Notes Due 2001 were part of a private placement the company announced on Jan. 15, 1998. The company had the right to convert the notes into common stock when the share price of the company's common stock averaged over $10.00 per share for 30 consecutive trading days. That occurred on April 21, 1999. Approximately 1.25 million shares of common stock will be issued to the noteholders to conclude the conversion.

5/5 **Lasik Vision Corporation** announced today that 5,092 paid laser procedures were performed at the company's refractive centres during the first quarter of 1999 that ended March 31, 1999. These procedures represent an 858% increase from the 593 for the same period in 1998. The 5,092 procedures represent a 137% increase from the 3,720 procedures performed in the fourth quarter of 1998. The more than 5,000 procedures in the quarter were performed at six Lasik Vision clinics in Canada. Of the six Lasik Vision refractive centres operating in the first quarter of 1999, three were opened during the first quarter. In addition to the Vancouver, Toronto and Calgary clinics that were already in operation, Lasik Vision opened centres in Ottawa on January 18, 1999, in Montreal on February 8, 1999 and in Halifax on March 22, 1999.

"We're pleased with the growth in volume of procedures at our Canadian clinics. We have gained dominant market share in many of our key Canadian locations, which demonstrates that our business strategies are working. As one of North America's fastest growing laser vision correction companies, Lasik Vision expects to gain further market share in Canada and expand in the U.S. during the second quarter of 1999," said Michael Henderson, president and CEO.

5/6 **BancBoston Robertson Stephens** senior medical device and medical technology analyst Wade King, M.D., today reiterated his "Buy" rating on **VISX**. "We are reiterating our Buy rating on VISX as we believe that the company's business momentum remains very strong, both in terms of LVC procedure volume and system sales," said King. "In our opinion, VISX's broad regulatory approvals and established track record of customer service continue to differentiate the company from competitors. In addition, we believe that any significant weakness in shares of VISX should be viewed as a buying opportunity."

5/6 Indianapolis Running Back Keith Elias' LASIK eye surgery was broadcast live over the Web on **AHN.COM**, the Internet's leading consumer health site, on Monday, May 10, 1999. The ten-minute procedure was to correct Elias' nearsightedness and astigmatism and eliminate his need for contact lenses. The procedure was performed by Dr. Cary Silverman, Medical Director of **Parsippany EyeCare Associates**. "I'm confident that the surgery will help Keith have a clearer view of `would-be' tacklers in this upcoming season," said Dr. Silverman. "LASIK is one of the most exciting advancements in the field of eye care since the invention of the contact lens. In most cases patients return to an active lifestyle by the following day."

5/7 I received a copy of **Warburg Dillon Read's** Matthew Dodds April 21, 1999 report on **VISX**, whereby Dodds rates the company a "strong buy". As Dodds put it, VISX is "still running at full throttle", accounting for roughly 150,000 procedures during the first quarter in the U.S. The company continues to outpace the competition, placing 38 laser systems in the U.S. during the quarter, three times greater than the competition. He also estimates that VISX lasers accounted for 75% of all procedures done during the quarter, and that 1999 will be a banner year, with concerns over the validity of two VISX patents overblown (see the clarification of the patent issues in my writeup following the first quarter conference call in last month's newsletter).

5/10 **Sunrise Technologies International** announced that the FDA had informed it that its PMA for LTK is tentatively scheduled for review at the July 22-23 meeting of the FDA's Ophthalmic Devices Advisory Panel. "We are enormously pleased to present our technology at the July Ophthalmic Devices Advisory Panel...We believe that, if approved, the Sunrise LTK System has the potential to revolutionize how hyperopia is treated," said Russ Trenary, Sunrise president and CEO.

5/10 The May issue of *Review of Ophthalmology* contains a writeup of the latest results of the **CRS** LASIK study. According to the results, LASIK is a safe procedure with either the **Summit** Apex Plus or **VISX** Star laser, with the VISX device having a slight edge in accuracy, but patients undergoing the procedure with the VISX laser also requiring significantly more enhancements. The results were from the 1736 eye CRS LASIK study, done by over 250 surgeons. At the six-month followup, 84% of the 1013 Summit patients and 76% of the 723 VISX patients were evaluated. Forty-seven percent of the Summit eyes and 53% of the VISX eyes saw 20/20 or better, while 92% of the Summit group and 95% of the VISX group saw 20/40 or better. For the complete result summary, see or request a copy of the article.

The same issue also contains a writeup edited by Fred Kremer of "The Dawn of Intacs", relating the experience of Dan Durrie, a clinical investigator for Intacs, in implanting more than 200 eyes with the device. As related by Durrie's clinical director, Dan can do the procedure in about 15 minutes, and in the approved range of -1 to -3.5 diopters (actually the device was only approved for up to -3.0 diopters), the results appear to be similar to excimer laser surgery, with 53% of the company's 410 clinical study group attaining 20/20 or better, and 97% with 20/40 or better. At

Durrie's center, 8 of the 200 implants were removed for various reasons, including superior migration, induced astigmatism, inflammation, and one channel depth too deep causing a microperforation. One patient had the Intacs removed for personal reasons. Her boyfriend said he could see the rings under certain conditions, and apparently found it distasteful.

This issue also contains a preview of the upcoming ARVO meeting in an article entitled, "What's New in Ophthalmology". It covers papers to be presented at ARVO on cataract, cornea and external disease, glaucoma, retina, refractive surgery, and contact lenses. In the refractive surgery section, papers covered PRK vs. LASIK; microkeratomes; Intacs; corneal topography; and PTK. (I have a copy of the complete section for anyone interested in any of the pre-meeting coverage.)

5/10 **MedNet International** and **LASIK Vision** announced that they were unable to agree to final terms related to a proposed merger, and have decided not to proceed with the transaction. LASIK's proposed sale of C$4 million principal amount of 10% secured convertible debentures with **MFC Bancorp Ltd.** as the selling agent also will not proceed. The companies first announced the proposed deal in April (see the April 26th brief in last month's newsletter).

5/10 According to *Optistock*, **Credit Suisse First Boston** and **ING Baring Furman Selz** initiated coverage of **QLT PhotoTherapeutics** at "Buy", while BT Alex. Brown started the company at "Strong Buy". CSFB also set a price target of $58 .

5/11 **Laser Vision Centers** said that the common shares of its recent public offering began trading. The company offered 1 million shares and certain stockholders an additional 720,000 shares. The shares were offered at $46.50 per share, giving the company $46.5 million before expenses. The company intends to use the proceeds to purchase additional equipment, fund potential future acquisitions, and for expansion of its patient financing program as well as for working capital and general corporate expenses.

5/12 Promising clinical trial results for Visudyne therapy to treat wet age-related macular degeneration (AMD) were presented at the annual meeting of the *Association for Research in Vision and Ophthalmology (ARVO)*. Co-sponsored by **CIBA Vision**, the eye care unit of **Novartis**, and **QLT PhotoTherapeutics Inc.**, the initial 12-month analysis of two on-going 24-month randomized Phase III studies (known as the TAP -- Treatment of AMD with Photodynamic Therapy -- investigation), first announced in January 1999, showed that Visudyne therapy preserved vision in a significant number of patients with the wet form of AMD, the leading cause of blindness in people over the age of 50.

Presenting the results to leading ophthalmologists and eye care professionals in attendance was Dr. Neil Bressler, Chair of the Phase III Study Advisory Group and a retinal specialist and Professor of Ophthalmology at the Wilmer Eye Institute of the

Johns Hopkins University School of Medicine in Baltimore, MD. "These results are compelling because they come from rigorous, well-controlled trials which prove that this new therapy can alter the progression of wet AMD," said Dr. Bressler. "I believe Visudyne therapy has the potential to change the way ophthalmology is practiced with respect to the treatment of some patients with AMD. It is important to understand that, while this is a promising new treatment because of its ability to confine retina damage, this therapy does not restore vision in eyes that have already been significantly damaged by AMD," said Dr. Bressler. A comprehensive analysis of the data is expected to be published in an upcoming issue of a leading ophthalmic peer-reviewed journal.

5/12 **Lasik Vision** announced that the company has received an extension to the filing deadline for its $15 million convertible debenture offering. Lasik Vision is now proceeding with an agreement with **Pacific International Securities Inc.** as agent, to sell on a proposed private placement of a $15 million 10% five-year convertible debenture, as previously announced in a February 5, 1999 news release. The completion of the private placement is subject to acceptance for filing by the Vancouver Stock Exchange. CEO, Michael Henderson said that the company intends to use the proceeds of the $15 million debenture financing to purchase additional equipment and as working capital to support Lasik Vision's expansion plans into the U.S.

5/12 **Eyemakers, Inc.** announced that it had completed an agreement to sell its **Budget Opticals of America, Inc.** subsidiary to a shareholder group led by Jim Mellon, former president of Eyemakers and of Budget, and Ed Lech formerly a director of Eyemakers. With this transaction, Mellon and Lech resigned from their positions with Eyemakers.

Eyemakers also announced that it had entered into a separate agreement with Dr. George Orm, formerly chairman of the board of directors of Eyemakers. In connection with this agreement, Dr. Orm resigned from the board of directors of Eyemakers.

John Edwards, president and CEO of Eyemakers stated, "We are pleased to have completed these two crucial steps in the restructuring of Eyemakers. As announced, we are refocusing Eyemakers to take advantage of tremendous growth in the laser vision correction business. The Budget Opticals subsidiary no longer fits into this plan and reaching a settlement with Dr. Orm clears up the largest past obstacle as we reposition Eyemakers for future growth."

Eyemakers is exploring various strategic options and financing alternatives, especially in the area of offering laser vision correction services, and expects to announce its progress in the area after its SEC filings are current. Eyemakers is an optometry practice management company which is repositioning itself to provide laser vision correction services throughout North America.

5/12 **TLC The Laser Center** announced a follow-on offering of 4 million shares of its common stock at a price of $43.00 per share. Of the 4 million shares offered, 2.6 million were sold by the company and 1.4 million were sold by certain selling shareholders.

5/13 Eye doctors from around the world were educated at a landmark Orthokeratology conference convened by the *International Orthokeratology Section (IOS)* of the *National Eye Research Foundation (NERF)* in Kauai, Hawaii during the weekend of April 23-25. Gathered in one place for the first time were the leading authorities in Orthokeratology research and clinical practice. With the conference, the Science of Orthokeratology, a non-surgical vision correction procedure for myopia, astigmatism and hyperopia, took a big leap forward. (Orthokeratology utilizes flattening of the cornea through the application of hard gas permeable contact lenses, in a procedure similar to that used in straightening teeth using wires and a retainer device.)

5/13 This month's issue of *Refractive Market Perspectives* discloses that procedure volumes in the first quarter rose 25.3%, with over 195,000 procedures being performed. This compares to the 156,000 procedures done during the fourth quarter, which itself was up 26.7% over the third quarter. David Harmon bases the continuing increases in procedure volume to a booming economy, a growing patient referral base, and an expansion in the number of laser centers and refractive surgeons. In light of this record-breaking volume and the rapid growth in new lasers, he has revised his forecast for the year to 980,000 procedures for 1999, and 1.3 million for 2000.

With this unexpected development, I have also raised my forecast for both 1999 and 2000. I am now projecting that at least 950,000 procedures will be done this year, and that 1.4 million will be done next year! (A copy of my table with these new projections is enclosed with this copy of the newsletter.)

Harmon is also projecting that 200 new lasers will be placed in service both this year and next, putting the total of operating lasers at 621 by the end of 1999 (taking into account retired lasers and secondary lasers), and 754 lasers in use by the end of 2000.

5/13 **Sterling Vision, Inc.** reported profitable results for its first quarter, with revenues of $37.3 million and net income of $468,000 (2 cents/share). Dr.Robert Cohen, chairman, stated the increase in net income for the quarter was principally due to the return to profitability of the company's retail optical business, the Laser Surgery division becoming profitable and the continued profitability of the company's Ambulatory Surgery Center.

5/14 According to *Federal Filings*, on May 12, a California state court overseeing a consolidated antitrust class action against **VISX Inc.** entered a stipulated conditional order certifying that the class will include patients in 17 states and the District of Columbia. The suit initially sought certification of a nationwide class of patients, according to the company's Form 10-Q filed with the Securities and Exchange

Commission on May 13. In addition, two more lawsuits were filed in May against VISX over its alleged unfair competition and antitrust violations involving its laser eye surgery business. Both suits were filed in Minnesota: one suit purports to represent a class of patients in several states while the other is on behalf of Minnesota patients only.

5/17 *OptiStock* reports that **VISX's** common stock split two for one Wednesday night after closing at 140-1/8. The issue will move from the *S&P SmallCap 600 Index* to the *MidCap 400* on May 17, replacing Agouron Pharmaceuticals, to be acquired soon by Warner-Lambert.

5/17 Over the weekend, three national publications contained mostly positive stories about refractive surgery, particularly LASIK. This month's issue of *Consumer's Report*, and this week's issues of *Parade Magazine* and *Barron's* all contained lengthy articles on the subject, sure to give a boost to the procedure. The Barron's piece was the personal experience of one of Barron's reporters, Jay Palmer, while Dr. Isadore Rosenfeld reported for Parade, based on his interview of Dr. Sandra Belmont of the **Laser Vision Correction Center of New York**. The Consumer's Report article contained the only negative information, relating the poor experience of one patient who apparently has halos following the procedure due to a large pupil. The latter also lists a web site purportedly run by disgruntled patients with bad surgical outcomes, at **www.surgicaleyes.org**. (I have copies of all three articles if anyone would like to see them.)

5/17 **Sunrise Technologies International** announced that it's board of directors amended the Stockholder Rights Agreement to increase the exercise price of stock issued pursuant to the rights to $70 from $20. The Rights will be exercisable only if a person or group acquires beneficial ownership of 15% or more of the company's common stock, or commences a tender or exchange offer upon consummation of which, such person or group would beneficially own 15% or more of the company's common stock. The company will be entitled to redeem the Rights at $.001 per Right at any time until 10 days following a public announcement that a 15% position has been acquired. The company said it was not aware of any activity to acquire a control position in its stock and the company had undertaken no discussions with any potential acquirors. The board was advised on the amendment by **Credit Suisse First Boston**.

5/17 In a move to expand into the rapidly growing ophthalmic surgical market, **CIBA Vision**, the eye care unit of **Novartis**, announced that it had entered into an agreement to acquire the intraocular lens (IOL) business of **Mentor Corporation**, in a cash-for-assets purchase of approximately $38 million. Sales from the IOL products being acquired were $15.5 million in the calendar year ended March 31st. As part of the agreement, CIBA will acquire an entire line of IOL products, including Mentor's MemoryLens (a pre-rolled foldable IOL developed by **ORC Corporation**, before its sale to Mentor). The purchase includes intellectual property, R&D in progress,

inventories, accounts receivables, manufacturing equipment, and a manufacturing facility in Cidra, Puerto Rico. CIBA expects to hire approximately 185 Mentor employees, including manufacturing, R&D, QA, and sales and marketing personnel. The deal is expected to close in a few months. The new products will reinforce several other CIBA products including Voltaren Ophthalmic and Miochol, both used in conjunction with cataract procedures.

5/17 **LaserSight** released its first quarter results and announced a strategic alliance with **Becton Dickinson's Ophthalmic Systems** division. As part of the joint venture, the two companies have entered into an exclusive arrangement to develop, manufacture and distribute keratome blades for refractive surgery. Additionally, the partnership will further expand the LaserSight product line by manufacturing co-branded cannulas, custom kits for refractive surgery, and other laser vision correction related accessories. LaserSight will access Becton Dickinson's sales and distribution capabilities around the world to accelerate the launch of its products and meet the market's growing demand.

Under the agreement, Becton Dickinson will manufacture the blades, taking over the current LaserSight production facility. It was not clear from the announcement, who would produce the keratomes, including the disposable and reusable systems. Becton Dickinson Ophthalmic Systems is the worldwide leader in the manufacture and sales of surgical blades and ophthalmic cannula under the Beaver and Visitec brands. This combination strategically positions the two companies to gain market share more effectively and efficiently within the rapidly growing refractive surgery market.

For the first quarter, LaserSight's revenues related to sales of laser systems, upgrades, and part sales increased approximately 17% to $4.9 million from $4.2 million in the first quarter of 1998, and up 48% from the $3.3 million for the preceding quarter. The company reported a net loss of $3.3 million (25 cents per share) compared to a net loss of $2.0 million (30 cents per share) reported for the first quarter of 1998 before the additional $1.1 million loss for that quarter of 1998, reflecting the effects of premiums, accretion and conversion discounts on the redemption of Series B Preferred Stock. Additionally, the net loss for the first quarter of 1999 narrowed significantly compared to the net loss of $6.0 million (46 cents per share) reported in the fourth quarter of 1998. The relative improvement during the first quarter of 1999 primarily resulted from the increased revenues and corresponding improved margin as well as a reduction of approximately $1.0 million in total operating expenses.

During the quarter, the company sold 13 refractive laser systems to international customers compared to 8 systems during the fourth quarter of 1998. In addition to an increase in average selling price during the quarter -- due to the sale of its LSX platform. The terms of sale also improved as a result of sales into Europe to which the company gained access through the CE Mark approval previously announced.

Michael Farris, CEO, commented, "We continue to be pleased with the progress we

are making with our laser system and keratome products. Our strategic alliance with Becton Dickinson, a well-respected and resourceful organization, strengthens LaserSight's position to compete with other broad line companies while allowing us to lead the industry with focused innovation. Focused on clinical quality and technological innovation, the partnership will increase LaserSight's ability to meet customer demand for its products, further establish its brand name recognition for quality and innovation, and increase market share in a rapidly growing industry."

During the conference call accompanying release of the financials, Farris said that the company and Becton Dickinson expected to begin shipping blades and keratomes during the second quarter, as soon as validation of the blades was completed.

According to an interview of Bill Kern, vice president of corporate development by Kathy Kincade, editor of *Medical Laser Report*, "The agreement is significant on many levels. It gives LaserSight access to Becton Dickinson's worldwide sales and distribution capabilities just as LaserSight is preparing to launch its first excimer-laser refractive surgery system, which is expected to gain FDA clearance in the third or fourth quarter of this year. In addition, given Becton Dickinson's size and reputation, it validates the laser segment of the eyecare market. Thus, although the Becton Dickinson sales force will not be directly involved in marketing the LaserSight laser, the relationship still gives LaserSight significant entree into the highly competitive eye-surgery market. In addition to the relationship with Becton Dickinson, LaserSight believes that its leading-edge technology and strong patent portfolio will help the company secure a solid position in the laser refractive-surgery. The company already has an installed base of 300 laser systems worldwide and an established support and service infrastructure. In addition, **TLC-The Laser Center** has invested more than $10 million in LaserSight and currently holds 15% of LaserSight stock. This means that, once LaserSight gains FDA clearance, its excimer lasers will have an immediate consumer outlet. And with the company's line of single-use and durable keratomes and blades, it has an underlying revenue stream that is tied directly to procedures."

"Technology will differentiate us in this market," Kern says. "The day we get [FDA] approval, we feel we are in a very strong position."

5/18 **Coherent, Inc.** announced that the Novus Verdi Diode Pumped Green Photocoagulator received clearance from the FDA for ophthalmic use. This represents Coherent's introduction of a fully solid state green photocoagulator to the market that the company created with the introduction of the first green laser photocoagulator in 1970. The Novus Verdi is a product brought to market through a collaborative agreement between Coherent and **Quantel Medical** of France, the first company to introduce a diode-pumped green photocoagulator in 1995.

"The refined optical design of Coherent's fiber based laser delivery devices coupled with Quantel's quality controlled manufacturing of the laser console, add up to a product offering that meets the exacting standards that ophthalmologists have come to

expect from Coherent," said Peter Falzon, director of Ophthalmic Marketing at Coherent. "We are pleased about bringing this collaborative project full circle and look forward to offering ophthalmologists this new technology choice for treating patients with sight threatening retinal diseases and glaucoma, backed by the customer service support that is the hallmark of Coherent's ophthalmology business." The Novus Verdi joins Coherent's Novus Omni multi-color photocoagulator, Novus 2000 argon laser photocoagulator, and Ultima 2000 portable argon laser photocoagulator as the newest addition to a complete line of products and accessories for ophthalmologists performing laser photocoagulation.

5/18 *The Boston Globe*, in its Globe 100 review, named **Summit Technology** to the number 9 position in New England, detailing the "stunning turnaround" that the company accomplished in 1998. Business editor Ronald Rosenburg stated, "While some Wall Street analysts expect Summit to be acquired by a large company in the ophthalmology market (rumors have **Bausch & Lomb** or **Alcon Pharmaceuticals** as possibilities), the firm's short-term future is in focus."

5/19 **Eye Care International (ECI)**, a leading discount vision plan, announced that Hall of Fame Quarterback Fran Tarkenton had become its corporate spokesperson and business consultant. "For $28 per family membership, which includes one free eye exam per year and access to a network of more than 11,000 vision provider locations in all 50 states, ECI offers the nation's best discount vision services available today," said Tarkenton.

The ECI program offers between 20% and 60% discounts on eyewear and eye care, including a 20% discount on all elective procedures including the now much sought-after vision corrective LASIK surgery and skin resurfacing. With a national network of providers, which includes ophthalmologists (EyeMDs), optometrists, and optical outlets, ECI represents a new market trend in comprehensive vision services which encourages member utilization.

5/19 Fred Toney and Al Kildani of **Pacific Growth Equities**, released a research report covering **TLC The Laser Center**, with a "buy" recommendation. The reasons given for the recommendation included: the North American laser vision correction industry is experiencing explosive growth; TLC is the largest provider of LVC services in North America with 50 centers in 24 states and experiencing 100%+ same center growth; its co-management model acts as a referral engine with its base of 11,000+ referring optometrists; and its next leg of growth to be driven by agreements with managed care, insurance, and corporate vision plans, validated by the deal with **Kaiser Permanente**.

Although Al and Fred remain very conservative in their numbers for U.S. procedures in 1999 and 2000 (800,000 and 1.2 million respectively), they recognize that they are low, and are willing to revise their numbers as it is called for.

5/19 **Sterling Vision** announced continued record increases in the number of laser surgery procedures performed, during the month of April, 1999, as compared to April, 1998, on the six excimer lasers owned by its wholly owned subsidiary, **Insight Laser Centers, Inc.**, including those performed at Insight's premier facility located in Trump Tower, New York City. Dr. Robert Cohen, chairman of the company's Board of Directors, stated "It has now become evident that the laser surgery procedure continues to gain widespread acceptance by the general public, all as evidenced by such increases; and we believe that this huge rise in laser procedures will have a positive impact on Sterling's 1999 financial performance."

5/19 According to **Federal Filings Newswires**, two purported class actions suits were commenced against **Summit Technology** in May, according to the company's latest quarterly report. Linda Brisson, an individual who allegedly has had laser vision surgery performed, commenced a suit in Minnesota state court against Summit, **VISX Inc.**, **Pillar Point Partners** and related defendants. The case purports to be a class action suit on behalf of all Minnesota purchasers of refractive laser surgery. The complaint alleges, among other things, violations of Minnesota antitrust law. Brisson's suit seeks among other things, compensatory damages alleged to be at least in the millions of dollars.

John Castino, also an individual who has allegedly had laser vision correction surgery, commenced an action in Minnesota state court against Summit Technologies and VISX. The case purports to be a class action on behalf of all residents of Alabama, the District of Columbia, Hawaii, Kansas, Maine, Michigan, Minnesota, Mississippi, New Mexico, North Carolina, North Dakota, South Dakota, Tennessee, and Wisconsin who have paid for laser vision correction surgery. (Without knowing the facts, it appears that these individuals are seeking compensation for the $250 Pillar Point fees that they and others have paid.)

5/19 **Laser Vision Centers** announced that same U.S. laser revenue for the month of April increased over 48% compared to the same month a year ago. Same U.S. laser revenue compares the revenue generated on 26 lasers that were in operation in April 1998 to the revenue generated by those same lasers in April 1999. Same U.S. laser revenue is not equal to total company growth which would be a higher percentage. The company operated a total of 38 lasers in the U.S. during April 1999.

The company said that it performed more than 19,950 U.S. surgical cases during the quarter ended April 30,1999, a 128% increase over the same quarter last year. U.S. cases for the year ended April 30, 1999 totaled over 56,750 and more than 60,480 worldwide. Beginning in June 1999, the company said that it would begin reporting on a monthly basis the total percentage increase in U.S. case volume for comparative months and discontinue the practice of reporting same U.S. laser revenue. LaserVision CFO Chuck Bono said, "LaserVision has begun a re-deployment of some higher volume mobile lasers into fixed locations. Due to this re-deployment, these lasers will initially have more moderate case volume. We believe that reporting case

volume rather than revenue will give a more accurate "apples to apples" comparison of the growth LaserVision is experiencing."

5/19 **Photogen Technologies, Inc.** announced preliminary results of an animal feasibility study of its proprietary phototherapeutic technology for use in the treatment of ocular melanoma, a cancer of the eye. The study, a joint research project of Photogen and the **Massachusetts Eye and Ear Infirmary (MEEI)**, is being led by Lucy Young, MD, and was designed to evaluate the use of ultrafast lasers for cancer treatment. Photogen's technology when applied to ocular melanoma does not rely on the introduction of a drug into the body, but rather, activates naturally occurring melanin precursors in the cancerous tumor in order to selectively kill diseased cells. Tests are being conducted using a rabbit ocular melanoma model. The preliminary results of the study are showing that tumors can be eliminated with one or more treatments and that the effects of the treatment are confined to the immediate area of the tumor with little or no collateral damage to healthy tissues. The results confirm earlier work by Photogen using subcutaneous melanoma tumors in mice.

"We are encouraged by Dr. Young's results, although preliminary and involving a small number of animals, which so closely match our own findings," said John Smolik, Photogen's president and CEO. "The trials at MEEI are the first step toward developing a variety of applications for treating diseases or disorders of the eye using ultrafast lasers and our photoactivation technologies. Concurrent with the ocular melanoma trial, we are conducting feasibility studies at MEEI with a variety of photoactive drugs for advanced macular degeneration, the leading cause of blindness among older Americans, a market estimated to exceed $800 million per year."

Photogen's system is believed to be the first ultrafast laser device for treating retinal disease. The new laser device utilizes Photogen's proprietary multi-photon activation technology, and makes use of special laser beam focusing and scanning capabilities.

5/19 **Gimbel Vision International** reported that it had received conditional approval for the listing of its common shares on the Toronto Stock Exchange. This approval is conditional upon the TSE receiving supporting documentation on or before August 11, 1999.

5/19 **TLC The Laser Center** said that it would open the only laser eye center in Canada to be affiliated with the University of Waterloo's School of Optometry. The center, is located in the School of Optometry's building. Elias Vamvakes, president and CEO said, "Working with the University of Waterloo on this collaboration, on what we hope will become a training facility for optometry students, will ensure we continue to achieve this goal in the future."

The following day, the company announced that the underwriters of its recent follow-on offering have exercised their over-allotment option. Pursuant to the option, the underwriters have purchased an additional 390,000 Common Shares from the

company and 210,000 Common Shares from certain selling shareholders of the company at a price of $43.00 per share. The offering was lead-managed by **PaineWebber Incorporated** with **RBC Dominion Securities Inc.**, **Hambrecht & Quist LLC**, **Warburg Dillon Read LLC** and **Pacific Growth Equities Inc.** acting as co-managers.

5/20 **STAAR Surgical Company** reported that the first TORIC Implantable Contact Lens(ICL) was placed in a patient's eye in Munich, Germany. The procedure was performed by Dr. Tobias Neuhann, a leading European ophthalmologist, marking the beginning of the clinical trial to obtain the CE Mark necessary to market the new lens in the European Union.

5/20 *NewsEdge* reported that a European Patent EP 98306703 had issued in August to **Escalon Medical Corporation**, entitled, "Laser apparatus for intrastromal photorefractive keratectomy". The abstract reads: A laser apparatus arranged for use in a method for performing intrastromal photorefractive keratectomy in the cornea of an eye, using a pulsed laser beam to photodisrupt a portion of the cornea, includes the initial step of focusing the beam to a focal spot at a selected starting point in the stroma. The starting point is located at a predetermined distance behind the epithelium of the cornea. While focused on the starting point, the laser beam is pulsed to disrupt a volume of the stroma which is approximately equal to the volume of the focal point. Subsequently, the beam is focused in a patterned sequence to focal spots at other discrete points in the stroma. At each point the stroma is photodisrupted. With this progressive pattern of photodisruption, each spot is placed substantially contiguous with adjacent a volume of previously disrupted tissue. The resultant photodisrupted tissue creates a layer which is substantially centro-symmetrical around the optical axis. A plurality of layers can be removed to create a cavity in the stroma. When the cavity collapses, the corneal curvature is changed as desired.

5/24 **BancBoston Robertson Stephens** senior medical device and medical technology analyst Wade King, MD, reiterated his Buy rating on **VISX**. "We are reiterating our Buy rating on VISX, advising investors to take advantage of any weakness in VISX shares related to the initial FTC ruling expected on May 24," said King. "We believe that the FTC case will not affect the company's business in a material manner, and that it will be vindicated regardless of the preliminary ruling. In our view, business momentum remains very strong at VISX, both in terms of LVC procedure volume and system sales," said King. "We believe the company represents an excellent long-term investment opportunity and should be a core holding for investors in medical device and medical technology companies."

5/24 **Sunrise Technologies International** announced today that FDA officials confirmed that the company's PMA application is scheduled for review on July 22nd by the Ophthalmic Devices Advisory Panel. The Panel will review the PMA for the Sunrise LTK System for the treatment of hyperopia (+.75 to +2.50 diopters).

5/24 The May issue of *EyeNet*, published by the American Academy of Ophthalmology, contains a very interesting article about **TLC The Laser Center**. Author Linda Roach Monroe takes a hard, but thorough look at the way TLC does business, questioning its close association with optometry. The story provides examples of the way TLC breaks down its fees, both to the operating ophthalmologist and to the consulting optometrist. One of the sidebars discusses what discounters **Lasik Vision**, **Rahmani Eye Institute**, and **Lexington Laser Vision** are offering and what the impact has been or not on the local area in which these companies operate. A second sidebar describes most of the major competing corporate center businesses, discussing their operating model and typical LASIK charges. (Anyone who would like to see a copy of the article, let me know.)

5/24 According to *OptiStock*, **Hambrecht & Quist** started coverage of **TLC The Laser Center** at "buy". **Warburg Dillon Read** also initiated coverage at a "strong buy", with a 12-month price target of $60. Warburg Dillon Read also initiated coverage of **Laser Vision Centers** at a "strong buy", while **McDonald Investments** started coverage of **Bausch & Lomb** at a "buy".

5/25 **Omega Health Systems** announced that it had secured a patient financing program for refractive surgery procedures through **HealthCapital Financial Group, LLC**, a healthcare financial services company. The program is customized for Omega and offers competitive financing terms for patients who undergo laser vision correction procedures in any of Omega's centers. In addition, the program will also be accessible to surgical candidates through optometrists in Omega's network. Patients will have the option to select a flexible payment plan and can choose to finance the procedure over a period of 12-60 months. Applications and program information will soon be available to patients through the Internet by accessing the Company's web site, **www.omegahealth.com**.

5/26 In a long-awaited broadside, Laura Johannes of *The Wall Street Journal* details the alleged patent fraud wrought by **VISX** and two of its founding ophthalmologists, Francis L'Esperance and Stephen Trokel. As described in the lengthy article, apparently Dr. Trokel learned of the idea of ablating the cornea with the excimer laser from both published articles about his work on exposing rabbit corneas to the excimer laser, written in 1979 by John Taboada, an Airforce physicist, and a later meeting with him. Trokel, intrigued by the prospects for the human eye, then found out about the work underway at IBM's Watson Laboratories by "Srini" Srinivasan, in using the excimer to trim plastics for semiconductors, and arranged to use **IBM's** laser to attempt to ablate calves eyes. This became the basis for his filing for a patent in late 1983. However, he was beaten to the punch by his then colleague at Columbia University Hospital, Dr. Francis L'Esperance, who learned what Trokel was doing, and claimed to have discovered the idea for ablating the cornea from library research he undertook early in 1983. L'Esperance beat Trokel to the patent office with his patent application by a few weeks, late in 1983.

The story goes on detail how the IBM patent was filed even earlier, covering the ablation of human tissue with UV energy, but not specifically mentioning the eye, thereby allowing the opening for the issuance of the L'Esperance (and Trokel) patents. L'Esperance assigned his patents to his startup company, **Taunton Technology**. When Trokel found out what L'Esperance had done, he assigned rights to his then contested patent, to the original VISX. VISX then began interference action against L'Esperance and Taunton, which allegedly uncovered the fraud perpetuated by L'Esperance's back-dating of his invention discovery notebook. But before the patent could be disallowed by the Patent Office, Taunton and "old" VISX entered into negotiations and Taunton bought VISX, renaming the new company the "new" VISX, with no action taken on the L'Esperance patents.

With the emergence of **Nidek**, and the marketing approval given late last year, VISX brought several suits against Nidek. This opened the way for the alleged L'Esperance patent fraud to be brought out into the open as part of these suits, including, as requested by Nidek, the patent office re-examination of the old L'Esperance patent (and John Warner's, a co-founder of Taunton, patent for LASIK). As a result, some of the L'Esperance claims have been challenged by the PTO. The bottom line, however, is that the patents remain valid and enforceable until all appeals are heard and final action is taken, which could be years from now. But, the story does make for some interesting reading.

5/26 **Omega Health Systems** announced that it had initiated its shared-site laser program with the delivery of its fourth **VISX** STAR S2 Excimer Laser System and its first customized truck for transporting the laser. The company's eye care centers located in Danville, Illinois and Marion, Indiana will be the first shared sites to utilize the equipment and laser vision correction procedures are scheduled for early June. The customized truck is fitted with special equipment to protect and transport the laser. An Omega technician, who has completed technical training with VISX will support the shared schedule between the two centers. With the addition of these two sites, five Omega centers have now added on-site laser access in connection with the company's previously announced new initiative to expand its laser vision correction capabilities nationwide. In connection with the new initiative, Omega has agreed to acquire a total of 12 VISX STAR S2 excimer lasers from VISX.

5/26 **STAAR Surgical Company** announced that the FDA had given the company approval to begin Phase III of its clinical trials for the Implantable Contact Lens (ICL) to correct hyperopia (farsightedness). The FDA's release will allow the company to expand the study to include patients with as little as 1.5 diopters of hyperopia, and to reduce the waiting period from six months to 45 days for patients to receive the ICL in the second eye. In addition, this will allow the company to implant 278 additional ICLs in patients and to expand from 14 to 18 clinical sites nationwide.

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5/26 **BancBoston Robertson Stephens** senior medical device and medical technology analyst Wade H. King, M.D. reiterated his Buy rating on **VISX**. "We are reiterating our Buy rating on VISX, in light of weakness surrounding the initial FTC patent ruling expected soon. A lead article in today's *Wall Street Journal* discussed a variety of patent litigation surrounding VISX, including the FTC case," said King. "We believe that the patent issues highlighted in the article will take several years to resolve, and that business momentum remains very strong at VISX, both in terms of LVC procedure volume and system sales."

5/27 According to *Reuters*, shares of VISX fell 10% after the *WSJ* report raised questions about patent protection for its core ophthalmic laser surgery product. The story outlined ongoing patent litigation regarding the original idea underlying its pulsating excimer lasers, which it sells for $500,000 each. "There was nothing new in the Journal article; it's all been published before, but perhaps there were some nuances, which caused the stock drop", **PaineWebber** analyst Charles Olsziewski told Reuters.

5/27 The *Globe and Mail* reported that *Profit Magazine* recognized **TLC The Laser Center** among its fastest growing companies in Canada, with a more than 22,000% increase in revenues over the past five years.

5/27 *ISRS In Focus* noted that **NovaMed Eyecare** announced plans to raise about $100 million in an IPO filed with the SEC. The initial prospectus, which is nearly two inches thick, discusses the company's current business. NovaMed owns and operates 10 eye surgery and laser centers in Chicago, Kansas City, Louisville, St. Louis, and Richmond, Virginia. The company also operates 44 eye care clinics and an eye research organization in Kansas City. The latter provides clinical research and site management services to ophthalmic device, product, and pharmaceutical manufacturers, with an emphasis on laser vision correction. The research facility currently has 30 research sponsor agreements, relating to over 500 subjects participating in clinical trials. In addition, NovaMed operates 27 optical dispensaries, owns and operates 3 wholesale optical laboratories, and an optical products purchasing organization that sells products and accessories, including eyeglass frames and contact lenses, to both affiliated and non-affiliated eye care providers.
The proceeds of the offering, being made through **Donaldson, Lufkin & Jenrette**, **Hambrecht & Quist**, and **William Blair & Co.**, will be used to repay all outstanding principal and interest on its existing bank debt, while the remainder will be used for working capital and to pursue its laser vision strategy through new affiliations, acquisitions, and expansion in existing and future markets.

5/28 **Gimbel Vision International** announced first quarter results, with refractive procedure volumes increased 57% to 5,266 from the prior year's first quarter. Refractive procedures performed in North America increased 54% during the quarter. Procedures performed at other centres increased 67% to 1,296. Continued rapid growth in the

company's procedure volumes is expected as a result of an aggressive focus on increasing market share at each of the company's centres, a commitment to new centre development, and further expansion of the refractive eye surgery market.

An aggressive move in February to increase market share in Canada has positioned Gimbel Vision as a provider of quality care at a reasonable price to the consumer. "We see the Canadian market as being at a maturing stage of evolution in the industry of refractive vision correction, and we have gained valuable experience with price compression in the market," says Don Baird, CFO. "We expect to see Canadian based revenues and net income improving in the second quarter and thereafter based on the steady growth we're seeing in procedure volumes at our existing centres and from planned future centres".

The company's consolidated first quarter revenues were CND$4.9 million, representing a decline of 7% from the same period in 1998. This decrease was due mainly to the exclusion of Australian-based revenues which resulted when the Australian operations were divested in the latter half of 1998, as well as lower revenues from the Canadian market segment following price compression early in the first quarter of 1999. As well, the current year's results exclude Australian-based revenues which were divested in the latter half of 1998. The decrease in Canadian based revenues was offset by a significant increase in revenue generated from operations based in the United States. Revenues from Brazilian operations have remained virtually unchanged from the prior year's first quarter. Earnings from continuing operations before interest, taxes and depreciation were CND$816,066 as compared to CND$1.2 million in the 1998 first quarter. This decrease was due to lower earnings from continuing operations and a tax recovery being recorded in the current year's first quarter results. Net earnings of CND$235,565 were virtually the same as in the prior year. On a geographic segment basis, Canadian operations generated segmented profit of CND$198,923 which was below the prior year's first quarter profit of CND$600,148. Profit from operations in the United States improved significantly from a loss of CND$126,917 in the first quarter of 1998 to a profit of CND$153,841 in the first quarter of 1999. Activities from operations in Brazil resulted in a loss of CND$117,199 as compared to a loss of CND$235,707 in the prior year first quarter.

5/31 *EyeWorld Week* reports that **VISX** continued its policy of seeking legal injunctions against users of **Nidek's** EC-5000 laser system, charging two laser centers and three ophthalmologists with patent infringement. In two actions taken on May 19th, the company filed lawsuits against **Laser & RK Eye Centers** and Glenn Kawesch, MD, in U.S. District Court in the Southern District of California, and against **Laser Eye Center** and Antione Garabet, MD, and Randa Garrana, MD, in U.S. District Court in the Central District of California. Both suits allege that the defendants' use of the EC-5000 infringes VISX's U.S. Patent 4,665,913; the suit against Laser & RK Eye Centers and Kawesch further charges that the defendants have performed commercial procedures under the guise of an investigational device exemption clinical study,

thereby losing the protection against patent infringement claims afforded by the law for such studies. VISX is seeking an injunction prohibiting the defendants' use of the Nidek system and an award of treble damages.

5/31 According to the FDA's web page, the FDA Ophthalmic Devices Advisory Panel meeting of July 22nd will discuss, make recommendations and vote on a PMA for the correction of myopia with and without astigmatism using LASIK. The committee will also review and vote on a holmium laser for the correction of hyperopia using LTK (the **Sunrise Technologies'** application). On the following day, the committee will review and vote on a soft acrylic IOL and on a second PMA for the correction of myopia with and without astigmatism using LASIK. (No word yet whether the LASIK PMAs are for a company or from an MD-sponsored study.)

6/1 **Lasik Vision** announced its first quarter results. Gross revenues were $3.5 million, reflecting strong, increasing growth in the number of procedures performed at Lasik Vision's existing laser refractive centres. More than 5,000 paid laser procedures were performed at the company's clinics during the quarter. These procedures represent an 858% increase from the 593 for the same period in 1998. The actual 5,092 procedures performed in the quarter represent a 137% increase from the 3,720 procedures performed in the fourth quarter of 1998. For the quarter, the net loss was $2.2 million, reflecting the costs associated with the company's rapid expansion in the Canadian market where it has become the largest operating laser eye surgery company, running nine clinics, three of which were opened during the quarter. The net loss is primarily attributable to development costs, which are expensed when a lease is signed for a new clinic, as well as start-up costs, which are incurred from the period between the signing of a lease and the commencement of operations. The company runs clinics in Vancouver, Toronto and Calgary and opened clinics in Ottawa on January 18th, in Montreal on February 8th, and in Halifax on March 22, 1999.

"The first quarter results meet our expectations as we expanded our leadership position in Canada and pursued expansion into the U.S. laser vision correction marketplace. The increase in our paid procedures demonstrates that our business model is effective at generating well above industry average volume at our clinics. In addition, we had anticipated an operating loss in the first and second quarters of 1999 as we continue to expense, rather than capitalize, all development and start-up expenses in the quarter that our new clinics commence operations," said Michael Henderson, President and CEO.

6/2 *The Seattle Times* carried a lengthy story about refractive surgery, entitled, "The Lure of LASIK -- Border Skirmish Erupts Between Eye Doctors on the Cutting Edge of Corrective Surgery". The story details the "price war" being carried out between Seattle and Vancouver over LASIK procedures, with the market being "particularly fertile" in British Columbia, where up to 25,000 LASIK procedures are expected to be carried out this year. The Canadian clinics offer cheaper prices and a longer track record of laser surgery, but many require a three-day stay in Canada for the surgery

plus followup. Seattle-area clinics charge an average of $2000 per eye, while some Canadian outfits are charging as little as $1500 for both eyes. This difference in price is the big factor pulling Americans across the border. In addition, the Canadian clinics are exempt from the $250 royalty fee that American clinics must pay to U.S. laser manufacturers for each eye procedure done. Among the most popular clinics in the Seattle area are the **University of Washington's Refractive Surgery Center** and **TLC Northwest Laser Center**. Less than a year old, the UW center now performs more than 100 LASIK surgeries each month. **LASIK Vision Canada**, which began as one clinic in Vancouver, and now has nine clinics across Canada, has seen even more dramatic growth, performing 5092 procedures in the first three months of the year, compared to 593 in the same quarter a year ago. The company plans to expand into the U.S., including the Seattle area, this year. At LASIK Vision's Vancouver office, about half of the 400 patients per month are Americans, the bulk coming from Washington, and others filtering in from Oregon, Idaho, and Alaska.[1]

In B.C., besides LASIK Vision and TLC, other competitors include **Gimbel Vision** and **Lexington LaserVision**, a new company focusing heavily on Puget Sound-area patients. Lexington, based in Surrey, BC, offers a $100 discount if you book with a friend, and can arrange for pre- and post-operative visits at **Focus Eye Care**, a private clinic in Bellevue, WA, rather than travel back to Canada.

6/3 **TLC The Laser Center** announced that over 90,600 paid procedures were performed at the company's refractive centers in the year-ended May 31, 1999. Over 29,200 paid laser procedures were performed at TLC refractive centers in Q4-99. This is a 110% increase from 13,928 for the same period a year ago. The increase was primarily driven by an 84% same-store procedure growth.

6/3 **KeraVision** said it had completed the acquisition of **Transcend Therapeutics, Inc.** and its net cash balance of approximately $8.4 million. Transcend had terminated its activities as a drug development company and now becomes a wholly owned subsidiary of KeraVision. No Transcend employees were retained. KeraVision intends to use the cash for market development activities in North America, to pursue regulatory approvals for products under development, for research and development, and for working capital and general corporate purposes. Transcend stockholders received approximately 980,000 shares of KeraVision common stock. The agreement was approved by Transcend stockholders last week.

6/3 **Pacific Growth Equities** analyst Al Kildani issued an initial report on **LaserSight**, with a recommended "strong buy" rating, and a 12-18 month target price for the company's stock of $26, up from the current selling price of $16.50. His reasons for the optimistic view included: the rapid growth of the LVC market; the company's

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[1] A 1/8th page ad ran in the June 21st *Boston Globe*, inviting Bostonians to travel to Montreal to have thier eyes done. The first 1000 applicants can get it done for $999 (US) for both eyes!

leading position with flying-spot small beam scanning technology; and its coupling the laser with its line of microkeratome products. In addition, Kildani noted the strategic relationships that the company held with **TLC The Laser Center**, which owns a 15% share of the company's stock, and its exclusive alliance with **Becton Dickinson's** ophthalmic product division to manufacture and distribute microkeratome blades and other refractive surgery products to the ophthalmic community. Kildani expects that the company will gain myopia FDA marketing approval for its laser system in the third quarter of this year, allowing the sale of its excimer laser into the U.S. market. However, to compete effectively, the company will need to achieve a broad range of approvals, including for the treatment of astigmatism and hyperopia. He expects the company to file for supplemental approval for astigmatism during the Q2 or Q3 timeframe, with approval anticipated by the end of the year. LASIK trials have begun and hyperopia should be approved during the first half of 2000.

One important step in entering the U.S. market will be how to handle the **VISX/Summit** patent situation. The company has not yet revealed its strategy, however Kildani believes that LaserSight might be willing to negotiate a licensing agreement with VISX, as long as the terms make commercialization of the LSX laser economically viable.

Kildani also believes that LaserSight is an attractive acquisition target, with potential acquirers including larger device manufacturers seeking to either augment their ophthalmic product line or entering the rapidly growing LVC market.

All in all, a very positive report on this company.

6/4 In an important announcement for **VISX**, administrative law judge Stuart Levin dismissed the remaining FTC charges against the company. This followed the consent order last March, settling all charges against **Summit Technology** and VISX, except for the allegations that VISX had obtained a patent (the Trokel patent) by fraud. The remaining allegations charged that VISX and others, on behalf of Dr. Stephen Trokel, the named inventor of the key patent for PRK (Trokel '388), willfully withheld from the PTO certain articles, patents, and patent applications which they knew were material "prior art". Had this "prior art" been disclosed to the PTO, Trokel '388 would not have been issued, FTC Complaint Counsel charged.

Judge Levin's initial 145 page decision ordering the dismissal of the remaining charges against VISX states that Complaint Counsel had not satisfied their burden of establishing by clear and convincing evidence that the prior art was actually withheld with intent to deceive. The complaint alleged that four material prior art references (the Keates, Karp, Girard, and Blum references) were not disclosed to the PTO examiner in connection with the prosecution of Trokel '388. Judge Levin outlined in detail the history of the Trokel '388 patent, including an "interference" proceeding initiated by Trokel against a previously filed patent (L'Esperance), and the post-interference prosecution of '388.

The decision found that it was undisputed that, in connection with the '388 patent prosecution, the examiner did not list Keates, Karp, Blum, and Girard as having been discussed. However, Judge Levin noted numerous references to Keates, Karp, Girard, and Blum cited during the interference process as well as in co-pending applications before the examiner. Complaint Counsel contended that none of the many disclosures satisfied VISX's duty of candor to the PTO. Judge Levin concluded, however, that no case involving hidden prior art cited by Complaint Counsel approximated the sheer volume and openness of the prior art disclosures actually put before the PTO during the interference proceeding and in co-pending applications before the PTO examiner.

As reported by *WSJ* reporter Laura Johannes, the judge added that he was "not persuaded" by the testimony of VISX's patent attorney that he had forgotten to file the prior art, but the judge did find that Steve Trokel was credible in his testimony.

Following the announcement, VISX's chairman and CEO, Mark Logan stated, "VISX is extremely pleased that the court recognized the strength of VISX's case and the enforceability of these patents."

According to *Dow Jones* and *The WSJ*, following the ruling, investors appeared to believe that the worst was over for the company and shares rose 31%, over 17 points, on trading of 11.8 million shares. Summit Technology, who cross-licenses the patents, also gained over 3 points.

BancBoston Robertson Stephens senior medical device and medical technology analyst Wade H. King, M.D., also added his "two cents", reiterated his Buy rating on VISX. "We are reiterating our Buy rating on VISX with a 12-month price target of $95, after the FTC announced today that it has dismissed its case against the company," said King. "In his decision, the administrative law judge stated that there was no convincing evidence that VISX or its founders committed fraud or had intent to deceive the patent office. While an appeal from the FTC's Complaint Counsel is possible, any such proceedings would take an additional year to resolve."

Although this announcement settled one of the outstanding legal issues facing VISX and the industry, several others, including the results of the ITC litigation against Nidek, expected to be announced this fall, are still outstanding. Also, the Trokel and Warner patent re-examination suit brought by ophthalmologist John Dishler also remains to be resolved. Both of these could have ramifications on the industry, first whether Nidek is allowed to market its laser system in the U.S., and secondly, whether the $250 per procedure fee will stand at that level or be reduced because of competition by competitors not charging a per procedure fee.

The FTC Counsel has 10 days in which to file an appeal.

The company also noted that it would become a component of the Nasdaq-100 index, effective June 10th, replacing retailer Nordstrom Inc. which is moving to the New

York Stock Exchange.

6/4 As reported by *Medical Industry Today*, Japanese doctors are curing some cases of blindness with transplants in which special tissue-making cells are surgically placed into the eye, according to results of recent research published in this week's *New England Journal of Medicine*. The discovery, which may encourage people who have lost their sight by fire, chemical burns, or illness, could overturn the fate of permanent midnight for many of the world's blind. Until now, blindness caused by damage to the eye's surface was considered largely untreatable. The new procedure, pioneered a decade ago, but since refined, would not be of help to those born with blindness or to those suffering from nerve or retina damage. It would, however, help patients who are legally blind but can still sense light, said the researchers at **Tokyo Dental College**, where the research is being performed at the medicinal unit. The new procedure provides patients with the epithelium factory, stem cells that produce other cells including new epithelial cells that cover the eye, and after 39 months, researchers said transplanted tissue was still generating the cells in 51% of the patients.

6/4 According to the *Xinhua News Agency*, via *NewsEdge*, as China becomes more urbanized increased leisure time dominated by watching TV and surfing the Internet is posing greater risks of shortsightedness and other problems with eyesight, particularly among the younger generation. This has been revealed from a survey carried out in Beijing, Shanghai and Guangzhou to link in with National Health Eye Day. More than 70% of those polled chose watching TV and reading books as their major recreations, while staring at computer screens occupied most of the spare time of many young people, the survey revealed. The average age for being affected by shortsightedness has dropped to 14.3 years from 14.7 years in Shanghai, and to 14.8 years from 15.2 years in Beijing.

6/6 **Dain Rauscher Wessel's** analyst Dave Therkelsen initiated coverage of **Iridex** on May 24th, with a "buy-speculative" recommendation, and a 12-month target price of $8 per share. Therkelsen believes that new products will drive growth, including the recently launched Iriderm 810 diode laser for hair reduction, launched at the American Academy of Dermatology meeting in March. Some of the applications offering "home-run" potential, include the treatment of both wet and dry ARMD using its OcuLight SLx laser, and work with its partner, **Miravant Medical** on the use of PDT to treat ARMD, using Iridex's diode lasers.

6/7 **Refractec, Inc.**, the developer of the Radio-Frequency Keratoplasty (RFK) for vision correction using the Refractec Corneal Shaping (RCS) System, announced the closing of a $5 million round of venture capital financing. Refractec is currently conducting clinical trials in the United States for RFK, a minimally invasive non-laser approach for correcting low to moderate hyperopia. Since February, more than 40 patients have been treated in Phase III clinical studies, and early indications look very promising. The source of the financing is **Brentwood Venture Capital** of Irvine, CA. Brentwood General Partner, William Link, will join the Refractec board of directors.

The proceeds from this funding will allow the company to complete domestic clinical trials and commercialize the RCS System. The potential refractive procedure market for the RFK System includes: low to moderate hyperopia, presbyopia, astigmatism, and eyes that have been overcorrected by excimer laser treatments.

6/7 *OptiStock* noted that **Advest, Inc.** had initiated coverage of the following companies: **VISX**, with a market perform rating; **KeraVision**, with a buy rating; **Laser Vision Centers**, with a buy rating; and **Ocular Sciences**, with a market perform rating. The extensive "Vision Correction" report, prepared by medical device analyst Ted Huber, provides complete analysis of the vision correction and contact lens markets served by the above named firms. As Huber states in his report, "Vision Correction: The Revolution is Upon Us", refractive surgery is fundamentally changing the way vision is corrected, and although new technologies will enter the market in 1999 (including Intacs from Keravision), LASIK/PRK will continue to dominate. He suggests that investors should own refractive surgery providers to hedge the impact that an adverse patent finding on VISX could evoke. In his coverage of the contact lens industry, he says that growth in weekly disposable lenses is slowing, but that international growth remains robust.

6/8 **LCA-Vision** announced the filing of a registration statement with the SEC for a public offering of 8,300,000 shares of common stock. The company is offering 5,000,000 shares, while selling stockholders are offering 3,300,000 shares. The selling stockholders also will grant the underwriters an option to purchase 1,245,000 shares to cover over-allotments, if any. LCA-Vision intends to use the net proceeds from this offering for expansion into new geographic markets, development of new centers, marketing, advertising, working capital and general corporate purposes. LCA-Vision will not receive any proceeds from the sale of shares by the selling shareholders. The offering is being lead managed by **Prudential Securities** and co-managed by **Dain Rauscher Wessels** and **Raymond James & Associates, Inc.** (See my review of the prospectus in the 6/21 brief below.)

6/8 **Vision Twenty-One** announced results for the first quarter with revenues up 30% to $65.9 million while EBITDA before business integration costs up 20% to $5.4 million. Excluding the impact of business integration costs in 1999 as a result of the company's previously disclosed restructuring plan, net income was $1.3 million (9 cents per share) or inclusive of business integration costs, $16,175. The business integration costs which are expected to continue to be incurred by the company through 1999 on a diminishing basis, are expected to provide approximately $8.0 million in total annual cost savings once fully implemented. These cost savings will increasingly be realized in 1999 as the year progresses. Refractive surgical procedures for the first quarter increased 213% to 4,189 as compared to 1,336 for the first quarter of 1998.

In addition, the company announced the completion of the sale of its Buying Group for an undisclosed amount. The company applied the cash portion of the purchase

price to repay a portion of outstanding borrowings under the company's credit facility. The sale of the Buying Group will reduce the company's revenues but will be beneficial to overall operating margins. The company had previously announced its intentions of selling the Buying Group which had little long-term strategic value to the company based upon its current vision and refractive care priorities.

The company also announced the conclusion of its previously announced accounting reconciliation process and the final results for its year ended December 31, 1998. For the year, revenues increased 221% to $223.4 million, while EBITDA before unusual items, grew 352% to $17.4 million. Unusual items consisted of: business integration costs of $8.3 million related to the previously announced restructuring plan; merger costs of $0.7 million; start-up and software development costs of $1.0 million, an extraordinary charge of $1.3 million related to early extinguishment of debt; and expenses for the intercompany reconciliation and other items totaling $4.2 million. The results of the company's reconciliation of the previously announced unreconciled items was a $1.6 million expense impact and this coupled with other one time items including receivables, revenue recognition regarding acquisition integration fees, and intangibles reduced income by $2.6 million. Excluding the impact of these items in 1998, and excluding an extraordinary charge in 1997, net income increased to $3.2 million (22 cents per share) compared to net income of $0.4 million (5 cents per share) on a comparable basis last year. After consideration of these items, the company reported a net loss of $8.0 million (55 cents per share) for 1998.

The following day, Vision Twenty-One and **Minnesota Eye Laser & Surgery Centers** announced that they had recently opened the first eye laser center in a downtown skyway location in Minneapolis. The new eye laser facility is located off one of Minneapolis' most traveled skyway bridges connecting the IDS Center and Investors Building on Marquette Avenue. The skyway location was selected to accommodate growing consumer demand for laser vision correction by offering working professionals and city residents convenient access to a full-service eye laser center. (For more on store-front and mall laser vision correction centers, see the 6/15 brief below.)

6/8 **Lasik Vision** announced that it had agreed to an exclusive contract with the **U.S. National Air Traffic Controllers Association (NATCA)** to offer a premium laser vision correction corporate program to more than 10,000 NATCA members and their families throughout the U.S. The NATCA Corporate Program includes LASIK or PRK surgery, initial examination fees, all in-house pre- and post-operative care and Lasik Vision' Lifetime Enhancement Commitment. The program will be offered at any of Lasik Vision's nine Canadian clinic locations.

6/10 **Laser Vision Centers** announced that its U.S. case volume for the month of May increased 127% compared to the same month a year ago. The company said that the month of May was its best month to date for U.S. surgical case volume. The company operated a total of 42 lasers in the U.S. during May 1999.

6/10 *The American Stock Exchange* announced it expects to trade options on the Nasdaq National Market stock of **LaserSight Incorporated**, under the symbol SUE, beginning Tuesday, June 15. SUE will open with initial strike prices of 10, 12-1/2 and 15, with position limits of 22,500 contracts. Initial expiration months will be July, August and November of 1999 and February of 2000. The specialist unit for the new options will be **Group One Trading L.P.**

6/10 **Sterling Vision** announced that, based upon its financial results for the month of April, it expects continued profitability in the second quarter of 1999. The company attributes this continued profitability to the initiatives taken by its new management team which continues to implement aggressive cost controls and new marketing strategies, as well as the continued profitability of its laser and ambulatory surgery centers. Dr. Robert Cohen, chairman, stated "The company is focusing its resources on its **Insight Laser Center** division and Internet initiatives which it expects to gain momentum during the coming summer months. In addition, Sterling is negotiating various agreements which are anticipated to result in the opening of four new laser centers in the second half of this year."

6/10 This month's issue of *Refractive Market Perspectives* details the recapturing of share by the corporately-owned laser centers. The centers group performed 45.6% of the procedures done during the first quarter, growing its market share by 3.6%. Surgeon-owned centers lost some share, dropping to 38.1% of the market, while institution-owned centers lost significant share down to 16.5%, compared to 19.4% for the fourth quarter. Of the corporate management companies, **TLC The Laser Center** continues to lead the pack with a 26.6% share down, however, from 27.9% for the previous quarter. **Laser Vision Centers** had a gain, increasing from 20.2% to 22.0% during the quarter. Others sharing the market included: **Clear Vision**, 15.3%; **LCA-Vision** 10.3%; **Aris Vision**, 7.7%; and others with 18.1%.

David Harmon notes that with the new suits brought by **VISX** against **Nidek** laser users, described in the 5/31 brief above, it now has brought four cases against surgeons using these lasers. He goes on to say that the critical decision pending for VISX is the one with the ITC against Nidek, which has the potential to stop Nidek from importing lasers, parts, and service into the U.S. As he states, most experts expect the case to be a watershed event. (Which could lead to either stopping Nidek, or a potential lowering of the per procedure fee, if Nidek prevails.)

David also reports that the weighted average of global patient fees declined slightly from $2180 in June, 1998, to $2134 in his recent survey of refractive surgeons, completed in March. Although, looking at the accompanying graphic, it appears that more surgeons have raised their prices in the $1800-$2400 range, than have dropped them.

6/11 Wade King of **BancBoston Robertson Stephens** continues to post "buy" ratings on **VISX**. This time he notes that "VISX should be a core holding for investors in

medical device and medical technology companies...There is no comparable growth and investment opportunity in the medical device universe today."

6/11 **Sunrise Technologies** announced it rejected the claims of a **Sturza Institutional Research** report issued about the company on June 7th. The company completely rejects Sturza's analysis and findings, charging that the report distorts the clinical data and the company's business and prospects. The company characterized the report as slanted and incomplete. For example, according to the company, Sturza's report ignored the impact of the most recent and the most extensive clinical data that is currently being reviewed by the FDA.

"We welcome fair comment, analysis and critique. Our shareholders and potential investors deserve the benefits of many differing points of view. However, we strongly object to writings that are unbalanced, incomplete, and which attempt to unfairly discredit good science," said Russell Trenary, President and CEO. The company has asked its outside counsel to conduct an investigation of the report and share its findings with the company's Board of Directors no later than June 30, 1999.

6/14 **Bausch & Lomb** and **Control Delivery Systems**, a privately held research company in Watertown, MA, announced that they had signed an agreement to develop groundbreaking ophthalmic products to treat a variety of sight-threatening retinal and other intraocular diseases, including age-related macular degeneration (ARMD), the leading cause of blindness in older people in the developed world. Bausch & Lomb and CDS will develop sustained release pharmaceutical implants based on CDS' proven technology used in Vitrasert, a drug-delivery implant that successfully treats a complication of late-stage AIDS, which causes blindness when left unchecked.

Under the terms of the agreement, Bausch & Lomb obtains exclusive worldwide marketing rights for all ophthalmic products based on the patented CDS drug delivery technology. Bausch & Lomb will make a series of milestone payments to CDS, and will fund research and development costs. Bausch & Lomb will also pay royalties on product sales. No other financial details are being disclosed.

6/14 According to *EyeWorld Week*, the FDA's Ophthalmic Devices Panel will talk to microkeratome users and manufacturers as early as this summer. The FDA asked the group to make findings about the instruments' safety and quality. Quyah Hoang, an FDA reviewer, said the organization has not yet provided a list of questions the committee must answer. Hoang said that manufacturers and others interested in testifying will be given 2 months' notice of the meeting. She said the schedule would depend on the number of instrument applications before the board, because they are given priority over this hearing. The panel will be asked to make a microkeratome recommendation, which could lead to an FDA ruling, Hoang explained.

The newsletter also reports that **Autonomous Technologies'** LADARVision excimer laser system received its first commercial use in the United States on June 8th.

Company investigator and EyeWorld Medical Editor Marguerite McDonald, MD, used the laser to perform LASIK on 12 myopic eyes at **Southern Vision Institute** in New Orleans. The FDA approved the LADARVision system in November for myopia of 1 to 10 D and for astigmatism of up to -4 D.

6/14 *Contact Lens Today* editor Joe Barr, OD commented, "I think the next few years of observing whether extended wear contact lenses or overnight orthokeratology will have any impact on refractive surgery will be interesting. A few say these procedures will slow the tide of refractive surgery patients. However, I wonder if eventually those who want surgery are destined to have it, no matter how good or convenient we make contact lenses."

6/14 **Block Vision, Inc.** announced it will host an educational seminar on the topic of refractive surgery -- one of the fastest-growing procedures in healthcare today -- at this year's AAHP Managed Care Institute. The seminar, "Refractive Surgery: A Vision Care Option for the Next Millennium" will take place on Monday, June 21, 1999, at the San Francisco Hilton and Towers in San Francisco. The seminar will describe the highly popular LASIK refractive surgery procedure, as well as data regarding the explosive growth of this procedure, which is fast becoming a key form of vision correction. Attendees from the managed care industry will have the opportunity to engage in an open discussion regarding the addition of this procedure to their benefits packages.

Block Vision, a leading national vision benefits manager, is a wholly owned subsidiary of **Vision Twenty-One, Inc.**, which specializes in the management and delivery of vision care, with a growing emphasis on refractive surgery. Vision Twenty-One has vision care delivery systems in 40 markets located in 26 states and 14,000 affiliated eye care providers.

6/15 Shareholders attending the annual meeting of **Summit Technology** heard senior executives describe their strategy to reclaim leadership of the fast-growing laser vision correction business, one in which industry procedure volume had been doubling annually since Summit introduced the first laser system in 1996. CEO Robert Palmisano said that since joining the company in April, 1997, he has recruited new executives, accelerated FDA submissions, divested the company of its retail vision centers, which generated ill-will among its customers, purchased the state-of-the-art **Krumeich-Barraquer** microkeratome and acquired the technology of the future with its purchase of **Autonomous Technologies, Corp.** in Orlando, Florida.

"Today, we are ready to reclaim the industry leadership," he declared, citing large gains in customer regard over the past two years as solid evidence that Summit's focus on 'meaning more to the customer' is starting to pay off. Independent research by **Gordon Black & Associates** has shown that customers' willingness to recommend Summit has risen from 63% a year ago to 81% today. We have in place what it takes -- leading technology, broadening FDA approvals, management focus and key

priorities -- to expand our market share. We expect to produce solid growth by year end. With less than 1% of the US patient population treated today, there is an enormous opportunity to grow," Palmisano continued, noting that the enthusiasm of patients is the largest factor driving industry growth.

Other presenters included Verne Sharma, COO, who outlined Summit's many programs to assist refractive surgeons in building their laser vision practices, and Summit's educational programs, which include founding sponsorship of the LASIK Institute, whose board is comprised of 24 of the world's leading surgeons. Menderes Akdag, president of Lens Express, said that he expected to report year-on-year gains and to introduce a new e-commerce capability to serve lens customers over the Internet.

Randy Frey, president of newly-acquired Autonomous Technologies, discussed the pathfinding LADARVision laser system now being introduced to the US market. Frey described progress on Autonomous' CustomCornea wavefront sensing technology, a revolutionary approach to vision correction that promises to correct vision to the quality enjoyed by famed Boston Red Sox slugger Ted Williams, whose 20/10 eyesight (I thought it was 20/15?) is thought to have contributed to his legendary prowess at the plate. "This could also quadruple the addressed market by extending vision enhancement to the mildly impaired," Frey noted.

6/15 **VISX** reported the release of a new software upgrade for the Star S2, Custom VisionKey 3.1, which improves upon the existing capabilities of the Star excimer laser system. The new software enables VISX owners to treat myopic astigmatism with larger optical zones, and will give international users the ability to treat irregular corneas using variable offset ablations, using the Contoured Ablation Pattern (CAP) method. The new software features an option to treat myopic astigmatism up to 6.5 mm. In addition, the minimum ablation zone size for cylindrical corrections has been increased to 5.0 mm. According to the company, these changes should result in improved quality of night vision, especially for those with large pupils. The update package will be mailed to U.S. certified physicians soon, with new Star S2 systems shipping in mid-June having the software installed.

6/15 *Dow Jones Business News* reported that **Sunrise Technologies'** stock fell 5.9% Tuesday, its second decline in as many days, amid a growing dispute within the investment community concerning the company's LTK product, which is up for regulatory review in July. CEO Russell Trenary attributed the two-day stock drop to highly critical reports issued by two research analysts last week, who cast doubt on Sunrise's laser achieving FDA clearance. Those negative opinions were refuted by both Trenary, who spoke in a telephone interview with Dow Jones Newswires Tuesday, and **Standard and Poor's** analyst Mark Arbeter, who published a bullish report about Sunrise on Tuesday morning.

"We're confident going into the panel," Trenary said. "We wouldn't be at the panel

meeting in July if we didn't think we could win."

On Thursday, **Avalon Research Group**, Boca Raton, Fla., said in a research note that there was "limited chance" that the FDA would approve a pre-market application for Sunrise's LTK device, which is used to surgically correct farsightedness. Avalon issued a "new sell/sell short" recommendation, and set a 12-month price target on Sunrise stock of $5. On June 7, **Sturza's Medical Research** issued a report critical of Sunrise's LTK system, citing adverse effects on patients in clinical trials. The report also predicted insignificant demand for the laser device.

But Trenary refuted both opinions, saying neither analyst contacted the company before making their comments, nor, to his knowledge, witnessed a procedure using Sunrise's LTK system. He said Sturza's report focused on 28 eyes that were treated with varied procedures between 1992 and 1994. The FDA's review will be based on a more complete study of a more specific procedure using the LTK system, Trenary added. This study included data from more than 600 eyes treated with one specific procedure. Disagreeing with both Avalon and Sturza's analysis, Arbeter was confident the LTK system would receive FDA approval, citing its simplicity, efficacy and lack of adverse effects. Arbeter pegged a price target of more than $20 on Sunrise stock before the end of 1999.

The company went to pains to issue a special shareholder's report on its web page. The letter reviewed a series of factors that it believes have positioned it for success, and reiterated its position about the two analyst reports noted above. (I have a copy of the shareholder letter from the web page, if anyone cares to view it.)

Not having seen copies of either of the two negative reports, I can only suppose that they are based on "old" clinical information that did show regression prior to a newer technique used for the majority of the clinical trial, similar to the information in the **MFC Merchant Bank S.A.** report that I disagreed with back in February (see the February 14/15 brief in the February newsletter). If I obtain copies of either report, I will give you a better opinion.

6/15 This month's issue of *EyeWorld* contains an interesting article about "Refractive Surgery: Coming to a store near you". The story discusses **Visual Freedom Center** and **Minnesota Eye Consultants PA** both opening shopping mall storefronts for refractive surgery. The former has opened in the Fair Oaks Mall in Fairfax, VA, while the latter opened **Eye Care Inc. Laser Vision Center**, a retail surgical center in the Minneapolis Skyway. Apparently, others have similar plans, with **Eyemakers**, which recently joined with **Icon Laser Centers of North America**, also having similar plans, planning to open Total Vision Solution stores, which will have both optical retailing and refractive surgery under one roof.

(Isn't that what **Sight Resource** originally planned to do before it reverted back to primarily optical retailing?)

6/16 **HCFA** announced the publication of a new regulation to ensure that cutting edge technology in cataract surgery is made available to the nation's Medicare patients. The regulation provides additional reimbursement to ambulatory surgical centers that implant new technology IOLs, which should have a significant impact on the estimated 1.8 million Americans who undergo lens replacement each year. Examples of new technology IOLs include multifocals (from **Allergan**) and toric designs (from **Staar Surgical**), recently approved by the FDA.

6/16 An independent consumer/patient group called the **Council for Refractive Surgery Quality Assurance (CRSQA)** has been formed to educate the public and provide a yardstick for measuring the success of U.S. refractive surgeons. CRSQA answers a pressing public need for objective information regarding refractive surgery, whose use has skyrocketed across the country, according to CRSQA Executive Director-Elect Glenn Hagele. Well-known Kansas City, Mo. ophthalmologist Daniel Durrie, MD, has been named chairman-elect of the CRSQA Board of Trustees. The board plans to hold elections this summer after candidates are identified to fill remaining vacancies. "Eye care professionals who wish to earn the CRSQA 'stamp of approval' will have to demonstrate outcomes that meet certain standards," Durrie noted. The standards will be determined by the board, whose members include ophthalmologists, optometrists, industry representatives, allied health care professionals, refractive surgery patients, and consumer advocates. CRSQA is in the process of applying for nonprofit status in California.

In addition to certification, CRSQA will provide educational opportunities both to professionals and the public. The organization is establishing a Website at **www.usaeyes.org**. The site offers information about CRSQA and the various refractive surgical procedures available to the public. Once CRSQA establishes its certification process, the site will offer contact information for all CRSQA-certified refractive surgeons. "CRSQA will handle complaints from individual patients, suggest remedial action for surgeons where appropriate, and withdraw certification from those surgeons who do not continue to meet our criteria," Hagele said.

In addition to Durrie and Hagele, current members-elect of the board include Keith Croes, president of **Croes Communications**; David Eldridge, OD, an officer with **TLC The Laser Center**; Kenneth Hagele, a board member of the **Idaho Legal Aid Services**; John Herman, OD, in private optometric practice; Randy McDonald, founder and president of **Magnum Marketing**; Jack Melton, OD, founder and chief executive officer of the **LExES (Laser Excimer Eye Surgery) Center** and senior partner of **Omni Eye and Laser Center**; James Townsend, executive vice-president for medical services at **CalFarm Insurance**; and Katherine Weber, RN, guidelines and outcomes analyst, **Intracorp, Inc.**

6/10 **Premier Laser Systems** announced that it has proposed to acquire 100% ownership of **Ophthalmic Imaging Systems Inc. (OIS)** through a merger of OIS with a wholly-owned subsidiary of Premier. Premier currently owns approximately 51% of

OIS' outstanding shares of stock. Premier's proposal is nonbinding, and the proposed transaction would be subject to numerous contingencies. In particular, the Board of Directors of OIS and shareholders representing 75% of OIS' outstanding shares (including at least a majority of the OIS shares that are not held by Premier) would need to approve the transaction, the parties would need to negotiate and sign a definitive Merger Agreement (which would contain customary conditions to closing), and OIS would need to obtain a fairness opinion. In addition, prior to closing, Premier would need to register with the SEC the shares of stock issuable to OIS shareholders in the proposed merger.

According to Premier Laser chairman, president & CEO Colette Cozean, "Based on the progress that has been made through our association with OIS, it has become clear to management that OIS can be a far more valuable asset as part of our **EyeSys Vision Group** than as a stand-alone entity. Specifically, the board recognizes immediate and significant synergies and cost savings that can be gained across product development, manufacturing, marketing and sales, and accounting activities."

6/17 **Eye Care International (ECI)** announced a strategic relationship with **Senior Publishers Media Group (SPMG)**, a national and regional advertising representative firm for more than 380 mature market publications, representing a national circulation reach to more than 18 million seniors. Through ECI's Senior's Exclusive Plan, mature market readers will be able to access ECI's extensive panel of ophthalmologists (EyeMDs) and optometric providers saving as much as 68% on all eyewear and eye care needs. This includes savings even on all elective procedures, including the much sought after LASIK vision corrective surgery, and $C0_2$ laser surgery (skin resurfacing). With a national network of more than 11,000 provider locations, the ECI Program is ideally suited for the senior market.

6/17 According to *NewsEdge*, **QLT PhotoTherapeutics** has been issued U.S. Patent 5,910,510, "Vision through photodynamic therapy of the eye". The abstract reads: Photodynamic therapy of conditions of the eye, especially those conditions characterized by unwanted neovasculature, such as age-related macular degeneration, results in enhanced visual acuity for treated subjects.

6/17 **Gimbel Vision International Inc.** announced that its common shares would be listed and posted for trading on the Toronto Stock Exchange as of Friday, June 18, 1999. The company will trade under the symbol "GBV".

6/19 According to *World Reporter*, as abstracted in *Borsen-Zeitung*, German laser systems technology manufacturer **Jenoptik AG** has, via its subsidiary **Deutsche Effekten-und Wechselbeteiligungsgesellschaft AG (DEWB)**, purchased a further 60% in German laser systems company **Aesculap-Meditec GmbH**. DEWB already had 40% of Aesculap, so it now owns the company entirely. Jenoptik announced that the new subsidiary will be taken to the stock exchange. In the 1997/98 financial year, Aesculap-Meditec turned over DM54.6 million with its 155 employees.

6/21 Saying that the company expects to exceed by at least 50% analysts' consensus revenue projections of about $2 million for the second quarter ending June 30, **KeraVision, Inc.**, announced that it had trained 187 ophthalmic surgeons to perform the Intacs treatment for myopia since April 9, when Intacs were FDA approved. In remarks given at the **Goldman, Sachs & Co.** 20th Annual Healthcare Conference in New York, KeraVision chairman and CEO Thomas Loarie said surgeon training is well ahead of schedule and that enrollment in the company's surgeon training sessions is fully booked through August. Previously, KeraVision said it intended to train 200 ophthalmic surgeons by year-end, or roughly 50 surgeons by the end of June. Second quarter revenues will largely reflect the sale of startup inventory of Intacs, instruments and surgeon training. (In other words, still no meaningful sales of implanted Intacs.)

6/21 **Vision Twenty-One** announced the opening of its **Arizona Eye Laser Center at Tucson** in Tucson. AZ. The company also operates a refractive eye laser center in Phoenix, AZ called the **Arizona Eye Laser Center at Phoenix**, which opened in February 1998. "Tucson will be a solid refractive market for Vision Twenty-One and the fifth market in our delivery system identified for an eye laser center," stated Theodore Gillette, Vision Twenty-One's CEO and president.

Vision Twenty-One has a strong presence and local delivery system in the Tucson market with more than 100 affiliated optometrists and ophthalmologists and four surgery centers including the new refractive center all serving the greater Tucson community. Additionally, Vision Twenty-One has exclusive managed vision benefits contracts that cover more than 250,000 members in both the Phoenix and Tucson markets.

6/21 **Ophthalmic Imaging Systems** announced that the proposal it had received from **Premier Laser Systems, Inc.** to acquire the balance of approximately 49% of its shares not currently owned by Premier had been rejected by a unanimous vote of its Board of Directors. Steven Verdooner, president of OIS, stated, "We have been working closely with Premier for some time, and we see a number of potential synergies and other benefits that might come from a combination of the companies. While our Board of Directors concluded that this offer was not adequate, we plan to continue discussions with Premier and are in the process of engaging a financial advisor to assist us in any further negotiations."

6/21 **VISX** announced that the FTC had filed a notice of appeal of the decision issued earlier this month by the FTC administrative law judge. As previously announced, the judge ordered that the FTC's complaint against VISX regarding certain patents be dismissed. VISX is confident that the judge ruled correctly. Given the FTC's extensive investigation and the thorough six-week trial, VISX believes that the judge considered the FTC's best arguments when he wrote his well-reasoned, 145-page ruling for VISX. This appeal is not a surprise, however, as the FTC almost always appeals adverse administrative rulings to the full Commission. The Commission is expected to review the case and issue its final decision in approximately one year. VISX plans to

appeal any adverse Commission decision to a federal court of appeals.

As expected, **BancBoston Robertson Stephens** senior medical device and medical technology analyst Wade H. King issued a statement in support of the VISX announcement, reiterating his support of the company. "We are reiterating our Buy rating on VISX. We believe the preliminary ruling in favor of the company was grounded upon extremely thorough analysis and articulate legal opinion. The appeal is not unusual, as we believe the FTC appeals nearly all unfavorable decisions to the FTC Commission," said King. He further commented, "We expect the appeal process to last approximately 12 to 18 months, during which time, no new trial or formal information gathering takes place. All VISX's patents in question remain fully valid and enforceable throughout the appeals process."

6/21 I received a copy of the **LCA-Vision** "red herring". The offering is composed of 8.3 million shares, of which the company is responsible for 5 million and founder's Steve Joffe and his wife are offering 2.7 million of the 3.3 million offered by shareholders. The company currently operates 22 laser vision correction centers, 19 of which are in metropolitan markets in the U.S., 2 in Canada, and 1 in Europe. The centers are supported by a network of over 2200 credentialed ophthalmologists and optometrists, who have performed over 60,000 refractive surgery procedures since inception in 1991.

The company expects to raise about $49 million and use the proceeds to open additional laser vision correction centers; purchase additional equipment; extensively market its centers and the LCA-Vision brand name; for funding possible future strategic acquisitions; and for working capital and general corporate purposes. As shown in the financials included in the offering statement, revenues from laser vision correction have almost completely overtaken revenues from the ever decreasing surgery management contracts that was an original focus of the company. In 1998, surgery revenues represented only 6% of total revenues, and further decreasing as a percent of total revenues in the first three months of 1999.

6/22-
6/24 **Omega Health Systems, Inc.** announced that it plans to change its corporate name to **VisionAmerica Incorporated**. The name change has been approved by the company's board of directors and is subject to final approval by the company's shareholders at the annual meeting to be held on August 11, 1999. The company will apply for a new corporate trading symbol to be effective upon approval.

On the following day, the company announced that it had accepted delivery of two additional VISX STAR S2 Excimer Laser Systems and had established laser centers at the company's eye care centers located in Albuquerque, NM, and Springfield, MO. The delivery of these two additional lasers brings the total number of new lasers delivered to Omega centers to six, and marks the company's continued expansion to offer laser vision correction capabilities nationwide through its 22 eye care centers.

With the addition of Albuquerque and Springfield, the company now has eight laser centers in its network. Other laser centers are located in Memphis, TN; Omaha, NE; Tampa, FL; Dallas, TX; Danville, IL; and Marion, IN.

"Our plan to offer laser vision correction procedures in all of our markets is on schedule, and we are pleased to announce the delivery and installation of two new lasers to serve these important centers," commented Thomas Lewis, president and CEO. "The favorable response we have had in our five initial markets has been tremendous and has helped our laser procedure volume grow to 3,566 for the period ending May 31, 1999. We are confident that this trend will continue as we execute our plan and develop this capability in other Omega eye care centers across the country."

The company then announced it had signed a letter of agreement with **Universal Health Systems** to develop and manage a national co-management panel of ophthalmologists and optometrists to provide refractive surgery services. Universal Health Systems markets ancillary health services to employers and other groups nationwide and currently has over 7 million enrolled members.

6/24 **IRIDEX Corp.** announced the publication of a pivotal clinical study which shows improved patient outcomes in ophthalmic retinal laser therapy. The study has shown that a new method of retinal laser treatment, so gentle that the patient cannot feel it, can be effectively performed without any sign of laser induced retinal burn or the associated loss in visual function currently seen with conventional laser photocoagulation. The study was performed by Doctors Moorman and Hamilton at the **Moorfields Eye Hospital** in London, and reported in the recent issue of the journal *Eye*, the official publication of the *British Royal College of Ophthalmologists*.

In the clinical study, 52 eyes of 33 patients with diabetic retinopathy or macular edema were treated with IRIDEX's **IRIS Medical** OcuLight SLx 810 nm infrared diode laser system in its unique MicroPulse operating mode and followed for six months. The results demonstrated that the nonvisible lesions created with the IRIDEX diode laser in MicroPulse mode were therapeutically effective without any complications or adverse effects, were extremely well tolerated by all patients, and in many cases no visible evidence of treatment was observed six months later.

IRIDEX's unique MicroPulse technology, now incorporated in all IRIS Medical OcuLight SLx infrared diode laser systems, carefully controls the delivery of laser energy by pulsing the semiconductor-based diode laser on and off in order to minimize the thermal spread of the laser lesion. This method provides the control to protect the sensitive adjacent tissues, such as the sensory retina, from damage.

6/25 **Visual Freedom Center, Inc.** announced the opening of a new Visual Freedom Center at The Mall in Columbia, MD. The Center, to be located on the lower level near Nordstrom, will provide convenient access for patients to state-of-the-art vision

correction technology. The new facility, the first of its kind in the Columbia area, is scheduled to open in September.

VFC, Inc. was established in 1996 to provide visual freedom through state-of-the-art refractive procedures. The initial Visual Freedom Center was located in Washington, D.C.

6/26 **VISX** announced that its national consumer launch will begin on July 9th, including full-page print ads in national publications, as well as drive-time radio spots on national networks.

6/28 **KeraVision** received a boost with the publication of a story about it being one of the companies to double its stock price over the past year in *The Motley Fool*. The "hook" of the story is that the company has now trained close to 200 surgeons in the implantation technique, well ahead of schedule. (As noted above, this has led to a doubling of revenues as well, as each of the trained surgeons "buys in" to an implantation kit.)

6/28 **Pharmacyclics** announced that the interim phase I/II clinical results with lutetium texaphyrin (Lu-Tex/OPTRIN) for the photodynamic therapy (PDT) of patients with age-related macular degeneration (ARMD) were presented at the meeting of the *European Society of Ophthalmology* in Stockholm. Fifty-eight patients with the wet form of ARMD were treated in this study, sponsored by the **Alcon** group, which is designed to evaluate various treatment regimens in successive cohorts of patients. Increasing doses of drug and light, and varying time intervals between drug administration and light delivery were examined in order to define the optimum treatment parameters. Although primarily a safety study intended to establish the maximally tolerated dose, clinical activity was assessed by fluorescein angiography and measurements of visual acuity. Patients received a single intravenous injection of Lu-Tex, followed by light delivered to the retina at various times up to 180 minutes after injection of the drug. In a subset of patients, fluorescence imaging was performed to evaluate pharmacokinetics and drug uptake in choroidal neovascularization (CNV) and clearance from normal retinal tissues.

Lu-Tex could be shown to localize selectively in CNV and, depending on the dose of drug and light and the interval between them, resulted in complete or partial closure of diseased vessels following activation with light. In patients treated with doses of drug less than or equal to 2 mg/kg, complete or partial closure of CNV was seen in 1 of 19 patients. In the combined groups of patients receiving 2.5 or 3.0 mg/kg of drug, complete or partial closure of CNV was achieved in 9 of 13 patients. Twenty of 26 patients had complete or partial closure when treated with 4 mg/kg of drug. Light dose was also an important parameter. Complete or partial CNV closure was seen in 3 of 18 patients treated with light doses of 50 or 75 Joules/cm^2. At a light dose of 100 Joules/cm^2, 19 of 31 patients had complete or partial CNV closure. In the combined group receiving light doses of 125 or 150 joules/cm^2, 8 of 9 patients had complete or

partial closure. Complete or partial CNV closure is a surrogate marker for treatment effect. In a preliminary analysis of the patients with complete or partial closure, visual acuity was found to improve by a mean of 0.50 +/- 0.28 lines at one week post treatment. In the patients without closure, there was a mean decrease in visual acuity of 0.33 +/- 0.25 lines at one week post treatment. The difference was statistically significant, $p<0.03$. Patients receiving higher doses of Lu-Tex experienced transient paresthesias (tingling) of the fingertips. For example, in patients receiving less than or equal to 2 mg/kg of drug, 1 of 19 experienced paresthesias, while in the combined group of patients treated with 2.5 or 3 mg/kg, 3 of 13 experienced paresthesias. In patients treated with 4 mg/kg, 20 of 26 experienced paresthesias. One patient developed facial phototoxicity following sun exposure. No other systemic toxicities were observed. In 5 patients, damage to collateral normal retina was observed. These patients either received the highest dose of drug (4 mg/kg) or received light within a short interval following drug administration (one patient). There was no retinal damage observed in patients who received high (125 or 150 Joules/cm^2) doses of light.

Pharmacyclics and Alcon entered into an evaluation and license agreement in December 1997 for the use of Lu-Tex for ophthalmology indications including ARMD, the leading cause of blindness in adults in the U.S. Under the terms of the agreement, Alcon conducts and bears all costs for the worldwide development and drug registration for ophthalmology indications of Lu-Tex. Alcon has been conducting preclinical and clinical development of Lu-Tex.

OPHTHALMIC LASER UPDATE -- July 1999

6/28 **STAAR Surgical Company** announced that it had received an unsolicited cash offer from an entity, whose principals were not disclosed, to purchase between 51% and 100% of the company at $15.00 per share.

6/29 **PacifiCare Dental & Vision**, the dental and vision division of **PacifiCare Health Plan Administrators**, has begun offering its national vision plan in Nevada and its preferred provider organization dental health plan in five Southern California markets. PacifiCare Health Plan Administrators is a wholly owned subsidiary of **PacifiCare Health Systems Inc.** The vision product includes a PPO plan, a full-service plan for small to large-sized employer groups and the *Eyewear Only* plan, which provides members with a materials-only benefit. An additional feature of the product offering in Nevada is that members can receive a discount on laser eye surgery through **Vision Twenty-One**, the contracted provider network.

6/30 **LCA-Vision** announced that its offering of 6 million shares had been priced at $8.00 per share, resulting in $37.8 million to be raised by the company. The offering was expected to close on July 6th. The offering was composed of 5 million shares from the company, and 1 million from certain selling stockholders. Coinciding with this

announcement, the company's shares will begin trading today on the *Nasdaq National Market System*. The company's ticker symbol "LCAV" will remain unchanged. The net proceeds will be used to open additional laser vision correction centers, purchase additional equipment, market current centers, and fund potential future acquisitions, as well as for working capital.

6/30 **Omega Health Systems** announced that it had established new laser centers at the company's eye care centers located in Birmingham, Alabama, and San Antonio, Texas. The delivery of two VISX STAR S2 Excimer Laser Systems to these locations brings the total number of laser centers to 10 and marks the company's continued expansion to offer laser vision correction capabilities nationwide through its eye care centers. Laser centers are also located in Memphis, Tennessee; Omaha, Nebraska; Tampa, Florida; Dallas, Texas; Danville, Illinois; Marion, Indiana; Albuquerque, New Mexico; and Springfield, Missouri.

As previously announced, the company plans to change its name to **VisionAmerica Incorporated**, subject to shareholder approval at the annual meeting on August 11, 1999.

6/30 **Sterling Vision** announced that it had reached an agreement in principal for its wholly owned subsidiary, **Insight Laser Centers, Inc.**, to open an additional vision correction center in lower Manhattan. The Insight Laser Center in the Soho district will be state of the art and is planned to open in July.

6/30 **Paine Webber** and **Bear Stearns** both initiated coverage of **Bausch & Lomb** with "attractive" ratings.

6/30 Analyst Richard Leza of **John G. Kinnard & Co.**, issued an update report on **Staar Surgical**, in response to the unsolicited offer made to the company by an undisclosed group. Leza believes that the $15 per share offer is too low relative to peer valuations, and will probably be rejected by the company. Based on his reasoning, the $15 offer would be fair just for the company's IOL business, but that the company's remaining business would justify a price closer to $23 per share, which is his one-year price target.

7/1 **Vision Twenty-One** announced the opening of its New Jersey Eye Laser Center at Bergen. "The New Jersey Eye Laser Center at Bergen is the eighth refractive surgery center in our system, adding to our existing strong presence in the laser vision correction market," said Theodore Gillette, CEO and president. "The residents of northern New Jersey will be introduced to the revolutionary benefits of laser vision correction through our network of affiliated optometrists, ophthalmologists and retail optical stores as well as through our managed vision benefit contracts covering 300,000 exclusive lives in this market," added Gillette.

7/1 **Prudential Securities** initiated coverage of **LCA-Vision** with a "strong buy" rating. Also, the **American Stock Exchange** said it expected to begin trading options of LCA

on July 9th.

7/3 Canada's *National Post* published an article by Laura Pratt detailing her experience "going under the beam" in having LASIK performed by Dr. Jeff Machat of **TLC The Laser Center's** Toronto center. Suffice to say, the author had a positive experience and wondered why she was so fearful of getting the procedure done in the first place.

7/6 **LCA-Vision** reported procedure volume for the three months ended June 30, 1999. The company announced wholly owned same-center procedure volume increased 78% to 8,365 procedures, compared with 4,692 procedures for the comparable 1998 period. The company's U.S. wholly owned same-center volume increased 87% to 8,012 procedures, compared with 4,291 procedures for the comparable 1998 period. The company's total procedure volume for the second quarter of 1999 increased 76% to 9,742 compared with 5,538 procedures for the comparable period in 1998.

"We are pleased to report that this is our 11th consecutive quarter of record procedure growth. We expect as more and more consumers become aware of the laser vision correction arena and patient confidence in procedure outcomes increases, this market will continue to expand," commented Stephen Joffe, chairman and CEO. "The company recently completed a public offering that contributed over $37 million and we plan to use these proceeds to fuel our regional growth. LCA-Vision continues to build strong networks of leading doctors contributing to our solid industry reputation and increased brand awareness."

7/6 **VISX** announced that its national consumer print campaign would open with an ad to appear in the July 9th issue of *USA Today*. Other publications scheduled for July include *Forbes* and *Newsweek*. Drive-time radio ads will debut during the week of July 12th.

7/6 As expected, **Staar Surgical's** board of directors concluded that the unsolicited offer made by an unnamed group was inadequate and not in the best interest of the company's shareholders. The party making the offer did not respond to the company's request to identify the party making the offer, its financial resources, and the specific terms of the offer.

7/6 I received the latest report from *Grassroots Research* on the excimer laser vision correction industry, written, as usual by Lynne Peterson. Her synopsis of what's happening in the industry:

- Refractive surgeons are interested in using corneal topography to customize ablations, but the technology is still in the developmental stages. **Autonomous Technologies** is considered to have the most advanced system.

- **VISX** is likely to continue to dominate the market with slightly less than 50% of total U.S. systems sales until **Bausch & Lomb's** Chiron Technolas 217 is

approved by the FDA. The balance of the market will be divided nearly equally between **LaserSight**, **Nidek**, **Summit/Autonomous**, and **Bausch's** Chiron Technolas 116. (I don't believe this, since the laser system is no longer being produced!)

– Laser owners are unlikely to swap a VISX laser for another brand unless the per-procedure fee drops significantly, but first-time buyers and laser owners adding a second or third machine may base their choice on the per procedure fee as much as technology.

– VISX is protecting market share aggressively with special second-machine pricing, creative financing options, and possibly by entering the microkeratome market. (This was alluded to during the VISX teleconference following release of second quarter results.)

A couple of rumors spelled out in the report; Bausch & Lomb may buy Summit Technology as a means of avoiding a patent infringement lawsuit with VISX, and **Alcon** is also eyeing Summit as a means of (re)entering the excimer laser market. (Recall that Alcon had the VISX international marketing rights until Tony Pilaro, a majority owner of VISX, via his original ownership of **Taunton Technologies**, the purchaser of VISX, forced the return of the marketing rights to VISX via a lawsuit against Alcon. I know its complicated, but its a part of the history of the industry!)

On the subject of "custom cornea", Lynne's sources aren't sure that laser owners believe the technique will be widespread, nor will they charge extra for it. I disagree. I think that once it is in place -- a few years from now -- and patients begin to learn that they have the option of "enhancing" their vision, rather than just correcting it, I believe that patients will be willing to pay a premium for the service, and/or it will become "the standard of care".

She concludes, "The excimer laser vision correction market is strong, and there are no signs of a slowdown. Refractive surgeons and laser center owners are interested in new lasers on the horizon, but mostly as additional machines, not replacements for the VISX lasers, which are likely to lead the market for at least the next year. If a technologically acceptable laser (with broad approvals) was available with a significantly lower per procedure fee, it might tempt laser owners to swap machines and new buyers to choose that system. But VISX is not expected to sit still while this happens, so any advantage is likely to disappear rapidly as VISX and other companies move to match the pricing. The most significant challenger to VISX may be the B&L/Chiron Technolas 217, when it is approved, provided it offers broad-range capability. Customized corneal ablation will be an important machine feature in the future, but it is not expected to be a major factor in the choice of a machine for at least a couple of years, and most manufacturers are developing a system to do this."

7/7 **Eye Care Centers of America** announced the signing of a definitive purchase

agreement with **Vision Twenty-One** to purchase substantially all of the assets relating to 76 retail eyewear outlets. In connection with the acquisition, ECCA will assume a business management agreement to manage certain of these stores for a private optometrist. Subject to certain potential purchase prices adjustments, ECCA has agreed to pay approximately $42 million for the assets and will utilize existing facilities to finance the transaction. Upon closing of the transaction, ECCA will operate approximately 351 stores in 32 states. Thirty-nine of the stores are primarily located in Minnesota operating under the name of **Vision World** and 18 of the stores operate in Wisconsin under the name of **Stein Optical**. In New Jersey, there are 19 stores owned by a private optometrist and operating under the name of **Eye DRx Optical**, which will be managed by ECCA under a business management agreement after the closing. At closing ECCA will enter into a strategic alliance with Vision Twenty-One to leverage both company's managed care resources.

Additionally, the agreement involves co-marketing of Vision Twenty-One's refractive surgery program. As part of the strategic alliance, both companys will educate ECCA customers about laser vision correction services and provide immediate access to those services through Vision Twenty-One's qualified refractive surgeons and eye laser surgery centers. The initiative is expected to begin in five markets and has the potential to expand to an additional 22 metropolitan markets.

7/7 **NovaMed Eyecare**. which owns and operates 10 eye surgery and laser centers in the U.S., said it planned to offer more than 7.1 million common shares, or 29% of total shares, in an initial public offering. The company said it is offering 5 million of the shares while some stockholders are offering the other 2.1 million shares. NovaMed estimated that the shares may be priced in the $11-13 per share range and trade on Nasdaq under the symbol NOVA.O. The underwriters for the deal include **Donaldson, Lufkin & Jenrette**, **Hambrecht & Quist** and **William Blair**. Last year, the number of laser vision correction procedures done by NovaMed's affiliated eye care professionals more than tripled to 5,083 compared to the prior year. To date it is affiliated with 76 professionals who practice in 44 eye care clinics which are leased and staffed by NovaMed.

7/8 **Laser Vision Centers** announced that its U.S. case volume for the month of June increased 126% compared to the same month a year ago. The company said that the month of June was its best month to date for U.S. surgical case volume. The company operated a total of 46 lasers in the U.S. during June 1999.

7/8 **TLC The Laser Center** announced that it had completed its joint venture agreement with Dr. Thomas S. Tooma in the State of California. According to the company, Dr. Tooma is one of the most experienced and highly regarded laser eye surgeons in the world. He is currently running one of the largest refractive practices in North America and is based out of Newport Beach, Calif. Dr. Tooma's existing practices are based on the same successful co-management model under which TLC operates. The deal, designed to expand the California market, is 50.1% owned by TLC. It includes TLC's

existing centers in Brea, Irvine, and San Diego, along with Dr. Tooma's practices in Newport Beach, Ontario, Fresno, and Redding. The joint venture will also include the 4 **Kaiser** centers currently under development in Northern California. More than 3,600 paid laser procedures are performed quarterly at the venture's existing sites.

Through this venture, TLC gains substantial coverage and a large share of the California market with seven clinics in operation and several more under development.

7/8 **Vision Twenty-One** announced the opening of its ninth eye laser center with the **Minnesota Eye Laser & Surgery Center** in Maplewood, MN, and treatment of the Center's first patient on the 500th **VISX** Excimer Laser System. "Our decision to purchase VISX's very first STAR S2 Excimer Laser was based on Vision-Twenty-One's commitment to providing the most advanced laser technology available to all of our affiliated physicians," stated Richard Lindstrom, MD, Vision-Twenty-One's chief medical officer and director. "Now, after performing thousands of successful laser vision correction procedures, our purchase of the 500th VISX STAR S2 Excimer Laser reinforces that commitment," added Lindstrom.

In 1998, Vision Twenty-One affiliated refractive surgeons performed more than 8,000 procedures. During the first quarter of 1999, more than 4,100 refractive procedures were performed in Vision Twenty-One's centers. With the addition of the Minnesota Eye Laser & Surgery Center at Maplewood, Vision Twenty-One has a total of nine refractive eye laser centers in five markets.

The St. Petersburg Times ran a story about **Vision Twenty-One**, relating if its annual meeting had been held a month ago, chief executive Theodore Gillette would have faced a hostile crowd. The company's stock was trading at all-time lows, financial reports for the previous year were delayed and company officials predicted a loss. However, Vision Twenty-One's shares have rebounded nearly 200% in the past month. And on Wednesday, investors boosted the stock to $10.06, a 52-week high, as they applauded Vision Twenty-One's sale of its retail optical chains, the latest step in a major corporate overhaul. The company, which once wanted to own every link in the eye care chain, signed an agreement to sell its **Vision World**, **Stein Optical** and **EYE DRx** chains to **Eye Care Centers of America** for $42-million. Vision Twenty-One had acquired the chains, which have 76 locations, within the past year for a total of $31 million. Proceeds will be used to repay debt. At the same time Vision Twenty-One is selling off its retail stores, it is strengthening its ties with San Antonio-based Eye Care Centers of America through a strategic alliance that will allow the company to market its laser surgery to the chain's retail customers. The two companies also will partner to offer comprehensive eye care coverage to managed care companies and employers in selected markets.
The deal is key to the creation of a new Vision Twenty-One. It no longer wants to own the eye care world, it just wants a focus on the most lucrative parts: managed care and laser surgery.

7/8 James Hale of *The Online Investor* chose **VISX** as its stock of the day, with the story entitled, "VISX: Eye Carumba! Laser Eye Surgery is Hot". The story went on to detail VISX's share of the market and how it collects a $250 fee for each procedure done on its lasers in the U.S.

7/12 **LCA-Vision** and **Cole National** announced that LCA-Vision has entered into an arrangement with Cole Managed Vision, a division of Cole National Corporation, to provide access to laser vision correction to Cole Managed Vision members nationwide. This is the first time that laser vision correction is being offered through a managed care organization on a nationwide basis. More than 50 million people are enrolled in Cole Managed Vision's programs. Under the terms of the arrangement, LCA-Vision will establish **The National LASIK Network (NLN)**, a nationwide network of laser vision correction providers, which will include LCA-Vision's U.S. centers, as well as individual surgeons and other laser vision correction centers. Cole Managed Vision will market the opportunity to new and existing plan sponsors and to their members or employees.

According to Stephen Joffe, chairman and CEO of LCA-Vision, "We are pleased to be associated with Cole Managed Vision, and look forward to expanding LCA-Vision's reach through establishing relationships with the highest-quality practitioners across the country." Commenting on today's announcement, Dennis Osgood, president of Cole Managed Vision, stated, "We are delighted to offer this popular laser vision correction procedure to our large and growing membership base."

Beginning January 1, 2000, LASIK vision correction surgery will be offered by LCA-Vision to Cole Managed Vision members whose sponsors have indicated an interest. In addition, LCA-Vision patients will be eligible to participate in LCA-Vision's Continuum of Care program following completion of this surgery. This program is designed to achieve the level of vision correction agreed to by the patient and the ophthalmologist.

7/12 This month's issue of *Refractive Market Perspectives* notes the trend of the leading ophthalmic physician practice management companies shifting into refractive surgery. Three that are making this effort include **Omega**, **Vision Twenty-One**, and **NovaMed**. Omega who has committed to purchasing at least 12 **VISX** Star S2 lasers, having already opened ten centers (and 2 more announced during the month), announced it was selling off its managed care business, and was changing its name to **VisionAmerica**. Vision Twenty-One has opened 8 laser centers over the past year, has sold its 76 optical shops, and plans aggressively to open more laser vision centers. NovaMed, in the midst of its initial public offering, has also recast itself as a laser vision correction company, operating 7 excimer laser centers, mostly in the Midwest.

Dave Harmon also notes that the upcoming FDA Advisory Panel Meeting will discuss **Sunrise Technologies** PMA for hyperopia with LTK along with **CRS-USA's** PMAs for LASIK, using both the **Summit** Apex Plus and the VISX Star lasers. Summit has

the rights to its PMA with the application filed directly on behalf of the company, while VISX has an agreement with CRS for the rights to its PMA to be assigned after FDA approval. The Summit PMA covers myopia up to 14 diopters with 5 diopters of astigmatism, based on the results for over 1000 eyes. The VISX application contains data on 720 eyes with myopia up to 14 diopters and astigmatism up to 6 diopters.

The newsletter also contains an interesting table of U.S. laser center ownership at the end of June. According to Harmon, their are 214 corporately owned laser centers (with **TLC** leading with 50, closely followed by **Laser Vision Centers** with 46 lasers servicing over 300 locations); 110 institution owned laser centers; and 246 physician owned lasers/centers; for a total of 570 lasers/centers in operation. This breaks down to 37% corporate; 31% institutions; and 34% physicians. During the first half of the year, 127 centers were opened, with 83 of these being physicians establishments, mostly surgeons breaking away from institutions or corporate or mobile centers to own their own laser.

7/12 **Bausch & Lomb** announced it sold its Miracle Ear hearing aid business to **Amplifon SpA** of Italy, thus continuing in its strategic transformation to focus on its core eyecare business.

7/12 Dave Therkelsen of **Dain Rauscher** began coverage of **LCA-Vision** with a "strong buy-aggressive" rating, and a target price of $14 per share, from its current $9-10 range. Therkelsen issued an analyst report on the company, calling it one of the leading operators of fixed-site centers. He notes that the company has established leadership in the markets it serves (19 U.S. centers and 3 internationally), focusing on key under- penetrated metropolitan markets in the Midwest, East Coast and California.

Therkelsen estimates that LCA's centers are capable of doing about 600 procedures per month, and are currently operating at about 25% of capacity, or at about 150 procedures per month.

7/12 **LaserVision Centers** announced results for its fiscal fourth quarter and fiscal year. The company said that revenues for the fourth quarter increased 141% to $18.8 million from $7.8 million for the same quarter in 1998. Net income was $3.0 million (28 cents per share) compared to $127,000 (1 cent per share) for the same quarter a year ago. Revenues for the 1999 fiscal year were $52.4 million, a 123% increase over fiscal 1998 revenue of $23.5 million. Net income was $6.5 million (63 cents per share) compared to a net loss for fiscal 1998 of $3.5 million (59 cents per share).

LaserVision noted that excluding a tax benefit of $1.5 million for the year ended April 30, 1999, earnings per share were 48 cents. Excluding a tax benefit of $687,000 for the quarter, earnings per share were 21 cents.

The company also said that the Board of Directors had approved a 2-for-1 stock split

payable August 9, 1999 to shareholders of record at the close of business on July 23, 1999. "We are proud to report another banner year. The company continues to exceed internal and external expectations. LaserVision continues to experience growth in terms of procedures, new surgeons and lasers," LaserVision chairman and CEO Jack Klobnak said. "We are extremely pleased with the growth in earnings and cash flow. We are also very pleased with our recent acquisition of **Midwest Surgical Services**, which is exceeding our projections. The continued growth in the marketplace and the predictability of our business model have required us to expand at a more rapid rate than we had anticipated to keep up with demand." Klobnak noted LaserVision had added four new lasers to its U.S. laser fleet in May, four in June and plans to add six in July. He said LaserVision had 11 additional lasers on order with VISX.

Of the 46 lasers in place at the end of June, 15 were in fixed sites, and that number should increase by the end of the year; 29 were roll-on/roll-off; and 2 were mobile on trucks. A few interesting notes came out of the accompanying teleconference: the company puts its new lasers into roll-on/roll-off service, taking some of the replaced lasers and converting them into fixed site units. As ophthalmologists that are using the mobile service grow and want their own laser, the company can accommodate them. The mobile lasers are currently making 10 to 11 stops per month, and they will move higher as demand grows. The company presently services 520 surgeons at 209 sites. Of the 11 lasers on order, LaserVision will take them as quickly as VISX can supply them, although they are scheduled for delivery over the next four months. The company is doing about 155 procedures per month, with the fixed sites doing somewhat higher and the mobile laser about 150 cases. The fixed sites can do as many as 40 cases a day.

Klobnak noted that hyperopia cases were running between 10-12% of volume, which could go a little higher when astigmatic approval is obtained.

Al Kildani of **Pacific Growth Equities** issued an update report on Laser Vision Centers the following day. He reiterated his "long-term buy" rating and raised his estimates for the company based, as he said, on its "strong momentum".

7/13 **Sunrise Technologies** announced that it had received conditional approval from the FDA to treat, in its ongoing U.S. clinical trials, the second eye on the same day as the first eye using the Sunrise laser thermal keratoplasty (LTK) treatment for mid-hyperopia from +2.75 to +4.0 diopters. The approval allows for treatment of the second eye of the current subjects as well as treatment of both eyes of future subjects on the same day. On May 4, Sunrise announced it had received approval from the FDA to expand its study for the treatment of mid-hyperopia. The study was expanded to 80 patients at up to six clinical investigation sites in the United States. Twenty patients at two sites have already been treated under a study that began in April 1998. Sunrise LTK surgeons and patients reported that they were eager to have immediate treatment of the second eye after receiving initial treatment.

7/13 **TLC The Laser Center** announced its fiscal fourth quarter and fiscal year results for the period ending May 31, 1999. In the fourth quarter, gross revenues grew to more than $65.7 million compared to $32.3 million in the same period last year. Gross revenues for the fiscal year were a record $208.3 million, an increase of 130% over last year's $90.6 million total.

For the fourth quarter, net revenues totaled $46.6 million compared to $20.6 million in the same period last year. Net revenues for the fiscal year were $146.9 million, which was up 148% from last year's $59.1 million total.

Refractive net revenues totaled $41.6 million in the fourth quarter, up from $18.6 million in the same period last year. For the year, refractive net revenues were $132.4 million, an increase of 159% from last year's $51.1 million total. Refractive net revenue growth reflected the year's growth in laser procedure volumes. More than 90,600 paid procedures were performed at TLC centers in fiscal 1999, which is an increase of 153% over the fiscal 1998 total.

For the 1999 fourth quarter, net income before a restructuring charge was $4.6 million (13 cents per share). This compares to a 1998 fourth quarter net loss of $2.8 million (9 cents per share). TLC's net income before a restructuring charge for the fiscal year 1999 was $9.3 million (27 cents per share). This compares to a net loss for fiscal 1998 of $9.5 million (34 cents per share).

TLC reported by press release on April 21, 1999, that it intended to restructure its secondary care practices and its managed care division, **Partner Provider Health**. TLC completed the restructuring during the fiscal 4th quarter. As contemplated in the April 21 press release, TLC took a charge in its fiscal 4th quarter of $12.9 million against secondary care and managed care operations. For the fourth quarter, the net loss after the restructuring charge was $8.3 million (24 cents per share). TLC's fiscal 1999 net loss after the restructuring charge was $3.6 million (11 cents per share).

Following release of the fiscal data, **Warburg Dillon Read** analyst Rebecca Irwin cut her rating on the company to "hold" from "strong buy" after it reported fiscal fourth quarter 1999 earnings slightly below her expectations. Irwin said the company narrowly missed her earnings forecast for the fourth quarter as a result of "lower per procedure fees than anticipated, as well as higher than expected marketing costs." She said the company's performance in the quarter had created "earnings uncertainty". Shares of the company dropped 17% after its report and Irwin's announcement. Other analysts were not as unhappy with the results. "I don't feel as depressed as the market," said analyst Claude Camire of **Groome Capital** in Montreal. "They had less earnings than expected, but they're still the market leader." However, analyst John Rooney of **Hornblower & Weeks** was not as positive, "TLC was once the leader, but there are now **Laser Vision Centers**, also **LCA-Vision**, and a bunch of private doctors as well." He recently changed his rating on the stock to "hold" from "buy".

Al Kildani of **Pacific Growth Equities** issued an update report the following day, stating that despite earnings slightly below expectations, the company's fundamentals remain strong and he reiterated his "buy" rating. His biggest concern, not just for the company, but for the industry, is procedure pricing. With TLC's Advantage program, wherein a 43-person sales force in now calling on corporate and managed vision care accounts, he anticipates the company will secure contracts that should begin to contributing to earnings by the third quarter and beyond. In June, the company signed up over 300,000 employess from companies like **Merrill Lynch Canada** and **Lockheed Martin**. In addition, TLC has contracted with the **National Rifle Association** to offer discounted procedures to that organization's 2.5 million members.

7/14 **Gimbel Vision International** announced that it was not aware of any specific current corporate development that could account for the recent increase in the share price. (The stock increased by 50% during the day.) As previously disclosed, the company is actively examining alternatives to expand into new markets and increase the number of centres under management. These may include partnerships with exceptional practitioners, business combinations, or other strategic initiatives.

7/14 **VISX** announced financial results for the second quarter with revenues of $62.5 million compared to $31.7 million for the comparable period of the prior year. Net income was $21.5 million (32 cents per share) compared to a net loss of $15.3 million (25 cents per share) in the comparable period of the prior year which included a $35 million litigation settlement. (Of the quarterly revenues of $62.5 million, 76% was from licenses, royalties, and service, of which about $5 million -- or 8%, was service income. This is up from about 70% for the second quarter last year.) Revenues for the six-month period were $116.5 million compared to $56.0 million for the comparable period of the prior year. Net income was $41.3 million (61 cents per share) for the six-month period compared to a net loss of $6.4 million (10 cents per share), in the comparable period of the prior year which included the $35 million litigation settlement. Non-systems revenues represented 77% in 1999, compared to 70% for the same period in 1998.

Commenting on the announcement, Mark Logan, chairman and CEO, stated, "Another tremendous quarter with record results. We are closing in on the one millionth procedure performed in the U.S. on VISX lasers since FDA approval. The driving force in this market is the outstanding results experienced by consumers who have had their vision corrected on VISX systems by VISX-trained physicians. The recent start of our consumer advertising campaign is intended to strengthen our leadership in the dynamic laser vision correction industry."

During the accompanying teleconference, Logan said that the company had over 700 laser systems installed worldwide, with about half in the U.S. The company shipped 61 lasers in the second quarter, 80% of which were in the U.S., and expects to increase the number of systems shipped for each of the next two quarters as manufacturing is ramped up, with the percentage of U.S. shipments to stay about the

same due to the high demand. He also noted that the consumer print advertising campaign had begun the previous Friday, with a full page spread in *USA Today*. (The ad also ran in this week's *Newsweek* and *Forbes*.) Commenting on the litigation situation, although the FTC dismissal of the company had been appealed by the FTC attorneys, he said the hearing before the FTC tribunal wouldn't occur until late this year, and a decision for another 6-12 months following the hearing, in mid- to late-2000. The ITC litigation is on schedule, with a trial date of August 18th, and an initial decision on or about December 1st. As for the Patent Office action, the first hearing is scheduled for mid-July, with further actions likely and final appeals carrying out the timeline for 4-10 years.

Logan expects the percentage growth in procedures to slow down in the next quarter, due to seasonality, stating that he was comfortable with analysts expectations of 900,000 procedures for this year. (Although, he commented that the best market share numbers were coming from David Harmon of **Marketscope**, who has predicted 980,000 procedures for this year.) Discussing the new CAP program for off-center ablations, Logan said it was only meant for a small group of patients who may need it. And topography as a driver for ablation may not be enough, indicating that the "wavefront" type systems may be what is needed, similar to what **Autonomous** is doing and **B&L/Orbtek** may try, although he didn't mention those two companies by name. When asked about the situation in Japan, Logan said that VISX and its competition (**Nidek**?) were roughly in about the same situation, with approval hopeful for later this year.

The following day, as is his rule, Wade King of **BancBoston Robertson Stephens** reiterated his "buy" rating on VISX and said he was raising his estimates following the excellent second quarter results. He raised his 1999 and 2000 revenue estimates to $261 million and $320 million respectively. (By the way, I also have raised my 1999 forecast for VISX from the $180 million previously reported, to $250 million for this year.)

7/15 An interesting lengthy interview of Hakan Edstrom, president of **Bausch & Lomb Surgical**, was conducted recently by Joe Hoffman of *Ocular Surgery News*. It appears in the current issue of the newsmagazine. In the interview Edstrom discusses the problems and opportunities faced in the integration of **Storz Instruments** and **Chiron Vision** into B&L. In a discussion about refractive surgery, Edstrom commented on Bill Link's vision that resulted in Chiron/B&L's position in the microkeratome business (both the ACS and Hansatome) and the potential of the Technolas laser, once it is FDA approved, which he hopes occurs during the second half of this year. He also noted that B&L's acquisition of **Orbtek** positions his company for providing custom ablations through the Topolink program using the Orbscan. All of these will enable B&L to bundle instruments and pharmaceuticals along with lasers, to differentiate B&L from its competition in the industry.

7/15 This month's issue of *Review of Ophthalmology* contains a very interesting article

detailing a system for the management of persons with glaucoma. Prepared by George Spaeth, MD, the artilce provides a substantive argument for changing the way physicians look at this disease and focus on how he/she can preserve or enhance the person's health and quality of life. It details a worksheet and method for evaluating the progression of the disease and stage in life of the person with the disease. It then provides a methodology for whether or not the disease should be treated aggressively or in a more benign way. A very interesting look at the treatment for glaucoma.

7/14 **Omega Health Systems** announced that it had completed the sale of certain assets of its managed eye care subsidiary, The **Eye Health Network (EHN)**, to **OptiCare Eye Health Centers, Inc.** "We are pleased to complete the transaction with OptiCare Eye Health Centers," commented Thomas Lewis, president and CEO of Omega Health Systems. "OptiCare is well-equipped to pursue managed care initiatives and we look forward to our new strategic alliance with this strong company. This transaction marks another step in our previously announced plan to expand our laser vision correction business and enhance the operations of our national network of eye care and surgery centers. We are confident about our prospects for growth and believe that we have set a course that is in the best interest of Omega's doctors, patients and shareholders."

The following day, the company announced that it had established its eleventh and twelfth laser centers, opening new centers in Nashville, TN and Houston, TX. "Laser vision correction surgery continues to gain wide acceptance and we are excited about the opportunity to expand this capability in Nashville and Houston, two of our fastest growing markets", said Thomas Lewis, president and CEO. "Improved technology, positive outcomes, and the convenience this procedure offers to individuals with active lifestyles have all resulted in dramatic growth in the demand for the procedure. Omega is at the forefront of meeting this demand with our strategic initiative to offer laser vision correction through our national network of eye care centers. We continue to be confident in our plan to have laser technology available in 18 markets by the end of July, and in 25 markets by the end of August. Laser vision correction represents an exciting growth opportunity for Omega and we believe we are well positioned to execute on this initiative nationwide." As previously announced, the company will change its name to **VisionAmerica** at its August annual meeting.

7/15 **Gimbel Vision International** reported that primary refractive procedures for the second quarter ended June 30, 1999 totalled 6,427, an increase of 56% over the second quarter volumes performed in the prior fiscal year and a 22% increase over 1999 first quarter volumes. A total of 5,043 procedure were performed at the company's North American centres which represents a 57% increase over the same period in the prior year and a 30% increase over the first quarter of 1999. Primary refractive procedures performed at centres outside North America amounted to 1,384, a 51% increase over the same period in the prior year and a 5% increase over 1999 first quarter volumes.

7/15 **KeraVision** reported financial results for the second quarter, with revenues of $3.9 million versus $112,000 for the same period a year ago and $472,000 for the first quarter of 1999. Revenues for the first six months totaled $4.4 million versus $264,000 for the same period in 1998. The increase in second quarter revenues was primarily the result of sales of instruments used to perform the Intacs procedure to the initial group of U.S. surgeons who participated in Intacs training courses during the second quarter. As of June 30, KeraVision had trained 243 surgeons.

Operating results for the second quarter also reflected increased marketing and sales expenditures related to the Intacs launch in the U.S., offset by reduced research and development expenses, which resulted in a second quarter net loss of $5.7 million (45 cents per share). This compares to net losses of $7.3 million (60 cents per share) for the first quarter of 1999 and $5.6 million (65 cents per share) for the second quarter of 1998. The company also announced that it had filed a registration statement with the SEC with respect to a proposed public offering of 4 million shares of the company's common stock. All of the shares are to be issued and sold by KeraVision. Proceeds from the sale of the shares will be used by KeraVision for sales and marketing efforts related to the U.S. launch of Intacs; the development and clinical testing of products based on the Intacs technology; prepayment of short-term debt, and working capital and other general corporate purposes. The offering is to be made through an underwriting group managed by **Donaldson, Lufkin & Jenrette**; **Dain Rauscher Wessels**; **Prudential Securities**, and **SG Cowen**.

7/15 *TheStreet.com* issued a report on the "shorts" action on **Sunrise Technologies**. They have raised questions about the results being obtained by the company, alluding to data on the company's web page, that apparently isn't the same as was presented to some investors that visited the company. "I know that when I came away from the meeting, I said, `After six months, patients stabilized. That's great.' After I read the data on the web site, I had a different impression, said a West Coast hedge fund portfolio manager, who attended the meeting at Sunrise. Another attendee said, "I don't think it was consistent with what's shown with the other data." According to a company spokesperson, "I believe the people in the audience are mistaken. The substantive discussion of our data will occur next Thursday at the FDA meeting." The online report also quoted from the **Sturza's Institutional Research** report, "We believe the product will be a commercial failure, due to its limited efficacy and inability to treat most refractive disorders." (As stated previously, Sturza is believed to be a short seller, who's aim is to move the stock price downward.) The online report goes on to say that despite all the negative publicity, the short-sellers are resigned to the fact that Sunrise may actually gain approval.

In an accompanying online report, *TheStreet.com* also has a story about Sunrises' storied past, including going back to the days when it was a dental laser company. Of course, this is all irrelevant, as the company has undergone a complete change and is no longer in the dental laser business, or being run by the people who founded it.

7/16 **Sterling Vision** announced continued record increases in the number of laser surgery procedures performed during the month of June 1999, as compared to June 1998, on the six excimer lasers owned by its wholly owned subsidiary, **Insight Laser Centers, Inc.** Without providing any numbers, the company said that there was a 250% increase in procedures.

7/16 *The Motley Fool* got into the medical laser industry act by publishing a story by Matt Richey entitled, "Clear Vision at **VISX**". The positive story relates how the vision correction industry is growing and how VISX is participating in that growth.

7/19 **TLC The Laser Center** announced the signing of a letter of intent for the formation of a national laser vision correction service partnership with **Vision Service Plan (VSP)**. More than 15,000 organizations, including a variety of Fortune 500 companies, associations, labor unions and government agencies, have VSP coverage. As part of the agreement, TLC and VSP will develop an exclusive, national education program designed to educate VSP's 28 million members on laser vision correction. The Program will include materials such as publications and videos, as well as the delivery of seminars and representation at employee benefit fairs throughout the United States. In addition, TLC will partner with VSP to serve the laser surgery needs of VSP members.
"As a company that puts patients needs first, we're continually looking for ways to better serve our members," said Roger Valine, VSP president and CEO. "We believe laser vision correction will only grow in popularity and we wanted to develop a program that makes the procedure more accessible and that our members can understand and trust." Elias Vamvakas, TLC's president and CEO, stated, "we are very pleased with our ongoing success in implementing the TLC Advantage program, designed to market TLC's laser vision correction services through HMO's, employer groups, and vision plans."

The program will begin on November 1, when Vision Service Plan members nationwide will have access to laser vision correction coverage that will make the surgery easier to get and more affordable. VSP's program will make high-quality laser eye surgery available at a reduced cost, including the two most common procedures used to correct nearsightedness, farsightedness and astigmatism. The arrangement with TLC substantially broadens VSP's network, teaming the organization's 18,000 private-practice eye doctors with TLC's network of eyecare professionals and 47 laser centers.

Prior to developing its national program, VSP pioneered the idea of providing laser vision correction coverage nearly three years ago. More than 200 employees at **VISX**, the leading manufacturer of the excimer laser, were the first to receive coverage toward the procedure in 1997. Earlier this year, 11,000 employees at **Southern California Edison** began receiving coverage as well.

Following the announcement, Al Kildani of **Pacific Growth Equities** issued an update

report on TLC, stating that he believed that the new agreement would have minimum impact on the company's average revenue per procedure, making the partnership a financially attractive opportunity for the company. He estimates that the VSP discount would reduce the average per procedure fee by only $100 (for VSP procedures only), while potentially driving significantly higher procedure volumes.

7/19 Online publisher, *Individual Investor Online*, wrote another positive piece about **VISX**, entitled, "VISX: Still Great Growth Visibility". As author Chris Bulkey noted, "The desire among the four-eyed set to shed their specs has made VISX one of the hottest non-internet companies around." The bottom line: "momentum stocks are prone to volatility, so we recommend building a position slowly, which would enable investors to take advantage of any pullbacks." A pretty cautious outlook for the company by IIO.

7/20 **Summit Technology** announced that it had filed a registration statement with the SEC to sell 4 million share of its common stock. The offering will be managed by **Hambrecht & Quist LLC**, **USBancorp Piper Jaffray**, and **Dain Rauscher Wessels**. The net proceeds will be used to help fund the commercial introduction of the LADARVision system from **Autonomous Technologies**, and for general corporate purposes.

7/20 *TheStreet.com* reported that **Sunrise Technologies** has decided to fight back against the negative reports prepared **Sturza's Institutional Research** and **Avalon Research**, two boutique firms that wrote sharply critical research reports on the company. According to *TheStreet.com*, Sunrise filed to get an emergency injunction and restraining order against both firms, to have them immediately stop writing about the company and sharing investment opinions with clients. Apparently, that suit was thrown out by a judge in Northern California District Court last Friday. But Sunrise hasn't given up. Late in the week it sued both firms for defamation as well.

The aggressive legal actions illustrate the lengths some companies will go to shut up critics. Increasingly companies are seeking to identify and pursue critics, whether on Wall Street or on Internet message boards. Even if a suit is groundless, legal action can cost thousands of dollars in legal fees and be a time-consuming distraction for the alleged provocations.

"Litigation as a form of attacking adverse analysis is not entirely new. [But] I think it's quite rare. The concern a public company has is that you draw more attention to the thesis being expounded," says Karl Groskaufmanis, a securities lawyer and partner at **Fried Frank Harris Shriver & Jacobson**, which isn't involved in the case. "If what's being issued is purely opinion, my own view is that it's not productive to go suing analysts. The best antidote to a research report you don't like is to perform well and prove them wrong."

Neither Sunrise nor its law firms, Chicago-based **Holleb & Coff** and San Francisco's

Duane Morris & Hecksher, returned calls seeking comment. Evan Sturza, who heads Sturza's Institutional Research, and Avalon declined to comment on the lawsuits or on the firms' current positions in Sunrise. Both firms have investment arms that can take trading positions, long and short.

Another element of the case is that several partners at Holleb & Coff have ownership stakes in Sunrise Technologies, according to a June 16 filing with the SEC. Says Fried Frank's Groskaufmanis, "Particularly in high-tech and development stage companies, the practice of giving stock for fees is by no means unprecedented and it seems to be becoming more common. It can create a conflict of interest, which is why it's disclosed." A potential benefit, he says, is that such compensation can align the lawyers' and the client's desires better.

Potential conflicts of interest notwithstanding, Frankel doesn't think the suits have a chance, "I don't see it at all. The First Amendment says that if you say something and, if on a good-faith basis, you believe what you're saying, you're covered."

7/20 **VISX** reported that its consumer ad campaign was in full swing. Thirty-second radio spots are now being broadcast over 3400 stations nationwide, while the print ads appear this month in *USA Today*, *Newsweek*, and *Forbes*, with a male version of the first print ad appearing in the July 13th issue of *USA Today*.

7/21 **TLC The Laser Center** announced that both its Nasdaq and Toronto Stock Exchange ticker symbols will change, effective July 26th. The Nasdaq symbol will become TLCV (from LZRC), while the Toronto Exchange symbol will be TLC (from LZR).

7/21 *NewsEdge* reports that U.S. Patent 5,923,399, entitled, "Scanning laser ophthalmoscope optimized for retinal microphotocoagulation" has issued to Jozef F. Van de Velde. The abstract reads: A combination of scanning laser ophthalmoscope and therapeutic laser source expands the range of clinical applications of the conventional scanning laser ophthalmoscope, being capable of simultaneous imaging, microperimetry and the delivery of therapeutic laser applications to the retina in a preferred non-contact mode. The combination, including a therapeutic laser source, optic-mechanical Maxwellian view coupling device allowing a similar Maxwellian view entrance location in the eye for both the scanning laser ophthalmoscope and therapeutic laser source, and real-time electronic registration of the therapeutic beam location, permits precise positioning and dosage of the retinal applications. Additional safety mechanisms include a shutter activation based on digital image processing techniques.

The same publication also notes that a U.S. Patent, 5,921,981, entitled "Multi-spot laser surgery" was assigned to **Alcon Laboratories, Inc.** The abstract reads: Various embodiments of optical fiber cables and laser probes are disclosed for providing multi-spot laser beams from a single laser beam source. This permits time-intensive but repetitive laser surgical procedures such as panretinal photocoagulation to be

performed with increased accuracy and in a fraction of the time currently allotted for such procedures.

7/21 Danielle Sessa of *The Wall Street Journal* wrote a lengthy story about how some of the clinical investigators for **Sunrise Technologies** held shares of the company's stock. According to Sessa, 7 of the 11 investigators were shareholders, and she claims that these investigators hold more of the stock than 9 top-level executives. Although the FDA requires disclosure of such shareholdings, apparently that rule went into effect prior to Sunrise's filing its PMA. I guess the implied message of the story is that these investigators might appear to be biased in favor of the company in conducting their clinical trials, but I would rather believe that they just believe in the company's technology and thought it represented a good investment.

One of the clinical investigator/shareholders David Brown, MD when asked about his large stake in the company, was quoted as saying, "One of the things about my job is to be up on everything that is new and exciting in our profession. I tend to like to pick up companies that are in the early stages of development and have some promise." Another investigator/shareholder, Dr. Alan Aker said, "You basically have to be convinced that the technology works to take part in a private placement. If I had doubts about the technology I would have never invested in the company."

7/22 **IRIDEX** reported that second quarter sales were $6.5 million, an increase of 8% from $6.0 million in the corresponding 1998 quarter. Net income for the quarter was $325,000 (5 cents per share) as compared to $525,000 (8 cents per share)in the corresponding 1998 quarter, a decrease of 38%. Net income decreased primarily as a result of accelerated investments in research and development and in developing new sales channels. Specifically, research and development expenses increased 29% to $874,000 as compared to $677,000 in the second quarter of 1998. The company expects research and development expenses to continue at least at this level for the next few quarters to support new product development and to fund clinical studies primarily in treatments of age-related macular degeneration (AMD).

President and CEO Theodore Boutacoff commented, "The second quarter had significant positive developments for IRIDEX. We experienced sales growth in both our core ophthalmology and dermatology markets compared to the second quarter of 1998. More important, however, after a year of soft markets in Asia, we are seeing strength across our entire medical product line. This recovery, coupled with a strong domestic market, gives us confidence of solid growth in the third and fourth quarters."

Boutacoff commented on the recently reported results using the company's Iris Oculight diode laser to treat AMD, saying that the good results obtained in treating occult sub-foveal wet AMD in a procedure called Transpupillary ThermoTherapy (TTT), showed that blood vessels stopped leaking in 94% of eyes and visual acuity was stabilized or improved in 77% of eyes, was significant since recently presented PhotoDynamic Therapy (PDT) results have not yet shown an ability to treat occult

sub-foveal AMD, a stage of AMD that accounts for over 70% of all cases of wet AMD.

7/22 **Lasik Vision** announced that **No. 145 Cathedral Ventures Ltd.** has elected to convert its term loan under the terms and conditions previously announced on March 24, 1999. An aggregate of 274,737 shares have been issued at a deemed price of $2.15 per share on the conversion of the $500,000 principal amount of the loan, interest in the amount of $25,685 and the $65,000 structuring fee. In addition, Lasik Vision announced that it has received subscriptions for $1.6 million of the $2 million equity financing previously announced June 21, 1999. The special warrants will be issued on receipt of final approval by the Vancouver Stock Exchange.

Finally, the company announced that **Pacific International Securities** has proposed a $10 million equity offering to be completed during the third quarter of 1999, subject to agreement with Pacific International on definitive terms of the financing as well as Vancouver Stock Exchange approval. As a result, Lasik Vision and Pacific International will not be proceeding with the $15 million debenture offering previously announced May 12, 1999.

Lasik Vision intends to continue pursuing other financing opportunities, including mergers, convertible debt instruments or other strategic alliances that will support its planned expansion into the U.S. laser vision correction marketplace.

7/22 **STAAR Surgical** reported revenues of $14.7 million for its second quarter, 5% above last year's second quarter revenues of $14.0 million. Net income for the quarter was $677,000 (5 cents per share), compared with $1.5 million (11 cents per share) for the second quarter last year.

Revenues for the six-month period also increased 5% to $29.6 million, from $28.1 million for the same period last year. Net income for the first half of 1999 was $1.3 million (9 cents per share), compared to $3.2 million (24 cents per share) for the same period in 1998. John Wolf, chairman and president said, "This has been one of our most exciting quarters with the FDA approval of our STAARVISC viscoelastic solution, the implant of our first TORIC ICL in Europe to begin CE Mark trials on this important product, receiving FDA clearance to begin Phase III clinical trials on the ICL to correct hyperopia, and receiving the European CE Mark for the Collamer IOL. We have worked many years to get to this point. I am proud of our achievements and excited about the potential that lies ahead for STAAR and the people who use our products."

7/22 Peter Pae of *The Washington Post* wrote about laser eye surgery being conducted at malls, in his story, "Making a Spectacle of Eye Surgery: Passerbyes Gawk as Patients Undergo Laser Procedure at Fairfax Mall". As Pae put it, "Somewhere between getting your tires rotated and your hair coiffed, it is now possible in Fairfax County to get your eyes fixed at the mall. What's more, the entire 15 minute procedure can be

performed in front of gawking spectator, though only if you allow them the thrill. Patients preferring privacy can pull the blinds closed." The idea is that of **Visual Freedom Center**, the nation's first laser surgery center to be located in a shopping mall. A similar center opened last month in Minneapolis (see our June 15th brief in the June 1999 newsletter), and others are in the pipeline -- a second Visual Freedom Center will open in suburban Maryland in September.

7/21 **Northern Gaming Inc.** announced that it had entered into an agreement to amalgamate with **ICON Laser Centre of London Inc.**, a company incorporated in the Province of Ontario. Northern and ICON, subject to certain conditions, have agreed to amalgamate to continue as one company under the name **ICON Laser Eye Centers, Inc.**, which will effectively result in a reverse takeover of Northern.

ICON, together with its group of subsidiaries, namely, **CONI Investments S.A.**, **TEMAV SpA** and **Vista Vision SpA**, collectively, the **ICON Group**, is a provider of laser vision correction services, owning and managing one fixed LVC centre in London, Ontario and 2 fixed centres and 2 mobile lasers in Milan and Rome, Italy. The ICON Group also intends to introduce its mobile laser concept called the **ICON Laser Tour** into the North American and European markets.

The ICON Group is pursuing a strategy designed to make it a world leader as a provider of LVC procedures and support services. The ICON Group has a multi-part strategy: 1) deliver excellent results at a market leading price through its "Direct Response Model"; 2) offer insured "Lifetime Care Commitment" to all patients; 3) increase market penetration through strategic acquisitions and corporate development; 4) increase market share through innovative corporate marketing programs; and 5) impact tertiary markets where no laser or LVC doctor resides using its LaserTour program.

A meeting of the shareholders of Northern at which the proposed amalgamation of Northern and ICON is to be considered is scheduled for August 18, 1999 and will take place in Toronto, Ontario. Northern, which is a reporting issuer in the provinces of Ontario and Alberta, has been relatively inactive for the past year or so since termination of its operations (conducted through its wholly-owned subsidiary, Wolf Corporation and its 95.1% subsidiary, Wolf Gaming LLC) in the casino and gaming industry in the United States. Accordingly, the Proposed Amalgamation, if approved, will permit the shareholders of Northern to have an ownership interest in an active business enterprise, namely, the LVC industry in which the ICON Group is currently engaged. In turn, upon completion of the Proposed Amalgamation, Amalco will become a reporting issuer in Ontario and Alberta which will provide ICON and its shareholders with an enhanced capacity for financing future growth and development while providing liquidity and marketability to ICON's securities. Completion of the Proposed Amalgamation is subject to a number of conditions, including all necessary shareholder and regulatory approvals of Northern and ICON, respectively.

7/21 Prior to **Sunrise Technologies'** meeting before the FDA's Ophthalmic Devices panel, analyst Richard Leza of **John G. Kinnard** issued his coverage initiation report on the company, targeting a price for the stock well below its then trading price. As reported on *TheStreet.com*, under the title "Sunset on Sunrise?", Leza considered the best-case scenario at $3 1/2 -- for a stock that closed on the prior day at 15. His reason for the recommendation, his concern about the company's potential to sell its laser treatment for corrective eye surgery, even if it obtained FDA marketing approval. Other factors that played into his analysis included: the large financial interest of its trial investigators, six of whom hold a substantial interest in the company -- the top four holding 17.6% of outstanding stock; the limited range of vision correction to be obtained with initial FDA approval; and minimum use contracts which are likely to limit LTK system sales to lower volume surgeons. However, he did feel, in the report, that the data the company had collected during the clinical trial were sufficient to support its approval.

7/22 The FDA's Ophthalmic Devices Panel took two actions this afternoon; deeming **CRS Clinical Research's** PMA for using the **VISX** Star laser to perform LASIK approvable, and turning down **Sunrise Technologies'** PMA for its LTK procedure for hyperopia.

In the case for VISX, the panel voted 8-0 to recommend that the FDA approve the procedure. Since most doctors already perform LASIK as an "off label" procedure, the final approval, when it comes should have little effect on VISX's stock price, but will enable the company and doctors using its lasers to advertise the availability of LASIK, which they cannot now do. "It'll make the people who get the procedure a little more comfortable knowing it's approved by the FDA", said Rob Faulkner, an analyst with **Hambrecht & Quist**. "Will it cause the market to grow more? No." The recommendation for approval, came with several conditions, which must be worked out between the company and FDA before final approval is given. These included labelling that asserts the stability of the correction by dioptric levels; that in some cases there was a stability loss over time with some corrections; that good night vision without halos is a function of pupil size; and that the clinical trials didn't treat enough patients with severe nearsightedness to assess the laser's performance for that group. The company's stock reached $101 3/4 the following day.

The Sunrise turndown was somewhat of a surprise, since the FDA only days before had allowed expansion of Sunrise's clinical trial for mid- to moderate hyperopia, and for the treatment of both eyes at the same session. However, the panel members felt that the data did not support approval. Because some patient's eyesight, over time, returned back to the pre-surgery state, the panel said it couldn't recommend the laser for approval.

FDA medical officer, Dr. Malvina B. Eydelman, gave her assessment of Sunrise's data. She told the panel that after two years a higher percentage of patients reported that their eyes start to revert back to their original eyesight. "The accuracy is quite

questionable for 24 months," Eydelman said.

The FDA panel voted 12-0 to turn down the application. Although panelist Woodford Van Meter expressed the general opinion of the panel that the company's device was safe, there were too many questions about its refraction and regression stability. Panel member Marian Macsai congratulated the company for performing a great job, but felt it was just "too soon to tell" whether the device works. She expressed that further follow-up will determine the efficacy of the LTK system. Based on calculations conducted by panelist Mark Bullimore, considering all of the data presented, the device worked in the order of 50% of the time. The panel requested that the company perform a statistical analysis of the first 46 eyes not considered in the "updated" cohort. (Company representatives stated 50 cases were initially omitted, but that was rounded up from 46. The company stated the additional four cases were not of significance to the results.) The panel also requested a patient questionnaire from the "updated" cohort assessing the patients' visual symptoms. The company was also asked to conduct an analysis of the data by gender, with a 90% accountability at 24 months. In closing, Mark Bullimore, stated that they were hampered by the lack of a hyperopic guidance document, but indicated that if one applied common sense to the data, it can be seen that the company's data did not demonstrate efficacy. Therefore, panel member Min Wang made it a point to have a hyperopic guidance document constructed for assistance.

Based on this unexpected turn of events, the following day the company's stock price dropped precipitously, from the $15 prior to the meeting, to close down nearly $12 at slightly less than $4, a 75% drop, with over 27 million shares traded.

The company issued a statement following the meeting saying that it would continue to pursue FDA approval of its LTK System for the treatment of low to moderate hyperopia. "We will continue to work with the FDA to respond to the recommendations and issues presented by the Panel and to pursue approval of the Sunrise LTK System," said Russell Trenary, president and CEO of Sunrise Technologies. "While we are of course disappointed with the Panel's vote, we continue to be cautiously optimistic that we will ultimately obtain approval from the FDA, which may or may not accept the Panel's recommendation," noted Mr. Trenary.

According to Jeannie Cecka, the company's vice president of Clinical and Regulatory Affairs, 656 cases were submitted in the PMA in the U.S., and the results met or exceeded target endpoints set by the FDA in its existing guidance pronouncements, with no reported sight-threatening complications or adverse reactions. However, the Panel suggested other criteria might be appropriate for discussion, including more long-term data.

Richard Leza of **John G. Kinnard** issued a followup report following the FDA turndown, further lowering his target price for the company to $2.00. He based that target on the delays involved in obtaining approval which would include increased

spending to satisfy the FDA demands.

7/23 **Omega Health Systems** announced that it was forming a strategic alliance with **EBW Laser Inc.** Through this relationship, EBW Laser will set up a program that offers optometrists an equity investment opportunity in excimer lasers located in eye care centers. To date, Omega has established laser centers in 12 of its markets with plans for laser centers in all of its markets by August 31, 1999. This program will be offered in all Omega markets, and, through this alliance, EBW Laser and Omega plan to establish laser center programs in new markets across the country.

"We are pleased to announce this strategic initiative to expand our laser vision correction capabilities," commented Thomas Lewis, president and CEO of Omega Health Systems. "Through this alliance, optometrists will have the opportunity to invest in excimer technology and further benefit from the significant growth in the demand for laser vision correction. With the advent of the excimer laser, laser vision correction is now one of the fastest growing areas in eye care services in the nation."

Attempts to reach officials with EBW Laser were unsuccessful, although I learned that the company was recently formed by Dr. Richard Epps of Greensboro, NC, to allow optometrists to own or participate in the laser business, and allow ophthalmologists to have access to the lasers for their patients.

Omega also announced that it was forming two strategic alliances as part of an initiative to use the Internet as a tool for supporting the company's national co-management network of ophthalmologists and optometrists. Omega will become the exclusive eye care partner of **Central Point Services, LLC.** Through this partnership, the company will establish a vehicle to provide an e-commerce service for doctors and vendors. Central Point Services is based in Grand Junction, Colorado and has an exclusive endorsement by the **National Cooperative of Health Networks**. The company is also working with **Yahoo! Broadcast Services**, a division of **Yahoo! Inc.**, to develop doctor and patient education programs on laser vision correction and webcasts for special company events. Based in Dallas, Texas, Yahoo! Broadcast Services aggregates and broadcasts streaming media programming on the web with the network infrastructure to deliver live and on-demand audio and video programs over the Internet.

7/23 As with **VISX**, the FDA's Ophthalmic Devices Panel voted 8-0 in favor of the **CRS Clinical Research's** PMA for using the **Summit Technologies'** Apex Plus laser in performing LASIK for myopia with and without astigmatism. The company is seeking the laser's use for up to 14 diopters of myopia and up to 5 diopters of astigmatism. We will have to wait to see what the FDA's final label recommendation will be, although, it is expected that similar labeling restrictions as were recommended for the VISX application will probably apply to Summit's. If the higher limits are upheld, it will expand Summit's current approval range, putting the company more in line with VISX's approvals (except for hyperopia). If the high limits

are approved, it will expand Summit's current approval range, bringing it more in line with VISX's approvals for myopia.

Following the announcement, Summit's stock price rose 11% to 20 1/2, on 2.2 million shares traded.

7/26 **Bausch & Lomb** announced the results of its operations for the second quarter. Revenues from the company's continuing operations, its vision care and pharmaceuticals/surgical segments, were $453.3 million, an increase of 11% over the $408.3 million reported in the second quarter of 1998. Excluding gains from the sale of businesses recorded in both periods, as well as certain items recorded in the second quarter of 1998, the company reported net earnings for the second quarter of $47.1 million (80 cents per share) compared to $37.6 million (66 cents per share) in the same period last year. Continuing operations contributed $28.9 million (49 cents per share) to the results, compared to $22.2 million (39 cents per share) in the second quarter of 1998.

Net earnings in the quarter were augmented by a gain of $126.3 million after taxes ($2.14 per share) from the sale of the sunglass business and by an after-tax gain of $33.0 million (58 cents per share) in connection with the sale of the skin care business, but were reduced by $15.3 million after taxes (26 cents per share) as a result of a purchase accounting adjustment and restructuring charge recorded in that quarter. Including these items recorded this quarter and in the same period last year, the company reported net earnings of $173.4 million ($2.94 per share) in the quarter, compared to $55.3 million (98 cents per share) in the second quarter of 1998.

For the first half of the year, revenues from continuing businesses were $843.2 million, an increase of 10% from the $765.9 million reported for the first two quarters of 1998. Net earnings, excluding gains on the sales of businesses in both years, and restructuring charges, purchase accounting adjustments and write-off's in 1998, were $69.5 million ($1.19 per share), compared to the $51.6 million (93 cents per share) through the first half of 1998. Including these items, 1999 net earnings through the second quarter were $195.8 million ($3.34 per share) compared to $32.0 million (58 cents per share) for the same period in 1998.

Revenues from the company's pharmaceuticals and surgical businesses grew 16% over the second quarter last year. Pharmaceutical sales grew 24%, benefiting from price increases in non-ophthalmic generic products. Sales of surgical products increased 11% from last year, driven by continued strong double-digit growth in sales of products for refractive surgery.

"Our core businesses continue to perform very well. Not only did they demonstrate solid revenue growth, they delivered increases in operating earnings that have allowed us to make significant incremental investments in research and development and new products to ensure that we continue as the preeminent company in eye care," said

William Carpenter, Bausch & Lomb's chairman and CEO. "We are very pleased that since our announcement last November of our intention to focus our portfolio solely on eye care, we have been able to move expeditiously to complete our portfolio realignment," Carpenter continued. "We will use the proceeds from the sale of our non-core businesses to strengthen our balance sheet and give us the flexibility to make external investments to accelerate the growth of our core businesses."

The company also announced that it had signed an agreement to sell **Charles River Laboratories** to **Global Health Partners**, a unit of **DLJ Merchant Banking**, for $400 million in cash and a promissory note of $43 million, with B&L retaining a minority interest in the divested business.

OPHTHALMIC LASER UPDATE -- AUGUST 1999

7/21 Brenda Moore of *The Wall Street Journal* was kind enough to send a copy of her article that appeared in the "Heard in California" section of the Journal the day before **Sunrise Technologies** appeared before the FDA's Ophthalmic Devices Panel. It was entitled, "Sunrise Sues over Analysts Critical Reports", relating the reaction by Sunrise Technologies International over the critical "sell" recommendations and reports written by **Sturza's Institutional Research** and **Avalon Research Group**. (I was able to obtain a copy of the Sturza report -- see the August 2nd brief below, but not the Avalon report.)
As Moore wrote, "The company's reaction (filing the defamation suit) may have made its employees and backers feel better and calmed investor's nerves. But others say it also may have drawn increased attention to the reports and contributed to the stock's volatility over the past six weeks, when its price has ranged from $8.75 to $20.375. Others say Sunrise may end up alienating securities analysts in general." The article goes on to quote from Stephen Sabba, MD, the Sturza analyst who wrote the report, "We're just saying that this stock is overvalued and this is why. What you do with the information is up to you entirely." It also reports that David Harmon of **Market Scope** noted that Sunrise might have been better off to ignore the Sturza reports, which came out a day ahead of the Avalon piece, as neither had visibility until Sunrise made a big deal out of it.

7/26 **Summit Technology** followed up the ODP's recommendation for approval of LASIK on its laser by issuing a news release noting that if the FDA labelling followed the recommendation, it would have the widest range of myopia and astigmatism approved, surpassing that of its rival **VISX**, increasing the approved range to 14 diopters from the current 7 diopters, and astigmatism from 4 diopters to 5. The panel also recommended making the procedure available to persons as young as 18, lower than Summit's current labelling range of persons over 21. As noted last month, following the panel's recommendation, Summits share price soared, reaching nearly $25, before settling back to below $20.

7/26 **Paradigm Medical Industries** announced that it will report profits for its second quarter ending June 30, 1999. The company reported that second quarter revenues were over $1 million, up 60% over the same period for 1998. Net pretax profits for the period were approximately $25,000. Company president and CEO, Thomas Motter stated, "This is a milestone for the company, demonstrating the successful in-house manufacturing of our new ultrasound diagnostic product line, and the management of our resources to achieve profitability." Motter further noted, "The outlook for the remaining year is positive as the company moves toward completion of its laser cataract clinical trials, and expands sales of its revolutionary Ultrasound Biomicroscope system into the growing glaucoma market."

7/26 In response to all of the turmoil surrounding **Sunrise Technologies International** disappointing news after being turned down by the FDA's ODP, the company posted a "Dear Shareholder" letter on its web site, explaining what had happened and what the company intended to do in working with FDA to gain approval. In the letter, company president Russ Trenary posted a number of questions and their answers. As the days went by, additional questions and answers were posted.

7/27 **Sight Resource** reported financial results for its second quarter and six months with revenue for the quarter of $17.6 million, an increase of 21% from revenue of $14.5 million for the second quarter of 1998. Net income was $288,000 (3 cents per share) compared with $77,000 (1 cent per share), for the second quarter of 1998. Quarterly results include the operations of **Shawnee Optical**, acquired effective January 1, 1999, and **Kent Optical**, acquired effective April 1, 1999.

For the six-month period, the company reported revenue of $33.3 million, an increase of 19% from revenue of $28.1 million for the same period in 1998. Net income was $461,000 (5 cents per share) compared with $90,000 (1 cent per share) for the first six months of the prior year.

7/27 **Summit Technology** announced that its **Autonomous Technologies** subsidiary had been granted an IDE to begin investigational feasibility studies for customized ablations using the combination of its CustomCornea measurement device and its LadarVision system. The study will include the treatment of myopia and hyperopia and astigmatism for both PRK and LASIK. The results of the feasibility study, of a limited number of eyes, scheduled to begin in August, will provide the basis for an expanded U.S. clinical trial.

7/27 **Lasik Vision** announced plans to open a new refractive center in Edmonton, Alberta. Located in the downtown Edmonton business district, the new clinic is scheduled to open in August. The Edmonton center will be Lasik Vision's eleventh in Canada, further reinforcing its position as Canada's largest operating laser eye surgery company. In addition to the Edmonton opening, the company also reported that it intended to open its first U.S. refractive center, located in Bellevue, Washington in September 1999.

According to Michael Henderson, president and CEO, "Beginning with the opening of a refractive center in Bellevue, our focus for the rest of 1999 will be on expanding into key urban U.S. markets."

7/27 **Sterling Vision** announced that one of its wholly owned subsidiaries had signed a lease for an additional, state of the art, **Insight Laser Center** expected to open in September 1999 in Queens, New York. Dr. Robert Cohen, chairman, stated, "This is part of the aggressive expansion we are undertaking for Insight Laser Centers. Insight continues to prosper, as demonstrated by the record increases in the number of monthly procedures performed on its lasers."

7/27 **Avalon Research Group** changed its "sell/sell short" opinion for **Sunrise Technologies International** to "neutral". In a research update following the company's unsuccessful appearance at the FDA Ophthalmic Devices Panel review, Avalon recommended that its investors cover their short sale positions. Avalon's target price of $4.00 was exceeded. Avalon issued its original "sell/sell short" recommendation on June 10, 1999, when Sunrise shares were trading at $12.38 and subsequently raised its rating to a "strong sell/sell short" on July 19, 1999, when the company's shares were trading at $19.00. Avalon based its sell/sell short recommendation on various concerns over potential problems with the clinical data for the company's Hyperion Laser and the LTK procedure for Hyperopia submitted to the FDA. These concerns were borne out when the ODP unanimously rejected Sunrises's PMA on July 22, 1999. Since the rejection, the company's shares have plunged over 75% in value, resulting in achieving Avalon's price target and the subsequent rating change.

7/27 **LaserSight** announced that it had begun shipment of its UltraEdge Keratome Blades in the United States, Canada and other international markets. The shipment marks LaserSight's entry into the market for per-procedure laser vision correction products on a value-added basis to physicians and patients. The blades are the product of a joint venture between LaserSight and **Becton Dickinson, Inc.**

(As previously announced in May, LaserSight and **Becton Dickinson Ophthalmic Systems** entered into an exclusive agreement to develop, manufacture and distribute keratome blades.)

7/27 *TheStreet.com's* Jesse Eisinger wrote "Defiant Spirit Doesn't Set on Sunrise", discussing the defiant attitude that **Sunrise Technologies** took following the rejection of its PMA by the FDA's ODP. On a conference call the day after the meeting, the company said the panel didn't think there were any safety questions with the technology and that the company already had supplied enough data to prove the laser effective. The company went so far as to suggest to listeners that the FDA would agree. Some professional investors were aghast. In fact, the panel had safety concerns about astigmatism, and it asked Sunrise to provide more data on side effects. The panel had efficacy concerns as well, which were shared by the FDA's presenter.

Nevertheless, Sunrise has its own version of the events. Don Sanders, an eye doctor, investigator and major investor in Sunrise, said on the Friday call that the FDA "usually considers it just as much their failure" when a panel rejects a technology. "They have the opinion that it's approvable; otherwise they don't allow it to go to panel." He added, "And they are anxious to remedy it," speaking of the panel outcome. An FDA spokeswoman says, "The FDA holds a panel when we have questions or are looking for additional expertise, for a variety of reasons."

Also on the call, a consultant to Sunrise, Doyle Stulting, explained, "Functionally, an application that is disapproved for reasons and an application that's approvable with conditions are really the same." Wrong. A panel thumbs-down just ain't the same -- even "functionally" -- as an approval with conditions. While panel verdicts aren't binding, the FDA more than often pays heed."

7/27 **The Council for Refractive Surgery Quality (CRSQA)** announced that it had published the standards by which its approved doctors will be measured. Judged primarily on postoperative uncorrected visual acuity obtained, surgeons who maintain certification will be provided referrals from patients who seek information from CRSQA's website at www.usaeyes.org.

Patient outcomes required for certification:

- 90% must achieve 20/40 or better UCVA
- 50% must achieve 20/20 or better UCVA
- Not more than 3% may experience debilitating refractive surgery complications such as glare, arcs, starbursts, halo, etc.
- Not more than 1% may experience vision-threatening postoperative complications such as infection, flap complications, epithelial ingrowth, etc.

"The standards are designed to reflect national norms," says Richard Meister, MD, chairperson of CRSQA's Quality Standards Advisory Committee, which developed the standards.

7/28 **Summit Technology** said that its revenues for the three months ended June 30, 1999 increased 14% to $27.4 million from $24.1 million for the three months of the same period a year ago. The quarter results included the effects of operations of **Autonomous Technologies** from the date of acquisition which was April 29, 1999. In connection with the acquisition, Summit recorded one-time charges of $19.8 million for acquired in-process research and development and $2.8 million to write-down inventory to its net realizable value. Excluding one-time charges, the net loss for the second quarter of 1999 was $1.3 million (3 cents per share). Including the one-time charges, the net loss was $23.9 million (61 cents per share), compared to net income of $31.2 million ($1.00 per share) for the second quarter of 1998. In the second quarter, Summit received a $29.9 million litigation settlement, net of taxes and related expenses.

Revenues for the six months were $53.1 million, an increase of 15% over revenues of $46.1 million for the six months last year. The net loss for the first half, including the one-time charges described above, was $21.5 million (61 cents per share) compared to net income of $21.5 million (69 cents per share) for the same period last year. The second half results also included a one-time non-cash charge of $10.1 million (32 cents per share) representing the cumulative effect of adopting a new accounting principle as of January 1, 1998.

Second quarter procedure volume in the US, measured by the company's sale of OmniCards, increased 100% over the second quarter of 1998 and 14% over the first quarter of 1999. "We are pleased with the increase in procedure volume we experienced this quarter," stated Robert Palmisano, CEO of Summit. "We recently announced a public offering to sell 4 million shares of our common stock, and with the proceeds we will continue to execute our business plan to grow our market share and regain leadership in this industry," commented Palmisano. "We believe that with Summit's leading technology, customer focus and a broadening of FDA approvals, procedures performed on our systems will continue to grow," he concluded.

Excluding contact lens related revenues, the company's excimer laser business (including the sale of blades and keratomes) realized $15.7 million, up from $13.5 million for the previous quarter, and up from $12.9 million in last year's second quarter. During the quarter, the company placed 7 Autonomous lasers, while 11 were on contracts, and shipped 17 new Apex Plus systems; 8 direct sales, 7 on a per procedure basis, and 2 upgrades. In addition, 6 systems were converted from the per procedure basis to outright sales, for a total of 23 systems. Of the 17 Apex lasers placed, 14 were in the U. S. and 3 were outside. Palmisano said that by the end of this year, he hoped that the company would sell 50 Autonomous lasers, being produced at the rate of 4-5 per month now, ramping to 12 per month by the end of the year, and 60 Apex Plus systems. He also noted that the ASPs for the Apex laser were up from a year ago. Thirty-one SKB microkeratomes were sold during the quarter, with demand still exceeding supply. But the company was ramping up microkeratome production to meet the demand.

7/28 **LCA-Vision** reported results for the 1999 second quarter. Laser vision correction revenues for the quarter increased 73% to $14.3 million compared with $8.3 million for the same period last year. Total revenues were $14.7 million compared with $9.0 million for the same period last year. For the three month period, the company reported net income of $2.3 million (5 cents per share), compared with a net loss of $11.6 million (32 cents per share) in the comparable period last year. The 1998 loss includes a restructuring provision of $10.5 million.

Laser vision correction revenues for the first half of 1999 increased 88% to $27.7 million compared with $14.7 million for the same period last year. Total revenues for the half year were $28.6 million compared with $16.2 million. Net income for the six months was $4.0 million (9 cents per share) compared with a net loss of $13.2 million

(36 cents per share) in the comparable period last year.

"The highlight of the quarter was unquestionably the significant gains in year over year revenue growth and profits. We continue to exceed expectations both internally and externally, and to generate significant cash flow. In July, we successfully completed a public offering that will enable us to pursue our strategy to roll out new centers in contiguous markets, and allow LCA-Vision to leverage its established reputation for consistent and quality patient care. The growing consumer awareness, and increased patient confidence in our physicians' outcomes continues to fuel our growth," said Stephen Joffe, chairman and CEO.

As previously reported, LCA-Vision raised over $37 million in a secondary equity offering, the proceeds of which will be reflected in the 1999 third quarter financial results. Coinciding with the public offering, the company's shares began trading on the Nasdaq National Market System. Also during the quarter, the company announced it had entered into an arrangement with **Cole Managed Vision**, a division of **Cole National Corporation**, to provide access to laser vision correction to Cole Managed Vision members nationwide.

7/28 *The International Society of Refractive Surgery (ISRS)* put out a news release with further clarification of the recent FDA ODP recommendation for approval of both **Summit** and **VISX** laser systems for LASIK. The ISRS acted as the affiliated peer-group to the **CRS** LASIK studies, as administered by **CRS-Clinical Research**, which were funded by the surgeon participants. "The study was established in 1996 to validate LASIK with the lasers available in the U.S." explained Charles Casbeer, MD, chairman and founder of CRS-Clinical Research. "We accomplished that and LASIK has become the standard of care in refractive surgery. These applications will allow the lasers to be labeled for their actual use."

7/29 Effective August 1st, 10 million members of **Eye Care Plan of America (ECPA)** programs and their dependents will have the choice of laser vision correction. This service comes as **First American Health Concepts Inc.**, which markets and administers third-party managed vision care plans nationwide under the trade name **Eye Care Plan of America**, unveiled a program for laser refractive procedures.

"Industry estimates anticipate that approximately 1 million refractive surgeries will be performed in the year 2000. Due to the growing popularity of refractive surgery and ECPA's commitment to offer choice to our membership, the laser vision correction program as a value added benefit was an obvious inclusion," said John Raycraft, president and CEO. Laser vision correction, which includes PRK and LASIK, is now available through ECPA's national network. The network includes some of the nation's most highly qualified surgeons and all surgeons have been fully credentialed to meet NCQA guidelines, with primary source verification performed by an independent NCQA certified organization. Each surgeon is board certified, has performed more than 1,000 successful laser procedures, and uses FDA-approved

lasers. "The 34 surgeons currently participating in the laser vision correction network were hand picked and/or highly recommended by their peers," said Lee Nordan, MD, surgical director, **Laser Vision Correction** for ECPA. "We elected to set-up the network using independent ophthalmologists who may participate in the day-to-day decisions regarding their patients' care without the potential influence of a commercial intermediary, such as a public laser vision corporation." Nordan added, "All procedure outcomes will be monitored by the surgeons to ensure the quality of care and integrity of the surgical provider network and program."

7/30 **Omega Health Systems** announced that it had established a new laser center at the company's eye care center located in Jackson, Tennessee. The addition of this location brings the total number of laser centers to 13 as the company continues to expand its laser vision correction capabilities nationwide through its eye care centers.

7/30 As has become customary upon any competitive news, Wade King of **BancBoston Robertson Stephens** reiterated his "buy" rating on **VISX**. "This week, the company's principal domestic competitor, **Summit Technology**, announced its June-quarter financial results. During the quarter, Summit placed 22 new lasers worldwide. In contrast, VISX placed 61 new lasers worldwide during the same period. We believe the back order for VISX's STAR S2 lasers remains quite significant, and estimate that VISX will place up to 80 new lasers worldwide in third-quarter 1999, and a similar number in the fourth quarter. In our view, the percentage of U.S. LVC procedures performed on VISX lasers exceeded 78% in the second quarter. We believe that VISX's strong procedure momentum and extension of market-share dominance continues through July. We believe that there is no comparable growth and investment opportunity in the medical device universe today. We are raising our price target for shares of VISX to $125."

7/30 **Sunrise Technologies International** announced financial results for the second quarter. Cash and cash equivalents as of June 30, 1999 were $19.6 million which, at the present rate of cash usage, were expected to fund the company's operations through mid-2000.
Revenues for the three- and six-month periods were $3,000 and $16,000, respectively, compared to $222,000 and $324,000, for the same periods in 1998. Revenues for 1998 were the result of sales of SUN 1000 ophthalmic laser units to international markets and domestic sales of Paradigm dental units. Sunrise Technologies is no longer engaged in the sale of dental units and the SUN 1000 production was discontinued in 1999 as the Hyperion LTK System, the company's new Laser Thermal Keratoplasty instrument, is in final stages of development. Revenues for 1999 represent sales of accessory parts for older machines on the market.

Operating expenses for the three- and six-month periods were $4.1 million and $9.3 million respectively. Prior year comparative periods showed operating expense levels of $4.6 million and $6.5 million respectively. The 43% increase in operating expenses for the six months of 1999, as compared to the same period of 1998, reflected the

company's increased expenditures in research, development, engineering and manufacturing.

Net losses for the three- and six-month periods were $5.8 million and $14.3 million respectively. Net losses for the same periods of 1998 were $5.6 million and $9.4 million. For the six months of 1999, $5.6 million or 39% of the accumulated net losses result from non-cash expenses of which $4.2 million were associated with the amortization of financing costs of convertible debt financings for 1999 and prior years. $1.4 million of these accumulated losses were associated with non-cash costs for warrants issued and compensation charges incurred with the issuance of Non Qualified Stock Options. For the same six months of 1998, $4.6 million or 49% of the accumulated net losses were attributable to non-cash expenses.

8/2 As noted above, I was able to obtain copies of the **Sturza's Institutional Research** reports on **Sunrise Technologies**, including the original June 7th and followup July 14th and 22nd reports. The June 7th "sell" report states that "serious adverse events with the company's LTK laser have not been reported, the procedure has caused some adverse effects, including foreign body sensation, increased light sensitivity (temporary), unintended over or under corrections, fluctuations in refraction during the healing process, and regression of the procedures effect." (If I didn't know better, I would have thought I was reading the results for PRK!)

The report goes on to state that the author (which turned out to be analyst Steven Sabba, MD), does not believe there will be significant demand for the laser, based on his opinion that most refractive surgeons are extremely satisfied with the efficacy and safety provided by the excimer laser. "Assuming Sunrise receives a positive Panel recommendation, we believe SNRS would be worth approximately $110 million (market capitalization), or $1.94 per fully diluted share. Alternatively, should the FDA Advisory Panel reject Sunrise's PMA outright, these shares would immediately plummet."

The rest of the report goes on to attempt to justify these conclusions, in some cases using old clinical data to show regression of the effect, including data from the old "contact" studies conducted (and halted) by **Summit Technologies**. The Sturza report comments on the size of the potential hyperopia market, which we also have questioned, and also notes the "non" sales of the LTK system in Europe, which the company has explained was intentional. The report also questions the "sizeable stakes" of six of the company's 11 clinical investigators (which the FDA addressed as a non-event at its review meeting).

In its conclusions, Sturza claims that "although we are unaware of any serious safety issues, we believe there is a 70% probability that the Panel will vote to reject Sunrise's PMA due to the LTK laser's inability to treat moderate hyperopia, the frequent tendency for the treatment to regress -- often completely --- within several months, and the lack of adequate long-term data." (It was almost as if the author knew ahead

of time how the panel members would be thinking.) The report goes on to state, "Even if the Panel recommends that Sunrise's LTK system be approved, we believe the product to be a commercial failure, due to its limited efficacy and inability to treat most refractive disorders. We do not expect there to be significant clinician demand for an expensive laser that cannot treat a wide range of visual defects (e.g., astigmatism, moderate to severe hyperopia). Clinicians who have already purchased (or leased) a VISX or Summit laser are not likely to invest in another expensive piece of capital equipment that does not expand their capabilities. Lastly, we expect those patients who do receive treatment with the LTK system to become frustrated by the procedure's tendency towards regression." (I guess the author never heard of the word, "retreatment"!)

The July 14th followup report discussed the runup in price of Sunrise's stock price in anticipation of the July 22nd ODP meeting. It also noted that the company's lawyers had accused Sturza of "publishing a report on Sunrise Technologies that contained false, misleading, inappropriate, and inflammatory statements", and had demanded an immediate retraction. Sturza denied the allegations and stood by its original report. It reiterated its "sell" recommendation and its one-year target price of $2.

The final report, written following the panel meeting on July 22nd, summarized the ODP's findings, that Sunrise "failed to prove that corrections achieved with the LTK system were stable at six months, and that data beyond six months were inadequate." The one-page summary also noted that the FDA had "voiced concern over the safety of the procedure due to its tendency to induce shifting astigmatism." (Not the way I read the outcome of the hearing and, it should be noted -- as reported in our July 13 brief last month -- the FDA allowed the company to begin two-eye same day studies just several days ahead of the hearing!)

8/2 *The Associated Press* carried a story about the first refractive surgery center in a mall, entitled, "They're slicing eyeballs at the Fair Oaks Mall". This story, first reported by *EyeWorld* (see our June 15th brief in the June 1999 newsletter), tells the story of the visible mall surgical center operated by ophthalmologist Robert Johnston in Fairfax, Virginia. The **Visual Freedom Center** is believed to be the first center to be located in a shopping mall. As noted by Jan Beiting, spokeswoman for the *American Society of Cataract and Refractive Surgery (ASCRS)* in Fairfax, "There's definitely a buzz about it among our members".

Since the center moved to the mall from Johnston's office in Leesburg in February, business has jumped about 40%, with about 15 patients treated daily, said marketing director Shannon Fredericks. The center has been so successful that a second shop will open in a Columbia, Md., mall in September. Two more are in the works for the Chicago and Washington-Baltimore areas by the end of the year, Fredericks said. David Karcher, executive director of the ASCRS, cautioned against trivializing the seriousness of the procedure and said this is as close as physicians have come to "going retail".

Craig Conroy, head of **Conroy Research Group** and a former mall developer, said the Visual Freedom Center is part of the "doc in a box" phenomenon in which physicians have moved out of their traditional sterile environments to attract customers. Dentists' offices have been in malls for years, and chiropractors have made the move too, he said. While people may get sweaty palms when they walk into a hospital, nobody's nervous about visiting the mall. "Malls have become the town squares in many communities, and it makes sense for physicians to locate there." And there's one other perk: Patients get free videos of the surgery -- for their friends who couldn't make it to the mall.

8/2 *Federal Filings Business News* carried an article prepared by Todd Goren, titled, "Goren's View: Lots Of Money To Be Made, Or Lost, At FDA Mtgs". The article discussed the FDA hearings, held on July 22nd and July 23rd, as providing examples of how someone could make, or lose, a stack of money. Examples given included **Summit Technology** and **Sunrise Technologies**. "For those not aware of how the process works, after a company performs clinical trials on a proposed new product to prove that it is safe and effective for a specific use, the company submits the data to the FDA. In many cases, there is the desire by the FDA to get the opinion of a panel of outside experts on any lingering questions the agency may have about a product. These questions run the gamut from things as simple as potential labeling issues to if the product is truly safe and/or effective for use in humans. The FDA advisory panel only makes a recommendation to the FDA, and the agency is free to make its own decision on any and all products. However, the vast majority of the time the agency will follow the recommendation of its advisory panels.

As examples of how to make a lot of money, check out what happened with Summit Technology Inc. On July 23, an FDA advisory panel recommended that the agency approve the company's laser for the treatment of nearsightedness using the LASIK procedure. Pretty much immediately, shares of Summit jumped $2 to $20.50, a rise of nearly 11%. Since then the shares continued to gain altitude to a 52-week high of $29.38 on July 27, but have since settled back to a recent $23.94, still a 29.4% increase in a week.

Contrast this with Sunrise Technologies which didn't have such a happy ending to its FDA panel meeting. As reported, late on July 22, the panel voted unanimously against recommending the company's Laser Thermal Keratoplasty (LTK) for approval to treat far-sightedness citing concerns about the long-term stability of the treatment, i.e. the device's efficacy. Panel members stated that there just wasn't enough long-term data to prove that the device worked. Safety was not an issue of concern to the panel. The next day, investors couldn't get rid of their shares quickly enough, and the stock plummeted 11 5/16 points, or 75%, to close at $3.72. The stock has moved somewhat higher since then, mostly attributed to short-covering, to a recent $5.38. The drop looks even worse when compared with the 52-week high of $20.38 set July 9 in anticipation of a positive FDA meeting.

Part of the reason Sunrise Technology cratered due to the negative outcome is because LTK for far-sightedness was what the company had banked its hopes on. As detailed in the company's annual report, Sunrise Technology focused its efforts on the far-sightedness part of the market, rightly or wrongly, due to the large number of competitors in the market to treat nearsightedness. For larger, more established companies, the FDA's request for more clinical data wouldn't be that much of a hindrance. Yes, it would delay the introduction of the product and may throw earnings off for a while, but it wouldn't be the kiss of death. However, in this case, it might be."

8/3 Still moving ahead with its expansion plans, **Omega Health Systems** announced that it had established laser centers at the company's eye care centers located in Tallahassee, Florida; Orlando, Florida; and Metairie, Louisiana. The addition of these locations brings the total number of laser centers in Omega markets up to 16. The company also entered into access fee arrangements with ophthalmologists in Baltimore, Maryland and Gainesville, Georgia. Ophthalmologists practicing at the laser center in Baltimore are currently performing cases, and the Gainesville location has its first surgeries scheduled for later this month. With the addition of these two new markets, Omega has established laser centers in 18 markets overall.

"We continue to see strong demand for this procedure, and our operating strategy is to continue to develop laser centers in all of our markets and find opportunities to expand into new ones," commented Thomas Lewis, president and CEO. "The access arrangements in Maryland and Georgia allow us to establish a presence in markets where we do not currently have eye care centers and create an additional opportunity to increase our nationwide branding effort."

8/3 Responding to rumors floating over the internet (from Yahoo! Finance) that its senior management team was planning to resign, **Laser Vision Centers** announced that its Board of Directors had recently voted to extend the employment agreement of its chairman and CEO John Klobnak for an additional three years. The company also extended the agreements of three other senior executives: James Wachtman, president and COO; Robert May, vice chairman and General Counsel; and Charles Bono, executive vice president and CFO. James Garvey, managing partner of **Schroder Ventures** and a Board Member of the company, said, "This was in recognition of the outstanding job Jack Klobnak and the LVCI management team have done in delivering value to shareholders, and the Board wanted to be assured of retaining their services for the long term."

The following day, *Dow Business News*' Nicole Ridgway wrote about the situation. As she put it, when Jack Klobnak heard that someone on the internet was spreading rumors that he had unofficially resigned, he thought it was a joke. But after close to 50 frantic calls from fund managers and other investors, he stopped laughing, especially as the rumor apparently caused the company's stock price to drop. The company's general counsel Robert May contacted the host (in this case Yahoo) to see what could be done about it. Apparently, Yahoo was unresponsive, which caused the

company to consider a lawsuit to determine the source. The company did respond, as noted above, by announcing that the board of directors had recently voted to extend the employment agreement of Klobnak, and three other senior executives as well. Seeking justice, Klobnak said that the company would pursue "whatever means possible" to find out the identity of the person or persons behind the recent rumors (also one of irregularities in accounting). After doing some digging, Klobnak said he learned that the person posting the message had used the name of another board participant that normally posts legitimate information.

8/4 **Bausch & Lomb**, in response to heavy trading in its stock, apparently triggered by questions about the regulatory status of its Technolas 217 laser, said that it was still awaiting word on whether the FDA will require the company's PMA to be reviewed by the agency's ODP. Panel meetings are scheduled for September 23-24, and November 18-19, and agendas for the meetings will be finalized and published 15 days prior to each meeting. The company acknowledged that its PMA had been accepted for filing in mid-July and that it expected to know within the next few weeks whether or not the application would require review by the panel. (Since four other laser have been approved to date, it is likely that B&L's application will not require panel approval, similar to what had been announced by **LaserSight** previously.)

8/5 **TLC The Laser Center** also found it had to respond to certain rumors that apparently were driving its stock price. The company said it was aware of the existence of a rumor that suggested it's president and CEO, Elias Vamvakas, had already or intended to tender his resignation from the company. But in fact, Mr. Vamvakas had not tendered his resignation from TLC, nor did he intend to. Mr. Vamvakas also continued to be one of TLC's largest individual shareholders. Moreover, no other member of TLC's senior management team had tendered their resignations, nor do any other members of TLC's senior management team intend to do so. The company believed that this rumor may have resulted from confusion over a similar false rumor regarding the CEO of one its competitors (**Laser Vision Center**), circulated a few days before on internet message boards. The company also advised that it was unaware of any pending announcement or corporate development that would explain the recent market activity in its common shares.

8/5 Yet another story, that began to hit the newswires may have triggered reactions to several companies' share prices. A story on laser eye surgery was posted on *The BBC Online* that commented on what was purported to be "new" scientific research from Germany that showed that 7 out of 10 patients who had undergone laser vision correction had been left with "defective vision" after the surgery. Allegedly, the experimental ophthalmology department at the University of Tubingen Eye Hospital, had been carrying out tests on post-operative laser patients for nearly 10 years. Its latest findings showed that despite improvements in technology, over 70% of patients were still suffering from poor night vision.

Thanks (this time) to Wade King of **BancBoston Robertson Stephens** and Ken Taylor

of **Arthur D. Little**, I was able to track down the original study, which was an old German study by Schlote et al, "Impairment of Mesopic Vision following PRK of Myopia", done on 26 patients who underwent PRK using an old Summit Excimed with a 5 mm optical zone. This clearly would lead to a great number of those treated to have "night vision" problems. It certainly should have no effect on current patients being treated with LASIK, using lasers with much larger ablation zones.

8/5 And yet another rumor came to the fore, this time, *Bloomberg News* issued a news announcement on August 3rd, stating that **Summit Technology** had been warned about problems with its eye surgery device. The story was related to a warning letter received by Summit, dated July 14th, that disclosed during an inspection of Summit's Cork Ireland plant on May 4-7, the FDA's investigator had determined that microkeratome blades manufactured for Summit by its supplier in Germany were adulterated, because the Master Record failed to contain sterilization specifications for the blades as sterile, nor was documentation available to show that the packaging for the sterile cutting blades had ever been tested for integrity. The letter went on to state that the lack of documentation "raised concerns as to whether the microkeratome blades were adequately sterilized". During a meeting with Robert Palmisano, CEO of Summit, during his August 5th "roadshow" presentation for the secondary offering by his company, I posed the question about the FDA warning letter. He assured me that the blades had been properly sterilized, and the documentation was in order. The problem had been that all of the documentation was in German, and couldn't be read by the FDA inspector. When the documents were translated into english, the problem went away, and the blades are currently being shipped into the U.S. for sale to customers.

Another question that I was able to clarify concerned the cross license agreement between Summit and **VISX**, especially with the acquisition of **Autonomous** falling under the umbrella of that agreement. It had been speculated that the cross license allowed either participant to access the technology of the other. To some degree this is true. The cross license agreement does allow royalty-free rights to practice the technology covered by the various patents in the agreement, including any new patents that issue to either participant (or by acquisition) that concern ablation of the cornea, but it does not allow access to the underlying technology(s). In other words, if VISX, for example, could develop a tracking system similar to that used by Autonomous, it could practice the invention. But the agreement does not give VISX direct access to Autonomous' underlying technologies, only a royalty-free right if it develops its own technology.

8/5 **LaserSight** announced its participation in an international clinical study of customized corneal ablation utilizing its LaserScan excimer laser system. This study is the first of its kind to be performed on an internationally available commercial excimer laser system, and reflects data collected over one year that demonstrates the precision of the company's high speed excimer laser system when used to customize the treatment for laser vision correction. The study was conducted at the University of Bari Eye Clinic,

Bari, Italy and evaluated software for Corneal Interactive Programmed Topographic Ablation (CIPTA) developed for interaction between a corneal topography system and a refractive laser in the treatment of irregular astigmatism and other corneal irregularities.

The CIPTA software was developed for use with a small diameter scanning beam platform. The LaserScan, therefore, was the platform of choice because of its capability to provide, under software control, high-resolution corneal ablations with variable shape, depth, and overall size which makes the small diameter (under 1 mm) flying spot laser uniquely adaptable to custom refractive correction. Results of the University of Bari study will be presented at the American Academy of Ophthalmology Annual Meeting, October 24 - 27, 1999 in Orlando, FL. In addition to the on-going clinical study at the University of Bari, LaserSight continues its activities to advance its scanning laser platform for custom ablation utilizing the expertise of Jack Holladay, M.D., McNeese Professor of Ophthalmology, University of Texas Medical School, Houston, TX, a consultant to the company. Dr. Holladay commented, "I reviewed the data on the more than 100 custom ablations performed by Dr. Alessio's team from Bari University utilizing the LaserScan system. Their results are the best I have seen, with some patients with irregular astigmatism actually achieving 20/10 vision...remarkable."

8/8 In an interview conducted by Ian Karleff of *Reuters*, Elias Vamvakas, CEO of **TLC The Laser Center**, told the news agency that his company "eyes U.S. growth and plans to launch clinics in Europe". "There's no question we will have clinics throughout the world, it's a matter of when. Europe is kind of the thing that we are most interested in at this point because it's the closest to what we are doing in North America." He went to say that TLC is on track to perform 150,000 surgeries in fiscal 2000, up from 36,000 in fiscal 1998. He also said that he was not concerned about cut-rate competitors offering surgeries at $499 per eye, compared with TLC's $2400, potentially driving down the industry leader's price. "My concern is not from a business concern, but what's going to happen industry-wide when a whole bunch of unhappy patients report poor results." The article noted that TLC was sitting on a $150 million war chest from its recently completed stock offering, and had launched a $20 million television and radio campaign in the U.S. and Canada.

The company has also hired Rochelle Stenzler, as president of its international operations. She is examining a barrage of international proposals to find one that's worth pursuing. Commenting on overseas expansion plans, Vamvakas said, "It has to be substantial and big enough to have the resources to be able to run itself, because we're not going to run it out of here (Toronto)." Claude Camire, a healthcare analyst at **Canaccord Capital Corp.**, said vision-care companies are now plentiful in North America with Canadian firms **Gimbel Vision** and **Lasik Vision Corp.**, St. Louis, Mo.-based **Laser Vision Centers Inc.** and a host of others chasing the consumer trend toward laser vision correction. Companies that have tried international expansion have all lost money, but when the U.S. market becomes saturated in three or four years,

opportunities will exist in the highly fragmented European and Japanese markets.

8/9 **Gimbel Vision** reported increased second quarter revenues and earnings, based on an increase in procedure volumes. During the second quarter, the company performed 6427 refractive procedures, up 56% from the number done in last year's second quarter, and 22% from the first quarter's results. The company's North American centers performed 5043 procedures during the quarter, while 1384 procedures were performed at centers outside of North America. For the six month period, a total of 11,693 procedures were performed, a 58% increase over the corresponding period a year ago. Of these, 8912 procedures were performed at North American centers.

Revenues for the three months were $5.8 million -- including $3.2 million from Canadian operations and $2.1 million from U.S. operations -- up 4% over the prior year, and 19% over the first quarter. Canadian segment revenues rose 39%, in response to action taken by the company given the intense price competition during the first quarter. For the six month period, consolidated revenues were $10.7 million -- including $5.6 million in Canada and $4.3 million in the U.S. -- compared to revenues of $10.8 million a year ago. Although procedure volume has increased significantly, revenues remained unchanged, as a result of the price compression that took place in the Canadian market at the beginning of the current year, and the exclusion of Australian-based revenues from the current year with the divestiture of that investment in the latter part of 1998.

Net earnings for the quarter were $250,310 (1 cent per share), a 49% increase over net earnings of $168,460 for the second quarter a year ago. This was a 6% increase over net earnings of $235,565 for the first quarter of 1999. For the six month period, net earnings were $485,875 (2 cents per share), a 16% increase over earnings of $419,782 a year ago. On a geographic basis, Canadian operations generated a profit of $169,462 and $368,384 for the three and six month periods. Operations based in the United States generated a profit of $94,579 and $248,421 for the respective periods, representing a significant increase over a profit of $1463 for the second quarter last year, and a loss of $125,454 for the six months.

The company continues to focus its resources on developing the North American segment of its business, and is committed to establishing 3 to 5 new centers by year's end.

8/9 **CIBA Vision Corporation** and **QLT PhotoTherapeutics Inc.** announced the filing of Visudyne therapy with the *European Medicines Evaluation Agency (EMEA)* for marketing clearance in the European Union (EU) for the treatment of wet age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50 in the western world. The specific indication requested was for the treatment of AMD in patients with predominantly classic subfoveal choroidal neovascularization, the most aggressive cause of vision loss associated with the disease and for which Visudyne showed a dramatic benefit. The centralized filing, when approved, will

allow the marketing of Visudyne in all fifteen EU member countries comprising Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. CIBA Vision and QLT plan to submit applications to additional regulatory authorities worldwide, starting with the United States and Switzerland in the coming weeks, and Canada and Norway shortly thereafter.

8/9-
8/11 **LaserSight** announced financial results for the second quarter and six months. Revenues for the quarter increased approximately 8% to $5.3 million from $4.9 million in the second quarter of 1998. The company reported a net loss of $3.5 million (21 cents per share) compared to a net loss of $1.8 million reported for the second quarter of 1998, before the additional $2.4 million loss attributable to common shareholders for that quarter of 1998, reflecting the effects of premiums, accretion and conversion discounts on the redemption of Series B Preferred Stock and the issuance of Series C and D Preferred Stock. The total loss per share in the second quarter of 1998 was $0.34.

Revenues for the six months increased approximately 11% to $10.2 million from $9.2 million in the comparable period of 1998. The company reported a net loss of $6.8 million (46 cents per share) for the six month period, compared to a net loss of $3.7 million for the same period in 1998, before the additional $3.6 million loss attributable to common shareholders for that period of 1998. The total loss per share for the six months was $0.64.

During the quarter, the company sold 16 lasers, compared to 15 systems during last year's second quarter. Terms of sales continued to improve, with an increase in average selling price of the LaserScan LSX excimer laser system of approximately 20% net of commissions over the first quarter of 1999. In addition, the company began shipment of its UltraEdge Keratome Blades in the U.S., Canada and other international markets in late July. The blades are manufactured for the company by **Becton Dickinson** as part of a joint venture first announced in May.

Michael Farris, CEO, commented, "We are pleased to report an increase in revenues for the second quarter, along with the recent shipment of our UltraEdge Keratome Blades. Through our joint venture with Becton Dickinson, our manufacturing partner, we have increased our available manufacturing capacity to meet the refractive market's growing demand for these products." Separately, the company provided an update on the status of the FDA approval process for its excimer laser technology, stating that its PMA application was on track for third or fourth quarter approval. The FDA had waived review by its Ophthalmic Devices Advisory Panel, as the company's clinical data was found to meet or exceed the requirements of the FDA's Guidance Document. The review of the clinical data and a biomonitoring audit had been successfully completed and the FDA's Good Manufacturing Practices (GMP) inspection was currently underway. Final FDA approval is expected within 30-60

days following successful completion of the GMP audit, during which the approved final labeling will be defined.

During the accompanying teleconference, Farris noted that Becton Dickinson expected to be able to ramp up to produce 15,000 UltraEdge blades per month in August, and that LaserSight expected to begin shipping both its disposable and reusable microkeratomes either late in the third quarter or by the beginning of the fourth.

The following day, Al Kildani of **Pacific Growth Equities** issued an update report on the company, reiterating his "strong buy" rating, based on the good second quarter results and FDA marketing approval "on the horizon".

On August 11th, LaserSight announced that it had successfully completed the Quality System/Good Manufacturing Practices Inspection (QS/GMP) following the FDA's field inspection of its manufacturing facilities for the LaserScan LSX excimer laser system. Completion of the inspection clears the way for the last step in the pre-market approval (PMA) process, agreeing on final labeling. After receiving pre-market approval the Company plans to offer its excimer laser system for laser vision correction in the U.S. (Left unsaid was how the company planned to approach the licensing question with **VISX** and **Summit Technology**.) The company said that FDA, on August 9th, concluded that there were no significant deficiencies at the Company's manufacturing facility. The last step in the pre-market approval process is expected to take 30 - 60 days from that date. Following completion of this last step, initial approval for the company's excimer laser system would be for treatment of myopia, with approval for astigmatism to follow shortly thereafter.

8/10 **Laser Corp.** announced that it had received a Medical Device License from the Canadian Health Ministry to sell its Laser PhotoLysis System (the Dodick system) in Canada. The Laser PhotoLysis System uses a Nd:YAG laser with a specially designed patented handpiece for the removal of human cataractous lenses. It is estimated that there are over 2.3 million cataract extraction procedures performed in the United States each year. (And perhaps less than 10% of that number in Canada!) The laser PhotoLysis technique of cataract removal is an alternative to the current method of ultrasound phacoemulsification and provides a number of distinct advantages, including a small, disposable surgical handpiece. Because of its unique design the laser energy is delivered in a safe, efficient manner that produces no clinically significant heat (making it impossible to cause corneal burn). Also, the Laser PhotoLysis, which does not expose the eye to laser light, is able to remove lenses in as little time as one to two minutes with a greatly reduced incision size.

Joyce Wickham, president and CEO commented that this license is a significant milestone for the company. The company can now begin to deliver on Laser PhotoLysis sales in Canada and anticipated that these sales will make a positive contribution to its operations this quarter. The company also believes that the Laser

PhotoLysis will not only provide significant equipment sales growth opportunities for the company but growth opportunities in the multi-million dollar a year disposables market. Each PhotoLysis procedure is performed with the single use disposable handpiece and certain additional accessories which the company intends to sell.

Wickham also stated that the company will soon submit 510(k) premarket notification to the FDA for clearance to sell the Laser PhotoLysis System in the United States. Such submittals are typically cleared within 90 days. The company is currently marketing and selling the Laser PhotoLysis through its wholly owned subsidiary, **A.R.C. Laser Corp.**

8/10 The *Wall Street Corp Reporter* conducted an interview with John Klobnak, chairman and CEO of **Laser Vision Centers**. Klobnak noted that "this industry was the result of a business plan I wrote back in the late '80s when I first saw the excimer laser. At that time, I was in the advertising business running an ad agency for eye doctors when I stumbled upon this technology. It occurred to me that you could start a company to share access to this technology, which was very expensive and which we felt doctors would want to use, but wouldn't necessarily want to own. That is why I began the process of developing this company, which was actually the founding company of this industry. I have a strong background in ophthalmology and marketing, but above all, have put together a team of people here who we let do their jobs. Of course, one person is not capable of running a company, but one person who brings in the right people is probably the right guy to be the boss." The lengthy interview goes on to discuss the LVCI strategy and business model, including how the company moves its lasers around the country into smaller markets. (Anyone wishing to see my truncated version of the article should email or call me.)

8/10 This month's issue of *Refractive Market Perspectives* stated that second quarter procedure volumes, as reported by laser centers, refractive surgeons and laser manufacturers, were up 14.5% over the first quarter, but lower than the 25.3% growth achieved in the first quarter. Dave Harmon said that demand for refractive procedures remains strong, driven by a growing patient referral base, a strong economy, and an explosion of new laser centers. He reported that over 225,000 procedures were done during the second quarter, bringing the year's total to 420,000, as compared to 107,500 during last year's second quarter, and 190,500 procedures for the half year in 1998. Of the 225,000 procedures, approximately 211,000 were licensed procedures on **VISX** and **Summit** or **Autonomous** lasers, with the remaining 14,000 done on unlicensed U.S. lasers, or on U.S. patients traveling to Canada. According to Harmon's estimates, more than 1.25 million procedures have been performed in the U.S. and 735,000 U.S. patients have had one or both eyes treated. He also noted that an estimated 72 new lasers were sold in the U.S. during the quarter, with many going to corporate operators. He expects that procedure volume will continue to grow at about 15% for both the third and fourth quarters, bringing the full year estimate to just below the 1 million procedure level.

Another story in this month's issue details the more than $300 million raised by the corporate centers for expansion of their operations. This included $37 million raised by **LCA Vision**; $45 million by **Aries Vision**; $111.8 million by **TLC The Laser Center**; $46.5 million by **Laser Vision Centers**; and an undisclosed amount raised by **Clear Vision Laser Centers**. In addition, **Vision Twenty-One** got $42 million from its sale of **Eye Care Centers of America**, and **Omega Health Systems (now VisionAmerica)** sold off its managed care division, **OptiCare Health Centers**, and **NovaMed** was expected to raise approximately $60 million through its IPO, a portion of which was designated for laser vision center expansion.

8/11 **Bausch & Lomb** said that, based on updated information concerning the progress of its pre-market application through the FDA's approval process, the company is highly confident that the agency will not require review of the company's pre-market application for its Technolas 217 laser by the agency`s Ophthalmic Devices Panel. The company cited the following factors to support its conclusions:

- Prior panel review of similar devices
- The quality and quantity of Bausch & Lomb's clinical data
- The fact that the application review process had recently progressed to labeling review

"Our plans are on track to introduce the Technolas 217 into the U.S. market by the end of this year," said Hakan Edstrom, senior vice president and president-pharmaceuticals/
surgical for Bausch & Lomb. "A decision by the FDA to waive panel review of our application should give us additional flexibility."

8/11 **Omega Health Systems** reported revenues and earnings for the second quarter and six months period. Net revenues for the quarter totaled $26.5 million, an 8.2% increase compared with $24.5 million for the second quarter last year. Net earnings from continuing operations were $692,000 (8 cents per share) for the quarter compared with $636,000 (7 cents) per share, in the second quarter of 1998.

Net revenues for the six months totaled $52.2 million, up 9.5% from $47.7 million reported for the first six months of 1998. Net earnings from continuing operations were $1.3 million (14 cents per share) compared with $1.2 million (14 cents per share) for the same period in 1998.

"We are pleased with the considerable progress we have made in developing the infrastructure to support our strategic initiatives for growth in 1999," commented Thomas Lewis, president and CEO. "Our operating strategy has been focused on the continued development of our laser program on a national scale through our network of eye care centers. We are pleased with our success since we launched this initiative earlier this year, and we have now expanded this capability to a total of 18 markets, compared with three markets at the end of the first quarter of 1999. The impact of our

laser program on net revenues will be more significant in the second half of 1999 since we have now taken delivery of all of our initial order of 12 **VISX** Star S2 excimer laser systems. During the first half of 1999, surgeons practicing in our centers performed 4,421 laser procedures, compared with 1,736 procedures performed in the first half of 1998. During the quarter 2,350 procedures were performed, compared with 1,053 in the same period of 1998. In July 1999, we had a record month with 1,057 laser procedures performed. We expect this growth trend to continue as we expand in other markets, and we are confident that we will meet our projection to perform over 10,000 procedures by the end of 1999. In tandem with our laser vision correction initiative, we have also embarked on a complementary strategic initiative to utilize the Internet to support the company's national co-management network of ophthalmologists and optometrists by providing an E-commerce service for doctors and vendors and using the Internet to communicate directly with doctors, patients and vendors. Our goal is to build an Internet community that will support our proven co-management model and create added-value for doctors, patients and shareholders."

The company also announced that its shareholders approved the corporate name change to **VisionAmerica Incorporated** at the annual meeting of shareholders held at the company's Memphis headquarters. "We believe the VisionAmerica name captures the essence of our eye care business and operating philosophy and more clearly reflects the new strategic direction of the company," commented Thomas Lewis. "Since the beginning of this year, we have focused on repositioning the company and building the infrastructure to support our new initiatives - capitalizing on the growing laser vision correction market and on the evolving impact of the Internet on doctor, patient and vendor relationships. We are excited about the many opportunities we see to leverage the strength of our co-management model and create a nationwide brand identity with the VisionAmerica name. We remain confident that our new corporate identity and strategic focus will offer exceptional value to doctors, to patients and to shareholders."

8/11 **VISX** announced that it would place a full page ad in the August 13th sports section of *USA Today*, congratulating Wade Boggs on achieving his 3000th hit. Boggs had laser vision correction performed by Drs. Antonio Prado and Sal Musumeci of **Omega Eye Associates** of Tampa, FL, on a VISX laser during spring training. Boggs, who is happy with the results, allowed VISX to create the ad. The company also announced the formation of the VISX News Bureau, for noting interesting and noteworthy stories about laser vision correction, and called for doctors who had treated celebrities or athletes at their practices to contact the company or its PR agency.

8/11 **Miravant Medical Technologies** announced financial results for the second quarter with revenues and net interest income having increased to $6.3 million from $2.3 million for the same period in 1998. The net loss for the quarter was $4.9 million (27 cents per share), compared to a net loss of $9.1 million (64 cents per share) for the same period last year. The company has cash and marketable securities of $21.1

million and $15.0 million available under a credit agreement with Pharmacia & Upjohn.

"Since the initiative to streamline Miravant's costs was announced in September 1998, Miravant has continued to operate more efficiently as evidenced by this quarter's results," stated Gary Kledzik, chairman and CEO. "We have reduced our burn rate while remaining focused on our core programs, with an emphasis on late-stage clinical trials in ophthalmology."

In June, favorable results of Miravant's phase I/II clinical study for treating "wet" age-related macular degeneration (AMD) were presented at the Congress of the European Society of Ophthalmology, Stockholm, Sweden. The data suggest that patients given a single PhotoPoint treatment with Miravant's drug SnET2 can experience stabilized or improved vision with persistent beneficial effects seen in some patients as long as six months. Miravant and its pharmaceutical partner, Pharmacia & Upjohn, are conducting phase III clinical studies to confirm these early results. The trials are being conducted at over 50 centers throughout the United States under the FDA "fast track" designation, which may enable expedited marketing approval.

8/12 **KeraVision** announced that it had offered 4 million shares of its common stock at a price of $13.00 per share. The offering was underwritten by **Donaldson, Lufkin & Jenrette**; **Dain Rauscher Wessels**; **Prudential Vector Healthcare Group**; and **SG Cowen**. All of the shares came from KeraVision. The net proceeds from the offering of approximately $48.2 million will be used for sales and marketing efforts related to the U.S. launch of Intacs corneal ring segments, the continued development and clinical testing of products based on the Intacs technology, prepayment of short-term debt and for working capital and other general corporate purposes.

8/12 **Summit Technology** also announced the pricing of its secondary offering of 3.5 million shares of common stock priced at $16.00 per share. The offering was managed by **Hambrecht & Quist LLC**, **U.S. Bancorp Piper Jaffray** and **Dain Rauscher Wessels**.
"With this infusion of capital Summit can accelerate the launch of the LADARVision system and continue to aggressively pursue our key corporate objectives," stated CEO Robert Palmisano. "We will remain focused on gaining the broadest range of FDA approvals for our systems and becoming the preeminent provider of refractive vision correction products to ophthalmologists, clinics and hospitals," continued Palmisano. "This offering further solidifies our strong capital position as we move into the next millennium."

8/12 Al Kildani of **Pacific Growth Equities** issued an update report on **TLC The Laser Center**, upgrading his rating of the company to "strong buy". He stated that the company's fundamentals remained strong despite recent stock price weakness, and that there were no problems to account for that weakness, with all of the recent

rumors totally unfounded. "Furthermore, we believe TLC has the best business model in the industry to drive sustained growth in procedure volume. This model is focused on patient acquisition through co-management, corporate contracts, direct-to-consumer advertising, and word-of-mouth. We believe that most, if not all, of the LVC service providers are re-positioning their models to be more like TLC's. We view this as a validation of our belief that TLC is the strongest LVC provider with the most attractive growth prospects."

8/13 Lawrence Keusch of **Goldman Sachs** issued a research note on **VISX**. "We maintain our trading buy on VISX shares. Following a visit with senior management this week, we believe that fundamentals at VISX remain strong. With procedure volume remaining solid, the company's third quarter is tracking to meet or exceed our estimates. We would buy VISX shares at current levels as procedures accelerate into the fourth quarter. We continue to believe that the shares are headed towards $110 within the next three months. The company continues to expect that it will be in a position to generate license fees as competitors gain FDA marketing clearance. Based on industry conversations, we believe that VISX has probably had initial licensing conversations with several companies that are expecting FDA approvals shortly. This should position the company to further benefit from procedures not done on VISX lasers, further increasing profitability."

Keusch went on to say that management expected an acceleration of procedure growth during the fourth quarter and into the first quarter of 2000, as holiday bonuses and flexible benefits fund procedures. "In fact, we believe that there could be a pent-up demand building as many patients became convinced of the procedure this year but do not currently have the funds to have it performed. Once holiday bonuses are received and flexible benefit elections are made for 2000, we expect the procedure growth to accelerate. In fact, one physician that we spoke to is already booking procedures for January and February of 2000. Our current model assumes an 11% sequential increase in procedures in the fourth quarter as compared to our 8% estimate for the third quarter."

He also reiterated that VISX management continues to expect that it will be in a position to generate license fees as competitors gain FDA marketing clearance. In particular, **Bausch & Lomb** and **LaserSight** are both anticipating an FDA marketing clearance by the end of 1999 or early 2000. "With the VISX intellectual property position appearing to be extremely strong, we believe that both Bausch & Lomb and LaserSight will need to seek a license. Based on industry conversations, we believe that VISX has probably had initial licensing conversations with several companies that are expecting FDA approvals shortly. Management at VISX continues to indicate that it will structure any license arrangement to protect its franchise, maintain reasonable pricing, and expand the overall market. With this in mind, we believe that B&L will be in a good position to obtain a license later this year. What remains an unknown is the economics of a license arrangement. Regardless of the license arrangement, we believe that VISX will retain the vast majority of the $250 per

procedure fee."

8/13 **Saratoga Resources, Inc.** announced that it had completed its merger with **OptiCare Eye Health Centers, Inc.** and **PrimeVision Health, Inc.** Saratoga Resources has changed its name to **OptiCare Health Systems (OptiCare)**, and will start trading on the American Stock Exchange (OPT) on Monday, Aug. 16, 1999.

OptiCare is headquartered in Waterbury, Connecticut, and offers a broad range of services to eye care professionals, health plans and consumers. OptiCare has four operating divisions, including an optometry and retail optical operation, a managed care business, an eye care products buying group, and an integrated eye care services unit for consumers, including ambulatory and laser vision surgery services.

8/15 This week's issue of *Ocular Surgery News* contains a lengthy writeup of the FDA ODP meeting that reviewed the **Sunrise Technologies** PMA, with comments from both the FDA reviewer and from the panel members. Anyone wishing a copy can phone or email me.

8/16 *Individual Investor Online's* Craig Schneider wrote about **Bausch & Lomb**, in his column, "Bausch & Lomb Investors: Eyes Wide Shut". As he put it, "Investors who bought into the idea of Bausch & Lomb leaping into the laser vision correction (LVC) industry may want to have their eyes checked." He noted that over the past three months, shares of the lens and eye care company dropped about 24% -- triggered in part by uncertainty about whether the FDA would require B&L's Technolas 217 laser to be reviewed by the agency's Ophthalmic Devices Panel. Over the past two weeks, analysts at firms including **Goldman Sachs** and **Lehman Brothers** jumped to the company's defense, reiterating their "buy" recommendations and $90 price targets. But B&L expressed confidence that the FDA won't require a panel, indicating a speedier time to market for the Technolas 217.

Sheryl Zimmer of **Deutsche Banc** wrote in a recent report that if no FDA panel is required for Technolas 217 that it could be approved in about 60 to 90 days. On the other hand, she noted that B&L's laser could still end up on the September 23-24th panel or be bumped onto the next panel on November 18-19th. But Schneider doesn't believe its worth while hanging around to see what happens.

"Let's put this in perspective. Assuming the FDA does allow the laser to go without panel review, Marc Goodman of **Morgan Stanley Dean Witter** says most analysts haven't assumed more than $10 million in revenue from the laser sales next year. That's a tiny amount, or just 0.55%, of the $1.8 billion total revenue expected for next year, by **McDonald Investments'** Hans von der Luft. If you love the idea of investing in laser manufacturers, look elsewhere. Do not buy Bausch & Lomb stock if the LVC industry excites you. **Visx** and **Summit Technology's** lasers have about an 80/20 market-share split and a 75/25 ratio for new market penetration. But let's say there's room for Bausch & Lomb to join the LVC fray. Well, B&L at this early stage is only

having its laser approved for a narrower range of uses (low myopia versus the broader low-to-high myopia capability of its competitors). And even if it did have the full range, B&L's narrow beam technology is no different from Summit's narrow beam." In other words, Schneider does not feel that B&L is the place to "pin your hopes" on the LVC industry. "In fact, we wouldn't suggest pinning anything on the company at the moment."

8/16 According to *OptiStock*, recent analyst actions have included: **Pacific Growth Equities** upgrading **TLC The Laser Center** to "Strong Buy"; **Prudential Securities** starting **KeraVision** at "Strong Buy"; **Dain Rauscher Wessels** starting **Summit Technology** at "Strong Buy"; **S.G. Cowen** starting **VISX** coverage at "Strong Buy"; and **ING Barings** raising the 12-month price target of **QLT PhotoTherapeutics** to $84/share from $70.

8/16 After filing with the European Medicines Evaluation Agency (EMEA) for marketing clearance of Visudyne therapy for the treatment of age-related macular degeneration (AMD) in patients with predominantly classic subfoveal choroidal neovascularization, **CIBA Vision Corp.** and **QLT PhotoTherapeutics** have now submitted a New Drug Application (NDA) to the FDA seeking U.S. marketing clearance for Visudyne therapy. The companies have requested a priority review within a six month period as there is no current satisfactory treatment for the majority of patients with wet AMD.

"On the heels of filing in the European Union last week, this U.S. submission underscores our commitment to bringing this treatment as quickly as possible to patients throughout the world affected by this deleterious disease," said Dr. Julia Levy, president and CEO of QLT. "There is tremendous demand for more effective treatments for macular degeneration," said Luzi von Bidder, president of CIBA Vision's worldwide Ophthalmics Business Unit. "The approval of Visudyne therapy has the potential to improve the lives of many thousands of people."

The submission is based on 12-month data from two 24-month randomized, double-masked, placebo-controlled Phase III trials known as the TAP (Treatment of AMD with Photodynamic therapy) Investigation. The trials are taking place at 22 centers in North America and Europe and have enrolled a total of 609 patients. At the 12-month follow-up visit, among the 243 patients in the trial with predominantly classic lesions, those treated with Visudyne therapy exhibited a large treatment benefit. Specifically, based on an intent-to-treat analysis, vision was stable (defined as a loss of less than three lines of vision on a standard eye chart) or improved in 67% of these patients treated with Visudyne therapy compared to 39% of patients administered placebo. Accordingly, patients treated with Visudyne therapy were 72% more likely to retain their vision compared to the placebo group. These results were found to be statistically significant in this population for each of the two studies, as well as for the combined data. Statistically significant results on the combined data favoring Visudyne therapy were also obtained for all secondary endpoints, including contrast sensitivity and lesion growth. Visudyne therapy was more likely to confine the growth of the lesion as well as maintain contrast sensitivity relative to patients

receiving the placebo.

Two days later, on August 18th, the two companies announced the filing for approval of Visudyne therapy with the Swiss regulatory agency, Interkantonale Kontrollstelle fur Heilmittel (IKS). (The same indication as was filed in Europe and the U.S. was used in this submission.) As the IKS has granted a Fast Track review, an approval is expected within six months. Additional regulatory submissions seeking marketing approval are expected to be made shortly in Canada and Norway.

8/16 **Sterling Vision** announced financial results for the six months ended June 30, 1999. Net Income was $760,000 (4 cents per share) as compared to a Net Loss of $5,064,000 (35 cents per share) for the comparable period in 1998. Revenues for the quarter were $8.9 million and $18.2 million for the six month period, on systemwide sales of $36.4 million for the quarter and $73.5 million for the six months. Dr. Robert Cohen, chairman of the Board, stated "The increase in net income for the six months ended June 30, 1999, was principally due to the continued positive effects of our new management team's 1998 initiatives and the continued focusing of our resources on our **Insight Laser Center** division, as well as on our Internet initiatives, which we expect to launch in the third quarter of 1999."

8/16 **Vision Twenty-One** announced that based upon its significant growth in refractive surgery procedures, the company would be accelerating its development of refractive surgery centers for the remainder of 1999 and in 2000. The company also disclosed that it had agreed with **Eye Care Centers of America (ECCA)** to close the sale of Vision Twenty-One's retail optical chains on August 31, 1999. Refractive surgical procedures for the second quarter increased 173% to 4,669 as compared to 1,709 for the second quarter of 1998. The company currently operates nine refractive surgery centers, four of which have been added since June 9 of this year. The company also announced that it planned to develop an additional 21 refractive surgery centers by fiscal year end 2000 in existing markets and/or through its previously announced strategic alliance with ECCA.

The company also released financial results for the second quarter, with revenues of $41.5 million and a net loss of $4.3 million (29 cents per share). For the six months period the company had revenues of $92.2 million and a net loss of $4.3 million (20 cents per share). President and CEO, Ted Gillette stressed the tremendous strides of the company in furtherance of its business plan for the year to date through deleveraging its balance sheet and substantial growth in refractive surgery procedures. "As a result of our progress and success to date, we are now committing to an accelerated roll out of our development schedule through year 2000. Also, as part of the new company focus, we are committed to completing planned steps to reduce costs which were identified through our restructure plan. While the operating results of all of our actions will not be felt immediately we are confident that our actions at this time will be successful in achieving long term shareholder value."

8/16 According to *Federal Filings*, **Sunrise Technologies** went ahead with its defamation lawsuits against both **Sturza Medical Research** and **Avalon Research Group**. Stephen Hibbard, an attorney for Avalon said that the defamation suit was "totally without merit". The suit concerns a privately distributed analyst report about Sunrise that said that the firm's laser had no better than a 50/50 chance of receiving recommendation of approval from the FDA's ODP panel. the report put a "sell/sell short" rating on the company. Hibbard stated that Sunrise apparently saw a copy of the report, became distressed and sued Avalon, seeking a temporary restraining order, which was rejected by the Court. The attorney is confident that this latter suit will also be dismissed.

Evan Sturza of Sturza Medical Research echoed the thoughts of the Avalon attorney. "This is an entirely frivolous suit and in all likelihood it will be thrown out as soon as it gets before a judge."

8/16 In a surprise announcement, **Staar Surgical** said that it had formed a wholly-owned subsidiary, **Laser and Implant Technology Centers, LLC (LITC)** which would further expand the company's presence in the refractive market through a chain of laser vision correction centers. The centers will be known as **STAAR Laser Centers** and will be located in small and mid-sized U.S. markets where refractive procedures are currently limited. The centers will offer laser vision correction and, after the STAAR Implantable Contact Lens (ICL) receives FDA approval, ICL vision correction. STAAR expects to have up to 20 of the fully-equipped centers in operation by the end of 2000.

John Wolf, chairman and president of STAAR said, "While we believe our ICL will become a major vision correction procedure once it is approved by the FDA, STAAR Laser Centers allow the company and its shareholders to more immediately profit from today's flourishing U.S. refractive market. The laser centers will also provide us with an excellent platform for introducing the ICL to ophthalmic surgeons and their patients upon approval. STAAR Laser Centers will provide ophthalmic surgeons with the most advanced refractive technology available today. Until now, laser technology has been prohibitively expensive in small markets," said Wolf. "Placing STAAR Laser Centers in markets that currently have limited access should generate tremendous demand, which will increase the likelihood of our success. In addition, research has shown that centers in smaller markets typically have a near monopoly on their respective locales, enabling the centers to enhance pricing and, thus, profitability. We are extremely excited about this opportunity and expect these new laser centers to be accretive to earnings in a very short period of time."

STAAR Laser Centers will feature the **VISX** STAR S2 System. (If the company can get them!) "In choosing VISX, we have found a laser supplier whose quality products complement our ICL", said Wolf. "We believe there is room for substantial growth in refractive vision correction, as only 3,000 to 3,500 of the 15,000 U.S. ophthalmologists are performing this type of surgery. By offering doctors the broadest range of refractive technology available at a price that they can afford, as well as

providing the value-added training and services, we believe we will attract the finest ophthalmologists. More importantly, STAAR Laser Centers will give participating doctors the opportunity to invest in LITC, something none of our competitors are presently doing. An equity interest in LITC will further allow doctors to economically benefit from their growing and successful refractive practices."

Two analysts following Staar quickly filed reports on the heels of the announcement. William Gibson of **Cruttenden Roth** gave the announcement a positive spin, saying, "We view its entry into the laser center market as a way to help drive earnings growth in the meantime, and establish an infrastructure to roll out the ICL if and when it is approved." Cathy Park of **JG Kinnard**, in a more extensive analysis, rated the company's move with a "strong buy", based on a careful analysis of the potential of all of the company's products becoming approved and successful.

Ms. Park does question the ability of the company to pull off this event in the time frame given, especially with the shortage/backorder of lasers from VISX. The one question not asked by either analyst is will this move alienate Staar's customers, similar to what **Summit Technology** did when it entered into the laser vision correction market? I have asked this of both analysts, and will be interested in their response.

8/17 Craig Schneider of *Individual InvestorOnline*, not wanting to take sides in the laser vision correction industry, this time writes about **VISX**, and the impending International Trade Commission court battle with **Nidek**. This trial is over whether that company should be allowed to import its lasers and support systems into the U.S., because of possible infringement of VISX's patents. His piece, "Update: Visx Suit to Resurface Patent Concerns" discusses the upcoming court fight between the two beligerants. "Investors of Visx...could get another buying opportunity when a patent infringement trial against rival Nidek begins on Wednesday, August 18th. Market jitters on patent issues have put holes in Visx's body armor before. In late May, the stock fell 12% to $50 ahead of a decision in a Government case that accused Visx of patent fraud. However, on June 4, when a U.S. Federal Trade Commission (FTC) judge dismissed the case, shares soared over 30%, hitting a 52-week high of $73.38 during the day. Since then, it has been clear sailing, with Visx hitting a new 52-week high of $103.88 just two weeks ago. But with two patents thrusts into the spotlight in its suit against Japan-based Nidek, analysts say the stock could once again come under fire. The main cause of debate stems from Nidek selling its own laser in the U.S. market without paying the required royalty to Visx, a $250 per procedure fee. Visx is claiming infringement on patents 762 and 418."

Ted Huber of **Advest Inc.** expects the decision to have a huge impact on VISX's future. "A big watershed will come from the VISX case," he says. "It's game set and match if they win this one." Huber is convinced that a decision in VISX's favor will mean that the year 2000 won't be fraught with the ups and downs that ruled this year. On the other hand, "it could be a real rollercoaster if the International Trade

Commission (ITC) doesn't rule in its favor."

Some analysts also feel that VISX's highly valued royalty fee could be put in jeopardy with an unfavorable ruling. Hans von der Luft of **McDonald Investments** says the legal precedent could give other entrants like **Bausch & Lomb** and **LaserSight** a bargaining chip when negotiating fees with the company. "Just don't expect VISX to go quietly in the event of a negative outcome." Lola Wood, a company spokesperson, insists that there is "no downside risk for VISX." The company would merely turn around and file complaints for other patents against Nidek. And the ITC case is by no means its only offensive. VISX has a pending lawsuit against Nidek in a federal district court in Northern California to collect further damages. What's more, VISX is also suing some of the doctors who use Nidek's laser. Many doctors have abstained from purchasing Nidek's equipment because they fear litigation, says von der Luft, and a Nidek offer to pay for potential legal fees hasn't really helped.

Though the cards appear stacked against Nidek, analysts are quick to point out that there is no way of really guessing the outcome of the case. Whereas VISX was unsuccessful proving a patent case against Nidek in the U.K., blaming the country's disclosure laws for the adverse ruling, the rules are entirely different in the States. The patents are also different here. McDonald's von der Luft believes the patents are in good standing because they are not in review by the FTC or U.S. Patent and Trademark Office. That, he says, will bode well for the company.

"Bottom Line from Schneider: Taking into account the risks in this case, the prior rulings of the FTC and the wide range of trading ahead of that announcement, we would look at any jittery market reaction to VISX relating to this decision as a potential buying opportunity. Watch this one very closely."

8/17 The *Associated Press* carried a story titled, "Americans visit Canada for laser eye treatment". According to the story, a favorable exchange rate and lower equipment costs mean that laser eye surgery can cost thousands of dollars less across the border. "The American people are currently being ripped off," said Michael Henderson, president of **Lasik Vision Corporation**, to the *Albany Times Union*, "I would classify it as gouging." Henderson's company has been advertising in newspapers and seminars to customers in Albany and in other U.S. cities. In the Northeast, the procedure can run about $5000 (for two eyes), while Montreal doctors offer the same procedure for about $1500. In the more remote Halifax, the price is even less, about $999. One of the factors is that Canadian doctors don't have to pay the $250-$260 per procedure fee required in the U.S. But critics say that price alone shouldn't be the deciding factor in choosing an eye surgeon. Although the laser used most frequently in Canada hasn't yet been approved by the FDA, patients should also look for experienced surgeons, and Americans don't get the same malpractice coverage in Canada as they would in the United States, according to Dr. Michael Belin, medical director of **LCA Vision** in Albany, NY. Belin said that he's not threatened by the competition. "I think there will always be enough people who want quality care, and a sub-group who wants the

cheapest care," he said.

8/17 **Vision Twenty-One** said it had been selected to offer laser vision correction surgery as a vision correction option to **PacifiCare Dental & Vision Administrators'** plan members in Arizona, California, Colorado, Nevada, Oregon and Washington. PacifiCare Dental & Vision Administrators, a division of **PacifiCare Health Plan Administrators**, provides vision benefits to health plan members in those states. "We are constantly looking for ways to add benefits and value for our customers. Our partnership with Vision Twenty-One will maintain our competitive edge in this rapidly changing industry," said Bruce Cacciapaglia, director of marketing for PacifiCare Dental & Vision Administrators.

Vision Twenty-One markets laser vision programs to managed care and employer groups on either an insured or discounted arrangement through its wholly owned managed care subsidiary **Block Vision**. A national refractive provider panel is being developed by Block Vision in support of Vision Twenty-One's plans to expand laser vision correction offerings to new and existing managed care clients currently numbering more than 100 and covering five million exclusively contracted lives. Surgeons who become members of the national refractive provider panel are credentialed using criteria specific to the laser vision correction procedure.

8/17 Joining the lengthening list of celebrities and athletes who have undergone laser vision correction, Courteney Cox, star of the NBC Television series "Friends" and the box office hit "Scream," had laser surgery performed on July 15th, 1999 to correct her extreme nearsightedness by Dr. Kerry Assil of **Aris Vision** in Santa Monica, California. Courteney was below the legal limit for blindness, her eyesight having deteriorated to about 20/400 in each eye. She could no longer see adequately with the aid of glasses and contact lenses were a frustration for her. Cox's visual impairment had become a hindrance to her career and active lifestyle. "I won't have to panic when I have to do a visual presentation because I will be able to read the teleprompter instead of memorizing everything!" exclaimed Cox. "Having the surgery was the easiest and most effortless thing I have ever done that provided the greatest reward." The result of Courteney's surgery has corrected her eyesight to better than 20/20.

8/18 **LaserVision Centers** announced that revenue for its first quarter, ended July 31, 1999, was $21 million compared to $9.1 million for the same period a year ago. Net income for the quarter was $4.1 million (17 cents per share) compared to a net income of $333,000 (3 cents per share) for the same quarter last year. The company noted that excluding a tax benefit of $747,000 earnings per share (EPS) were $0.14.

LaserVision completed a 2-for-1 stock split on August 9, 1999.

U.S. refractive surgical case volume increased 119% to 22,350 for the quarter, from 10,206 for the same period a year ago. More than 580 surgeons accessed LaserVision's services during the quarter compared to 382 for the previous year. As of

July 31, 1999, LaserVision operated 48 lasers in the U.S. The company said that in the first two weeks of August it had added its 49th and 50th lasers to its U.S. laser fleet. "Demand for both our refractive laser and cataract business remain very robust," said LaserVision CEO, John Klobnak, "our pipeline remains full and we expect this to continue as more surgeons enter the business. We expect to continue to add more excimer lasers during the current quarter to handle the growing demand."

8/18 Just to show the effect that an analyst's report can have on an industry, Dave Therkelsen of **Dain Rauscher** issued a report on **LCA-Vision** describing that company's "test driving" a new operating model, and the bottom fell out of the stock prices for all of the service providers and even the laser system suppliers. As Dave put it, in an aggressive response to competitor **TLC The Laser Center's** buyout of one of their high-volume surgeons, LCA "tested" a new model in two centers in the Baltimore/Annapolis, Maryland markets. The two LCA centers were renamed **LasikPlus** and began aggressively advertising bilateral LASIK at $2995, or roughly $1500 per eye. That compared to LCA's previous price of $2250 per eye, and TLC's price of $2700 per eye in that area. Under the test model, LasikPlus centers no longer are "open access" but rather have hired one surgeon as an employee to perform all of the procedures at the center. He/she is paid a fixed monthly salary of approximately $10,000 plus a substantially reduced $150-$175 fee per procedure. This compares to the previous procedure fee paid to surgeons of approximately $900. According to the report, LCA reported that initial results of the test were encouraging, with procedure volumes during the first four weeks up 10%-30% over the monthly levels earlier in the year (before the high-volume surgeon was bought out by TLC), suggesting that lower prices did indeed spur demand. While only a test, investors anxiously await the implications for LCA and many of the other companies participating in laser vision correction.

Dave went on to answer some of the obvious questions: Is this a price war? (no, not really); Are other markets next? (maybe, it the test is successful); What are the implications for the income statement? (nothing negative over the short term, especially as the surgeon seems to be absorbing the price cut, not the center); and others. His conclusion was, given that it was just a "test model", and not a full-scale rollout, he was not changing his estimates for the company at this time. He felt that LCA was committed to maintaining its position in laser vision correction, and that the primary trade-off for investors was reduced visibility on earnings per share as the business model evolved.

However, the newswires screamed as stock prices began dropping in response to the "supposed" price war. *CBS MarketWatch* "Screamers: LCA-Vision shares drop on price-war expectation." Also on *CBS MarketWatch*, "LCA-Vision losses its way. Price war seen hampering stock." On *Bloomberg*, "LCA-Vision, **Laser Vision** Shares Fall on Price Fears." And on the *DowJones Newswire*, "Investors Dump LCA-Vision in Wake of Analyst's Report on Price Cuts", probably the only source that really knew what was going on.

LCA issued it own statement in which chairman and CEO Steve Joffe said, "We believe there is no reason for the recent volatility in our stock price. Our fundamentals remain strong. We are confident that the market for laser vision correction will continue to expand and LCA-Vision's position in this market is solid."

The following day, *Individual Investor Online* summed it up best, "Laser vision companies suffered from blurry eyesight today as the market continued to fret about price war speculation among the centers. After traders rubbed their eyes and finally got a clear look at their monitors, they saw that TLC The Laser Center lost $2.63 to $25.88 and **Laser Vision Centers** lost $0.81 to $23. But LCA-Vision gained $0.91 to $7.41. LCA-Vision, in an aggressive response to TLC buying out one of its high volume surgeons, has started to test the pricing waters in Baltimore by putting its own doctors in centers instead of just charging a fee to independents who want to use its laser facility. Stevens Monte of **Security Capital Trading** says LCA is "a screaming buy." He adds, "It would be ludicrous for them or a doctor at this early stage to engage in a price war."

8/18 **NovaMed Eyecare** announced the offering of 4 million shares of its common stock at a price of $8.00 per share. Of the 4 million shares being offered, 3 million were sold by NovaMed and 1 million by certain of its stockholders. The IPO was managed by **Donaldson, Lufkin & Jenrette**, **Hambrecht & Quist LLC**, **William Blair & Company, L.L.C.** and **DLJdirect Inc.** The company is an eye care services company focused on laser vision correction and owns and operates 10 eye surgery and laser centers, including two laser vision correction centers in five U.S. regional markets, where it is affiliated with 83 eyecare professionals.

According to *CBS MarketWatch*, the offering opened at $8 and rose about 15% to $9.20, but the company received less than expected as the offering was trimmed down from a $9-$10 offering, which was down from an earlier expected $11-$13, and downsized from the 7.1 million shares originally anticipated to be sold.

8/18 **Wavelight Laser Technologie AG** announced that it would float 45% of its capital stock on Frankfurt's New Market in the autumn of 1999. The shares are partly the result of a capital increase. Company founders Max Reindl and his wife intend to retain their 18.6% stake in Wavelight. The rest of the new shares are currently held by several venture capital specialists, who will sell part of their holdings in Wavelight as part of the flotation. Wavelight also announced that sales had doubled in the 1998/99 business year, which ended on 31 July 1999. The Erlangen-based company is hoping to break even in the 1999/2000 business year.

8/19 **Hambrecht & Quist** analysts Robert Faulkner and Chris Shibutani returned **Summit Technology** to their "buy" focus list, after the "pricing scare" (noted above) attempted to "throw the baby out with the bath water". They said that the pricing panic was a clear buying opportunity, as lower procedure pricing was neutral or positive for both Summit and **VISX**, and as quarterly procedure growth was on track for the year. Their bottom line analysis: "We worry about pricing, but the sky does not appear to be

falling now and the market seems to tell us that it is. One focus for fear has been a cut-rate provider from Canada making noise about entering the U.S. To date, neither laser company is eager to sell to it (**Lasik Vision**), the financing for expansion is not readily apparent, and the lawsuit associated with using **Nidek** lasers are likely to be highly burdensome."

8/20 **VISX** said that it expects the millionth procedure to be performed on a VISX laser will take place between mid-September and mid-October. The company expects to broadly promote the event.

8/23 **Dain Rauscher** analyst Dave Therkelsen initiated coverage of **Summit Technology** with a "strong buy-aggressive" recommendation, and a target price of $23. His reasons for the recommendation included: 1) the booming laser vision correction market (and Summit's roughly 18% share of procedure royalties); 2) the company being undervalued relative to its peers; 3) visible signs of renewed momentum, as procedure volumes using Summit's lasers are growing faster than the industry's growth rate; 4) the acquisition of **Autonomous Technologies** providing the company with a next-generation technology platform; and, 5) the value of the company's intellectual property and the cross license to **VISX's** broad patent portfolio.

8/23 **CIBA Vision Corporation**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics Inc.** announced that the FDA had assigned priority review status to the new drug application (NDA) for Visudyne therapy (verteporfin for injection), indicating that the agency will act on the application within six months. CIBA Vision and QLT filed for approval of Visudyne therapy for the treatment of wet age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50 in the western world, on August 16, 1999. "This priority designation underscores the need for an effective treatment for the many thousands of patients that lose their vision every year to this devastating disease," said Dr. Julia Levy, president and CEO of QLT. "We are pleased with this development and look forward to working closely with the FDA over the next six months as they review our submission," said Luzi von Bidder, president of CIBA Vision's worldwide Ophthalmics Business Unit.

8/24 **Gimbel Vision International Inc.** said that it currently had 1 million Series A common share purchase warrants outstanding, exercisable at a price of $1.50, and 1.5 million one half share purchase warrants outstanding, with each whole warrant exercisable at a price of $1.50. These warrants are due to expire at 4:30 p.m. (MST) on August 26, 1999. To date 380,950 Series A common share purchase warrants and 441,854 one half share purchase warrants had been exercised.

8/24 **Lasik Vision** announced that it had signed an exclusive contract with **Studentcare.net/works**, the largest provider of student health care programs in Canada, to offer a special Student Preferred Pricing Program to the organization's more than 135,000 members. The Student Program includes LASIK or PRK surgery, initial examination fees, all in-house pre- and post-operative care and Lasik Vision's

Lifetime Enhancement Commitment. The program will be offered at all eleven Lasik Vision Canadian clinic locations.

Universities eligible for the special Student Preferred Pricing Program during the 1999/2000 school year are: McGill University; Concordia University; University of Montreal; Osgoode Hall Law School; Cite Collegial; Laurentian University; University of Quebec at Trois Rivieres; University of Sherbrooke (Grad program); University of Quebec at Hull; Polytechnic (Grad program); and Mount Allison University.

8/24 **Bausch & Lomb Surgical** said it had filed a federal lawsuit charging that French surgical manufacturer, **Moria**, and its American distributor, **Microtech**, were violating one of the company's patents covering its Hansatome Microkeratome. The suit was filed August 23 in U.S. District Court for Eastern Pennsylvania in Philadelphia. The lawsuit alleges that Moria and Microtech are infringing on the Hansatome patent by marketing and selling the Carriazo-Barraquer microkeratome in the United States. Bausch & Lomb had already filed a similar lawsuit in France against Moria on another patent. The company won the first round of this lawsuit in January. At that time, the French Court ordered Moria to post a bond of 3.5 million French francs if the company planned to continue to manufacture the microkeratome. The trial on this matter is expected to extend into 2000.

The patent in question, U.S. 5,624,456, was issued in April 1997. **Bausch & Lomb Surgical** holds exclusive rights to the patent.

In its complaint, Bausch & Lomb requests that Moria and Microtech be found to have willfully infringed on the Hansatome patent. The lawsuit seeks unspecified damages, as well as a permanent injunction against the companies barring any further sale of their infringing products within the United States. "As we've stated previously with the French action, Bausch & Lomb will aggressively defend its extensive portfolio of intellectual property," said Hakan Edstrom, senior vice president and president-Surgical/
Pharmaceuticals. "We have invested considerable resources to bring the latest technology to ophthalmic surgeons. As the innovator in this field, we have both the right and the responsibility to protect our interests."

8/25 **The Foundation Fighting Blindness, Inc.** has awarded researchers from the **Cleveland Clinic's Cole Eye Institute and Lerner Research Institute** $1.5 million over five years for the study of retinal degeneration. "The award will be used to fund a series of five projects related to the causes and prevention of inherited retinal disease, including age-related macular degeneration," said Joe Hollyfield, director of research in the Cleveland Clinic's division of ophthalmology. The grant will support research being conducted by Dr. Hollyfield and colleagues Drs. John Crabb, Bela Anande-Apte, and Elias Traboulsi.

8/25 Analysts Arch Smith, Francesca Miglori, and Stephen Simpson of **US Bancorp Piper Jaffray** issued an update note on **Summit Technology**. They noted that sale of laser units into vision centers were slightly ahead of their expectations, "adding spice to the BEAM story". They also noted that integration of **Autonomous Technologies** into Summit was proceeding on plan, and they reiterated their "buy" recommendation, changing its suitability to "aggressive" from "speculative".

In their note, they stated that they believed that Summit had signed contracts for a total of 12 Apex Plus units with two vision center companies, **Insight Laser**, a subsidiary of **Sterling Vision**; and with **NovaMed**. They said that the upcoming approval for hyperopia prompted the centers' decision to purchase the Summit lasers, and that at least 4 of the 12 purchases had been shipped, with the remainder to be shipped within the next six months. They also noted that Summit's procedure fees remained in the $230 range (including the erodible mask), slightly below **VISX's** fees of about $250. Laser prices also remained stable, with the Apex Plus selling for between $200,000 and $250,000, again, slightly below VISX pricing of between $250,000 to $300,000. (I was not aware that VISX prices had fallen to that level.)

Concerning Autonomous, the analysts noted that manufacturing capacity of the LadarVision was up to six units per month, on target to reach 12 units per month by year's end. At the end of July, the U.S. installed base of LadarVision systems was 10 units.

On August 26th, Sterling Vision and Summit issued a joint statement acknowledging the agreement for Sterling's Insight Laser Centers to purchase up to six Summit Apex Plus lasers. Dr. Robert Cohen, chairman of Insight's Board of Directors, stated "Insight's purchase of these new excimer lasers strengthens our commitment to become one of the Northeast's leading providers of laser vision correction services. In addition to already having installed one such laser in its premier Trump Tower facility, the company is readying two new Centers in New York City, including a Soho location schedule to open in September. The Northeast expansion plan also anticipates at least four more Centers in the near future."

At press time, there was no word from NovaMed.

8/25 **U.S. Vision, Inc.** announced its second quarter financial results, with pro forma net income per share at 11 cents versus pro forma net income per share of 17 cents in the second quarter of last year. Net sales for the quarter increased 12.1% to $35.6 million compared to $31.8 million for the second quarter last year. Comparable store sales were up 4.3% for the second quarter. As part of the company's commitment to strengthening its business, it said that it was currently in negotiations to form a strategic alliance with a leading provider of laser vision corrective services to offer laser vision correction to its customers by year-end.

U.S. Vision is a leading national retailer of optical products and services primarily

through licensed retail optical departments located in regional and national department stores, such as **May Company**, **Federated Department Stores**, **J.C. Penney** and **Proffitts**. The company currently operates 650 locations in 48 states in the United States and in Canada.

8/25 In an attempt to determine how the **VISX** vs. **Nidek** battle was going before the International Trade Commission, I asked several industry sources what they had heard about the progress of the trial, now underway. No one to whom I spoke seems to have a good handle on the proceedings, although one analyst said that he had heard that VISX's testimony had gone very well. Most believed that no word would be forthcoming until Judge Debra Morris released her decision on December 1st.

8/27 **Coherent, Inc.** announced that the FDA had assigned priority status to its new joint device/drug application for Visudyne therapy for the wet form of ARMD, indicating that the agency would act on the application within six months. (See the related August 23rd brief above.) The application was filed jointly by Coherent and **QLT PhotoTherapeutics**, and covers Coherent's new OPAL photoactivator laser, as well as the vertoporforin drug which is activated by the special purpose 689 nm diode laser. Visudyne therapy will be marketed globally by **CIBA Vision Corporation**, the eye care unit of **Novartis**.

Jim Taylor, **Coherent Medical Group** president, said, "We are excited that Coherent's research with the original investigators exploring the field of ocular PDT has culminated in a therapy that will save the sight of many AMD patients."

8/27 In a week-long series on eye care, *CNN Interactive* ran a series of pieces on ways of correcting vision, including the use of eyeglasses and contacts, as well as all the forms of refractive surgery. In the last piece, posted on August 27th, author Kathleen Doheny took a look at the future, in her piece entitled, "On the Horizon: New Solutions for Vision Defects", with descriptions of what was happening with phakic IOLs, keratoplasty, presbyopia remedies, improved techniques for cataract removal, and a last section simply called "caveats". It begins with an interesting note. "The prediction is echoed among eye surgeons: Contact lenses and eyeglasses will soon be obsolete, thanks to better surgical solutions for nearsightedness, farsightedness and other vision problems. According to Dr. Doyle Stulting, professor of ophthalmology and director of the cornea service at Emory University School of Medicine, Atlanta, and a member of the refractive special interest group for the American Society of Cataract and Refractive Surgery, "Within a decade, we'll have a (surgical) solution for everyone. Surgery will become the preferred method for (correcting) refractive errors." Some may disagree, including those who lack the financial resources for the often-pricey surgeries, as well as those too squeamish to undergo elective eye surgery. But one thing's certain: Plenty of new options to correct vision problems are in the pipeline, both for refractive errors and conditions such as cataracts, when the natural transparency of the eye's lens becomes cloudy."

The phakic intraocular lens discussion discusses the **Staar** ICL, but doesn't cover the other IOLs also under development for phakic eyes. Although Dr. Marguerite McDonald is quoted as saying, "I think phakic IOLs (intraocular lenses) will be big for high degrees of myopia." Under keratoplasty, both the radiofrequency from **Refractec** and the holmium laser approaches for hyperopia from **Sunrise Technologies** are covered. For presbyopia, the **C&C Vision** accommodating/refractive IOL, and the "surgical reversal of presbyopia" approach of the **Presby Corporation**, are noted. The former appears to work by the lens moving backwards and forwards along the axis of the eye when the patient decides to change focus, while the latter employs four tiny plastic segments embedded into the sclera above the ciliary muscles, to expand the sclera, supposedly remedying the "crowding" of the muscles, allowing the natural fibrils to tighten again and the ciliary muscles to work better, according to the theory.

As for cataract removal in the future, the Catarex device is mentioned, a high-speed propeller-like device, rotating at 70,000 revolutions per minute to break up and remove the cataract, under development by **Atlantic Pharmaceuticals** and licensed to **Bausch & Lomb**. And only the Photon laser from **Paradigm Medical Industries** is given play, whole laser from **Premier**, **ARC**, and others are left out. The "caveat" section is the authors way out. As she put it, "As exciting as some of the new techniques might sound, some may not make it to market, derailed by unexpected complications such as a lack of research and development funds, or a lack of government approval. Even the techniques that do become available won't be right for everyone. There is no one-size-fits-all solution because vision problems vary from person to person."

OPHTHALMIC LASER UPDATE -- September 1999

8/16 In a story I missed, carried in the *Business Courier* of Cincinnatti, staff reporter Richard Curtis wrote about **LCA-Vision**, in the story, "LCA, finally, has success in its sights". As reported, the company which had been on the brink two years ago, has made a remarkable turnaround. As put by chairman and CEO Steve Joffe, "When we thought the company would not survive financially, that was the lowest point." As Curtis points out, not only has Joffe stemmed LCA's losses in the time since, but the company's resurgence has put it on a path that industry analysts believe will finally lead to sustained growth.

One of the things that helped turn the company around was Joffe immersing himself into becoming a better businessman. "Physicians are usually very smart, but they often make business decisions without enough information and analysis, more on emotion," Joffe said. "I was like that, too." But over the period between the low and now, he acquired Summit Technology's chain of laser vision correction centers, and then pared his growing chain of centers from 38 to 20, weeding out the poorest performing locations. As word of mouth began feeding refractive surgery patients into

centers, led by the LASIK procedure, volumes began to increase exponentially during the latter half of 1998. In a recent report on LCA, analyst Ken Bohringer of **Prudential Securities** wrote, "One million domestic laser eye surgeries this year (1999) would equal about half the procedures performed over the past decade. Even so, this would only represent less than half of one percent of the estimated 160 million Americans suffering some form of refractive disorder."

The story goes on to tell about the two physicians that left the fold, one in Baltimore to join the competition (**TLC The Laser Center**), and the other to open his own center in Columbus, which sent shockwaves through LCA's management team. To answer the TLC threat in Baltimore, the company bought out its hospital partner and re-opened its two centers there under a new name (LasikPlus) and marketing plan -- offering LASIK at a 33% reduction to what it had previously offered. So far, the centers are holding their own against the competition. To combat other physicians leaving the fold, the company has initiated marketing the LCA-Vision brand, and with the help of an ad agency, building a "patient capture model". With all of the changes and the recent arrangement with **Cole National** to create a network of laser vision centers, Joffe believes he has positioned LCA-Vision for growth.

8/30 Ted Huber of **Advest** issued a report on **VISX**, with a "market perform" recommendation, and no target price. Basically, he feels that VISX is well positioned, with only the ITC patent ruling as a potential negative. As he stated, "Simply put, VISX needs the ITC to put **Nidek** out of business in the U.S...with importance beyond Nidek, as other competitors are nearing FDA approval and U.S. market launch...A victory by VISX would get Nidek off the U.S. market by the end of 1Q00, and potentially others, offering access to excimer lasers with no fees or discounted fees." In other words, he sees (as do many others), the ITC ruling as a direct challenge to the continuing $250 royalty procedure fee, both by Nidek, and the others who may have to license VISX's patent portfolio.

8/30 **Prime Medical Services** announced that it had acquired a 60% interest in two laser (refractive) surgery centers, operated by **Barnet-Dulaney Eye Center (BDEC)**, effective September 1st. BDEC will retain ownership of the remaining 40% of the centers, located in Phoenix and Tucson, Ariz., and will continue to manage both centers. Prime paid approximately $8.8 million in cash plus an earnout to be paid at the end of the first year for this acquisition.

Ken Shifrin, chairman of Prime, stated, "Prime entered the lithotripsy field in 1992 and eventually became the largest operator of lithotripters in the United States. We believe that our entry into the rapidly growing refractive surgery field is a natural, as there are many similarities between the lithotripsy and laser surgery industries, including the importance of such factors as: quality of care, physician relationships, measurement of outcomes data, and fleet management of high cost medical equipment. Particularly exciting, the refractive surgery field has seen spectacular procedural growth, due to the enthusiastic reaction from treated patients. While this is

our first acquisition in laser surgery, we are currently evaluating other potential acquisitions. I believe that we can grow the laser surgery business even faster than we have grown lithotripsy. Our strong financial position, which includes excellent cash flows, approximately $25 million in cash and an untapped $100 million line of credit, places Prime in a unique position to build a sound business in the rapidly growing field of vision correction."

Joseph Jenkins, MD, president of Prime added, "Significantly, we have also entered into a joint venture with the principals of BDEC, which is one of the premier eye centers in the United States. This joint venture, which is 60% owned by Prime and 40% owned by the principals of BDEC, plans to expand both through additional acquisitions and the development of new laser centers."

Prime currently operates a fleet of 63 lithotripters and two refractive surgery centers in 34 states. These centers perform approximately 39,000 lithotripsy and 5,500 LASIK procedures on an annualized basis.

According to *OptiStock*, **Donaldson, Lufkin & Jenrette** maintained its "Buy" rating on Prime Medical, with a 12-month price target in the mid-teens. **Ryan, Beck & Co.** maintained its "Strong Buy" rating, with a 12- to 18-month target of $16-$18.

8/30 Al Kildani of **Pacific Growth Equities** issued an update on **TLC The Laser Center**, maintaining his "strong buy" recommendation. He noted that stocks in the LVC sector had been slammed in recent weeks (see our August 18th brief in last month's newsletter), largely regarding procedure pricing, but that he had not seen any weakening of prices, with the average charged in the U.S. still above $2000, with some TLC surgeons still charging and getting as much as $2750.

Along the same lines, Craig Schneider, of *Individual InvestorOnline*, wrote that the weakness in laser vision stocks offered a buying opportunity. "After solid gains through the first half of 1999, the laser center stocks like **LCA-Vision**, **TLC The Laser Center**, and **Laser Vision Centers** fell out of favor this summer...A second look at these pressured centers may be worthwhile. Ophthalmologists come to a center like LCA to use its laser systems, which are licensed from VISX...Competitive pressures are forcing doctors to lower their fees, but have so far not affected the amounts going to the centers or Visx. But investors have feared that the same competitive pressures will eventually drive down the centers fees, and that's been behind some of the bearishness holding these stocks down. The bottom line: The biggest question investors should concern themselves with is whether the laser vision centers are still fundamentally sound. The answer is yes. These are growth stocks that are now moving out of a high-cost, start-up phase into a period of growing profits. The share prices will ultimately reflect that."

8/30 **Lasik Vision Corporation** reported financial results for its second fiscal quarter, with revenues of $6.2 million. That represented a 78% increase over the first quarter. The

company performed 8906 paid laser procedures during the second quarter, up 388% over the same period last year, and a 75% increase over the 5092 procedures performed in the first quarter. The net loss for the quarter was $1.3 million, compared to a net loss of $2.2 million for the first quarter. For the six month period, the revenues were $9.7 million and the net loss was $3.4 million.

Michael Henderson, president and CEO said, "The consumer response to our pricing strategy and the quality of our treatment continues to be overwhelmingly positive. Our positive momentum is carrying over into the third quarter where Lasik Vision has already performed a record month for procedures in July. We continue to anticipate achieving profitability much sooner than it has taken our industry competitors."

8/31 **VisionAmerica** announced that it had established a new laser center at the company's eye care center located in Lancaster, Ohio, and was also finalizing the transition of two of its laser centers in middle Tennessee from outside third party access arrangements to the VisionAmerica program. The addition of these locations brings the total number of laser centers in VisionAmerica markets to 21 as the company continues to expand its laser vision correction capabilities nationwide.

9/1 **Sight Resource** announced the signing of a letter of intent with **Laser Vision Centers** to offer excimer laser correction and other refractive surgical procedures within the Sight Resource primary eye care network. Initial efforts will focus on developing the appropriate model and methodology for offering and delivering excimer laser correction services in Michigan, where Sight Resource operates the **Kent Optical** chain of 28 primary eye care centers. By January 2000, the companies intend to expand their efforts to New England where Sight Resource operates two chains: **Cambridge Eye Doctors** and **Vision World**. Cambridge Eye Doctors operates 23 primary eye care centers in Massachusetts and southern New Hampshire, primarily in the heavily populated areas of eastern Massachusetts, while Vision World operates 7 eye care centers in Rhode Island. Cambridge Eye Doctors and Vision World currently have an established business base in excimer laser correction.

Under the terms of the agreement, each company will contribute towards expanding marketing of refractive surgical procedures to existing Sight Resource customers and potential customers. Jointly, Sight Resource and Laser Vision Centers will provide: excimer laser access for affiliated ophthalmologists to provide excimer laser correction services; training for optometrists, opticians and staff; telemarketing and patient information centers; and, marketing materials. The agreement provides both companies with incentives to extract the full potential of the growing refractive surgery market.

9/1 **Vision Twenty-One** announced that it had completed the sale of its retail optical chains to **Eye Care Centers of America, Inc. (ECCA)**, a **Thomas H. Lee Company**. Simultaneously with closing, the companies entered into a comprehensive Strategic Alliance Agreement related to joint initiatives in managed care and Vision

Twenty-One's refractive surgery programs. Vision Twenty-One received $37.3 million at closing with the final price subject to post closing adjustments. Ted Gillette, chairman, president and CEO of Vision Twenty-One stated, "This transaction reflects another important step in de-leveraging the balance sheet and continuing our strategic plan to focus on refractive surgery and related vision care initiatives in our core markets. Furthermore, the strategic alliance with ECCA opens up incremental market opportunities for developing refractive surgery centers and contracting with local health plans."

9/1 **STAAR Surgical** announced that it had received approval from the FDA to begin marketing a new foldable IOL for refractive corrections in cataract patients. The new lens will be made in the +4 to -4 diopter range, the first foldable lens designed for correction of cataract patients with severe myopia. Until now IOLs were designed for 10.0 diopters of correction or greater.

Kevin Miller, MD, Cataract and Refractive Surgeon, Jules Stein Eye Institute, UCLA commented on the lens saying, "The new low diopter IOL is an innovative product from Staar Surgical, a long-time leader in products for small-incision cataract surgery. With this foldable lens implant, cataract surgeons can finally perform sutureless phacoemulsification for patients with severe myopia that previously required a large incision, a rigid lens implant and sutures. What is even more exciting, however, is that we now have a lens that we can use in a `piggyback' fashion to correct residual refractive errors in patients who had cataract surgery some time ago, but were unhappy with their visual outcome. Previously, it was hard to justify making a 6-mm incision to correct a 1 or 2 diopter myopic or hyperopic refractive error. With the new foldable lens it will be a snap."

9/1 **Paradigm Medical Industries, Inc.** reported unaudited results for its second quarter with revenues of $1.0 million compared with $626,000 in the prior-year second quarter. Operating income grew to $30,000, from a loss of $355,000 for second quarter of 1998. Net income for the quarter was $34,000 (.5 cents per share) compared with a net loss of $327,000 (8 cents per share) during the second quarter of 1998. For the six months period, revenues increased 13% to $1.1 million compared with $978,000 last year. The net loss decreased 6%, to $693,000 (11 cents per share), compared with a net loss of $740,000 (19 cents per share). President and CEO Thomas Motter stated, "The outlook for the remainder of the year is positive as the company moves towards completion of its laser cataract clinical trials and expands sales of its ultrasound surgical and diagnostic products."

9/1 A multidisciplinary program to identify the causes and potential treatments for age-related macular degeneration (AMD) and other retinal degenerations, is the focus of an initial $6 million, global research project established by three leading worldwide organizations. Participants in the unique collaborative program include: **CIBA Vision**, the eye care unit of **Novartis AG**; **The University of Iowa Center for Macular Degeneration**; and **The Laboratory of Cellular and Molecular Biology of the Retina**

and the Eye Clinic at the Universite Louis Pasteur, Strasbourg, France. The interdisciplinary program between industry and academia will focus on biological causes of and potential treatments for retinal degenerations, including age-related macular degeneration, the leading cause of irreversible blindness in the developed world.

The goals of the program are to identify key pathways and genes that are involved with the etiology of AMD, and to develop strategies for diagnosing, delaying, and/or preventing the progression of this devastating disease. "This is an unprecedented venture, combining innovative global academic research and industry support towards identifying the causes, cures and treatments for AMD," said Glen Bradley, CIBA Vision CEO. "It complements our current research and development efforts and significantly strengthens our commitment to improve, protect and preserve the vision of people around the world."
The project will establish a dynamic and close collaboration among the organizations which will allow for significant progress in understanding the etiology of AMD and allied diseases. The program combines the intellectual and clinical resources within the universities with the expertise of Novartis and CIBA Vision in drug identification and development.

9/1 **NovaMed Eyecare** announced that the underwriters of its initial public offering exercised their over-allotment option in full to purchase an additional 600,000 shares of common stock from NovaMed at a price of $8.00 per share.

9/2 **TLC The Laser Center** announced that over 33,200 paid laser procedures were performed at the company's refractive centers in the three-month period ending August 31, 1999. This was an 87% increase from 17,781 the same period a year ago. The increase in this quarter was primarily driven by 72% same-store procedure growth. Pricing for the procedure remains strong. Based on preliminary analysis of Q1-00 financial results, TLC expects average refractive net revenue after doctor compensation per procedure for the quarter to exceed $1,320. This compares to an average of $1,321 for fiscal year 1999 and is up from $1,288 for the previous quarter.

Following the company's announcement, Al Kildani of **Pacific Growth Equities** issued an update report on the company, in which he said that the results "put to rest the recent rumors of a potential shortfall in quarterly procedure volume...and any weakness in per procedure revenues."

9/2 **Lasik Vision** announced that it had engaged **McDonald Investments Inc.** to serve as its financial advisor and placement agent in connection with a proposed private placement financing of up to $15 million. McDonald Investments will provide financial advise and assistance, including assistance in structuring the terms of the securities which may be offered pursuant to the financing, identifying prospective investors and assisting Lasik Vision in negotiating the terms of the securities with those investors.

"Lasik Vision's plans to aggressively expand in the U.S. will benefit from our partnership with a strong and established firm in the U.S. financial marketplace. McDonald Investments brings together the experience of one of the Midwest's premier investment banking firms and one of the U.S.'s most powerful full-service financial institutions," said Douglas Mason, chairman of Lasik Vision.

9/3 **Advest's** Ted Huber issued an update on **VISX**, based on **TLC's** 14% sequential procedure growth, as TLC is VISX's largest customer, and the vast majority of TLC's procedures are in the U.S., driving royalty income for VISX. His rating of the company remains "neutral", equal to the previous "market perform", based on the risks inherent in the battle with **Nidek** and the effect on per procedure fees.

Wade King of **BancBoston Robertson Stephens** also weighed in on VISX, saying that business remains very strong, reiterating his "buy" rating. He also commented on TLC's results, noting that the company's net revenues per procedure remained up in contrast to the recent fears of a price decline. He also said that he expects both **Bausch & Lomb** and **LaserSight** to obtain marketing approvals before year's end, and that both will need to obtain a domestic license to VISX's patents, as they have done internationally.

9/3 I received a copy of **Advest's** Ted Huber's initial coverage report on **Laser Vision Centers**. He recommends a "strong buy" on the company with a target price of $36.00. As he puts it, with an accelerating level of laser placements, having placed 9 systems in fiscal Q100, and expected to add an additional 8 in Q2, and 6 per quarter thereafter, the company should beat his estimate of 29 new lasers in fiscal 2000, a 74% increase in its installed base. LVCI's business model gives it a strong and sustainable competitive advantages over its rivals and, with an emphasis on surgeons in smaller markets, its strong local market share enhances pricing flexibility and profitability. The only potential risk is the liklehood that high volume surgeons would want their own laser. But, LVCI allows roll-on/roll-off surgeons, who build up their volume, to obtain a fixed-site system when their volume justifies it (over 50 cases on a mobile system).

9/7 According to *EyeWorld Week*, **KeraVision's** quest to gain approval to treat a wider range of myopia with its Intacs corneal ring segments advanced when the FDA approved the company's application to finish enrolling patients in Phase III-B clinical trials. Intacs have been approved to treat mild myopia (1 to 3 D); the treatment of very mild myopia (0.75 to 1 D) and moderate myopia (3 to 4.5 D) are being evaluated in the Phase III-B studies. KeraVision expects patient enrollment to be completed by early 2000 and will then apply for premarket approval to treat the wider indications.

9/7 Several people posted part of the results of David Harmon's **MarketScope** *"Survey of Refractive Surgeons"* on the Raging Bull bulletin boards, so I contacted David and he was kind enough to send me a copy of the summary. This is the second year he has surveyed refractive surgeons on a number of subjects. The complete survey is

available from MarketScope for $3500, and runs over 300 pages with cross tabs on everything. Over 300 surgeons responded, representing all parts of the nation, types of practices, and surgical volumes. It contains data on how and where surgeons practice; their procedure volumes; what procedure they use to treat low and moderate myopia, hyperopia, and with or without astigmatism; what keratome is used; what laser is used; their attitude towards custom ablations; and a lot more. Those of you who haven't obtained a copy of this important report, should contact Dave and get one. (His new phone/fax numbers -- he recently moved from Keller, TX to St. Louis -- are: 314-835-0600/314-835-0606, and his email address is daveharmon@mktsc.com.

Of particular interest were some of the results of which excimer laser surgeons expect to be using in two years -- and how that has changed since last year's survey:

Excimer Lasers	1998	1999
VISX	58.5%	60.9%
Summit	21.5%	13.7%
Nidek	19.3%	19.2%
Autonomous	18.6%	34.7%
LaserSight	5.8%	4.1%
B&L/Technolas	11.9%	12.2%

A second interesting finding was what refractive technology the surgeons expected to be using in two years, in addition to the excimer laser (numbers add to greater than 100% as respondents chose more than one response):

Other Technologies	1999
Sunrise LTK	32.5%
Refractec RTK	1.5%
KeraVision Intacs	49.1%
Phakic IOL	48.3%
Scleral Expansion Bands	22.1%

The most surprising finding, especially to me, was the number of surgeons that expect to use scleral bands to correct presbyopia! This will have to be watched closely over the next several years.

Another interesting result of the survey was that custom ablation scored extremely high, as more than 94% of respondents consider custom ablation to be important, with nearly half of the respondents considering it "very important".

The report contains much more information. I urge you to obtain a copy.

9/7-
9/8 **Preferred Capital Markets** announced that it had initiated coverage of four ophthalmic companies: **LaserSight** with a "strong buy" recommendation; **Summit Technology**, also with a "strong buy"; **VISX** with a "buy" recommendation; and **Staar**

Surgical with a "strong buy". Senior analyst Kate Sharadin and associate analyst Jason Mills issued the first three reports on September 3rd, and the Staar report on September 8th.

Their comments on LaserSight were based on the company having a strong laser technology and microkeratome (and blades) platform that positions it favorably to capitalize on the growth of the laser vision correction market. Their twelve-month target price for the company is $24. They also noted **TLC The Laser Center's** 15% stake in the company as a positive endorsement of its superior technology. They expect FDA marketing clearance for the LSX laser before the end of the year (the company has cleared FDA inspection and just awaits approval of labelling claims). And the company will file for supplemental approvals for astigmatism and hyperopia once initial approval is obtained.

Summit Technology's acquisition of **Autonomous Technologies** gives that company access to "next generation" laser technology which, according to the analysts, could allow it to regain market share in the LVC industry. They believe that going forward, the Autonomous LadarVision system should be the primary driver of revenues and earnings, especially with its per-procedure placement model. (Other than just a mention of having them, no credence was given to Summit also having a line of microkeratomes for sale, which could be bundled with laser sales as a sales incentive. Another shortcoming of this report was the lack of commentary on the possible importance of CustomCornea in the sale of next generation lasers.)

The VISX report shows a 12-16 month target price of $110, seemingly low for a company already at nearly $100, and having a 70%-75% share of a fast growing LVC market. Their model shows a 75% share in 1999, dropping to 70% in 2000, even though it is supplying up to 80 lasers per quarter for the remainder of this year, and at least 200 systems next! (I guess I don't follow their thinking. Perhaps they give more credence to the ITC case, and **Nidek** winning, than do other analysts -- although this is not clear in their report.)

The most complete of the four reports is their coverage of Staar Surgical. They cover all of the bases of Staar's product lines, including the ICL for refractive surgery and the Aqua-Flow device for treating glaucoma. Considerable effort is given to covering the company's IOL products, including the newer acrylic lenses, both from the competition and from Staar, and its hydrogel lenses, currently on an expedited approval track in the U.S. A brief section of the report is devoted to Staar's recently announced intention to enter the laser vision correction market via opening twenty of its Laser and Implant Technology Centers by the end of 2000. I think these analysts are giving the company more of a benefit of the doubt that they can pull this off, than most other analysts.

The two analysts have issued a lengthy industry report which purportedly expands on their limited comments noted above. I expect to receive a copy of this report before

this newsletter is published, and will report on it when it arrives.

9/8 **VisionAmerica** announced that it had entered into an agreement with **EBW Laser of Chicago, LLC (EBW-Chicago)**, for EBW-Chicago to provide a VISX STAR S2 excimer laser system and related equipment for use in VisionAmerica's Chicago practice. EBW-Chicago is owned by over 50 Chicago area optometrists and will be managed by **EBW Laser, Inc. (EBW)**. As previously announced, VisionAmerica formed a strategic alliance with EBW Laser to provide optometrists the opportunity to own an equity stake in excimer lasers located in VisionAmerica centers. This program will be offered in VisionAmerica markets, and, through this alliance, EBW Laser and VisionAmerica plan to establish laser center programs in new markets across the country.

Mark McDaniel, CEO of EBW Laser, Inc., commented on the agreement, "This is the first of many projects we expect to complete with VisionAmerica. We believe that together we can make a significant impact on the laser facility industry." Jayne Kulhanek, executive director of **United Eye Care Providers**, a Chicago optometric network which participated in forming EBW-Chicago added, "This project represents an important step in the participation of optometrists in providing access to laser vision correction to their patients."

9/8 **Moria** and its American distributor, **Microtech**, responded to the patent infringement lawsuit **Bausch & Lomb** filed against the companies August 23rd by denying that the Carriazo-Barraquer microkeratome violates a B&L patent and vowing to vigorously defend its intellectual property. Further, Moria claimed that B&L misrepresented the results of its patent infringement litigation against Moria in France, by claiming in a recent company press release that it "won the first round." According to Alain Duprat, CEO of Moria and Michael Bartell, president of Microtech, "Bausch & Lomb Surgical has again misstated what has occurred in the French courts, and it continues its misguided effort to intimidate us (and our customers) with unfounded litigation." According to Duprat and Bartell, "Bausch and Lomb sought a cease-and-desist order (the equivalent of a preliminary injunction) in the French courts against Moria's microkeratome, but the courts refused to grant the order (as reported in *EyeWorld Week*, Jan. 25 and our brief of the same date)...The bond that Moria posted in that case was a routine condition of a denial of a request for injunctive relief.

Moria holds an exclusive worldwide license to the Carriazo-Barraquer Microkeratome technology and its U.S patent application is in the final stages of review; the company expects it to be approved this fall.

9/8-
9/9 **STAAR Surgical Company** announced enrollment had been completed of its FDA clinical study of the AQUA-FLOW collagen glaucoma drainage device. STAAR is studying the device in 195 eyes at nine clinical sites throughout the U.S. under an IDE. "The data obtained from this study are excellent," said Stephen Bylsma, MD of

the **Shepard Eye Center**, the study's medical monitor and most experienced U.S. surgeon in the AQUA-FLOW procedure. "Early study results showed that control of intraocular pressure by the AQUA-FLOW is excellent with minimal dependence on postoperative glaucoma drugs. Those observations have been maintained throughout the study as follow-up data spans over a longer period. The data appears to be compelling enough to justify presentation to the FDA after one-year follow-up, rather than the two year follow-up in the study protocol. This data may indicate a potential paradigm shift in the manner in which glaucoma is treated in the U.S. Consequently, it is appropriate to present this data to the FDA as quickly as possible."

Accordingly, STAAR will be preparing data from the clinical study for an early PMA submission to the FDA. Since there is no similar device to the AQUA-FLOW currently marketed in the U.S., no exact regulatory pathway for approval has been established. STAAR intends to submit one-year data on the first 100 patients in the first quarter of 2000 with a commitment to continue following and reporting data on each study patient.

In other Staar news, Vladimir Feingold, who resigned as executive vice-president of R&D of Staar Surgical and president and director of Staar Surgical's Swiss subsidiary, **Staar Surgical, AG**, (see the "people" brief in this newsletter) has filed a lawsuit in the Los Angeles Superior Court against Staar alleging that the company, among other things, breached his employment agreement. The action asserts that the company began a course of conduct in mid-1997 designed to demote, or which had the effect of demoting, Feingold from his positions with Staar, and which negatively reflected on Feingold's reputation. Feingold claims that the course of conduct escalated and continued through the date of his resignation. Feingold is seeking in excess of $1.7 million in damages.

The company also reported on favorable data regarding its implantable contact lens (ICL) that was presented at the *European Society of Cataract and Refractive Surgeons Conference (ESCRS)* in Vienna, Austria. Data presented at the meeting indicated that over 98% of the patients maintain their best corrected visual acuity with the ICL, while more than 40% show an improvement in their best corrected acuity. From one month post-operative up to five years after surgery, the eyes with the ICL maintained stable refractive correction with no regression over time. The data show that predictability with the ICL is excellent, with over 90% of patients achieving a final refraction within one diopter of their intended final refraction and over 80% being within 0.5 diopter. STAAR Surgical AG has sold more than 10,000 ICLs around the world in the last five years for patients ranging from five to ninety years of age.

9/9 **Lasik Vision** announced that it had granted options to acquire up to 1.5 million common shares to its employees and to the company's directors and officers at an exercise price of $4.00 per share under the terms of the company's stock option plan.

9/10 In another case of sport celebrities obtaining LASIK, Dr. Scott Hyver, **Aris Laser**

Vision surgeon in Atherton, California performed successful LASIK surgery using the **VISX** excimer laser on Terrell Owens, wide receiver, and Dave Fiore, offensive lineman, for the San Francisco 49ers. Fiore's uncorrected vision is now 20/20 and Owens boasts an amazing 20/10.

9/10 This month's *Refractive Market Perspectives's* lead story was about the quarterly growth of the various surgeon/corporate center segments of the industry. According to David Harmon, overall growth, as previously reported, was 14.5%, with 75 new lasers installed during the quarter, and 130 year-to-date. After accounting for trade-ins of older lasers and secondary lasers, an estimated 60 new laser centers were opened during the second quarter. Surgeon-owned centers now account for 40.3% of refractive procedures performed during the quarter, a 2.2% gain, while corporate centers now hold a 43.4% share, down from 45.5% in the first quarter, and institution-owned centers declined to 15.9%, down from 16.5%. Of the corporate-owned centers, **TLC** still holds a commanding 27.6% share, followed by **Laser Vision Centers** at 22.3%, **Clear Vision** at 14.5%, **LCA-Vision** at 10%, **Aries** at 6%, and all others at 19.2%. This latter segment includes **Vision Twenty-One** - 4.7%; **NovaMed** - 2.7%; and **VisionAmerica** -2.4%.

The other cover story was about the new corporate entrants that have recently announced intentions to expand refractive surgery choices, including **Staar Surgical**, **Sterling Vision**, **Prime Medical**, and the aforementioned expansion plans of VisionAmerica, Vision Twenty-One, and NovaMed -- in addition to the aggressive growth plans of industry leaders TLC and Laser Vision Centers.

9/13 **Donaldson, Lufkin & Jenrette** announced that analyst Mimi Willard had initiated coverage of **NovaMed Eyecare** with a "buy" recommendation.

9/13 **Gimbel Vision International** announced that it had signed an agreement with Brian Gillespie, MD to be the associate medical director of a Gimbel Vision centre to be located in Winnipeg, Manitoba. The company continues to focus its growth efforts on the North American market and anticipates the announcement of additional new centres before the end of the year.

9/13 **CIBA Vision**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics** announced the initiation of a Treatment-Investigational New Drug (T-IND) clinical program for Visudyne therapy for the treatment of the wet form of age-related macular degeneration (AMD). The program, for which enrollment will begin September 15, will provide Visudyne therapy within a controlled clinical setting, prior to regulatory approval, to a certain number of patients who meet specific eligibility criteria. The T-IND clinical program will allow the treatment of up to 4,000 patients. Treatment will take place at approximately 200 sites across the U.S. and Canada, each enrolling up to 20 patients at each site.

Under a T-IND protocol, the FDA allows drug developers to provide pre-approval

access to experimental drugs that are intended to treat serious or life-threatening conditions for which there are no satisfactory treatments, and to provide additional safety information in a larger cohort of patients than were treated in initial phase III trials. "Initiating a T-IND program allows us to offer Visudyne therapy immediately to a broader number of patients most in need of a treatment for this devastating disease prior to regulatory approval," said Luzi von Bidder, president of CIBA Vision's Worldwide Ophthalmics Business Unit. "At the same time, we continue to aggressively work to complete the remaining regulatory steps required for approval, to make this breakthrough therapy available to the widest number of patients as quickly as possible."

"We are well aware of the urgent need for an effective treatment for the thousands of people who lose their vision because of this disease," said Dr. Julia Levy, president and CEO of QLT. "Our ability to offer the treatment early, while we continue to pursue regulatory approval, offers hope and the potential for an improved quality of life for the many patients who need this therapy now."

9/14 **ICON Laser Eye Centers, Inc.** announced that it had recently completed two separate acquisitions involving five laser vision correction centers. The first acquisition, which occurred immediately prior to the previously announced amalgamation under which **ICON Laser Centre of London Inc.** and **Northern Gaming Inc.** amalgamated to form ICON Laser Eye Centers, Inc. on September 1, 1999, involved the purchase of three centers from Dr. Donald Johnson and related entities. The centers are located in Vancouver, British Columbia; Prince George, British Columbia; and Honolulu, Hawaii. The purchase price consisted of newly-issued shares of one of the amalgamating corporations which were exchanged for common shares of ICON on the amalgamation. Dr. Johnson joined the board of directors and is co-medical director of ICON.

ICON also acquired on September 8, 1999 two laser vision correction centers in the United Kingdom operating under the name "**The Eye Academy**". One center is located on Harley Street, London and the other is located in Nuffield Hospital in Birmingham. The purchase price consisted of 1 million newly-issued shares of ICON. These acquisitions bring the number of centers and mobile lasers operated by ICON to 10. Several additional centers have been targeted for purchase or joint venture as ICON proceeds with its strategy of aggressive international expansion.

ICON Laser Eye Centers is a leading international provider of laser vision correction services. In addition to its own centers, ICON has developed working relationships with laser vision correction centers around the world with the intention that they will be acquired by or enter into joint ventures with ICON. ICON and these other parties operate approximately 24 excimer lasers in mobile sites and 17 fixed centers with multiple mobile sites in Toronto; Rome; Milan; Florence; London, Ontario; Windsor, Vancouver; Prince George; London, U.K.; Birmingham; Leeds; Chester; Scottsdale; Honolulu; Colorado Springs; Dallas; Stockholm; and Malmo (?). ICON mobile units

are currently in Europe only.

9/14 **Laser Vision Centers** announced that its U.S. case volume for the month of August increased 116% compared to the same month a year ago. The company operated a total of 52 lasers in the U.S. during August.

9/14 *The New York Times* personal health section, carried an article on laser vision correction entitled, "Promise and Risks of Laser Eye Surgery". It covers both the good and the bad, telling of the success of 98% of patients who have had surgery, but also relating the problems encountered by the remaining about 2%, mostly taken from the surgicaleyes.org web page. No new ground is covered.

9/15 **Preferred Capital Markets** announced the publication of a 102 page industry report "Refractive Vision Correction: Profitability in Sight with a Keen Eye on the Market". The report was prepared by senior analyst Kate Sharadin and associate analyst Jason Mills, who have published a comprehensive research report addressing the refractive vision technology sector including updated research reports on: **LaserSight**, **STAAR Surgical**, **Summit Technology** (and **Autonomous**), and **VISX**. (My review of this report is shown below in the 9/22 brief.)

9/15 **Visual Freedom Center (VFC, Inc.)** opened a new laser vision correction center at **The Mall** in Columbia, MD. Located on the lower level near Nordstrom, the center provides convenient access to state-of-the-art vision correction technology. The center features a unique, open environment, which encourages education and exploration of laser vision correction surgery, as well as comprehensive pre- and post-operative care. "We are all delighted with the opening of our second location in the Baltimore/Washington market," said Myles Weiner, CEO of VFC. "Patient response over the past year has been phenomenal. The number of patients we treat per month more than doubled in the first few months at our **Fair Oaks Mall** location in Fairfax, VA, and we are predicting similar growth at our new center in Columbia, MD." The center will be open seven days a week for information and patient screenings, and surgeries can be performed everyday except Sunday.

9/15 **Gimbel Vision International** announced that it had retained **Carin Financial**, an independent financial and strategic advisory firm, to assist the company in developing and implementing its strategy to expand North American-based operations. As previously stated, the company intends to actively examine alternatives to increase the number of centres it owns by partnering with exceptional practitioners, business combinations or other strategic alternatives. Carin Financial will act as an additional resource to the company in implementing this strategy by identifying potential strategic acquisitions or business combinations with partners whose operating philosophy and commitment to patient focused care are complimentary to the company.

9/15 *The Wall Street Journal's* "Heard in Florida" column, running in the Florida edition of

the Journal, featured an article on **LaserSight**, entitled, "LaserSight, Eye-Surgery Latecomer, May Be Ready to Play Catch-Up". Written by Carrick Mollenkamp, the article plays up the words of the two analysts following the company, Kate Sharadin, of **Preferred Capital Markets**, and Al Kildani of **Pacific Growth Equities**. The two analysts say there's a good chance that little-known LaserSight of Winter Park, Fla., could be one of the few companies cashing in on the red-hot laser-surgery market, which has doubled in just the past year. Already this year, the laser manufacturer's shares have risen to about $14 from the $5 range in anticipation of federal regulatory approval of LaserSight's new laser, the LaserScan LSX. "I expect a lot of people to start looking at the stock," said Sharadin. "This is on the verge of hitting [investors'] radar screens." Ms. Sharadin sees the stock hitting $24 within the next 12 to 16 months, while Kildani predicts the stock will touch $26 within 12 months. But LaserSight has a lot of ground to make up first. While the LaserScan has been mired in five years of clinical trials and other FDA tests, two competitors have taken over a market created in 1995 when the FDA first approved the use of lasers to correct vision. **VISX** of Santa Clara, Calif., controls some 70% of the market, while **Summit Technology** of Waltham, Mass., has 30%, according to Kildani. However, both Kildani and Sharadin say there will be plenty of demand for LaserScan because the market is expanding so rapidly.

9/16 Bob Hopkins of **Donaldson, Lufkin & Jenrette** issued an update report on **Keravision**, saying that the third quarter looks solid. This was based on the management team speaking at DLJ's growth stock conference where they expressed a high degree of confidence in meeting DLJ's current revenue forecast of $4.2 million for the quarter and mentioned that procedure rates were above plan, doctor training was as expected, and reorder rates among the doctors that had worked through their inventory of Intacts were above 50%, if not higher. The analyst expects that 190 physicians will be trained by the end of Q3, and that 600 Intacts procedures performed. Kit revenues will continue to be upwards of 75% of total revenues until a critical mass of physicians are trained, and that it won't be until the second quarter of 2000 until expectations on procedure numbers become a significant challenge.

9/16 Dave Therkelsen of **Dain Rauscher Wessels** issued an update report on **LCA-Vision**, in which he said that the increasingly competitive environment will reduce the company's near-term visibility. According to Therkelsen, "Laser vision correction remains one of the fastest growing segments within healthcare in our view, and we believe continues to have a very strong growth outlook for the foreseeable future. As is typical in a fast growing and profitable market, the competitive dynamics appear to be evolving as new and existing players look to increase their exposure to this compelling opportunity. Given the high barriers of entry on the manufacturing side of this business (FDA approvals and patent litigation), the level of competition appears to be increasing for the most part on the provider segment of the market. For the service providers, assets such as affiliated surgeons hold significant value to companies looking to grow their laser vision correction business. Consequently, we believe surgeon departures, whether to a competitor or to their own independent

practice, is one of the most important risks for investors participating in this arena."

He goes on to say that he learned that LCA had lost another high performing surgeon to a competitor, the second significant departure this year. "The surgeon was a primary surgeon at one of the company's more successful centers, representing somewhere around 10% of the procedure volumes and revenues in recent periods. While the surgeon is just one of a handful of surgeons utilizing this location, we believe he did constitute a meaningful percentage of procedure volumes at that location. We acknowledge that this is a busy center and consequently we would expect some of the other surgeons at the center to step up and offset some of the decline. However, we are conservatively assuming there will be at least a modest impact from the departure over the next few months. Consequently, our estimates for fourth-quarter revenues and EPS has been reduced for the time being." For that reason, he lowered his rating on LCA to "Buy-Aggressive", given the reduced visibility on EPS over the next few quarters as a result of several competitive developments, including the loss of key surgeons. In addition, LCA-Vision is evaluating a modification of its business model in anticipation of changing competitive conditions. This proactive approach does suggest LCA-Vision is committed to maintaining its position in laser vision correction.

9/17 **Laser Vision Centers** announced that it had signed five agreements under its newly developed market development program. The market development program focuses on small- to mid-sized cities with populations of approximately 300,000. The announced agreements cover Brunswick and Savannah, Georgia; Westbrook, Maine; Lake Charles, Louisiana; and Branson, Missouri. Under the agreements, LaserVision will provide excimer lasers, marketing support, patient financing and an in-practice refractive coordinator. In exchange, LaserVision receives the majority of the patient fee, and contractually obligates the participating surgeon for 3-5 years. The company said that it would continue to offer its open access model in other cities.

"We are pleased to announce the roll-out of this new program," said LaserVision chairman and CEO, John Klobnak. "This is the first of many agreements which we intend to sign with surgeons in similar markets. We believe this program achieves two things. First, it formally binds a surgeon to the LaserVision organization and second, it increases the average selling price LaserVision receives on each case which should increase our already strong revenue growth."

9/17 **Summit Technology** announced it had entered into an arrangement to participate in the recently launched, **Amway/Quixtar** web site program. Under the terms of this arrangement, participating Summit doctors will have the exclusive opportunity to provide laser vision correction to Amway's 40 million retail customers worldwide. The web site is designed to provide contact information to interested Amway members by matching them with a participating doctor in their area. "This program represents a stepping stone on the road to future corporate and e-commerce practice development initiatives," said Robert Palmisano, CEO of Summit. "We believe with

our continued emphasis on customer focus, Summit will be instrumental in helping doctors achieve the highest level of success in their practice, as well as providing high quality patient care."

9/21 **TLC The Laser Center** announced that it had implemented a shareholder rights plan. The rights will be distributed at the close of business on October 4, 1999 to holders of record of TLC on that date. The Plan has been developed and refined following consultation by management with TLC's advisors and **Fairvest Securities Corporation**. The purpose of the Plan is to ensure that all TLC shareholders receive fair and equal treatment and to guard against unfair take-over tactics. The Plan protects shareholders if any person or group acquires 20% or more of TLC's common shares otherwise than pursuant to a permitted bid (as that term is defined in the Plan) to all shareholders or pursuant to certain other exceptions. Upon the occurrence of a triggering event under the Plan, the rights issued to shareholders under the Plan will entitle each holder, other than an acquiring person or group, to acquire common shares of TLC at a substantial discount to market value.

9/21 **Paradigm Medical Industries** reported that the lead clinical investigator for its laser for cataract removal had completed his laser cases for Paradigm's FDA Phase II clinical study with positive results. Michael Limberg, MD, is the first of seven clinical trial doctors to complete his cataract laser cases. Paradigm's goal for completion of the study is late October 1999. Concerning the study cases, Dr. Limberg stated, "I am extremely pleased with how well the patients are doing post-operatively and how quiet and comfortable the eyes have been." The success of these operations brings final FDA approval for the Photon Laser one step closer.

9/21 *The Wall Street Transcript* published an in-depth interview with Ted Boutacoff, CEO of **IRIDEX Corporation**, in which he talks at length about his company's future. In the interview, he states, "IRIDEX Corporation is the world leader in providing desktop laser systems for the ophthalmology and dermatology markets. Our products are based on the latest semiconductor laser technology, which makes them highly efficient, compact, portable, very reliable, versatile and overall a better value to the customer." He asserts, "IRIDEX has a number of clinical studies underway. Results from a number of them will be reported over the next several years which will be key milestone events. An important milestone has just occurred. It was the publication of a pivotal clinical study which showed improved patient outcomes in the treatment of diabetic retinopathy. Diabetic retinopathy is the leading cause of blindness in the U.S. for the 45-65 year old age group. This study reported a new method of retinal laser treatment using our unique MicroPulse Mode (diode laser)."

Looking forward, he states, "The current ophthalmology and dermatology market for our products is in the range of about $150 million/year. We will be introducing a new product later this year which will expand our available market to over $300 million/year." (I have downloaded the complete interview for anyone who wishes to read it, or you can do it yourself at: **www.twst.com/ceos.htm**.)

9/22 I received a copy of the **Preferred Capital Markets** refractive industry report, "Refractive Vision Correction: Profitibility in `Sight' With a Keen Eye on the Market", prepared by senior analyst Kate Sharadin and associate analyst Jason Mills. The comprehensive report covers the technologies, companies, and products, with an eye to the controversies that exist. The analysts believe that the refractive "revolution" is underway and growth is just beginning. They see significant opportunities for several companies due to a huge, untapped market, with laser placements accelerating as the driving force in collecting per procedure fees for those companies with the intellectual properties to drive those fees. With this report, and the previous brief reports, they initiate coverage of **VISX**, with a "buy" recommendation; **Summit Technology** (including **Autonomous Technologies**) with a "strong buy"; and **LaserSight** and **STAAR Surgical**, also with "strong buy" recommendations.

Sharadin and Mills have derived a "target" refractive population of about 68 million people within the age range of 25-54, of which about 35.4 million are myopic (with and without astigmatism), and 32.6 million are hyperopic. They have assumed that only 50% of these are "realistic potential patients", but when you double the number for two eyes, you end up with a total procedure base of 68 million for 1999, growing of course as the population grows over the next several years, to 69.3 million in 2001. (This compares favorably with others that have done similar analyses, including 57 million potential eyes as estimated by Michael Lachman of **Hambrecht & Quist** in his 1997 seminal report, and our original 1992 calculation that 12-15 million people (24-30 million eyes) represented the prime pool of candidates for refractive surgery.)

Several exhibits caught my eye, one which illustrates both the approved and pending approval indications for all of the major participants; another that forecasts the total U.S. laser vision correction market revenues, including laser sales and service revenues, procedure fee revenues/royalties, and microkeratome and blade fees, providing a $2.1 billion market in 1999, growing to $5.8 billion in 2001! The other exhibit that was interesting was a list of laser vision service centers, breaking down the universe to corporate centers, physician practice management centers, surgeon-owned centers, and institution centers. This exhibit shows a total of 583 centers, with corporate centers having 25% of that total, but doing 48% of procedures, while surgeon-owned centers were 43% of the total, doing 32% of the procedures. The PPMs owned 13% of centers and did 12% of procedures, while the institutions had 20% of centers but only did 8% of procedures.

There is an interesting discussion of custom ablation as the possible future of excimer laser technology, covering the companies involved, and a brief discussion of microkeratomes and future technologies, Intacs, ICLs and LTK, but no mention of implantable IOLs.

Finally, there is an intersting section of potential merger and acquisitions, based on the two companies, Summit and VISX collecting per procedure fees. They speculate that a new entrant might acquire Summit to access the cross-royalty agreement it has

with VISX; **Allergan** or **Alcon** might buy Summit to enter this arena; or **Johnson & Johnson**, who already has an investment in **KeraVision**, might purchase either VISX or Summit to strengthen its refractive surgery portfolio.

The report concludes with updated individual reports on the companies that the analysts have chosen to cover -- LaserSight, Summit Technology, VISX, and STAAR Surgical. These updated reports are more inclusive than the original reports published earlier in the month and contain additional information on some of the key points that were missing in the originals (see my 9/7-9/8 brief above).

9/22 **Laser Vision Centers** announced that it had been notified that the company's common stock would be added to the **S&P SmallCap 600** index after the close of trading today.

9/22 **VISX** said that the 1 millionth VISX laser vision correction procedure, expected to be performed between late-September and mid-October, would be broadcast live online on **Yahoo!**. Anyone wishing to tune in can register at **www.visx.com** by pressing the special MVP (Millionth VISX Procedure) button. Special free software to view the procedure can be downloaded on the site. E-mail reminders will be sent to all registrants prior to the event.

9/22 **Lasik Vision** announced its plans to open three new Canadian refractive centres in Saskatoon, Saskatchewan; London, Ontario; and Niagara Falls, Ontario. The Saskatoon centre is scheduled to open in November 1999 while both the London and Niagara Falls clinics will open in December 1999. The company also announced that its first U.S. clinic will officially open October 4, 1999 outside of Seattle in Bellevue, Washington. The three new refractive centres increase the number of Lasik Vision's Canadian locations to fourteen, along with its first clinic in the U.S., for a total of fifteen refractive centres in North America. "Lasik Vision's continued rapid expansion across Canada will enable it to increase its significant share of the Canadian market. Our entry into the U.S. market further reinforces Lasik Vision's position as one of North America's fastest growing laser vision correction companies," said Michael Henderson, president & CEO.

In addition to the new clinic openings, the company also announced that it would expand its Vancouver, Windsor, and Montreal locations. Henderson commented, "To meet the increasing demand for our laser vision correction services, Lasik Vision plans to add additional lasers and floor space at our Vancouver, Windsor and Montreal locations."

9/22 **RGR Financial Corp.** sees **Sight Resource (VISN)** expanding its market position in the highly fragmented retail eye care industry. According to Joseph DiLustro, research analyst for **Alchemy Investment Strategies**, he sees VISN's decision to re-focus its efforts in offering excimer laser surgery services to its estimated customer base of over 320,000, as the catalyst for new life for VISN shareholders. Also, Chet Dubov, senior vice president of RGR Financial Corp., is optimistic about the company's

overall turnaround potential because of the company's new CEO, Bill Sullivan. He believes that Sullivan has the company focused on implementing cost savings as well as overseeing the integration of the company's recent acquisitions of **Shawnee Optical Chain** and **Kent Optical Chain**. DiLustro believes that VISN's management can produce $0.12 in calendar 2000. He further estimates 2000 revenues of $76.8 million, which should move VISN ahead of some of its competitors according to revenues among the top 100 domestic eye care retailers. (RGR Financial Corp. has a correspondent relationship with Alchemy Investment Strategies.)

9/23 **Sunrise Technologies International** announced it had received conditional approval from the FDA to evaluate a modified algorithm for its Sunrise LTK System for the treatment of hyperopia. The study will allow treatment of up to 130 eyes at up to 8 clinical sites around the United States. In addition, the company reported that it has ongoing discussions with the FDA regarding its PMA application to treat hyperopia from +.75 to +2.50 diopters. The application is still under active review by the Agency, and the Company described those discussions as "productive."

The new study modifies the company's current mid-hyperopia algorithm. Conditional upon age and amount of correction required, treatment of hyperopia from +1.25 to +5.6 diopters will be addressed. The approval allows for treatment of both eyes of future subjects on the same day as well as treatment of the second eye of current subjects of the study. Twenty patients at two sites have already been treated under the current mid-hyperopia study that began in April 1998. The study will evaluate a modified algorithm that is designed to address some undercorrections that were noted in the Company's PMA study. The algorithm modifies treatment based upon age of the patient and the amount of laser energy that is delivered to the cornea. The technique for treating hyperopia in this study encompasses two rings of sixteen spots of laser energy applied to the mid-periphery of the cornea at the six and seven millimeter zones. "It is the normal course of product development to refine technologies and treatment parameters. We will always be working to optimize our procedure. This study complements our PMA application and will provide the ophthalmic community additional information about various ways to treat hyperopia utilizing the Sunrise LTK methods," said Russell Trenary, president and CEO.

9/23 **Coherent, Inc.** announced today that the U.S. Food and Drug Administration (FDA) is reviewing its regulatory submission which seeks marketing clearance for the Selecta 7000(TM) laser, designed to perform Selective Laser Trabeculotherapy (SLT). SLT is an exciting new therapy for the treatment of open angle glaucoma, the leading cause of preventable blindness in Americans over the age of 40. The specific indication requested is for the treatment of open angle glaucoma in patients who are uncontrolled on maximally tolerated medical therapy and/or in whom argon laser trabeculoplasty (ALT) has failed. The only alternative previously available to these patients was conventional invasive surgery called trabeculectomy, a procedure that many patients resist. Market estimates indicate as many as 300,000 Americans may be waiting for an alternative to trabeculectomy.

SLT lowers intraocular pressure by using short pulses of low energy laser light to illuminate specific cells in the eye's trabecular meshwork -- resulting in increased fluid outflow. SLT is much less traumatic to the eye than the current laser technique called ALT. ALT does irreparable damage to the eye, and can only be performed twice on each eye during the patient's lifetime. SLT works at a cellular level, preserves the tissue structure and appears to be fully repeatable. Clinical data indicates SLT can lower intraocular pressure in patients that have already exhausted their ALT treatment options. SLT is being performed today in many international markets using Coherent's Selecta 7000. Domestically, Coherent has received exclusive license to commercialize SLT and market the relevant laser technology.

The company also announced that on Wednesday, September 29, 1999, Coherent will present in Washington, D.C. to Senator Connie Mack (R-FL), Chairperson of the Joint Economic Committee (JEC) at a Research and Development fair. The fair will showcase some of the latest breakthroughs in the biotechnology and biomedical community and demonstrate how these breakthroughs are changing and improving our standard of living. The R&D fair is being held in conjunction with the Summit the committee is holding that day, "Putting a Human Face on Biotechnology," to explore the effects of biotechnology on our economy, our standard of living and our everyday lives.

9/24 Senior medical device and medical technology analyst Wade King of **BancBoston Robertson Stephens**, reiterated his "buy" rating on **VISX**. "We are reiterating our Buy rating and $125 price target on VISX," said King. "We believe that with the quarter almost complete, VISX is well on track to meet our third-quarter 1999 financial projections. Our estimates for the quarter are $69.6 million in revenue, associated with earnings-per-share of $0.34. In our opinion, the fundamentals remain very strong at VISX. The back order for VISX's STAR S2 lasers remains quite significant and we estimate that VISX will place up to 80 new lasers worldwide in third-quarter 1999, and likely a similar number-per-quarter for the next several quarters."

9/24 The controversy among refractive surgeons over the benefits of simultaneous bilateral [both eyes at the same time] LASIK versus sequential bilateral [each eye separately, at different times] LASIK continues with the publication of two new studies in *Ophthalmology*, the journal of the **American Academy of Ophthalmology**.

In a study from the U.S., authors Peter Chiang, MD, and Peter Hersh, MD, concluded that it may be advantageous to perform bilateral LASIK sequentially rather than simultaneously, using outcomes from the first eye to more accurately predict the correction for the second eye. They also found that "waiting approximately one week was potentially as effective as waiting longer periods of time between treatments." This study was based on an analysis of sequential LASIK in 196 eyes of 98 patients. The authors acknowledge that "the improved outcomes of sequential treatments are theoretical and not clinically proved," and that a larger "randomized, prospective study would better address the practical clinical situation."

In a nonrandomized retrospective Canadian study of 2,142 LASIK procedures, authors Howard Gimbel, MD, et al, concluded that "simultaneous bilateral LASIK is as safe and effective as sequential bilateral LASIK surgery." This conclusion is virtually identical to the conclusion of an earlier randomized prospective clinical study by Waring, et al (Ophthalmology, 4/99). The Canadian study also suggests simultaneous bilateral LASIK may offer several benefits to patients, including: less time away from work; a slightly lower rate of retreatment; less variability of surgical procedures and refractive results between the two eyes; avoidance of unequal vision during the time between surgeries; and no increase in risk of complications. However, the authors acknowledge that the ability to predict outcomes in the second eye of sequential cases was not improved, perhaps because the procedures were done as close as four days apart.

Though the two new studies reach different conclusions about simultaneous versus sequential LASIK, they contribute to the ongoing efforts of ophthalmologists to provide choices and to improve treatment options for potential refractive surgery patients.

9/27 This week's issue of **Fortune** contains a major story on refractive surgery, entitled, "Should You Have Your Eyes Lasered?". The subtitle is "Critics say we won't see the truth about laser eye surgery for years. That hasn't slowed this growing business--soon it will be the most popular surgical procedure in the U.S." Author Mary Murray does an excellent job describing the latest in refractive surgery, explaining that complications occur in some 5% of patients, but in fewer than 1% of those whose surgeons are experienced. The story covers both the laser companies and the corporate service providers. In addition, it covers some of the newer techniques that are coming down the pike, including custom ablation and treatments for presbyopia. Sidebars describe nearly all of the options, including Intacs, implantable IOLs, LTK, CK (conductive keratoplasty using radiofrequency), and scleral expansion devices.

OPHTHALMIC LASER UPDATE -- October 1999

9/13 In an S1 filing, **TrueVision International, Inc.**, announced that through its operating subsidiaries, **TrueVision Laser Center of Albuquerque, Inc.** and **TrueVision of Nevada, Inc.**, the company provides laser vision correction and image enhancement procedures to individuals at its TrueVision centers. Its doctors and those with which its is affiliated, provide these services using state-of-the-art excimer laser technology. The company also offers patients ancillary image enhancement procedures and other vision correction devices on a limited basis, including eye glasses and contact lenses. It acquired its first TrueVision center in Albuquerque, New Mexico in April 1998 and opened its second center in Las Vegas, Nevada in July 1999. The company does not currently perform any procedures at its Las Vegas center.

The company was incorporated on January 19, 1988 as **Topform, Inc.** On March 16, 1999 changed its name to TrueVision International, Inc. In April 1998, through a

stock purchase and reorganization, it acquired a controlling interest in TrueVision Laser Centers of Albuquerque, Inc., which had been providing laser vision correction services using the VISX, Inc. excimer laser since June 1996. In July 1999, it opened its second center in Las Vegas, Nevada, through our wholly-owned subsidiary, TrueVision of Nevada, Inc., formed in Nevada in August 1999.

9/27 I received Ted Huber's (**Advest**) latest report on **KeraVision**, in which he recommends "waiting for signs that Intacs are taking hold". He feels that the company has a good chance to be successful, as its current ICR ring product addresses a demographically adjusted U.S. market of over 19 million potential patients. (This includes myopes to -3D, and between 21 to 59, with less than 1.5 D of astigmatism.) He projects that between 100,000 to 150,000 excimer laser procedures will be performed on low myopes in 1999 (about 10% to 15% of the total), and that about 5000 ring implants will be performed. He projects that about 59,000 rings will be implanted in 2000, 136,000 in 2001, and 190,000 in 2001 (with an additional 3000 to 4000 rings implanted internationally.

"Because the momentum behind LASIK is significant and building, early indications of Intacs' clinical and commercial success are critical." Huber continues to believe that Intacs can carve out an important niche in the low myopia refractive market. He expects the number of surgeons certified in the procedure to reach 388 by the end of this year, climbing to 838 in 2000, 1138 in 2001, and over 1400 by 2002.

9/27 **Prime Medical Services, Inc.** announced that it had acquired 60% of the outstanding stock of **Horizon Vision Centers, Inc.**, which operates four laser surgery centers in California, through its recently created, majority owned acquisition subsidiary. The remaining 40% of the stock will continue to be owned by nine investors, including eight ophthalmologists who utilize the centers. Prime paid approximately $10.8 million in cash for this acquisition which was effective September 1, 1999. Ken Shifrin, chairman of Prime, stated "Prime recently entered the refractive surgery field with an acquisition of a 60% interest in the **Barnet Dulaney** laser surgery centers in Arizona. We are very pleased that we have been able to follow up with a second acquisition in a short period of time, an indication of our commitment to rapid expansion into this field. We are very impressed with Horizon's ability to achieve a high degree of market penetration in each of its four centers and are excited about the opportunity to partner with the ophthalmologists affiliated with Horizon, whom are among the leading refractive surgeons in the country." The four refractive surgery centers, located in San Leandro, San Jose, Sacramento, and Petaluma, have performed over 20,000 procedures since 1996. The centers performed over 6,000 procedures during the first six months of 1999.

Prime currently operates a fleet of 63 lithotripters and six refractive surgery centers in 34 states. These centers perform approximately 39,000 lithotripsy and 19,000 LASIK procedures on an annualized basis.

9/27 **Coherent, Inc.** announced that Senator Connie Mack (R-FL) Chairman of the Joint Economic Committee (JEC), had invited the company to participate in a special medical technology fair showcasing breakthrough medical technologies. The Fair is part of a day long program devoted to exploring how medical technologies are improving and enhancing the lives of Americans and what public policies can encourage these innovations. Coherent is one of 22 firms featured at the Fair and will be displaying new laser technology for treating the wet form of Age Related Macular Degeneration, the leading cause of blindness in people over the age of 50 in the westernized world. The company will be displaying the Opal Photoactivator laser, which was specially developed for use in ophthalmic photodynamic therapy and specifically for use with Visudyne therapy. Visudyne is a trademark of **Novartis AG** and co-developed by **CIBA Vision** and **QLT PhotoTherapeutics**. Visudyne therapy has currently been assigned priority review status for its new joint device/drug application by the FDA. The review specifically seeks clearance to market Visudyne therapy for the treatment of wet AMD in patients with predominantly classic subfoveal choroidal neovascularization, the most aggressive cause of vision loss associated with the disease and for which Visudyne therapy showed a dramatic benefit. The application, filed jointly by Coherent and QLT, covers Coherent's new Opal Photoactivator laser, as well as Visudyne, the drug which is activated by the special purpose 689 nm diode laser device. Visudyne will be marketed globally by CIBA Vision Corporation, the eye care unit of Novartis.

9/28 **UltraVision Corporation,** announced a strategic alliance, with the **Vision Corporation**, an internet-based product distribution company specializing in ophthalmic products, and **Vision Source**, a leading group of private practice optometrists. Under the terms of the Alliance UltraVision will supply a full line of exclusive, privately labeled contact lens and lens care products to Vision Corporation, Vision Source, and several other associated managed care groups. Both Vision Corporation and Vision Source are subsidiaries of **TLC The Laser Center**. Paul-Michael Hawkins, president of Vision Corporation, said his company's internet-based, doctor-supported patient fulfillment program "can easily be utilized with other doctor/patient care networks throughout the industry. Furthermore, our unique marketing strategy will drive additional laser vision correction patients to our associated doctor network."

9/28 **VISX** announced that the "millionth" VISX laser eye procedure would take place on October 7th, and would be broadcast over the internet via Yahoo!.

9/29 Al Kildani of **Pacific Growth Equities** released an updated report on **TLC The Laser Center**. The report centered on a survey that he had conducted on pricing at hundreds of refractive surgery clinics and physician offices across the country, compared to a similar survey conducted in January. He found that pricing remained stable, and in fact many centers had raised prices. He concluded that he saw no imminent collapse in pricing and remained comfortable with his modeled price decline over time.

The current average at refractive centers for LASIK was $2176 versus $2180 reported in January. Further, over 79% of providers charged a global fee of $2000 or greater, almost 15% charged over $2500. Fees ran between $1926 in the southwest to $2462 charged in the mid-Atlantic, followed by $2378 charged in the northeast (where TLC centers were strong). He also found that there were pockets of discounting, but only under unique circumstances, i.e., surgeons charging $1500 were relatively inexperienced, and usually had performed less than 1000 procedures. Second, a number of lower-priced providers were using the **Nidek** laser, and were not currently charging the extra $250 royalty fee. Certain geographic regions, including Michigan, Washington state and Arizona had some softness in pricing -- Michigan and Washington state residents can easily travel to Canada to take advantage of the favorable exchange rate, while Arizona doctors continue to be price leaders due to what Kildani perceived to be a lack of corporate centers. He is forecasting a gradual decline in pricing over time, with, in TLC's case, an assumption of a 2% quarterly sequential decline in that company's ASPs (net revenues after doctor compensation). With the U.S. market at an average price of $2176, he believes that TLC will not have to change its pricing structure significantly in the near future.

9/30-
10/1 **Nidek Inc.** announced that its EC-5000 excimer laser system won premarket application supplement approval from the FDA for the PRK treatment of moderate myopia with astigmatism. The expanded indication for the device will allow the correction of myopia from -1 D to -8 D, with astigmatism from -0.5 to -4 D cylinder by manifest refraction. The laser system is already approved for the reduction and elimination of myopia in the low, moderate, and high ranges (from -0.75 to -13.00 D) diopters, using PRK. Hiroshi Okada, vice president and general manager of Nidek said, "This new approval enables physicians to expand current applications of the Nidek EC-5000. What this means is that doctors can now provide more treatment therapies for nearsighted patients in their practices."

The company also announced that its MK-2000 Keratome System was granted 510(k) clearance. The microkeratome is fully automated and has single-hand-operation design. Okada said, "The Nidek MK-2000 Keratome System is one component of both our multi-product offering, and our comprehensive commitment to ophthalmic and refractive solutions; and this FDA clearance is an important step in our continued commitment."

10/4 **Sight Resource** and **Laser Vision Centers** announced the signing of a definitive agreement to offer excimer laser correction and other refractive surgical procedures through Sight Resource's network of 130 primary eye care centers. Utilizing their combined experience and expertise, the two companies expect to begin offering excimer laser correction services in the Michigan market in November, and in the Massachusetts and Rhode Island markets by year-end. Similar programs will be rolled out in other Sight Resource markets in early 2000.

Sight Resource believes that the new agreement provides the best method for expanding its refractive surgical services business to its loyal base of customers throughout the eastern United States. Sight Resource primary eye care centers see approximately 320,000 customers annually. The company's existing excimer laser correction business is predominantly based in the Boston and Providence markets. The company believes that the aggressive expansion opportunities made possible as a result of its new relationship with LaserVision, could increase excimer laser correction revenue to more than $5 million in 2000.

The companys' initial efforts will focus on the Michigan market, where Sight Resource's **Kent Optical** chain operates 28 locations. A significant marketing program will begin in October. Treatment of patients is expected to begin in early November. Training of store personnel, development and placement of point-of-purchase promotional materials and other business development activities will begin immediately. Treatments will be provided by ophthalmologists with whom LaserVision has established contractual agreements for providing excimer laser access. Concurrent with their efforts in Michigan, the companies will begin the planning and development of a similar business venture in the New England market. Through its **Cambridge Eye Doctors** and **Vision World** chains, Sight Resource operates 30 primary eye care centers in the region, primarily in the Boston and Providence markets. Treatment of patients is expected to begin in late December. Sight Resource has offered excimer laser correction services in these markets since 1995.

10/4 **Bausch & Lomb Surgical** announced that it had received FDA clearance to market its Keracor 116 excimer laser system. The Keracor 116 was approved for PRK to treat between -1.50 and -7.00 diopters of myopia, as well as up to -4.50 diopters of astigmatism. However, the company has no plans to market the Keracor 116 in the United States, said Hakan Edstrom, senior vice president for Bausch & Lomb and president of the surgical and pharmaceutical divisions. The use of the 116 will be limited to the Investigational Device Exemption users originally recruited to perform the clinical studies. "We are pleased with the FDA's decision to grant marketing clearance to the 116, but it is Bausch & Lomb's intent to focus its efforts on securing approval of the Technolas 217 and marketing the advanced laser system in the U.S.," said Edstrom. "This strategy makes sense given the growing number of LASIK procedures and the fact that the 217 is the only laser specifically designed for the specialized procedure. Our plans anticipate the introduction of the Technolas 217 into the U.S. market by the end of this year." As previously stated, Bausch & Lomb believes that an Ophthalmic Devices Panel review of the Technolas 217 will not be necessary.

The Technolas 217 is a true scanning, flying-spot laser which means that the small, fixed beam is delivered to specific, non-overlapping locations on the cornea with each pulse of laser energy. This creates a much more uniform treatment area. (Compared to the wide-area fixed beam of the Keracor 116 system.) According to Bausch & Lomb,

the Technolas 217 combined with the Hansatome microkeratome and the Orbscan II multi-dimensional diagnostic system will provide surgeons with a total approach to refractive surgery. The company further noted that it had an installed base of 431 Technolas 217 laser systems worldwide.

10/4 **LCA-Vision** reported that procedure volume for the three months ended September 30, 1999 at the company's Baltimore and Annapolis, Maryland centers increased 152% compared with the three months ended September 30, 1998, and increased 38% compared with the three months ended June 30, 1999. Third quarter 1999 same-center procedure volume for the company's 21 U.S. and Canadian centers increased 51% to 8,769 procedures, compared with 5,818 procedures for the comparable 1998 period. Nine-month 1999 same center procedure volume increased 77% to 27,107 procedures, compared with 15,283 procedures for the 1998 nine-month period.

The company's plan for growth is to increase utilization of existing capacity and to expand its geographic presence. Based on initial successes, LCA-Vision will expand the testing of the LasikPlus model to its California markets beginning in October. The company will continue testing the "value pricing" model pending positive consumer reaction and favorable business results. To establish LasikPlus in new markets, marketing expenses are elevated in the short term. After a period of high-impact advertising and marketing programs, the expenditures are expected to return to traditional levels. Commenting on the LasikPlus "value pricing" model being tested in the Maryland markets, Stephen Joffe, chairman and CEO, stated, "Our initial test has proven to be very successful. In the 10 weeks since we introduced LasikPlus in Maryland, the program has exceeded our most aggressive expectations and accounted for the highest center procedure volume in the quarter. While our per procedure contribution margin was comparable to that under our `open access' model, more importantly we have maintained clinical outcomes and patient satisfaction. These results support our belief that `value pricing' expands the market because it lowers the affordability bar."

The company also announced that it had completed physician enrollment in its National Lasik Network, a network of laser vision correction providers formed to support the company's recently announced agreement with **Cole National Corporation**. "We are ready to begin bringing the benefit of laser vision correction surgery to the 50 million **Cole Managed Vision** members beginning January 2000," said Joffe.

10/4 **CIBA Vision Corporation**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics Inc.** announced that a key advisory subcommittee of the FDA, the Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee, will convene on November 17, 1999, to review the companies' recent NDA, filed by the companies on August 16, for marketing clearance for Visudyne therapy for the treatment of wet age-related macular degeneration (AMD). As previously announced, the FDA had assigned priority review status to the NDA for

Visudyne therapy, indicating that the regulatory agency will act on the application within six months of the August filing date. Pending regulatory approval, CIBA Vision and QLT expect Visudyne therapy will be available in the U.S. in early 2000.

10/4 **NovaMed Eyecare, Inc.** announced that its LVC procedure volume for the third quarter ended September 30, 1999 totaled 3,615. This represents an annual run rate of 14,400 LVC procedures. The 1999 third quarter procedures increased 135% over the 1,536 LVC procedures performed in the third quarter of 1998 and sequentially increased 33% over the second quarter of 1999, when 2,718 LVC procedures were performed. For the nine month period, NovaMed's LVC procedure volume was 8,765, up almost 160% from 3,387 in the 1998 comparable period. "We are pleased to report continued strong growth in LVC procedures," said Stephen Winjum, chairman, president and CEO of NovaMed. "Most of this LVC procedure growth occurred in our five regional markets where we are leveraging our existing market positions. We expect strong LVC procedure growth to continue in the fourth quarter." The company also announced that it will report its financial results for the three and nine-month periods ending September 30, 1999 on Wednesday, October 20, at which time it will comment further on the LVC procedure growth.

10/4 **Refractec, Inc.** announced that it had initiated numerous international Post-Marketing Studies using Conductive Keratoplasty (CK) to treat hyperopia, presbyopia, astigmatism and retreatment of patients with prior alternative refractive procedures. These trials are being conducted in international markets where the device has regulatory approval or clearance including: Australia with Dr. Michael Lawless, and Dr. Ronald Stasiuk; in Canada with Dr. Raymond Stein, Dr. Harold Stein, Dr. Albert Cheskes, and Dr. Howard Gimbel; in Ireland with Dr. Patrick Condon; in the United Kingdom with Dr. Emanuel Rosen; in Brazil with Dr. Mauro Campos; and in Argentina with Dr. Carlos Argento. "Conductive Keratoplasty treatment for hyperopia is a novel technique, using straightforward equipment," said Dr. Raymond Stein after his first cases last week. "At the Bochner Eye Institute in Toronto, we are carefully evaluating this modality comparing outcomes and safety profiles to other accepted refractive procedures."

Mitchell Campbell, president and CEO of Refractec stated, "I am excited to have these renowned surgeons participating in our international trials. We anticipate that the findings will be similar to those seen in our U.S. and other international studies."

10/4 *The Wall Street Transcript* has published two analyst reports as part of a special 203 page edition produced for the **Warburg Dillon Read LLC** "Global Life Sciences Conference". The report features interviews with five analysts plus CEOs or top management from 58 companies. (The only management interviews of those involved in refractive vision care are with **LaserVision Centers** and **Summit Technology** and **Wesley Jessen** and **CooperVision** about contact lenses.) The two analyst reports are Emil Westergaard's *Global Medical Technology* overview, and Rebecca Irwin's *Vision Care Industry* report. In the latter, Rebecca discusses the latest products and

technologies, the growth of refractive surgery, the next wave of back-of-the-eye developments and drug delivery techniques for treating diseases, including ARMD.

In the refractive surgery section, she discusses **VISX**, and its market leading share, but also competing products from companies such as **KeraVision** and **Staar Surgical**. She also takes note of the pricing pressure on practitioners and corporations servicing the market. In the drug section, she discusses **QLT's** and **CIBA Vision's** trials of PDT for ARMD, and **Bausch & Lomb's** drug delivery system, Vitasert, also for treating ARMD.

10/5 **IRIDEX Corporation** announced the results of a clinical study published in the October issue of *Ophthalmology*, the *Journal of the American Academy of Ophthalmology* which holds the promise for an effective treatment for the vast majority of patients with wet Age-Related Macular Degeneration (AMD). The study, performed by Dr. Elias Reichel and colleagues at the **New England Eye Center**, **Tufts University School of Medicine** in Boston, used Transpupillary Thermotherapy (TTT) to treat patients with subfoveal occult wet AMD. The TTT treatment was effective in improving or stabilizing vision in 75% of eyes and in decreasing subretinal fluid in 94% of eyes. Over 70% of patients with wet AMD have the occult type for which there is no proven therapy.

In the retrospective clinical study, 16 eyes of 15 patients with subfoveal occult wet AMD were treated with IRIDEX's **IRIS Medical** OcuLight SLx 810 nm diode laser photocoagulator in its unique LongPulse operating mode using a TTT protocol and followed over a period of 6 to 25 (mean 13) months. The results demonstrated that TTT was effective in improving vision by two or more Snellen lines in 3 treated eyes (19%) and stabilizing vision in another 9 eyes (56%). Four eyes (25%) declined in vision, defined as a one line or more worsening in visual acuity. Fifteen eyes (94%) demonstrated a reduction in subretinal fluid (exudation) confirmed by angiography and optical coherence tomography (OCT).

"We are pleased with the outcome of this study," commented Dr. Reichel, Assistant Professor of Ophthalmology at the New England Eye Center. "We undertook the study because we were encouraged by the good results that have been obtained using TTT to treat other choroidal lesions, such as choroidal melanomas, and observed the similarities between choroidal tumors and occult choroidal neovascularization (CNV) secondary to AMD. There has been no treatment for patients with occult CNV who comprise the majority of patients with wet AMD. Even new treatments like photodynamic therapy (PDT) have not yet been shown to be effective for occult CNV making a positive outcome for this preliminary study particularly satisfying. The minimally invasive treatment did not produce any clinical or angiographic evidence of retinal damage yet was adequate to produce a favorable therapeutic outcome in terms of CNV closure, reduction of exudation and improvement or stabilization of visual acuity. This treatment appears to produce localized hyperthermia which causes the choroidal vessels that supply the CNV to close, thus reducing the blood supply to the

CNV."

"I believe this paper will be considered a milestone in the treatment of wet AMD," commented Giorgio Dorin, Director of Clinical Applications Development at IRIDEX. "Hyperthermia is a natural healing mechanism and closure of the choroidal vessels during high fever has been reported in the literature. The possibility of inducing localized hyperthermia to close CNV without damaging the overlying central retina and without the use of exogenous agents such as those used in photodynamic therapy (PDT), may mark a turning point in the management of patients with occult CNV secondary to AMD. A follow-up prospective, randomized, sham-controlled trial is currently in preparation to solidify the role of TTT in the treatment of occult CNV membranes secondary to AMD."

Ted Boutacoff, president & CEO of IRIDEX, commented, "This has been a very good year for AMD research. Recently there has been an increased awareness on new treatments for AMD mainly stemming from the very favorable results from the photodynamic therapy (PDT) clinical trials, which has demonstrated effectiveness in treating predominately classic wet AMD. It now appears that TTT will be able to effectively treat occult wet AMD, which accounts for 70% of wet AMD cases. Thus, PDT and TTT appear to be complementary. The beneficiary will be the patient with AMD. TTT for the treatment of subfoveal occult CNV is only one of five approaches IRIDEX is investigating to treat AMD - two approaches are directed at treating the dry form while three approaches are directed at treating the wet form. Therefore, unlike most companies who are developing a single magic bullet to treat a specific stage of AMD, IRIDEX is developing a number of applications to treat AMD at various stages."

10/5 **Lasik Vision** announced that 12,929 paid laser procedures were performed at the company's refractive centres during the company's fiscal third quarter. These procedures represent a 501% increase compared to the same period in 1998, and a 45% increase from the 8,906 procedures performed in the second quarter of 1999. The procedures were performed at 11 Lasik Vision clinics in Canada. Of the 11 centres operating in the third quarter, two were opened during the quarter.

"Lasik Vision's momentum from procedural volume increases and centre openings continued in the third quarter, allowing us to gain more dominant share in key markets. As one of the laser vision correction industry's fastest growing companies, Lasik Vision expects to achieve profitability in this quarter and the fourth quarter of 1999 as the company continues to expand in Canada and the U.S.," said Michael Henderson, President and CEO.

10/5 According to *Ocular Surgery News* (online), as will be reported in its October 15th issue, a case has been reported of cataract formation following implantation of an implantable contact lens (ICL), produced by **STAAR Surgical**, in a high myope, as a late-onset complication.

10/6 Taking advantage of the October 11th cover story on refractive surgery that ran in *Time* magazine, which stated that LASIK could well become the most popular elective surgery among "baby boomers" since they had their tonsils removed in the 1950s. Because of the LASIK complication rates running up to 5%, and 10% to 15% needing "enhancement", **Ciba Vision** put out a news release touting its one-day disposable contact lenses as an alternative. According to Dr. Judson Briggs, an optometrist in Atlanta, many people seeking laser vision correction have had negative experiences with their contact lenses, due to discomfort or the hassle of lens care. "I would encourage people considering surgery to first try the new, improved contact lens options now available. As contacts become better and better, they provide a viable alternative for patients who are nervous about having surgery, or who can't afford the $2500 per eye price tag," said Dr. Briggs. "The convenience of one-day disposable lenses is making this category increasingly popular...Since wearers of one-day lenses put in a fresh pair every morning and discard them at night, they never have to clean their lenses or buy lens care products."

10/7 **Lasik Vision Corporation** announced that it had negotiated, subject to regulatory acceptance, a private placement of up to 660,000 Units at a price of $3.27 per Unit. Each Unit will consist of one common share and one half of one share purchase warrant. Each whole share purchase warrant will entitle the holder thereof to purchase one additional common share for a period of two years at a price of $3.50 per share if exercised in the first year or at a price of $4.00 per share if exercised in the second year. There is no finder's fee payable in connection with this proposed transaction. The proceeds will be used for general working capital purposes.

The company further announced it had granted options to acquire up to 297,000 common shares to employees of Lasik Vision and to the Company's directors and officers at an exercise price of $4.00 per share under the terms of the Company's stock option plan.

The company operates 14 clinics in Canada and, through its U.S. subsidiary, **Lasik Vision U.S.A.**, it operates a clinic in Bellevue, WA.

10/7 **VISX** announced that the millionth laser vision correction using its lasers had been performed by Dr. Debra DiStefano of Chattanooga, TN.

10/7 **VisionAmerica Incorporated (formerly Omega Health Systems Inc.)** announced that eight of its surgeons had completed the training for **KeraVision** Intacs corneal ring segments and will begin performing the procedure at VisionAmerica centers in the near future. An additional group of surgeons will be trained on the procedure during November. "We are excited to be able to offer KeraVision's Intacs at a number of our centers across the country," commented Thomas Lewis, president and CEO of VisionAmerica Incorporated. "This procedure will complement our strong laser vision correction program which currently utilizes **VISX** STAR S2 excimer lasers at 22 sites across the country, and it will offer patients yet another alternative to traditional vision

correction. In several markets, we will be the first to offer this procedure. We want to ensure that the surgeons who practice at VisionAmerica centers are at the forefront of advances in new technology and KeraVision Intacs provides another exciting opportunity."

10/7 **TLC The Laser Center** announced its results for its fiscal first quarter ended August 31, 1999. Results were characterized by continuing record revenues and profitability. All were driven primarily by strong growth in the number of refractive laser procedures performed. Fiscal 2000 first quarter net revenues grew to $52 million, up 80% from $29 million for the same period a year ago. Refractive net revenue grew to $50 million, up 90% from $23.8 million for the same period a year ago. Income from operations for the quarter was $10.2 million (27 cents per share), representing a 662% increase from $1.3 million (4 cents per share) for the fiscal 1999 comparative quarter. TLC's net profit for the quarter was $6.3 million (17 cents per share), up from $0.4 million (1 cent per share) for the corresponding period a year ago.

Over 33,200 paid laser procedures were performed at TLC refractive centers in the first quarter of fiscal 2000 which is an 87% increase from 17,781 for the same period a year ago. Pricing for the procedure remains strong. On September 2nd, the company announced that, based on preliminary analysis of Q1-00 financial results, it expected average refractive net revenue after doctor compensation per procedure for the quarter to exceed $1,320. Actual average refractive net revenue after doctor compensation per procedure for the fiscal 2000 first quarter was $1,368. This compares to an average of $1,338 for the same period a year ago and up from $1,288 for the previous quarter.

Elias Vamvakas, TLC's president & CEO, commented that the company "was very pleased with its first quarter results. This quarter clearly demonstrates the strength of TLC's business model and the financial leverage associated with it. Indeed, operating income from this quarter alone matched operating income achieved for the entire fiscal 1999 year."

Some comments garnered during the accompanying teleconference with analysts noted that the company's Advantage Program was exceeding expectations. In addition to Kaiser and Vision Service Plan, two other smaller healthcare providers had signed on, and the corporate program now involved 362 corporations with over 900,000 employees. Commenting on the alleged pricing pressures on the business, Elias Vamvakes said that his company had not been affected. Prices were holding steady, even in markets where there was head-to-head competition with discount centers. The only place that TLC was seeing price cutting was in Canada and in a few other areas, such as in Baltimore. But that its 55 centers were holding their prices and were not really affected. TLC expected to open three additional centers in the current quarter, in Milwaukee, Minneapolis, and in Sacramento, CA. Vamvakes said his centers were still running at between 35% to 40% of capacity, and when a center got to better than 300 to 400 procedures per month, the company looked to open another center nearby to take care of the need. TLC is trying to accommodate any patient that wants the

procedure within two weeks of making that desire known. TLC has identified 60 major North American market and now has clinics in at least 30-32 of these. As for international expansion, the company is still formulating its plans and has held discussions with interested partners.

The following day, Al Kildanin of **Pacific Growth Equities** released an updated report on the company, reiteritaing his "strong buy" recommendation, as both the revenue and per procedure net revenue after doctor compensation results exceeded his expectations.

10/8 **Sterling Vision** announced that, based upon its financial results for the months of July and August, 1999, it expects continued profitability for the third quarter of 1999. Dr. Robert Cohen, chairman of the board, stated, "The company attributes its continued profitability to the initiatives taken by its new management team, which continues to implement aggressive cost controls and new marketing strategies, as well as the continued profitability of its **Insight Laser Center** subsidiary."

10/11 **Refractec Inc.** clinical investigators are scheduled to release a scientific summary of clinical results for the first 54 subjects enrolled in the company's U.S. Phase III IDE study of Conductive Keratoplasty for hyperopic vision correction. Robert Maloney, MD and Edward Manche, MD will present their Conductive Keratoplasty data at the 1999 Fall World Refractive Surgery Symposium (WRSS) in Orlando, FL. Conductive Keratoplasty preliminary data demonstrates six-month post-op uncorrected visual acuity (UCVA) of 56% 20/20 or better and 88% 20/40 or better. Mitchell Campbell, president and CEO of Refractec stated, "Early data demonstrate visual stability in the three- to six-month time frame. We are actually seeing less regression than that reported by VISX in their FDA-approved submission for the treatment of hyperopia." Refractec is currently conducting Phase III clinical trials in the Untied States for Conductive Keratoplasty (CK), a minimally invasive non-laser approach for correcting low to moderate hyperopia.

10/12 In this month's issue of *Refractive Market Perspectives*, Dave Harmon writes about the corporate contracting that looms on the horizon -- such as the program undertaken by **TLC**, and also noted above. As he puts it, "certainly the rest of the industry is not standing still as all major laser center management companies have some programs underway designed to make sure that they have a future share of the market". He notes that the TLC/VSP plan, that covers about 25 million lives, will allow participants to go to a TLC center and get LASIK for about a 25% discount, or about $1800 per eye. But, because of VSP's size, it will allow other laser centers that are in its eye care network, that meet its credentialing requirements to offer the same deal. But TLC will have a marketing advantage.

Harmon also announced the results of his annual survey of refractive surgeons' pricing. The weighted average, based on surgical volume of the over 300 respondents was $2157, as compared to $2180 in a similar survey conducted in 1998. Thus, the

decline in pricing was only minimal.

Another story of interest concerned the ongoing battle between **Bausch & Lomb** and **Moria** over the microkeratome patent rights. Apparently, more than one patent is involved: the Helkamp patent is being contested in the U.S., while the Ruiz patent is under fire in France.

10/12 **OptiCare Health Systems, Inc.** announced that it had signed a letter of intent to open a Laser Vision Correction site in Rocky Mount, North Carolina. The terms of the proposed transaction were not disclosed. Commenting on the expansion, Dean Yimoyines, MD, president and CEO of OptiCare stated, "This opening would be another step in our plan to expand into the growing LVC market, which is estimated to reach 900,000 procedures by the end of 1999. The opening of new laser surgery centers is consistent both with our business model to provide services and systems to the eye health industry and with our growth strategy to expand our services in the rapidly expanding LVC market. Based on our success in the Connecticut market providing services to ophthalmologists specializing in LVC procedures, we believe that this will be a high growth market for the company." OptiCare intends to open additional LVC sites in the U.S., and will continue to play a role in providing services for these refractive sites to meet the demands of the LVC market.

OptiCare Health Systems, Inc. is an integrated eye health services company that delivers a range of services and systems for eye health professionals, managed care plans and consumers, including laser vision correction. The company was created this year by a merger of **Saratoga Resources, Inc.**, **OptiCare Eye Health Centers, Inc.** and **Prime Vision Health, Inc.** On a pro forma combined basis, OptiCare Health Systems had revenues of approximately $104 million for the year ended December 31, 1998 and approximately $30 million for the first quarter ended March 31, 1999.

10/13 **Laser Vision Centers** announced that its U.S. case volume for the month of September increased 93% compared to the same month a year ago. The company operated a total of 55 lasers in the U.S. during September 1999.

10/13 **VISX** announced financial results for the third quarter, with revenues of $79.7 million compared to $35.8 million for the comparable period of the prior year. Net income was $24.7 million (36 cents per share) compared to net income of $14.7 million (22 cents per share), in the comparable period of the prior year. Revenue for the nine-month period was $196.1 million compared to $91.8 million for last year. Net income was $66 million (97 cents per share) compared to net income of $8.4 million (13 cents per share) in the comparable period of the prior year.

Commenting on the quarterly results, Mark Logan, chairman and CEO, said, "The record revenues and earnings in the third quarter, combined with the one-millionth VISX procedure in the United States, demonstrates the strength of VISX's unique business model. Because VISX grows as a result of increased procedure volume at

our customers' sites, this model aligns our clinical and financial incentives with those of our customers and the consumer."

During the accompanying teleconference with analysts, Logan said that the company shipped 90 laser systems during the third quarter, for a total of 202 for the year. Of the 90 Star S2s, 69 were shipped domestically, and the remainder internationally, bringing the totals to 435 installed systems in the U.S. and 360 internationally, for a grand total of 795 laser systems around the world. The average selling price increased during the quarter, but was down somewhat from a year ago, due to multiple placements and volume discounts. He expects the company to ship about the same number of laser systems in the fourth quarter. He also mentioned that the company had now trained and certified 4000 physicians on its laser equipment. There was no news to report on the patent re-examination front, nor on the ITC investigation, with the preliminary judgement still expected on December 1st. He also had no comments on any possible negotiations with **Bausch & Lomb**.

In an important announcement, Liz Davila, COO, mentioned that the company was about to announce an alliance with a German company, **20/10 Perfect Vision**, who was developing wavefront technology to couple with the VISX lasers. Initially, this equipment would be used to obtain a better measurement of refractive error, but possibly could also be coupled to the laser to obtain custom ablations. Liz noted that VISX was funding development of the wavefront technology and had an exclusive on what would be developed. (More information about this new technology will be presented at a briefing to be held prior to the AAO meeting later this month. I plan to attend and report on it following the AAO. In the invitation that arrived the next day, it was revealed that the founder of 20/10 Perfect Vision is none other than old friend Josef Bille, founder of the former **Intelligent Surgical Laser (ISL)**, developer of the picosecond intrastromal laser system.)

Prior to the VISX financial release, Craig Schneider of **Individual Investor Online** released an industry analysis, expecting VISX to report strong third quarter results. He had quotes from several analysts following the company, including Ted Huber of **Advest** and Kate Sharadin of **Preferred Capital**. Huber said, "I think they'll come in a penny or two ahead of that," referring to the Street's consensus of 32 cents a share. He also expected VISX to place 80 new lasers worldwide (up from 61 in the June period) and strong volume growth of its largest customers to bode well for the company. (As reported, they did better on all counts.) In reference to the upcoming ITC ruling and Bausch & Lomb and **LaserSight's** entrance into laser refractive surgery, Sharadin noted that she expected VISX will be forced to lower its royalties to a range of $200-$225 per procedure just from negotiating with Bausch & Lomb and LaserSight, regardless of the outcome of the trial.

Following the release, both **CBS MarketWatch** and **Motley Fool** both chimed in with short reviews. MarketWatch headlined, "The view wasn't clear for Visx Inc. Thursday despite the fact that the medical laser maker posted better than expected third quarter

results and analyst comments were mostly favorable.", while Motley Fool said, "With VISX's impressive momentum, execution, and leading market position, the future looks bright; so bright, investors might wanna wear shades. Preferably -- to VISX -- shades without corrective lenses." And Wade King of **Robertson Stephens** raised his earnings estimates "due to the strength in the quarter...raising our fiscal 1999 and 2000 earning per share from $1.33 to $1.36, and from $1.82 to $1.85. Despite all of the upside exaltations, the stock price dropped over $8 to finish at $71.25.

10/14 **LaserSight** announced that clinical validation of the UniShaper single-use keratome had been completed. Clinical validation was the final step to commercial release of the instrument. The UniShaper had previously received FDA clearance for U.S. distribution. The product is being released for manufacturing, along with a purchase order to the manufacturer, **Frantz Medical Development, Ltd.**, to produce units for November 1999 delivery. The UniShaper single-use keratome is the second product in LaserSight's MicroShape family of keratome products to be released to commercial production. In July 1999, the company announced shipment of its UltraEdge keratome blades manufactured under its agreement with Becton Dickinson.

As previously announced during August 1999, the company successfully completed the FDA's Quality System Regulation/ Good Manufacturing Practices (QSR/GMP) audit for its LaserScan LSX excimer laser system. The company is working closely with the FDA to finalize labeling which is the last step remaining before being approved to market in the U.S.

10/14 For the first time in any leading peer-review medical journal, the October issue of *Archives of Ophthalmology* published extensive positive results from Phase III clinical trials involving Visudyne (verteporfin for injection) therapy to treat the wet form of age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50 in the western world. The overall results of the study report that Visudyne therapy reduces the risk of vision loss, compared to a placebo, during the first year of the study in patients with the wet form of AMD. The comprehensive analysis reveals that Visudyne therapy shows beneficial effects in the total study population. Additionally, the data shows that a subgroup of patients whose lesions were characterized by a specific, more aggressive, disease pattern experienced a large, clinically relevant benefit.

Regulatory applications, based on the data, requesting marketing clearance for Visudyne therapy have recently been submitted to the US FDA, as well as boards of health in the European Union, Switzerland, Australia, and New Zealand. In the United States, Switzerland, Australia and New Zealand, the applications have been granted accelerated review status.

Visudyne therapy is being co-developed for various ocular conditions by **CIBA Vision Corporation**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics Inc.** Upon commercialization, CIBA Vision will market the product worldwide while QLT

will be responsible for manufacturing Visudyne. Pending regulatory approval, the companies hope to make Visudyne therapy commercially available by early 2000. Visudyne therapy involves the use of a specifically designed laser that produces the low level, non-thermal 689 nm light required to activate the drug. These lasers have been developed by two of the world's leading laser companies, **Coherent Inc.** and **The Carl Zeiss Group**, based in Germany.

10/14 **Bausch & Lomb** announced that revenues from continuing businesses for the third quarter, were $446.3 million, up 11% from the $403.1 million reported in the third quarter of 1998. Excluding gains recorded in the current period on the sale of its remaining non-strategic businesses, and a non-recurring gain on the redemption of certain investments, the company reported net earnings for the third quarter of 1999 of $45.8 million (78 cents per share) compared to $36.2 million (64 cents per share) in the same period last year. Continuing operations, consisting of the company's vision care and pharmaceuticals/surgical segments, contributed $37.3 million (64 cents per share) to these results in the third quarter of 1999, compared to $33.7 million (60 cents per share) in the third quarter of 1998. Net earnings in the third quarter of 1999 were augmented by gains of $170.7 million after taxes ($2.90 per share) from the sale of **Charles River Laboratories** and $11.2 million after taxes (19 cents per share) from the sale of the **Miracle-Ear** hearing aid business. Additionally, during the quarter the company realized a pre-tax gain of $6.7 million from the redemption of securities received as part of the 1995 divestiture of the sports optics business. This gain represented 7 cents per share after taxes. Including these items, the company reported net earnings of $231.8 million ($3.94 per share) in the third quarter of 1999.

Revenues from the company's pharmaceuticals and surgical businesses grew 20% over the third quarter last year. Pharmaceutical sales grew 29%, benefiting from price increases in non-ophthalmic generic products. Sales of surgical products increased 14% from last year, driven by continued strong double-digit growth in sales of products for refractive surgery.

During the accompanying teleconference for the media, Bill Carpenter chairman and CEO noted that refractive surgery remains strong, with an anticipated 1 million procedures in the U.S. this year, and an additional 1.5 to 1.6 million globally. In discussing the Moria lawsuits, he said that the company intends to protect its intellectual property, but did allow that different patents were involved in both the U.S. and in France. (See the 10/12 Refractive Market Perspective brief above.) Commenting about wavefront technology for coupling to its Technolas 217 platform, he said that the company already has an aberrometer in clinical trials which could be used with the Orbscan to accomplish the task. (I will find out more about this at the upcoming AAO meeting.) (Bausch has about 10 or 11 Technolas 116s, which was recently FDA approved, in operation in the U.S., and 8 Technolas 217s in the U.S., conducting clinical trials, with an additional 423 217s installed and operating worldwide.)

10/15 The Albany, NY *Times Union* carried a story about **LCA Vision Centers** cutting the price of laser eye surgery at their **LasikPlus** centers in Maryland and California centers (to $2995) in response to growing competition from cheaper Canadian providers (?), but that the company had no plans to lower the price in their Albany center, even though the $5000 surgery in the states is only $1600 in Montreal. At its Toronto center, however, the price has been lowered to $2025, to compete with **LASIK Vision** centers' $1600.

10/15 **Summit Technology** announced that Marguerite McDonald, MD had performed the first customized laser vision corrections in the United States using the **Autonomous** LADARVision system and proprietary CustomCornea wavefront measurement technology. In July, Autonomous was granted an IDE by the FDA to begin clinical trials of its CustomCornea wavefront technology on nearsighted, farsighted and astigmatic patients using both PRK and LASIK. The investigational procedure was performed in connection with these clinical trials. CustomCornea is the first wavefront measurement device of its kind to begin clinical studies in the United States and Dr. McDonald's investigational procedures mark the first human surgeries performed using this technology. (Recall that Dr. McDonald also performed the first sighted human PRK procedure in the States.)

By using the CustomCornea wavefront sensing measurement device developed by Autonomous, Dr. McDonald was able to objectively measure the unique optical aberrations in each patient's eyes and treat the patient with a customized ablation pattern to reshape the cornea. The customized ablation was applied to the cornea using the Autonomous LADARVision System. LADARVision is currently the only FDA approved laser vision correction system to utilize a narrow beam scanning laser and a sophisticated eye-tracker, which compensates for involuntary eye movement during the surgery. Customized ablations are intended to improve the outcome of laser vision correction surgery.

The five patients treated underwent LASIK surgery this week for the correction of nearsightedness. Commenting after the surgery, Dr. McDonald stated, "Today is a watershed moment in laser refractive surgery. This is probably as important a milestone as the development of laser surgery, it is that much of an improvement on current technology." (Initial clinical results from the IDE study will be announced October 23rd, 1999, at a special session of the International Society of Refractive Surgeons in Orlando, Florida.)

10/18 According to this week's *EyeWorld Week*, **Presby Corp.** said that it had signed a letter of intent for a strategic alliance with the **Clear Vision Laser Centers Inc.** chain, in which Clear Vision "may make a significant investment" in Presby Corp.'s kits for the surgical treatment of presbyopia (including diamond blades and scleral expansion bands), and will become the exclusive distributor of the kits in the United States, as well as some international markets. Clear Vision may also assume responsibility for training physicians and technicians to implant the expansion bands.

10/18 **Paradigm Medical Industries** announced that it would acquire the assets of **Mentor's Ophthalmics Phaco Cataract Removal Division** in a stock swap transaction valued at $1.5 million. Thomas Motter, Paradigm chairman and CEO, said, "This transaction expands our installed user base by 180 sites and adds $400,000 annually in disposables generated revenue. At the same time, it provides Paradigm with a more competitive, entry level line extension to its Cataract Removal Systems Product Line which will facilitate easier transition and entry into the **Paradigm Pharmacia & Upjohn Alliance's** Cataract Surgery Programs. In addition, Paradigm will receive forty of Mentor's CE Marked cataract removal systems with a retail value in excess of $1 Million which can be sold into the European market immediately, as part of the $1.5 Million in inventory and equipment that adds to the company's balance sheet upon completion of this transaction." He went on to note that current ophthalmic surgeons, hospitals and surgical centers, who had expressed concern over Mentor's departure from eye care, should be pleased to learn they will now have the support of the Paradigm Pharmacia & Upjohn Alliance whose financial resources exceed those of the other 3 industry leaders combined.

10/18 Distressed by all the bad calls against the Boston Red Sox during the divisional playoff series, Dr. Carmen Puliafito, Director of **New England Eye Center** and chairman of the **LASIK Institute**, is offering umpires free Red Sox champion season eye care -- including thorough eye examinations, prescription lenses, and even laser eye surgery. "The Umpires have created a crisis, and emergency actions are needed. I'm willing to give away services at both the Wellesley and Boston locations to ensure the Sox get a fair shot at the World Series. I said it before for [the June 14th issue of] *Sports Illustrated*, and I'll say it again now, if there's any segment of the population who can benefit from laser vision correction, it's umpires," Dr. Puliafito declares. "We have conducted the research studies to prove that laser vision correction works, and now it's time to reach those who need surgery most."

10/19 *The San Francisco Examiner* carried a story about cut-rate LASIK, entitled, "Cheaper vision surgery popular", discussing the fact that lower prices are prompting thousands of San Franciscans and others to seek the deep-discount prices available in Canada. As writer Ylysses Torassa put it, "Nearsighted Americans, many from the Bay Area, are flocking to a chain of Canadian clinics that offer the procedure on both eyes for $1,598, about a third less than most U.S. surgeons charge. This summer the clinics offered a special, $999 for both eyes. The company, **Lasik Vision Canada**, says it plans to open an office in San Francisco in the next several months. Another chain of laser eye surgery centers with two Bay Area locations (**LCA Vision's LasikPlus** centers) just sliced $1,500 off its former price of $4,500 for surgery on both eyes, and says it's getting three times as many calls and appointments as before. Other surgery centers, like **LaserVue**, offer discounts to groups such as firefighters and police officers. More lower-price options are expected, and consumers could be the ultimate winners."

As previously reported in this newsletter, Al Kildani, of **Pacific Growth Equities**, who

conducted a survey of the laser surgery market, said prices have dipped somewhat in states where competition from the Canadians is nearby, but he doesn't expect much of a price war if Lasik Vision comes to San Francisco. "As far as I know, the doctors in this area are doing a brisk business," he said. "There are always going to be certain people who will want to go to the low-end provider, but other people are going to realize at the end of the day this is still a surgical procedure, where price is only one of many other, more crucial factors." Also interviewed, David Harmon, senior editor of *Refractive Market Perspectives*, said he expects to see an array of high- and low-priced options; "just as there is a need for a Wal-Mart and a Nordstrom's in the same market."

According to Torassa, Lasik Vision recently opened a clinic in Bellevue, Wash., which offers prescreening and postoperative care for U.S. patients and will soon be open for surgeries as well (once it is approved for operation in the U.S.). The company said that it planned to open centers in Beverly Hills and Newport Beach, as well as San Francisco, over the next few months.

10/19 **KeraVision** announced financial results for the quarter ended September 30, 1999. Revenues were $4.2 million compared to $239,000 for the same period a year ago and $3.9 million for the second quarter of 1999. Revenues in the quarter were primarily driven by sales of Intacs start-up kits, which include surgical instruments and a small initial inventory of Intacs, and by Intacs reorders. The net loss for the third quarter was $5.0 million (32 cents per share), compared to $5.7 million (48 cents per share) for the third quarter of 1998. KeraVision said it trained 205 doctors during the quarter, bringing the total number of U.S. ophthalmic surgeons who are credentialed to perform the Intacs procedure to 448. The mix of surgeons completing Intacs training shifted during the quarter to accommodate more doctors belonging to corporate partner groups as well as associates of doctors previously trained. Since Intacs start-up kits already were purchased in these instances, revenues from these "associate" doctors were for training only.

Revenues for the first nine months of 1999 totaled $8.6 million compared to $503,000 for the same period in 1998. The net loss for the period was $17.9 million ($1.34 per share) compared to $16.8 million ($1.57 per share) for the same period a year ago.

KeraVision chairman and CEO Thomas Loarie said, "During the quarter, KeraVision continued to see strong surgeon demand for Intacs training and procedure growth in line with our upwardly revised expectations. I am also pleased to announce that the 20/20 visual outcomes being achieved by surgeons who are performing their first-ever Intacs procedures are as high as we saw in U.S. clinical trials." Noting that the first Intacs outcomes data from the commercial launch will be presented next week at the American Academy of Ophthalmology meeting, Loarie added, "These early commercial results point to the strength of our training and proctoring program."

10/19 **Robertson Stephens'** analyst Wade King, MD, upgraded **VISX** to a "Strong Buy"

rating from a "Buy" and also upped his year 2000 price target for VISX to $125. "We are upgrading our rating on VISX to a Strong Buy rating from a Buy, based on the current valuation, the company's phenomenal top- and bottom-line growth and the strong fundamentals of VISX's core business," said King. "Shares of VISX are down more than 35% from highs established earlier this year, presenting investors with an excellent buying opportunity, in our opinion. Clearly, domestic LVC procedures continue to grow at a phenomenal pace, with VISX capturing the dominant domestic market share. Laser system sales have also been stronger than expected, as doctors seek to expand their practice capabilities and laser centers continue to add laser systems. In our opinion, VISX is in the best position to capitalize on strong LVC growth, given the company's broad regulatory approval, strong customer service organization and established track record. We believe that VISX is a core holding for investors in medical device and technology companies."

According to *CBS MarketWatch*, VISX shares shot up 11% after King's announcement.

10/19 **Summit Technology** sued **ICON Laser Eye Centers Inc.'s** U.S. affiliate in the U.S. District Court, for alleged infringement of two patents. In court papers, Summit said the patents at issue are for a "surgical apparatus for modifying the curvature of the eye cornea" and for "surface erosion using lasers". It turns out that the ICON centers in question are using **Nidek** lasers, and that is the reason for the suit.

10/20 **VISX** said that two topography companies, **Zeiss Humphrey Systems** and **Dicon Software Development** would be previewing ablation planning software that will work in tandem with VISX's CAP method for treating irregular corneas at the upcoming AAO meeting.

10/20 **Bausch & Lomb** officials issued a statement that they knew of no reason for the recent decline in the company's stock price. B&L stock had lost 17% following the release of its third quarter financials. "Our core vision care, surgical and pharmaceutical businesses are solid and continue to grow; our pipeline is filled with innovative new products that are beginning to roll out around the world; and we have significantly strengthened our balance sheet," said William Carpenter, chairman and CEO. "We are highly confident that we will be able to continue to deliver strong growth in earnings from our continuing businesses next year. We remain comfortable with the earnings consensus for 2000."

10/20 **NovaMed Eyecare** announced that its net revenue of $27.2 million for the third quarter ended September 30, 1999, represented an increase of 57% over the third quarter of 1998. Net income in the quarter nearly doubled from the prior year third quarter to approximately $1.4 million (6 cents per share), up from 3 cents per share in the prior year's quarter. Surgery and laser center operations accounted for $8.3 million of total revenues, up from $5.2 million in last year's quarter.

For the nine month period, net revenue was $72.0 million representing an increase of 61.5% over the first nine months of 1998. Net income for the period nearly doubled to $2.8 million (12 cents per share), up from 7 cents in the prior year period. During the nine month period, surgery and laser center operations accounted for $21.6 million of revenues.

"This was a landmark quarter for NovaMed," said Stephen Winjum, chairman, president and CEO. "We completed our initial public offering in August. We also continued to grow profitably at high rates through a focus on laser vision correction and the significant operating leverage opportunity in our five regional markets. We are pleased to report strong laser vision correction procedure growth, net revenue growth and earnings growth for the third quarter. We are well positioned to continue that growth in the fourth quarter."

10/20 **Refractec, Inc.** announced the addition of several U.S. investigators in anticipation of expanding their Phase III clinical trials of Conductive Keratoplasty (CK). These additional investigator's include: Penny Asbell, MD, associate professor at Mount Sinai Hospital in New York; Stephen Brint, MD, associate professor at Tulane University School of Medicine; William Culbertson, MD, professor of ophthalmology at the University of Miami School of Medicine; Daniel Durrie, MD, assistant clinical professor of ophthalmology at the University of Kansas Medical Center; Bruce Grene, MD, associate professor at Kansas University School of Medicine; Vera Kowal, MD, director of refractive surgery at Black Hills Regional Eye Institute; Peter McDonnell, MD, professor of ophthalmology at the University of California, Irvine School of Medicine; and Alan Sugar, MD, professor of ophthalmology at the University of Michigan School of Medicine. Refractec is currently conducting Phase III clinical trials in the United States for Conductive Keratoplasty (CK), a minimally invasive, non-laser, radio-frequency approach for correcting low to moderate hyperopia.

10/20 **STAAR Surgical** reported revenues of $13.8 million for its third quarter, a 7.1% increase over third quarter 1998 revenues of $12.9 million. Net income for the quarter was $527,000 (4 cents per share). This compares with net loss of $1.3 million (10 cents per share) in last year's third quarter. Revenues for the nine-month period were $43.4 million, up from $41.0 million for the first nine-months of 1998, an increase of 5.5%. Net income for the period was $1.9 million (13 cents per share). This compares to $1.9 million (14 cents per share) last year.

10/20 **Premier Laser Systems** announced that its **EyeSys Vision Group** had released software Version 4.2 for its EyeSys System 2000 corneal topography product. The new System 2000 software is Y2K-compliant and provides the practitioner with several important features that allow clinicians to better utilize topography data for refractive surgery, contact lens fitting, corneal history analysis and post-operative comparison. Software Version 4.2 enables practitioners to use automatic limbus detection and mapping.

10/20 **TLC The Laser Center** said that on June 15th, the Illinois Appellate Court decided that TLC had the right to enforce a non-competition covenant against two ophthalmologists in Illinois. "We are pleased the courts have recognized the right of a non-medical company to enforce non-compete agreements with its doctors," said Ron Kelley, TLC's General Counsel. In TLC v. Midwest Eye Institute, the court recognized that TLC has the right to enforce a covenant not to compete against a physician as long as TLC did not purport to base its request for injunctive relief upon "a protectable interest in practicing medicine". In the course of its decision, the court flatly rejected the physician's argument that Illinois' prohibition on the corporate practice of medicine "constitutes a blanket prohibition against non-physicians enforcing restrictive covenants against physicians".

The decision has significance for non-physician managers and investors in medical practices. The decision recognizes that -- even though they many not compete directly with physicians in the practice of medicine -- non-physicians and non-medical corporations may have the right to protect their investment and their disclosure of confidential information by means of a reasonable non-competition agreement.

10/20 **IRIDEX Corporation** reported that third quarter sales were $6.3 million, an increase of 21% from $5.2 million in the corresponding 1998 quarter. Net income for the quarter was $325,000 (5 cents per share) as compared to $43,000 (1 cent per share) in the corresponding 1998 quarter, an increase of over 650%. "We are pleased to report that our third quarter 1999 results exceeded expectations for both sales and net income," commented Ted Boutacoff, president and CEO. "This was an important quarter for us to perform well as it demonstrates that we are successfully recovering from the severely reduced sales in Asia which occurred in last year's corresponding quarter."

Sales increased for the third quarter as compared to the corresponding prior year period, primarily as a result of increased domestic sales of dermatology products and international sales of ophthalmology products. Since the third quarter of 1998, the company has invested in its sales channels and research and development to improve sales in these areas. Boutacoff continued, "The third quarter was a good one for IRIDEX. The sales growth we are experiencing today is the result of course corrections we made over the last year. We continue to see strength across our entire medical product line and as we approach the annual AAO meeting, we are confident we can attain solid growth in the fourth quarter. Emerging treatments for Age-related Macular Degeneration (AMD) will generate some of the highest interest at the AAO. IRIDEX has been involved in the development of five approaches to treat AMD, two targeted at the dry type and three at the wet type. Results from a number of these studies will be presented at the AAO. I predict that this AAO will show us that as refractive surgery has been the ophthalmic procedure of the 90's, AMD treatments could be the ophthalmic procedure opening the next millenium."

The company also announced that it was introducing three new **Iris Medical** products

at the AAO meeting: the IRIS Medical Tri-Mode OcuLight SLx, a new family of TruFocus Laser Indirect Ophthalmoscopes (LIO), and the EasyFit Conversion Kit to upgrade outdated argon laser photocoagulators. The OcuLight Slx (810 nm) infrared laser photocoagulator already has the largest installed customer base of infrared photocoagulators worldwide and is routinely used to treat a wide selection of retinal diseases as well as glaucoma. The new Tri-Mode feature gives the ophthalmic surgeon the ability to operate this single laser console in three different treatment modes, CW-Pulse (continuous wave), MicroPulse, and LongPulse to maximize clinical versatility. While CW-Pulse mode is used to produce conventional endpoints, MicroPulse and LongPulse modes are unique to the OcuLight SLx and are designed for use with emerging clinical applications. MicroPulse mode results in subclinical (invisible) endpoints which have been demonstrated to provide a gentler treatment option for patients with diabetic retinopathy. LongPulse mode produces localized hyperthermia during transpupillary thermotherapy (TTT) to take advantage of emerging clinical treatments of diseases such as intraocular tumors and age-related macular degeneration (AMD).

10/21 **Summit Technology** announced that the FDA had approved the company's Apex Plus Excimer Laser Workstation for the treatment of hyperopia. The approval is for hyperopic photorefractive keratectomy (PRK) in the range of +1.5D to +4.0D, with less than 1.0D of astigmatism. "Having a broad range of FDA approvals is a key element of our strategy," stated Robert Palmisano, CEO. "With this additional FDA approval, we have extended the range of treatment options available to Summit ophthalmologists and their patients and leveled the playing field in this industry."

The company also announced that the FDA had granted approval for the company's Apex Plus Excimer Laser Workstation for the LASIK treatment of myopia with or without astigmatism. The approval is for the correction of myopia in the range of 0D to -14.0D with or without astigmatism in the range of -0.5D to -5.0D. This approval gives Summit the widest range of treatments for nearsightedness and astigmatism in the industry. "This is an industry milestone," said Palmisano. "Today, more than 80% of all laser vision correction procedures are LASIK procedures and that number continues to grow. I am very pleased that Summit is now the leading company, as the first manufacturer with LASIK approval in the United States. We are the only company able to offer an approved laser system and microkeratome package to physicians for LASIK procedures, including the Summit Apex Plus Excimer Laser Workstation and our SKBM microkeratome. Now, we also can offer in depth training and marketing for the Summit LASIK system."

10/21 **Premier Laser Systems** announced that its **EyeSys Vision Group** was announcing the commercial availability of Foresight for **VISX**, a software package for surgeons who use a VISX STAR S2 Excimer Laser System and the EyeSys System 2000 topographer for the PRK/LASIK procedure. The program produces a simulated post-op map based on the surgeon's planned ablation data and allows the refractive surgeon the ability to better plan and execute vision correction procedures.

The company also announced that it would be demonstrating its multi-application Centauri Er:YAG laser for ophthalmic procedures at the AAO meeting. The Centauri being demonstrated has been cleared to market by the FDA for such procedures as dermabrasion, or skin resurfacing (treating "crows feet"), blepharoplasty, end-stage glaucoma treatment and anterior capsulotomy. In addition to these procedures, Premier's application to market Centauri for cataract removal is currently being reviewed by the FDA. In August, the FDA reviewed the Phase II controlled, randomized clinical trial cases for cataract removal and requested the documentation necessary to begin the final review process for approval of the Centauri Er:YAG laser for this cataract procedure. The five-site clinical trial included removal of all grades of cataracts, including grade four cataracts, which are difficult to remove with phacoemulsification.

10/22 **Sunrise Technologies International** announced it expected its PMA application to be considered by the Ophthalmic Devices Advisory Panel of the FDA in the first quarter of 2000. As a result, the company is preparing an amendment to its PMA application for the *reduction of hyperopia* within the range of +0.75 to +2.5 diopters. (This is different than its previous PMA application, that was turned down in July, which was for the *treatment/correction of hyperopia*. The company will now only claim "safety" and the "reduction of hyperopia", which should allow easy passage before the panel, and a recommendation for approval.) Since the company's first appearance before the ODP on July 22, 1999, Sunrise has had very productive meetings with the FDA Ophthalmic Devices Branch to review its PMA submission. The company's PMA amendment contains a substantial increase in the number of patients followed through two years compared to that presented at the July panel meeting. As a result of discussions with the FDA staff, the company's amended PMA will quantify and explain the postoperative outcome that LTK patients may experience, thereby addressing earlier concerns regarding change in refractive effect over time. According to Russell Trenary, president & CEO, "We believe the additional two year data support our claim that our patient population achieves an improvement in vision due to a reduction in the amount of their preoperative hyperopia. We are looking forward to sharing these results with the ODP in the first quarter of 2000."

The following day, the company's stock price rose 50%, according to *Reuters*.

10/22 **Gimbel Vision International** announced that it had acquired a 51% interest in a new refractive vision correction surgery centre to be located in the Tri-City region of Albany County, New York. The remaining 49% is held by Dr. Jordan Kassoff, Dr. Aida Wakil, and Dr. Robert Webb, all of whom are corneal fellowship trained, experienced refractive surgeons. The centre is expected to be opened during the first quarter of 2000 and will draw patients from counties in upstate New York as well as southern Vermont and western Massachusetts. Dr. Robert Webb said, "After investigating various companies in this industry, Gimbel Vision clearly became our partner of choice based on their mandate of putting the patient first and remaining on the cutting edge of technology. We believe their long history of honesty and integrity

will result in a successful and profitable partnership based on mutual trust and understanding."

Gimbel Vision also announced that Dr. Howard Gimbel was the first surgeon in North America to remove a cataract by laser using the regulatory approved device known as the Dodick Laser Photolysis system. Using a laser to remove the lens is the latest development in the field of small-incision cataract and refractive lensectomy surgery. Dr. Gimbel, founder and Senior Medical Director of Gimbel Vision, said "It is tremendously exciting to perform the first photolysis procedure in North America. Twenty-five years ago it was my privilege to pioneer in Canada the first small-incision cataract surgery, which greatly improved the experience and the outcomes of cataract surgery for patients. This new laser procedure has the potential to revolutionize cataract surgery once again."
Canadian doctor, Jack Dodick, MD, now living in New York but originally from Thunder Bay, ON, invented this exciting new laser technology. One of the benefits of the laser technology is a dramatically smaller incision. The technology will also be used for refractive lensectomies, one of the vision correction options that is gaining popularity for people with very high correction needs.

10/22 **Preferred Capital Markets'** Kate Sharadin and Jason Mills have published an industry update on Refractive Vision Correction -- "Customizing the Laser Vision Correction Experience: A Preview of the Hottest Topic in LVC". Custom Ablation is the process of "hitting the peaks and missing the valleys" on the cornea to give the patient the highest quality vision physically attainable. (Not quite true, as custom ablation takes into account all of the aberrations of the eye, and attempts to correct for them on the cornea's surface. I will address all that was shown and presented about "custom ablation" at the AAO in my writeup, now in preparation, and which will accompany next month's newsletter.)

10/22 **Medennium Inc.**, known as **IVI Medennium**, announced that it had received an office action letter from the U.S. Patent Office, granting it a patent for its self-centering PRL Phakic Refractive Lens, which should issue within the next three months. The PRL is a revolutionary design that is not fixated in the eye as other IOLs and implantable contact lenses, but is a posterior chamber IOL. Medennium merged with **International Vision Inc.** in May, to combine the capabilities of the two companies in the development and manufacturing of the new lens, which is in Phase II clinical trials.

10/25 **Vision Twenty-One, Inc.** announced a number of developments substantially completing its transition to a vision care company focused on laser vision correction and surgery centers. The company has entered into a binding letter of intent for an equity investment in the company of $35 million that will be co-led by **MedEquity Investors, LLC** and **Chase Capital Partners**. The proceeds from the equity investment will be used to continue the company's aggressive development and acquisition of refractive and ambulatory surgery centers. In addition, the new equity

investment will position the company to restructure its existing credit facility and substantially exit the physician practice management (PPM) business. The company also disclosed additional positive information regarding its capital structure. It has tentatively agreed on a term sheet with **Bank of Montreal**, the Agent Bank, whereupon simultaneous with the closing of the equity investment, the company's $48 million credit facility will be amended. The company also received a waiver for certain items in anticipation of finalizing the amendment to the bank credit facility. The modifications to the existing facility are expected to provide the company with increased financial flexibility and a procedure for the release of collateral upon divestiture of practice groups under management pursuant to its PPM exit plan.

The company additionally announced, subject to completion of the capital structure changes, it has developed an initial plan to substantially exit the business of managing practices of optometry and ophthalmology. This is a crucial step in the company's strategy of redirecting its corporate resources towards developing refractive eye laser and surgery center initiatives in these same markets. The company expects the majority of the affected physicians to continue to be part of the Vision Twenty-One national eye care delivery network and/or participate in its eye laser and surgery center initiatives. The exit of the PPM business is expected to be accomplished through the sale of the practice assets back to the physicians or affiliates, the restructuring of the individual operating models to focus substantially on refractive surgery, and the discontinuation of select managed care contracts that are not consistent with the business plan. As part of the strategic restructuring, the company substantially completed its previously announced integration plan and related organizational changes, as it eliminated over 70 positions and completed the retail chain divestiture in September 1999. These actions will result in charges being incurred in both the third and fourth quarters. The company expects to recognize an expense of approximately $1 million in the third quarter related to the termination of managed care contracts and severance expenses. In the fourth quarter, the company expects to record a restructuring charge of up to $35 million related to the sale of practice assets. If successful, the company could receive back and retire up to 3 million shares in connection with the transactions.

10/25 **Paradigm Medical Industries** announced that it had engaged **R.F. Lafferty** to perform its investment banking services. Thomas Motter, chairman, stated that with the acquisition of the **Humphrey** Line of Ultrasonic Diagnostic Products recently put into production at its facility in Salt Lake, its acquisition of the **Mentor Ophthalmic Surgical Products** division, its anticipated approval of its revolutionary Laser Cataract Removal System currently completing successful clinical trials and its expanding opportunities with strategic alliance partner, **Pharmacia & Upjohn**, it was time to go to the next level in the investment banking community. "R.F. Lafferty is one of the most well respected houses on Wall Street. Paradigm has earned and deserves to be associated with an organization of its stature."

10/25 **STAAR Surgical** announced enrollment had been completed for the FDA Phase III

clinical study of its foldable Implantable Contact Lens (ICL) for the correction of myopia. Under the Phase III trial initiated a year ago, 278 patients have been enrolled for the ICL. The FDA expanded the Phase III trial to include patients with -3 diopters to -20 diopters. During this phase, the waiting period for patients to have an ICL implanted in their second eye was reduced to 45 days from six months. Patients participating in the study were between 21 and 45 years of age without severe astigmatism, cataract or a history of refractive surgery.

Of the ICLs for myopia implanted within the clinical study, there is post-operative data of at least one-month on 311 eyes. These patients had severe myopia that averaged 10.4 diopters. They were unable to read the big "E" on an eye-chart and their myopia was in a range too high to effectively treat with the excimer laser. Only one week post-operative, the average myopia of these patients was reduced to 0.7 diopter and was stable at one year post-operatively. Approximately 82% of the patients saw 20/40 or better without glasses or contacts, which would be sufficient to pass the driver exam in most states.

10/25 **Sunrise Technologies International** hosted a highly successful and well-attended Scientific Session entitled "Sunrise LTK: The Full Story" during the AAO Annual Meeting. A special guest at the session was world-renowned ophthalmologist Charles Kelman, MD, recently named one of The Ten Most Influential Ophthalmologists of the 20th Century by the *American Society of Cataract and Refractive Surgery*. Dr. Kelman is a patient in the Sunrise Technologies Laser Thermal Keratoplasty (LTK) U.S. clinical trials, and recently underwent the procedure for correction of hyperopia. "As a patient with 4.0 diopters of hyperopia, I had severely compromised vision both near and far, and unlike myopic patients, getting closer to an object did not improve my ability to see it," said Dr. Kelman. "My first eye was treated seven days ago, and I was able to read my notes for this evening's talk through my operated eye. I am aware of all of the procedures available to treat hyperopia and I felt the Sunrise LTK procedure offered my best opportunity for success."

Several hundred ophthalmologists from the U.S. and abroad attended the seminar, which was hosted by Russ Trenary, president and CEO of Sunrise. The seminar was presented by a team of Sunrise clinical investigators from the U.S., Great Britain, Europe, South Africa, and Mexico. The Scientific Session provided a review of clinical results of the Sunrise LTK technology, which is currently being considered for approval by the FDA. "We were extremely honored to have Dr. Kelman join our presentation, and offer a personal perspective on LTK," said Trenary. "This event represented the largest single group of ophthalmologists ever exposed to the Sunrise LTK System and its clinical results. We believe it was an important educational and scientific event for the ophthalmic community."

10/25 **LaserSight** announced that **BD Ophthalmic Systems**, a Worldwide Business of **Becton Dickinson**, will, subject to limited exceptions, become the exclusive distributor for LaserSight's MicroShape Keratome System products in the U.S., the United

Kingdom, Ireland and Japan. The MicroShape family of products includes LaserSight's UniShaper single-use keratome, the UltraShaper durable keratome, the MicroShape control console for both keratomes, UltraEdge keratome blades, and other single-use accessories utilized during laser refractive procedures. LaserSight believes that it is the only company to offer both a single-use and durable Keratome utilizing the same control console. BD has agreed to utilize its extensive sales force to promote, market and sell LaserSight's MicroShape family of keratome products into their territory. In other markets, LaserSight intends to sell its keratome products through existing distributors and its direct sales force. The Distribution Agreement has a term of five years and specifies minimum product sales requirements during the first two years of the agreement.

Michael Farris, president and CEO of LaserSight commented, "Our strategic relationship with Becton Dickinson brings together the products and expertise of two companies focused on refractive surgery. BD's extensive marketing and distribution infrastructure will assist us in penetrating the U.S. and international markets. Industry estimates have the number of laser refractive procedures in the U.S. reaching approximately 1 million during 1999. LaserSight intends to participate in the on-going stream of revenues associated with single-use products such as our UltraEdge blades and UniShaper single-use keratomes".

10/25 In its response to a patent suit brought by **Summit Technologies**, over its use of Nidek EC-5000 laser systems, **ICON Laser Eye Centers** said it was assured by Nidek that no patents have been infringed upon and plans to vigorously defend the lawsuit. Simone Mencaglia, CEO of ICON stated "It appears that Summit has obviously taken this action to help stimulate their laser sales in front of the major 1999 industry meeting of the AAO. ICON believes that the Nidek technology is superior to that of Summit and therefore has chosen to offer laser vision correction to the public with the latest technology available." ICON has initiated a joint venture program offering to negotiate the upgrade of all Summit lasers for current Summit users to Nidek lasers whereby ICON will bear all upfront costs of the upgrades to the Nidek EC-5000 technology. ICON will further demonstrate to refractive surgeons a dramatically increased flow of new patients to the joint ventures. ICON and the surgeons will share laser vision center profits, where allowable by law. Summit currently charges its users a $250 manufacturer's royalty tending to perpetuate an average price per procedure approaching $2,000 per eye. With ICON's U.S. pricing program the consumer is charged prices as low as $499 per eye at both its U.S. and Canadian centers.

ICON Laser Eye Centers, Inc. is a leading international provider of laser vision correction services. In addition to its own centers, ICON has developed working relationships with laser vision correction centers around the world with the intention that they will be acquired by or enter into joint ventures with ICON. Agreements in principle have been reached in respect of certain of these centers but no definitive agreements have been entered into in respect of such acquisitions or joint ventures. ICON operates fixed laser centers in Canada, the USA, England, and Italy. ICON

mobile units are currently in Europe only. ICON affiliated centers are currently operating at a rate of approximately 4,000 procedures per month.

10/26 **Sight Resource Corporation** reported financial results for its third quarter and nine months ended September 25, 1999. Revenues for the quarter were $18.2 million, an increase of 27% from revenues of $14.3 million for the third quarter of 1998. Net income was $3,000 (0 per share) compared with $143,000 (2 cents per share) for the third quarter of 1998. EBITDA (earnings before interest, taxes, depreciation and amortization) was $1.1 million for the three months ended September 25, 1999, compared with $825,000 for the same period in 1998. Third quarter results include the operations of Shawnee Optical, acquired effective January 1, 1999, and Kent Optical, acquired effective April 1, 1999.

For the nine-month period, reported revenues were $51.5 million, an increase of 22% from revenue of $42.4 million for the same period in 1998. Net income was $464,000, (5 cents per share), compared with $233,000 (3 cents per share), for the first nine months of the prior year. EBITDA was $3.9 million for the nine months, compared with EBITDA of $2.2 million for the same period in 1998. Commenting on the results, William Sullivan, president and CEO stated, "As we communicated in the previous quarter, substantial softness in sales volumes is being experienced across the optical retail industry this year. While there are many explanations for this softness, we have taken significant steps to better position our company for the current environment. Chief among these is our commitment to substantially expand our laser vision correction services. Through our strategic alliance with **Laser Vision Centers**, we are better prepared to extract the full value of our traditional retail optical customer base by being a convenient source for quality professional advice on, and access to, laser vision correction services. We also have new initiatives underway in third party contracting and are continuing our operating cost improvement program."

10/27 **LCA-Vision** announced that the company had demonstrated strong growth of its value-priced **LasikPlus** centers, bringing LASIK surgery to a larger customer base by lowering the affordability bar, while maintaining the highest standards of care. The company owns and operates 27 centers, of which the Baltimore and Annapolis, MD; Minneapolis; Columbus, OH; and California centers have adopted LasikPlus. The company plans to convert additional centers to the LasikPlus model before year's end.

"Based on our research, offering pricing of $2995 for both eyes -- which is significantly less (40%) than the customary $4500-$5000 -- has grown the number of procedures substantially. Our LasikPlus centers have booked more appointments in their first weeks of operation than they have in previous months," stated Stephen Joffe, chairman and CEO of LCA-Vision. "While the benefits to the patient are obvious, so are the benefits to LCA-Vision. We realize there are costs associated with jumpstarting LasikPlus, but the positive impact on next year's financial results will be tremendous, as the company increases profitability while maintaining per procedure revenue. This is a short-term tradeoff between slight sacrifices in profitability and

gaining market leadership in the future."

For the third quarter, the Baltimore and Annapolis offices, which only began operations as LasikPlus three weeks into the quarter, performed 1629 procedures, compared with 1178 during the second quarter, an increase of 38%. This represented an increase of 152% on a same center basis compared with the 1998 third quarter. Baltimore and Annapolis continue to generate dramatic increases in incoming call volume at a rate of 3700 calls, achieving 3000 scheduled appointments and high surgery conversion rates, all while maintaining the excellent clinical results and patient satisfaction found in the open-access LCA-Vision centers. In October of this year, the company expanded LasikPlus to its California markets, where same center growth has exceeded the company's most aggressive expectations.

"With our new LasikPlus centers, we are experiencing a larger percentage of younger patients having surgery. In addition, the length of time taken by prospective patients to have laser vision correction surgery has shortened. As we expected, we are broadening the market to include consumers with less disposable income," stated Joe Dzialo, executive vice president of LCA-Vision.

10/27 **Sight Resource Corporation** announced that it had signed an extension to its managed vision care agreement with **Harvard Pilgrim Health Care**. William Sullivan, president and CEO of Sight Resource, stated, "We are very pleased that our long-standing relationship with one of New England's preeminent healthcare providers will continue into the new millennium. The future of primary eye care is closely linked to managed care and we believe that we have positioned our company to benefit from the increasing role that managed vision care will play in our industry. I am particularly proud of the high level of customer satisfaction expressed by our managed care partners and believe that this speaks to the success of our strategies in this area."

10/28 **LCA-Vision Inc.** reported financial results for the 1999 third quarter. The company reported net income of $1.4 million (3 cents per share) compared with a net loss of $759,000 (2 cents per share) in the comparable period last year. Third quarter laser vision correction revenues increased 77% to $14.9 million, compared with $8.4 million for the same period last year. Total revenues for the quarter were $15.0 million compared with $9.1 million for the same period last year.

Net income for the nine months was $5.4 million (11 cents per share) compared with a net loss of $14.0 million (38 cents per share) in the comparable period last year. Laser vision correction revenues were $42.6 million compared with $23.1 million for the same period last year, an increase of 84%. Total revenues for the nine months were $43.6 million, compared with $25.3 million for the same period in 1998.

"This period marks our fourth consecutive quarter of profitability. We have seen a continued increase in acceptance of laser vision correction surgery and have

maintained our financial leverage enabling us to pursue our newly introduced `value priced' model, LasikPlus. Joining our Baltimore and Annapolis, Maryland centers, additional markets, such as Minneapolis, Minnesota; Columbus, Ohio; and all California markets have recently adopted this model, with outstanding initial results," stated Stephen Joffe, chairman and CEO of LCA-Vision.

As previously announced earlier this month, procedure volume at LCA-Vision's Baltimore and Annapolis, centers increased 152% compared with last year's third quarter, and were up 38% compared with the 1999 second quarter. The company continues to experience additional growth with the expansion of LasikPlus as demonstrated by dramatic increases in incoming call volume and comparable high conversions of inquiries to surgeries. "We are experiencing all the leading indicators for a segmented market, where younger consumers with less disposable income are demanding value priced procedures without sacrificing the quality of clinical outcomes or care," continued Joffe. "While enhanced initial marketing expenditures for LasikPlus are expected to continue to increase for the next two quarters, the positive impact on future earnings will be tremendous and drive additional market dominance."

In addition, the company completed physician enrollment in the **National LASIK Network (NLN)**. This network of ophthalmologists was established subsequent to an agreement with **Cole Managed Vision**, a division of **Cole National Corporation**, to offer laser vision correction services to Cole members nationwide. Joffe added, "This relationship will include such managed care organizations as **Aetna/U.S. Healthcare**, **Blue Cross and Blue Shield** as well as **MetLife**, **Healthnet** and **Cigna**. We expect to reap the benefits of this program -- the first nationwide program of its type -- beginning January 2000. This agreement will provide us with the opportunity to access over 50 million managed care lives."

During the accompanying teleconference, Joffe noted that sponsored market research had shown that there was a two-tiered market for vision correction, one segment composed of younger people with less disposable income looking for convenience and value (and likely to embrace the LasikPlus model), and a second segment who would choose their ophthalmologist to have the procedure, and have higher disposable income, and thus would be more likely to embrace the "open access" model. For this reason, the company will continue to operate both models, maintaining about a dozen open access facilities, while converting some existing and all new centers into LasikPlus operations. He further noted that in the currently operating 22 centers, there were approximately 25 lasers being used, with a few having two or more systems.

10/28 **KeraVision** reported on the two-year clinical results for its Intacs, with the devices showing stable correction two years after treatment with 76% of treated eyes seeing at least 20/20, 55% seeing 20/16 or better, and 21% seeing at least 20/12. "Clinical data from the FDA trials show that Intacs are effective in correcting mild myopia and are safe, well-tolerated in the eye, and stable over time," said David Schanzlin, professor

of ophthalmology at the University of California in San Diego and chief medical investigator for the Intacs clinical trials. "The fact that Intacs can be removed and that the wearer's prescription can be exchanged much like contacts and glasses is a major advance for the consumer."

10/28 Both analysts Rebecca Irwin of **Warburg Dillon Read** and Jim Molloy of **Leerink Swann** downgraded **Laser Vision Centers**. Irwin cut her rating to "buy" from "strong buy", and her price target to $20 a share from $40. She said that she expected weak second quarter results due to seasonality, and that doctors were demanding to transition to fixed laser sites from mobile laser sites sooner than in the past and that this hurts revenue, while doctors are in process of revising prices downward. She further noted that the company is shifting from receiving a fee from the surgeon for each procedure done to sharing profits and risks of pricing pressure with the ophthalmologist, which will result in stock volatility over next couple of quarters.

Molloy noted that stock prices of the laser eye surgery service providers have decreased dramatically based primarily on concerns that new entrants to the industry will cut price to gain market share. **LCA Vision**, he observed, which has rolled out a $3000 for both eyes model in both Maryland and California, is expected to roll out this pricing strategy nationwide in the upcoming months. This move, combined with the expected entry of **Lasik Vision Canada** into the US, has further fueled investor concern that an industry-wide meltdown in procedure pricing is now upon the market. He downgraded his rating from a "Buy" to a "Hold" based upon concerns that the company may have difficulty reaching its revenue and EPS expectations for its Q2 99 which ends this October 29th. He lowered Q2 2000 and FY 2000 revenue and EPS estimates to factor in a more accelerated decline in procedure price from approximately $2100 per eye today to $1500 per eye by FY 2001.

10/29 **Sunrise Technologies** announced financial results for the third quarter ended September 30, 1999. Revenues for the three- and nine-month periods were $6,000 and $21,000, respectively, compared to $180,000 and $504,000, for the same periods in 1998. Year to date revenues for 1998 were the result of sales of SUN 1000 ophthalmic laser units to international markets and domestic sales of Paradigm dental units. Sunrise Technologies is no longer engaged in the sale of dental units and the SUN 1000 production was discontinued in 1999, as the Hyperion LTK System, the company's new Laser Thermal Keratoplasty instrument, is in final stages of development. Revenues for 1999 represent sales of accessory parts for older machines on the market.

Net losses for the three- and nine-month periods were $5.8 million and $20.1 million, respectively. Net losses for the same periods of 1998 were $3.6 million and $12.9 million respectively. A significant portion of the accumulated net losses for the nine months of 1999 and 1998 resulted from non-cash expenses. For the nine months of 1999, $6.5 million or 32% of the accumulated net losses result from non-cash expenses. From this total, $5.1 million are associated with the amortization of

non-cash financing costs of convertible debt financings for 1999 and prior years and $1.4 million are associated with non-cash costs for warrants issued and compensation charges incurred with the issuance of Non Qualified Stock Options. For the same nine months of 1998, $4.2 million or 33% of the accumulated net losses were attributable to non-cash expenses.

OPHTHALMIC LASER UPDATE -- NOVEMBER 1999

10/29 **Stanford University Medical Center** announced that it was one of 22 North American and European eye centers that participated in the trial involving 609 patients with the wet form of age-related macular degeneration (AMD), sponsored **QLT Phototherapeutics**, of Vancouver, B.C. and **CIBA Vision AG**, based in Bulach, Switzerland, which is currently under review by the FDA.

11/1 **Summit Technology** announced that the FDA had accepted for filing **Autonomous Technologies'** PMA Supplement for treatment of myopia and hyperopia with or without astigmatism using LASIK. The Supplement seeks new approvals for the Autonomous LADARVision System for the correction of hyperopia (up to +6.0 D sphere and up to -6.0 D of astigmatism) and myopia (up to -11.0 D sphere and up to -6.0 D of astigmatism) with or without astigmatism using LASIK. Filing the PMA Supplement by the FDA is the first step in the approval process. The FDA has indicated that its Ophthalmic Devices Panel will review the PMA sometime in the near future.

11/1 **Sight Resource** announced that it had entered into agreements to provide vision care services to **Neighborhood Health Plan** members and **Health New England** members in New England. Neighborhood Health Plan, a not-for-profit affiliate of **Harvard Pilgrim Health Care**, provides healthcare coverage to 107,000 members in Massachusetts. Health New England, which is jointly owned and operated by **Harvard Pilgrim Health Care** and **Baystate Health System**, provides coverage to approximately 83,000 members in western Massachusetts. Sight Resource, through its **Cambridge Eye Doctors** and **Vision World** optical chains, also provides managed vision care products and services to Harvard Pilgrim Health Care members.

11/1 **Visual Freedom Center** claims to be offering what it believes is a first, a 20/20 Promise. If a patient does not obtain a final 20/20 result, VFC will refund the full purchase price paid for the procedure. While some specific terms and conditions will apply, approximately 90% of all patients seen at the Visual Freedom Center will be eligible for the 20/20 Promise. (Visual Freedom Centers was the first in the country to provide laser vision correction in a mall environment. At the Visual Freedom Center all patient care is performed at one location with the added convenience of operating hours that correspond to major shopping malls. The center is open seven days a week for information and free patient screenings. Surgeries are performed everyday except Sunday. The company operates at malls in Fair Oaks and Columbia, Virginia, with a third mall operation scheduled to open in November in the Woodfield Mall.)

11/1 **SurgiLight, Inc.** announced that it had completed mergers that include medical laser and infrared technologies, laser eye centers, and mobile cosmetic centers. The Company is currently focusing on the development of new infrared (IR) lasers for vision correction, which the Company believes will be mutagenically safer than ultraviolet (UV) lasers made by most of its competitors. The laser was demonstrated, at the American Academy of Ophthalmology (AAO) recently held in Orlando. The Company has three US pending patents to protect its proprietary infrared technologies. Clinical trials in US and Latin America using the Company's new infrared laser for vision correction will start in the next two months. SurgiLight currently operates 18 Laser Centers internationally in Asia, and Latin America and the U.S., including one Vision Center and two Cosmetic Mobile Centers in Florida, and is organized into four divisions: Medical Laser Technology, Laser Eye Centers, Cosmetic Mobile Laser Centers, and Infrared Imaging Technology. The Company continues to pioneer leading edge developments in scanning lasers, infrared lasers for vision correction, laser presbyopia reversal, and diode-lasers for microsurgery.

11/2 **Ophthalmic Consultants** of Boston is currently recruiting patients for a *National Eye Institute (NEI)*sponsored clinical trial which will determine if laser treatment decreases vision loss for people at risk for severe age-related macular degeneration (ARMD). Ophthalmic Consultants of Boston is one of 24 sites in the country selected to participate in this trial. The clinical trial, called Complications of Age-Related Macular Degeneration Prevention Trial (CAPT), is designed to assess the safety and effectiveness of low intensity argon laser treatment. Researchers hope to determine if low intensity laser treatment might prevent disease progression and loss of vision in people who are at risk for severe ARMD. The CAPT will enroll a total of 1000 patients in 24 clinical centers across the United States during an 18-month period. The trial will last at least five years.

11/2 **Gimbel Vision** reported that refractive procedure volumes for the three and nine month periods ended September 30, 1999 increased 41% and 50% over prior year procedure volumes. 6,016 procedures were performed during the third quarter, with North American centers doing 4,557 of that total. For the nine month period, 17,709 procedures were done, with 13,469 were done in North America. Consolidated revenues for the three months were $5.6 million, up from $5.3 million a year ago, while for the nine month period, revenues were $16.3 million, up from $16.1 million in 1998. Net earnings were $463,412 (2 cents per share) for the three months and $949,287 (4 cents per share) for the nine months.

Canadian operations generated a profit of $569,603 and $937,987 for the two reporting periods, while U.S. operations sustained a loss of $62,085 for the three months, and profit of $186,336 for the nine months. Operations in Brazil generated losses for both periods.

11/3 **IRIDEX Corporation** announced the results of a clinical study presented at the 103rd annual meeting of the AAO held last week in Orlando, Florida. The study treated 22

eyes with occult subfoveal choroidal neovascularization (CNV) using transpupillary thermotherapy (TTT). After an average of 6.5 months follow-up, the CNV resolved in 71% of treated eyes and visual acuity stabilized in 86% of treated eyes. These results combined with results from a recent study performed at **The New England Eye Center** indicate that TTT may be an effective treatment method for patients with occult wet AMD, which accounts for approximately 70% of patients with wet AMD. The study titled "Transpupillary Thermotherapy for the Treatment of Choroidal Neovascular Membranes (CNVM)" was presented by Dr. Richard Newsom and co-authored by Drs. Dominic McHugh, James McAllister, Manzar Saeed and Bina Parmar. Dr. Newsom reported clinical outcomes in treating 42 eyes of 39 consecutive patients with occult and classic CNV, secondary to a number of causes, with the IRIDEX OcuLight(R) SLx 810 nm diode laser following a TTT protocol performed at the King's College Hospital in London, UK.

"Although using a slightly different treatment strategy, these data confirm and support the results originally obtained at The New England Eye Center by Dr. Elias Reichel in the TTT treatment of patients with occult subfoveal CNV caused by AMD," commented Giorgio Dorin, Director of Clinical Applications Development at IRIDEX. Dr. Reichel's study, which appeared in the October issue of the peer-reviewed journal *Ophthalmology*, demonstrated that TTT treatment was effective in improving or stabilizing vision in 75% of eyes and in decreasing subretinal fluid in 94% of eyes, and we at IRIDEX believe that the TTT approach represents the promise for an effective treatment for the vast majority of patients with occult wet AMD. Furthermore, this new study suggests that the use of TTT may be expanded for the treatment of other CNV membranes in addition to occult CNV secondary to AMD."

11/3 **Refractec** announced that it had gained FDA approval to expand the company's Phase III clinical trial of Conductive Keratoplasty, a minimally invasive, non-laser technique for vision correction. The trial focuses on Conductive Keratoplasty (CK), which uses radiofrequency energy to correct low to moderate levels of far-sightedness (hyperopia) with the Refractec Viewpoint CK System. Expansion of the trial marks a significant achievement for the company and will allow Refractec and its clinical investigators to complete enrollment of 400 eyes, including bilateral treatment. "I am pleased that the expansion of this trial is approved," said Dr. Marguerite McDonald, medical monitor for Refractec. "I think that it shows that the FDA continues to be supportive of this new refractive technology. The addition of bilateral treatment will definitely help to speed up enrollment, as all of my currently enrolled patients want to have their second eye treated."

The Viewpoint CK System uses radiofrequency energy applied deep into the intrastromal layer of the cornea to shrink and tighten collagen fibers. The radiofrequency energy is released by Refractec's proprietary microprobe at several spots on the periphery of the cornea, outside the optical zone. This process changes the shape of the cornea to correct visual defects, without cutting the cornea as is required by LASIK surgery techniques. This technology is also significantly different

than either the hot probe used years ago or Laser Thermal Keratoplasty (LTK), which is a laser applied to the surface of the cornea. "With other technologies, there have been concerns about regression, which is a drift of vision back to a less corrected state," said Mitch Campbell, Refractec president and chief executive officer. "In our clinical trial, we are seeing less than 0.25 diopters of regression between three and six month time periods with the Viewpoint CK System."

11/3 Analyst Richard Leza of **Craig Hallum Capital** initiated coverage of **STAAR Surgical** with a buy rating and an 18-month price target of $24.00 a share. Leza wrote that "STAAR Surgical is one of the most successful and perhaps least understood competitors in the vision care industry, intimately involved in the areas of cataract, refractive and glaucoma surgery...the company also has developed two new products that have the potential to generate over $75 million in revenue in 2003 -- an implantable glaucoma device and an implantable contact lens that offers a wide range of vision correction." (I received a copy of the complete report, if anyone is interested in seeing it.)(Leza was formerly with **JG Kinnard**, and wrote a controversial report on **Sunrise Technologies** just prior to its appearing before the FDA's ODP panel in July.)

11/3 **Premier Laser Systems** announced that it, along with its subsidiaries, released new advanced technology products and systems for eyecare professionals at the recent AAO Conference in Orlando. According to Premier Laser chairman, president and CEO Colette Cozean, the combined entities of **Ophthalmic Imaging Systems** and **EyeSys/Premier** received more than $2.4 million in orders during the national conference.

11/3 **ICON Laser Eye Centers** announced that it had filed a Rights Offering Circular with the Ontario Securities Commission for an offering to ICON's shareholders of rights to subscribe for up to 1,494,735 additional common shares at a subscription price of US$4.00 per share, for aggregate proceeds of up to US$6 million. **Thomson Kernaghan & Co. Limited** had agreed to act as Solicitor Dealer in connection with the Offering.

11/4 **CIBA Vision Corporation**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics Inc.** announced the filing of Visudyne (verteporfin for injection) therapy with the *Canadian Therapeutics Products Programme (TPP)*, for the treatment of wet age-related macular degeneration (AMD). The specific indication requested is for wet AMD in patients with predominantly classic subfoveal choroidal neovascularization, the most aggressive cause of vision loss associated with the disease and the form for which Visudyne therapy showed a dramatic benefit. Additional regulatory submissions seeking marketing approval have been filed in the U.S., European Union, Australia, New Zealand, Switzerland, Norway and Iceland.

"This filing is a significant development for Canadian patients with wet AMD and is particularly satisfying, given that the drug was discovered in this country," said Dr. Julia Levy, president and CEO of QLT.

The submission is based on results of the pivotal Phase III trials, known as the TAP (Treatment of AMD with Photodynamic therapy) Investigation, which showed a statistically significant benefit at 12 months to those patients treated with Visudyne therapy compared to those administered a placebo. Results also showed that Visudyne therapy was well tolerated, with the majority of adverse events occurring in similar numbers among the treatment and placebo groups. Those events that occurred more often with Visudyne therapy were reactions at the injection site that occurred in 10% more treated patients; transient mild to moderate visual disturbances that occurred in 2% more treated patients; and self-resolving photosensitivity reactions that usually were mild and occurred within 24 hours post treatment in less than 3% of treated patients.

11/4 Since the Academy meeting, I had been trying to determine who had performed LASIK on Tiger Woods, which started him on his phenomenal winning streak -- over $6 million in winnings this year, and still counting! I finally heard back from Stephen Kilmer, Director of Investor Relations at **TLC The Laser Center**, that the surgery had been performed by Dr. Mark Whitten, medical director of the TLC center in Rockville, MD.

11/4 **Lasik Vision** announced its results for the three months ended September 30, 1999. In addition to record revenues and a 501% increase in laser procedures performed from the same period a year ago, Lasik Vision also reported a net profit for the first time since becoming a public company in April 1999. The net profit for the three months was CAN$1.0 million on revenue of CAN$9.6 million compared to a net loss of CAN$1.3 million on revenue of CAN$6.2 million for the second quarter of 1999. Revenue and profitability in the third quarter were primarily driven by increasing growth in the number of procedures performed at Lasik Vision's existing laser refractive centres.

Lasik Vision performed 13,158 laser procedures during the third quarter, up 501% over the same period in 1998, and up 45% from the 8,906 procedures performed during the second quarter of 1999. "We're very pleased with our third quarter results. Reaching profitability is a significant milestone for Lasik Vision, particularly as it occurred much sooner than our industry competitors. Our performance has enabled Lasik Vision to gain dominant market share throughout Canada. As we expand into the U.S. market, we'll continue to carefully manage our resources and our expenses to maintain the momentum we have gained in 1999, which has seen us grow from 3 to 16 refractive centres," said Michael Henderson, president and CEO.

11/4 **TLC The Laser Center** announced that it intends, subject to regulatory approval, to purchase up to 1.87 million of its common shares, representing approximately 5% of the 37.5 million common shares currently outstanding. The prices which TLC will pay for any common shares will be the market price of the shares at the time of acquisition. Any common shares acquired by TLC will be canceled. TLC believes that currently and from time to time, the market price of its common shares may not fully

reflect the value of its business and its future business prospects. In such circumstances, the purchase of TLC's outstanding shares may represent an attractive investment and an appropriate and desirable use of its available funds.

11/4 **Summit Technology** announced its third quarter results with revenues for the three months ended September 30, 1999 increasing 21% to $28.1 million from $23.1 million for the three months ended September 30, 1998. The net loss for the quarter was $0.6 million (1 cent per share) compared to net income of $1.6 million (5 cents per share) for the third quarter of 1998. (The third quarter's net loss included a net gain of $1.5 million (3 cents per share) from the sale of 500,000 shares of **LCA Vision**. Revenues for the laser-related business increased 44% to $16.1 million, compared to $11.2 million for the same quarter a year ago.

Revenues for the first nine months from the company's laser vision correction business increased 32% to $45.3 million, up from $34.2 million for the same period a year ago. Total revenues for the first nine months of 1999 were $81.2 million, an increase of 17% over revenues of $69.3 million for the first nine months of 1998. The net loss for the nine months of 1999, including $22.6 million of one-time charges associated with the **Autonomous Technologies** acquisition, was $22.2 million (58 cents per share), compared to net income of $23.0 million (74 cents per share) for the first nine months of 1998. The results for the nine months of 1998 include the receipt of a $29.9 million litigation settlement, net of taxes and related expenses and a one-time non-cash charge of $10.1 million (32 cents per share), representing the cumulative effect of a new accounting principle adopted as of January 1, 1998.

"We are very pleased with our third quarter results. We realized significant gains in the key areas of laser system placements and procedure volume growth," stated Robert Palmisano, CEO. "With our recent FDA approvals and the successful commencement of human trials of our exciting CustomCornea wavefront sensing technology, we continue to make excellent progress in our stated objective of becoming the undisputed technology leader in this industry, with the widest range of FDA approvals." Palmisano also noted that the Apex Plus system had been re-launched as the Infinity Lasik System, incorporating the previous Infinity modular enhancements package into the newly designed system, which includes unique features for remote diagnostics and pre-programming procedures, including integration of its SKB microkeratome. He also announced that the Department of Defense had appropriated $2 million in its 2000 budget for laser vision correction study using ablatable disc technology.

Third quarter 1999 procedure volume in the U.S., measured by the company's sale of OmniCards, increased 79% over the third quarter of 1998 and 10% over the second quarter of 1999. (This compares to a 6% increase for the quarter noted by **VISX**, indicative that Summit gained some ground during the quarter.) Thirty one laser systems were placed during the third quarter, 14 of which were Autonomous LadarVision systems, compared to 13 Apex laser systems placed during the third

quarter of 1998. Therefore, a total of 70 laser systems were placed during the first nine months of 1999, 21 of which were LadarVisions. During the accompanying teleconference, Palmisano said that he anticipates an additional 30 LadarVisions will be placed during the fourth quarter, plus 30-40 Apex Plus, now called Infinity (see above). He also acknowledged that Summit had about 375 laser systems in place and operating, of which about 25 were LadarVisions. Of the 31 systems placed during the quarter, all but one were placed into the U.S. (With one LadarVision shipped Internationally.)

Discussing the wavefront technology, Palmisano said that the company may accelerate the launch of the device as a stand-alone diagnostic, and get it to market sometime next year, perhaps as early as the ASCRS meeting, while continuing the work to integrate it into the LadarVision system. The company sold 15 SKB microkeratome systems during the quarter, bringing the year's total to 64, and expects to reach the 100 mark by the end of the year. In discussing the average sales price of his lasers, he noted that the Apex Plus systems were averaging between $240,000-$260,000, while the Infinity's were at $325,000. (He noted that the company had signed four Infinity deals at the AAO meeting.) Since the LadarVision sales price depends on the volume levels, he noted that most LadarVision deals were at the 600 procedures per year level, while some were at 2000 procedures per year levels. As for production of the LadarVisions, in September Summit was up to 8 units per month, and expected to be at 12 per month by December. He also noted that the new selling cycle had become quite short, much less than the 6 months to a year former cycle. Finally, he said that the company no longer included its **Lens Express** subsidiary as part of its strategy, and was looking at offers for the company. This situation would be clarified by the end of the year.

11/5 Yet another "short seller", issued an opinion about **Sunrise Technologies** with a news release issued by **TheTruthseeker.com**. The Truthseeker said it had initiated coverage on Sunrise with an immediate "Sell" and "Short Sell" recommendation. The release went on to say that the company had placed a price target, within the next 6 to 9 months, of less than $1 per share. Apparently, this person, one Floyd Schneider, is misinformed as he believes that Sunrise will not be able to gather the data requested by the FDA for at least another 12-18 months. The release goes on to state "that the range of vision correction that SNRS has applied for, to treat with the LTK laser, is very narrow, a range of +.75 to +2.5 diopters, noting that the procedure performed on Dr. Kelman with much fanfare, was not within the range of Sunrise's current application to the FDA, or its supporting studies, as his treated eye required a 4 diopter correction". First, the company has accumulated the needed data, and will present it to the ODP, probably at their January meeting, and secondly, Dr. Kelman's procedure was part of the expanded protocol for moderate hyperopia accepted by the FDA. As with other purported "shortsellers", they should do their due diligence before issuing unsupportable statements.

11/8 **Warburg Dillon Read** analyst Rebecca Irwin said she had initiated coverage on **VISX**

with a "buy" recommendation, and had set a target price of $85 per share. The recommendation was based on VISX having over 60% of the lasers installed in the U.S. and having a nearly 75% share of lasers being shipped. Further, "The company's solid portfolio of patents should continue to allow it to keep competitors out of the marketplace, while it continues to increase its percentage of the installed laser systems in the U.S."

11/8 **SurgiLight** announced financial results for the third quarter ended September 30, 1999. Revenues for the three- and nine-month periods were $891,000 and $2.3 million, respectively, compared to $204,000 and $724,000, for the same periods in 1998. The total revenue for the third quarter is attributed to the company's four divisions. The Laser Eye Centers had a gross revenue of $561,000, or 63% of the total quarterly revenue. The Cosmetic Centers had a gross revenue of $73,000, or 8%, and Laser Technology and Infrared Thermal Imaging Division had a gross revenue of $261,000, or 29% of the total quarterly revenue. In the quarter, the company established 3 more international Eye Laser Centers and sales of eye laser systems also increased 14% over the second quarter 1999. For the quarter, the company reported an operation income of $150,000, excluding the facility depreciation of $55,000. The net income (after the facility depreciation) was $95,000 compared to a net loss of $47,000 for the same period of 1998. R&D costs and clinical trials costs will continue to increase in the future quarters to support our focus on the company's new infrared lasers and the related ongoing clinical trials in Latin America and Mt. Sinai Hospital in New York City. As announced earlier, the company demonstrated the world's first IR-laser to be used for vision corrections at the AAO. The protocols for the clinical studies in U.S. using the new IR-laser will be submitted within 30 days.

11/9 An appeal by **Les Cliniques Michel Pop** regarding a reprimand by the discipline committee of the **College des Medecins du Quebec** in the matter of a laser eye surgery infomercial was favorably received by the **Tribunal des professions**. Since Les Cliniques Michel Pop was exonerated, the College des medecins du Quebec was ordered to pay costs to the Tribunal des professions. This decision was announced on May 19, 1999.

On March 10, 1998, the discipline committee of the College des medecins du Quebec found Dr. Michel Pop, president of Les Cliniques Michel Pop, guilty of having committed "acts that violate the honor and dignity of the profession...in misleading the public by using an actor to falsely represent one of his patients in an infomercial about laser eye surgery, broadcast on or about October 21, 1996...in violation of articles 2.02.06 and 2.03.39 of the Code of Ethics." According to Article 2.02.06 of the Code of Ethics, the physician may not engage in, or allow the use of, by any means whatsoever, advertising in his name, about him or for his benefit that is unsuitable, false, misleading or liable to mislead. Article 2.03.39 states that a physician must not, directly or indirectly, deceive his patient or the public, either when acting alone or with others. He must, in particular, avoid any misrepresentations of his level of competence. The infomercial produced by Les Cliniques Michel Pop portrays Dr. Pop

with a nurse, a patient and his wife. The nurse, the patient and his wife are played by professional actors. The infomercial provides a re-enactment of how a patient is treated before, during and after surgery, without explicitly showing the surgical act.

According to the Tribunal des professions, the goal of Les Cliniques Michel Pop's infomercial is clear: to provide information about the anatomy of the eye and the techniques of laser eye surgery. The use of a professional actor acting as a foil to Dr. Pop in no way adds to or subtracts from the truth of the infomercial's message. Nothing in the message, in its substance or its overall content is false, misleading or likely to mislead. The tribunal therefore concluded that the interpretation by the discipline committee of the College des Medecins du Quebec was an unconscionable error. The reprimand dated July 9,1998 is thereby revoked.

"We are very pleased with the tribunal's decision and sincerely hope that this precedent will be useful for other health-care professionals who use advertising in their performance of their duties," said Dr. Pop.

11/9 **Icon Laser Eye Centers** said that today was the record date for a rights offering to its shareholders, with shareholders able to subscribe for up to 1.5 million shares at $4.00 per share.

11/10 **IRIDEX** announced the results of a clinical study published in the November issue of the journal Ophthalmology which holds the promise for an effective treatment for certain patients with vision loss caused by dry age-related macular degeneration (AMD). The treatment, using an IRIDEX infrared diode laser system, was shown to be effective in improving visual acuity by two or more lines in 24% of a subset of treated eyes compared to none in the observation group. There are about 1.8 million new cases of dry AMD each year in the U.S. and an estimated 5-10% of these patients may benefit therapeutically from this treatment.

"These results are significant and important because this treatment could potentially benefit up to 13.5 million Americans who have the dry form of AMD," stated Dr. Joseph Olk, Director of the Study and Director of **The Retina Center** of St. Louis, Missouri. "To date, there has been no clinically proven interventional therapy for dry AMD. The current annual incidence of AMD is approximately two million Americans, 1.8 million of whom are affected by the dry form. Furthermore, it is anticipated that both the incidence and prevalence of AMD will increase substantially with the aging of the population. This treatment is performed as an outpatient procedure, usually performed in the doctor's office, typically takes ten to fifteen minutes, and is essentially painless."

The prospective clinical pilot study was conducted at four centers in the U.S and randomized 229 eyes of 152 patients with dry AMD to either treatment with the company's IRIS Medical OcuLight SLx infrared laser photocoagulator or observation. The two year results demonstrated that the accumulated deposits (drusen) associated

with the early stages of this disease can be safely and significantly reduced or eliminated after only one treatment in 68% of treated eyes vs. 3% of observation eyes (p less than 0.0001). In addition, the study showed that resorption of drusen significantly improved visual acuity. Overall, vision improved by two or more visual acuity (VA) lines in 11.4% of all treated eyes vs. 0% of observation eyes (p less than 0.001). However, in a subset of patients, those who had drusen in both eyes and the treated eye had the potential for a two or more line improvement, the percentage of eyes that improved by two or more VA lines reached 24.4% vs. 0% of observation eyes (p less than 0.002).

"This study showed that resorption of central drusen appears to benefit the visual outcome for certain patients with dry AMD," commented Giorgio Dorin, Director of Clinical Applications development at IRIDEX. "Vision improvement associated with laser-induced reduction of drusen has also been reported in at least three other peer reviewed published studies (Little, Sarks, Ho). Therefore, safe "sub-threshold" infrared (810 nm diode) laser macular grid treatment may become the accepted therapeutic treatment for patients with dry AMD who have significant reduction of vision (i.e., 2 or more lines) caused by presence of drusen in the central macula."

One purpose of this clinical study was to determine the appropriate laser intensity to be used in a subsequent larger multi-center randomized clinical trial called the Prophylactic Treatment of Age-related Macular Degeneration (PTAMD) Trial. The PTAMD Trial, also sponsored by IRIDEX, is designed to answer the question of whether reduction of drusen using very light "sub-threshold" infrared laser treatment would halt or delay the progression of the AMD from the dry form to the wet form. Dr. Thomas R. Friberg, Professor of Ophthalmology, University of Pittsburgh, is the Director of the PTAMD Trial that is currently enrolling patients at 20 centers.

11/11 **Sight Resource** announced that it had begun a program of consolidating its optical manufacturing laboratories. As a result of these actions, the company expects to reduce costs by over $250,000 per year beginning in the year 2000. Sight Resource's optical manufacturing facilities in Holliston, Massachusetts and Metairie, Louisiana will cease operations next month. The closing of the facilities will result in a net reduction of 25 positions associated with the manufacturing process. Job orders previously processed by the affected facilities will be handled by the company's existing laboratories at **Kent Optical** in Muskegon, Michigan and **E.B. Brown Opticians** in Cleveland, Ohio. The consolidation effort will result in one-time expenses of approximately $150,000, primarily associated with severance costs, which will be recognized in the quarter ending December 25, 1999.

11/11 **VisionAmerica** announced that it was delaying the release of its third quarter 1999 results pending discussions regarding the disposition of certain operating units and concerning impairment provisions, principally those related to prior acquisitions. These discussions stem from the company's ongoing campaign to narrow its business focus, as well as the implications of replacing medical directors in three acquired

centers. The company plans to release its third quarter 1999 financial and operating results within the next ten business days, following the completion of these discussions.

11/11 **TLC The Laser Center** began trading on the Nasdaq National Market System under the new name, **TLC Laser Eye Centers Inc.**

11/12 **Banc of America** said it initiated coverage of **VISX** with a "buy" rating on a strong growth-rate estimate in 2000. Analyst Kurt Krueger said, "We expect robust growth in 2000, projecting 1.4 million eyes in the U.S. market and fee revenues to manufacturers of $335 million." According to BofA, VISX controls over 60% of the industry's installed lasers in the U.S.

11/15 The November issue of *Ophthalmology Management* contains an article written by Dave Harmon of **MarketScope** entitled, *"Why Refractive Surgery is Booming"*. Harmon explains that from a small start in 1994 with a few surgeons performing about $200 million per year in RK patient fees, in 1999 the market will generate more than $2.1 billion in fees and "its rapid growth and upside potential is attracting national and international attention from surgeons, corporations, investors, and institutions". He goes on to explain the phenomenon of LASIK and how word of mouth is spreading the word, stating that more than 7000 surgeons have been trained and certified by the laser manufacturers, while more than 3000 actually perform the surgery. (A copy of the article is attached for your review.)

11/15 This month's *Refractive Market Perspectives* notes that third quarter refractive volume growth slowed to 9.8%, down somewhat from the previous quarter's 14.5% growth. According to Dave Harmon, a significant portion of the growth came from unlicensed procedures performed on **Nidek** lasers and from U.S. patients traveling to Canada in search of low-cost surgery. He expects procedure growth of about 25% during the fourth quarter, bringing the quarter to about 310,000 procedures, as consumers take advantage of medical reimbursement accounts, attempt to squeeze tax deductible medical expenses into 1999, or give refractive surgery as a holiday gift. The year-to-date count of procedures is at 668,000, with projections remaining in line for 980,000 for the full year. Harmon believes that an estimated 112 new lasers were sold during the quarter, which has diluted his average procedures per laser to 121.3 per month.

11/15 **LaserSight** announced that the FDA had granted pre-market approval for its excimer laser system, the LaserScan LSX, to perform PRK to treat low to moderate myopia. The approval enables LaserSight to market, sell, and distribute its excimer laser system for laser refractive vision correction procedures in the United States. The approval will allow ophthalmologists to use the LaserScan LSX for the elimination or reduction of low to moderate myopia ranging in severity from -1.0 D up to -10.0 D. The company has also filed a PMA supplement for the additional indication of myopia with astigmatism. Currently, patients with up to +8.0 D of hyperopia, with or without up to +6.0 D of astigmatism, are being treated in ten clinical sites with the

LaserScan LSX under an IDE. The company expects to file its PMA for hyperopia and hyperopic astigmatism in the middle of next year.

Michael Farris, president and CEO, commented, "We are pleased with our FDA approval, which will allow LaserSight to commercialize its scanning excimer laser system in the world's largest market for refractive laser systems and procedures. We intend to vigorously pursue the U.S. market, offering the LaserScan LSX excimer laser, together with our MicroShape family of keratome products. We believe this combined platform of products will allow us to become a single-source supplier of refractive vision correction solutions to the growing number of refractive surgeons who perform laser refractive vision correction procedures. Further, the number of installed excimer lasers in the U.S. marketplace is expected to increase to accommodate growth in the number of procedures. We continue to explore and develop strategic alliances for the distribution of our products. We believe that our ability to offer our laser systems and single-use keratomes and keratome blades to individual and group practices, as well as corporate laser centers in the U.S. and worldwide where growing physician and procedure bases require high-volume capabilities, affords us the opportunity to participate in the anticipated growth of laser vision correction procedure volumes."

The company expects to begin manufacture of systems for the U.S. market during the fourth quarter of 1999 with shipments expected during the first quarter of 2000.

The company also announced financial results for the third quarter and nine months ended September 30, 1999. Revenues for the quarter increased approximately 32% to $6.9 million from $5.3 million in the third quarter of 1998. The company reported a net loss of $3.0 million (17 cents per share) compared to a net loss of $2.1 million (also 17 cents per share) reported for the third quarter of 1998. Revenues for the third quarter increased approximately 32% from $5.3 million in the second quarter of 1999. The company's net loss for the quarter showed improvement over prior quarters of 1999, narrowing from the $3.5 million (21 cents per share) reported in the second quarter, and from the $3.3 million (25 cents per share) reported in the first quarter. The increase in losses during 1999 compared to the comparable quarters in 1998 is attributed to costs associated with developing, testing and launching the company's new MicroShape family of keratome products, and development of the infrastructure necessary to support the introduction of the LaserScan LSX excimer laser system into the U.S. market.

During the quarter, the company began shipment of its UltraEdge Keratome Blades in the U.S., Canada and other international markets. The blades are manufactured for LaserSight by **Becton Dickinson** as part of a joint venture first announced in May 1999. In October 1999, the company reported its expansion of this relationship, resulting in **BD Ophthalmic Systems** becoming the distribution arm for all of its MicroShape family of keratome products, including blades, in the U.S., the U.K., Ireland and Japan.

Michael Farris, president and CEO, commented, "Our revenue growth and reduction in net loss for the third quarter can be attributed to an increase in international sales of our LaserScan LSX excimer laser and sales of our UltraEdge Keratome Blades that were launched in the U.S., Canada and other international markets in late July. We sold 19 systems this quarter compared to 13 in the same period last year."

Revenues for the nine month period increased approximately 18% to $17.1 million from $14.5 million in the comparable period of 1998. The company reported a net loss of $9.8 million (62 cents per share) compared to a net loss of $5.9 million (79 cents per share) reported for the same period a year ago, before the additional $3.6 million loss attributable to common shareholders for that period of 1998, reflecting the effects of premiums, accretion and conversion discounts on the redemption of Series B Preferred Stock and the issuance of Series C and D Preferred Stock.

During the accompanying teleconference with analysts, Farris said that the company was in negotiations with **VISX** to obtain a marketing license, even though they believed that they do not infringe on the VISX patents. A license would allow the company to bring the LaserScan LSX to market in a timely fashion. He expects to begin shipping systems in next year's first quarter, with U.S. units to be produced in Orlando (an FDA approved manufacturing site), while international units will continue to be produced in Costa Rica. Farris noted that manufacturing capacity would be about 20-25 units per quarter for both facilities, although that could be expanded if the demand requires it. He expects that an astigmatism supplement, which has been filed, will come through by the end of the first quarter, and will only require a software upgrade to implement. Hyperopia, with and without astigmatism clinical trials are underway and results will be submitted sometime next year, with marketing approval anticipated in 2001. With the advent of customized ablations, the company is working on an improved tracking system, and expects to get supplemental approval for 200 Hz rep rate shortly (also just a software upgrade), giving it an excellent platform for customized ablations. LaserSight is also working on a "next generation" topography device that will give much more information about the cornea, which controls 80% of the vision correction. As for setting up a service organization, the company will have its own force, and is exploring a strategic partnership for responsive field support.

11/15 **Atlantic Pharmaceuticals** announced that its subsidiary **Optex Ophthalmologics** had been notified by the U.S. Patent Office that Optex had been issued U.S. Patent No. 5,957,921 "Devices and Methods Useable for Forming Small Openings in the Lens Capsules of Mammalian Eyes." The new patent covers a device and system for creating small, less than 3 mm and preferably about 1 mm in cross dimensions, openings in the anterior lens capsule of a mammalian eye to facilitate the removal of the lens nucleus and cortex. This device, coupled with Optex's Catarex surgical device for cataract removal, creates an integrated system that the company believes will revolutionize the way in which cataract surgery is performed. In addition, the new device would, in conjunction with the Catarex device, facilitate the use of liquid

injectable replacement lenses.

Atlantic recently announced that Optex's development and license agreement with **Bausch & Lomb Surgical**, a subsidiary of **Bausch & Lomb Incorporated** had been amended to provide for an expanded role for Optex in development of the Catarex surgical device.

11/15 **LCA-Vision** announced that its new LasikPlus centers in California experienced a 117% increase in procedure volume in October, when compared with September volumes. The company attributed the triple-digit increase in California last month to the conversion of all its West Coast centers to the new "value-priced" LasikPlus format. "Our `value-priced' LasikPlus centers have lowered the affordability bar, accelerated acceptance and opened our markets to a far larger base of potential patients," stated Stephen Joffe, chairman and CEO of LCA-Vision. "The impact of LasikPlus on revenues and procedure growth has been dramatic, further validating our new `value-priced' business model. In California, for example, call volume and appointments scheduled in October were 24 to 26 times higher than in September. By offering LASIK at $2,995 for both eyes, we are delivering high patient satisfaction and excellent clinical outcomes, all at about 40 percent below the customary $4,500-$5,000."

In the interest of sharing information on the progress of the LasikPlus conversion, Mr. Joffe stated, "We will issue periodic updates on procedure growth and acceptance levels in various key markets. The important thing for investors to grasp is that our margins have not been hurt by our competitive pricing. Our new model gives our patient's access to some of the nation's finest Lasik surgeons, while changing the economics of providing Lasik for the benefit of both the patient and LCA-Vision. From a cost and organizational standpoint, LasikPlus is far more efficient and easier to manage."

As LCA-Vision rolls out additional LasikPlus centers, overall marketing and advertising expenses will increase, reflecting the costs associated with the introduction of LasikPlus in each new market. The company does expect these expenditures to wind down as brand recognition grows and word of mouth kicks in. "Our market research indicates that positive word of mouth is among the most influential factors in persuading potential patients that LASIK is right for them," continued Mr. Joffe. "Among those who know someone who has had a positive experience with laser vision correction, they are three times more likely to have their procedure performed by the same doctor or center."

LCA-Vision owns and operates 22 centers and plans to convert additional centers and open new ones before year-end.

11/15 **Laser Vision Centers** announced today that its U.S. case volume for its fiscal second quarter ended October 31, 1999, was almost 22,600 compared to more than 11,620 for the same period last year, a 94% increase. Worldwide case volume was 23,543 for the

quarter compared to 12,622 a year ago. As of October 31, 1999, LaserVision had 59 lasers in operation in the U.S. and a total of 64 worldwide. More than 620 U.S. surgeons accessed LaserVision's services at 264 locations in 44 states.

11/15 **Sterling Vision** announced its financial results for the nine months ended September 30, 1999. Net Income was $872,000 (4 cents per share) for the nine months ended September 30, 1999, as compared to a Net Loss of $8.8 million (61 cents per share) for the comparable period in 1998. EBITDA (earnings before interest, taxes, depreciation and amortization) increased to $3.6 million for the nine month period, as compared to a loss of $3.8 million for the comparable period in 1998.

Dr. Robert Cohen, chairman, stated, "The increase in net income for the nine months ended September 30, 1999, was principally due to the continued positive effects of our new management team's 1998 initiatives and the continued focusing of our resources on our **Insight Laser Center** division, as well as on Internet initiatives, which the company expects to launch in the first quarter of 2000."

11/15 **Vision Twenty-One** indicated that it was going to be exploring a number of strategic alternatives and additionally announced results for the third quarter ended September 30, 1999. The company's Board of Directors voted to explore a number of strategic alternatives intended to maximize shareholder value. As a result of the company's previously announced letter of intent with **MedEquity Investors** and **Chase Capital Partners** regarding a proposed preferred stock transaction, the company has received interest from other third parties regarding various options ranging from a purchase of certain business units from the company to a purchase of the entire company. The company's Board is focusing on such other possible alternatives at this time. The previous proposed transaction with MedEquities and Chase Capital Partners is not likely to be pursued although the parties continue to analyze various ways to jointly pursue the strategic options available to Vision Twenty-One. The company has engaged **PaineWebber Incorporated** as financial advisor in conjunction with assessing its current strategic alternatives. Ted Gillette, CEO, indicated that, "The Board of Directors has a duty to evaluate the existing possible strategic alternatives before us and we are committed to exploring these options fully with a goal of selecting the path which will maximize shareholder value."

As the company is in a transitional stage, management cautioned that third quarter results should not necessarily be relied upon as indicative of future operating performance. Revenue for the quarter was $37.7 million and a loss from continuing operations at $4.4 million (28 cents per share). The net loss for the quarter was $7.8 million (51 cents per share). As previously announced the third quarter was negatively impacted by a total of $1.2 million for restructuring and other charges and medical claims in excess of revenue on a terminated managed care contract. For the nine months period, the company reported revenue of $130.0 million and a net loss of $9.4 million (62 cents per share) from continuing operations. The net loss for the nine months was $12.1 million (80 cents per share). The company noted the prior year was

not comparable as a result of the business unit divestitures.

Refractive surgical procedures for the third quarter increased 130% to 4,719 as compared to 2,051 for the third quarter of 1998.

11/15 **Image Sculpting International Inc.** announced that it had entered into a letter of intent to acquire **D.R. Josephson Limited (Josephson's)**, a company that has been in the fashion optical retail business in Canada for 65 years and the Toronto 7-store retailer is recognized as the leading Canadian up-scale retailer in this sector. This acquisition will form one of the key strategies of ISII's business expansion. ISII intends to expand Josephson's and to offer a more complete range of vision correction options than any other Canadian company. The product offering will be expanded, from its current offering of "high-end" eyeglasses and contact lenses, to also include laser vision correction and laser cosmetic procedures. Josephson's attracts more than 800 shoppers per week. Stores will be equipped with marketing materials and technical specialists to help promote ISII's services. The acquisition will be funded through the issuance of 833,333 common shares of ISII, $600,000 in cash and a $700,000 note.

11/15 This week's issue of *Ocular Surgery News* carries an interestng story about the remaining anti-trust suits still carrying on in the wake of the breakup of **Pillar Point Partnership**. Rochelle Nataloni interviewed the attorney representing several of the parties involved (which includes **New England Laser Vision and Eye Care Surgery Center of Maine Inc.**; **The Eye Professionals, P.A.**, of Millville, N.J.; **Metropolitan Eye Center and Outpatient Surgical Facility Inc.**, of Clair Shores, Mich.; and **David R. Shapiro, MD**, of California, among others). The plaintiffs allege in their complaint that **Visx** and **Summit** illegally fixed the price of the per procedure royalty fee through Pillar Point Partners. The plaintiffs are seeking the amount between the "competitive" amount and the amount charged. A damages analysis is underway to arrive upon a specific dollar amount. Trial dates have yet to be set.

11/16 Ted Huber of **Advest** published an update on **TLC The Laser Center**, continuing his "buy" recommendation, and telling his clients "not to panic" with the apparent price reductions occurring in the industry. His reasons: TLC leads the rapidly growing industry, where scale and market share matter; although the U.S. market will segment in 2000 (into low and premium price locations), it will allow TLC to maintain its growth in the "premium" (albeit lower) pricing segment; barriers to entry are growing as TLC leads the "corporatization" of refractive surgery, and stakes out valuable strategic positions; and, its financial model offers powerful operating leverage.

The main take away message, as discounting becomes more pervasive, TLC needs to manage down its average sales price to maintain a palatable price differential of between $500 to $750 per eye. Its current prices range from $2400 to $2750 in most U.S. markets, while others prices average $1800 to $2200, with the price discounters coming in at about $1500 (with **Lasik Vision** on the low end at about $1250 per eye). A premium of between $500 to $750 per eye for premium service/quality is

sustainable.

Huber sees the segmentation occurring at three levels: the deep discounters, like Lasik Vision; the value players, like **LCA-Vision's LasikPlus** model; and the high-end players, like TLC and **Laser Vision**.

11/16 *Reuters* reported that Federal advisers are set to review a treatment developed by a unit of Switzerland's **Novartis AG** and Canada's **QLT PhotoTherapeutics**. The firms will present data to an FDA advisory committee on Visudyne, a treatment for age-related macular degeneration (AMD). Pharmaceutical industry analysts said Visudyne's approval is considered vital for Canadian biotech firm QLT, which specializes in light-activated therapies. It also could prove important for Novartis, which would split revenues that analysts said would be several hundred million dollars a year. QLT and its investors are counting on Visudyne to make the company profitable for the first time, analysts said. QLT already sells another drug, a cancer treatment called Photofrin, but Visudyne is expected to dwarf that product, analysts said.

"It's very important," **Nesbitt Burns** analyst Christine Charette said of Visudyne. "This drug is QLT."

11/16 Also, according to *Reuters*, **VISX** has sued **LaserSight** and two of its subsidiaries for alleged patent infringement. In papers filed on Monday in the U.S. District Court in Delaware, VISX alleged that its patent for an "Apparatus for Ophthalmological Surgery" was infringed by LaserSight's LaserScan LSX system. This followed LaserSight's announcement that the LaserScan LSX had received FDA approval to treat low to moderate myopia.

The company said that it had received word of the suit late in the day on November 16, 1999, advising it of the litigation filed by VISX asserting that LaserSight's technology infringed one of VISX's U.S. patents for equipment used in ophthalmic surgery. LaserSight does not believe its technology infringes VISX's patents, but has entered into license negotiations in order to help facilitate commercialization of its laser systems in the U.S.

The following morning, LaserSight issued a statement claiming that it had reached agreement with VISX to stay the patent litigation filed by VISX on November 15, 1999 to continue negotiations toward a U.S. license agreement. The parties have been in negotiations and have made substantial progress. During the stay, LaserSight will commence manufacturing its laser systems in the U.S. but will not sell, offer to sell, ship or use commercially its systems in the United States until the parties enter into a license agreement or the stay is otherwise lifted. This stay does not affect LaserSight's ability to manufacture or sell its laser systems outside the U.S. LaserSight believes that this will not alter its previously announced plan to begin U.S. manufacturing in the fourth quarter of this year and to commercially ship units to U.S. customers in the

first quarter of 2000. Both parties have retained the ability to withdraw from the licensing negotiations and allow the litigation to proceed.

11/16 **Atlantic Pharmaceutical** announced results for the third quarter ended September 30, 1999. The company reported a net loss of $330,441 (7 cents per share) for the quarter compared to a net loss of $1.8 million (45 cents per share) for the same quarter in 1998. Total revenue for the three-month period was $276,750 compared with no revenue for the same period last year.

11/17 The Ophthalmic Drugs Subcommittee of the FDA recommended approval of Visudyne (verteporfin for injection) therapy for the treatment of wet age-related macular degeneration (AMD), the leading cause of blindness among people over the age of 50. Both the panel and the FDA concluded that Visudyne therapy was most appropriate for patients with predominantly classic subfoveal choroidal neovascularization (CNV), the indication proposed by co-developers **CIBA Vision**, the eye care unit of **Novartis**, and **QLT PhotoTherapeutics Inc.**

Typically, the subcommittee, a panel of expert consultants to the FDA, would be asked to vote on whether or not they recommend a product be approved. In the case of Visudyne, the FDA did not ask the panel to formally vote on approvability, but sought guidance on efficacy and confirmation of safety and product labeling. At the conclusion of the hearing, the panel members voluntarily expressed their view that the therapy should be approved.The panel's conclusions will be taken into consideration by the FDA as it completes its review of the NDA for Visudyne therapy, which was submitted on August 16, 1999. The FDA is expected to make a final decision regarding the approval of the Visudyne application on or before February 2, 2000. Regulatory applications are also pending in the European Union, Canada, Switzerland, Norway, Iceland, Australia and New Zealand. The panel and the FDA concurred that Visudyne therapy is generally safe and well-tolerated, with minimal adverse events relating to treatment. Currently, only 10-15% of the estimated 500,000 patients who develop wet AMD worldwide every year are eligible for existing treatments. Medical experts estimate that between 40-60% of all wet AMD cases will develop predominantly classic lesions as the disease progresses.

Visudyne therapy involves the use of a specifically designed laser that produces the low level, non-thermal 689 nm light required to activate the drug. These lasers have been developed by two of the world's leading laser companies, **Coherent Inc.**, based in California, and the **Carl Zeiss Group**, based in Germany, and comprise the two device PMAs submitted in conjunction with the NDA. (In the U.S., Zeiss's subsidiary, **Zeiss Humphrey Systems** will market the device.)

Additional Phase III trials are being conducted to determine the effectiveness of Visudyne therapy in patients with an earlier stage of AMD who were originally excluded from the initial Phase III investigation as well as patients with a similar but distinct condition of abnormal blood vessels associated with progressive

near-sightedness known as pathologic myopia.

Coherent Inc. issued its own news release stating that the FDA's Ophthalmic Drugs Subcommittee had recommended approval of the Opal Photoactivator and Visudyne Therapy for the wet form of age-related macular degeneration (AMD). The application, filed jointly by Coherent and QLT PhotoTherapeutics Inc., covers Coherent's new Opal Photoactivator laser developed specifically for use in photodynamic therapy and Visudyne, the drug which is activated by this special purpose 689nm diode laser.

11/18 The *Associated Press* reported that advisers to the FDA indicated support for a light-activated drug to battle a form of creeping blindness that afflicts the elderly, but stopped short of giving it a formal endorsement. "The committee looked favorably upon the benefits over the risks of Visudyne," said Dr. Donald Fong of *Kaiser Permanente Medical Center* in Baldwin Park, CA, chairman of the FDA's ophthalmic drugs advisory subcommittee. His comments followed a daylong session discussing the drug, used in light therapy for macular degeneration, the major cause of blindness in the elderly. Visudyne is made by **QLT PhotoTherapeutics** of Vancouver, British Columbia, Canada. The panel did not take a formal vote on whether to recommend approval of the drug, which the FDA is considering. Several committee members indicated they wanted to see the results of a second year of clinical trials. Fong noted that some patients required more than one treatment in the initial trials. Even if the panel had voted, the FDA is not bound by advisory committee recommendations. However, it does give them serious weight in making decisions on what drugs to approve.

11/18 **TLC The Laser Center Inc.** officially introduced its new corporate name, **TLC Laser Eye Centers**, and a redesigned corporate logo.

11/18 **Vision Twenty-One** announced the opening of its tenth eye laser center with the Arizona Eye Laser Center at Scottsdale. "Our decision to add a third refractive surgery center to the Arizona market is supported by the positive response we've received from local ophthalmologists wanting to expand their refractive surgery practices," said Ted Gillette, CEO. In addition to the Scottsdale center, Vision Twenty-One operates the Arizona Eye Laser Center at Phoenix, (opened in 1998) and the Arizona Eye Laser Center at Tucson (opened in 1999). Vision Twenty-One also manages three ambulatory surgery centers in the Phoenix and Tucson markets.

11/19 **Goldman Sachs** said it had cut **KeraVision** to "market performer" from "market outperformer". No further details were available.

11/19 **VISX** and **CRS Clinical Research Inc.** announced that the FDA had approved the use of its VISX STAR S2 Excimer Laser System as safe and effective for the LASIK treatment of up to 14 diopters of myopia with up to 5 diopters of astigmatism. (Thus, the company joins **Summit Technology** -- and Dr. Fred Kremer, with his home-made

laser
-- as approved for LASIK.)

Charles Casebeer, MD, CEO of CRS, remarked, "We are pleased that this doctor's-sponsored study was so successful, resulting in an approval for VISX this week and one for Summit Technology a few weeks ago. These accelerated approvals show the value of doctors working together to collect data to submit to the FDA for approval and thereby changing the way medicine is practiced."

11/20 Dave Therkelsen of **Dain Rauscher** sent along his *Refractive Surgery Update: Highlights from the AAO Annual Meeting*. Reflecting my views, the "hot" topics at the meeting were "custom correction"; the movement of refractive surgery to the "next level" as the technology moves beyond the "early adopters" into the mainstream population; and the increasing excitement surrounding the potential of laser treatments for AMD. In the report, Therkelsen maintained his "strong buy-aggressive" ratings on **Bausch & Lomb**, **Summit Technology**, and **VISX**; his "buy-aggressive" rating on **KeraVision**, and his "buy-speculative" ratings on both **Iridex** and **LCA-Vision**.

In the report, Therkelsen writes about how better refractions could help improve patient's outcomes, with manufacturers such as VISX, B&L, and Summit probably marketing/
commercializing their wavefront analyzers prior to these devices being available as part of integrated custom ablation systems. He also presents updated information on each of the companies he follows, based on what he saw and heard at the AAO meeting.

11/23 **Sunrise Technologies International** reported that the FDA had posted on its website that the company's PMA Application is scheduled for review at the January 13-14 meeting of the Ophthalmic Devices Panel (ODP). The Panel will review the PMA application for the Sunrise LTK System for the reduction of hyperopia within the range of +0.75 to +2.50 diopters. Since the company's first appearance before the ODP on July 22, 1999, Sunrise and the FDA Ophthalmic Devices Branch have met extensively regarding the company's PMA Application. The application contains a substantial increase in the number of patients followed through two years. At the January 2000 ODP meeting, the company will quantify and explain the postoperative outcome that LTK patients may experience, addressing earlier concerns regarding change in refractive effect over time.

The company believes that the data support its claim that the Sunrise LTK patient population achieves an improvement in vision due to a reduction in the amount of their preoperative hyperopia.

11/23 **Zeiss Humphrey Systems** announced that the Ophthalmic Drugs Subcommittee of the FDA recommended approval of Visudyne (verteporfin for injection) therapy and the use of Zeiss Visulas 690s for the activation of the Visudyne photosensitive treatment

of wet age-related macular degeneration (AMD), the leading cause of blindness among people over the age of 50. The Zeiss Visulas 690s laser activates Visudyne for the treatment of AMD. "We are extremely encouraged by the results of the clinical trials and the recommendation from the subcommittee. This represents a significant step towards improving the lives of thousands of people around the world. We feel very proud to be a partner of **CIBA Vision**, and **QLT PhotoTherapeutics** in the treatment of this debilitating disease. The technology has proven its efficacy and I am positive that by using our laser, Visudyne will set the standard for treating AMD," said Lothar Koob, president of Zeiss Humphrey Systems.

11/23 **VisionAmerica** announced that it has entered into a letter of intent to sell its ophthalmic buying group, **Primary Eyecare Network (PEN)** of San Ramon, CA, to **HMI Buying Group**. The proposed sale has been approved by PEN's advisory board of participating optometrists. PEN will continue to operate as a stand-alone organization from its headquarters in San Ramon. The transaction is expected to be completed by December 31, 1999. "We are excited to have the opportunity to add such a high quality organization as PEN to our family of buying groups," said Jerry Hayes, OD, owner and CEO of HMI Buying Group. This acquisition will strengthen our position in the industry and further enhances our commitment to the independent eyecare professional." The addition of PEN to the HMI Buying Group organization will create the largest purchasing entity dedicated to the independent eyecare professional, with over $90 million in annual sales. "Each buying group offers a unique set of assets," added Hayes. The combination provides our customers a win-win situation, everyone will benefit."

The company also announced the results of its third quarter and its progress in transforming the company to emphasize its core business, ophthalmic center operations and in particular, refractive surgical services. Net revenues from continuing operations for the third quarter totaled $16.4 million, a 16.2% increase compared to $14.2 million for the third quarter last year. The company reported a net loss from continuing operations for the quarter of $1.7 million (19 cents per share) compared to net earnings from continuing operations of $512,000 (6 cents per share) for the same quarter last year. During the quarter, the company reported unusual charges totaling $2.1 million in connection with the company's change in strategic focus and restructuring of certain physician relationships.

Net revenues from continuing operations for the nine months period totaled $46.4 million, up 15.8% from $40.1 million reported for the same period last year. The company reported a net loss from continuing operations of $622,000 (7 cents per share) compared to net earnings from continuing operations of $1.3 million (15 cents per share) in the same period of 1998. During the third quarter, the company made significant progress in transforming itself to focus on its core business, center operations. This narrowing of its business strategy was significantly advanced through a variety of activities including the following:

-- The company name change to VisionAmerica Incorporated from **Omega Health Systems, Inc.** in order to identify itself in the eye care industry as well as establish a platform for consumer branding opportunities.

-- The planned disposition of its non-core business units, including the company's managed care division, its group purchasing division and its wholesale optical lab.

-- The accelerated development of VisionAmerica's refractive surgery program including: the recruitment and training of a national marketing director and refractive surgery coordinators in all VisionAmerica markets, the launch of a comprehensive internal and external marketing program known as the "Freedom Campaign", the creation of a national in-house telemarketing service for patient scheduling and patient satisfaction reviews, the training of 17 VisionAmerica surgeons on the Keravision Intacs procedure, and the delivery of the last of its initial order of 12 **VISX** Star S2 Excimer Laser Systems to be used in fixed and mobile sites. As a result of the new lasers, 61% of all VisionAmerica Lasik procedures performed during the quarter were performed on its own lasers.

-- The continued development of VisionAmerica's information technology infrastructure in the areas of accounting and practice management. Currently, 32 of 36 reporting locations have converted to Great Plains Dynamics C/S accounting software and 14 of 22 center operations have completed the conversion to Paradigm by Millbrook practice management software. This quarter proved to be VisionAmerica's most intense period to date for travel and training to support these efforts. The company also initiated a national "Help Desk" for problem solving support on all conversion projects.

-- A decision to de-emphasize acquisitions other than the occasional strategic acquisition that adds depth to existing markets. During the quarter, the addition of a practice located in Alabama is an example of this modified approach.

-- The restructuring of physician agreements in several centers allowing for new physician leadership and stronger success-alignment with physicians in several center markets. In addition, the company added four more surgeons to help expand center operations.

The evidence of VisionAmerica success related to these changes include: a record quarter for LASIK procedures volume (3,011); a record quarter for cataract procedures volume (5,008); a record quarter for same stores revenue growth (19%); and a record quarter for revenues from operations ($16.4 million). In addition to the previously announced sale of its managed care division, the **Eye Health Network (EHN)**, VisionAmerica elaborated on the plans to sell its ophthalmic buying group, Primary Eyecare Network, Inc (PEN). and its optical laboratory, **Providers Optical**, as a part of its continuing efforts to focus on its core operations. The operations of these business units, along with those of EHN have been classified as discontinued

operations in the company's financial statements for all periods presented. Previously reported financial information has been restated to conform to the current presentation. The company closed on the sale of EHN in July of this year, has executed a Letter of Intent to sell PEN in the next sixty days and is in active negotiations to sell Providers Optical. After these operations are discontinued, VisionAmerica's operations will consist of its eye care and surgery centers and mobile surgical services that support the centers. The company offers laser vision correction services in all of its centers.

11/26 **Lasik Vision** announced that it had completed its previously announced (October 20, 1999) private placement of 275,871 units, consisting of one common share and one half of one non-transferable share purchase warrant.

OPHTHALMIC LASER UPDATE -- December 1999

11/29 **Laser Vision Centers** announced that revenue for its second quarter ended October 31, 1999, was $20.8 million, compared to $10.4 million for the same period a year ago. Revenue for the six-month period was $41.8 million, up from $19.5 million for the same six-month period last year. Net income for the quarter was $3.9 million (15 cents per share), compared to a net income of $958,000 (5 cents per share) for the same quarter last year. For the six-month period, net income was $8.1 million (32 cents per share), compared to $1.3 million (6 cents per share) for the same period a year ago.

"The past quarter has been challenging for our entire industry as it attempts to understand the dynamics of pricing and growth. We are pleased that at this inflection point Laser Vision is positioned to capitalize on these dynamics," LaserVision chairman and CEO John Klobnak said. "Laser Vision continues to believe the landscape of our industry will change over the coming year. We continue to explore avenues to continue our growth as this exciting industry matures."

11/29 **Icon Laser Eye Centers** announced results for the nine months ended September 30, 1999. This is the first quarterly announcement as a publicly listed company, now trading on the Canadian Dealing Network (CDN). Revenues for the nine months were $4.9 million reflecting the results of its 4 Italian centers for 9 months; its London, Ontario center for 4 months; its 2 centers in the United Kingdom for 1 month (acquired as of September 8,1999); and its 3 centers in Vancouver, Prince George (BC) and Honolulu, for 1 month (acquired as of September 1, 1999). Net loss for the nine months was $9,108 or (0 cents per share) vs. 1998's net loss of $87,866 (1 cent per share). Net loss for the third quarter of 1999 was $530,582 (5 cents per share) vs. a net loss in 1998 of $164,230 (2 cents per share) reflecting higher expenses associated with acquisitions and expenses of corporate reorganization. Revenues in the third quarter are seasonally lower due to the August vacation period in Italy.

Simone Mencaglia, CEO, commenting on the results of the third quarter said, "Our results for the quarter are encouraging considering the seasonality experienced by our Italian subsidiaries and our intensive development and corporate reorganization efforts in the quarter. More importantly, we are quickly gaining critical mass to rapidly accelerate growth in year 2000 in both Europe and North America." Procedure volume for the full nine months for units operated by ICON was 16,217 and 4,866 for the third quarter. At the end of the third quarter, ICON owned and operated 10 laser vision correction centers, including 3 in Canada; 1 in the USA; 2 in the United Kingdom; and 2 fixed centers, 1 mobile surgery suite and 1 roll-on/roll-off unit in Italy. The company also manages an additional 4 LVC centers, 1 in Canada and 3 in the USA.

11/29 **Nidek** announced that the appeal court case, filed by **Summit Technology** against the Nidek EC-5000 refractive laser system, which claimed the Nidek system infringed the Azema Patent, (Japanese Pat. No. 2,125,313), was rejected by Justice Tanaka of the Tokyo High Court. The judge maintained the initial verdict. On January 29, 1999, the Tokyo District Court had ruled that the EC-5000 did not infringe on the Azema Patent. However, Summit Technology had appealed to the higher court for a reversal of the judgment. The decision by the Court reconfirms Nidek's assertion of non-infringement. Nidek had been requesting that the Japanese Patent Office, Board of Patent Appeals find that the patent was invalid. Despite this request, the decision by the Tokyo High Court will provide the final resolution to this patent dispute of infringement or non-infringement. Nidek has decided to continue to seek the determination of invalidity to send a strong warning to those who try to file a suit without sufficient grounds.

Summit Technology also filed a suit on December 28, 1998 in the U.S., claiming infringement by Nidek to the U.S. Azema Patent (4,937,330) and the Marshall Patent (4,941,093). Nidek is preparing a strong defense against this assertion.

11/30 Al Kildani of **Pacific Growth Equities** issued an update report on **Laser Vision Centers**, lowering his recommendation to "neutral", based on his downward revised earning estimates, reflecting less robust growth in the company's LVC case volume. Kildani remains optimistic about the long-term prospects both for the industry and for Laser Vision Centers, but with the company transitioning its business model toward more fixed-site services, and increased involvement in operating surgeon practices, he expects the transition to last for the next several quarters, and due to the uncertainty, lowered his rating to neutral from long-term buy. As he explained, he expects a sustained shift away from mobile access toward fixed-site for the foreseeable future, which will lead to further declines in ASPs. The company added 11 new VISX lasers to its fleet in Q2:00 with 9 of these installed in fixed-site locations. He also noted that the company had publicly acknowledged that it was exploring strategic options that could include a significant merger or acquisition.

11/30 **Miravant Medical Technologies** announced that it had exceeded its enrollment goal,

entering more than 900 patients in the PhotoPoint SnET2 Phase III clinical trials for "wet" AMD. Miravant and its pharmaceutical partner, **Pharmacia & Upjohn**, are jointly sponsoring the Phase III studies and are in the process of closing patient enrollment. Patients are participating in two nationwide placebo-controlled, double-masked clinical studies, at over 50 ophthalmology centers specializing in retinal disease. (Also see the 12/8 bried below.)

Gary Kledzik, Miravant chairman and CEO, stated, "It's very gratifying for us to achieve our enrollment target in these large clinical studies, and we thank both the clinical investigators and the hundreds of patients who have elected to participate. This is a major accomplishment for Miravant and one step closer to bringing the PhotoPoint treatment to patients with this serious, vision-threatening disease."

As provided in the SnET2 license agreement, Pharmacia & Upjohn will market and distribute the PhotoPoint drug worldwide upon regulatory approvals, paying royalties to Miravant on gross sales. Iridex Corporation co-developed the drug-activated laser devices used in the Phase III AMD studies and will manufacture the laser devices upon regulatory approval.

11/30 **CIBA Vision**, the eye care unit of **Novartis AG**, has signed a co-development agreement with **Destiny Pharma**, a growing technology company based in Brighton, England. The agreement grants CIBA Vision exclusive global rights to develop Destiny's photodynamic therapy technology for the treatment of ophthalmic diseases. Under the agreement, CIBA Vision will pay Destiny a series of milestone payments and royalties, and will take over development once the current research program is completed. Destiny Pharma retains all rights for this technology platform for other disease indications. This project originated from an early discovery program developed jointly by Destiny Pharma with the School of Chemistry at the University of East Anglia and partly funded by the UK Department of Trade and Industry. (The news release does not mention what ophthalmic indications the Destiny Pharma PDT program is pursuing, nor anything about the photosensitive drug.)

This new investment is CIBA Vision's second significant entry into ophthalmic photodynamic therapy, solidifying the company's leadership position in this exciting new treatment area. This agreement comes within the overall arrangement with **QLT PhotoTherapeutics** to develop photodynamic therapy for the eye, a partnership that has already produced Visudyne therapy, a breakthrough therapy for age-related macular degeneration, currently under review by the FDA and other regulatory agencies worldwide.

12/1 Today's **Motley Fool** took a look at **Bausch & Lomb's** recent action to streamline its contact lens manufacturing operation, including the elimination of 850 jobs. As noted by author Brian Graney in his story entitled, *Bausch & Lomb Eyeballs Itself*, "the consolidation caps a busy year for B&L, whose core eye care business has witnessed a major reorientation of the competitive environment...Increasingly, investors are

demanding that companies show a great degree of business momentum with double- if not triple-digit growth rates. This means the bulk of the eye care investor's money had lately been flowing into the fast-growing area of laser vision correction, benefiting whippersnappers such as **VISX** and **Summit Technology**."

12/1 **ICON Laser Eye Centers, Inc.** announced that it had completed an offering to its shareholders of rights to purchase common shares. A total of 1.5 million common shares had been subscribed for and purchased representing a 100% takedown of the shares available under the rights offering. Total proceeds from the offering were approximately $6 million. Simone Mencaglia, CEO of ICON stated, "ICON has added the proceeds of its successful rights offering to its working capital, creating a pool of funds of approximately $10 million after the pay off of its debt of $2 million. These funds will be used to fund acquisitions and joint ventures as our ongoing laser vision correction operations are currently generating positive cash flow. We are excited about our growth opportunities as a leader in selling Value LASIK product directly to the consumer. We are interested in making strategic acquisitions in targeted North American and European markets."

12/1 **WaveLight Laser Technology AG**, of Erlangen, Germany, recently became a public company. We have established a relationship with the company and will begin reporting on both financial and technical news that the company releases.

In the first quarter of the 1999/2000 financial year, WaveLight more than trebled its sales compared to the same period in the previous year. Between 1st August and 30th October 1999, the company recorded a turnover of DM 3.27 million (1.67 million euro -- approximately $1.67 million at the current exchange rate of about parity with the dollar) against DM 1.07 million (0,5 million euro) in the prior-year quarter. This favorable trend is attributable primarily to the successful distribution of laser systems for dermatology and urology. In September, WaveLight signed a cooperative deal with **Dornier Surgical Product Inc.** in Atlanta, with 300 laser systems (for urology) to be delivered by 2001, a deal worth several million euro. In addition, Allegretto, the new WaveLight excimer laser system for ophthalmology, has been successfully launched into the market.

The operative loss was lower than expected for the first three-month period at DM 0,49 million (0,25 million euro). The quarterly result was a net loss of DM 3.42 million (1.75 million euro). The cash-flow amounted to DM 0,62 million (0,31 million euro). The costs of going public on 15th September 1999 were DM 2.93 million (1.5 million euro) which were within the anticipated scope. WaveLight intends using all issue proceeds of around DM 27 million (13.8 million euro) for the consolidation of its business activities. The company has increased its workforce, especially in the fields of technology and administration. As announced when it went public, WaveLight AG expects to break even in the current financial year. With brisk demand for WaveLight laser systems and the imminent approval for the Allegretto system on the American market, WaveLight believes it is in good shape for the current financial

year.

Globally, WaveLight is a technological leader in the field of solid-state lasers for medical and cosmetic applications. WaveLight develops, produces and markets laser systems which optimize medical application methods. The Erlangen-based company was founded in 1996 by CEO Max Reindl. Since 15th September, WaveLight AG's shares have been listed on the Frankfurt stock exchange under the identification number 512 560.

12/3 A few days prior to the release of the ITC decision on the dispute between **VISX** and **Nidek**, *The Wall Street Transcript* interviewed senior research analyst Wade King of **Robertson Stephens**. In response to the question, "Which are the companies with your strongest buy recommendations at the moment?", King responded, "I have a strong buy recommendation on VISX. VISX is the dominant market share leader in laser vision correction, which has been about the highest growth sector in medical technologies. VISX makes an excimer laser that allows ophthalmic surgeons to perform refractive procedures to basically eliminate the need for millions of people in this country to wear contacts or spectacles. They're the dominant leader. VISX has over 70% market share, the best management team in the business, and a phenomenal recurring revenue stream that's based on the license fees that must be paid to use VISX lasers to perform laser vision correction surgery. So VISX has been a strong buy recommendation of ours."

Analyst Kurt Kruger of **Montgomery Securities International**, also issued a research update on December 2nd, entitled, "Only One Shopping Day Left to Buy VISX pre-ITC". In the update, he and analyst Nathan Weems noted, "We would encourage investors to take advantage of the VISX price opportunity still available as we wait on pins and needles for Monday's ITC results. Recall that VISX, the leader in laser vision correction is seeking relief from the ITC against Japan supplier Nidek. Judge Morris is scheduled to issue what is called an "initial determination". We still believe that the ITC will rule in favor of VISX. A positive ruling has important implications on other parties that are readying lasers for the market, including **Bausch & Lomb** and **LaserSight**. A positive "initial determination" on Monday, while one of many installments, could provoke a sharp upward movement in VISX common. We understand that it is impossible to divine the thoughts or intentions of Judge Morris and therefore appreciate the five to ten point upside/downside risk associated with taking positions now against the outcome. (The stock acutally dropped nearly 40 points on the negative ruling -- see below.) However, mitigating the downside exposure are two factors: 1) quite simply, a negative ITC outcome is unlikely, and 2) a negative ITC outcome may take a toll on the stock temporarily, mostly for psychological reasons, but is not likely to alter our earnings model. Therefore, to the extent that VISX's valuation has any basis or grounding in its future earnings stream, the stock would likely return to trace the same upward trajectory in spite of taking an initial blow. Sizing up the risk/reward, we recommend that the investors take advantage of this last shopping day and buy VISX."

12/6 And then the bottom fell out, beginning with **VISX's** announcement that an Administrative Law Judge of the International Trade Commission (Judge Morris) had issued an Initial Determination finding that **Nidek Co., Ltd.** and its U.S. subsidiaries had not violated Section 337 of the Tariff Act of 1930, as amended. The company further said that it planned to file a petition with the full Commission for a review of the Initial Determination. If the review is denied, the Initial Determination will become the Final Determination of the Commission. If review is granted, the Commission is expected to issue its Final Determination by March 6, 2000, following briefing from the parties. Any Final Determination will be subject to review by the United States Court of Appeals for the Federal Circuit.

12/7 Following the announcement, **Nidek** released a press release, commenting on the decision. The Administrative Law Judge (ALJ) found that Nidek's EC-5000 does not infringe either of the two patents at issue. Further, the ALJ found that Visx failed to demonstrate that it was practicing its own patents. Critically, the ALJ found that the Trokel patent (U.S. Patent No. 5,711,762) is invalid and unenforceable, due to improper inventorship. The ALJ thus found no Section 337 violations. "We are very gratified with the judge's ruling on this case, as it substantiates our claim that we do not infringe the patent rights of others," stated Hiroshi Okada, vice president and general manager of Nidek, USA. "This represents a clean and indisputable victory for Nidek. This decision is a very important step in a detailed and lengthy process Nidek is working on with its legal counsel. The decision in this case follows another ruling in cases between Nidek and Visx in Great Britain, where Visx had brought similar claims against Nidek and lost," added Okada. "Nidek strongly believes and supports the refractive surgeons' right to freely choose the best and latest refractive technology for their patients and practices. Nidek is committed to providing the most advanced and cost effective technology to all ophthalmologists, as we have done for over 28 years."

And then the media kicked in. *Bloomberg* reported, under the banner, "This is the Ruling...Not Good...VISX's Patents not Infringed by Nidek lasers, ITC Judge Rules". *The Wall Street Journal's* Laura Johannes wrote, "U.S. Says Japanese Firm Doesn't Infringe VISX", bringing in the facts that Judge Morris "found that the evidence supported Nidek's claims that one of the patents covering a fundamental discovery attributed to Columbia University ophthalmology professor Stephen L. Trokel, was invalid and unenforceable based on `improper inventorship'." She noted that Nidek had argued that former **IBM** scientist Rangaswamy Srinivasan deserved at least part of the credit for the invention, as he and Trokel had jointly worked on lasering a calves' eye in Srinivasan's lab, using his laser.

Reuters reported that VISX's stock tumbled following the announcement, down 41% at one time, to 52, off 36 1/8. Reuters also picked up the comments of several analysts, including Kate Sharadin and Jason Mills of **Preferred Capital Markets**, and Rebecca Irwin of **Warburg Dillon Read**. Sharadin cut her rating on shares of VISX to "hold" from "buy", saying the ITC ruling "places VISX in the most precarious

position facing the company to date." Mills said "VISX has asserted that Nidek and other rivals have no right to sell their own excimer lasers in the United States without paying VISX royalties." He went on to say that VISX approached the ITC with that argument and was rebuffed. Irwin said she maintained her "buy" rating as the fundamentals of the company remain intact, and that the Judge's ruling was appealable. "No matter how the commission ultimately rules, VISX planned to continue to charge $250 to doctors each time a procedure is done using one of it's machines. However, to the extent that this decision emboldens doctors to buy a Nidek laser instead of a VISX laser, this decision will cause a slight shift in the competitive dynamics of the industry."

Sharadin and Mills reiterated their "strong buy" rating on **LaserSight**, which they said is expected to launch a sophisticated excimer laser early next year. Mills went on to say that the ITC case, by calling into question the VISX patent, could help LaserSight and other companies that do not wish to pay VISX royalties.

CBS MarketWatch reported that analyst Ted Huber of **Advest** on October 14th had expressed concern about the ITC ruling, saying he saw risks inherent in the pending decision, while **Hambrecht & Quist** had trimmed its rating on VISX to "market perform" from "buy".

Motley Fool also got into the fray, with a story entitled, "VISX Gets Sliced". "Investors, many who have ridden VISX stock to eye-popping gains of late, must grapple with what amounts to the first real blow to what has been one of the most attractive aspects of the company: its well-protected intellectual property...Much of the talk today is about whether today's news might signal some kind of death knell for VISX's business model, which has benefitted from the recurring revenue stream it gets from per-procedure fees -- which Nidek doesn't charge. It's something to think about, particularly when trying to refigure VISX's growth potential in light of an eventual Nidek victory...Furthermore, with some uncertainty here over the next few months over how Nidek might step up marketing efforts and how surgeons will evaluate this development when making equipment purchase decisions investors might want to scale back their expectations for Q1 at the least...But that's not the whole story. VISX, analysts say, could very well bring up Nidek on charges concerning entirely different patents and hit more Nidek-using doctors with lawsuits. Expect the legal wrangling to continue in U.S. courts...Furthermore, VISX, for all this uncertainty, still holds the leadership position in the laser eye surgery market. Assuming it was prepared for this eventuality, long-term investors may have the opportunity to benefit from today's move as things shake out."

No fewer than a dozen analysts issued statements or reports in the day's following the FTC announcement, many of which we have captured in this newsletter. Hans von der Luft and Alexandra Hall of **McDonald Investments**, rated VISX an "aggressive buy". "If the initial ruling stands, we believe the decision puts new market entrants **Bausch & Lomb** and **LaserSight** in a somewhat stronger position in negotiations with

VISX over license fees. We do not anticipate any changes in VISX negotiation terms with new manufacturers as a result of the decision. Nidek should expand its number of U.S. laser placements as a result of the ITC decision. Some U.S. refractive surgeons may seek to avoid the $250 license fee by purchasing a Nidek laser. The ITC decision should translate into a more challenging environment but we continue to believe that VISX will retain its leading market position (est. 70% procedure market share in 2002). We do not envision any change in its ability to collect its $250 license fees due to the unfavorable outcome of the case. While the ruling is a blow to VISX, we view the decision as a first round loss in a lengthy intellectual property bout. In early 2000, the potential for a stronger Trokel '388 patent (a broad patent covering the laser surgery method) emerging from the PTO reexamination could be a significant weapon in future patent infringement proceedings. Wade King and Amrit Nagpal of **Robertson Stephens** said, "While we view the ITC judge's interpretation of the case evidence as remarkably narrow, clearly the ruling in favor of Nidek is disappointing for VISX. Further, while the ITC decision has bearing on trade considerations only, the judge's opinion was surprisingly strong as relates to not only issues of patent infringement, but also validity...While we believe that VISX will remain far and away the market leader in the laser vision correction (LVC) industry, we are uncertain about potential market share changes that may be affected by yesterday's ITC ruling. We are also uncertain as to the effects of this decision on VISX's position in pursuing its competitors in license negotiations and, if necessary, the U.S. court system. Given the limited visibility on the long-term effects of this decision, we are lowering our rating on shares of VISX to `Long-Term Attractive'...We do expect VISX to continue its ongoing efforts in the U.S. court system to defend its stable of nearly 150 patents protecting its intellectual property. We anticipate the company will pursue multiple legal strategies against Nidek in its patent infringement suit in the District Court of Northern California. We expect the company's suit against Nidek to go to trial in approximately one year. VISX also plans to continue with its suits against individual physicians using Nidek lasers. These suits may advance more quickly through the court system...While we expect significant volatility in shares of VISX following this news, we continue to believe that VISX will be far and away the primary long-term beneficiary of the phenomenal growth in laser vision correction going forward. In our view, VISX will continue to dominate the laser vision correction industry, both in terms of laser placements and procedural market share."

Dave Therkelsen of **Dain Rauscher** also changed his recommendations on both VISX and Summit Technology, lowering both to "neutral". For Summit, he explained tht the ITC preliminary ruling against VISX should have a negative effect on near-term earnings visibility, and lowered his rating to reflect short-term volatility and uncertainty. For VISX, he felt that the negative ruling would effct investor physchology, and reduce revenues and earnings visibility for the near term.

Mark Logan, chairman and CEO of VISX gave an interview to *CNBC/Dow Jones*, discussing the ITC decision. Logan said that the ITC decision would not have any impact on its business, as the ITC does not have the ability to invalidate patents, a task

that belongs to the Patent Office only (and the U.S. District Courts). Logan went on to explain that VISX had taken the ITC action route, hoping to expedite proceedings, but now that that route had been denied, pending an appeal to the full commission, the company would go back to the courts and fight it out the long way.

Summit Technology CEO Robert Palmisano also issued a statement following the ITC decision, reiterating that the decision would have no effect on the patent infringement action brought by Summit against Nidek. The press release noted that Summit had brought patent infringement suits against Nidek and **Icon Laser Centers** (using Nidek lasers) in US District Courts in Massachusetts and elsewhere and the company would continue to vigorously defend its patent position. "We have a lot of confidence in the validity and breadth of our patents and our right to license our customers to practice the art covered by VISX's key patents...We believe that our patent licensing policies are fair and reasonable given the tremendous investments we have made through the years, and continue to make, in order to bring this technology to our customers and the public."

Finally, leave it to David Harmon of **MarketScope** to ferret out the details of Judge Debra Morris's decision. In a faxed copy of her decision, he learned that she had ruled, "There was no violation of Section 337 of the Tariff Act of 1930, as amended, on the following basis:

1) The evidence offered by Complainant VISX failed to demonstrate with respect to either US Patent 4,718,418 (the '418 patent) or US Patent 5,711,762 (the '762 patent) satisfaction of the technical prong of the domestic industry requirement of Section 337.

2) The evidence of record did not demonstrate that the accused products infringe the asserted claims, Claims 26 and 27 of the '418 patent.

3) The evidence of record supported the claims of Respondents Nidek Co., Ltd, Nidek Technologies, Inc. of invalidity and unenforecability of the '762 patent based on improper inventorship.

4) Even assuming arguendo the validity and enforceability of the '762 patent, the evidence of record did not demonstrate that the accused products infringe the asserted claims, Claims 1,7,10 and 12 of the '762 patent.

Harmon also noted that the next key date in the ongoing test of intellectual property rights will be a decision from the Patent and Trademark Office, regarding the validity of certain claims pertaining to two U.S. Patents, which could be as soon as three months from now according to president and COO Liz Davila. (We have since learned that the FTC attorneys have decided to drop their appeal of the FTC decision that went in favor of VISX, purportedly because of discussion they had with the Patent Office which will affirm the validity of the '388 (Trokel) patent by reissuing it with new claims.)

12/6 **TLC Laser Eye Centers** announced procedure volumes and issued a corporate update for the three-month period ending November 30, 1999. Over 31,600 paid laser procedures were performed at the company's refractive centers in the second quarter. This is a 76% increase from 18,017 the same period a year ago. The increase in this quarter was primarily driven by 58% same-store procedure growth.

Traditionally the weakest quarter from a growth perspective, TLC experienced a 5 % sequential decline in second quarter paid procedure volumes, similar to those reported recently by some of the company's industry peers. While revenues are expected to be in-line with paid procedure volumes, increased wages and marketing expenses will result in net income for the second quarter to fall below current analysts' consensus estimates. Based on analysis of preliminary financial data, the company expects to report second quarter income per share of approximately 2 cents to 4 cents, as compared to 2 cents in the same period last year. Actual second quarter results will not be available until mid- January and could differ from the estimated announced range.

The increase in wages and marketing expenses in the second quarter were a direct result of the unexpectedly rapid success of the company's Advantage program, along with its web and e-commerce initiatives. TLC has hired and is aggressively training more than 70 new staff in its Information Response Center and its Information Systems and Operations Departments to handle the increased procedure volumes expected to result from these projects. The company has also been in the process of designing, producing, and amassing marketing materials in preparation for their implementation. During the quarter, the company continued to enjoy exceptional success in executing the TLC Advantage program. The TLC Advantage sales force has secured exclusive contracts with more than 1,100 employers, directly covering over 1.5 million employees. In addition, the company has entered into exclusive marketing and service partnerships with several HMO's and vision plans, now covering more than 45 million individual lives. The vast majority of these partnerships, covering approximately 20% of the U.S population, are scheduled to commence early in calendar 2000.

Following the announcement, Al Kildani of **Pacific Growth Equities** issued an update report, highlighting most of what the company said in its release. All in all, the performance data was well below what he had estimated for the company, causing him to lower his rating to "buy" from "strong buy".

12/6 **Summit Technology** said that on November 9, 1999 its Autonomous Technologies subsidiary was issued U.S. Patent No. 5,980,513 entitled "Laser Beam Delivery and Eye Tracking System". "We believe this to be a fundamental patent in the area of narrow beam shot placement and we are very pleased with the claims that the patent office allowed," said Randy Frey, president of Autonomous. "Our goal is to be the technology leader in the laser vision correction industry and issuance of this patent evidences our continued strength in this area," Frey concluded.

According to David Harmon of **Market Scope**, the patent covers "a laser that employs a plurality of laser beam shots spatially distributed over the surface to avoid the plume of eroded material and to achieve a desired shape. Harmon also said that the patent was supported by another patent related to the development of a shot pattern, and control of the number and placement of laser beam shots on the cornea, U.S. Patent No. 5,849,006, issued in December 1998.

12/6 **Market Scope** announced the release of its newest report on the refractive surgery market, *The Comprehensive Report on the US Refractive Market*, which predicts that a growing demand for laser vision correction generated patient fees of $2.1 billion in 1999, and that in the coming year, 1.5 million refractive surgical procedures are expected, a 58% increase over 1999. Market Scope's in depth study predicts continued strong growth in the market through 2005. Refractive surgery will become increasingly competitive as rapid growth and high margins attract new surgeons and encourage expansion of laser centers. Low price competitors such as **LCA Vision** and **Lasik Vision** are entering the market with business models built on high volume and intensive advertising, while **TLC**, **Laser Vision**, **Aris**, and **Clear Vision** position themselves as premium providers. According to Market Scope president David Harmon, laser centers and surgeons will begin to segment the market based on price and quality in the coming year.

"Despite continuing healthy growth in procedures, sales of excimer lasers grew faster than procedures during the last half of 1999. This trend has placed pressure on laser center companies and individual surgeons to maintain procedure volume," says Harmon. "Market leader **Visx** will sell almost double last year's number of lasers, with **Summit** and **Nidek** also achieving record sales. Market saturation of new lasers will continue in 2000 with the approval of two new excimer lasers and lower entry barriers for both new laser centers and surgeons."

The Comprehensive Report on the US Refractive Market is priced at $1,250 alone or $2,000 with quarterly updates of key tables and information. Additional information including Table of Contents and Index of Tables is available on the company's web site at **www.mktsc.com**.

12/6 **Icon Laser Eye Centers** announced that it had performed 3,675 LASIK and PRK paid procedures in its owned and/or managed care centers in the month of November. These procedures were performed at 14 laser eye centers; comparable bookings for October 1999 were 2,982 procedures (a month to month increase of approximately 23%).

"ICON's primary concept in the U.S. can be defined as "Direct Marketed Value LASIK" (DMVL). Each U.S.-based DMLV center when mature should do in excess of 400 LASIK procedures per month," stated Simone Mencaglia, CEO of ICON. "This level of volume, which allows ICON to take advantage of the economies of scale and pass savings on to the consumer, makes it possible for ICON to charge as

little as $499 per eye for pure myopic procedures during introductory offers."

12/7 Al Kildani of **Pacific Growth Equities** released an update report on **LaserSight**, stating that in the wake of the ITC ruling, LaserSight's bargaining position with **VISX** should be strengthened. "Although VISX plans to appeal the ITC decision, we have little reason to believe that it (the decision) will be overturned. The ITC ruling is mostly significant because it represents the first sign of vulnerability in VISX's patent portfolio. While VISX has clearly been the leading excimer laser manufacturer to date, we believe much of its premium valuation was contingent upon the perceived invincibility of its patent portfolio. The strength of VISX's patents is now clearly called into question with this ruling. We believe that this is good for other laser manufacturers, including LaserSight who is in the process of negotiating a license to the relevant VISX patents." With this basis, he reiterated his "strong buy" recommendation for the company.

Preferred Capital's Kate Sharadin and Jason Mills also came out with an announcement reiterating their "strong buy" rating of LaserSight, mostly for the same reasons, along with these comments, "LaserSight represents the best investment idea in the Laser Vision Correction sector due to superior FDA-approved laser technology, strong refractive product portfolio, potential relationships with large corporate provider, and our perception that LaserSight ranks as the best acquisition candidate in light of the ITC calling VISX patents into question."

12/7 **Paradigm Medical Industries** announced that it had submitted its "notice of intent to market" along with results from recent clinical trials of its patented probe and revolutionary laser cataract removal system (the "Photon") to FDA for final approval. "We are pleased with the clinical performance of the Photon and, together with legislation recently enacted which allows for the inclusion of results using the device from sites outside the U.S., we feel the approval will be expedited," said CEO Thomas Motter. "We believe the laser removal technology is an easier, safer, more user-friendly way to take out cataracts and should replace the current ultrasound needle technology which, under some conditions, is dangerous. Cataract removal technology and related disposable sales account for $200 million in eye care expenditures by hospitals world wide annually and is growing. Our unique patented system should afford Paradigm a significant share of this market for the foreseeable future."

12/7 **Laser Vision Centers** announced that its U.S. case volume for the month of November increased 118% compared to the same month a year ago. The company said that November was its best month to date for U.S. case volume.

12/7 **New York Eye Surgery Center**, in an effort to educate consumers, released the following recommendations for people to consider before having LASIK eye surgery:

-- LASIK can dramatically reduce one's dependence on glasses and contact lenses and

expand an individual's visual and functional freedom. However, realistic expectations are critical before making the decision to have refractive surgery.
-- Carefully select a qualified eye care specialist who offers a thorough candidacy screening process to see if you're eligible.
-- Have an idea of what you expect from the surgery and prepare a list of questions before you go for the initial consultation. Your doctor should be able to address any concerns you may have. And, as with any surgical procedure, you should provide your surgeon with a complete medical and ocular history.
-- You should discuss with your doctor his or her experience and training in refractive surgery. Ask your doctor what percentage of patients need a second procedure. A rate of under 10% is optimal. However, rate of enhancement is typically higher for farsighted patients.
-- Beware of anyone trying to "hard sell" the procedure to you. This should be your decision and LASIK is not right for everyone.
-- If you plan on getting pregnant in the next six months, you should wait to have the procedure.
-- If you are over 40 years of age and ONLY having trouble with reading, this procedure is not for you.
-- Since the procedure to treat farsightedness is relatively new, patients should take added measures in selecting a refractive surgery expert who can very carefully qualify them for the procedure.
-- Consider your lifestyle, and the possible side effects, night glare for example, from the procedure, including: career, exercise, hobbies and how often you drive and if you drive at night, etc.
-- Remember the best source for getting a sense of what the procedure is like is to speak to someone who has had the procedure. Speaking to someone with first-hand experience can give valuable insight into many facets of the procedure you might not have considered.

12/8 **Sterling Vision** announced that it had entered into an Amendment to its Convertible Preferred Stock and Warrants Subscription Agreements. In essence, the company agreed to reduce the price of converted stock from $3.00 to $.75; reduce the price of the warrants from $4.00 to $2.00; and to eliminate the price protection guaranty previously afforded the Holders with respect to any shares of Common Stock sold by any such Holder within the 180 day period following the conversion of such Convertible Preferred Stock into Common Stock.

12/8 **Lehman Brothers**, along with **Raymond James**, said they had initiated coverage of refractive laser technology company VISX with a "buy" rating. Lehman based its recommendation on VISX's market share leadership, participation in a growing LASIK market, excellent management, potential from incremental licensing fee income from Bausch & Lomb, LaserSight, and possibly Nidek, as well as slowing LASIK procedure growth rate. Analyst David Gruber said, "The ITC ruling will not have a major effect on LASIK market dynamics, but it does alter investor's perception of the strength of VISX's patent portfolio, relative to that of Bausch & Lomb's

negotiating position." He went on to say that the prospects for the LASIK growth market in 2000 remain strong and that the competitive position of Nidek remains limited despite the ITC decision. Further, the `barriers to entry' remain substantial in the LASIK market.

Raymond James analyst Maria Liotta had the following comments about the refractive surgery industry and VISX:

- The refractive surgery (RS) industry is a dynamic and robust sector characterized by high revenue growth and escalating procedure numbers. We believe excellent investment opportunities exist within this space, predicated by the size of the eligible population, the quality of surgical outcomes, and technological developments.
- The market for refractive surgery represents one of the largest medical markets. Approximately 50% of the U.S. population, or about 150 million people, require vision correction. Because there is no known method to prevent nearsightedness, farsightedness, or astigmatism, we expect this large, renewable population will continue to propel market growth.
- We believe future growth in the sector will be fueled by advances in technology and surgical technique, improved outcomes, increasing numbers of surgeons entering RS, and increasing acceptance of RS by consumers.
- A defensible patent position confers substantial competitive advantage to select companies in the sector. Rapid revenue growth and swelling profit margins characterize these companies, which benefit from escalating procedure revenues that significantly boost gross margins.
- We estimate that revenues from product sales, license fees, and services related to RS will account for $380 million in domestic revenues in 1999. In our view, the sector will achieve sales growth of 32% for 2000, bringing potential total U.S. revenues to roughly $500 million.

In our view, VISX and Summit Technology, excimer laser manufacturers, represent the best investment vehicles in this dynamic market. We believe VISX will continue to dominate the RS market by virtue of its patent position, large installed base, and leading edge technology. We believe Summit, which already has a meaningful presence in the market, is very well positioned for impressive gains in both the top and bottom lines. Both VISX and Summit are approved to treat nearsightedness, farsightedness, and astigmatism -- a distinct advantage these companies have that we do not expect will be shared by other competitors for at least 12 to 18 months.

Downgrades for VISX came from **Advest** (Market Perform to Underperform), **Bank Boston Robertson Stephens** (Strong Buy to Long-Term Attractive), **Dain Rauscher Wessels** (Strong Buy to Neutral), **Hambrecht & Quist** (Buy to Market Perform), and **Preferred Capital Markets** (Buy to Hold).

Lehman Brothers, along with **Raymond James**, also initiated coverage of **Summit**

Technology with a "buy" rating (see Raymond James' analyst Maria Liotta's comments about both Summit and VISX, just above). Lehman analyst David Gruber based his recommendation, also on the company participating in a large, rapidly growing LASIK market. Gruber also said that "the company is an acquisition candidate; has declining per procedure fees; and that there was a deceleration of LASIK procedure growth. He also said that divestiture of **LensExpress**, combined with profitability is likely to lead to multiple expansion and that the company may be unable to differentiate its narrow beam technology from the **VISX** S2 and **Bausch & Lomb** Technolas 217.

Hambrecht & Quist downgraded Summit from Buy to Market Perform, while Preferred Capital Markets downgraded the company from Strong Buy to Accumulate.

12/8 **ICON Laser Eye Centers** said that it will enter 100 targeted U.S. markets and seek to install up to 100 **Nidek** lasers within the next two years. ICON currently has 5 Nidek lasers operating in the U.S., with an additional 15 lasers in ICON centers outside of the U.S.. Each of the 5 U.S. Nidek lasers has enjoyed IDE status for clinical trials with the FDA for the treatment of myopia with astigmatism, which has since been approved. ICON intends to apply for IDE status to treat hyperopia using Nidek lasers. (The following day, the company announced that it had applied to **CRS Clinical Research** for an IDE exemption status for hyperopia on five of its Nidek lasers located in the U.S. -- in Scottsdale, Dallas, Colorado Springs, Honolulu, and Quincy, IL.)

ICON will seek 100 acquisition candidates in their targeted markets for installation of Nidek lasers. ICON normally operates new state-of-the-art Nidek lasers which it installs along side the **VISX** or **Summit** first generation lasers, usually in place at existing centers. ICON is able to increase productivity of most acquired centers to perform in excess of 400 procedures per month using its "direct marketed value LASIK" program that allows consumers to subscribe for LASIK at prices as low as $499 per eye for pure myopia in special introductory markets. Simone Mencaglia stated, "With the favorable decision of the ITC toward the Nidek laser, it is time for ICON to roll-out the next stage of its strategic plan. We will put on the street our corporate development team that will actively seek acquisition candidates which operate laser vision centers or represent ophthalmic surgeons. We have targeted 100 U.S. cities for development. The ICON formula selling of "Excellence at an Affordable Price" works. We are hoping to find ophthalmologists and optometric partners that share our vision."

12/8 **Miravant Medical Technologies** announced that it had closed patient enrollment in its PhotoPoint SnET2 PDT Phase III clinical trials for the treatment of "wet" AMD. A total of 934 patients were enrolled and treated at 59 U.S. ophthalmic centers during the last year, in two placebo-controlled, double-masked clinical studies, jointly sponsored by Miravant and its pharmaceutical partner, **Pharmacia & Upjohn**. "The completion of the enrollment phase of these large AMD clinical trials is one of the

most significant operational milestones achieved at Miravant," stated Gary Kledzik, chairman and CEO. "Following this achievement, our attention is focused on the many activities to successfully follow-up patients and prepare for future regulatory submissions."

12/8 *Individual Investor Online's* Craig Schneider commented on **Sunrise Technologies** future in his online story, "Sunrise Technology's Cloudy Outlook". "Shares of Sunrise Technologies may not have much rise left in them after next month's highly anticipated FDA panel review of its laser for vision correction. Even if approved, investors should be wary of what lurks just over the horizon for the company." Commenting on the recent ITC ruling, and the bringing into question of the $250 pre procedure fee charged by **VISX**, Schneider said, "Analysts have speculated that Sunrise, upon approval of its laser, may charge its own per procedure fee close to $250 to provide better growth and visibility in earnings. But with the doubt cast over Visx, `it's going to be more difficult for Sunrise to establish equivalent prices,' says Ted Huber, an **Advest Inc.** analyst covering Visx." Another analyst quoted in the article, Kate Sharadin of **Preferred Capital Markets** said, "If the procedure is temporary, then its overall adoption rate will be much lower than if it were permanent because living with the instability of eyesight is a negative for patients. I think it all comes down to the data."

So despite the renewed enthusiasm for a positive outcome next month, analysts remain cautious. Schneider goes on to say, "Even assuming doctors still like Sunrise's laser because its less invasive and are willing to buy a $250,000 system, Sunrise will be up to its eyeballs in competition from excimer laser manufacturers in no time. Bottom Line: Sunrise has a rough road ahead to change the market sentiment on the farsighted procedure and even a rougher road for selling its laser. All things considered, we don't recommend purchase of the stock at current levels."

12/9 **Photogen Technologies** announced that Lucy Young, MD, working under a research agreement with the company, presented findings showing complete eradication of ocular melanoma tumors in 84% of lab animals following a single treatment with its multi-photon excitation (MPE) technology. Ocular melanoma is the most common form of eye cancer in adults, growing in the back of the eye, under the retina. While the number of annual cases of ocular melanoma is small, the technology serves as a stepping stone to the treatment of other melanomas. Human experiential trials for the treatment are anticipated to begin in 2000 or 2001.

Dr. Young, a leading researcher at **Massachusetts Eye and Ear Infirmary**, a **Harvard Medical School** teaching affiliate, delivered her findings at the *Retina Society Annual Meeting* in Maui, Hawaii. The results were based on the fact that melanin precursors become extremely phototoxic in melanoma tumor cells when activated with certain light sources. Using Photogen's multi-photon excitation (MPE) technology, tumorous cells die, while healthy tissue remains unharmed. No additional phototoxic agents were administered. "Current treatments for ocular melanoma may involve surgery,

radiation or even removal of the eye," said Dr. Young. "I am pleased to share these highly promising results that I've found using Photogen's MPE technology with my colleagues at the Retina Society meeting." "Our joint research with Dr. Young will go a long way, not only to drastically improve treatment for ocular melanoma, but to also open the doors to treatment of so many other diseases," said John Smolik, president and CEO of Photogen.

12/10 **Raymond James'** analyst Maria Liotta also initiated coverage of **KeraVision** with an "accumulate" rating. She explained that KeraVision manufactures and markets a non-laser approach to RS that we believe will garner a meaningful niche position in the market. The company's Intacs product, which recently received FDA approval, hits the mark on our themes for success in this market, that is, outstanding quality of vision and indication for a large patient population. The product also uniquely offers removability and exchangeability features.

12/10 Larry Keusch of **Goldman Sachs** held a conference call for his clients in which he discussed the impact of the ITC ruling against **VISX**. Some of the highlights:

- The ITC cannot invalidate patents. While the administrative law judge at the ITC found that the Trokel patent was invalid, it cannot overturn issued patents. Only a District Court decision can affect the validity of a patent. In fact, patents remain valid and enforceable until the Court of Appeals delivers an adverse decision. As a result, the ruling by the ITC does not impact the validity of VISX's patents.

- The ITC case did not use the core trokel '388 patent. The decision of the administrative law judge for the ITC included the determination of invalidity of the Trokel patent. Importantly, we note that the patent used in the case was the '762' patent, a prodigy patent of the core Trokel '388 patent, not the base equipment and method patent. The company did not use the '388 patent in the ITC case as it was likely to be dismissed from the case as it was undergoing re-exam at the U.S. Patent and Trademark Office (PTO). Additionally, the L'Esperance '418' patent used in the ITC case was also not the core '913' patent. The large number of patents within the VISX intellectual property portfolio is a substantial advantage for the company as it still has plenty of patent `fire power' left in the coffers. While the California case does not include the Trokel '388 patent, we suspect that after a positive patent re-exam the company will amend the suit with the patent. In turn, this should strengthen the VISX position against Nidek.

- Next steps following the ITC decision. Following Monday's adverse decision from the administrative law judge at the ITC, VISX has 10 days to file for a review by the Commission. Once VISX files for a review, the Commission has 45 days to consider the appeal. A final decision by the Commission will be delivered by March 6, 2000. We believe that it is highly unlikely that the ITC

Commission will overturn the decision of the administrative law judge. Assuming that the Initial Determination is not overturned, the company will pursue its case in the U.S. District Court of the Northern District of California. We note that as with any federal proceeding, the final outcome is likely to be years with the VISX patents remaining valid until a Court of Appeals decision.

- B&L probably was not very focused on ITC decision. In speaking to B&L management, we do not believe that the company was very focused on the outcome of the ITC decision given its limited impact on the validity of VISX's patents. Rather, we suspect that B&L management is watching the outcome of the reexamination of the Trokel '388 patent by the U.S. PTO. If VISX comes out of the re-exam with its claims intact, and perhaps even strengthened, it could prove to be a substantial obstacle for any competitor attempting to enter the U.S. laser vision correction market. VISX management has indicated that the patent re-exam could be completed in early 2000. With B&L not likely to gain FDA marketing clearance until late 1999 or early 2000, we believe that any licensing discussions will center on the decision of the U.S. PTO. With indications that the patent re-exam is progressing well for VISX, we believe that there is a high likelihood that B&L will need to gain a license before entering the U.S. market. While many investors believe that B&L has gained an improved negotiating stance following the ITC ruling, we believe that the far bigger issue is the state of the Trokel '388 patent. As a result, a licensing arrangement with B&L is not likely until sometime in early 2000. We continue to believe that B&L is unlikely to gain anymore than $25-$50 per procedure fee.

12/10 Dave Therkelsen of **Dain Rauscher** initiated coverage of **Iridex** with a glowing report on the company, especially the company's approach to treating the leading causes of blindness, including AMD, diabetic retinopathy, and glaucoma. He also noted that the company was entering into other areas, such as dermatology and hair removal as well. His investment highlights include:

- Iridex's versatile leading-edge semiconductor-based infrared and green laser systems are recognized worldwide as a smaller, lighter, and more efficient platform relative to competing technologies. As a result, the technology is typically more economical and reliable than standard argon-gas laser systems.

- The company's laser system address large ophthalmic markets, including treating three of the leading causes of blindness. He estimates that approximately 26 million American adults are presently affected by potentially sight-compromising disorders, and that number could grow significantly as the baby-boomer population ages. As a result, Iridex addresses an ophthalmic market opportunity that could reach $250 million by 2005.

- Several of the conditions being researched by Iridex represent applications

with "home-run" potential. The largest opportunity and the most promising clinically targets age-related macular degeneration. (Also, see my accompanying writeup on potential treatments for this dreaded disease, which will appear in both *Ocular Surgery News* and *Medical Laser Report*.)

- Therkelsen also notes that Iridex is leveraging its demonstrated technological expertise in semiconductor-based lasers, by expanding its product offerings into the dermatology market, with its DioLite 532 green laser for vascular and pigmented lesions, and a hair removal diode laser, called the Apex 800, expected to be launched during early 2000, following FDA 510(k) clearance. (The announcement of approval came through on December 21st, as shown in the brief of that date in the "Medical/Surgical section of this newsletter.)

12/11 **Vision Twenty-One** disclosed that in connection with its previously announced strategic initiatives, it is currently conducting ongoing discussions with a number of eye care organizations related to a possible sale of either certain business units, or alternatively, a sale of the entire company. **Paine Webber Incorporated** is serving as the company's financial advisor during the process. The company disclosed that it had amended its credit facility today with its bank syndicate to provide for additional capital for operations to the company as it explores its strategic alternatives. The company's bridge facility has been increased from a previously reported $3.0 million to $9.4 million. Additionally, the banks have extended waivers on a short term basis regarding certain covenants in the loan. The bridge loan term was extended to March 31, 2000.

12/13 **Cruttenden Roth** initiated coverage of **Staar Surgical** with a "buy" rating. Highlights of the accompanying report indicated that enrollment had been completed for Phase III clinical trials for the company's implantable contact lens (ICL); the FDA had given approval to market low diopter IOLs for nearsighted patients; and that the first three Laser and Implant Technology vision centers were up and running in small to medium-sized markets. The company plans to have five centers running by end of year 1999, and twenty centers by the end of 2000. As analyst Bill Gibson put it, "In our opinion, Staar's move to open laser centers is an attempt to boost earnings in the rapidly growing refractive surgery market until its ICL is approved in two or three years. The risk is that Staar is entering the business just as price competition is beginning to emerge. We also think there's risk that Starr's model dooms it to low volume centers because we doubt the doctors will spend enough on marketing in small markets. Lastly, we view laser centers as a distraction for a management team, which in our opinion, is already stretched too thin, and Staar could alienate potential IOL customers who choose to operate independently or at a competing laser center, including mobile units."

12/13 A new laser player has entered the fray, as **SurgiLight, Inc.** announced that it had completed development of two new technologies for vision correction using infrared (IR) lasers and had obtained a 15-year exclusive license from **GAM Laser, Inc.** The

first new technology, SurgiLight's Model IR-3000, was demonstrated at the AAO in October and is designed for microsurgery and presbyopia correction. It is the most compact solid-state IR laser capable of performing the new procedure for presbyopia correction.

The second new technology, SurgiLight's Model IR-3001, has a laser head made by GAM Laser, Inc. and is integrated into a scanning system designed by SurgiLight. The IR-3001 will be used for vision correction, including both LASIK and presbyopia procedures. Surgilight has an exclusive 15-year medical use right for this IR laser. The company believes that this IR laser is unique with a 15 nanosecond short pulse, 500 Hz repetition rate, and is a "cold" IR laser comparable to UV excimer lasers for vision correction. The company has three patents pending for IR laser systems for refractive surgery, cataract treatment, dermatology, and microsurgery. Clinical trials have begun in selected Latin American countries and U.S. trials will begin in early 2000. SurgiLight believes that it will be the first and only company to introduce this new technology into the laser vision market. SurgiLight also believes that its "cold" IR (3 microns) laser, used for LASIK and presbyopia correction, is fundamentally different compared with the "thermal" IR (2 micron) laser made by **Sunrise**, used for hyperopia correction. Further, SurgiLight believes that its patent pending IR laser technology will generate long term recurring income from procedure royalty fees without incurring patent and licensing fees payable to **IBM** (for UV laser patents), **Visx** and **Summit** (for excimer laser patents).

In correspondence with JT Lin, founder of SurgiLight (and also of **LaserSight**), he indicated that the IR-3000 was a flash-lamp pumped, solid-state laser with dual-pulse features, with a wavelength of about 3 um, and output of about 2 W in 15 ns pulses at 500 Hz, but he would not disclose the laser source until a patent is granted. The IR-3001 laser is also a new gas laser, also patent pending, with a wavelength of about 3.1 um, but not erbium-based. It also has unique short pulses (15 ns) and the highest repetition rate (500 Hz) suitable for both LASIK and treatment of presbyopia. Their are five patents pending covering the technologies. An IDE for patient treatments will start during the first quarter with Dr. Penny Asbell at Mt. Sinai in New York.

12/13 **ICON Laser Eye Centers** said that it had filed a motion in the Delaware Courts seeking to stay a lawsuit filed against ICON by **Summit Technology** pending the outcome in the courts of claims and counterclaims of the patent litigation of **VISX** and Summit vs. **Nidek**. Simone Mencaglia, CEO of ICON stated, "We believe that the consumer should not be hurt by the exorbitant pricing of laser vision correction charged by users of VISX and Summit lasers. We use all three lasers: Nidek, VISX and Summit; however, on the Nidek laser we charge substantially less to the patient. We will pay the $250 royalty only if forced to do so after all appeals by the U.S. courts."

12/13 **Nidek, Inc.** announced today that U.S. District Court Judge Charles Breyer in San Francisco lifted the stay of its antitrust case against **VISX, Inc.** The Court's decision

permits Nidek to pursue immediately its antitrust allegations against VISX. The lifting of this stay follows a decision by the ITC Administrative Law Judge on December 6, 1999 in favor of Nidek.

12/13 This month's issue of *Refractive Market Perspectives* discusses how corporate and surgeon-owned laser centers led the growth in the third quarter. However, despite overall procedure growth of 9.8%, average procedures per laser were down in all three segments (including institutional centers). Record sales of lasers were the cause, with 111 new lasers installed during the quarter. After allowances for the addition of secondary lasers by several centers, a net of 86 new laser centers were added during the quarter. According to Dave Harmon's latest surveys, surgeon-owned centers had the largest growth during the quarter, up 13%, with surgeons now owning more than 47% of all lasers, and these lasers performing roughly 43% of all procedures. Corporate centers operate 32% of laser centers, but account for about 42.8% of procedures, while institutions account for about 21% of lasers and do only about 14.2% of procedures.

Of the corporate entities procedure market share, **TLC** still leads with a 30.3% share; followed by **Laser Vision** at 21.7%; **Clear Vision** at 13.2%; **LCA-Vision** at 8.6%; **Aris** at 6.1%; **Prime Vision** at 5.7%; and others (including **Vision Twenty-One** (4.6%), **Vision America** (2.9%), and **NovaMed** (3.1%)) comprising 14.7%.

12/13 **Lehman Brother's** analyst David Gruber initiated coverage of **Sunrise Technologies** with an "A-1 Buy" rating. His reasons for the rating included the following:

- Untapped hyperopia market
- Ease-of-use features makes LTK adoption appealing to all ophthalmologists
- Favorable economics
- Off label procedures
- Immediate adoption by Excimer Laser LASIK Centers

Some of the risk include:

- Failure to obtain FDA Panel recommendation for approval
- Restrictive labeling
- Market acceptance of holmium lasers for hyperopia, and
- Manufacturing capacity

His investment conclusions: Here comes the Sun(rise)!

Hyperopia (far-sightedness) remains an unmet need; LASIK penetration of this indication is minimal. Sunrise' holmium laser offers physicians an easy-to-use, in-office procedure with good clinical outcomes. FDA Panel review is scheduled for January 13, and represents a primary risk. We expect panel recommendation for approval of the revised labeling request; i.e., reduction (rather than correction) of

hyperopia. Our price target of $15 reflects a price-to-sales multiple of 11x our 2001E sales estimate of $69m.

12/14 **Sunrise Technologies International** reported that is had become aware of an unsolicited tender offer by **Growth Capital Corporation** to purchase up to 2.3 million shares of common stock from stockholders of Sunrise at $12.50 per share, net to the Seller in cash. Sunrise recommended that shareholders reject the offer because the price was inadequate and shareholders had no withdrawal rights. Tenders of shares made pursuant to the offer were irrevocable, even if the offer was extended. Accordingly, Growth Capital Corporation could extend the offer for an indefinite period of time without tendering payment for the Shares. Without withdrawal rights, shareholders have no ability to liquidate their investment. Shareholders who have tendered securities in response to the offer are advised to consult with their broker and legal counsel with respect to their rights and obligations.

12/14 **LCA-Vision** said that consumer response to its value-priced LasikPlus centers had been "overwhelming." During the month of November, the company's LasikPlus centers in five markets -- Baltimore/Annapolis, Minneapolis/St. Paul, Columbus, OH, Northern and Southern, CA -- completed 1,657 procedures, a 138% increase in volume versus the same one-month period in 1998. Since the launch of its first value-priced LasikPlus center in July, call volumes and screening appointments in the five markets have also surged. On average, call volumes, or requests for information, grew 233%, while the number of scheduled screening appointments more than tripled from the comparable period last year. The company said that nearly all of its LasikPlus centers were fully booked for the month of December.

Stephen Joffe, LCA-Vision chairman and CEO, commented, "As in Baltimore/Annapolis, our experience in our four newest LasikPlus markets confirms that value pricing opens a floodgate of consumer demand. We have made the procedure affordable to a significantly larger portion of the potential patient population, while maintaining excellent vision correction outcomes and the highest standard of care. In each of our LasikPlus markets, heavy launch-related marketing and advertising for LasikPlus have allowed us to achieve exceptional name recognition in a very short period of time. While launch-related marketing costs are quite high, initially, we believe these costs will decline over time without diminishing the appeal of LasikPlus or our position in the marketplace. This has been our experience in the Baltimore/Annapolis market, which was launched in July. Even with the rollout still underway, we remain very confident that LasikPlus will have a positive impact on both year-over-year and sequential fourth-quarter procedure growth. The rapid success of LasikPlus has made it the focal point of our business strategy. Since 1999 must bear much of the financial burden of launching this new format, we believe year 2000 will certainly reap the rewards of any short-term sacrifice in profitability."

12/16 **CIBA Vision**, the eye care unit of **Novartis AG**, and **QLT PhotoTherapeutics**

announced that the Swiss Regulatory Agency -- *Interkantonale Kontrollstelle fur Heilmittel* -- had given approval for the marketing of Visudyne (verteporfin) therapy, for the treatment of the wet form of age-related macular degeneration (AMD), the leading cause of blindness in people over the age of 50 in the western world. Specifically, the agency approved Visudyne for the treatment of wet AMD in patients with predominantly classic subfoveal choroidal neovascularization. Visudyne therapy will be made commercially available in Switzerland imminently. The registration application for Visudyne was submitted to the Swiss regulatory agency on August 18th, 1999. Regulatory applications are currently pending in the European Union, Canada, Norway, Iceland, Australia, New Zealand and the US.

"The approval of Visudyne by the Swiss regulatory agency is a major event for patients suffering from wet AMD," said Luzi von Bidder, president of CIBA Vision's worldwide Ophthalmic Business Unit. "At last there is an approved, effective treatment that can help preserve the vision of many patients suffering from this terrible, sight threatening condition. We will make Visudyne available to eye care professionals and their patients across the country in the coming days. We will also use this approval to apply for a free marketing certificate which will enable us to gain approvals in a number of other markets around the world."

"This is a monumental day for QLT and CIBA Vision," said Dr. Julia Levy, president and CEO of QLT. "We are proud to have been able to transform our discovery of Visudyne into a significant vision saving treatment. Today's achievement is a testament to the strong partnership and successful research collaboration between QLT, CIBA Vision and Novartis."

Visudyne therapy involves the use of a specifically designed laser that produces the low level, non-thermal 689 nm light required to activate the drug. These lasers have been developed by two of the world's leading laser companies, **Coherent Inc.**, and the **Carl Zeiss Group**. Additional clinical trials are being conducted to determine the effectiveness of Visudyne therapy in patients with an earlier stage of AMD who were originally excluded from the TAP Investigation as well as patients with a similar but distinct condition of abnormal blood vessels associated with progressive near-sightedness known as pathologic myopia.

Following the Ciba/QLT announcement, Coherent issued its own press release: This important step clears Coherent's Opal Photoactivator laser, already CE mark approved, for the treatment of many thousands of patients who lose vision every year. Additionally, the approval allows application for free marketing certificates, which will enable approvals in a number of other countries around the world. Jim Taylor, president of **Coherent Medical Group**, said, "Coherent is proud to provide the laser technology that activates the Visudyne therapeutic drug. We're excited to be a partner in the battle to prevent blindness from AMD. This is part of Coherent's on-going effort to provide ophthalmologists world wide with a full range of breakthrough technologies to treat eye diseases."

12/16 In an announcement that came "out of the blue", Seymour Kern, MD, of **Mindsurce** and the Eye Laser Institute Medical Group in San Diego, "found" an old patent of his 4,676,790, that issued in 1987, that apparently contains a claim on "lasering the bed of an eye and then capping it", which he believes may be a forbearer to LASIK, and is seeking an attorney to take on his case for collecting royalties, which he believes may run in excess of $100 million over the next five years. (I wrote about Dr. Kern and his Autokeratomileusis Laser in my 1986 report, "The Outlook for Refractive Surgery: The Impact of the L'Esperance Laser Refractive Keratoplasty", based on a paper he delivered at a 1986 BBI Emerging Medical Technology Conference, which I attended.)

After retrieving a copy of the patent claims -- via the IBM patent search site -- I'm not sure Dr. Kern can claim that his patent precedes LASIK, or claims it. Claim 3 describes a process for replacing a portion of the corneal tissue...comprised of preparing a lens blank; shaping said lens blank into a lens configuration; preparing a recess in the eye by "laser milling" said corneal tissue...and adapted to receive the shaped blank; and bonding the shaped blank into the said recess. I can't quite see this description as describing LASIK. Dr. Kern can be reached at **mindsource@mindsource.net**.

12/16 Matthew Dodds and Peter Bye of **SG Cowen Securities** released an update report on **VISX**, reiterating their "strong buy" rating on the company, based on a meeting with management, in which it suggested positive news flow. The key points of the report:

- The company remains comfortable with procedure growth of 10%-15% sequentially.

- It is becoming more likely that positive actions by the FTC and PTO could arrive shortly. Apparently, VISX has received a document from the FTC that indicates they would drop their appeal of that decision. Based on that document, the FTC appears to have had conversations with the PTO examiner and those conversations have indicated that the PTO will uphold an amended version of the '388 patent, which may emerge stronger than its original version. Thus, the FTC would not be able to prove that the patent was fraudulently obtained.

- Positive actions on these two fronts would significantly strengthen one of the company's core patents, the '388 (Trokel), and provide a significant deterrent for new market entrants. If the '388 patent emerges stronger from the re-exam, it also increases the liklehood that **Nidek**, **LaserSight**, and **Bausch & Lomb** could be found to infringe in federal court, re-upping VISX's leverage in obtaining licensing agreements. The Cowen analysts believe that a settlement would produce a royalty payment to VISX "north of $200".

- The procedure growth reported by the large LVC service providers may no

longer serve as an accurate barometer for VISX performance, because the corporate centers growth in procedure volumes appears to be uneven across the group, while the significant growth is occurring within the surgeon-owned center arena.

12/16 **Summit Technology** announced that its **Autonomous Technologies** subsidiary and **Zeiss Humphrey Systems**, a division of **Carl Zeiss Inc.** had entered into an exclusive manufacturing and marketing joint venture for Autonomous' proprietary wavefront measurement device, CustomCornea. The joint venture will utilize the design and manufacturing expertise of Zeiss Humphrey Systems and Autonomous' proprietary wavefront sensing technology to develop and produce a freestanding wavefront measurement device. Commenting on the relationship, Randy Frey, president of Autonomous, stated, "Autonomous is currently undergoing investigational trials for its CustomCornea wavefront technology and has completed the first customized ablation surgeries in the US. The initial CustomCornea surgery results are very encouraging and this alliance will accelerate the commercialization process."

As a result of the joint venture, Zeiss Humphrey Systems will obtain future access to the technology as a platform to supplement or enhance its range of refractive products. Lothar Koob, president of Zeiss Humphrey Systems added, "This agreement provides us with an opportunity to strengthen our world wide leadership position in diagnostic and therapeutic instrumentation and apply our design and manufacturing expertise to a rapidly growing market. We are delighted to be associated with such a high caliber company as Summit/Autonomous."

12/17 **Sterling Vision, Inc.** and **Rare Medium, Inc.**, the Web consulting services arm of **Rare Medium Group, Inc.** announced that they had signed an agreement to develop a world-class, web-based, optical portal business. In addition to a cash payment, Rare Medium will receive an equity interest in Sterling Vision. As part of the long-term arrangement, Sterling Vision, Inc. and Rare Medium, Inc. will work together to develop and launch a new web business strategy. It is anticipated that this new e-commerce capability will be the state-of-the-art information site for all eye care needs, offering Sterling customers the ability to fulfill their optical needs directly through the site, as well as an unparalleled ability to customize their optical needs to individual tastes and lifestyles. This new capability is expected to set the standards for new levels of online customer shopping and customer care experience by offering sunglasses, contact lenses and numerous other products and services.

In addition, the companies intend to develop strategic business models and design and build the new web capabilities to launch these new operations, in addition to managing ongoing operations and hosting. This capability also will feature ASP outsource components. The parties expect to execute a definite agreement within thirty days.

12/17 Johanna Bennett, staff reporter for *Dow Jones Business News*, reported that the FTC

might be ready to drop it's appeal in the **VISX** case. According to Bennett, a spokeswoman for VISX confirmed the FTC had filed a motion earlier this month to dismiss its claims against VISX. But according to legal documents, the FTC's motion, which has yet to be ruled on, hinges on whether the U.S. Patent and Trademark Office issues an amended version of the company's '388, or Trokel patent. The FTC's motion to dismiss its appeal doesn't change the agency's allegations against Visx. But according to legal documents, the FTC believes that "in all likelihood an amended version of the '388 patent will emerge from the (patent office's) re-examination proceeding" and the changes will make the FTC's case against Visx moot.

News of the FTC's motion and the patent re-examination have led to some bullish statements by analysts. But others involved in the matter are more cautious. "It's a positive indication. But nothing matters as far as we are concerned until it is done," said Lola Woods, company spokeswoman. Lawyers for the FTC have suggested the commission wait until after the patent office approves the amended patent before dismissing the appeal. Action by the patent office could take months, during which time the patent examiner could change his mind about the proposed amendments, according to legal documents.

As expected additional analysts came out with statements following the notice about the FTC's lawyers dropping of their appeal. Dave Therkelsen of **Dain Rauscher** issued a statement saying that "this is a positive for VISX as it removes one of several nagging legal issues, and may imply that the PTO is closer to completing its re-examination of the Trokel patent...Perhaps more important than the dismissal itself is the reasoning behind the FTC's decision. It appears that the PTO is getting closer to completing its re-examination of the Trokel patent. The FTC's decision to drop the appeal implies that the PTO may award VISX an amended version of the Trokel patent (as opposed to taking it away, which would help the FTC's case). While the PTO has not released its final decision as of yet, an amended patent could actually turn out to be stronger than the original, which clearly would be positive for VISX."

Greg Simpson of **AG Edwards** initiated coverage of VISX with a "maintain" rating. His neutral rating was based in part "on valuation, as well as the uncertainty surrounding VISX in the near-term...we believe VISX faces additional unknowns related to the near-term entry of both **Bausch & Lomb** and **LaserSight** into the U.S. market...we believe caution remains warranted at this point in time." A summary of the highlights of his report said: "Despite our optimistic outlook for this industry over the past few years, we are clearly late to the party on VISX, having been deterred by constant concern over the company's patent situation. VISX has repeatedly turned back every challenge to the extensive patent portfolio, though the surprise ruling from the International Trade Commission (ITC) on the company's complaint against Japanese laser manufacturer **Nidek** has served to cloud the issue in the minds of investors. We continue to believe, however, that VISX will remain the leading player on the laser manufacturing side of this industry, and that the industry will continue to enjoy attractive growth for the foreseeable future. Before looking to upgrade our

rating on the shares, we will look for: 1) signs of clarification on the legal front; and 2) efforts by the company to solidify and retain its key customers. In the near-term, our expectation would be that licensing agreements with LASE and BOL will serve to boost VISX shares, offering investors some independent validation of the validity of the VISX patent portfolio. Subsequent loss of customers, however, could negatively impact the shares. We would prefer to stay on the sidelines at least until see the licensing agreements in place, and until we have a sense of the BOL model for entering this market.

12/20 According to *OptiStock*, **Medjet** received notice of termination of its license agreement with **Nestle S.A.** and its subsidiary **Alcon Laboratories**. *EyeWorld Week* added that under the exclusive worldwide license, Alcon was to have begun paying certain royalty payments in 2000, and the two parties disagreed about the terms and conditions of the agreement, which was for the use of Medjet's waterjet keratome for corneal refractive surgery. Medjet will continue development of the device on its own, and might again seek to license its technology.

12/21 **Nidek** announced that it had once again prevailed over **VISX**, this time in Canada. On December 16th, 1999, Federal Court of Canada Justice J.E. Dube ruled that VISX excimer laser patents nos. 1,243,732, 1,271,813, and 1,254,658 had not been infringed by Nidek. The long-running suit, filed by Visx in 1994 against Nidek and two prominent Canadian eye surgeons was "dismissed with costs" by Justice Dube.

Hideo Ozawa, president of Nidek, responded to this company's latest legal victory stating, "We are very pleased our position has again been vindicated, although we regret the ordeal our Canadian customers have been forced to endure. Hopefully, this decision will put to rest the unprecedented climate of fear and intimidation. It is indicative to note that outside of the questionable North American monopoly presently held by VISX, Nidek's excimer laser is by far the instrument most often chosen by eye surgeons world-wide."

12/21 **ICON Laser Eye Centers** said it had placed orders for 23 Nidek lasers for delivery over the next four months into targeted U.S. markets. Most of the Nidek lasers will be placed into joint venture and/or acquisition structured transactions with local partners. These lasers are part of ICON's 100 cities program scheduled for the next 18 months. Simone Mencaglia, CEO of ICON stated, "ICON has an aggressive pricing strategy for LASIK which yields the consumer an excellent result for prices as low as $499 per eye on introductory special pricing. We attract the best ophthalmologists and optometrists by offering joint venture or acquisition terms that make them ICON partners in selected markets."

12/21 Announcing that the company surpassed the 2,000-procedure mark since receiving FDA approval for Intacs in April 1999, **KeraVision** said Intacs-related surgical instrument sales will be lower in the fourth quarter of 1999 compared to the third quarter. Revenues for the quarter are expected to be in the range of $1.8 million to

$2.2 million. The company also announced that it had trained more than 600 surgeons in the Intacs procedure during 1999 -- three times KeraVision's original surgeon-training goal. KeraVision chairman and CEO Thomas Loarie said, "Our goal is to build procedure volume. In the fourth quarter, KeraVision moved from training surgeons and selling start-up instrument kits to creating models that are designed to integrate Intacs into surgeons' practices and make Intacs the procedure of choice for mild myopia in these practices. We also intend to support our core surgeon group with cooperative advertising."

The company said that since the commercial launch of Intacs in the U.S., clinical outcomes for Intacs users including visual recovery, high levels of acuity and minor patient discomfort -- appear to be generally consistent with clinical results obtained in U.S. clinical trials for Intacs, based on initial tracking analysis. During the fourth quarter, more than 160 surgeons were trained in the Intacs procedure, bringing the total number since April 1999 to over 600 trained surgeons (vs. 200 as originally planned). Most of the 160 were "associate" surgeons, meaning they belong to medical provider groups that already purchased surgical instruments for all of their associate doctors. As a result, associates generate less revenue than "primary" surgeons who pay for start-up instrument kits.

Commenting on KeraVision's announcement, analyst Lawrence Keusch of **Goldman Sachs** said, "The company announced total revenues for Q4 would be significantly below expectations, at $1.8-$2.2 million compared to our estimate of $3.9 million. Moreover, we believe procedures may have been down sequentially in Q4. While we believe Intacs have some limited clinical utility, disappointing 4Q results underscore sluggish adoption rate. Not only are Q4 results lower than our estimate, but off markedly from the $4.2 million reported in Q3. Management indicated a bottleneck in the proctoring of physicians was responsibe for the downturn in revenues. While we acknowlege proctoring programs have limited the number of physicians qualified to perform Intacs surgery, we suspect procedures declined on a sequential basis. Management indicated 2,000 surgeries have been done since the product was launched in April. We estimate 1400 surgeries performed through 9/99, with 850 in Q3. Based on the reported number of surgeries to date, it is conceivable there were only 600 surgeries in Q4. Even in a best-case scenario, procedures were probably no better than flat sequentially...We remain extremely concerned about the ultimate penetration of the Intacs procedure."

12/21 Analysts Kenneth Bohringer and Cynthia Capitena of **Prudential Vector Healthcare Group** issued a report on the LVC service sector, specifically on **Laser Vision Centers** and **LCA-Vision**. They see the laser eye surgery market to see pricing pressures and consolidation, with winners emerging. "The leading companies providing laser access to ophthalmologists performing PRK/LASIK surgery for the correction of corneal refractive errors encompassing nearsightedness, farsightedness, and astigmatism share a striking similarity in their stock price charts for 1999 to date: an upward trend through most of the first half, peaking around July, and then a

dramatic descent. The sawtooth shape is readily explainable. Rising volumes carried the refractive market skyward until about mid-year. The laser stocks were riding the wave of LASIK surgery volumes: Through mid-July, capital appreciation for the three top laser access providers -- **TLC The Laser Center**, Laser Vision Centers, and LCA-Vision, Inc. -- averaged an astounding 350%..However...despite this breathtaking trend, the market remains virtually unpenetrated...What brought the party to an end was the fear that grew rampant in the investment community during the summer that a coming LASIK price war would wreak havoc on laser company profits. So eager have investors begun to dump the shares."

12/22 **Gimbel Vision International** announced that it had acquired a 51% interest in a new refractive vision correction surgery center to be located in Houston, Texas. Gimbel Vision's partner is a well-respected ophthalmic surgeon who has been practicing in the Houston area for more than 10 years. The center is expected to be opened during the second quarter of 2000. Glenn Gimbel, president, and CEO, said, "Our partnership model is becoming increasingly attractive to quality surgeons who wish to build successful refractive vision correction practices with a corporate partner who has the knowledge and experience to make the venture successful. As well, our partnership model allows surgeons to participate in the ownership and management of their own surgery center while retaining complete ownership of their medical practice. We look forward to establishing a strong presence in the Houston area."

12/22 **Goldman Sachs** analyst Lawrence Keusch issued a statement following the **Nidek** announcement of its "win" in Canada against **VISX**. According to Keusch, "In what was not a surprising decision, VISX did not prevail in its patent infringement suit against Nidek in Canada. We believe that the decision has little impact on VISX as (1) there are no per procedure fees charged in Canada, and (2) the core method patents were not used in the case. More importantly, some interesting and positive developments have occurred in the U.S. ITC case. Specifically, the ITC lawyers have petitioned the Commission to review the decision against VISX by the administrative law judge. The challenge by the ITC lawyers suggests that the decision for Nidek was a surprise and should be revisited.

Expounding on the Canadian decision, Keusch went on to say, "In our opinion, the Canadian Court decision has little impact on the competitive position and profitability for VISX. In particular, we note that there are no per procedure fees in Canada. As a result, the Canadian market is driven entirely by capital equipment sales and has only modest potential as compared to the United States. In addition, we note that the patents used in the Canadian case were apparatus claims under the L'Esperance intellectual property portfolio. The more powerful Trokel method patents were not utilized in the Canadian case as the intellectual property is almost exclusive to the United States. With no change to the competitive situation in Canada and the U.S. laser vision correction market remaining the market of choice, we do not see any downside to VISX as a result of the Canadian Court decision.

And on the ITC petition for review, he said, "We have learned that the lawyers for the ITC have petitioned the Commission to review the decision against VISX by the administrative law judge. The action by the ITC lawyers joins the petition by VISX to review the decision by the judge. The decision by the Commission to review the ruling will be determined by January 28. If the Commission chooses to review the administrative law judge's decision, a ruling will come in early March of 2000. We view the decision by the ITC lawyers to review the ruling as a positive for VISX as it underscores the surprising outcome for Nidek.

12/23 **Lasik Vision** announced that it had closed its brokered private placement with **Groome Capital.com Inc.** of 1.1 million special warrants at a price of $3.27 per share for gross proceeds of $3.7 million. The net proceeds from the private placement will be used for continued expansion of clinics in Canada and the United States.