**OPHTHALMIC LASER UPDATE -- JANUARY 1997**

12/30 The December issue of *Eyeworld* contained two interesting articles: "The LASIK lasers: Technology in high gear", which discussed the new lasers for LASIK, which, according to the article, "have gained prominence outside the United States"; and an interview of Bill Telfair of **IR Vision**, who is developing an erbium:YAG laser for refractive surgery. The LASIK laser article unfortunately missed out on the "newest" lasers, not mentioning either the Technolas C-LASIK, or the Aesculap Meditec MEL 70, combination moving slit/scanning spot devices.

The article on erbium lasers for refractive surgery was also remiss in that it did not mention any of the others also working in this area, such as Premier, Wavelength, Theo Seiler, and Aesculap Meditec on refractive applications, and Coherent on vitreoretinal disease.

12/30 Dave Harmon e-mailed me to let me know that his new website was operational, and I checked it out (WWW.mktsc.com) and found it to be quite informative. Besides the latest information from his Market Scope newsletter, he gave me a web page (which I used to post my latest PRK estimates -- check me out under "industry analysts"), and has links to associations (ASCRS, ISRS, AAO, OSN, Review of Ophthalmology, etc., laser companies (**VISX** and **Sunrise**) and refractive laser centers. I linked into the VISX homepage and downloaded their Global Patent Strategy; some information about the FDA approval process, and a list of analysts that cover the company. Pretty neat.

1/2 Talking about **VISX** and the FDA process, I received a notice from the company that it had been notified by FDA that its astigmatism application would be reviewed at the January 14th ophthalmic panel meeting. It is anticipated that the company will walk through the process and receive approval within 30 to 60 days after getting panel approvability. The notice also stated that it had received approval to expand its hyperopic trials last October (probably to counter the recent -- December 3rd -- announcement from **Summit Technology** about its hyperopic trials expansion). The press notice also mentioned that VISX had sold over 200 excimer lasers into the international market and had been successfully treating astigmatism since 1990. Based on its international experience, approximately two-thirds of the patients undergoing PRK have been treated for astigmatism and, therefore, U.S. approval could significantly increase the number of domestic PRKs.

1/3 The January 1st issue of *Ocular Surgery News* was loaded with information about PRK, LASIK, and ophthalmic lasers (with the latest version of the newspaper's annual listing of suppliers). Many of my contributions from last fall's AAO meeting finally showed up in print, including my piece about the turnaround at Summit Technology; the writeup about the pre-academy refractive surgery meeting; my annual roundup of new lasers appearing on the show floor; and an updated table listing the clinical status of all of the refractive laser companies. (Anyone who missed the issue and/or who

would like another copy of any of the above, give me a call.) In addition, the issue contained an interesting table put together by Dave Harmon listing the current U.S. Laser Vision Center and a list of contact information on the next page; and an interesting debate on whether PRK or LASIK would dominate the excimer laser refractive surgery market in 1997. A series of opinions for each approach, or for both, was presented. And finally, there is an interesting article describing the work underway to treat choroidal neovascularization with PDT, as a precise, selective, and repeatable technique for treating this affliction.

1/6 The January 6th issue of *EyeWorld Week* mentions that both **Summit Technology** and **Nidek** are challenging the validity of certain **VISX** patents, in response to separate patent-infringement actions filed by VISX in Canada in 1995. In a statement of defense and counterclaim filed with the Federal Court of Canada, counsel representing Summit and several of its laser owners, charged that a key VISX patent issued to inventor Francis L'Esperance, MD, includes claims that were "known and used by other persons", namely, Alain Azema and his French colleagues who had previously filed their PRK patent application in Canada. Nidek in its counterclaim, charges that many papers on PRK were published before L'Esperance applied for Canadian patents, and that VISX is violating federal laws by attempting to control the excimer laser market in Canada.

In an industry brief in the same issue, it was noted that **eyeFix, Inc.** had received FDA approval to market the Eye Fixation Speculum developed by refractive surgeon, Neal Sher. The disposable device stabilizes the eye for any non-intraocular procedure.

1/7 **Autonomous Technologies** was a presenter at the 1997 Hambrecht & Quist Healthcare Conference, held in San Francisco on this date. According to a company release, Randy Frey, CEO, and Rick Capozza, COO, were to discuss the ATC unique T-PRK excimer laser system for PRK. (In an e-mail message from a friend that attended the presentation, I was told that the Autonomous people did a great job! I requested a copy of the handout, if there was one, and will discuss it when I get it.)

1/7 I received the second of Lynne Peterson's reports on the refractive surgery industry. This one, entitled "Excimer Lasers", and published by *Grassroots Research*, a division of RCM Capital, is dated November 18, 1996, but was held for release until January. Some of the highlights include: new laser centers continue to open and most organizers plan to continue the rapid pace of development even though few are breakeven, while two have curtailed expansion plans; according to Lynne, no one is buying Summit lasers, all players are buying VISX; procedure volumes continue to trend upward, with more procedures performed in each succeeding month; a great number of doctors prefer LASIK, but patients are satisfied with either procedure; VISX is expected to receive astigmatism approval at the January panel meeting and this should boost procedure volume; most center advertising is aimed at obtaining referrals from optometrists and other ophthalmologists rather than the general public,

which is responding best to word-of-mouth testimonials. All in all a pretty bullish report. (Anyone who would like a copy of the complete report should call me.)

1/8 I received a package of information from Paul Malin, the new VP of Sales and Marketing for **Sunrise Technologies**. The accompanying letter was meant to bring me (and you) up-to-date on the company's activities in ophthalmology. Basically, Paul said that Sunrise had moved ahead into Phase 2A of its hyperopia trials with the Corneal Shaping System, based on the nomogram developed in the Phase 1 study. As of the date of the letter, December 30th, doctors had enrolled over two dozen patients into the study, and company management was evaluating new support tactics to support enrollment at the study's centers, to ensure further expansion of the study late this year. The letter also discussed its presence both at the AAO meeting and at the European Society of Cataract and Refractive Surgery meeting. They claim to have gathered nearly one hundred leads during the AAO, and placed one laser as a result of the ESCRS.

1/9 **Vista Technologies** announced that it intends to raise up to $10 million in a private placement of a new series of convertible preferred stock to accredited individual and institutional investors. Net proceeds are planned to be used to help finance its North American expansion of laser vision correction centers, and for marketing and other working capital purposes.

1/9 **VISX** sent out a press release congratulating the **Minnesota Refractive Surgery Center**, located at the **Phillips Eye Institute**, for performing its 1000th excimer laser procedure.The center began began using the VISX Star laser last April, and averaged approximately 125 procedures per month to reach the 1000 total. Phillips is one of **Laser Vision Centers'** premier locations, according to LVCI president Jack Klobnak. Shareef Mahdavi, director of marketing for VISX, attributed the success to "the great job of developing their referral network". (Not mentioned in the release, but pointed out in the January 13th issue of *EyeWorld Week*, was that 90% of the procedures were off-label LASIK's, performed by Drs. Dick Lindstrom and David Hardten.)

1/13 The same issue of *EyeWorld Week* also noted that Regional Sales Manager Steve Parks of **VISX** was offering members of the "Unapproved Laser Users Group" Star lasers for $350,000 with the trade-in of their lasers. The price could drop to $300,000 if five or more of the members participated. The offer expires on January 31st. The new laser could be leased from the **Hillside Group** at its nominal price of $525,000, in which case, Hillside would issue a check for the difference back to the customer, $175,000 to $225,000, depending on the final price of the laser. A VISX spokesperson confirmed that VISX was offering trade-in deals to custom laser owners. (This was also reported in Lynne Peterson's report, noted previously.)

1/13 The January issue of *Market Scope* contains several interesting stories. The newsletter provides additional information about the clinical status of the nine active (in the U.S.) laser companies, discussing the phase of clinical study and the estimated time to

completion for low to moderate myopia, astigmatism with myopia, and for low to moderate hyperopia. The article speculates that **Chiron/Technolas** could be next to gain myopia approval, not taking into account that almost all of the clinical trials were done with the Keracor 116 laser, which is no longer being marketed, and that the newer Keracor 117 is a spot scanning device that will probably require re-starting clinical trials! What comes through loud and clear is that **Autonomous Technologies** has taken over second place, perhaps along with **Nidek**, and either or both of these companies will probably be the next to clear the FDA for myopia. Of course, as we have mentioned, **VISX** is on the verge of astigmatism approval, with **Summit**, perhaps, about six months behind. Hyperopia should be another battle, with both Summit and VISX running neck-and-neck.

The other major story, other than the reports about everyone's stock value dropping during the year just past, was about procedure volumes. Dave Harmon agrees with my projections for 1996 (he came up with 105,000 vs. my 108,000), and we are close again for 1997. He looks for 210,000 procedures, while I'm still holding out for 252,000. Dave has posted his analysis of laser centers for the year past on his web site (www.mktsc.com), and it has also been picked up by *EyeWorld* and *Medical Laser Insight* (although not yet published).

1/13 Officials of **Autonomous Technologies** presented at the January 7th Hambrecht & Quist Healthcare Conference. The company plans to submit a PMA application for its T-PRK tracker-assisted excimer laser system in the fourth quarter of 1997, much earlier than previously expected. According to CEO Randy Frey, the application will include results from the company's Phase III clinical trials which began last October on up to 500 patients, and includes data on low to moderate myopia, astigmatism, and higher degrees of myopia. A good manufacturing practices audit of the company's facilities is also scheduled for the fourth quarter. Other highlights of the presentation include: comments on the company's proposed marketing strategy, which consists of a low upfront investment of about $100,000 for the laser system, and a procedural fee of $500 per eye treated, which will guarantee against technology obsolescence and include all service and upgrades; changing over from all in-house manufacturing to partial outsourcing during 1997, and full outsourcing in 1998; and first mention of a technique under development for producing a "custom cornea", using laser mapping of optical aberrations developed in 1997, to provide a custom ablation shot pattern during 1998, and eventual targeting of a multifocal cornea to provide both near and distance vision for presbyopes in 1999 and beyond. Other milestones include beginning hyperopia and LASIK trials during the second quarter of 1997; an ISO 9001 audit scheduled for the 3rd quarter; and the beginning of its custom cornea clinicals in the 4th quarter of this year.

1/13 *Market Scope* reported that **Comprehensive Refractive Surgery-USA** had enrolled 180 surgeons in its independent LASIK study for high myopia and astigmatism.

1/13 The *Los Angeles Times* ran a complimentary story about **VISX** on the day before the company appeared before the FDA's Ophthalmic Advisory Panel. The story mentioned that market prospects could improve significantly if the FDA approved VISX's application for astigmatism correction, a condition effecting 23 million Americans.

1/14 **VISX** presented its case for approval of astigmatism to the FDA's Ophthalmic Advisory Panel, reporting on both a five-center U.S. clinical study of 116 patients, wherein 88.1% of patients achieved 20/40 vision or better, and a 64% reduction in astigmatism, and in three worldwide trials, with 741 eyes treated with 85% analyzed at 12 months or longer, with astigmatism reduced by 70%. By a 4 to 3 vote, the panel recommended approval of the application for astigmatism between 0.75 to 4.0 diopters, in patients with myopia between -1 to -6 diopters, with three conditions: that the lower age limit of patients be 21; that surgeons be trained in astigmatism surgery; and that the labeling state that patients 21 to 30 have a higher risk of complications. The reviewers noted that the VISX laser appeared to perform significantly better in treating myopia than treating astigmatism. Whereas 93.7% of patients treated for myopia achieved 20/40 corrections or better, while only 86.6% of those with astigmatism achieved 20/40 or better.

VISX put out three news releases following the recommendation from the panel. Mark Logan commented that he complimented the FDA on its expedited review and said that the final approval would lead to an increase in the overall numbers of PRK procedures performed in the U.S. Another release noted that VISX's international experience revealed that approximately two-thirds of all patients undergoing PRK have been treated for astigmatism, and one Canadian doctor noted that at his clinic, 97% of patients with myopic astigmatism achieved 20/40 or better, with 93% doing so after one week. The last release noted that the company would be sending each laser center a press kit with information about treating astigmatism when the company receives final FDA marketing approval (which most analysts believe will be within 30 to 60 days). According to Shareef Mahdevi, Director of Marketing, approval will also mark the beginning of consumer marketing and public relations efforts in selected test markets around the U.S., with results used for planning national marketing efforts.

At least two VISX users chimed in with their congratulations, with news releases coming from **Laser Vision Centers** and Dr. Joseph Dello Russo, of the **New Jersey Eye Center**.

1/16 **Beacon Eye Institute** expects that the recent FDA panel recommendation for approval will be beneficial for the company's market penetration in the U.S. According to Keith Moore, Beacon's chairman and CEO, over 130 million North Americans may be candidates for laser PRK. Penetration of less than one percent of this potential market would create an industry of $2 to $4 billion annually. He went on to comment that over 100,000 incoming calls have been received at its Information Response Center since September 1995, and over 3000 consumers have visited its U.S. Laser Centers

or have attended seminars to learn about PRK, with more than 3800 procedures performed since the opening of its first center in Toronto in May 1995. In addition to the Toronto facility, the company operates nine U.S. centers in San Antonio, Austin, Dallas/Ft. Worth, Houston, Denver, Fort Lauderdale, Tampa, Atlanta, and Orange County. Further expansion is planned as the market for laser vision treatment continues to grow.

1/16 I received a followup report on **LCA-Vision** written by Jane Freedman, of J. Freedman & Associates, that was bullish on the company. One highlight states that about 25% of PRK-certified ophthalmologists are affiliated with LCA-Vision Centers, which, the report claims, commands a 14% of the commercial laser centers in the U.S.

1/16 **TLC The Laser Center** reported its second fiscal quarter results, ending 12/31/96, with revenues for the quarter at $8.9 million, up $7.2 million from the same quarter last year. Net revenues were $5.4 million, compared to $4.6 million for the previous quarter, as the number of refractive procedures continued to grow. The net loss for the quarter was $2.6 million (15 cents/share), associated with its rapid expansion and start up costs. The company reported that it opened five clinics in the quarter, up from the two to three during previous quarters. The company also announced that effective January 15th, its Toronto laser center would begin offering correction of hyperopia, based on a specially designed laser and software developed by Drs. Machat and Slade, TLC's National Medical Co-directors.

1/16 **Sight Resource** held a teleconference with shareholders and analysts to discuss its ongoing business development plans. COO Steve Blinn discussed how the company intends to grow the three segments of its business: laser vision correction; eyecare centers; and the managed care of vision. Steve explained that Sight intends to make its LVC business profitable in 1997, especially as the number of patients treated increases; has plans to expand its eyecare business into other regions, and intends to partner with ophthalmology for the surgical/medical referrals generated by its optical business, so that it can retain the patients and collect the $200 followup fees for cataract and glaucoma referrals. In the managed care arena, Sight is already contracted with Harvard/Pilgrim in New England, a panel provider for HMO Blue in Rhode Island, and about to sign a contract in Cleveland. They intend to expand this business in the coming year, as they have the available chair time with their optometrists at the eyecare centers. Steve then compared how Sight was doing with its closest competitors, **Sterling Vision**, as a similar type of operation, and **Laser Vision Centers** and **LCA-Vision** in the centers business. Looking directly at the revenues for Sterling and its market cap, Sight has similar revenues, but only one-third the valuation. In fact, Sight has the lowest valuation of any of the companies mentioned, including **LaserSight**. (Anyone wishing a copy of the comparison chart provided -- give me a call.) As of October 1996, Sight Resource operates 72 eyecare centers; 10 laser vision correction centers; and has better than 875,000 lives under managed care contracts. Its annualized revenue rate is at $38 million, up from $19 million a year

ago. (The Sight Resource update -- "What a Difference a Year Makes" is also available for those that care to see it.)

1/16 The editorial page of *The Wall Street Journal* ran a story written by Robert Goldberg concerning "The Ethical Mess at the FDA". It reiterated in agonizing detail the sordid story about **Summit Technology** and its founder David Muller, and the allegations of misproprietary concerning the alleged influence peddling in giving contributions to Senator Edward Kennedy's political campaign for re-election, with the express purpose of pressuring the FDA into speeding up the approval of Summit's application for its excimer laser system. I don't understand why this story has so much "legs". I would have expected that the FBI investigation would have turned up misdoing, if there was some, and put this matter to rest by now. (There is also another story about this matter in the January issue of *Medical Device & Diagnostic Industry*. Columnist James Dickinson wonders if there will be "Another Bloody Season in the FDA-Congress Wars?" He raises the question of partisan politics heating up again, with the medical device industry as the ultimate victom, especially if House Member Joe Barton re-convenes his investigation into the Summit-FDA situation and it turns into a "full-blown scandal".)

1/17 **The Society for Excellence in EyeCare, Inc. (SEE)** announced that it has called on the FDA to halt its recent actions against advanced forms of refractive eye surgery. In a letter to FDA the society noted that those eye surgeons that were operating their own developed lasers (custom lasers or"black boxes") and performing LASIK, were doing so under the practice of medicine and should not fall under the FDA's jurisdiction. The SEE letter was prepared and submitted by the Washington law firm of **Arent Fox Kintner Plotkin & Kahn**, and cites FDA law in support of its contention that physician designed lasers qualify for "custom device" exemption, and therefore, are exempt from the PMA provisions of the law. (I have a copy of the 13 page document and would be happy to share it with any interested parties.)

According to *Market Scope's* web site, the FDA received three IDE requests from custom laser owners, and ten applications for certification of "gray boxes" under the program announced last October, whose deadline was January 15th. According to the January 20th issue of *Ocular Surgery News Intelligence Report*, Morris Waxler, acting chief of the FDA's Diagnostic and Surgical Devices Branch, eight of the ten "gray box" applications were inadequate, and the filers were asked to file an IDE. The agency asked the two other users for more information before reaching a decision about certification.

1/17 **Omega Health Systems** announced that it had entered into a strategic alliance with **ClearVision Laser Centers**. The alliance is designed to increase refractive surgery procedures at Omega co-managment centers and assist ClearVision in the establishment of additional laser centers. Omega will contribute its expertise in developing co-management programs and the marketing resources of its VisionAmerica Laser program. In addition, Omega has acquired a minority equity

interest in ClearVision. (ClearVision currently operates three centers in Colorado and Salt Lake City, and plans to add eight to ten additional locations over the next three to four months.)

1/17 **Shooting Star Technologies** has signed a joint venture contract worth $10 million in Bangkok, Thailand, as part of a Team Canada delegation to Asia. The Canadian-Thai partnership between Shooting Star and **Asoke Sin** will allow Shooting Star to acquire a 45% interest in a new laser refractive eye center to be located at the Rutnin Eye Hospital. (See the December 2nd brief in last month's newsletter for the preliminary announcement of this venture.)

1/20 **Sunrise Technologies** and **EyeSys Technologies** announced that they had terminated their proposed merger discussions. According to a spokesperson for Sunrise, as reported by *Dow Jones*, the company had completed its due diligence and realized that it would take a lot of investment on Sunrise's part to make the acquisition work, and decided it was not in its interest to proceed.

1/20 **LCA-Vision** opened its 13th free-standing U.S. facility in Albany, NY, to serve this metropolitan area. The company, which operates two Canadian centers and an international center in Helsinki, Finland, intends to open its 17th center in Mountain View, CA later this month, to serve patients in the Silicon Valley. Dr. Stephen Joffe, CEO noted that the number of procedures performed in existing centers continues to accelerate as promotional activities and positive word of mouth have their impact, and that the company performed close to 4000 procedures during 1996 at its various locations. Dr. Michael Belin will serve as Medical Director of the Albany site. Currently some 350 ophthalmologists are affiliated with LCA-Vision centers across the country.

1/20 This week's edition of *EyeWorld Week* notes that **Laser MedCare**, based in Ottawa, Ontario, has developed a multifaceted approach to cosmetic surgery which ensures maximum use of space and cross-referrals within its patient base. In addition to performing approximately 80 PRK procedures per month with its Meditec excimer, the center offers several other aesthetic treatments via a diverse group of staff surgeons, including skin resurfacing, laser-based hair removal, hair transplantation, liposuction, and breast augmentation. According to center medical director Dennis Conrad, "The versatility of our business plan ensures constant use of our facility and a positive cash flow situation." For details on this management approach, Conrad can be reached at 619-739-3088.

1/20 This week's issue of *Ocular Surgery News Intelligence Report* states that the FDA had cleared the **Amoils** Epithelial Scrubber for marketing under a 510 (k) clearance. The device is being marketed by **Innovative Excimer Solutions**.

1/21 Another VISX laser user commented on the recent astigmatism approval by the FDA's ophthalmic panel. Peter McDonnel of USC/Doheny Refractive Laser Medical

Center, which claims to have been the first site to study the treatment of astigmatism using the VISX laser in 1991, said that the eventual marketing approval of the procedure will dramatically increase the number of patients that can be helped with this (PARK -- Photorefractive Astigmatic Keratectomy) simple outpatient procedure.

1/21 The January 27th issue of *Business Week* has a Personal Business story about refractive surgery, "Eye Surgery? Take a Close Look". The story emphasizes LASIK but discusses the pros and cons of RK and PRK as well, and also talks about unilateral vs. bilateral surgery. The story, a consumer's eye view, is conservative in nature, and ends with the statement that if you aren't sure the procedure is worth the potential risks, there is no hurry. "Your eyes are one part of your body you won't want to put on the medical cutting edge."

1/22 **Sunrise Technologies** announced that it had expanded its manufacturing agreement with **Paradigm Medical Industries**, to deliver laser units for Paradigm's Photon laser system used for cataract removal. Under the expanded agreement, Sunrise will supply 20 completed units by the end of March 1997, and up to an additional 60 units by the end of 1997. Prior to FDA clearance of the Paradigm device, the Sunrise laser units will be incorporated into Paradigm Photon systems shipped outside of the U.S. (The lasers used in the Paradigm system are pulsed YAGs.)

Sunrise also announced the award of another U.S. patent for shrinking collagen tissue, in this case in the tympanic membrane of the ear. Because of the impact of loud music, as we age, the tympanic membrane tends to become flaccid, resulting in hearing deterioration. Shrinking collagen tissue within the tympanic membrane tightens the membrane and, like tuning a drum, restores hearing capability. Sunrise is not actively pursuing this application, focusing its efforts on the treatment of hyperopia using its Corneal Shaping System, but the company feels that the hearing disorder segment could be a huge market opportunity. David Light, Sunrise CEO said, "In the future, we can envision Sunrise having a portfolio of treatments stemming from our base technology, with our ability to offer solutions for treating hyperopia, glaucoma, and hearing loss as examples of byproducts enabling us to leverage the demographics of an aging population that demands a high quality of life. We will continue to pursue our objective of having the predominant patent position in the markets in which we choose to compete." (I wonder where the division occurs with these patent rights, some of which are owned by **New Star Laser**, the spin off from Sunrise, and New Star's spin off, **Laser Aesthetics**!)

1/24 According to *Dow Jones*, **Ray Dirks Research**, a division of **National Securities Corporation**, has raised **VISX** to a strong buy from neutral. In a research report, the firm noted that VISX will be reporting its fourth quarter results next week and the analyst expects that the company will report double the street's estimate for earnings, much of that from accelerating cash flow from Pillar Point revenues.

1/26 **Extra Corporation** announced that it had signed an agreement with **Sterling Optical Corporation** to allow Sterling to use its electronic healthcare transaction technology to enable Sterling to confirm patient insurance eligibility and to file insurance claims electronically.

1/27 **Pillar Point Partners** announced that it had filed another of its patent infringement suits, this time against JT Lin, Chung Lee, and **Photon Data, Inc.**, claiming that the company was manufacturing and marketing laser vision correction equipment without a license. In addition, Pillar Point believes that Photon Data is manufacturing and selling a laser without FDA approval.

1/27 The January issue of *Review of Ophthalmology* reports that an off shore source from the Caribbean is providing "doctored" **VISX** keycards that enable the user to provide astigmatic and high myopia correction for a fee. For $30 each, plus $100 for shipping and handling, the unknown source will alter a minimum of 30 cards per shipment. A spokesperson for VISX said that the company had not heard about this until called by the reporter for the magazine.

## OPHTHALMIC LASER UPDATE -- FEBRUARY 1997

1/29 **LCA-Vision** opened its 14th U.S. free-standing laser vision correction center in Mountain View, CA, to serve Silicon Valley. The facility is the company's first on the West Coast.

1/29 **VISX** reported its financial results for the fourth quarter, showing revenues of $18.9 million, compared to only $6.3 million for the same quarter last year. Net income was $5.9 million (37 cents/share). For the year, revenues were $69.7 million with a net income of $17.3 million ($1.08/share). Revenues for the quarter included systems sales of $13.8 (which translates to about 34 systems sold, because of discounted pricing) and royalties and service revenue of $5.1 million. Unfortunately, there is no way of estimating how much of this is from Pillar Point procedure revenues. For the year, systems sales were $53.1 million, representing sales of about 118 Star systems.

In an analyst conference call following release of the fourth quarter results, as reported in the February 6th *Market Scope*, Mark Logan, company president, indicated that the company was considering several alternatives for capitalization of its $89 million in cash. Some of these included a large cash dividend, stock buy back, and acquisition of new technology, with the latter being of high priority. The company also announced that some target marketing for refractive surgery would begin during 1997. Logan also indicated that he was comfortable with projections for 200,000 Pillar Point procedures during 1997.

1/30-

1/31 **Summit Technologies** announced that it intended to divest its growing but unprofitable Vision Center business, which would be treated as a discontinued business going forward. The company did not announce how the business would be divested, although speculation in the press (*Boston Globe* and *Wall Street Journal*) said that the company had been planning for the event for several months and that prime candidates might include other major vision center companies.

2/3 The February 3rd issue of *Eyeworld Week* noted that the Japanese equivalent to the FDA's Ophthalmic Device Panel had declined to approve **Nidek's** application for PRK, apparently because the panel wanted more studies with Japanese patients to show that the 193 nm wavelength was not carcinogenic. I had thought that that subject had been laid to rest in the late 1980's and early 1990's by the definitive work done on the subject showing no harm. But, according to a note received from Ray Sayano of Nidek, all excimer laser approval in Japan is on hold pending additional safety data on the effects of 193 nm on DNA. The issue had been raised by a Ministry of Health panel member, who even thought aware of the published information on the matter, was requesting additional data. Sayano indicated that the MHW would probably approve the use of excimer lasers to treat PTK prior to PRK.

2/4 **VISX** announced the extension of its Ambassadors' Program, offering free keycards (and the payment of the Pillar Point fee) for any eye doctor interested in having PRK, as indications are that having the procedure leads to increased procedure volumes for any office where the doctor has been treated. The program also offers up to 8 keycards for use on the staff, who then also become "ambassadors".

2/4 **Paradigm Medical Industries** announced the successful completion of an agreement with **Sunrise Technologies** for the latter to supply the laser sub-assemblies that will be incorporated into Paradigm's Photon Ocular Surgery System, the first commercially available laser-based cataract removal system. The contract stipulates that Sunrise would deliver 20 units to Paradigm by March and up to an additional 60 units by the end of the year. Prior to FDA approval of the system, Paradigm will export it into the international market, while selling its phaco ultrasound system in the U.S. Because of the modular nature of the system, it can be upgraded with the laser upon its FDA clearance.

2/5 Verne Sharma, president of **Summit Technology**, in a letter to the editor, responded to the editorial that had appeared in the December 16th *Wall Street Journal*, attacking the company and its former chairman, David Muller (see our writeup in last month's newsletter). Sharma said that the editorial "contained falsehoods damaging to the reputation and credibility of Summit Technology", as the article relied on the sworn statement of a disgruntled former employee, who was terminated for cause, and later sued the company, a suit which was dismissed by the U.S. District Court of Los Angeles. Sharma also denied the allegation that the company used political influence to gain FDA approval, and the charges with respect to the company's role in getting the FDA to act against "gray market" laser owners.

2/5-
2/6 **KeraVision** reported to *Dow Jones* that its Phase 3 trial "was in good shape", with 20 procedures having been performed to date, and the goal of 360 patients being treated, expected to be reached by mid-year. Progress is also being made in Europe, with 35 doctors in France and Germany trained and a backlog of other physicians waiting for training. Through mid-December, more than 110 procedures had been completed in Europe, both from the clinical study participants, and by others since the product's commercial release on December 3rd.

The following day the company released its financials for the year, reporting a net loss of $12.9 million, as compared to a loss of $7.1 million for 1995. The increased loss was reported to be primarily due to efforts to launch sales in Europe and for expanded clinical studies.

2/6 **Medjet** announced the completion of the prototype of its HydroBrush, a small hand tool with a transparent applanating surface that is placed against the area to be debrided. A circular jet of water operated at 4000 psi acts as the brush, to produce a perfect 7-8 mm circular debridement of the cornea in approximately two seconds. This technique could possibly replace the scraping of the epithelium necessary to perform PRK. It will compete with both the rotary brushes, developed by Drs. Amoils and Pallikaris, for the same end use. Medjet said that the prototype of the company's other product, the HydroBlade Keratome for therapeutic lamellar keratoplasty, is expected to be available for clinical testing by the end of the first quarter of 1997.

2/7 **Premier Laser Systems** said that its previously announced ophthalmic joint venture with **Refractive Surgical Services** has been completed. The joint venture company, **Data.Site** is 51% owned by Premier, and 49% by RSS. Data.Site will focus on assisting physicians and researchers with ophthalmic data collection and outcomes analysis, with anticipated revenues for 1997 of $1.5 million, with more than 15 prominent U.S. ophthalmologists involved in the program. The company has also recently signed a contract with **CRS-Education**, to provide data collection and analysis for LASIK.

2/10 **Iridex Corporation** announced fourth quarter results with sales of $4.8 million, up 97% from last year's same quarter. Net income was $356,000 (8 cents/share). For the year, sales were $12.4 million and net income was $1.0 million (16 cents/share). The company began shipping its new product, the OcuLight GL at a rate which almost doubled sales volume from a year ago. The company is still experiencing supply difficulties with respect to the diode lasers used in the product, they continue to work with their supplier to resolve the issue, but expect the delays to continue for a few more months.

2/10 This week's issue of *EyeWworld Week* states that a patent has been issued to **Kera Technology** for the random projection of single or multiple spots in an excimer delivery system. Inventors George Huang and Gabriel Simon also share another

patent for symmetrical multiple laser beams, both of which are employed in the company's IsoBeam D200 laser, currently in European clinical trials. The laser's delivery system allows for the homogenous hydration during ablation and avoids hydration-related irregularities such as central or lateral islands, according to company literature.

2/10 **VISX** announced a share repurchase program, to repurchase up to 2 million shares of the approximately 15.4 million outstanding. The program will be conducted over the next 12 months through open market transactions.

2/11 **TLC The Laser Center** announced the closing of the acquisition of 99.9 percent of the outstanding shares of **20/20 Laser Centers**, which operated nine laser centers in the north-east and Florida. The acquisition, valued at approximately $25 million, was funded through the issuance of TLC common shares, based on a TLC price of C$7.25/share. 20/20 centers will continue to operate as an independent subsidiary of TLC, with headquarters in Bethesda, MD. With the acquisition, TLC becomes the largest provider of excimer laser vision correction in North America, with 30 locations across the continent. The company also announced the acquisition and letters of intent for practices providing total eye care. Acquisition of Midwest Eye in Chicago has been completed and will add two secondary eye care facilities in the Chicago area, bringing the total to four. One of the sites has been equipped with a VISX laser and will begin performing laser surgery. Letters of intent have been signed with Eye Care Physicians of Michigan, which currently operates five clinics and holds interest in two surgery centers, and with Pacific Eye Institute AMG, which includes an ambulatory surgery center and a secondary eye care clinic.

2/11 I received a letter from **AllSight Laser Center**, formerly **WPRK** (Western Pennsylvania Refractive Surgery), an independent refractive surgery center run by a group of 98 optometrists and ophthalmologists. The letter states that the group has grown to be the largest refractive surgery center in Western Pennsylvania with the largest network of affiliate providers (243 affiliates, of which 60% are non-investors). Anyone interested in learning more about AllSight can call them at 412-934-2020.

2/11 In response to an apparent decline in stock price, **Sterling Vision** stated that it was unaware of any facts and/or circumstances regarding its business, operations, or other conditions that would cause the trading price of its common stock to decline.

According to *The Boston Globe* of February 20th, Sterling got caught up in the fallout from Centennial Technologies, whose stock plummeted the same day, after the firing of its chief executive. It appears that both company's stock (along with several others) were touted by the same broker in Connecticut, and felt the downdraft of the fall of Centennial.

2/11 **Escalon Medical** announced its fiscal second quarter results with revenues of $1.3 million and a net loss of $579,000 (6 cents/share). The revenues were attributable to

the sale of products of the old **Escalon Ophthalmics**, primarily AdatoSil, silicone oil used in vitreoretinal surgery, Betadine, and other vitreoretinal specialty products. As for the ISL Picosecond laser, Sterling Johnson, president and CEO, said that the company was committed to the development and commercialization through both internal product development and utilization of strategic partnerships.

2/12 **Laser Vision Centers**, at its annual meeting, told shareholders that the company has seen growth in the number of excimer procedures for the past five quarters. U.S. case volume was up 42% from the first to second (fiscal) quarter, and up 32% from the second to third. (The company has an April 30th fiscal year and is currently in its 4th quarter.) Jack Klobnak, company chairman and CEO expects case volume to be up again in the fourth quarter. Klobnak said that the company had opened seven new sites in the third quarter and expects to open up to 25 additional sites in the current quarter, to remain the largest provider of refractive surgery in North America and the World. Klobnak said he was very comfortable with predictions of 200,000 procedures industry-wide in the U.S. in 1997, and said that the number could be even higher if FDA approval of the treatment of astigmatism and for its MobilExcimer come in 1997. He also noted that the St. Louis center had filled all of its slots for patient screening for several weeks, as an indication of patient interest in the procedure. Klobnak went on to say that the company intends to open up to forty additional sites with its strategic partner **Columbia/HCA** in the coming months, with the MobilExcimer system used to serve many of these locations.

2/12 **VISX** announced the expansion of its patent portfolio, with the acquisition of the rights to the patent portfolio previously held by **Phoenix Laser Systems**. In a fax I sent to Mark Logan, I said that I never expected to hear the Phoenix name used in a positive way again, following the company's collapse several years ago. (For those of you unaware, I was engaged by Phoenix, while still with **Arthur D. Little**, to prepare two reports about their technologies, that was used to raise capital in 1990. I stopped working for the company shortly thereafter, after asking for clinical data to support their claims of intrastromal correction, which was not/could not be provided!)

The package acquired contains 11 issued patents and two pending applications, together with their foreign counterparts, which cover scanning and tracking technologies for ophthalmic surgical lasers, as well as novel methods of charting corneal topography and depth. (Anyone wishing to see my descriptions of seven of the patents, as included in my March 1990 report about the company, give me a call.) VISX noted that it intends to notify ophthalmic laser manufacturers of its ownership of the patents, and to enforce them where appropriate. The patents are not included in the Pillar Point Partners agreement.

2/13 **BeaconEye Inc.**, which operates as **Beacon Eye Institute**, announced its results for the year ended December 31st. Revenues were $5.0 million, an increase of 400% over the $1.0 million for 1995. The revenues were generated by a full year of operation at the company's Toronto center, and approximately half a year at the five U.S. centers. Net

loss was $24.5 million ($7.27/share), compared to $11.6 million ($12.77/share) for 1995. The net loss included $15.2 million of development expense compared with $8.3 million a year ago. The company is in the midst of starting up an additional four centers, expected to be in operation by the end of March. The company notes that nearly 2800 interested consumers have visited its U.S. centers for a preliminary evaluation, and numbers of procedures booked are increasing significantly. Volume at the Toronto facility is being sustained at over 300 procedures booked in the last five weeks, while more than 250 procedures are booked in the five established U.S. centers. The current monthly booking rate in these U.S. centers is more than 2½ times the monthly average achieved for the centers in 1996. In addition to Toronto, Beacon centers are located in San Antonio, Austin, Dallas/Ft. Worth and Houston, Texas; Denver, Colorado; Ft. Lauderdale and Tampa, Florida; Atlanta, Georgia; and Orange County, California.

2/13 **Summit Technology** reported that the first two patients had been treated under their Phase 3 protocol for hyperopia using the SVS Apex Plus laser system. The procedures utilized the company's emphasis mask to create a 6.5 mm ablation, followed by use of an Axicon lens to create a blend zone extending out to 9.5 mm, in a procedure that has been performed outside of the U.S. for nearly two years. The U.S. clinical trials are being conducted at seven sites.

2/13 **Shooting Star Technologies** has signed a joint venture agreement with **Vicary Eye Care Services** in Australia, for the provision of cataract and refractive surgery services. The agreement calls for the formation of a company to be called **Pacific Eye Centre (Australia)** which will be 75% owned by Shooting Star's wholly owned Australian subsidiary, and 25% owned by Vicary. As of March 1st, the new company will acquire the assets of the two existing Pacific Eye Centres located in Brisbane and Mackay. With conservative estimates for gross revenues of over $5 million for these two centers, this should double Shooting Star's revenues for 1997; which, for the first nine months of 1996, were $5.6 million.

2/14 **VISX** announced that it had received an "approvable" letter from the FDA for its excimer laser to treat low to moderate degrees of myopia with astigmatism. The letter, which came one month after the Advisory Panel recommendation for approval of the application, is the last step before final approval, and usually amounts to reaching an agreement over final labeling for the procedure.

2/18 **Summit Technology** announced that it had received FDA approval to market its SVS Apex Plus excimer laser in the U.S. for the treatment of mild to moderate myopia (-1.5 to -7 diopters), with up to 1.5 diopters of astigmatism (matching the approval for the SVS Apex laser system). Verne Sharma, president, said that owners and lessors of the SVS Apex will be able to upgrade, either in the field, or at the company's Cork Ireland plant, for $55,000, the company's cost. Once upgraded, no further hardware modifications will be needed to enable the system to treat astigmatism or hyperopia, once those applications are approved by the FDA.

The company also announced its fourth quarter and year results. For the quarter, revenues were $17.9 million, compared to $26.8 for last year's quarter, and a net loss of $8.4 million (27 cents/share) for continuing operations, compared to a net income of $2.4 million last year. Legal expenses of $2.4 million were recorded in the quarter. The loss from discontinued operations was $9.0 million (29 cents/share) (which includes a $4.6 million provision for operating losses prior to divestiture), compared to a loss of $1.9 million for the last year's fourth quarter, giving a total net loss of $17.4 million (56 cents/share) for the quarter, compared to net income of $544,000.

For the year, the company had revenues of $80.5 million compared to $95.9 million, and a net loss of $13.5 million (44 cents/share) from continuing operations, compared to a net income of $1.6 million (6 cents/share) last year. The year's loss included $6.0 million in legal expenses. The loss for discontinued operations was $23.4 million (75 cents/share), giving a total loss of $36.9 million ($1.19 per share) for the year. The year end results reflected a decrease in equipment sales, partially offset by an increase in royalty income.

As previously announced, the company plans to divest, through sale or spin off, its growing but unprofitable Vision Centers business. It will be treated as a discontinued operation going forward.

The company said that procedure volume continues to increase, with approximately 16,100 laser vision procedures performed during the fourth quarter in the U.S. using Summit lasers. That raises the total for the year to over 54,400 (and over 58,000 from approval in October 1995).

An analysis of the quarter's revenues, disclose that 10 or fewer laser systems ($3.8 million) were sold during the quarter, assuming that Lens Express contributed about $12.5 million in revenues, and royalties accounted for about $1.6 million.

2/19 **Autonomous Technologies** reported its financials for the quarter and year. The company had no operating income and an operating loss of $3.0 million, including $1.4 million for R&D and clinical trial expenses for the quarter; and $4.1 million, including $2.3 million for R&D and clinicals for the year. Net loss for the quarter was $2.8 million (42 cents/share) and $9.0 million ($1.12/share) for the year.

2/20 In the second significant patent purchase of the month, **LaserSight** announced that it had entered into an agreement with **IBM** to acquire worldwide exclusive rights to "certain" ophthalmic-related patents (probably the "Blum", "Braren", and "Hanna" patents), relating to ultraviolet light ophthalmic products, and procedures for UV ablation. These patents have issued in Australia, Austria, Belgium, Brazil, Canada, France, Germany, Italy, Japan, Spain, Sweden, Switzerland, and the United Kingdom, as well as the United States. In addition, the agreement provides for IBM to transfer its rights under the patent license agreements with **VISX** and **Summit Technology**. Subject to the closing of the transaction by July 1st, LaserSight will receive all

royalties accrued after January 1st. (It is my understanding that the agreement does not cover IBM's other ophthalmic license agreements, with **Aesculap Meditec** and **Schwind**, and the recently concluded agreement with **Autonomous Technology**, which may include a per procedure royalty fee.) No purchase price for the patents was disclosed, but LaserSight has agreed to place a $1 million deposit into escrow pursuant to the negotiated agreement by March 7th, and closure by July 1st.

2/20 **Laser Eye Center of Boston**, owned by **Cornea Consultants** has been selected as one of five clinical investigation sites to participate in a multi-center study of the **VISX** Star excimer laser for the correction of hyperopia. The other four sites include **Cedars-Sinai Medical Center**, Los Angeles; **Columbia-Presbytarian Medical Center**, New York; the **Wilmer Eye Institute**, Baltimore; and **Kraff Eye Institute**, of Chicago who, according to the February 24th issue of *Ocular Surgery News Intelligence Report*, performed the first two hyperopic procedures under the protocol.

2/21 **Staar Surgical's** implantable contact lens was granted an IDE to begin human clinical testing for the correction of mild to severe myopia and hyperopia.

2/21 **Shooting Star Technologies** announced the "official" opening of the new **Gimbel Eye Centre-Toronto**. An open house was scheduled for February 23rd. The site is the third new development announced in 1997 by the company. Earlier it announced the acquisition of two Australian surgery centers. (See the February 13th brief in this issue.) It expects to open 14 new centers by year's end in Australia, Japan, Thailand, Taiwan, China, as well as several new sites in South America and two in North America.

2/22 The February issue of *Review of Ophthalmology* contains two interesting reviews by managing editor Kristine Morrill; "Which Excimer is Next?" and "Update on the `New' Refractive Lasers". The first article speculates that the PMA application for three laser systems could go to the FDA before the end of this year. The systems discussed are the **Chiron Vision/Technolas** Model 116, which uses a moveable iris and fixed laser beam, but which is no longer being produced, having been replaced with the Models 117 and 217C-LASIK; **Autonomous Technologies'** T-PRK scanning system; and the **Nidek** EC-5000 moving slit beam. The article also discusses the **Aesculap Meditec** MEL 60 system, also a moving slit beam machine, which is still in Phase 2B clinicals. (It is my understanding that Chiron intends to file for approval with its Model 116, and then obtain a supplemental approval, showing equivalency of effect, with its Models 117 and 217C-LASIK.)

The second article discusses the **Novatec** LightBlade semi-solid state laser; the **Escalon Medical** ISL picosecond laser (which originally was intended for intrastromal ablation, but now is under investigation as a microkeratome for cutting the flap, the first step in LASIK); and the erbium refractive laser under development by **IR Vision**, the new company founded by Bill Telfair, Paul Yoder, and Carston Becker. This laser is expected to sell for $150,000, well under the quoted prices for all the other

refractive systems. (For a more complete writeup about this latter company, see the October 1996 issue of *Medical Laser Report*. Or call me for a copy.)

2/24 **TLC The Laser Center** announced the signing of a letter of intent for the acquisition of **Vision Sources, Inc.**, a Houston, TX-based management and marketing services company, and provides consolidated purchasing capabilities to 76 independently-owned eye care practices in three states. The affiliated practices market their professional services under the Vision Sources name. Vision Sources, which receives a fee based on a percentage of its affiliates revenues, received over $1 million in 1996. In 1997, the company plans to increase its affiliate base to more than 200 practices throughout North America.

**OPHTHALMIC LASER UPDATE -- MARCH 1997**

2/24 I received Lynne Peterson's latest "Excimer Lasers" report, published by *Grassroots Research*. Lynne reported on her observations from the January 14th Ophthalmic Panel Meeting, at which **VISX** received its OK for astigmatic correction. Other highlights include that excimer laser sales have slowed, but should remain good through 1997; laser centers plan to open as many as 30 new sites in 1997 (for more on this, see the *Market Scope* brief later in this report); procedure volume continues to grow, with December surprisingly strong; astigmatism approval is likely to boost the number of **Summit** lasers swapped for VISX machines; and a growing number of used Summit lasers are being offered for sale, but with few buyers -- used VISX Star lasers are not available. (Anyone wanting a copy of this report should give me a call.)

2/25 **Sight Resource** announced that it had obtained a new $10 million credit facility from Creditanstalt Corporate Finance of CT, which will be used to refinance existing debt, finance future acquisitions, provide ongoing working capital, and for other general corporate purposes. Combined with the company's existing cash balance, it gives Sight Resource approximately $20 million in available capital and enables it to meet growth plans for 1997. The company now includes 72 eye care centers, ten laser vision correction centers, and a managed vision care program that services third party payor plans with approximately 850,000 enrollees. In an interview with *Dow Jones*, chairman Bill McLendon said that the company would report a profit for 1997, with sales growing more than 50% from 1996 levels. He also said that the company would meet analyst's estimates for sales of $28 million in 1996. (The company has recently been running advertisements in the ophthalmic magazines, offering some of its used excimer lasers from the UK for sale. I don't know how successful they have been in moving any of their lasers.)

2/27 **Laser Vision Centers** said that it had signed a Refractive Management Services Organization (RMSO) agreement with Lindstrom, Samuelson & Hardten Ophthalmology Associates of Minneapolis. Under the agreement, LaserVision purchased the refractive surgery assets of the practice and entered into a management services agreement with the principals. The agreement is the first contract under the

newly established RMSO program which is expected to help better position LaserVision for the anticipated entry of managed care into the refractive surgery market. The company said it now intends to begin the sales process of its initial target group of industry leaders.

2/28 **LCA-Vision** announced its fourth quarter results with revenues of $3.3 million, compared with revenues of $3.5 million for the same quarter last year, and a net loss of $1.4 million (8 cents/share). For the year, total revenues were $13.8 million, compared with $13.7 million a year ago, and the net loss was $4.1 million (21 cents/share). Dr. Stephen Joffe commented that as expected, substantial startup costs associated with opening of new centers impacted profitability in 1996, but the investment has made LCA-Vision a market leader, well positioned to benefit from the growing demand for laser eye surgery to correct nearsightedness. In 1996, there were 3737 laser vision correction procedures performed at LCA centers which opened during the course of the year. The company plans to grow its existing business during the first half of the year, but will continue to review opportunities to open new centers and make selective acquisitions during the second half of 1997. The company presently operates 17 centers in the U.S., Canada, and Finland.

2/28 **Hambricht & Quist** initiated coverage of the vision correction industry, issuing a report entitled, "Profits in Sight: An Overview and Assessment of Trends and Investment Opportunities in the Laser Vision Correction Industry", written by Michael Lachman. The report covers the refractive industry, including the **Keravision** ICR and the **Staar** implantable contact lens, with emphasis/profiles on **VISX** (a strong buy), **Summit Technology** (hold), and **Autonomous Technologies** (buy).

The author is quite conservative in his estimates for the number of lasers in place by 2000 (615 units) and the number of procedures that will be done annually (680,000 PRK/LASIKs), although he does admit that he might be on the conservative side. I have a copy of the 77 page report, and suggest if you want a copy, call Michael Lachman directly at 415-439-3128.

3/3 **LCA-Vision** said that it had engaged an investment banking firm to arrange a $12 million private placement of equity securities for the company. The proceeds will be used for future rollouts of new laser surgery centers and for general corporate purposes.

3/3 **Sterling Vision** announced that it had completed an $8 million financing, through a convertible debenture and warrant offering.

3/4 **LaserSight** said that it had reached agreement with **Intermountain Managed Eyecare** of Salt Lake City to add approximately 160,000 managed vision care lives. IME is a third party managed vision care administrator, which contracts with HMOs to manage vision care carveouts -- a business strategy comparable to that of **MEC Health Care**, a wholly-owned subsidiary of LaserSight. IME brings to LaserSight an established

network of eyecare providers including 48 ODs and 14 MDs located in 51 clinics throughout Utah. The addition of IME's lives brings LaserSight's managed care lives to approximately 750,000.

3/4 **Sight Resource** reported its fourth quarter and year-end results, with quarterly revenues of $8.6 million, an increase of 83% over the same quarter last year, and a net loss, before a non-recurring $2.6 million provision for fixed asset impairment (?) of $1.3 million (15 cents/share). The non-recurring provision brought the total net loss for the quarter to $3.9 million (45 cents/share). For the year, the company had revenues of $30.0 million, up 65%, and a net loss before the non-recurring provision of $3.2 million (44 cents/share). With the provision, the final net loss was $5.9 million (79 cents/share).

3/4 **Shooting Star** has signed a joint venture agreement with **Clinica Dr. Ricardo Guimaraes**, in Brazil, for the provision of refractive surgery services. This is the first international healthcare joint venture permitted under new Brazilian law which became effective on January 1st. The joint venture covers expansion into all the Mercosul territories, which includes Brazil, Argentina, Uruguay, and Paraguay, as well as Bolivia, Chile, and Columbia. A new company, **Gimbel Guimaraes Vision Centers S/C Ltda** will be formed, and will be 51% owned by Shooting Star's wholly-owned Brazilian subsidiary and 49% owned by Clinica Dr. Richard Guimaraes S/C Ltda. Effective May 1st, the new company will acquire the assets of the existing refractive practices at Clinica Dr. Richard Guimaraes in Belo Horizonte, Brazil. Shooting Star will pay Clinica by providing a Nidek excimer laser, USD $50,000 cash, and the balance in Shooting Star common shares. The number of shares will be determined on a number of factors, including the tax required for importing the laser and the final 1997 surgery procedure volumes performed at the Clinica.

3/5 **Sterling Vision** announced that it had entered into an agreement to acquire **Singer Specs**, a chain of approximately 30 retail optical stores, primarily located in PA, NJ, DE, and VA. Upon consummation of the deal on or about March 17th, Sterling will have approximately 350 locations.

3/6 **LCA-Vision** announced the opening of its 18th laser eye surgery facility, and the 15th in the U.S., with the opening on March 10th of a treatment center serving the Warren/Youngstown metropolitan area in northeastern Ohio. A group of 15 area MDs and ODs will be affiliated with the facility, the firm's sixth in Ohio. Dr. Stephen Joffe said that, "Our national rollout remains on schedule with the opening of this newest center. As planned, we expect to slow down the rate of new center openings for the balance of 1997, and focus on building the business and growing the company's existing facilities." LCA opened its first U.S. facility at the beginning of 1996, soon after FDA approval, and has performed approximately 4000 procedures at its various centers.

3/7 **LaserSight** said that it and **IBM** had successfully negotiated the terms of an escrow agreement pertaining to the purchase of certain IBM patents related to UV interaction with tissue, which was announced last month (see the brief of February 20). The signing of the escrow agreement is scheduled for March 10th.

3/11 **Sight Resource** announced it had formed a new division to accelerate development of its managed primary eye care business. The new division, called **SightCare**, will be dedicated to developing, packaging, marketing, and selling the company's fully integrated managed primary care programs. SightCare will first be introduced in the New England region, and then expanded into Ohio later this year. According to the company, more than 85 million Americans receive their health benefits through managed care and nearly 40 million of them receive some type of primary eye care benefits as part of their managed care plan. The trend towards managed care has had a direct affect on how primary eye care is delivered, and analysts estimate that managed eye care now has a 30% share of the U.S. eyewear market, compared to 20% just a few years ago.

3/12 The March issue of *Market Scope* contains David Harmon's forecast for the number of laser centers for 1997. David claims that their were 341 laser centers operating at the end of 1996, 38% of which were corporately operated. He believes that the corporate share will grow in 1997, with the opening of 138 new centers, of which 48 will be fixed centers, 60 will be mobile (from **Laser Vision Centers**), and 30 will be institutionally or surgeon owned. That will raise the corporate ownership percentage to nearly 50%. David details the corporate plans for opening new centers in his newsletter.

3/13 **Hawker Siddeley** announced that it would invest an additional $4 million in **Beacon Eye Institute**, subject to regulatory approval. In connection with the investment, Hawker Siddeley would receive 571,430 shares of common stock, raising its ownership from 38.1% to 42.85. The additional investment will strengthen Beacon's balance sheet. According to president Keith Moore, the company remains encouraged by the increasing number of procedures being booked by the five U.S. centers established during 1996 and the continued pace of about 250 procedures per month at its Toronto center.

Beacon also announced its year-end results, with revenues of $5 million and net losses of $24.5 million ($7.27/share). The net loss included $15.2 million of development expense for the year. The company has opened three additional centers so far this year, with another scheduled to begin operating this month (giving a total of ten).

3/14 **Laser Vision Centers** released its fiscal third quarter results (January 31st), with revenues increasing 136% to $2.0 million. Nine-month results showed revenues of $5.4 million, up 110% from revenues of $2.6 million for the same period last year. The net loss for the quarter was $2.3 million (26 cents/share), while the nine-month period showed a net loss of $6.8 million (83 cents/share). As previously announced,

the company has experienced a 32% increase in U.S. surgical case volume in the quarter, as compared to the previous quarter. Chairman Jack Klobnak said that he expects sales to continue to improve due to the company's strategy of redeploying lasers from underperforming locations, the anticipated FDA approval for astigmatism, and a rapid increase in the number of sites served by the company. Approximately 100 contracts with new sites are pending.

3/17 Dr. Fred Kremer announced that the FDA had accepted his PMA filing for the use of his homebuilt excimer laser for Laser-K, his name for LASIK, in treating nearsightedness and astigmatism. This is the first physician sponsored PMA. In his news release, Dr. Kremer noted that he "looked forward to making the treatment available to people nationwide". How he intends to do this with a homemade laser is beyond my comprehension! (It should be noted that **Chiron Vision** is also working on the clinical approval of LASIK with its C-LASIK 217 Technolas laser.)

3/17 **TLC The Laser Center** announced its affiliation with the University of Waterloo's School of Optometry, to jointly develop a facility to provide education and training in refractive surgery. The school's clinic, which has more than 25,000 patient visits each year, will be involved with pre- and post-procedure care along with clinical research in the area of refractive disorders and laser refractive surgery.

3/18 **LaserSight** reported its fourth quarter results with revenues of $6.4 million and a net loss of $764,000 (9 cents/share). For the year, revenues were $21.5 million, compared to $26.0 million in 1995, and a net loss of $4.1 million (56 cents/share), compared with net income of $4.6 million in 1995. LaserSight's Technology segment had 1996 revenues of $10.6 million, compared to $19.9 million last year, and the Health Care Services segment showed revenues of $10.9 million, compared to $6.1 million. Technology had an operating loss of $2.0 million compared to a profit of $4.7 million in 1995, while Health Care reported an operating loss of $468,000 in 1996 compared to an operating profit of $1.1 million in 1995.

Sales in the fourth quarter of $6.4 million were up from sales of $5.4 million in the third quarter, with Technology accounting for $1.6 million of the $1.9 million increase, with sales of 22 new excimer lasers compared to sales of 13 in the third quarter. The positive trend in system sales was partially offset by sales returns recognized in the fourth quarter. These returns were attributable to sales made prior to the company's credit and return policies now in place. Beginning in the second quarter of 1996, systems have not been sold with return rights. The fourth quarter returns reduced operating results by approximately $1.2 million, resulting in a consolidated operating loss of $801,000.

The company also announced that it was engaged in negotiations with **Foothill Capital** for a loan of up to $8 million, to be secured by substantially all of the company's presently unencumbered accounts receivable and other assets. In connection with the loan, the company expects to issue warrants to purchase a number

of common shares equal to approximately six percent of the shares presently outstanding. The company also noted that the escrow agreement associated with the patent agreement between it and **IBM** had been negotiated and executed. One million dollars in the company's common stock has been placed in escrow.

3/20 **Hawker Siddeley** announced that it had completed an investment of an additional $4.0 million in **BeaconEye**, operating as **Beacon Eye Institute**. (See the 3/13 brief above for more details.)

3/25 Randy Frey, chairman, president, and founder of **Autonomous Technologies** will be the opening day luncheon speaker at the National Small Business Innovation Research (SBIR) Conference to be held early next month in Orlando, FL. Frey led his company in winning three Phase II SBIR grants in programs for the development of laser radar (LADAR) used in military and space applications for pointing, tracking, and laser beam delivery for directed energy weapons. From this research, Frey created LADARVision technology, the basis for his company's advanced eye tracking system employed in his T-PRK excimer laser.

**OPHTHALMIC LASER UPDATE -- APRIL 1997**

3/26 In consultation with the Federal Trade Commission, a working group of five ophthalmic organizations, headed by the Academy of Ophthalmology, has developed guidelines for refractive surgery advertising. The working group, which began discussions in July 1996, includes ASCRS, the International Society of Refractive Surgery, the Outpatient Ophthalmic Surgical Society, and the Society for Excellence in EyeCare. Although the guidelines have not been formally endorsed by the FTC, the commission was consulted throughout the development process. The guidelines clarify the claims about safety, efficacy, predictability, success rates and permanence that can be made. A copy of the "Guidelines for Refractive Surgery Advertising" is available from the Academy's Fax-on-demand services at 908-935-2761, document #1210.

3/26 **Pillar Point Partners** announced that it had reached agreement to settle outstanding patent infringement litigation with **LaserSight, Inc.** In the settlement, PPP, **VISX**, and **Summit Technology** will grant LaserSight a release from liability for patent infringement claims arising before the effective date of the agreement. Subsequent to action brought by PPP, LaserSight moved its sales and manufacturing activities outside of the U.S. LaserSight has agreed to a nominal payment and to notify PPP before it begins manufacturing or selling laser systems in the United States.

3/27 **LaserSight** announced that its subsidiary **LaserSight Technologies** has submitted an IDE to the FDA to begin an expedited clinical study of its patented laser trabeculodissection (LTD) technique for glaucoma, using its scanning excimer laser. In contrast to conventional glaucoma laser surgery, in which a full-thickness hole is created through the trabecular meshwork, LaserSight's LTD method creates a deep

dissection through the sclera, leaving a very thin membrane separating the inside of the eye from the outside. This thin membrane allows fluid to drain from the eye relieving the pressure. LTD is self-limiting because the fluid that begins to drain out of the eye stops the laser from having a further effect on the eye. (**Summit Technology** was an advocate of a similar technique several years ago, to create a window in the sclera with its excimer laser for the relief of glaucoma pressure, but apparently abandoned the technique in favor of concentrating on the treatment of myopia.)

3/27 The annual report/10K season has begun. According to *Federal Filings*, **VISX** intends to launch a national consumer public relations effort as soon as it receives FDA approval for the treatment of astigmatism. The company intends to use the astigmatism PR effort to help establish the company's name, reputation, and "brand" of laser vision correction.

3/28 The same source also reported that **Autonomous Technologies** reported the filing of two separate patent-related lawsuits in October 1996, against **VISX** about noninfringement use of its T-PRK system in the UK, and by VISX against Autonomous' T-PRK systems use in Canada. In addition, Autonomous filed against **Pillar Point Partners** about noninfringement of PPP's U.S. patents (see our 10/25 brief in the October 1996 issue). Autonomous expects that it may incur legal costs up to $100,000 per month for the foreseeable future, depending upon timing of a resolution of the suits.

3/31 Fortuitously, **Autonomous** announced that it had entered into a patent license agreement with **VISX**, for the use of certain VISX patents for laser vision correction outside of the U.S., settling the lawsuits in Canada and the UK. The settlement grants Autonomous a non-exclusive worldwide license, excluding the U.S., for the use of VISX patents for UV laser vision correction, and encompasses payment of equipment royalties on a per-machine basis.

3/31 At the beginning of this month, I received several pages from **Vista Technologies** 10-Q for the quarter ending December 31, 1996, which contains several notes of interest. Note 11 on page 16 discusses the company's inability to obtain NASDAQ listing, which has altered the company's strategy of obtaining independent financing for its regional joint venture affiliates through proposed IPOs. "The primary reason for altering this strategy has been the unanticipated inability of two Regional Joint Ventures to obtain listing of their securities on the NASDAQ...primarily because of prior relationships between the company, on the one hand, and its former financial advisor, EC/American Ltd, and persons associated with EC/American, (or introduced to the company by EC/American), on the other hand." The note singles out a Mr. Jac J. Lam, a European consultant to various foreign investors introduced to the company by EC/American. Mr. Lam also served as a director of VLC-Michigan and the company, and was a former CEO of the company. VLC-Michigan filed an appeal to NASDAQ based in part on the complete termination of all relationships between the

company and VLC-Michigan and Mr. Lam and EC/American and its affiliates, except for continued ownership of the company's common stock by certain clients of Mr. Lam. (Who is this mysterious Mr. Lam?) That appeal was denied by NASDAQ in October 1996. Although no formal action was taken on the application filed by VLC-Pacific, counsel was informed by NASDAQ staff in November 1996, that VLC-Pacific would not be approved for listing for essentially the same reasons articulated by the review panel in denying the appeal filed by VLC-Michigan. As a result, the company does not believe it is practical for any regional joint venture associated with the company to plan on processing an IPO in the immediately foreseeable future.

In addition, the company's prior relationships with EC/American and Mr. Lam...may render it impractical for the company to seek a listing of its own securities on the NASDAQ within the near future. In this regard, the company notes that certain clients of Mr. Lam also own shares in **Atlantic Central Enterprises Ltd.** (the successor in interest to **Pharma Patch PLC**) which currently is the company's largest single shareholder. (Also see our brief of February 5th, last month, regarding Atlantic Central Enterprises and its controlling interest in **ICON Centers for Cosmetic Surgery**.)

3/31 **Shooting Star Technologies** announced its 1996 earnings, with revenues of $7.2 million, and net income of $0.6 million (3 cents/share). This compared to revenues and net earnings of $3.1 million and $5000 respectively for 1995 (only a nine-month period). Revenues were generated from the operation of four laser eye surgery centers and an ophthalmic equipment distribution company in 1996. The company expects to open fourteen new sites in 1997, with four locations open to date.

3/31 **Iridex Corporation** announced that it had secured a second source for a key semiconductor diode laser component for its new OcuLight GL product, the smallest and most portable green laser photocoagulator for treating eye disease. The new supplier is **Opto-Power**, a subsidiary of **Spectra Physics**. The agreement allows Iridex the use of a key patent from Spectra Physics, to allow the use of Opto-Power products in medical devices to be sold by Iridex. The component that is the heart of the agreement had inconsistent delivery in 1996, leading to the company's inability to build and ship the OcuLight product on a timely basis. Iridex hopes to begin utilizing the Opto-Power diodes during the second quarter of 1997.

3/31 **Sunrise Technologies** reported its fourth quarter and fiscal year results. For the quarter, the company had revenues of $1.3 million and a net loss of $1.9 million (7 cents/share). For the year, revenues were $5.7 million, compared with $5.3 million for 1995, and a net loss of $6.0 million (23 cents/share), compared to a loss of $4.1 million (28 cents/share) a year ago. The revenue increase was attributed to expanded sales of the company's dental abrasive device and dental laser system sales. (The dental business was sold to **Lares Research** in late March, which is expected to close within the next 30-45 days -- see the 3/26 brief in the medical/surgical section immediately following.) Revenues from its ophthalmic business were insignificant as

the company concentrated its limited resources on FDA clinical trials. In 1997 the company focus will continue to be on the ophthalmic clinical trials as well as on ophthalmic product positioning and sales and marketing activities outside of the U.S. The combined net proceeds of the sale of the dental division and the recently completed private placement, will enable the company to focus on its ophthalmic business and the goal of achieving U.S. marketing clearance in the next several years.

4/1 **Paradigm Medical Industries** announced that its operating revenues for the first quarter will be approximately $1.2 million. The revenue was generated from initial shipments of the company's Photon laser cataract removal system and its laser-ready Precisionist ThirtyThousand ultrasound technology. Both cataract removal systems were launched simultaneously in March, with a total of 19 systems shipped, the laser systems exported to international markets and the ultrasound system shipped domestically.

4/1 **Sterling Vision** reported its year-end results, with system-wide sales of $34.8 million for the quarter, and $131.6 million for the year, up from $26.8 million and $112.3 million respectively, from last year. The company reported a net loss for the three months and year of $3.7 million (30 cents/share) and $4.5 million (36 cents/share), compared to $2.6 million and net income of $767,000 respectively for 1995. The decrease in net income for the year was primarily due to operating losses relating to the acquisition of the stores acquired from **Benson Optical Company** and its affiliates in the fourth quarter of 1995, and the operations of the company's subsidiary, **Insight Laser Centers**, an increase in administrative costs related to store acquisitions, and certain non-recurring expenses. Company president Robert Greenberg expects that the Benson stores will be profitable in calendar year 1997, and Insight Laser Centers has reorganized operations which should reduce the losses previously experienced.

4/7 According to the April 7th issue of *Ocular Surgery News Intelligence Report*, **TLC The Laser Center** has entered into an agreement with **VISX** to trade five **Summit Technology** excimer lasers for VISX Star systems, at several of TLC's locations. The lasers were purchased under a trade-in offer announced by VISX.

4/7 **LaserSight Inc.** announced the closing of an $8 million credit facility with Foothill Capital Corporation, a commercial finance unit of Northwest Corporation. LaserSight was represented by A.G. Edwards in the transaction. The asset-based financing consists of a $4 million term loan with interest of 12.5% and a $4 million revolver at prime plus 1.5%. LaserSight has granted the lender five-year warrants to purchase 500,000 shares of stock, approximately 5.6% of shares outstanding, exercisable commencing on March 31, 1998 at a price of $6.0667 per share. A portion of the loan was used to pay the balance due on the purchase of **MEC Health Care**, a wholly owned subsidiary. The company continues to explore various alternatives to enable it to fund the purchase price of its agreement to obtain certain IBM patent rights on or before July 1, 1997.

4/7 David Harmon's April *MarketScope* newsletter reports that based on his survey of laser centers, the volume for the first quarter reached 42,300 procedures, up 4500 over last year's fourth quarter. (These numbers include procedures performed using both approved and unapproved machines, as well as procedures performed on Americans traveling to Canada for astigmatic and LASIK procedures.) Dave also reports that during the quarter several centers closed, some lasers sent to warehouses or re-deployed to new locations, and there are a surplus of used Summit lasers available with few takers. He believes that there were few new lasers added to the mix. (However, see the April 16th VISX brief below.)

4/8 Items gleaned from the **LaserSight** 10K: About 50% of the company's $21.5 million 1996 sales were by its Technology division, with 82% of those sales resulting from distributors and representatives, while 18% were direct sales; 58 laser systems were sold in 1996, compared to 65 in 1995, and 12 lasers were returned compared to one in 1995; approximately 145 lasers are currently in place worldwide. The two major legal events reported were the agreement to purchase the IBM UV-related patents and the announced settlement of litigation with Pillar Point Partners.

4/8 **Sterling Vision** continues its expansion mode, with the acquisition of **Singer Specs**, a chain of approximately 30 retail optical and eye care stores, located in Pennsylvania, New Jersey, Delaware, and Virginia. With completion of the transaction, the company has increased its holdings to 350 locations, giving Sterling a stronger presence in each of the above markets.

4/9-
4/10 **Laser Vision Centers** announced that it had completed a transaction for the financing of several of its **VISX** lasers, receiving approximately $1.5 million from Technology Finance Division of Transamerica Business Credit. The company can receive additional funding depending on agreed performance criteria. The company said it had agreements to serve 50 sites in 25 states and recent reports that it would open an additional 60 (mobile) sites within the next twelve months were "achievable". (See next brief.) According to chairman and CEO Jack Klobnak, March was the best month ever for surgical volume in the U.S., increasing 15% over February's volumes, the previous best month ever.

The next day, the company announced that it had received FDA approval for its MobilExcimer laser system, and it would begin deployment of the first mobile excimer within days. (The mobile excimer uses a VISX laser mounted on a specially-built truck body made by Calumet Coach of Chicago.) Klobnak noted that over 500 ophthalmologists had expressed interest in LaserVision's MobilExcimer program.

4/11 I received a copy of the February 10-16 *Wall Street Corporate Reporter*, which contains a profile of **LCA-Vision**, based on an interview with president Steve Joffe. Please give me a call if you are interested in a copy.

4/14 I also received a one-page profile of **Shooting Star Technologies** from that company. Give me a call if you want to see it.

4/16 **VISX** released its first quarter results and held an analyst teleconference to discuss them. For the quarter, laser sales were $10.1 million, royalties and service revenue was $5.6 million for total revenues of $15.7 million, down from the $18.9 million, of which $13.7 million was equipment sales, reported for last year's fourth quarter. For the quarter, the company showed a net profit of $2.7 million (17 cents/share). Royalty income was up $500,000 for the quarter. (According to my estimates, the company sold 20 systems, at an announced average price of $440,000, into the U.S. market during the quarter, and approximately 7 systems, including some Model B's, priced at about $260,000, internationally.) The company said that it had an installed base of 150 domestic lasers, and 220 internationally. Mark Logan, CEO, is still looking for about 200,000 procedures for 1997, even though, according to one analyst's count, Pillar Point had only about 30,000 procedures during the quarter. (I believe, along with Dave Harmon, that between 42,000 - 44,000 procedures were done in the quarter -- including some 8500 "black" or "gray box" procedures.) Logan also claims that for the first time, more procedures were done on VISX machines during the quarter, than on Summit machines.

4/17 **Sight Resource** announced that its laser center at Massachusetts Eye and Ear Infirmary in Boston had performed its 1000th procedure.

4/17 **Sterling Vision** said that its **Insight Total Managed Care** division had finalized an agreement with **National Preferred Provider Network**, the nations' largest provider-based network, to become its exclusive optical provider for NPPN's 4.6 million members. Sterling will organize and administer a closed panel of providers, including all Sterling stores, which will offer optometric and opticianary service in locations selected by Sterling to provide the covered vision programs. NPPN services many major U.S. companies and several governmental agencies. It is associated with over 3200 hospitals and 37,000 ancillary facilities, as well as 330,000 participating doctor sites.

4/17 **TLC The Laser Center** reported its fiscal quarterly results for the period ending February 28th. Gross revenues more than doubled to $10.2 million from the same period a year ago, with the growth primarily coming from an increase in the number of refractive laser procedures performed. TLC performed over 2200 procedures in its third quarter, representing a 225% increase from that same quarter a year ago, and a 105 increase from the last quarter, ending November 30th. The growth in procedures does not include those performed by recently acquired **20/20 Laser Centers**. The third quarter financials do include 18 days of operations of the 20/20 Laser Centers, which was acquired on February 10th. The nine clinics on the U.S. eastern seaboard performed 1326 procedures during the third quarter.

For the quarter, the company had a net loss of $3.5 million (16 cents/share), versus $0.7 million (6 cents/share) a year ago. The increase in net loss reflects the cost

associated with TLC's rapid expansion in the U.S. market, where most of TLC's centers have been open for less than six months. Traditionally, it takes about 18 months for a TLC laser center to show a profit. The loss reflects only $0.9 in operating costs, as there was $1.6 million in development and startup costs, and $1.0 million amortization. The company now has 34 clinics and 9 network centers operating in 24 states and 3 Canadian provinces.

4/17 **Laser Vision Centers** said that it had completed its first refractive laser treatments on Monday April 14th in the United States on its MobilExcimer system. The procedures were performed by LaserVision Medical Director Dr. Richard Lindstrom and Dr. David Hardten at the Phillips Eye Institute in Minneapolis. According to Dr. Lindstrom, the procedures went very well, with the environment comfortable for both the surgeon and the patient, and no difference between performing cases in the MobilExcimer and any other surgery center. According to company officials, prior to approval (April 7th), more than 500 ophthalmic surgeons had expressed an interest in accessing the MobilExcimer. Since approval, the company has received numerous calls inquiring about the service. Jack Klobnak, chairman and CEO said that the company would be announcing very shortly which region of the country will be receiving the first unit. In a prior announcement -- see above -- Klobnak had said that up to 60 MobilExcimers might be deployed.

4/17 **Iridex** announced its first quarter results with revenues of $3.3 million. Net income was $185,000 (3 cents/share). Shipments for the quarter continued to be adversely impacted by the shortage of diodes for the OcuLight GL. The reduced level of shipments, combined with a larger than planned percentage of international sales, caused a reduction of gross margins. Diode deliveries from the company's primary source improved toward the end of the quarter. Projected deliveries for the second quarter, along with expected deliveries from its new second source, should meet requirements for this quarter. In addition, the company has received approval for its new DioLite 532 dermatologic laser for the treatment of vascular and pigmented lesions, and is expected to begin shipping these lasers during its third quarter.

4/19 **VISX** announced that it was offering a custom VisionKey Card to international customers that would allow those refractive surgeons the flexibility to define and perform multiple pass corneal ablations with a single card. In addition to standard PRK procedures, the custom keycard includes laser only plano/spherical epithelium removal, custom multipass/multizone, including variable treatment diameters, and variable diameter hyperopia treatments. The cost is the same as previous key cards.

4/22 **Autonomous Technologies** announced its first quarter results, with an operating loss of $2.7 million resulting in a net loss for the quarter of $2.6 million (38 cents/share), compared to a loss of $1.4 million a year ago. The major increase occurred in clinical trial expenses, which jumped to $589,300, compared to only $195,300 for the same quarter last year.

4/23 **Paradigm Medical Industries** announced that it had signed an agreement with **Surgidev Corporation** to act as a general distributor for the latter's intra-ocular lenses (IOLs) in the U.S. ophthalmic market. With the recently launched Precisionist ThirtyThousand cataract removal system, as well as the OmniPak and PhacoPak accessory packs, the sale of IOLs will broaden the company's line of products for ambulatory surgical centers and hospitals that are used in cataract procedures. When its laser cataract system is approved, it will have a full line of products to offer the cataract removal surgeon.

4/24 **Summit Technology** announced that it had received both CE certification and ISO 9001/EN 46001 registration for its laser products manufactured in its Cork Ireland plant.

4/24 **LaserSight** said that it expects to report a significant reduction in its loss for the first quarter of 1997, compared to the first quarter of 1996, along with a positive trend of consecutive quarterly improvements in turning around its technology segment while reporting further membership and revenue growth with existing contracts in its managed vision care segment. LaserSight estimates it will report a loss of between $550,000 to $700,000 (6 to 8 cents/share) on revenues of approximately $6.5 million. In addition to favorable prior year comparisons, quarter to quarter comparisons, beginning with last year's third quarter are also favorable, with revenues increasing while maintaining gross profit margins. Michael Farris, president and CEO reported that the company sold 15 laser systems with no returns in the first quarter. If they had sold 20 systems, the company would have shown a profit. Further, the company will be debuting a new laser model at this week's ASCRS meeting in Boston, its LaserScan LSX, with a unique ceramic laser head which doubles the repetition rate to 200 Hz (speeding up the PRK process). Farris also noted that the company may be in position to submit a PMA for PRK and PARK (astigmatic correction) late this year or in the first quarter of next year.

4/25 **VISX** announced that it had received approval to treat low to moderate myopia with astigmatism. Based on international experience, nearly two-thirds of patients receiving treatment for myopia also obtain treatment for astigmatism. VISX will now focus its attention on consumer education and to make the VISX name synonymous with laser vision correction. The company also plans to initiate a training program to certify current laser users for the treatment of astigmatism, and to begin distributing VisionKey cards for astigmatism treatment immediately.

In an allied release, **Laser Vision Centers** said that the approval to treat astigmatism would have a positive impact for the laser vision correction market, and on LVC. The company noted that 80% of its lasers are VISX systems, capable of treating astigmatism with no hardware modification, and that all of its MobileExcimer systems employ VISX lasers. Jack Klobnak, chairman and CEO, noted that the company has agreements to serve 60 sites in 25 states, and expected that number to increase. A recent analyst's estimate of 60 new LVC centers this year is achievable.

4/25 **Premier Laser Systems** announced a definitive agreement to acquire Houston-based **EyeSys Technologies**, a privately held developer and supplier of corneal topography systems, with an installed base of over 3500 systems worldwide. EyeSys provides Premier with a well-recognized name and international distribution channels with a global presence to market Premier's current ophthalmic products as well as those to be released later this year. According to Premier chairman, president, and CEO Colette Cozean, the transaction is being accounted for as a purchase in exchange for $10.6 million being paid entirely in Premier common stock, subject to certain restrictions. Premier will also exchange 165,000 options, at fair market value, with employees and holders of options and warrants of EyeSys. Closing is anticipated by June 30th. EyeSys will operate as a wholly-owned subsidiary and will continue to do business under the EyeSys brand name. For the most recent 12 month period ended December 31st, EyeSys had revenues of approximately $8.1 million.

**OPHTHALMIC LASER UPDATE -- MAY 1997**

4/25 **Summit Technology** announced that it had submitted its PMA to treat astigmatism to the FDA, for its Apex Plus laser system utilizing the erodible laser disk. In markets outside the U.S., Summit has installed over 90 Apex Plus laser systems over the past two years.

4/26 **TrueVision Laser Centers** announced an aggressive nationwide expansion, with the intent of positioning the company among the top five laser vision correction companies in the U.S. The company currently operates centers in Albuquerque, NM and Honolulu, HI, and plans to add at least five new centers to its portfolio in the near future. TrueVision recently completed a $2 million media financing program with First Capital Investments, which will be used specifically for national and local advertising campaigns. It has also entered into a four-phase $3.2 million financing agreement with Brookstreet Securities Corporation. The financing agreement will facilitate the acquisition or development of at least 30 additional laser centers over the next two years. According to the company, it has identified its first round of acquisitions and will develop or acquire at least 15 more locations by year's end. (You may recall that this company had plans to develop a mobile excimer that were announced at last year's AAO meeting. In speaking to a spokesperson for TruVision, I learned that that plan has been put on the back burner in favor of fixed site development.)

4/28 **Autonomous Technologies** announced the completion of the minimum patient enrollment for its Phase 3 clinical study for the correction of low to moderate myopia (up to 10 diopters) with up to 6 diopters of astigmatism. The PMA application to the FDA is expected to be submitted later this year.

4/28 **Laser Vision Centers** hosted a teleconference call to discuss the recent FDA approval of astigmatism correction for **VISX**, the impact of the company's MobilExcimer program, and the development of the U.S. excimer laser market. According to

company chairman Jack Klobnak, all three events indicate positive growth of the industry. For LVC, case volumes continue to increase month to month, with the latest results indicating a 15% increase. The approval of the MobilExcimer has spurned great interest, with over 100 pending agreements and 600 leads in the first two days of the ASCRS meeting. And the approval for treating astigmatism should lead to further increases in case volume. One interesting development occurring within the LVC centers is the increase in LASIK procedures over PRK. According to Dr. Dick Lindstrom, medical director for LVC, more LASIK procedures than PRKs are now being done. This was verified by John Stiles of the company, who told me that during March and April, more than 60% of the procedures being done within LVC centers in the U.S. were LASIKs. (I estimate that about 15% of the total refractive procedures done in 1996 were LASIKs. If the percentage of LASIKs reported by LVC holds up for other centers, the overall percentage of LASIKs could reach about 40% nationwide in 1997!)

4/28 **Premier Laser Systems** continued making news, announcing that **EyeSys Technologies**, slated to become a Premier subsidiary by June 30th, had entered into a nationwide distribution agreement with **Marco Technologies**, a leading ophthalmic instrument distribution company. EyeSys has already received an initial product order from Marco valued at $480,000, as well as an upfront licensing royalty fee. Under terms of the agreement, EyeSys will provide Marco its corneal topography systems, composed of both hardware and software, as well as other technology innovations as they are cleared for marketing. Several of Marco's products are manufactured for it by Japan-based **Nidek**, a major ophthalmic equipment manufacturer, and according to the May 5th issue of *Ocular Surgery News Intelligence Report*, Nidek will participate in the marketing and sales alliance, although the company has yet to spell out the details.

4/29 **Summit Technology** announced its first quarter results showing revenues of $20.7 million, compared to $25.2 million for the first quarter a year ago. The net loss for the quarter was $1.4 million (5 cents/share). The financial results include revenues for Lens Express, which average about $12.5 million per quarter. Summit's revenues from equipment and royalties were about $8.2 million versus about $12.7 for last year's first quarter, but up from the estimated $5.4 million for the fourth quarter. No breakout of Pillar Point revenues or number of procedures for the quarter were shown in the results.

4/30 **Sight Resource** released its first quarter results with revenues of $10.4 million, an increase of 82% over last year's first quarter, and a net loss of $387,000 (4 cents/share), down from a loss of $648,000 from last year. The company expects to be profitable before the end of the year.

4/30 **LaserSight** said it had received excellent response from its introduction of the newest version of its LaserScan system, the model LSX. The new model operates at 200 Hz, up from 100 Hz for the previous model, has an active tracking system, and improved reliability with its ceramic laser head. According to president Michael Farris, the

company plans to submit its PMA for approval of the LaserScan 2000 in the fourth quarter of this year, or early in 1998. This would be followed by a supplemental PMA to allow marketing of the model LSX in the U.S. The company is scheduled to begin shipments of the LSX on a limited basis in the third quarter of 1997, following completion of field evaluation. The LaserScan 2000 will remain part of the line as a moderately priced product when the higher-priced LSX model is introduced.

5/2 **Sight Resource** announced that it Board of Directors had adopted a shareholder's rights plan to assure that all shareholders would receive fair and equal treatment in the event of an unsolicited attempt to acquire the company. According to the May 12th *Ocular Surgery News Intelligence Report*, the move was in response to the company's low stock price and not because of any current takeover attempt.

5/2 **Medjet Inc.** announced that the FDA is processing its 510(k) application for its HydroBrush Keratome for removal of the epithelium as the first step in PRK. Use of the HydroBrush is claimed to be substantially quicker than currently used scraping techniques. The HydroBrush utilizes a hair-thin high speed water jet beam, activated by compressed gas.

5/6 The May issue of *Refractive Market Perspectives*, from **Market Scope**, contains an interesting table showing the "large center company" financing deals. It indicates that **TrueVision Laser Centers** has received the largest amount of money, some $37 million, followed by both **TLC The Laser Center** and **BeaconEye** with $18.3 and $18.0 million (last June) respectively, **LaserVision Centers** with $14.1 million, and **BeaconEye**, again, with another $8.6 million back in December. The same issue also has a good writeup of the recent ASCRS meeting, for those of you who weren't there, and an interesting set of charts showing quarterly revenues and earnings for half-a-dozen players. (The only company of those listed showing net earnings was **VISX**!)

5/8 **LaserSight** announced its first quarter results with revenues of $6.5 million and a net loss of $648,000 (7 cents/share). The revenues were a 41% increase over last year's first quarter. The Technology segment reported revenues of $3.5 million, representing the sale of 15 laser systems with no returns, compared to 10 sales last year with 3 returns. The company also reported that cash used in operating activities was $26,000, compared to $1.8 million during last year's first quarter.

5/8 **Shooting Star** announced that it had signed a letter of engagement for a special warrants private placement and secondary offering to provide gross proceeds of not less than $2.8 million. The transaction will serve the dual purpose of increasing the size of the company's public float by 3.75 million shares and providing funds for expansion.

5/12 *Ocular Surgery News Intelligence Report* provided some additional information about the closing of **Global Vision**, first reported in last month's newsletter. According to Louis Catania, OD and vice president of professional services, the company simply

ran out of money at a time when its optometric referral program was starting to provide substantial leads. Global's panel of doctors included more than 400 optometrists and 200 ophthalmologists.

5/12 *EyeWorld Week* contains two interesting items. Apparently some unidentified "corporate entity" is suspected of reprogramming **VISX** keycards in Bermuda, with some U.S. vision centers and physicians reportedly sending batches of card to the "entity" for reprogramming. Since the keycards are part of a regulated device, they fall into a legal "gray" area, concerning practice of medicine issues. VISX claims to not be involved in the operation.

In the second item, the FDA has issued a warning letter to **Photon Data** for apparently distributing its excimer lasers in the U.S. and overseas without an approval. Apparently JT Lin is attempting to take over an IDE granted to Dr. Mark Kislinger in Pasadena, CA, and somehow apply the custom laser IDE to others to whom he has sold lasers. At least four PDI lasers shipped internationally are either being returned or put on hold awaiting appropriate approvals for export, according to Dr. Lin's response letter. (I downloaded a copy of both the warning letter and Dr. Lin's response. Call me if you would like to see them.

5/12 The latest clinical results on the use of **QLT PhotoTherapeutics'** benzoporphyrin derivative (BPD-MA) in the treatment of age-related macular degeneration were presented at the annual ARVO meeting in Ft. Lauderdale. The treatment is being co-developed with **Ciba Vision Corporation**. Results of the Phase 1/2 clinical trials show that BPD-MA can selectively close abnormal leaking blood vessels without causing the vision loss associated with currently-available treatments. The two-step PDT treatment consists of intravenously injecting the drug, which is preferentially absorbed in the abnormal blood vessels, and then activating the drug with a non-thermal laser, which then causes occlusion of the abnormal vessels. A multi-center Phase 3 trial investigating BPD-MA is underway at 22 sites throughout Canada, the U.S., and Europe.

A second presentation showed that AMD patients can be re-treated with BPD-MA and the therapeutic benefit may be repeated and often improved. The study showed that either two or three treatments suggested that the area of leakage was reduced without any negative impact or vision loss.

5/14 **VISX** announced that it had signed a two-year contract with the Department of Veteran Affairs which will allow different branches of the U.S. military to purchase VISX excimer laser systems. The U.S. Air Force has purchased the first laser under this contract, which will be installed a the Lackland Air Force Base in San Antonio, TX. In 1996, the U.S. Navy was the first branch of the military to purchase a VISX excimer laser, which was installed at the Navy Medical Center in San Diego.

At present, active duty personnel and prospective military pilots are prohibited from selecting incisional surgeries for refractive correction. If the two year military study shows stable visual acuity within the 20/40 or better range, pilots and special forces personnel in all branches of the service may no longer be excluded from choosing laser vision correction to correct common visual disorders. Commercial pilots are eligible for PRK/LASIK.

5/14 **LCA-Vision** reported its first quarter results, showing total revenues of $2.8 million, compared with $3.7 million for the same quarter last year. The net loss during the quarter was $1.8 million (9 cents/share), compared with $524,000 last year. The prior year's loss was reduced by a $546,000 gain from the sale of an investment. Commenting on the results, Dr. Stephen Joffe, CEO, said that as anticipated, cost reduction programs instituted by health care providers impacted negatively on LCA's maturing, hospital-based, multi-specialty laser surgery management programs, resulting in a decreasing number of facilities under contract. In addition, the substantial start-up costs associated with the opening of new laser eye surgery centers, affected profitability during the quarter. However, the number of procedures performed in the centers opened a full year increased by 190 percent. In addition, the number of procedures performed since the year-end has increased by 34 percent. "Looking ahead," Dr. Joffe said, "we will concentrate on growing our existing business. This should reduce expenses involved in rolling out new centers as we build a strong base for future profitable growth. We will continue to review opportunities to open new centers and make selective acquisitions during the latter part of 1997."

5/15 In a press release from **Sunrise Technologies**, the company reported on Dr. Douglas Koch's presentation at the ASCRS meeting in Boston about the three year results from the Sunrise LTK clinical trials. According to Dr. Koch, the FDA trial results show that the non-contact LTK approach for hyperopia provides patients with good results and negligible regression over three years. Donald Sanders, MD noted that the recent data utilizing new monograms and treatment parameters also look excellent. The next phase of the clinical trial will hopefully include treatments for patients with presbyopia, patients overcorrected in PRK, and patients who want their second eye treated because of satisfaction with their original treatment for hyperopia, according to a spokesperson for the company. Sunrise has also been given approval to add three new clinical sites, bringing the total to eight.

5/16 **Paradigm Medical Industries** reported its first quarter results, with net sales of $873,800 and an operating loss of $106,700 and a net loss of $82,700 (2 cents/share). This compares with sales of only $23,200 in last year's first quarter. The dramatic improvement in performance is the result of the launch of the Precisionist ThirtyThousand and Photon Ocular Surgery System cataract removal systems, as well as the disposable accessory packs that accompany them. Production of 19 phaco units was completed, but only 13 were shipped in the first quarter. The remainder will be shipped during the second quarter. The company expects to achieve similar sales

results for the second quarter, and than anticipates increasing production steadily through the second half of the year.

5/16 **Sterling Vision** reported its first quarter financials with systemwide revenues of $36.7 million, up from $30.9 million for the same period last year. Net income for the quarter was $326,000 (2 cents/share), double the amount from last year's first quarter. Robert Greenberg, CEO, believes that the first quarter results puts the company on track for the remainder of the year.

5/16 **Laser Vision Centers** announced that it had reached agreements to serve ten additional sites in the U.S. With the new agreement, the company now has agreements to serve 70 sites in 28 states, and expects to serve over 100 sites by year's end.

5/19 *EyeWorld Week* identified the company in Bermuda which was "enhancing" the capabilities of the **VISX** keycards, sent to it by companies and physicians within the U.S. The company is **Technological Health Care Products**. THCP believes that its service does not violate any U.S. or Bermuda laws, since it does not market its service directly, and only obtains keycards for changing into the international program by word of mouth. As of the date of contact, the FDA had not been in touch with company officials.

5/21 **PDT, Inc.** reported at its annual meeting, that it was seeing favorable interim results in its clinical studies to treat advanced age-related macular degeneration using Purlytin PDT. In a presentation to shareholders, Edgar Thomas, MD of Retina Vitreous Associates, and a clinical investigator for the Phase 1/2 study, stated that he has seen a dramatic initial improvement in vision in patients he has treated. Gary Kledzik, chairman and CEO recapped the company's achievements for the year, including advances with its new PDT drug, BNZ203 in preclinical studies, expanding PDT research facilities, increasing manufacturing capacity for both pharmaceuticals and light devices, and new drug and device patents.

5/23 **Shooting Star Technologies** annual report notes the company's expansion plans for 1997. Believing that the U.S. market is quickly becoming saturated, Shooting Star will only consider expansion there under unusual circumstances, such as partnerships with well respected ophthalmologists who currently operate high volume refractive practices. However, the company continues its expansion plans with the addition of fourteen new sites before the end of this year. By the end of May, six new sites were either developed or under construction. The new sites are located primarily in the Asia Pacific and South American regions. The company operates one U.S. site in Las Vegas.

**OPHTHALMIC LASER UPDATE -- JUNE 1997**

5/28 **VISX** announced that it had entered into a patent license agreement with **LaserSight** for the use of certain VISX patents for laser vision correction outside of the United

States. The agreement will settle the outstanding lawsuit between the parties in Canada. In return for the license, LaserSight has agreed to pay royalties to VISX on the past and future sales of its excimer lasers worldwide, excluding the U.S. LaserSight joins **Aesculap Meditec**, **Chiron Vision**, **Schwind**, and **Autonomous Technologies**, in licensing the VISX patents for use outside of the U.S.

5/28 **Shooting Star Technologies** announced the results for the three month period ending March 31st. Revenues were $2.9 million, up 124% from the same period a year ago, while net income before taxes was $466,200, up 421%. Net income after taxes was $121,200. The company plans to open 14 new centers for eye surgery in 1997, with six sites already added. Funds for expansion will be sought from a special warrants financing and a secondary offering, which are expected to raise an additional $2.8 million.

6/2 This week's issue of *Newsweek* contains an overview of PRK and LASIK vs. RK. Author Brad Stone got a good grasp of the differences between the procedures and provided a positive view of refractive surgery. The only error in the story, in my opinion, was his high estimate of $1700 for optometric referrals.

6/2 This month's issue of *Refractive Market Prospectives* from **Market Scope** notes that **Chiron Vision** was assigned the rights to a Gholem Peyman June 1989 U.S. Patent, 4,840,175, which describes a method for modifying corneal curvature via a process similar to LASIK. The patent discusses a method of removing a thin layer of the cornea and exposing the internal surface to excimer laser energy and replacing the thin layer of corneal tissue. According to Market Scope, Chiron has been very quiet about their patent rights to date, but with LASIK becoming more popular -- accounting for 50% of all laser refractive procedures, according to David Harmon of Market Scope -- will Chiron attempt to cash in ala Pillar Point? The company could add a royalty fee to their charge for disposable blades for their microkeratome (and could go after the other companies selling microkeratomes on the same basis!). Anyone wanting a copy of the Peyman patent can either access the IBM.com/patents web site for a copy of the abstract and claims, or call me.

The newsletter also contains an interesting chart illustrating the number of surgery centers by the volume of procedures they perform. As of March 1997, Harmon claims that 28 surgery centers were performing more than 100 procedures per month, up from only 10 last October. He also said that there are 70 centers doing between 50 and 100 procedures, and about 230 doing less than 50 procedures per month. The total number of centers being tracked has risen to 328 from 295.

Market Scope also reports that Phase III clinical studies are underway for treating hyperopia with the **VISX** Star laser. (I have seen notices from about half a dozen laser centers seeking patients to participate in the clinical study -- see a typical notice for **LCA-Vision** shown below in the 6/6 brief.) Harmon notes that whereas the astigmatism upgrade only involved a software change (in the keycard), the hyperopia

platform requires a significant hardware upgrade. According to Market Scope, the word on the street is that the upgrade will cost $50,000 when it becomes available.

6/3 Another class action suit was filed against **Summit Technology**, this time by options trader William Myers of Philadelphia, for all persons who purchased Summit call options or sold Summit put options during the period March 31, 1995 through July 3, 1996.

6/4 **LCA-Vision** announced that its fastest growing U.S. facility, in Baltimore, had performed its 1000th laser refractive procedure. Opened a little over one year ago, the center is one of 18 facilities currently operated by LCA in the U.S., Canada, and Europe. The average fee at LCA-Vision centers is $2250 per eye.

6/5 According to *Dow Jones* **VISX** and **Summit Technology** are engaged in court-mandated settlement talks regarding the patent infringement lawsuit between them. According to VISX CEO Mark Logan, the talks could result in a wide-ranging settlement of all the patent disputes between the two companies. The court-mandated talks concern the dispute over the Azema patent, that Summit acquired from **Synthelabo**, and which VISX turned down when Summit offered to put it into the **Pillar Point Partners** package of patents. If the two companies fail to reach a settlement, the matter is scheduled to go to trial in July.

6/6 The **Albany LCA-Vision** refractive surgery center is one of eight sites advertising for patients to take part in the **VISX** clinical trial for treating hyperopia. According to the news release put together by VISX, approximately 60% of the American population is farsighted. Results from the international use of the VISX Star laser in the treatment of hyperopia have been excellent. In a study conducted last year at the University of Ottawa Eye Institute, 96% of patients treated attained 20/40 or better. (The other seven refractive surgery centers participating in the hyperopic clinical trial are: the **Mountain View LCA Laser Vision Center** in Mountain View, CA; the **Wilmer Eye Institute**, Lutherville, MD; **Cornea Consultants** in Boston; the **Kraff Eye Institute** in Chicago; **Cedars-Sinai Medical Center** in Los Angeles; **Columbia Presbyterian Medical Center**, New York; and the **Zale Lipshy University Hospital** at the **University of Texas Southwestern Medical Center at Dallas**.

6/6 *Dow Jones* noted that the Federal Trade Commission had cleared the **LaserSight-IBM** transaction (acquisition of certain IBM patents related to the use of UV lasers for treating tissue by LaserSight from IBM -- see the February 1997 issue of the briefing). The companies were granted early termination of the waiting period under the Hart-Scott-Rodino Act. The Act requires companies to notify the FTC if they intend to acquire a minimum of 15% of a company's outstanding shares, or assets or stocks valued at a minimum of $15 million. (That means that the LaserSight-IBM transaction is valued at $15 million or greater.)

6/6 **BeaconEye Inc.** announced that it had entered into a special warrant transaction with **Yorkton Securities**. Beacon will issue 2.25 million special warrants, priced at $3.75 each, for gross proceeds of $8.4 million. The warrants will be exercisable for units of the company, which consist of one common share and one-half of a common share warrant. Each whole warrant will entitle the holder to acquire one common share at a price of $4.65 for a period of 18 months from the closing date. The private placement is scheduled to close on June 20th. Beacon currently operates 10 centers, with revenue increasing by greater than 40% per quarter over the past four quarters, due to the increasing number of laser PRK being preformed in its U.S. based centers, while its Toronto center continues to perform more than 200 procedures per month.

6/9 **Sunrise Technologies International** announced its results for the first quarter with a net loss of $2.4 million (9 cents/share) on revenues of $1.0 million, down from revenues of $1.5 million a year ago. The loss was up from $1.4 million in last year's first quarter, and was the result of a non-cash interest expense of $812,000, recorded in connection with the issuance of the redeemable convertible notes in February and March. There was also a decrease in demand for the company's dental products, in part, because of the uncertainty surrounding the sale of its dental division, still awaiting closure, which will be the subject of a special stockholder's meeting on June 24th. The company intends to concentrate its efforts on the ophthalmic LTK clinical trials and the sale of its holmium LTK system outside of the U.S.

6/9 According to this week's issue of *EyeWorld Week*, a clinical trial of the **Kera Technology's** IsoBeam D200 laser is set to begin this month in Taiwan. According to the company, the laser, which uses twin flying spots to provide "fractal ablation", i.e., curved layer ablation, will be tied into a corneal topographic system to aid in the correction of irregular astigmatism.

6/9-
6/11 In one of the strangest stories that I have written about in the last few years, the saga of JT Lin, **Photon Data**, and the FDA, ranks amongst the best. As I reported last month, Photon Data received a warning letter from the FDA for allegedly distributing its excimer lasers in the U.S. and overseas without the appropriate documentation. According to Dr. Lin's response letter to the FDA, at least four PDI lasers shipped internationally were either being returned or put on hold awaiting appropriate approvals for export. Also, PDI was attempting to take over an IDE granted to Dr. Mark Kislinger in Pasadena, CA which, somehow, would allow PDI to ship "custom" lasers to others under the IDE.

On June 9th, the FDA issued a Talk Paper in which it said that it had authorized the seizure of PDI's unapproved lasers, and had requested U.S. Marshals to seize the lasers. The paper went on to say that at least 9 excimer lasers and components, valued at approximately $3 million were seized at two Photon Data locations and at a private freight forwarder used by the company. This news was picked up by the *AP* the same day, and by *The Washington Post* and *The Wall Street Journal* the following day.

However, in a strange twist to the story, *Medical Industry Today*, a daily faxed newsletter published by **Medical Data International** reported that in an interview with Dr. Lin, no seizures had occurred! Dr. Lin confirmed that agents had appeared at his company, but that U.S. Marshals did not seize any equipment. According to Lin, "They did not take anything out of the building...there were some inspectors here, but the systems we are developing are not in use, they are just for product testing."

Since there was so much inconsistency in the above story, I attempted to contact both the FDA and Dr. Lin to find out what really happened. A spokesperson for the FDA told me that the lasers were removed, and that they now resided in the hands of the Court! Dr. Lin has yet to respond.

6/11 And the numbers keep growing! **VISX** sent out a congratulations notice marking the fact that 15 refractive surgery centers using its lasers had hit the 1000th procedure mark. According to the release, three **ClearVision Laser Centers**; two **Horizon Vision Centers**; the **Kraff Eye Institute**; the **Laser Eye Center of the Silicon Valley**; **The Phillips Eye Center/a Laser Vision Center**; a **LaserVue Eye Center**; the **LCA Greater Baltimore Vision Laser Center**; the **Mericos Eye Institute at Scripps Memorial Hospital**; the **Saddleback Eye Center**; and three **TLC-The Laser Centers** all reached the 1000 procedure milestone, many in less than one year.

In an allied notice, **LCA-Vision** announced that one of its 400 affiliated ophthalmologists, Dr. James Sanitato, at the **Cincinnati Laser Vision Center** would perform the 10,000th procedure completed at the company's facilities later this day, claiming that its 18 centers are pacing the industry in volume and experience.

6/11 **Laser Vision Centers** announced that it had formed a strategic alliance with the **University of Missouri-St. Louis School of Optometry**. The agreement provides access for UM-St. Louis facilities and staff, and for classes for students and continuing education programs for alumni, to Laser Vision Centers facilities and personnel. Researchers at the school will also have access to laser equipment. According to LVC CEO Jack Klobnak, "Certain facility members of UM-St. Louis have been pioneers in developing the co-management process between optometry and ophthalmology...we feel this relationship is very important in including optometry in this exciting new technology."

6/12 **VISX** announced that weaker than anticipated demand for its excimer lasers in the U.S. is expected to cause revenue and net income levels to fall below the company's expectations for the second quarter and year. With the approval of astigmatism correction in April, the company expected an increase in demand for its laser systems over the first quarter levels. However, while laser correction procedure volumes continue to increase, the demand for the company's lasers has not. The company expects unit shipments of laser systems in the U.S. for the remainder of the year to remain in line with first quarter shipments. (I estimate the company sold/shipped about 20 laser systems in the first quarter.) Company CEO Mark Logan also attributed

the lack of increase in sales to the continuing sales of non-approved laser systems in the U.S., taking note of the FDA seizure action against **Photon Data** as a positive sign of improvement in that area. He also noted that procedure volume has increased strongly in 1997, significantly improving utilization of existing systems. (The announcement of weaker sales caused a 21% drop in VISX's stock price according to the next day's issue of *The Wall Street Journal*.)

(I am estimating that the more than 400 approved laser systems in place are performing between 30 and 45 procedures per month. This means that industry is in line to perform nearly 200,000 procedures this year. With the 100 or so un-approved systems, also performing close to 45 procedures per month, I remain convinced that nearly 250,000 PRK/LASIK procedures will be done in 1997!)

6/12 **Laser Vision Centers** reported that its domestic excimer laser procedure volume was up 32% in May over what had been reported for April. Jack Klobnak, CEO, commented, "We are experiencing tremendous growth, not only from our mobile laser programs, but in our fixed centers as well." He also commented on the **VISX** announcement about flat laser sales -- which incidently drove the company's stock down 21%, saying that LVC expected to require additional excimer laser equipment much sooner that its business plan had projected, and that they were "looking at a variety of options to obtain additional equipment."

6/16 According to both *Ocular Surgery News Intelligence Report*, and *EyeWorld Week*, the FDA did seize the nine excimer lasers belonging to JT Lin and **Photon Data**. Lin plans to contest the seizure order in court, asserting that they (the lasers) fall under the custom device exemption laws. Lin intends to respond to the FDA's action within the mandated 10 days, but if he can't convince the FDA to return his lasers, he may be forced to move his operations offshore. According to Wayne Matelski, an attorney with **Arent Fox**, who represents Photon Data, the FDA has also started a major regulatory effort against custom excimer laser owners by issuing warning letters and sending inspectors to the ophthalmologist's offices who use them. Many of these were the physicians who had filed for IDEs but hadn't received them. Matelski, who also represents several of the custom laser owners, said that, to date, none of the lasers had been seized, and that the FDA had asked their owners to stop using them, but he wasn't aware that any had.

6/17 **Autonomous Technologies** announced that it had entered into agreements with accredited institutional investors for the purchase of 3 million shares at $3.00 per share. According to CEO Randy Frey, the financing will provide the company with the resources to market its T-PRK laser system in Europe and Canada while continuing the FDA approval process for marketing in the U.S.

6/18 **VISX** and **Summit Technology** announced that they had reached a settlement on all outstanding U.S. and international patent disputes between them, including the litigation related to the Azema patent and the Canadian dispute over the L'Esperance

patents. This followed a Delaware Federal Court urging them to arbitrate the disputes. The companies have cross-licensed each other's foreign patents for laser ablation or corneal tissue, and the Azema patent will be added to the **Pillar Point Partners** package of patents. The settlement required an exchange of payments that resulted in a net payment of $4.5 million to Summit. Excluded from the settlement is the lawsuit brought by **VISX Partner**, VISX's entity in the Pillar Point Partners, against Summit, over royalty payments claimed due to Pillar Point on sales of Summit's lasers.

Lola Woods, VISX's PR spokesperson said that the new management at Summit made entering into negotiations easier. According to the June 23rd issue of *EyeWorld Week*, industry sources had reported that the VISX and Pillar Point patent position was at risk if the Azema patent claims were upheld, as Summit had already won patent infringement suits over **Chiron** and **Schwind** in Europe. A patent infringement case against **Nidek** in Japan is ongoing.

6/18 **Shooting Star Technologies** announced that it shareholders had voted to change the company's name to **Gimbel Vision International**. Reflecting the manner in which the company provides surgical eye care to patients on an international basis using the **Gimbel Eye Centre** model.

6/20 **Beacon Eye Institute** announced that it had completed the special warrant transaction with **Yorkton Securities** (see the June 6th brief for details). Rather than the $8.4 million anticipated, the deal raised $10.5 million by issuing 2.8 million warrants.

6/20 **Laser Vision Centers** said that it had completed the private placement of $6 million of its Series B Convertible Preferred stock to **A.G. Edwards & Sons**. The funding will allow the company to accelerate it business plan to accommodate growing demand for this fiscal year, allowing LVC to serve more surgeons seeking access to its technology, according to Jack Klobnak, chairman and CEO.

In a profile story published by the *St. Louis Business Journal*, the author Margie Manning states that the company could see booming times ahead. She goes on to note that the company had changed its business strategy to provide more procedures with lower overhead costs, by removing several lasers from sites where they had been permanently installed and were now transporting them from market to market to meet the demand. The company has gone from 18 lasers serving 18 locations to 18 lasers servicing 70 locations. Quoting Jack Klobnak, "Last year we were asking, where are the patients? Where are the doctors? This year its how are we going to serve all these doctors who want access to a laser?"

6/23 In a surprise announcement, *Ocular Surgery News Intelligence Report* reports that Drs. George Waring and Keith Thompson will be the presenters of their LASIK data before the July 11th Ophthalmic Devices Advisory Panel meeting. The doctors plan to present data on 1054 consecutive eyes using the **Summit** Apex laser with multizone software, and the **Chiron** Automated Corneal Shaper microkeratome, along with a

proprietary software and nomogram program. The data was gathered as part of the **Emory Vision Correction Center's** FDA monitored study, the first institutional LASIK study conducted under an FDA IDE. If the procedure is approved, Drs. Waring and Thompson will be allowed to teach their techniques to other surgeons, just as **VISX** and Summit do for their lasers. The surgeons will be allowed to market their LASIK procedure as FDA-approved, through the Emory Vision Correction Center in Atlanta. This is the flagship laser vision correction center in a growing network established in the Southeastern U.S. According to Dr. Waring, Emory Vision Correction has plans for expansion. Although Dr. Doyle Stulting also worked with the investigators, he will not present his data as he is chair of the ophthalmic devices panel and will absent himself from the proceedings.

Also according to *OSN's Intelligence Report*, **Physicians Resource Group** has filed a counterclaim of fraud, conversion, and breach of representation and warranties against **EquiMed**, in the action pending before the American Arbitration Association. In May, EquiMed claimed that PRG owed it $30 million, PRG's counterclaim is for $45 million. Time will tell which side wins this contentious battle.

6/23 This week's *EyeWorld Week*, in addition to the Summit/VISX coverage, also noted some of the results coming out of the **World Refractive Surgery Symposium of ISRS**, held in Orlando. Jack Holladay, MD reported that in a study comparing LASIK using broadbeam Summit and VISX lasers, and the Schwind multiscan system, against the Technolas flying spot laser, the latter scanning laser produced better visual acuity and corneal topography results following LASIK than either of the broadbeams or the multiscan device, especially as the amount of excimer laser treatment increases with higher corrections.

In another brief, EW Week reported that the board of directors of the **Outpatient Ophthalmic Surgery Society** believes that the **Pillar Point Partners** should significantly reduce the current royalty fee of $250 per procedure for PRK, PTK, and LASIK. (It is my understanding that PTK is exempt!) The board passed a resolution stating that the fee had impeded the ability of surgeons to acquire and maintain these lasers, thereby depriving many patients of vision-enhancing surgical treatment.

6/25 **LCA-Vision** announced that it had acquired the interest of its physician partners in the firm's Westchester County, New York location. LCA-Vision now has 100% ownership of the facility, opened last July in Mt. Kisco. The nine local ophthalmologists, organized as **Laser Sight, Inc.**, will continue to be affiliated with the center, and manage its operations.

6/30 According to this week's issue of *Ocular Surgery News Intelligence Report*, **Vision Twenty-One**, a physician practice management company, has filed with the SEC to conduct an IPO to repay debt and finance future acquisitions. The company will offer 2.1 million shares at an expected price of between $11 to $13 per share. The money raised is expected to fund operations for the next 18 months, and pay off the $8

million in debt accumulated to date. Vision Twenty-One manages 21 ophthalmologists and 41 optometrists, and contracts with nearly 600 more through its managed care contracts. The company recently bought 19 optical shops and 2 ambulatory surgery centers in Arizona. The company was founded by Ted Gillette, OD. Richard Lindstrom, MD and Bruce Maller of **BSM Financial** are directors.

6/30 **Sight Resource** announced that it had signed a stock purchase agreement to acquire all of the outstanding shares of **Vision Plaza**, one of the leading optical chains in Louisiana. The company expects the transaction to be completed by July 31st. Vision Plaza operates 17 eyecare centers, primarily in the New Orleans area, where the chain is one of the leading providers of primary eye care products and services. For the year ending March 31st, Vision Plaza revenues were approximately $11 million. No price for the transaction was announced.

**OPHTHALMIC LASER UPDATE -- JULY 1997**

6/26 **Medjet** said the FDA had determined that the company's HydroBrush Keratome was not a significant safety risk and requires no prior approval to begin clinical trials. The device, a high speed waterjet for corneal surgery, is designed to remove the outermost layer of the cornea, the first step in many surgical procedures. Animal studies indicated that the waterjet was about 20 time faster in removing the epithelium as compared to a knife blade. Medjet has a 510(k) application pending with the FDA.

7/1 Catching up on some information taken from the ASCRS website re: the recent ASCRS meeting in Boston. During the "Advanced Topics in LASIK" course, an angry exchange of words took place between the course instructor, Kurt Buzard, MD and Dr. Morris Waxler of the FDA re: the illegality of the so called "Bermuda Cards" (VISX keycards sent to Bermuda for reprogramming by a firm called **Technological Health Care Products** --see the May 1997 Briefing). Dr. Buzard took the opportunity to castigate Dr. Waxler and the FDA for delaying the introduction of lasers and regulating procedures rather than instruments. Dr. Waxler agreed that the FDA had entered into the "practice of medicine" arena. Dr. Waxler went on to say that there was a way to use the Bermuda Cards as long as the doctor informed his/her patients that their use was investigational.

A similar conversation about the Bermuda Cards took place during the "Advanced Issues in LASIK: An Interactive Forum" course. Dr. Charles Casebeer noted that the cards could be used as part of the CRS study of LASIK. Dr. Lindstrom said that to him, it was no different than doing a custom procedure, such as LASIK. "Its an off-label use of an approved device. We do it with IRB approval and...with special patient informed consent...we send your cards, personalized for your laser to Bermuda (where) for $100 plus $40 per card, they will reprogram them to basically function as a full international card...up to -25 and up to 15 D of astigmatism, with multizone capabilities, etc."

On Friday May 2nd, *EyeWorld* sought an opinion on the above exchange from Morris Waxler of the FDA. Basically he said, "I think physicians who get involved in this are in a vulnerable legal position...attorneys believe that the practice is illegal and that surgeons are vulnerable...the IRB approval doesn't make a difference...the use of the cards adulterates the machine."

(Anyone wanting a copy of the above transcripts can download them from the ASCRS web site (www.ascrs.org), or give me a call.)

7/1 More information about the JT Lin/**Photon Data** FDA seizure. According to the June 9th *Gray Sheet*, Photon Data attempted to thwart the FDA seizure by trying to obtain the transfer of a physician IDE to the company, from one of four physicians who had obtained a PDI laser, Dr. Mark Kislinger. According to the *Gray Sheet*, PDI's request had been granted. Further, Dr. Stephen Weinstock of the Laser Center of W. Florida, Largo, FL, another Photon Data laser user, was denied a physician IDE for his laser. Another ophthalmologist, Frank Lowry, of Raleigh, NC also received a warning letter for his home-built system, assembled with the help of Edward Sullivan, an engineering consultant with **Exsull**. I further understand that the nine seized PDI lasers, were not physically removed from PDI's facilities, but rather "wrapped" and labeled as belonging to the Federal Courts by the U.S. Marshals. (As you may recall from last month's briefing, Attorney Wayne Matelski of Arent Fox, representing Photon Data, is contesting the action. I will keep you posted as more is learned about this matter.)

7/1 **LaserSight** announced that it was working with several funding sources, including other industry participants, to come up with the nearly $15 million needed to obtain the **IBM** patents, as previously announced (see the February Briefing). LaserSight expects the transaction will close in July, subject to the successful completion of the financing arrangements.

7/2 **Autonomous Technologies** said that it had closed on the previously announced transaction for the private sale of 3 million shares of common stock at $3.00 per share. **Everen Securities** acted as placement agent for the offering.

7/2 It was learned today that the FDA had issued a "Dear Doctor" letter on June 27th, stating its concerns about the continued use of unapproved lasers, and the possible injuries to patients in photorefractive surgeries using those lasers. According to the letter (copy available to those that request it), the FDA has "uncovered...what appears to be a pattern of serious patient injuries attributed to the use of some "black box" lasers...these include several injuries requiring corneal transplantation, additional (and repetitive) corneal surgery, severe night vision problems, and frequent overcorrection...(attributed) to a laser beam that has a relatively small optical zone, has considerable inhomogeneity, and produces a nonspherical ablation pattern."

The letter also addresses the "gray laser" problem, stating that, "Our experience with certification has led us to conclude that the process described in our October 10 letter cannot be implemented legally...no imported Summit lasers may be considered to be covered by...PMAs unless the laser has been remanufactured by Summit to conform to the specifications of the company's approved lasers...unapproved lasers outside of an FDA approved clinical trial violate the Act...(noting the seizure of "black box" lasers) we intend to take additional regulatory action against other unapproved "black box" and "gray market" lasers used in refractive surgery."

The July 7th *Gray Sheet* notes that only Dr. Fredric Kremer and the Atlanta-based **Vision Correction Group** had submitted PMAs for their systems to the FDA. Kremer's laser is self-built, while the VCG's laser is a modified Summit system.

7/3 **Paradigm Medical Industries** announced that the scheduled product shipments of its Precisionist ThirtyThousand cataract removal system was not delivered by it OEM supplier, **Zevex International**. Consequently, Paradigm has delayed shipments originally scheduled for June and July. Zevex stated that a combination of factors contributed to the delayed shipment to Paradigm; including moving into an expanded facility while undergoing product refinements to increase system manufacturability and reliability. Shipments of the Paradigm system are expected to resume by July 30th. (The ThirtyThousand system is a modular platform that allows the ultrasound system to be upgraded with the Photon laser once FDA approval is achieved.)

7/7 According to a news release from *The American Academy of Ophthalmology*, an Oklahoma County District Judge, Eugene Matthews, has ruled that under Oklahoma law, only licensed physicians are authorized to perform surgery using lasers. The judge's ruling overturns a 1993 decision by the Oklahoma Board of Examiners in Optometry that allowed optometrists to use lasers. The court supported the claim that the performance of laser surgery by optometrists amounts to the unauthorized practice of medicine and creates a risk of harm to patients. A similar ruling in Idaho last year established that optometrists cannot perform surgery and the Idaho State Board of Optometry does not have the power to enlarge the scope of practice of optometry to include laser surgery.

7/8-
7/10 **Sterling Vision** announced that it had secured a new $20 million credit facility with S.T.I. Credit Corporation, a subsidiary of Sun Trust Bank. According to CEO Robert Greenberg, the financial arrangement will give us greater resources for our expansion and growth.

The company also announced that it had been selected to offer vision care services and products to members of **Oxford's Healthy Bonus Program**. Through this program, Oxford, an HMO with 1.8 million members in the Tri-State area, contracts with companies that offer "healthy lifestyle" products and services at a discount to Oxford members.

7/11 *The Associated Press* reports that the FDA's Ophthalmic Advisory Panel has "cautiously" backed the next generation of lasers, by conditionally approving surgery with LASIK. The panel asked that the **Emory University** developers provide it with additional data including proof that patient's vision stabilized properly six to 12 months after surgery, and that side effects do not occur more often in eyes retreated to further enhance vision. According to *Dow Jones*, many of the panel members were concerned about the large number of patients lost to follow-up during the trial, which decreased the amount of long-term data available. Emory representatives explained that this was due to the study patients paying for the procedure and follow-up visits, and their decision not to return to the doctor if satisfied with their condition. The panel was not entirely convinced by this reasoning. The panel also wished that the Emory group had measured vision problems caused by the procedure, including glare, halos, haziness, and problems with night vision and night driving. The FDA will decide if all **Summit Technology** lasers in the U.S. can be upgraded to perform LASIK, following a training program provide by the Emory group. The marketing application covered a software upgrade developed by both Summit and the Emory group. No design or structural changes would be needed for the laser. Summit has at least 250 lasers in use in the U.S.

7/11 **The University of Michigan's Technology Management Office** announced the spin-off of **Intralase Corporation**, a startup company that will develop and commercialize novel ultrafast laser technology, beginning in the ophthalmic field. Because the technology has potential advantages in ocular surgery, the company's initial focus will be on those high precision applications, such as refractive surgery, treating glaucoma and, hopefully, for the removal of cataracts. Leading the development is Assistant Professor of Ophthalmology at U of M, Ron Kurtz, and U of M's TMO scientist Dr. Tibor Juhasz. The technology was developed as a result of collaboration between the University's Kellogg Eye Center, under the direction of Dr. Paul Lichter, and UM's NSF/Center for Ultrafast Optical Sciences, directed by Dr. Gerard Mourou. As part of the startup company's strategy, it expects to complete a collaborative industrial relationship with an industry participant, which is currently in negotiation.

A presentation about the company's laser was given at the *Advanced Ophthalmic Laser Surgery Congress*, which I attended (a writeup about the program is included with this issue of the newsletter) but, since the presentation was give on the second day of the Congress, which I was unable to attend, I only have the outline of the talk. In the talk, presented by Dr. Juhasz, the laser is said to be a diode-pumped YAG laser operating at 100 femtoseconds, with a few microjoules output, and a repetition rate of 6 kHz. A few of the applications noted were use as laser microkeratome (similar to what is proposed for the **ISL** picosecond YLF laser from **Escalon Ophthalmics**), as a laser trephine for precise cutting of corneal tissue in laser keratomileusis, for up to as much as 20 diopters, and to perform an interlocking donor-host junction for corneal transplants. During some consulting work I did for this group back in 1994, many other applications, including a host of non-ophthalmic uses, were discussed for this ultrafast technology.

7/14 This week's issue of *EyeWorld Week* notes that the FDA "arrested" a black box laser on July 2nd, according to the ophthalmologist who owns the laser, used to perform some 10 LASIK cases a week. FDA sources confirmed the seizure, an action technically taken against the instrument, and the first directed against an unapproved excimer laser owned by an individual ophthalmologist. The laser seized was owned by Dr. Trevor Woodhams, of Atlanta, GA, and was custom-built with the assistance of engineer Ed Sullivan of Drexel Hill, PA. Woodhams said that he has access to approved lasers and will continue to perform LASIK. EyeWorld estimates that their are between 12 to 20 black box excimers operating in the U.S.

The same issue of EyeWorld notes that a study performed at **TLC The Laser Center** in Toronto, by its director Jeffrey Machat, MD, indicates that the use of Voltaren before and right after LASIK surgery reduces postoperative discomfort, severity and duration of pain, and foreign body sensation. In the 204 eye study, half the eyes were given Voltaren drops 5 minutes pre-operatively, and 5 minutes post-operatively. In the 54 patients treated with Voltaren (48 bilateral, and six unilateral), only three patients (totaling five LASIK procedures) complained of significant pain 30 minutes after surgery. Of the 55 patients who did not receive Voltaren (47 bilateral and 8 unilateral), 41 (77 eyes) reported pain. That represented three-fourths of the non-Voltaren group.

The newspaper also noted that **Photon Data** had filed an answer to the FDA's seizure of its nine lasers, claiming the products were "custom devices" under federal laws.

7/14 This month's issue of *Refractive Market Perspectives* has an interesting article asking the question is there a market for new lasers? According to Dave Harmon's analysis, "Recent business models, which include the mobilization of lasers, have provided services to most attractive geographic markets. As a result, the industry may have reached a plateau in the demand for new excimer lasers...after sorting through excess capacity problems, increasing demand and geographic access issues, it appears that there will be limited demand for new lasers in the next few years. This year, the demand may be only 70 to 100 lasers and it should remain in that range for the next three years." The accompanying graphic shows about 150 operating lasers plus an additional 175 new lasers purchased, for a total of 325 lasers in 1996; increasing to 325 operating plus 75 new lasers purchased for a total of just under 400 lasers in 1997.

7/16 **VISX** released its second quarter results and, as previously announced, they were flat with first quarter results. For the quarter, the company had revenues of $16.0 million and a net loss of $675,000 (4 cents/share). For the six month period, revenues were $31.3 million, with net income of $2.0 million (13 cents/share). The net loss in the second quarter was partly due to the settlement agreement with **Summit Technology**, for $4.5 million, which resulted in a reduction of net income for the quarter of 25 cents/share (also for the six month period).

In a teleconference discussing second quarter results, Mark Logan, chairman and CEO, reviewed the several accomplishments that had occurred during the quarter, including the approval for treating astigmatism, and the settlement with Summit. He mentioned that the settlement also meant that Summit was now a licensee of the VISX patents outside the U.S., along with six of the seven other laser producers. Only **Nidek** had yet to sign on, and the company was working on that. He also noted the large increase in procedures during the quarter, putting the domestic goal in line for 200,000 procedures to be done on approved laser systems for the year. In that regard, he also mentioned the recent FDA action against gray box and black box lasers, which he felt would be good for the industry and VISX, as he hoped to capture some of the converts. Logan also said that he had just returned from a trip to Korea and Japan. In Korea, there were 45 VISX lasers installed, and VISX had better than a 50% share of the Korean market. Japan holds great potential, perhaps second only to the U.S. Although the approval process in that country has been painfully slow, he hopes that VISX might be first or second to gain regulatory approval in that country. During the Q&A session that followed, although Logan wouldn't give the exact number of procedures done during the quarter, he did say that June was the highest month to date. Asked about high myopia, Logan thought that approval could possibly come during this year, and hyperopic approval during the first half of 1998. I asked how many VISX lasers were installed in the U.S., and Mark said that there were 150 at the end of the first quarter -- and, given that the company only sold about ten lasers domestically during the second quarter (with another ten internationally), the total should be about 160 now. I also asked how many black box/grey box lasers he felt were out there? Mark said that the FDA believes that there are between 50 to 100, and he felt the lower figure might be closer to the truth.

7/17 **Summit Technology** issued a "Dear Shareholder" letter, perhaps in response to the above VISX teleconference. Basically, it repeated many of the items spelled out by Mark Logan of VISX. New CEO Robert Palmisano noted that royalty revenue was increasing at a dramatic rate, with more procedures done during the first half of 1997 than for all of 1996. He said that more than 37 million people in the U.S. were prime candidates for laser vision correction and, to date, less than 0.25% of the potential market had been captured (92,500 people <?>, based on about 170,000 procedures to date). Palmisano also mentioned the VISX settlement and the FDA crackdown on illegal lasers. He also said that significant improvements had been made in cost containment which should lead to improved financial performance.

7/17 **TLC The Laser Center** announced its Lifetime Commitment program. Under the new program past and future patients treated at a TLC center will be eligible for no-charge enhancements. At the time of the first procedure, the patient, the co-managing doctor, and the TLC surgeon will all agree on the level of correction to be attempted, and how to achieve that level. If the desired correction is not achieved in the initial procedure, and the co-managing doctor and treating surgeon are confident that a second procedure is likely to improve the visual outcome, then the patient will receive the second treatment at no-cost. That has been TLC's policy, and it will not change. What

will change is that after the initial 24 month post-operative period, TLC's commitment to the patient continues throughout the patient's lifetime, providing he/she returns to their TLC affiliated doctor for an annual eye exam and obtains documentation of that visit. Anytime during the patient's lifetime that his/her vision drops below 20/40 unaided, or a patient whose 20/20 best corrected vision pre-operatively experiences a loss of three or more lines of vision, that patient will receive a re-treatment at no additional cost. Patients with greater than -10 diopters of myopia and/or greater than -3 diopters of astigmatism are not included. TLC estimates that 99% of the patients it has treated will be included in the program.

7/17 **Sight Resource** announced that it had completed its acquisition of **Vision Plaza**, which operates 14 primary eye care centers and 3 specialty eyewear locations in Louisiana. For the year ending March 31st, Vision Plaza had revenues of approximately $11 million. The acquisition increases Sight Resource's annualized revenues to more than $50 million. (The company's revenues in 1996 were $30 million.) The company now operates 88 locations in seven states.

7/17 **Iridex** announced second quarter results with net sales of $4.4 million and net income of $514,000 (8 cents/share). With supplies of diode lasers ensured, shipments of both the OcuLight GL and DioLite 532 were being carried out. Late in the quarter, the company began shipping its new dermatology laser, the DioLite 532, for the treatment of vascular and pigmented skin lesions.

7/18 *The Academy of Ophthalmology* announced that it would host an informational breakfast in Washington for Congress on Monday July 21st covering an "Update on Refractive Surgery in the United States". (I requested a press kit and will fill you in on the details upon receipt.

7/21 Both *EyeWorld Week* and *Ocular Surgery News Intelligence Report* noted that the FDA Ophthalmic Panel has requested the Emory University group return to the October panel meeting with the added information requested for the approval of LASIK. The approvable status, when given, will be for myopia between 1 D and 15 D, with less than 1 D of astigmatism. As put by panel member Richard Ruiz, MD, "When the data's cleaned up a little bit, we're going to find this a very acceptable procedure".

*EyeWorld Week* also noted that Ophthalmologist Edward Yavitz has embarked on a wrinkle removal commercialization project with the Cool Touch laser from **Laser Aesthetics**, the subsidiary of **New Star Lasers**. (You may recall that this 1.44 nm YAG laser is based on the Bruce Sands' patent, and supposedly shrinks collagen under the skin's surface without affecting the surface.) The FDA has approved the process for general dermatology applications and **Palomar Medical Technologies** has a distribution agreement with Laser Aesthetics to market the Cool Touch laser.

*Ocular Surgery News Intelligence Report* said that the FDA had issued an approvable letter to **Ciba Vision** for Voltaren's use for the relief of temporary pain and photophobia after refractive surgery.

7/21 **LaserSite** announced that it had been designated as one of 20 centers to participate in a national study of LASIK, known as the American LASIK Study. The project will assess the effectiveness of LASIK in correcting high degrees of myopia and astigmatism. Surgeons Harvey Carter and Jeffrey Whitman will use the (**Chiron**) microkeratome and the **Summit** SVS Apex Plus laser in the study, which will include up to 100 procedures under the study protocol. LaserSite was formed as a cooperative by 36 North Texas eye surgeons and **Nexus Healthcare**, a medical services development and management company. The center is presently affiliated with over 125 ophthalmologists and optometrists.

7/21 **Summit Technology** released its second quarter results with revenues increasing to $23.6 million and net income from continuing operations of $2.6 million (8 cents/share). Second quarter income included a one-time gain of $1.7 million (5 cents/share) resulting from the $4.5 million settlement with VISX, net of costs associated with the reevaluation of the company's patent portfolio and legal expenses. (Revenues for the quarter include approximately $12.5 million from **Vision Express**, the company's mail order contact lens subsidiary.) (If both the Lens Express revenues and the one-time gain are subtracted, the remainder, or $9.4 million represents revenues from Pillar Point refractive surgery procedure royalties, and sales and service of lasers. Since no breakdown was provided, it is difficult to estimate how many lasers were sold/leased during the quarter, but my best guess is approximately 15 worldwide.) Robert Palmisano, Summit's CEO said that the plans to divest its vision center business is moving forward, and expects to report progress in the near future. (It turned out to be two days hence -- see the July 23rd brief below.)

For the six month period, revenues were $44.3 million, as compared to $42.5 million in 1996, and net income from continuing operations was $1.2 million (4 cents/share), compared to a net loss of $5.7 million (18 cents/share) last year.

7/21 **LCA-Vision** said that it had re-negotiated its line of credit with the Fifth Third Bank in Cincinnati. (As became apparent, this was for the blockbuster agreement announced on the 23rd with **Summit Technology**.)

7/22 **VISX** announced that a former "black box" laser user traded in his custom-built device for a VISX Star laser. Dr. Frank Lowry, of Raleigh, NC took advantage of the VISX trade-in program for "black box" and "gray box" laser owners. (I believe that this is the second black box trade-in, the other being a California ophthalmologist.)

7/23 **Summit Technology** and **LCA-Vision** jointly announced the acquisition of all the stock of Summit's **RCII** subsidiary, in exchange for 17 million shares of LCA-Vision common stock (worth about $50 million at LCA's current stock price!). The

agreement provides that RCII will have a cash balance of $10 million at closing. When the deal is completed, subject to regulatory approval, LCA will have 43 laser vision correction locations in the U.S., Canada, and Europe, including the 19 former **Summit Vision Centers**, and six additional "centers of excellence" located at prestigious university medical centers/hospitals.

Summit said it will distribute approximately 9 million of the acquired LCA shares to its shareholders, as soon as practical after the closing. The remaining shares, which represent approximately 20 percent of LCA's outstanding shares, will be held by Summit. Ron Herskowitz, executive VP of RCII will join LCA's board and will serve as LCA's COO, reporting to CEO Dr. Stephen Joffe. After the closing, LCA will have approximately 36 million shares outstanding. Summit president Robert Palmisano commented, "We believe that this transaction will serve the best interests of Summit shareholders, as we complete our commitment to our customers not to be directly involved in the same business as they are. The transaction will allow Summit to focus on building laser vision procedure volume, as well as the other aspects of our business."

In my opinion, this agreement is a "win-win" situation for both companies. LCA-Vision nearly doubles in size, and according to CEO Stephen Joffe, there is no duplication of location, while bringing them into several new locations. The acquisition also adds a strong manager to the LCA team, in Ron Herskowitz, a seasoned veteran of the optical industry. Meanwhile, the disposition of its laser vision correction business, shows Summit's current and prospective customers that it means to keep its word in looking out for their interests. And, furthermore, Summit can now put more effort into marketing laser vision correction, as more of its revenue stream now depends on Pillar Point fees.

7/24 **Beacon Eye Institute** posted its six-month results, with revenues for the second quarter of $2.9 million, up from revenues of $2.3 million for the previous quarter. The net loss for the quarter was $5.3 million, down from the $5.8 million in the first quarter. For the six month period, the net loss was $11.1 million ($1.53/share), as compared with a net loss of $9.5 million ($4.28/share) for the same period last year. Operating costs and development expenses totaled $15.8 million for the six months, and included the startup of four U.S. laser vision correction centers in Fort Lauderdale and Tampa, Florida; Atlanta; and Irvine, California.

The company also announced that it was expanding its services to include LASIK as an alternative to PRK, which will be introduced into its facilities beginning in August 1997. According to chairman and CEO Keith Moore, "Although revenue increased in the second quarter, the number of refractive procedures was not up to expectations. We expect to see a significant increase in the number of laser vision correction procedures, both laser-PRK and LASIK, performed in the second half of 1997...with an average of about 200 procedures booked per week in the last few weeks, compared to about 115 procedures per week during the second quarter."

7/25 **LaserVision Centers** announced that revenues had increased 110% for both the quarter and fiscal year ending April 30th. For the quarter, revenues were $2.8 million, with a net loss of $5.3 million (60 cents/share), while for the fiscal year, revenues were $8.2 million with a loss of $12.1 million ($1.45/share). The net loss for the fiscal fourth quarter included a $2.8 million non-cash, fixed asset impairment and $0.3 million of non-recurring expenses.

The company also noted that subsequent to the end of its fiscal year, surgical case volume in June increased 20% over May, giving LaserVision Centers its sixth consecutive record increase in month-to-month U.S. surgical volume. Chairman Jack Klobnak said that the company planned to expand its unique mobile excimer access program and its network of surgeons. Mobile excimer capacity had increased 150% during the quarter and should have a positive impact on its business.

7/28 *Ocular Surgery News Intelligence Report* noted that the LASIK study by **CRS-USA** had been expanded to 40 sites and an additional 8000 eyes for myopia up to 22D and cylinder up to 6D. The practical range of correction will be limited to less than 14D because of the limits of both the Summit and VISX lasers, being used in the study. All of the Summit sites have been named, but not all the VISX sites.

*EyeWorld Week* noted that Dr. Frank Lowry, who traded in his black box excimer for a VISX Star was the second to do so, with Dr. Stephen Hollis of Columbus, GA making the switch late last year. (It seems to me that a California doctor also traded in his laser for a VISX system last year, but I cannot recall who it was.) The newsletter also mentioned that Dr. Trevor Woodhams had released a statement about the seizure of his custom-built laser, describing the rationale for building it, and the steps he will take to defend himself, believing that the laser falls under the "custom device exemption", and other practice of medicine protections.

*EyeWorld* also contained a brief that officials at **Escalon Inc.** declined to comment on reports that it had discontinued work on its picosecond laser, the old **ISL** device that was being developed as a laser keratome.

**OPHTHALMIC LASER UPDATE -- AUGUST 1997**

7/14 *The Gray Sheet* reports that **C.L.McIntosh**, a Rockville, MD consulting firm, submitted a July 9th supplement to its September 1996 citizen petition reiterating the need for the FDA to act against unapproved excimer lasers being used for eye surgery. The supplement cites the proliferation of ophthalmologists' advertising for operations using unapproved systems and the inadequacy of the FDA's recently halted certification program for reimported lasers. (Shortly thereafter, the FDA began taking action on ophthalmologists operating "black box" laser systems.)

7/21 This week's issue of *The Gray Sheet* notes that **Advanced Corneal System's** Corneaplasty vision correction system is slated to complete Phase I clinical trials by

the end of 1997. The ACS system is a non-surgical approach to changing the shape of the cornea to correct refractive error and improve visual acuity. The system involves the use of a proprietary formulation of the drug hyaluronidase and a custom fitted rigid gas permeable contact lens. The drug is injected into the cornea to "temporarily alter the molecular bonds between proteoglycan molecules" of the cornea, making it more malleable to allow re-shaping by the rigid gas permeable contact lens that is worn for 10-16 hours per day for several days, and then during either the day or at night for approximately three to four months, after which time the cornea has returned to its normal firm state, according to ACS. In the Phase I trial, 12 patients have so far been enrolled by an ophthalmologist in Long Beach, CA. ACS received FDA approval in April 1996 to commence its INDA (investigational new drug application). Phase II trials should start in the U.S. in 1998, while a Phase II trial in Mexico is currently underway, with 69 patients enrolled, with reportedly significant improvements in vision. Twenty-two month followup data for the first 10 patients suggests long-lasting improvements in visual acuity. (I question how this approach differs from orthokeratology, the use of rigid gas permeable contact lenses alone to reshape the cornea, similar to the way braces straighten teeth. Also, during the 1970's, contact lens guru Charles Neefe obtained a patent on the use of a particular drug to soften the corneal surface, and reshape it with a hard lens -- at that time there were not any gas permeable lenses available.)

ACS is also developing the drug Vitrase for the treatment of vitreous hemorrhage, which can impair a victim's eyesight and prevent an ophthalmologist from accessing the retina. Vitrase is in Phase II clinical trials scheduled to conclude by the end of 1997, with more than 150 patients enrolled. ACS was founded in 1992 and has approximately 25 employees, headed by former Allergan vp Edward Danse.

7/30 **TLC The Laser Center** announced the issuance of a U.S. Patent, #5,630,810 to TLC and Dr. Jeffrey Machat. The patent covers an improved method for the elimination of central islands during excimer laser surgery, apparently via a pretreatment, which is widely used in the performance of PRK and LASIK (?). TLC said it is currently assessing the economic value of the patent and will formulate a strategy to maximize its benefits. (This can be interpreted as they are trying to figure out if there is any way they can collect any royalties from users! As with all method patents, it will be tough to enforce.)

7/30 **Sunrise Technologies** announced that it had received FDA approval to include fellow (second) eye treatments in the clinical trials currently underway in their study on treating hyperopia with their holmium laser. Russel Trenary, president and CEO notes that the notice indicates that the FDA has developed a comfort level with their data...and that it will make it easier to recruit new patients. The approval allows clinicians conducting the study to treat the second eye of those enrolled. (The company has renamed the former Corneal Shaper System, now calling it the Corneal Sparing LTK System.)

7/31 **LaserSight** announced that it was working with several potential funding sources, including other industry participants, and anticipates closing on the **IBM** patent agreement in August.

7/31 **Sight Resource** released its second quarter operating results showing revenue of $10 million and a net loss for the quarter of $205,000 (2 cents/share). The company noted that after adjusting for depreciation and amortization of $480,000, it had generated positive cash flow of $275,000 in the quarter. The results include operations of **E.B.Brown Opticians**, acquired effective July 1, 1996, but not those of **Vision Plaza**, acquired effective July 1, 1997.

8/3 **VISX** announced that it had engaged **Strategic Partners Group** to help it understand how laser vision correction is perceived by consumers. Findings from the research have provided the company with a better understanding of the factors affecting the consumer's decision to have laser vision correction. The results are being incorporated into VISX's communications and practice development programs for use by VISX users. According to the research, confusion and fear are still prevalent among consumers, with the majority not able to differentiate among the "K" procedures (RK, PRK and LASIK). Coupled with a natural fear concerning one's vision, candidates resort to procrastination instead of scheduling their procedures.

8/4 **Autonomous Technologies** announced its second quarter results. The company has significantly increased staffing and its clinical activities in anticipation of submitting its PMA to the FDA by the end of 1997. Autonomous reported a net loss for the quarter of $3.1 million (45 cents/share), with no revenue. For the six month period, the net loss was $5.7 million (83 cents/share), again with no revenues.

8/4 According to *Ocular Surgery News Intelligence Report*, the investment firm **Piper Jaffray** issued a bullish report on **Summit Technology** stating that a majority of Summit's future revenue would come from **Pillar Point** royalties and not excimer laser sales, making the company's stock now a "buy". The analysts involved with writing the report, Arch Smith and Francesca Migliori, noted that royalties constituted 30% of total revenues for the second quarter, as compared with 18% for last year's second quarter. Royalties could grow to 40% of revenues by June 1998. This year, royalties could account for $28.9 million and reach $46.5 million next year. (I have obtained a copy of this report, dated July 24th, along with an earlier one written in April, and would be happy to share them with interested parties. They contain two interesting tables, one showing a revenue model, breaking down the company's various income streams by units and procedures, and the other doing the same for revenues and earnings.)

8/4 This week's issue of *EyeWorld Week* contained an interesting item. The newsletter noted that as part of its ongoing campaign, the FDA had issued another warning to a custom laser user to stop using it. In a July 10th letter to Gary Tylock, MD of Irving, TX, the FDA cited knowledge about his laser, including the previous owner, Jerry

Tennant, MD, from whom Tylock obtained the laser in March 1996, which was originally built for Tennant by Edward Sullivan, an engineering consultant from Drexel Hills, PA, who also helped build Dr. Trevor Woodham's laser -- see the July 14th brief last month. Tylock was told that his laser was subject to seizure unless he filed a satisfactory response within 15 days.

Keeping in step with the above item, I managed to pull Dr. Woodham's statement in response to the recent seizure of his custom laser by the FDA, off of the ASCRS website. Basically, he claims that he has been using the laser for almost two years to perform LASIK without any problems. He said he was taking the necessary steps under the custom device exemption to regain the use of the laser, which remains in his operating room with a seizure seal around it. (Anyone wishing to see the full statement can see it on the ASCRS/EyeWorld website, in the background portion -- codewords "eyeworld" and "ewns" -- or give me a call.)

8/5 **LCA-Vision** reported its second quarter results with revenues of $3.8 million, compared to $3.5 million in last year's second quarter. The net loss for the quarter was $1.0 million (5 cents/share), up from $953,000 (6 cents/share) a year ago. For the six month period, revenues were $6.6 million, compared with $7.2 million a year ago, while the net loss was $2.9 million (15 cents/share), up from $1.5 million (7 cents/share). Commenting on the results, Dr. Stephen Joffe said that they were satisfied with the revenue growth, which is ahead of projections and that during the second quarter the number of laser vision correction procedures performed at the centers increased by 44% over the first quarter, representing total revenues of $2.4 million, up from $1.0 million in the same quarter last year.

8/7 According to *Dow Jones News Service*, the SEC has sued five former officers of **Phoenix Laser Systems** for alleged fraud, insider trading, and market manipulation. Phoenix, formerly based in San Francisco, and a client of mine while with **Arthur D. Little**, filed for bankruptcy in December 1995. The SEC said that the five (unnamed in the release I received) along with an unnamed New York broker, manipulated the price of the company's stock to maximize profits in stock sales, doing so through a carefully orchestrated end-of-day and intraday purchases. The officers also allegedly lied in press releases and SEC filings about the status of applications to the FDA, and about customer orders for their lasers. The six defendants are charged with various other offenses, including insider trading on company bad news as well as sales or unregistered securities. The SEC is seeking disgorgement of all profits from the illegal stock sales, as well as losses avoided through insider trading, plus civil penalties that could be three times those amounts. Injunctions from further securities law violations will also be sought. (More on this as I learn about it.)

8/10 **VISX** announced that it had received accreditation for continuing medical education, through an agreement with the Postgraduate Institute for Medicine. The agreement allows VISX to grant CME credits for the VISX University programs.

8/11 This week's issue of *Ocular Surgery News Intelligence Report* discusses the FDA's OK for **Staar Surgical** to begin its Phase 2 clinical trials for the Implantable Contact Lens for myopia, increasing its investigator base from four to ten surgeons.

A second story discusses the Society for the Advancement of Laser Technology (SALT) enlisting five members of Congress to petition government agencies on behalf of surgeons using reimported lasers and to call for the elimination of excimer laser "key cards" for lasers. Four representatives have signed a letter asking Donna Shalala, U.S. Secretary for the Dept. of Health and Human Services to take four courses of action aimed at protecting ophthalmologists:

- Cease harassing ophthalmologists who use reimported lasers;
- Remove debit card counters from approved lasers;
- Lift the FDA-issued import alert on reimported lasers; and
- Investigate the theft of VISX documents from the FDA offices.

A second letter, signed by the four representatives and a fifth congresswoman requests that the House Subcommittee on Oversight and Investigations look into the FDA's handling of reimported lasers. The second letter alleges that the FDA-enforced requirement for U.S. excimer lasers to have a key card counter is not necessary to monitor the safety or efficacy and, therefore, goes beyond the FDA's legal mandate.

I have downloaded copies of the letters from the *EyeWorld* web site if anyone would like to see them in their entirety.

8/11 *EyeWorld Week* also checked in with several interesting items. The first relates that John Taboda, the first to notice the effect of excimer laser energy on the human eye (as part of a military study of the effects of lasers on eyes) has sued Steve Trokel, **VISX**, **VISX Partners**, **Summit Partners**, and **Pillar Point Partners**, claiming that his name should have been on Trokel's patent filed in 1983, and granted in 1992. Taboda claims that he shared the results of his 1979 and 1980 experiments with Trokel in 1982 and, therefore, should be listed as inventor or co-inventor on Trokel's patent (which was assigned to VISX, and via VISX to VISX Partners to become part of the Pillar Point package). Taboda does not charge Trokel with wrongdoing, but points out that he was left off of the patent probably due to inadvertence, mistake, or some other innocent error. A patent attorney contacted by EyeWorld noted that if the court finds that the patent is based on any kind of fraudulent claims or data, it could be overturned entirely and nobody would own it. In addition to being declared inventor or co-inventor, Taboda seeks an unspecified amount of past and future royalties.

The second item describes **Chiron Vision's** attempt to gain payments from surgeons performing LASIK, that they claim falls under the Peyman patent assigned to them. A single use license is granted in the purchase of Chiron microkeratome blades, but a number of surgeons performing LASIK, but not using a Chiron microkeratome, have requested entering into some sort of license arrangement under the Peyman patent. A

copy of the letter sent out by Andy Corley, general manager, refractive surgery of Chiron is reprinted in this month's issue of *Refractive Market Perspectives*, sent to members of the Chiron Refractive Alliance, all of those who have taken a refractive course sponsored by the company. In addition to explaining the single use license granted with the purchase of Chiron microkeratome blades, the letter says that Chiron will accommodate physicians not using the Chiron blades with a direct license agreement. The license will grant the surgeons rights under the Peyman patent in return for a reasonable royalty (not specified) paid directly to Chiron Vision. The license will be with individual physicians, and not with other manufacturers or suppliers of ophthalmic goods. (I attempted to learn more about the details of the license agreement for those physicians not purchasing Chiron blades, but was told that that information was still being developed, and would be available from Mr. Corley sometime over the next few weeks. As soon as I learn something definitive, I will pass it along to you. However, the August 18th issue of *Ocular Surgery News Intelligence Report* states that according to information it received, a $40 per procedure fee may be sought by the company. A call from a Chiron representative said that the information in the OSN Newsletter is erroneous and, as noted above, is still under development.)

8/11 In an allied matter, **LaserSight** announced that it had acquired the rights to Dr. Frederic Kremer's PMA application for LASIK and a related patent issued to the doctor. The PMA submission was accepted for filing by the FDA in March and includes data on myopia and myopic astigmatism treatments on 1617 eyes, ranging up to correction of -20 diopters. The PMA represents the largest data set known to LaserSight to be submitted to the FDA on LASIK. It also includes data from LASIK cases performed in May 1993, affording excellent long-term follow-up data. Dr. Kremer's patent on a LASIK microkeratome with a pivoting head, U.S. 5,586,980, was included as part of the deal. If the PMA is approved, it will allow ophthalmologists to perform LASIK up to -18 diopters and up to 5 diopters of astigmatism. At closing LaserSight issued a combination of 535,515 unregistered shares of common stock and $383,000 as consideration for the PMA filing, the microkeratome patent, and a one-year consulting agreement with Dr. Kremer (roughly, $3.4 million). He will also receive a royalty on any microkeratome made for or by LaserSight using his patented technology, together with a percentage -- initially 30% and increasing to 70% -- of the aggregate amount of fees received by LaserSight from the licensing or sale of the microkeratome patent to third parties. If the FDA approves the PMA so as to allow LaserSight to commercialize a laser to perform LASIK in the U.S., it will pay Dr. Kremer an additional $1.75 million. If such FDA approval is not obtained by July 29, 1998, LaserSight has the option to return the PMA and receive back 274,286 shares of the 535,515 granted. In addition, if the FDA approves the use of a LaserSight-manufactured laser system for the treatment of hyperopia, LaserSight will make an additional payment in the form of LaserSight common stock with a market value of $1 million at the time of such approval. Further, if certain target dates are met for FDA approval of LaserSight's scanning laser system, currently in clinical trials, the company will make an additional payment of up to $1 million in cash. Finally, to the extent that U.S. gross sales of all LaserSight

manufactured laser systems exceed $14 million before March 31, 1999, or one year after LaserSight's first commercial sale of a laser system in the U.S., Dr. Kremer will receive additional payments equal to 25% of such excess. Dr. Kremer also has the right to purchase laser systems from LaserSight on favorable terms.

In essence, the agreement could possibly speed up LaserSight's entry into the U.S. marketplace -- but at what cost? Another unknown is how LaserSight can go about transferring the LASIK data collected by Dr. Kremer on his homemade excimer laser, to a commercial unit, such as its own scanning system. To my knowledge, the Kremer home-built system is a wide area ablation laser. (See the 8/13-8/14 brief below for more on this subject.)

The August 25th issue of *Ocular Surgery News Intelligence Report* states that according to *Health News Daily*, LaserSight could return the PMA it bought from Dr. Kremer if the FDA clearance does not allow commercial sales of the laser.

8/11 This month's issue of *Refractive Market Perspectives*, from **Market Scope**, states that laser refractive volume increased 19.4% in the second quarter, on track for about 220,000 procedures for the year (including some U.S. patients traveling to Canada for procedures and those done on unapproved systems). Since there has been little change in the number of centers open, the growth stems from increased activity at current centers. According to Market Scope, newly added lasers have been replacements, or they have been offsets to lasers withdrawn from the market. The newsletter also believes that FDA actions and business failures are expected to reduce the number of laser centers operating during the next quarter as well. During the quarter, 50,500 procedures were performed, up from 42,300 during the first quarter. This means that an average of 39.1 procedures per month per system, as compared to 32.9 during the first quarter. Market Scope expects volumes to continue growing at about the same rate shown in the second quarter.

The newsletter also notes that FDA action against imported and black box lasers continues. During July, at least three actions were taken, sending notifications that unless operators shut down, seizures will commence within 15 days or receipt of the letters. Both VISX and Summit have programs in place to replace black box and reimported laser systems, with Summit upgrading gray market lasers to Apex or Apex Plus systems.

During the FDA panel meeting on July 11/12, Dr. Morris Waxler reported on the status of laser IDEs, noting that there were 8 manufacturers with approved protocols for PRK and LASIK, and of the 34 applications for sponsor/investigator IDEs, 17 were submitted for additional studies using lasers with approved IDEs or PMAs and 17 were for black box or gray market systems. Upon reviewing the IDEs for additional studies, 6 were disapproved; 10 conditionally approved; and 1 is still under review. Of the black box/gray market system IDEs, 9 were disapproved; 6

conditionally approved; and 2 remain under review. Waxler also noted that 2 PMA applications from sponsor/investigators have been filed.

The newsletter noted that two additional legal suits relating to security fraud had been filed against Summit Technology. One relates to a shareholder suit, similar to the other class action suits already on file. The second deals with the acquisition of Lens Express by Summit, alleging that David Muller made material misrepresentations and non-disclosures which caused Lens Express shareholders to enter into the merger agreement. The suit asks for the merger to be reversed and Lens Express returned to its former shareholders.

Another brief notes that **KeraVision** investors were disappointed with the sales of the intracorneal ring in Europe. The company reported sales of only $114,000 for the second quarter, up from $56,000 in the first quarter.

Market Scope has announced a new market report on the U.S. Refractive Surgical Market, published in August. I have received a copy of the extensive report and will include a copy of the executive summary with this newsletter. The 100+ page report covers the eye care market in the U.S; the history of refractive surgery; patient economics of vision correction; the commercial development of PRK; the laser center operation market; alternative technologies; the market for microkeratomes; and the laser vision correction market. In addition, the report profiles 12 device suppliers and 15 service providers. For further information about this $1200 report ($950 for Refractive Market Perspectives subscribers), call David Harmon at 888-806-4015 or e-mail him care of report@mktsc.com.

8/12 **Sunrise Technologies** announced that it had received FDA approval to expand its hyperopia study to include an additional 100 patients, doubling the number of patients involved. Enrollment of the first 100 patients was completed July 3, 1997, with management commenting that they were progressing "very well". The approval stipulated that the company continue the investigation at the same 8 sites previously approved, as well as adding several tests and forms of analyses that had already been initiated. With respect to the first 100 patients, while only about a third could see 20/40 or better without correction pre-treatment, 88-90% were at this level three and six months post-treatment, with 60-65% achieving 20/25 or better.

8/13 **Laser Vision Centers** reported that same U.S. laser surgical volume for July increased 342% over July 1996. This is data on 19 lasers which were in operation last July. For the quarter, procedure volume was up 428% over last year and 91% over this year's previous quarter. The company also noted that during this fiscal quarter its operations worldwide had already achieved 50% of surgical volume for the previous fiscal year.

8/13-
8/14 **LaserSight** released its second quarter results and held an analyst teleconference to discuss the release, as well as the acquisition of the Kremer LASIK PMA and patent.

For the quarter, the company had revenues of $5.4 million resulting in a net loss of $2.4 million (26 cents/share). This compared to revenues of $6 million and a net loss of $24,900 (2 cents/share) in the second quarter of 1996. According to president and CEO Michael Farris, the second quarter loss was primarily due to a decrease in sales of lasers into the European market, with some sales delayed awaiting the introduction of the LSX model, which is not expected to begin shipping, in limited quantities, until the fourth quarter. The company is continuing to negotiate funding for its purchase of the IBM patents, and has signed a letter of intent with a Fortune 500 health care company for the non-ophthalmic rights to those patents. As consideration, LaserSight will receive a lump sum of $4 million and royalties on products and patent license fees outside of the cardiovascular and vascular fields. The company expects to complete the funding for the IBM patent purchase by the end of August.

The company reported that during the quarter it sold 8 laser systems, compared with 13 during the same quarter last year. Revenues for Technology were $2.1 million, compared with $3.5 million in last year's quarter.

During the teleconference, Farris said that the company is ramping up its regulatory activities for expedited entry into the U.S. market, pursuing both the LASIK PMA already filed by Dr. Kremer, as well as filing its own PMA for the scanning laser system by the end of this year or early next year. When questioned about the transferability of the Kremer PMA (allegedly performed with a wide area custom-built laser system -- see the August 11th brief above), Farris said that, if necessary, the company would market a wide area ablation system to gain entry into the U.S. market pending approval of its scanning system, or would attempt to show equivalency of a scanning laser with a wide area ablation system in the LASIK process.

8/14 **Sunrise Technologies** announced its second quarter results, reporting revenues of $1.5 million, and a net loss of $163,000 (1 cent/share). For the six-month period, revenues were $2.5 million, with a net loss of $2.6 million (9 cents/share). The company said that the net loss for the quarter and year to date, was due primarily to the decreased demand for the company's dental products and interest expense associated with the redeemable convertible notes issued in the first quarter, offset by the sale of the dental division, finalized on June 26th.

8/15-
8/19 In a flurry of activity, a series of news stories broke around the release of **Sterling Vision's** second quarter results. First, the company announced its second quarter financials, with sales increasing by 11.2% to $36.3 million, and six-month sales increasing to $72.9 million. Net income for the quarter was $105,000 (1 cent/share), while for the six months, $413,000 (3 cents/share).

This was followed by a story about Sterling that appeared in the "Inside Wall Street" column in the August 25th issue of *Business Week*, which noted that the "throng of short-sellers hasn't blurred the view of smart-money investors who have been

snapping up shares...(thinking) that recent moves by the operator of 350 optical stores in 27 states will send the shorts scrambling for cover...a far larger optical company is eyeballing Sterling for a buyout says one money manager...there is talk that Sterling may authorize a share buyback and hire an investment bank to find ways of boosting the stock."

Then, **Asensio & Company**, a NY-based institutional investment bank, issued a statement that noted "Investors have bid-up Sterling Vision's stock based on completely false, yet widely published, reports of large "smart money: buying on an anticipated "buyout" and a "share buyback" plan...neither of these events is remotely possible, and institutions have been selling not buying...Sterling is a poor preforming, financially troubled company with no prospects of being sold at a premium price, and no ability to repurchase its shares."

This prompted the company to respond, stating that the Asensio news release contained numerous falsehoods including statements regarding management, a recent registration statement, and the operations and future of the company, saying that no one from the company had ever spoken with anyone from Asensio. Robert Greenberg, Sterling's CEO said that he had referred the false statements to counsel for review its rights and to pursue all appropriate legal remedies. He further noted that he had concerns about Asensio's motives for issuing the report.

8/18 Both *Ocular Surgery News Intelligence Report* and *EyeWorld Week* noted that the FTC apparently is continuing its investigation of **Pillar Point Partners**. The agency has subpoenaed "tens of thousands" of documents from the **Barnet Dulaney Eye Center**, which had been collected during the discovery phase of its lawsuit against Pillar Point, accusing PP of antitrust violations. The suit was in retaliation of being sued by PP over the center's use of a black box laser in violation of its patent portfolio. OCSNIR also noted that the FTC had interviewed John Taboada, which led him to find out that his name was not on the patent that had issued to Steve Trokel, after assertions that it would be -- see the August 11 brief above.

EyeWorld Week also notes that the black box laser traded in by Dr. Frank Lowry of North Carolina last month, has been placed under a restraining order by a U.S. District judge, for its builder, Ed Sullivan. Mr. Sullivan claims that Lowry had broken a confidentiality and licensing agreement by transferring the excimer laser to **VISX**. However, VISX could not confirm the whereabouts of the laser.

8/18 **TLC The Laser Center** posted strong fourth fiscal quarter results, with gross revenues for the fiscal year increasing 200% to $47.9 million. For the quarter, revenues were $20.6 million, up from $7.7 million in the same quarter last year. "The strong revenues reflects continuing strong growth in the number of procedures at existing sites and TLC's expanding activities in the U.S. market. Including the twelve months activities of the TLC northeast clinics (formerly operated as **20/20 Laser Centers)**, TLC performed a total of 14,200 paid refractive procedures during the fiscal 1997

year, compared to 3700 in 1996. TLC performed 5200 paid procedures in the fourth (fiscal) quarter of this year, compared to 1100 in the same period last year." The company had a net loss in the quarter of $7.1 million (28 cents/share) and a loss for the fiscal year of $13.9 million (68 cents/share). The net loss for the year was associated with the opening of 24 new clinics. During a teleconference following the release of the financial results, Elias Vamvakas, CEO noted that much of the growth in procedures was occurring at their U.S. centers, which were charging a higher procedure fee, averaging $2400 per eye, as more and more procedures were LASIK, now standing at 70-80% of procedures, commanding the higher price.

8/19 Both **LCA-Vision** and **Summit Technologies** announced the completion of LCA's acquisition of Summit's laser eye surgery centers business. With the acquisition, LCA-Vision becomes the largest provider of laser vision correction, with twice as many centers as its nearest competitor. (Although, with its mobile and rollon program, **Laser Vision Centers** may own more lasers and operate at more locations than LCA.) With the addition of 19 wholly-owned and operated facilities, and working relationships with six additional treatment sites at prestigious university medical centers/hospitals, LCA now has 40 centers in the U.S., along with 2 facilities in Canada and 1 in Europe. According to LCA's press release, the 19 **Refractive Centers International's** 1997 revenues are projected to be $6 million, bringing LCA's projected annualized revenues to $20 million.

As previously announced, Dr. Ronald Herskowitz, who had been running Summit's vision center operations, has been named COO of LCA-Vision and will also join the board of directors. (A list of the locations acquired and medical center affiliations is contained in the news release for anyone interested.)

8/22 **LCA-Vision** announced that it had obtained a new financing agreement from the Fifth Third Bank of Cincinnati, to replace its expired existing package. The new package, effective August 18th, consists of an $8 million secured line of credit and a secured 13-month term loan in the amount of $3.1 million.

8/25 *EyeWorld Week* reports that refractive laser procedure volume in the United States continues to grow at a healthy rate according to statistics compiled by *Market Scope* and *Medical Laser Insight*. A survey of refractive laser center business activity in the second quarter revealed a 20% growth rate over the previous quarter, with approximately 50,000 procedures performed, an average of about 40 per center per month. According to Dave Harmon of Market Scope, he is predicting that 220,000 PRK and LASIK procedures will be done in the U.S. versus 105,000 last year. (A more concise report on these numbers is shown in the 8/11 *Refractive Market Perspectives* brief above.)

The same issue of EyeWorld also notes that *American Investigator*, a Washington, DC-based conservative group, had aired an update of the program it had aired last September (see the brief of September 30 in the October 1996 newsletter) charging

that the FDA had given preferential treatment to **Summit Technology** in its quest for FDA marketing approval. The update, entitled "Black Eye", aired on August 13th, and revealed that the congressional and federal agency investigations into the Summit affair had fizzled, but that the FDA continues to favor Summit by requiring a "debit counter" on Summit lasers.

**OPHTHALMIC LASER UPDATE -- SEPTEMBER 1997**

8/25 This week's issue of *Barron's* contains an expose of two penney stock manipulators, Barry Witz and Parvinder Chadha, in a story entitled "Buyer Beware". It turns out that these two were also involved in the ongoing saga of **Phoenix Laser Systems** (see our brief of August 7th in the August issue). According to the Barron's story, Witz asked Chadha for help with Phoenix. Chadha became Phoenix's chairman and attempted to place a Reg S stock placement with investors, but the deal never got off the ground. By November 1993, Chadha had stepped down from the chairman's post and, as noted in the August 7th brief, the SEC has filed a complaint against the former Phoenix managers charging the company's laser claims and some of its stock sales were frauds! (It will be interesting to see if the SEC can ever find some of the principals, who I understand have disappeared!)

8/25-
8/26 **Gimbel Vision International** announced the results for the six month period ending June 30th. Revenues were $7.5 million, with a net income before taxes of $1.0 million. Net income after taxes were $480,000. The company attributes the growth in revenues to the growth of the company's existing profitable operations, and the consolidation of three month's operations from its Australian surgery centers. The company intends to continue international expansion and will focus development in Australia and Brazil for the remainder of 1997. In a teleconference held by management, it was mentioned that the company's Las Vegas site was doing very well, and had performed over 1000 procedures since opening in January 1996, while its five Canadian centers were performing about 540 procedures/month.

Gimbel has agreed to offer up to 1.36 million units at $1.25/unit through its agent **McDermid St. Lawrence Securities Ltd.**. Each unit will be comprised of 1 share of common stock and one-half share purchase warrant, exercisable into one share of common stock at $1.75. It is anticipated that the transaction will raise $1.7 million.

The following day, the company announced that it had closed on the first part of its special warrant private placement and secondary offering, raising $1.1 million of an expected $2.8 million, which will be used to finance its international expansion in South America and Asia-Pacific.

8/26 According to *EyeWorld Post*, **Pillar Point Partners** has filed an amendment to its lawsuit against the **Barnet Dulaney Eye Center**, adding **Sun Valley Acquisition Corporation** as a defendant. Sun Valley is a subsidiary of **Physicians Resource**

**Group**, which has declared it will support Barnet Dulaney in it legal fight against Pillar Point.

8/26 **Autonomous Technologies** announced the first corporate revenues produced with its T-PRK laser system. The laser was recently installed at the **Vision Sculpting Center** in Toronto, under the direction of Dr. Steve Arsinoff. This is the first placement of a T-PRK laser under Autonomous' Affiliates Program, where the physician pays Autonomous on a per-procedure basis. The procedure fee includes ongoing service, maintenance, and technology and software upgrades, such as Custom Cornea, as they become available. Awaiting FDA approval, the T-PRK system is being marketed exclusively outside of the U.S.

9/1 *EyeWorld Week* reports that Health Canada has granted **Staar Surgical** approval to begin clinical trials of its implantable contact lens (ICL) for the correction of myopia and hyperopia. The approval permits the entry of 500 myopic or hyperopic patients into studies set for Calgary and Toronto. This could eventually involve up to 20 Canadian surgeons at various sites throughout the country. In the U.S., Staar is currently in Phase 2 clinical trials.

Another item in the current EyeWorld discusses **Odyssey Optical Systems**, one of the companies founded by **Mile Creek Capital**. Odyssey is developing a compact, hand held, scanning laser ophthalmoscope, developed by John Marshall and Greg Heacock of England, which Mile Creek hopes to have on display at next month's AAO meeting and will begin shipping units in early 1998. The system employs a unique aspheric lens optical system combined with a diode laser to produce high resolution images of a patient's fundus. (I have had preliminary discussions with Mile Creek and John Marshall about the device (see the introduction to the June Executive Laser Briefing), and will obtain more information about the device at the Academy meeting.) The device will probably be priced under $10,000.

9/1 *Ocular Surgery News Intelligence Report* also had a very interesting item. According to the newsletter, an attorney for **Chiron Vision** has sent a letter to **Microtech**, the U.S. distributor for **Moria SA**, demanding that the companies "immediately cease and desist all advertising and sales of LASIK ONE microkeratomes in a manner intended to actively induce infringement of U.S. Patent 4,840,175", the Peyman patent assigned to Chiron. Apparently, Chiron is accusing Microtech and Moria of "inducing infringement", which is different than actually infringing the patent. Other microkeratome manufacturers and distributors contacted by OSN claimed not to have received similar letters or did not return phone calls by press time.

9/2 **LaserSight** announced it had completed the acquisition of the **IBM** UV light patents, for both ophthalmic and non-ophthalmic use. With the purchase of the patents (for a reported $16 million), LaserSight also acquired the license agreements with **Summit Technologies** and **VISX**, covering royalties due from the beginning of the year. (However, with laser sales flat, few, if any, of the 2% royalties on the sales of lasers

will be paid this year.) What the acquisition means is that any unlicensed company desiring to enter the U.S. (or other of the 12 countries where the patents are valid) will have to acquire a license from LaserSight -- as well as **Pillar Point Partners** for U.S. entry. **Autonomous Technologies** holds a separate license from IBM, as does **Aesculap-Meditec** and **Schwind**, **Coherent's** partner. Other potential licensees include **Nidek** and **Chiron Vision**, as well as any "black box" laser operators. (It is believed that these others may be paying IBM a per procedure fee in addition to machine sales royalties.)

The two patents covered by the acquisition are the original Blum patent, U.S. 4,784,135, "Far UV Surgical and Dental Procedures", and U.S. 4,925,523, the Braren patent, "Enhancement of UV Laser Ablation and Etching Organic Solids", an enhancement of the Blum patent. The Blum patent is issued in 13 countries, with the latest expiration date of 2005 (the U.S., Spain, and Canada); while the Braren patent has issued in five countries, with an expiration date of 2009 (4 countries) and 2008 (the U.S.).

LaserSight has previously stated that it was in negotiations with a non-ophthalmic healthcare company for the non-ophthalmic rights to the patents in the cardiovascular and vascular fields, reportedly for a $4 million upfront payment and ongoing royalties, according to the September 8th *Gray Sheet*. (See the 9/23 brief for the announcement of sale of the non-ophthalmic rights.)

9/2 **Gimbel Vision International** announced that it had purchased a 51% interest in **Sacramento Refractive Laser Associates**, based in Sacramento, CA. The acquisition became effective on September 1st, and was made for $270,000. Additionally, Gimbel will contribute cash of approximately $75,000 in the form of a shareholder's loan, to match working capital on August 31st. The center has been performing refractive surgery since January 1996 and uses a shared access model. According to company officials, Gimbel's physicians have performed over 18,000 refractive eye surgeries.

9/3 **Shoreline Pacific Institutional Finance**, the **Institutional Division of Financial West Group**, announced that it acted as placement agent for the private placement of $16 million of convertible preferred shares of **LaserSight**. The money was used for the acquisition of the **IBM** UV patent portfolio.

9/4 **Premier Laser Systems** announced that the formal vote by shareholders of **EyeSys Technologies** for the acquisition of the company by Premier, is scheduled for September 23rd. Premier expects the acquisition to be approved, and is planning to move EyeSys operations to Premier's headquarters in Irvine, CA. EyeSys reported revenues for the year ending December 31st of $8.1 million.

9/8 According to *The Gray Sheet*, **Pillar Point Partners** is the subject of an antitrust complaint being readied by the Federal Trade Commission. **Summit Technologies**

disclosed the fact in its second quarter financial report. Also according to the Gray Sheet item, FTC staffers have "invited the company to engage in negotiations regarding these matters" as reported by Summit. **VISX** did not disclose this information in its second quarter filings. The Gray Sheet goes on to state that, "The FTC investigator's position likely increases the chances that the Pillar Point arrangement between vision correction laser manufacturers Summit and VISX will be modified". The FTC investigation began in October 1995, on the Pillar Point arrangement which was formed in June 1992. The Gray Sheet also acknowledges that at least two physicians, Robert Burlingame and John Shephard, have antitrust suits pending against Pillar Point.

9/8 **Autonomous Technologies** said that it had begun U.S. clinical trials in hyperopia, including astigmatism. The FDA approved supplement to its IDE for the T-PRK laser allows for the treatment of up to +6 diopters of hyperopia and up to -6 diopters of astigmatism. Randy Frey, Autonomous chairman and CEO, believes that the hyperopia market is potentially large, with limited success achieved to date by other laser systems because of a greater visual sensitivity to decentered ablations and a tendency for regression of the correction. He is optimistic that the T-PRK system with a combination of eye tracking and narrow beam shaping algorithms will improve on both of those limitations. The company anticipates filing its PMA application for myopia and astigmatism by the end of this year.

9/8 **Gaines Berland** initiated coverage of **Laser Vision Centers** with a strong buy recommendation, based on FDA approval of its MobilExcimer program. The recently issued research note sets a 12-18 month share-price target of $12 to $15, from the currently trading price of about $7.50.

9/8 **KeraVision** reported that nearly half of nearsighted patients achieved better than 20/20 vision in the first reported results of its multi-center U.S. Phase III clinical trials with its intra corneal rings. The results, presented at the European Society of Cataract and Refractive Surgeons meeting in Prague, showed that 47% of 113 nearsighted patients achieved 20/20 vision, with 97% achieving 20/40 or better. The company plans to seek expansion of its U.S. Phase III clinical trials later this year, to treat more moderate nearsightedness, in the range of from -3.5 diopters to -5.0 diopters. KeraVision rings designed to treat both low and moderate myopia are already commercially available in Europe.

9/9 **LaserSight** announced today that it had acquired worldwide distribution rights to the Ruiz disposable microkeratome for performing LASIK. The device, was developed by Dr. Luis Antonio Ruiz and engineer Sergio Lenchig of Bogota, Columbia, also the developers of the **Chiron Vision** Automated Corneal Shaper microkeratome, the world's most widely used device for LASIK. The disposable microkeratome blades were designed to fit the ACS control console. According to LaserSight officials, current microkeratomes range in price from $35,000 to $65,000, with an additional per-use price of $50 to $175 for non-reusable components. The expected price for the

new disposable microkeratome is approximately $7500 for the optional control console and a per-use price of approximately $125 for the disposable component.

LaserSight expects to begin distribution of the microkeratome in the international marketplace through its current network of ophthalmic device distributors late this year or early next year. The device, which will be on exhibit at the upcoming AAO meeting in San Francisco, is subject to a 510(k) approval in the U.S., for which an application is in process. The company has entered into a limited exclusive license agreement with Dr. Ruiz and Mr. Lenchig for the U.S. Patent RE35421, and its foreign counterparts. According to the company news release, these patents represent intellectual property for microkeratome products believed to include those products currently distributed by Chiron. LaserSight and Chiron are the only licensees to this patent.

At closing, LaserSight paid $400,000 and agreed to supply at no cost one LaserScan LSX scanning excimer laser to Dr. Ruiz. Six months after shipment of the microkeratome begins, LaserSight will pay an additional $150,000, with another installment of $150,000 due 12 months after the initial shipment date. LaserSight will share equally in the gross profit with the licensors, with minimum quarterly royalties of $400,000 beginning six months after the initial shipment date. Gross profit is defined as the selling price less certain costs of goods and sales.

(As a further note of interest, a LaserSight official has told me that the company has retained renowned refractive surgery teacher, Dr. Charles Casebeer, to head up its LASIK training efforts for the Ruiz microkeratome, and that both Casebeer and Dr. Ruiz will be lecturing at the company's booth during the AAO meeting next month.)

9/10 **VISX** said that the FDA had accepted for filing its PMA submission requesting approval to treat moderate to severe myopia of -6.00 D to -12.00 D, with up to -4.00 D of astigmatism. The submission has been granted expedited review. Upon approval, all Star lasers in the field will be capable of performing the expanded treatments with just a simple software modification.

9/10 **Sight Resource** announced that it had signed a non-binding letter of intent with **The Carlyle Group**, a Washington, DC based investment group, pursuant to which affiliates of the Carlyle Group would make a minority equity investment in the company. The relationship is expected to provide the company with additional capital to continue implementation of its plans for consolidating primary eye care chains. The transaction is expected to be completed within 30 days.

9/10 According to the September issue of *Refractive Market Prospectives*, **Physicians Resource Group** has reported spending $724,000 in legal fees challenging the **Pillar Point Partners** per-procedure fees. PRG is said to have 24 excimer lasers in operation, and thus, has much at stake.

The newsletter also contains an interesting story about the battle being waged over LASIK patents and microkeratomes. Apparently, **VISX** believes that the Peyman patent claims may be covered by the Warner U.S. 4,903,695 patent in the Pillar Point Partners portfolio, that was granted in February 1990, approximately eight months after the Peyman patent. The Warner patent describes the process of creating a flap and treating the underlying stroma, while the Peyman patent discusses a cap creation and the treating of the cap's interior surface.

The newsletter also says that many black box owners have stopped using their lasers and made arrangements to perform procedures on approved devices. At least two black box laser owners purchased VISX laser during August, and at least three others arranged to perform procedures on other community systems, or arranged for mobile lasers to be brought to their offices. Two others own multiple lasers and have shifted procedures to the approved systems, while other have applied for IDEs and are continuing to treat patients on their black box lasers under clinical protocols. Pillar Point is the obvious winner, with the shift to approved lasers and the reduction in procedures on unapproved systems. (I will have to adjust my projections to account for this shift. The projected total of about 250,000 procedures in 1997 still holds, but more procedures will likely be done on approved lasers than I had expected.)

9/10 **Premier Laser Systems** announced that **EyeSys Technologies**, which Premier will acquire after the September 23 vote of shareholders, has signed a six-year private label product development and manufacturing agreement with **Nidek, Inc.**. The agreement calls for Nidek to purchase and distribute on an exclusive basis worldwide, private labelled products designed for corneal topography and other advanced-technology ophthalmic applications. Under the agreement, Nidek must purchase at least $9.9 million in products over the six years to maintain distribution exclusivity. Nidek will pay an additional $1.8 million in licensing fees to EyeSys for certain technology distribution rights.

9/10 The September issue of *EyeWorld* has special coverage of refractive surgery, with a lead article on LASIK and a dialogue with leading surgeons about who should do LASIK. Two articles discuss custom lasers, the first, by Maxine Lipner, is entitled "Custom Lasers: End of an Era?" Maxine discusses the issues surrounding black box and gray box lasers and the recent FDA enforcement actions against both. The second piece is Michael Moretti's Laser Insight column, in which he talks about the FDA squeeze on renegade excimer laser users. (I have downloaded both articles from the EyeWorld web site and would be happy to share them with interested parties.)

9/12 **Laser Vision Centers** said that its same-site U.S. surgical case volume for August increased 455% over August a year ago, for the 21 lasers in operation at that time; while the August 1997 surgical volume was up 40% over July.

9/15 **Laser Vision Centers** reported first fiscal quarter results for the period ending July 31st, with revenues of $4.1 million, up 173% over the same period a year ago. The net

loss for the quarter was $1.5 million (18 cents/share), down from $2.3 million a year ago. Jack Klobnak, chairman and CEO said that he was pleased with the results, and that they justified the transition to a mobile strategy. He intends to increase its U.S. fleet by three lasers, adding one fixed and two mobile units, which should be operational by the end of the week. LVC may add an additional laser during October, and the new additions should help satisfy LVC's growing demand and help make existing units become more efficient by compressing their service areas.

9/15 *EyeWorld Week* reports that three new microkeratomes were introduced at the Prague Society of Cataract and Refractive Surgeons' meeting. These were the disposable Ruiz design, just acquired by **LaserSight**; the disposable Flapmaker, sold by **Refractive Technologies**, and the pivoting action Hansatome, sold by **Chiron Vision**.

The September issue of *Argus: Ophthalmology World News* contains an interesting article by Julia Petrauskus about some new alternatives to microkeratomes, including the picosecond laser and the two waterjet technologies -- the Medjet system from **Medjet Inc.** and the Visijet system from **Visijet Inc.** The article also contains a box about Academy courses and discussions about microkeratomes that will take place during the upcoming AAO meeting.

9/16 **Gaines Berland** reaffirmed its strong buy recommendation for **Laser Vision Centers**, following its announcement of increased surgical volume for August and its revenues for the quarter ending July 31st.

9/19 **LCA-Vision** announced that in a move associated with the recent acquisition of the 25-unit **Summit Technology** laser eye surgery network, it will close approximately 10 of its 40 U.S. locations in order to concentrate on building profitability at the company's best performing sites. The company expects to take a one-time, third quarter charge of $1.1 million to cover costs of the closings. In a discussion with chairman Steve Joffe, I learned that both he and Ron Herskowitz were still discussing which sites to close, and that it would probably be a mix of both existing LCA sites and Summit sites. Joffe also noted that he expects the market for laser eye surgery to surge again with the anticipated FDA approval to treat hyperopia by the end of the year.

9/22 *EyeWorld Week* had more about the FTC recommended action against **Pillar Point**, as reported in **Summit Technology's** second quarter report. According to the news item, the FTC investigating staff invited Summit "to engage in negotiation regarding these matters." Although the company disagrees with the staff's analysis, it will participate in the negotiation and present its position "on the merits," according to a statement Summit released to EYEWORLD. "We are confident of our position and hopeful the FTC staff will be persuaded," the statement read.

A second item dealt with the FDA warning letter to Dr. Fred Kremer, about the alleged violations of his FDA study of his homemade laser for LASIK. Kremer

released a statement last Thursday (9/18), saying that "issues in the warning letter," which was dated Sept. 4, "are being successfully resolved." The warning letter charged Kremer with using the laser for indications not approved under his investigational device exemption; for using a "substitute component" that was not part of the IDE; for having an institutional review board whose composition, which included his wife and staff members, did not comply with FDA regulations; for treating more patients than allowed by his IDE; for misrepresenting the device as safe and effective while the safety and effectiveness were being investigated; and for promoting the device in a patient brochure, a radio commercial, print ads, a Web site and a billboard along I-95 in Philadelphia.

According to Kremer's released statement, since issuing the warning letter, the FDA "has increased the number of patients we can treat under the IDE, allowing patient treatment to continue." The Kremer center "disagrees with many of the allegations in the warning letter," but continues "to work with FDA toward obtaining approval of the pending premarket approval application...We do not expect the warning letter to have any impact on obtaining PMA approval of the laser or on the ongoing clinical study."

9/22 *Dow Jones* reported that **Sight Resource's** stock rose 11% as investor interest strengthened following the announcement of **The Carlyle Group's** investment and anticipation of the company's first profitable quarter since going public. In a followup report, Dow Jones said that the stock was also boosted by a positive *New York Post* article hailing the Carlyle investment as a "jump start" that could trigger institutional investor interest in Sight Resource. Analyst Alan Ackerman of **Fahnstock & Co.** was quoted as saying that the investment was an endorsement of the company's consolidation strategy within the eyecare industry, and its move toward profitability.

9/23 **VISX** announced the end of its laser trade-in program. In a news release, the company said that the program will end on December 1st, for **Summit Technology** laser owners and for owners of unapproved laser systems. In the release, VISX noted that **TLC The Laser Center** had taken advantage of the program with the acquisition of five Star lasers, and that a number of black box laser owners had replaced their unapproved systems for Stars.

9/23 The *Academy of Ophthalmology* checked in with a statement supporting the FDA's position on black box lasers, stating that the AAO believes "the use of an excimer laser for refractive surgery is appropriate only if the use of the particular device is expressly permitted under federal law, or the device is being operated under an IDE. Lasers not approved by the FDA should not be used in the U.S."

9/23 **LaserSight** announced it had received a one-time lump sum payment of $4 million from a third party in exchange for an exclusive worldwide royalty-free patent license, covering the vascular and cardiovascular rights included in the patents acquired earlier this month from **IBM**. The company would not identify the acquiring party, which they previously had called "a Fortune 500 healthcare company". I speculate that the

acquiror is either **US Surgical** or **Baxter Healthcare**, both of whom have excimer laser development programs underway in the cardiovascular field. (See the US Surgical developments at the end of the Medical/Surgical section of this newsletter!)

9/23-
9/24 In a pair of announcements, **Gimbel Vision International** and **Beacon Eye Institute** announced that Gimbel had sold its 51% interest in **Gimbel Eye Centre-Toronto** to **D.E.W. Healthcare Consultants**, concluding their joint venture relationship. Gimbel said it intended to establish a wholly owned Gimbel Eye Centre in Toronto within the next 90 to 120 days, retaining the rights to the "Gimbel Eye Centre" name and trademarks. Until the new facility is opened, Gimbel has made arrangements to continue to perform eye surgery at an existing practice.

The following day, Beacon announced completion of the acquisition of the laser eye care center which formerly operated at the Gimbel Eye Centre-Toronto. The purchase, apparently from D.E.W. Healthcare Consultants, included a cash payment of $150,000, issuance of BeaconEye stock with a value of approximately $400,000, repayment of shareholder advances totalling $723,000, and assumption of financing obligations of approximately $650,000. Keith Moore, Beacon chairman, commented, "The acquisition...was made possible following the breakup of the founding partnership."

9/24 **Laser Vision Centers** announced that they had added four excimer lasers to its U.S. fleet, bringing the total to 21 systems, serving 80 locations. Two of the new lasers are in fixed locations, while the other two are mobile units. Three of the lasers were financed through Heartland Bank of St. Louis, and the other was purchased from existing cash. The company also announced that it had received $727,000 from the exercise of options and warrants, and expects to receive $838,000 in additional financing next week from TransAmerica Business Credit Corporation's Technology Finance Division.

9/25 The *Society for Excellence in Eyecare* said that it had filed comments with the FTC in connection with its anti-competitive investigation of **Pillar Point Partners**. SEEC believes that the conduct of **Summit Technology** and **VISX** through Pillar Point is having a deleterious impact on refractive surgeons and their patients from an economic and access to care standpoint. In the letter sent to the FTC commissioners SEEC points out that the $250 per procedure "price fixing arrangement" represents $50 million+ per year added to laser vision correction and ophthalmologists in particular. With the $500 per patient (two eyes) royalty, in addition to the $400,000+ laser acquisition price, and maintenance of $30,000 to $57,000, many ophthalmologists are unable to offer PRK or LASIK to Americans who would benefit from this surgery. The letter urges the FTC to take a close look at the $250 fee and its impact.

9/26 **Paradigm Medical Industries** announced that it had received FDA approval of a tonometer/ocular blood flow analyzer and that software and hardware problems associated with its Precisionist Thirty Thousand ultrasonic phacoemulsifier have been corrected and shipments resumed as of September 18th. The company also said that it had engaged **Win Capital Corporation** to serve as its investment banker.

9/29 *EyeWorld Week* reports that the number of FDA seizures of "illegal" lasers continues to mount. Following the July 2nd seizure of Trevor Woodhams' laser, others have included the Neumann Eye Institute of Deland, FL (Aug. 28), and the St. George Corrective Vision Center of Chicago (Sept. 2). The newsletter said that at least three additional warning letters, to Ralph Berkeley of Houston; David Dulaney of Phoenix; and Frederic Kremer of King of Prussia, all of whom were operating under IDEs.

9/29 **QLT PhotoTherapeutics** said that it and **Ciba Vision** had exceeded their objective of recruiting 540 patients for participation in two Phase III clinical trials using QLT's photosensitizer vertoporfin (BPD) as a treatment for age-related macular degeneration (ARMD). The clinical trials, randomized, placebo-controlled and double-masked, are under way at 22 sites throughout Canada, the U.S., and Europe. QLT and Ciba expect to file an NDA for the drug in 1999.

**OPHTHALMIC LASER UPDATE -- OCTOBER 1997**

9/22 **ClearVision Laser Centers** said that it had reached a milestone, celebrating the 10,000th laser vision correction procedure done on U.S. patients. ClearVision has member doctors in over 60 Colorado, Michigan, Tennessee, Utah, and Washington state communities.

9/29 In another announcement, **ClearVision Laser Centers** said that it had implemented its Multi-Site Single Laser (MSSL) program, with the development of a moveable transport system to bring laser vision correction to rural areas which could not support a full time laser center. The specially designed trailer is hauled by a technician/driver trained by the laser manufacturer to provide maintenance and service to the laser. Upon arriving at each location, the laser is fully tested and recalibrated, if necessary. A specialized laser skid was developed to allow movement of the laser and provide for laser isolation as it is transported from the independent motor transport vehicle, to the surgery suite. The MSSL system has been operational in Central Michigan since June. The same system has made several trips to Harrisburg, PA to provide laser service to doctors who lost access to a laser when another laser service provider ceased operations.

The company plans to have 3 MSSL units in operation by November 1st: one in Michigan; another in the Southeastern part of the U.S., around Nashville, Tennessee; and the third in northern Colorado. Ten additional mobile units are planned for 1998. All of the current and future lasers are/will be **VISX** Star systems.

9/29 This week's *Gray Sheet* reviews the proposed draft IDE guidance for refractive lasers that will be discussed at the October 21st meeting of the FDA's ophthalmic device review panel. Of note, the guidance states that refractive lasers used to treat high myopia should provide uncorrected visual acuity of 20/40 or better in at least 75% of postoperative eyes; for hyperopia (with or without astigmatism) the target UCVA of 20/40 cited is 85%! The guidance also recommends that 90% of eyes treated for high myopia should achieve predictability (attempted versus achieved) of the manifest refraction spherical equivalent of ±2.00 diopters, with sixty percent of eyes achieving ±1.00 diopters. For hyperopia, the target is 75% of eyes to achieve ±1.00 D, and 50% to achieve ±0.50 D.

9/30 **LaserSight** announced that it would redeem approximately 19% of the convertible preferred shares that had been issued to finance the purchase of the **IBM** patents in August. The company planned to use approximately 80% of the $4 million received in the sale of the vascular and cardiovascular rights. The redemption is scheduled for October 28th. The company said it was in discussions with other potential licensees, but did not name them.

10/1 **Premier Laser Systems** announced that it had completed the acquisition of **EyeSys Technologies**, the developer of corneal topography systems, with over 3500 units installed. The move reflects Premier's strategy to seek near-term expansion into the ophthalmic marketplace. The final acquisition price rose about $1.4 million over the previously announced $10.6 million, due to the enhancement of EyeSys by its recently reported license agreements with **Nidek, Inc.** and **Marco Technologies** (see the September 10th brief in last month's newsletter). Premier intends to close the EyeSys Houston facility, and move the operation to Irvine.

10/2 **Escalon Medical Corporation** reported results for its fiscal fourth quarter, ending June 30th. The company had revenues of $1.3 million for the quarter and a net loss of $4.3 million (41 cents/share). For the fiscal year, the company had revenues of $5.4 million, up from $2.3 million for the previous year. The net loss was $5.7 million compared to $4.1 million for fiscal 1996. Commenting on the company's strategic direction, Richard DePiano, chairman and CEO said that "Escalon's management team has spent time examining the diverse parts of its business...as a result...we have decided to discontinue funding our laser business, which has historically demanded a significant portion of our cash resources...we are currently negotiating a joint venture arrangement, in which the company, along with a well regarded university, would license the intellectual laser properties to a newly formed company in return for an equity interest in the new company and future royalties on product sales." (For those not familiar with Escalon's laser program, the laser technology referred to is the picosecond laser, originally developed by **Intelligent Laser Systems**, which was acquired in a reverse acquisition with Escalon.)

10/3 **Gimbel Vision International** announced that it had filed a preliminary prospectus in the provinces of Alberta and Ontario, to qualify the distribution of 1.36 million units

at $1.25 per unit. Each unit consists of one common share and one-half common share warrant, of which a whole warrant entitles the holder to purchase a common share at $1.75 until August 26, 1998.

10/6 *EyeWorld Week* reported that the Society for the Advancement of Laser Technology (SALT) lamented the recent AAO statement opposing the use of unapproved excimer lasers. SALT president Robert Dotson, MD, wrote to EyeWorld Week that, "It is clear that the power-to-be will do all within their power to uphold the monopoly enjoyed by VISX and Summit."

*OSN Intelligence Report* noted that **CRS-USA** had received approval to expand its IDE study of LASIK, to include hyperopic correction of 1 to 4 diopters, with up to 1 D of astigmatism, but cannot treat the cylinder. The FDA approved the treatment of 4000 eyes at 40 sites for the new phase, which will be divided equally between users of Summit and VISX laser systems. To be eligible for the study, surgeons must have satisfactorily completed two previous phases in the CRS IDE, treating low myopia and myopia with astigmatism. Surgeons using the Summit Apex Plus laser can start as soon as their ablation masks are released, while VISX users will require a machine upgrade, which is expected to happen in January. Twenty Summit sites have been enrolled, while several VISX sites are still open.

10/6 **Miravant** announced that it was awarded $1.2 million in two NIH Grants for testing its light-activated compounds: the first grant is designed to obtain information on new photosensitizers that have shown promise in early studies in treating cancer and in ophthalmology; while the second will fund research in PhotoPoint (Purlytin --SnET2) for treating age-related macular degeneration. The first study will be performed at Miravant's Santa Barbara labs, and at Massachusetts General Hospital in Boston. The second grant funds further research of PhotoPoint for choroidal neovascularization, which will take place at the Louisiana State University Eye Center in New Orleans.

10/6 This month's issue of *Refractive Market Perspectives* includes some of the results of **VISX's** analysis of the demographics of over 4000 patients presenting for PRK. According to analysis, 80% of patients are between the age of 30 and 50, with an average age of 39. There is a slightly higher percentage of females to males, with 55% women and 45% males, contrasting with the normal contact lens distribution, which indicates that some 60% of wearers are females.

10/8 **Sunrise Technologies International** announced that it had received conditional approval from the FDA to treat presbyopic patients in a new clinical trial. The investigation will be a substudy of the ongoing primary hyperopia study, and will include 60 patients at 4 sites. In the new study, patients 40 years or older will be sought with refractions between +0.75 to -0.25 diopters, and the procedure will consist of treatment of one eye, resulting in a modified monovision, with the treated eye seeing near, and the untreated eye being used for distance vision. Prior to laser treatment, patients will be fitted with a trial set of soft contact lenses to ensure that

they tolerate monovision. The four sites participating in the substudy include the Aker-Kasten Cataract and Laser Institute in Boca Raton, FL; the Eye Centers of Florida in Fort Myers; the Baylor College of Medicine-Cullen Eye Institute in Houston; and the Doheny Eye Institute in Los Angeles.

10/8 Some of the more interesting articles from the October issue of *Eyeworld*: Leslie Sabbagh continued with her interview of PRK thought leaders, asking questions like; does PRK deserve its lead over LASIK, and what about LASIK? The panel's consensus was that PRK was still delivering better results for low to moderate myopia, but that LASIK was preferred for higher corrections, over -6 diopters. Marilyn Haddril writes about RK: Dead, dying and deserving it? Most of the physicians she interviewed felt that the outlook for RK was grim and that the increasing popularity of laser procedures may put an end to RK over the next few decades, although modern techniques were acceptable for lower myopia. Marilyn also writes about the new leadership at **Summit Technology** in her article, "Eye on Industry: New leadership, new approaches at Summit. And finally, Mike Moretti comments about the shuffle for control of the LASIK revenue stream with the patent battle between **Pillar Point**, **Chiron Vision**, and now, **LaserSight**, with its recent acquisitions of both the Kremer and Ruiz patents.

10/9 The American Academy of Ophthalmology has adopted "eyeMD" as a consumer name for ophthalmologists, and is urging its 16,000 members to begin using the term. Its use is meant to reinforce the public's knowledge that ophthalmologists are medical doctors. The concept will be introduced by Dr. Dunbar Hoskins in his address to the Academy on October 27th.

10/13 According to brief posted on the *Market Scope* news briefs, **Summit Technologies** expects to receive an "approvable" letter from the FDA for the treatment of astigmatism. The company believes that the request is being reviewed directly by the FDA, bypassing the Ophthalmic Device Panel for review.

10/13 According to this week's *EyeWorld Week*, the FDA has approved **Innovative Optics** lightweight (12 gram) microkeratome with a sapphire crystal blade, designed specifically for LASIK. The Innovatome was designed with input from several high-volume LASIK surgeons, including George Waring of Atlanta. Innovative Optics plans to launch the microkeratome at this month's AAO meeting, at a list price of $49,500 in the U.S.

According to Innovative, quoting Mike Moretti of *Medical Laser Insight*, the LASIK market is expanding rapidly with an estimated 350,000 procedures performed this year and a 20% annual growth rate. Apparently Mike has authored a report on the LASIK market that reports that more than 4000 refractive surgeons will purchase new microkeratomes over the next 3 years, and that the disposable blade market is estimated to be 450,000 units annually by the year 2000. (For more information about Mike's LASIK report, he can be reached at 714-830-5409.)

10/13 A favorable report written by analyst Michael Lachman of **Hambrecht & Quist** boosted **VISX's** stock price by nearly 40% according to the September 29th *Gray Sheet*, as reported in this week's *OSN Intelligence Report*. Lachman's report states that he believes that **Pillar Point** revenues will surpass equipment sales, possibly this quarter. (However, as noted below, in VISX's quarterly report, this didn't happen, but probably will occur next quarter.) Lachman is looking for VISX to have revenues of $67.8 million this year, and top $83 million next year. (I have a copy of the report for anyone who wishes to see it.)

10/13 The *AOA News* has a lengthy story about John Taboada's claims to be the inventor of the use of the excimer laser for refractive surgery, and that his name should have been on Steve Trokel's patents. (In asking Trokel about this at the AAO meeting, I was told that he has no recollection of ever promising Taboada that his name would be on the patents.) The same issue of the AOA News also relates the various legal battles ongoing between **Pillar Point** and the **FTC** and **Barnet Dulaney** (the latter being funded by **Physicians Resouce Group**).

10/14 **Laser Vision Centers** reported on their U.S. surgical volume for September. For the same 21 centers in operation last year, the volume increased 436% over last September, and increased 9% over August of this year, the company's previous best month. According to chairman and CEO Jack Klobnak, the company is ahead of its business plan objectives for the 1998 fiscal year and on track to reach its goal of profitability in the fiscal fourth quarter. The company now operates 86 sites in the U.S., up from 77 last month. LVC cautions that it may experience lower case volume in October and December because of the upcoming AAO meeting, which many of the LVC surgeons will be attending, and the December holiday season which may result in a slowing of surgeries.

10/14 **Sight Resource Corporation** announced that it had signed a definitive purchase agreement for the sale of approximately $5 million of its Series B Convertible Preferred Stock and warrants to the **Carlyle Group**. The transaction is expected to close within 45 days. The investment is expected to accelerate opportunities for consolidating primary eye care chains and enhancing shareholder value, according to president Bill McClendon.

10/14 **TLC The Laser Center** released its fiscal first quarter results, for the period ending August 31, 1997. Gross revenues were $20.6 million, up 253% over last years same quarter, with net revenues of $13.8 million. TLC performed 6100 paid refractive procedures in the quarter, compared to 1600 a year ago. The net loss for the quarter was $3.7 million (14 cents/share), including $2.7 million in amortization and $1.6 million in development and startup costs.

10/15 **VISX** released its third quarter results, showing revenues of $18 million and net income of $5.1 million (32 cents/share). Revenues for the nine month period were $49.3 million, with net income of $7.1 million (45 cents/share). The settlement in

June with **Summit Technology**, resulting in a payment of $4.5 million to Summit, effected net income by reducing it $0.25 per share during the nine month period.

The company reported $9.2 million in equipment sales and $8.8 million in royalties and service income. During the teleconference accompanying the release of the quarterly results, one analyst suggested that $6.6 million of the $8.8 million was attributed to Pillar Point receipts, and management said that was in the ballpark. The analyst also noted that for the previous two quarters he estimated that $3.6 million and $5.3 million was collected from Pillar Point for the first and second quarters. Chairman Mark Logan acknowledged that he expected service revenues to also increase beginning over the next few quarters as many of the lasers sold over the previous year come off of warranty. Management also noted that U.S. procedure volume was still in line to reach 200,000 this year. Logan noted that six unapproved laser users converted to Star systems during the quarter, showing that the FDA enforcement program was having positive results for the company.

10/16 **KeraVision** released its third quarter results, showing net revenues of $91,000 from its European sales of the ICR. According to the company, revenues were concentrated in France and Germany, where the long summer holiday season slowed the company's entry into the market. Revenues in the second quarter were $114,000. Net losses for the quarter were $4.6 million (36 cents/share). Market development activities in Europe and increased support for U.S. clinical trials contributed to the increase in losses over the same quarter last year. The latest results of the clinical trials will be presented at this month's AAO meeting in San Francisco. KeraVision intends to submit its PMA for the treatment of mild nearsightedness (-1.0 to -3.5 diopters), a range that effects about 22 million Americans, next year. A KeraVision Ring for moderate myopia (-3.5 to -5.0 diopters) is in Phase II trials.

10/16 **Iridex** reported its third quarter results with sales of $4.6 million and net income of $596,000 (9 cents/share). For the nine month period, sales were $12.3 million and net income was $1.3 million (19 cents/share).

10/17 *Dow Jones News Service* reports on some interesting developments at **BeaconEye**. In a series of releases, DJ quotes Beacon president and CEO Keith Moore as stating that he expects consolidation in the North American laser eye surgery industry. On October 9, Beacon apparently announced that it had hired **CIBC Wood Gundy** to explore options to maximize shareholder value, including the options of new financing, a merger or acquisition, or the sale of the company. Moore noted that there were two types of potential partners, a competitor or another investor, likely a health-care company with deep pockets and an interest in entering the "relatively young" laser eye surgery sector. Moore said that the major players in the sector included **Laser Vision Centers**, **LCA-Vision**, **TLC The Laser Center**, and **Physicians Resource Group**, which provides physician practice management services, rather than operating laser eye surgery centers. John McIlveen, an analyst with **Scotia Capital**

**Markets** in Toronto, mentioned a couple of other public laser eye surgery companies that might be interested: **Sight Resource Corp.**, and **Gimble Vision International**.

Elias Vamvakas, chairman and CEO of TLC The Laser Center, doesn't appear to be interested. "They've done some things that I think have really hurt their business and I'm not sure how attractive they are because of that...they've had some moves of desperation, like lowering prices and that kind of stuff ruins the market, so I think they're making themselves less attractive." He went on to say that there had not been any talks between the two companies. He sees more potential in consolidation with individual private doctor practices, which, he estimates, make up about 75% of the market. (Our survey, conducted in August, indicated that private practices made up about 50% of the market; with laser centers doing the rest of the volume.) Vamvakas believes that his company has about a 15% share of the North American market, and expects TLC to be profitable in 1998. (TLC operates 34 clinics, including the 8 **20/20 Laser Centers** it acquired last February. The company is planning an additional 11 clinics.)

BeaconEye operates 11 clinics, two of them in Canada. In September the company completed the acquisition of a clinic in Thornhill, Ontario; the other Canadian clinic is in Toronto. In its first six months this year, BeaconEye lost C$11.1 million on revenues of C$5.2 million. McIlveen noted that the company could run out of cash in the first quarter of fiscal 1998, but said that many positive changes could occur before that time arrives. He sees evidence that BeaconEye is performing more surgeries, about 152 a week system-wide, not including the new Canadian facility in Thornhill, up from about 106 in June. However, the top U.S. BeaconEye clinics are only doing about 90 to 100 procedures per month, compared to about 225 at its Toronto clinic. McIlveen went on to say that 90 or 100 surgeries per month were needed to cover overhead, while to break even, the company needed to perform 160 surgeries per clinic in the U.S., while the Toronto facility had to maintain its 225 rate.

Moore went on to say that BeaconEye had changed its focus from mass consumer advertising to concentrating on doctor referrals. He said that the number of procedures will show an increase in the third quarter, which would be reported in a few weeks. Moore felt that the increase was because of the company's ability to offer LASIK as well as PRK in its U.S. clinics.

10/20 *OSN Intelligence Report* said that the FDA had seized additional custom-built excimer lasers. One **Photon Data** laser was seized from a Miami freight forwarder, while another was taken from the Chicago office of ophthalmologist Nicholas Caro. A third laser was seized at the Neumann Eye Institute in Orlando, FL.

*EyeWorld Week* reports that **SALT** members have voluntarily removed the 10 imported excimer lasers owned by them from service. SALT had agreed to do that earlier with the FDA. President Robert Dotson said, "SALT still disagrees with the FDA's handling of this entire issue and firmly believes that the agency has

overstepped its authority. In spite of lack of support from any of the large groups representing ophthalmology, we are fully prepared to take this battle into the courts should the agency continue its unprecedented -- and unconstitutional -- interference in the practice of medicine."

Another interesting note from EyeWorld, at a recent instructional course for the **Coherent** EpiLaser (the laser from **Palomar Medical Technologies**, now distributed by Coherent), designed for hair removal, a third of the attendees were ophthalmologists, according to an industry source. However, the source was wrong -- as the deal between Coherent and Palomar has yet to be completed, and any training course had to be run by Palomar!

10/21 **Medjet, Inc.** announced that it will introduce two fluid microjet based surgical devices at the AAO and ISRS meetings this week in San Francisco. The two are the company's HydroBrush and the HydroBlade Keratomes. The new tools are alternatives to the scalpel and the laser for removing surface epithelial layers and of the cornea, and for producing the hinged corneal flap for LASIK.

10/21 **Autonomous Technologies** announced that it had received notification from the FDA that its PMA on myopia of up to -10 diopters had been accepted for filing. This means that the FDA had completed its initial review and has determined that the filing is sufficiently complete to permit a substantive review. The PMA includes the data from both domestic and foreign studies on more than 550 eyes with up to 12 months of follow up. All surgeries were performed on the newly renamed LadarVision System, formerly called the T-PRK System. Early results for astigmatism correction were also submitted and further followup will be provided in an amendment to the PMA within the next several weeks. The astigmatism protocol involves cylinder correction up to -6 with the -10 diopters of sphere.

The company also reported that it received approval to begin U.S. clinical trials on LASIK up to -15 diopters of myopia, with up to -6 diopters of astigmatism, for a maximum spherical equivalent of -15 diopters. This study will be headed by Dr. Marguerite McDonald, who performed the first three cases using the **Chiron** Automated Corneal Shaper (ACS) and reported good early results.

10/21 In a surprise announcement, **Bausch & Lomb** and **Chiron Corporation** said they had signed a definitive agreement in which B&L would acquire **Chiron Vision** for $300 million in cash. B&L, a leader in the soft and gas permeable contact lens and premium sunglass arenas, and a strong force in ophthalmic pharmaceuticals, will re-enter the ophthalmic laser business and become an immediate force in refractive surgery via Chiron's strong franchise in microkeratomes for LASIK and its excimer laser program; become a player in the cataract market with Chiron's IOLs, cataract instruments, and viscoelastics; and will add the Vitasert Implant drug delivery system for the treatment of cytomegalovirus retinitis (CMVB) to its pharmaceutical line. Chiron, based in Claremont, CA, reported annual sales in 1996 of $211 million. The

acquisition is expected to have little impact on B&L's 1998 earnings, and should contribute to the company's financial performance thereafter.

Completion of the transaction, subject to regulatory approval, is expected to close early in 1998. B&L said it expects that Chiron's business will continue to operate from its current locations and under its present management.

For those of you with good memories, B&L was in the ophthalmic laser business briefly in the mid-1980s. The company acquired **Synemed**, which distributed **Biophysic Medical's** (a subsidiary of **Synthelabo** of France) ophthalmic lasers (argon, dye, and YAGs) from about 1983 to 1986, when B&L folded Synemed.

10/22 In a second surprise announcement, **Bausch & Lomb** and **American Home Products** announced today that they had signed a definitive agreement for the sale of AHP's **Storz Instrument Company** and affiliated companies (?) and certain assets relating to the Storz business for $380 million in cash. This transaction is also subject to governmental approvals and **the closing of the acquisition by B&L of Chiron Vision**. (I can't begin to guess the reason for that condition!) Storz, based in St. Louis, develops, manufactures, and markets a wide range of ophthalmic surgical products including intraocular lenses (competing with Chiron Vision), hand-held surgery equipment, diagnostic and cataract equipment and disposables, and pharmaceutical products including ocular vitamins. 1996 sales for the acquired Storz product lines were approximately $200 million.

According to B&L president and CEO William Carpenter, "We are bringing together two strong eye care companies...which combine to generate substantial strategic and financial synergies and provide powerful opportunities for leveraging their core capabilities...the combination of the two will create a strong competitive presence for B&L in the cataract surgery market; (provide) significant enhancements to B&L's existing pharmaceutical business... (and) a leadership position in the high-growth refractive surgery market, which completes the B&L continuum of product offerings for `in eye' vision correction, from cosmetic and specialty contact lenses through leading-edge laser surgical procedures." He went on to say that, "These acquisitions put B&L well on the way to realizing our corporate vision of becoming Number One in the Eyes of the World."

The combination of the two acquisitions is expected to have no financial impact on B&L's 1998 earnings, but should contribute to the company's financial results thereafter, especially as synergies are realized. This closing is also expected in early 1998, following the closing of the Chiron deal, and that both management teams will continue to operate from their respective locations. Over the longer term, the leaders of the two units will work together to develop a plan to maximize the growth and earnings potential of their cataract and refractive businesses.

According to the *AP*, the combined companies will drive B&L's sales above $2 billion, in the $25 billion global eye-care industry, pushing **Alcon Laboratories**, the subsidiary of **Nestle SA**, into second place, with about $1.8 million in revenues, followed by **Ciba Vision**, **Essilor** (the manufacturer of eyeglasses and the owner of **Lenscrafters**, the leader in the retail optical market), and **Allergan**. (No mention was made of **Johnson & Johnson**, the owner of both **Vistakon** (disposable contact lenses) and **Innotech**, producer of in-office eyeglass lenses.)

The following day, **Standard & Poor** placed B&L on its credit watch, stating that "although B&L maintains important global positions in diverse eye-care businesses, and the acquisitions further diversify the company's operations within the eye-care industry, marking an aggressive entrance into the high margin cataract and high-growth refractive surgery businesses, it concomitantly weakens B&L's financial flexibility".

10/21 *The Wall Street Journal* contains an interesting story about Julia Levy, president and CEO of **QLT PhotoTherapeutics**, and how watching her mother suffering from age-related macular degeneration (AMD), started her thinking about using one of her photosensitive drugs (BPD or bensoporphyrin derivative) to treat the disease. Encouraged by researchers at **Harvard University** and the **Massachusetts Eye & Ear Infirmary**, QLT teamed up with **Ciba Vision**, to develop a protocol for treating AMD using photodynamic therapy with BPD, now in Phase III clinical trials.

10/22 **The Boston Group** initiated coverage of **Sterling Vision** with a strong speculative buy rating. In his research note, analyst David Messer said he expects Sterling to earn 8 cents/share in 1997 and 45 cents in 1998. He also set a share target price of $10, up from its current trading at 7 3/8.

10/22 **Sunrise Technologies** received conditional approval from the FDA to retreat patients in the LTK clinical study for hyperopia on an as needed basis. The protocol approved consists of an initial study of 10 patients. Sunrise may request expansion of that number once the results from the initial ten are obtained. Retreatment with the non-contact simultaneous approach could be advantageous in a small number of cases. Since the study began in August 1996, utilizing the new treatment parameters and nomograms, three patients could have benefitted from retreatment.

10/22 The **FDA** released a "Talk Paper" updating its actions against unapproved excimer lasers. Basically, the paper reviewed the actions that the agency had taken against **Photon Data**; the **Woodhams Eye Clinic** in Atlanta; the **Neumann Eye Institute** of Deland, FL; **Pro Cargo** of Miami (Photon Data's shipper); and the **St. George Corrective Vision Center**, the Photon Data laser in Dr. Nicholas Caro's office. The paper went on to state that the FDA had issued 24 warning letters over the past three years and was continuing to investigate illegal activities and plans to take additional enforcement actions. It further warned consumers considering laser surgery for

nearsightedness to ask their doctors if the laser being used was either from **Summit Technology** or **VISX**, or was part of an FDA-sanctioned clinical study.

10/24 **Autonomous Technologies** announced updated results of its clinical studies on its newly named LadarVision system, formerly known as the T-PRK system. The news release summarized the results that were presented at the ISRS/RSIG pre-AAO meetings in San Francisco. The U.S. Phase III study on up to -10 diopters of myopia, included 467 eyes of 395 patients from six clinical sites. The six-month multicenter results of 187 eyes showed 72% having 20/20 uncorrected visual acuity (UCVA); 96% having 20/40+; 85% within ±0.5 diopters; and no patients losing more than 2 lines of BSCVA (best spectacle corrected visual acuity). The twelve month foreign study data on 102 eyes showed 70% 20/20; 99% 20/20+; 75% ±0.5 diopters; and no loss of more than 2 lines. For myopic astigmatism on 211 eyes, three month data showed 76% at 20/25+; 91% at 20/40+; and 75% within ±0.5 diopters of intended correction.

10/24 **Premier Laser Systems** announced that it would introduce seven new ophthalmic products and/or procedures at the AAO meeting through its **EyeSys.Premier** and **Data.Site** business units. The products EyeSys.Premier introductions include its Centauri erbium:YAG laser system capable of multiple surgical procedures -- including cataract emulsification and cosmetic skin procedures; its innovative Vista hand-held corneal topography instrument; a portable phacoemulsification system, while Data.Site would introduce a unique software program for office-to-database comparisons of individual surgical outcomes with national averages.

10/27 *EyeWorld Week* reports that **Chiron Vision** has confirmed an increasing number of its "180 plates", which allow the ACS to make a thicker, 180 micron cut for lower degrees of myopia, are being used around the world.

10/27 **Sunrise Technologies** announced that its board of directors had adopted a stockholders rights agreement to protect the company against possible unfriendly acquisition activity. The company is unaware of any such activity.

10/27 **Chiron Corporation** reported its third quarter results and noted that its **Chiron Vision** subsidiary, which is about to be acquired by **Bausch & Lomb**, contributed to the net loss of the corporation for the quarter of $13 million. The subsidiary results were not separately broken out, but it is generally believed that Chiron Vision is not profitable.

10/28 David Hwang, associate professor of ophthalmology at **The University of California/San Francisco**, and principal investigator of the FDA Phase III clinical trial of the **Nidek** excimer laser, reported on preliminary results of the national multicenter clinical trial of moderate myopia with astigmatism at the AAO meeting, stating that 91% of 148 patients achieved 20/40 or better.

Nidek announced at the AAO meeting that it had filed its myopic PMA, following close on the heels of **Autonomous Technologies**, whose PMA filing was accepted by the FDA earlier in the month.

10/29 **Sight Resource Corporation** reported its first profitable quarter, with revenues reaching $12.7 million, an increase of 30% over the same quarter last year. The company had net income of $78,000 (1 cent/share), compared to a net loss of $594,000 last year. For the nine month period, the company had revenues of $33.1 million and a net loss of $515,000 (6 cents/share). The company president, Bill McLendon, said he expects to reach sustainable profitability in 1998.

**OPHTHALMIC LASER UPDATE -- NOVEMBER 1997**

10/20 In a Dear Friend letter, **LCA-Vision** described how it fit into the laser vision correction industry that continues to gain momentum and grow. The company became the nation's largest corporately-operated network of free-standing and university-based laser eye surgery centers with its recent acquisition of the **Summit Vision Centers**. That acquisition has been successfully consolidated, leaving the company with over 30 top-performing sites in the U.S., two in Canada, and one in Europe. To date, more than 20,000 laser eye surgery procedures have been performed at the centers in the LCA-Vision network; nearly 600 trained and credentialed ophthalmologists and nearly 800 referring optometrists are affiliated with the centers.

In line with projections, consistent patient growth is occurring at virtually every one of the facilities, and the company intends to focus its resources on increasing patient volume at existing facilities before rolling out additional centers. In addition, the universe of patients eligible for laser eye surgery continues to expand. FDA approval for treatment of astigmatism using Summit equipment appears imminent, while the VISX laser was approved in April, and the green light for hyperopia should come in early 1998. That means that at least 150 million Americans who require vision correction will be potential candidates for laser eye surgery.

Included with the letter was a recent (October 16, 1997) analyst report by Jane Freedman of *J. Freedman & Associates* on LCA-Vision. Ms. Freedman notes that LCA was one of the first to consolidate in this multibillion dollar industry (forgetting, for the moment about **TLC The Laser Center's** acquisition of **20/20 Vision Centers**). LCA is also affiliated with premier medical institutions including UCLA, Stanford, Rush Presbyterian, and the Cleveland Clinic; and that the company's Canadian and European centers offer a window on developing new procedures not yet approved in the U.S.

10/27 This issue of *The Gray Sheet* discusses the intended acquisitions of **Chiron Vision** and **Storz Ophthalmics** by **Bausch & Lomb**. The article states that B&L expects to see considerable cost savings by 1999 from the consolidation of Storz and Chiron Vision, primarily through combination of their IOL businesses. The joint acquisitions would

give B&L an ophthalmic surgery business with more than $400 million in annual sales, with Chiron reporting revenues of $211 million, and Storz having revenues of about $200 million. Based on 1996 revenues, the combination would have generated 80-85% of its revenues from sales of cataract and surgical products, just under 10% from Chiron's refractive surgery business, and between 5-6% from ophthalmic pharmaceuticals. In an interesting sidelight, it was noted that Chiron was not aware that B&L was negotiating a separate deal with Storz until its announcement, while B&L's deal with Storz is contingent upon the completion of the Chiron deal. According to B&L president William Carpenter, in the short term, both companies will remain stand-alone businesses and will be run by current management. Chiron is headed by founder and CEO William Link; Storz is headed by president Robert Blankemeyer.

In an accompanying story, *The Gray Sheet* notes that the Chiron acquisition could put B&L into the U.S. laser refractive surgery market, as Chiron has a PMA for its excimer laser pending, and is expecting a decision from the FDA by the end of the year. If Chiron gets the marketing approval, it will become the third entry into the U.S. market, following **Summit Technology** and **VISX**. (One problem facing B&L/Chiron, is the lack of a license from either **Pillar Point Partners** or **LaserSight**, who hold rights to the **IBM** patent. It will be interesting to see how that game plays out!)

10/29 During the AAO meeting, I met with two of the CEO's of leading laser vision correction centers and was told of the formation of an industry association, made up of the CEO's of the leading vision correction centers, along with an excimer leasing company, to further the development of the refractive laser industry. In a news release from the group, now called the **Excimer Leadership Council**, the chief executives of **Beacon**, **ClearVision**, **Excimer Vision Leasing**, **Laser Vision Centers**, **LCA-Vision**, and **TLC The Laser Center**, have met to form the Council. The Council members represent approximately 50% of the installed base of excimer lasers in North America, and a higher share of the laser refractive procedures conducted in this market area. The initial meetings of the ELC were conducted during the AAO meeting and were focused on developing a concerted agenda for building growth in the industry, and identifying technological opportunities and challenges faced by the industry. To gain a perspective on the technological opportunities forthcoming from excimer laser vendors, the Council met with the CEO's of several of the laser companies. Elias Vamvakes, CEO of TLC The Laser Center was elected chairman and spokesperson and has set a schedule for regular meetings to advance the agenda. I will keep you posted about further information coming from this prestigious and influential group.

11/3 This week's issue of *OSN Intelligence Report* notes that **VISX** said at the AAO that it planned to file a PMA for hyperopia early in 1998. According to president Mark Logan, the early results from a Phase III multicenter trial of about 150 eyes suggests

that the scanning mode of the VISX Star laser works well in the treatment of hyperopia.

The newsletter also noted that the Phase III results for the **KeraVision** ICR showed that 97% of 244 patients achieved 20/40 or better vision and 87% achieved 20/25, when treated for myopia between 1 and 3.5 diopters. Patients treated for moderate myopia, between 3.5 D and 5 D achieved 20/40 or better 98% of the time and 20/25 vision 83% of the time, according to the latest Phase II clinical trials of 58 patients.

11/4 **Autonomous Technologies** reported its third quarter results with revenues of $11,000 and a net loss of $2.7 million (27 cents/share). For the nine months, the income was the same, while the net loss was $8.4 million ($1.06/share).

11/4 **Laser Corporation** announced that it had received FDA marketing clearance for two of its new medical laser systems for ophthalmic applications. The Nuvolase model 532 and model 720 laser systems are approved for use in retinal and macular photocoagulation, and trabeculoplasty procedures. The company introduced the products at the recent AAO meeting and anticipates sales of the two products in 1998.

11/5 **LaserSight** reported its third quarter results with revenues of $6.2 million and a net loss of $2.5 million (25 cents/share). For the nine month period, sales were $18.1 million and the loss was $5.6 million (59 cents/share). During the quarter, the company sold 10 lasers, compared with nine lasers for the same period in 1996, and an increase over the 8 lasers sold in the second quarter this year. Fourth quarter unit sales are expected to show continued improvement as the company begins shipping the LaserScan LSX model during the quarter. According to president and CEO Michael Farris, the company is strengthening its competitive position through several steps taken: the launch of the Automated Disposable Keratome planned for the fourth quarter; increased laser sales with the LSX model beginning shipment; patent rights enforcement and licensing initiatives; progress toward FDA approval of its laser system; and a focus on education and training of ophthalmologists for LASIK (with the bringing on board of Charles Casebeer, MD, for this purpose.)

The company noted that it planned to use $3.2 million of the $4 million license agreement it obtained for vascular and cardiovascular rights to the IBM patents, to redeem approximately 19% of the convertible preferred stock issued to purchase the patents. It sold its first laser into Russia, where it believes there are only 8 laser systems in place. It also received Kai-Tech (Korean) regulatory approval to sell laser systems into Korea.

During the AAO meeting, in addition to the excitement around its booth, especially with the demonstrations of the new disposable Ruiz keratome, LaserSight said it took orders for keratome consoles and over 3000 disposable keratomes (which also attaches to the Chiron ACS unit).

11/6 *Refractive Market Perspectives* for this month notes that laser refractive volumes are up 18% in the third quarter, with full-year volumes expected to reach 220,000 in the U.S., including U.S. patients traveling to Canada, and procedures performed on unapproved systems. There was minimal growth in the number of new laser centers during the quarter, but increasing activity in currently existing centers. Newly added lasers have been replacements or offsets to those withdrawn from the market. During the quarter, Market Scope believes that 59,800 procedures were performed, up from 50,500 during the second quarter. Procedures per laser averaged 45.5, compared to 38.7 in the second quarter. Corporate centers reported the largest volume increases with 20.7% growth. Collectively, corporate centers performed 18,920 procedures, an average of 56 procedures per center per month. With the closing of LCA-Vision centers, the number of corporate centers decreased by five during the quarter. Institutional and physician-owned centers showed a 12.2% increase to 41.6 procedures per center per month. Also of note, Pillar Point showed increasing growth due to FDA enforcement against unapproved lasers. According to Market Scope, today there are only a handful of unapproved lasers operating without paying Pillar Point fees. Most of those are limited to clinical study patients under approved IDEs. Continued volume growth, although at a slower rate, is expected through year end, because many refractive surgeons attended the AAO in October, and growth may be slower during the upcoming holiday season.

The newsletter also reports that **Nidek** has submitted its PMA for myopia correction, joining **Chiron** and **Autonomous** in the que.

11/6 **Summit Technology** released its third quarter results, with revenues of $23 million, an increase of 14% over last year's third quarter, and net income of $7.4 million (24 cents/share), which included a one-time gain of $10.7 million from the sale of the company's vision center subsidiary, and related losses of $3.3 million from discontinued operations. Net income from continuing operations was $24,000, or break even. For the nine month period, revenues were $67.2 million, up from revenues of $62.6 million last year. Net income for the period was $8.6 million (28 cents/share), which included the one-time gain and losses from discontinued operations noted above. Net income from continuing operations was $1.2 million (4 cents/share). According to our estimates, sales from laser operations for the quarter were approximately $10.9 million, after eliminating sales by Lens Express. And, since the company sold very few lasers during the quarter, most of that revenue had to be from its portion of the Pillar Point revenues. For the nine month period, I estimate that Summit's laser sales (and royalty income) totaled $28.5 million of the $67.2 million reported.

11/6 **Escalon Medical Corporation** reported is fiscal first quarter results with revenues of $1.4 million and an income from operations of $4400, with a net loss for the quarter of $30,900 or 3 cents/share. Contributing to the company's profitability was a 71% decline in R&D expenses from its decision to discontinue funding for its laser program. The company is in the final process of finalizing a proposed joint venture

arrangement with the University of Michigan, who will jointly license the intellectual laser properties from both institutions to a newly formed company, **IntraLase**, in return for an equity interest and future royalties on product sales. (For more on IntraLase and its intentions, see my writeup about refractive surgery from my coverage of the recent AAO meeting and the brief at the end of this section.) As Escalon is exiting the ophthalmic laser business, I will discontinue my coverage of the company, except as it pertains to developments made by IntraLase.

11/7 **Laser Vision Centers** announced that its same U.S. surgical case volume for October increased 509% over the same month a year ago, and by 2% over the previous month. The company believes that October's lower case volume is attributed to attendance at the AAO by many surgeons who were out of their offices for up to five days. Last year, October's volumes decreased 10% from September due to the Academy meeting. The company also noted that during September it had achieved positive cash flow for the first time in its history. Jack Klobnak, chairman and CEO noted that the company would be adding at least two new lasers to its fleet by the end of the year to accommodate the growing procedure demand.

11/9 *The Boston Sunday Globe* noted that **NET**, the television network, originally called **National Empowerment Television**, had ousted conservative activist Paul Weyrich, who had founded the network three years ago. As you might recall, Mr. Weyrich was the force behind the two divisive television programs lambasting **Summit Technology**, the **FDA**, and Senator Ted Kennedy for his alleged role in obtaining expedited FDA approval for Summit Technology, because of David Muller's alleged contributions to the senator's re-election campaign.

11/10 According to this week's issue of *OSN Intelligence Report*, the FTC has completed its antitrust investigation of **Pillar Point Partners** and has forwarded a recommendation to the director of its Competition Bureau. *FTC Watch*, a Washington regulatory newsletter reported that the staff probably has recommended that Pillar Point be considered an illegal restraint of trade, despite the organization's argument that it holds a blocking patent for excimer laser vision correction of myopia. It will be up to the director to decide whether to forward the recommendation to the commission members, which would cap the 2-year investigation into Pillar Point by the FTC.

The newsletter also notes that a third physician-led suit has been filed against Pillar Point alleging price fixing by the organization. Antione Garabet, MD, and Abraham Shammas, MD, of the **Laser Eye Center of Los Angeles** filed suit on November 5th, alleging price fixing and patent fraud in the acquisition of Pillar Point's Trokel patent. John Alioto, the San Francisco attorney representing the other two refractive surgeons who have filed Pillar Point suits, Richard Burlingame, MD of Sherman, TX and John Shepard, MD of Las Vegas, and said that more suits will follow.

11/13 **LCA-Vision** reported its three month results, reflecting the third-quarter's acquisition of Summit's **Refractive Centers International** network of vision correction centers.

For the quarter, revenues were $5.0 million, compared to revenues of $3.2 million for last year's third quarter, and the net loss was $2.6 million (8 cents/share). For the nine month period, total revenues reached $11.6 million, up from $10.5 million, with revenues exclusively from the company's refractive laser surgery centers rising 206% to $8.0 million from $2.6 million. The net loss for the period was $5.5 million (23 cents/share) and included a one-time charge of $1.1 million related to the closure of under-performing centers and a writedown of the carrying value of certain assets following the acquisition of the Summit centers in August. Commenting on the results, CEO Stephen Joffe noted that, "As projected, volumes continues to accelerate rapidly at all of our centers, bringing LCA-Vision significantly closer to profitability. For the third quarter and nine months of 1997, the number of procedures performed at centers opened for a year or more, rose 142% and 184% respectively, versus the same period a year ago." Dr. Joffe also reported that the company had filed an S-3 registration statement with the SEC covering the 9 million shares that Summit will distribute on a pro-rata basis as a dividend to its approximately 36,000 shareholders. LCA currently operates 30 refractive laser surgery centers, including 2 in Canada and 1 in Europe.

11/13 *NewsPage* notes that a patent describing an apparatus for removing tissue from the eye using a large beam that oscillates or dithers to prevent the formation of ridges was issued to **Chiron/Technolas GmbH**. (The patent number was not provided.)

11/14 **Beacon Eye**, which operates as **Beacon Eye Institute** has reached agreement with **MDS Capital Corp.** and a number of other institutional shareholders of Beacon, with respect to the terms of a $2.5 million convertible debt financing. It is convertible into common shares at $2.30 per share. As part of the financing, Beacon is also initiating a process that will permit it to undertake a rights offering.

The company also announced its operating results for the quarter and nine month period. For the quarter revenues were $3.1 million, up 6% from second quarter results, representing a 38% increase in procedures, up from 1465 to 2016. The company had a net loss of $6.2 million for the quarter. For the nine month period, revenues were $8.3 million and the net loss was $17.3 million ($2.24/share). Operating costs and development expenses totaled $24.9 million for the nine months, including startup costs of the four U.S. laser correction centers in Ft. Lauderdale, and Tampa, FL; Atlanta, GA; and Irvine, CA. Beacon now operates 11 centers, 2 in Canada and remainder in the U.S.

11/14 **Sterling Vision** reported its third quarter results, with system-wide sales of $42.0 million and for the nine month period, sales of $115 million. The net loss for the quarter was $399,000 and net income for nine months was $31,000. According to a company spokesperson, the company continues to operate just one laser vision correction center, at Trump Center in New York City (with two lasers), but owns four other lasers that are installed in private physician's offices. (See related brief below.)

11/14 **Sunrise Technologies** released its third quarter results with net sales of $76,000 for the quarter and $2.5 million for the nine month period. The company had a net loss of $1.6 million for the quarter (6 cents/share) and $4.1 million (15 cents/share) for the nine months. The third quarter results reflect the change in business focus made during the quarter, basing the business entirely on ophthalmic refractive technologies beginning at the end of June, with the sale of its dental division, and consequently, the effective elimination of dental revenues during the third quarter. For the nine month period, dental products still accounted for 77% of total revenues.

11/18 A *Newsday* brief written by James Madore, about **Sterling Vision** appeared in today's edition. The brief commented on the company's third quarter results, using the headline, "Sterling Vision sees Bluer Skies in the Future", stating that the company had cut its losses by nearly half in the quarter, thanks to a 25% increase in sales. Sterling operates about 350 optical stores under the Sterling name, some of which are company owned, and the remainder franchised.

11/18 **Premier Laser Systems** reported a significant response and record on-site sales of its new corneal topography systems, including a hand-held device that were introduced at the recent AAO meeting. In addition to being sold by Premier's subsidiary **EyeSys.Premier**, the devices will also be distributed by **Marco Technologies** and **Nidek**, who will market the devices under its private label.

11/19 **KeraVision** announced that the FDA had approved the expansion of its Phase III clinical trials of its intracorneal ring for a wider range of nearsightedness. The company has been conducting trials since December 1996 for treating 1 to 3.5 diopters of myopia (which would include an estimated 22 million Americans, according to the company). The new approval allows for treating myopia from 3.5 to 5.0 diopters, which should affect an additional 11 million Americans. Recently presented preliminary results of the Phase III clinicals showed 97% of nearsighted patients achieving 20/40 or better in the 1 to 3.5 diopter range, and early data on the Phase II higher myopia study showed 98% achieved that score. All Phase III low myopia patients have been enrolled and followup visits are being conducted prior to submission of a PMA.

11/19 **Sunrise Technologies** announced it had received FDA approval to move into Phase III of its study on treating hyperopia. The company will enroll an additional 200 patients to complete the hyperopia study. Three additional investigators, Drs. Ernest, Fine, and Lindstrom will join the eight Phase II investigators; Drs. Aker, Belmont, Brown, Durrie, Koch, Kraff, Martin, and McDonnell. As reported during this Spring's ASCRS meeting, using a new protocol, the results between six months and 3 years show negligible postoperative regression.

11/20 Today's *Globe and Mail* highlights the troubles being encountered by **Hawker Siddeley** and its **BeaconEye** subsidiary. As noted in the story, in the wake of its third consecutive bleak earnings report, Hawker Siddeley Canada Inc. announced that its

CEO is stepping down and that it may sell its laser eye surgery business. Hawker Siddeley president and CEO Keith Moore has resigned to devote his full attention to its money-losing BeaconEye subsidiary, in which it holds a 31.2% stake. Hawker Siddeley lost $6.1 million in the third quarter, compared with a profit of $16.9 million a year ago. BeaconEye reported no revenue for the quarter, compared with $1.7 million last year. "The figures are in stark contrast to Mr. Moore's predictions six months ago. He told shareholders...that he expected swift growth at BeaconEye and that the eye surgery company was within striking distance of a profit, perhaps within six months." Mr. Moore was quoted as saying that he believes that the laser eye surgery will boom in the future. But Hawker Siddeley appears unwilling to hold on, and has hired **CIBC Wood Gundy** to explore options, including new financing, a merger or acquisition, or the sale of BeaconEye. The company has opened the doors to its data and has invited industry players and competitors to look at the books.

One of the companies "kicking the tires" is competitor **TLC The Laser Center**. President Elias Vamvakes admits that he is interested, but at what price? Claiming to be the biggest in the industry, and capable of the acquisition, he believes he is the no. 1 candidate to do so. BeaconEye owns 11 clinics in Canada and the U.S., and has a market capitalization of about $25 million. According to the newspaper, however, some industry watchers peg the company value at only about $22 million. Other potential suitors could include **Laser Vision Centers**, **LCA-Vision**, as well as **Physicians Resource Group**, which provides physician practice management services (but is currently in turmoil itself).

According to analyst Christine Farkas of **Midland Walwyn**, "There is definitely growth in the industry...the issue the industry is facing is how to improve profitability...so far, the companies are spending a lot on advertising and on what they pay their doctors...procedures are growing at a healthy clip...about 40% at BeaconEye...(but) competition will likely continue putting downward pressures on margins."

11/21 **Premier Laser** announced that it had demonstrated its multi-application Centauri erbium:YAG laser for ophthalmic procedures at the recent AAO meeting, and that a record number of physicians visited the exhibit for the demonstrations, which included lens emulsification and dermabrasion or skin resurfacing. The laser has been cleared for use in dermabrasion, blepharoplasty, end-stage glaucoma treatment and for anterior capsulotomy. The cataract emulsification procedure is still in clinical trial.

11/21 **LCA-Vision** announced that it was strengthening its leadership in the growing laser vision correction market by ordering six new **VISX** Star lasers. The lasers will be acquired on a leased basis for mid-December delivery and will give the company a total of 43 lasers installed at 36 locations, including the six university-based hubs. The new lasers will be shipped to LCA-Vision locations serving Cincinnati, Chicago, Minneapolis-St. Paul, Los Angeles, Washington, DC, and South Florida metropolitan areas. Many of LCA's vision centers continue to be equipped with Summit Apex

lasers, and a few have Apex Plus systems. Several of the company's centers also maintain excimers from other manufacturers, including **LaserSight**, **Chiron**, and **Nidek**. At LCA's Toronto facility, three lasers, from Chiron, VISX, and **Sunrise** are in place, with all three used successfully to treat hyperopia. CEO Dr. Steve Joffe commented that he wants to provide his 600 affiliated ophthalmologists and 800 referring optometrists and their patients with the most advanced, state-of-the-art equipment, plus the highest level of service and maintenance. The company currently operates 27 laser vision correction centers throughout the U.S., and is directly affiliated with six other university/medical center-based locations. In addition, LCA operates two centers in Canada and one in Helsinki, Finland.

In a separate announcement from *Federal Filings*, LCA-Vision said it was sued last month for $6.5 million by **Cabrini Development Council** and others over the termination of a limited liability company formed to operate **Laser Refractive Surgery Centers** in New York City. The lawsuit alleges that LCA breached various agreements entered into between the company and the LLC. It also alleges fraud and conversion of the a business opportunity stemming from the operation of a center in Mr. Kisco, NY. The LLC formed by Cabrini and a New York professional corporation owned by certain physicians, began operating in 1995, but it was unprofitable and after its resources were exhausted, LCA-Vision paid its operating costs. The LLC ceased operating in August. The plaintiffs are seeking compensatory damages of at least $4.5 million, punitive damages of at least $2 million and the creation of a constructive trust over LCA-Vision's operations for the benefit of the LLC. LCA-Vision said it has not yet answered the complaint and it believes that the plaintiffs claims are without merit.

11/21 **Chiron Vision** announced that it had submitted its PMA for the Technolas excimer laser to perform PRK. The clinical data submitted included information on over 1000 eyes treated for 1 to 10 diopters of myopia and up to 4.5 diopters of astigmatism. According to Chiron, the Technolas laser is installed in China, Asia-Pacific, Canada, South America, throughout Europe, the Middle East, and Africa, as well as test sites in the United States. Outside of the U.S., the device is used for myopia, hyperopia, and myopic and hyperopic astigmatism.

11/24 According to *EyeWorld Week*, **VISX** has teamed up with **Hillside Group** to offer a per-use rental program that requires only a one-year commitment. Customers rent a new VISX Star laser under a program that costs $599 per procedure for the first 1000 procedures and drops to $299 after that. Combined with the VISX keycard, required for each case, this brings the physician's laser related costs to about $900 for each refractive surgery procedure performed. As noted by EWW, faced with sluggish sales and an over capacity of excimer lasers in the North American market, manufacturers are looking for alternative ways to move their systems. Nearly any financial arrangement that places lasers and generates per-use royalties is good news for both **Summit Technologies** and VISX. Based on an estimated 200,000 procedures this year, **Pillar Point Partners** stands to receive about $50 million in gross revenues.

Summit is also offering a deal. It will offer its Omnicards at a reduced $200 to owners of the Apex Plus system, and to those who upgrade from the Apex to the Apex Plus by the end of the year. According to a letter to Summit owners from Bernard Haffney, vp of marketing and sales, purchases are limited to 120% of the highest two month's Omnicard purchases. The cards normally sell for $250, the Pillar Point fee. According to Haffney, the offer is in anticipation of the pending approval of the astigmatism treatment, which requires an Apex Plus upgrade. The estimated cost of the upgrade is $55,000.

*OSN Intelligence Report* notes that **Refractec** is adding additional clinical investigators to collect patient data for the study of the intrastromal conductive keratoplasty procedure developed by Antonio Mendez, MD of Mexico. The device is used to treat hyperopia, astigmatism, and presbyopia.

11/24 **Escalon Medical Corporation**, announced that it had entered into a license agreement for intellectual laser properties with **IntraLase Corporation**, a newly created company, formed in collaboration with the **University of Michigan** to develop and market a new generation of lasers for eye surgery and other high-precision medical applications. Escalon also announced the execution of a 1 for 4 reverse split of its common stock, effective today. Escalon has licensed its ultrafast laser technology to IntraLase for combination with the University's intellectual properties. As previously noted, IntraLase intends to develop a femtosecond laser for forming the flap in LASIK, as well as adapting the laser to produce UV energy for precise removal of stromal tissue, performing both LASIK steps with the same laser.

In return for the Escalon license of 14 ultrafast laser patents as well as two additional patent applications, it will receive a 25% equity stake in IntraLase and be entitled to a 2.5% royalty on future products sold, which are based on the existing patents, and a 1.5% royalty on products that are not dependent on the Escalon patents. Escalon will also receive a reimbursement of $75,000 for previously incurred patent costs and IntraLase will be responsible for any future costs associated with the patents.

Escalon's partners in the new venture are the University of Michigan, also currently with a 25% interest, and co-founders Ron Kurtz, Asst. Professor of Ophthalmology at the University of Michigan Medical School, and Tibor Juhasz, Associate Research Scientist in the Univ. of Michigan Medical School's Kellogg Eye Center, and the College of Engineering's Center for Ultrafast Optical Sciences, who currently own the remaining 50%. Funding for IntraLase will come from Enterprise Development Fund, an Ann Arbor, Michigan venture capital firm.

In addition to LASIK, future laser products may target glaucoma, cataract, and dermatologic surgery.

11/25 **Sight Resource** announced that it had completed a previously announced financing with **The Carlyle Group**. The latter purchased 1.4 million shares of the company's Series B Convertible Preferred Stock, and a warrant to purchase 290,424 shares of common stock for an aggregate price of $5.1 million. In connection with the financing, The Carlyle Group has the right to appoint one member to the Sight Resource board of directors.

11/26 **BeaconEye**, which operates **Beacon Eye Institute**, completed its previously announced $2.5 million financing with a number of institutional shareholders. The financing has a four month term and carries a 15% interest rate. It is convertible into Beacon stock at a conversion price of $2.30 per share. (The recent fall in Beacon stock price, to less than a $1.00, reduces the value of the conversion feature significantly.) As part of the financing plan, the company is initiating a process that will permit it to undertake a rights offering. The company, in conjunction with CIBC Wood Gundy Securities is currently in discussions with a number of industry participants with respect to various strategic alternatives. (See last month's 11/20 brief for more on Beacon Eye's financial troubles.)

11/26 **LaserSight** announced that two key executives have advised the company that they purchased shares of the company on the open market. On November 17 and 18, Michael Farris, CEO, and Richard Crowley, who was recently promoted from COO to president of the company's Technologies division, collectively bought 6,000 shares of company stock. Both executives serve on the company's board of directors.

11/26 **LCA-Vision** filed for the sale of 19.1 million shares of its common stock on behalf of the selling shareholders, Stephen Joffe, Sandra and Craig Joffe, and Gregory Livingston. In addition, **Summit Technology** announced that it would issue a dividend of one share of common stock of LCA-Vision (that it acquired for the sale of its vision correction centers to LCA-Vision) for every 3.5 shares of Summit common stock outstanding. The record date for the dividend is December 18 and the distribution date is expected to be December 29. After the distribution, Summit will continue to own approximately 19.5% of the outstanding stock of LCA.

11/28 **Gimbel Vision International** announced results for the nine month period ended September 30. Revenues for the period were $12.2 million, attributable to the continued growth in the company's existing operations, combined with the effect of the new facilities in Vancouver, BC and Sacramento, CA. Net revenues were $792,000. No figures for the quarter were released.

12/1 This week's *EyeWorld Week*, reports that Phase 3 studies of **QLT PhotoTherapeutics** and **Ciba Vision's** photodynamic therapy approach to the treatment of age-related macular degeneration (ARMD), using QLT's second generation PDT drug benzoporphyrin (BPD), are in their final stages at 22 sites in the U.S., Canada, and Europe. Almost 600 patients have been enrolled in only 10 months, according to Neil Bressler, MD, who is coordinating the year-long study.

12/1 **Coherent Inc.** announced that **Coherent Japan, Inc.**, had received approval from the Japanese Ministry of Health and Welfare for its Selecta 7000 laser system for Selective Laser Trabeculoplasty (SLT), the new technique to treat primary open-angle glaucoma. The approval is especially significant given the rapidly increasing percentage of elderly people, aged 65 and over. In Japan, there are an estimated 3 million people with glaucoma and the market size for glaucoma lasers could exceed $15 million over the next three years, according to the company.

Selective Laser Trabeculoplasty was invented by Dr. Mark Latina of Massachusetts General Hospital, and licensed to Coherent. Coherent Japan was established in February 1996 to sell and service Coherent medical lasers in Japan and employs over 120 sales, service, and support staff in seven Japanese cities and is Coherent's largest laser market outside of the U.S.

12/2 **TLC The Laser Center** commented on the ongoing situation surrounding its discussions with **BeaconEye**. "After carefully assessing all available data, TLC made an offer to BeaconEye's board. That offer was to purchase certain assets of the Company which included 2 laser vision correction clinics in Canada and 9 in the U.S. The BeaconEye board rejected TLC's offer and there have been no discussions since."

On the following day, both of Canada's national dailies, *The Financial Post*, and *The Globe and Mail* commented on the situation. The Financial Post noted that "struggling BeaconEye had rejected TLC's offer to buy all of its laser vision correction centers, with the news causing both companies' stock to drop, Beacon's to $0.70, down 25 cents. The report went on to note that BeaconEye chief executive Keith Moore would not say why his board had rejected TLC's offer nor would comment on whether the company had sufficient funds to maintain operations through the next quarter, saying only that the company had engaged Wood Gundy to maximize shareholder value and that process was continuing. Apparently, there are other suitors interested in the business. The Globe and Mail just repeated the TLC quote noted above, without further comment.

12/3 **LaserSight** announced that it had received full authorization from the Canadian Medical Devices Bureau to sell and use the company's automated disposable keratome in Canada. The authorization represents LaserSight's first market entry for the new product. According to company spokesperson Charles Casebeer, MD, Canadian ophthalmologists are expecting the laser vision correction market to grow by as much as 20 percent, with LASIK procedures representing 60%-70% of procedures performed in that country.

Besides Canada, LaserSight has received orders for its ADK from both distributors and customers in Australia, Chile, Argentina, Mexico, Brazil, New Zealand, Columbia, the Philippines, South Africa, Sweden, Japan, Saudi Arabia, Spain, Turkey, and China. In addition, refractive surgeons in Europe, Asia, Latin America and Africa have inquired about the device. The company anticipates shipping the first

commercial ADK orders by late December or early January 1998. LaserSight has filed a 510(k) submission for the ADK with the FDA on October 22nd. Clearance is pending.

12/4 **Premier Laser Systems** announced that it had received FDA clearance to market its Vista hand-held corneal topography system, manufactured by the company's **EyeSys.Premier** subsidiary. The hand-held device will be priced below $6000, and the complete system, including an associated computer and printer, will cost approximately $9000. Shipments will commence during next year's first quarter. The device, which looks similar to a small hand-held video camera, can be used for both contact lens fitting and precision mapping for refractive surgery. It will be sold domestically by **Marco Technologies**. The company is also developing a desktop version of the corneal topography system in association with **Nidek** of Japan.

12/4 **Laser Vision Centers** reported that it had generated positive earnings before interest, depreciation, and amortization (EBITDA) for the quarter ended October 31st, a first in the company's history. The company reported a quarterly loss of $1.2 million (14 cents per share), of which depreciation and amortization were 103% of the loss, compared to a loss of $2.1 million (25 cents/share) for the same quarter a year ago. Sales increased to $5.2 million, up from $2.0 million a year ago. According to Jack Klobnak, chairman and CEO, "We believe our lasers are growing at nearly double the run rate of the industry and our operating margins continue to improve...the company's two newest lasers will be deployed in January to accommodate growing demand and to improve efficiency." The company also noted that same laser case volume for the month of November was off 6.9% from October, primarily due to the Thanksgiving holiday. Klobnak went on to say that he agreed with industry analysts who predict a "soft" December, but that January bookings were "robust", and ahead of plan.

12/4 **TLC The Laser Center** reported its second quarter procedure results with over 6,400 paid procedures performed at the company's centers in the quarter ending November 30. This is an increase of 323% over the same period a year ago. Elias Vamvakes, president and CEO stated that he was very pleased with the second quarter numbers, as this quarter is traditionally weaker than the first fiscal quarter. The strong increase in procedures is a reflection of the industry's growth and solid same store growth in his centers.

12/5 Standard & Poor lowered its corporate credit rating and its rating on **Bausch & Lomb's** medium-term notes to triple `B' from single `A' minus. These ratings are removed from CreditWatch, where they were placed October 21st, when B&L announced its intention to acquire both **Chiron Vision** and **Storz Instruments**. The actions incorporate B&L's increased debt burden following the cash acquisitions of the companies noted above. S&P noted that the outlook for the company was stable.

12/7 *The New York Times* ran a story in its Sunday business section by Richard Korman entitled, "A Rush to Laser Surgery and, Possibly, Profits". The story describes both PRK and LASIK, along with some skepticism by the editor of the *Red Chip Review*, who noted, "I don't know what they are making in that industry, but it isn't money". The story goes on to quote my projections of 950,000 procedures for the year 2000, which is higher than any other analysts' estimates. (I provided the author with projections for Ken Taylor of **Arthur D. Little**, Gil Kliman of **Health Partners**, and Michael Lachman of **Hambrecht & Quist**, all of whom are much less bullish than I am.) Specific mention was made of the strategies of **Laser Vision Centers**, **LCA-Vision**, and **TLC The Laser Center**.

12/8 According to this week's *OSN Intelligence Report*, **VISX** has sponsored a Public Broadcasting Service documentary called "Beyond Glasses and Contacts" that premiered on a Denver PBS station, and will soon be available for showing across the country. The 1-hour program was based on the book, "Beyond Glasses! The Consumers Guide to Laser Vision Correction", and features interviews with Drs. Richard Lindstrom, Robert Maloney, James Salz, and Roger Steinert, among others.

12/8 **Innovative Optics** announced that it had signed agreements with Asian distributors for an additional $8.7 million of InnovaTome microkeratome products. These sales are incremental to the $11 million in backorders announced in late October. In the most recent round of distribution contracts, various Asian importers agreed to purchase 150 InnovaTome microkeratome units immediately, as well as 90,000 disposable blades over a three-year period. The company plans to ship the first production units this month.

12/11-
12/17 I received an anonymous fax in the early morning hours of December 11th that contains a number of allegations that could have a serious impact on the **Pillar Point Partnership** and **Summit Technology**. The anonymous message alleges that there is a contract loophole in the Pillar Point agreement that states that non-accredited procedures, such as LASIK, are not specifically included in the partnership agreement. On that basis, **VISX** has begun withholding LASIK procedure fees from Pillar Point and filed a lawsuit on November 12, 1997, in which it claims that it believes it is not "obligated to pay royalties on account of Licensed Procedures [of which it agrees LASIK is] until it receives Pre-Market Approval for that Licensed Procedure".

According to the anonymous source, LASIK now represents about 80% of total refractive procedures, and VISX began withholding its LASIK procedure fees in August 1997.

The source goes on to say that, beginning in June, more procedures were done on VISX lasers than on Summit systems, that is, for the August/September/October period, 45,000 procedures were done on VISX systems, of which about 80% or

36,000 were LASIKs, equivalent to $9 million in revenues, plus the $140 split of PRK for the other 9,000 procedures, or an additional $1.26 million equals about $10.26 million in accrued royalties for that period. November and December could account for another 35,000 procedures generating another $7 million in LASIK fees, bringing the total to $17.26 million for the quarter.

VISX revenues could reach $29 million in revenues for its fourth quarter if system sales of $8 million, service revenues of $3 million, and Summit procedure fees of $1 million are added to the above. With procedures for the first quarter of '98 expected to reach about 60,000, LASIK could contribute $12 million for the quarter. In addition, growth in system sales and service of about $10 million, plus Summit's procedure fees, could result in VISX producing revenues of $28 or $29 million in that quarter as well.

On Monday December 15th, I spoke with principals from both Summit and VISX, with both denying any knowledge of who might have sent the anonymous message. However, I was able to determine that the lawsuit mentioned has been filed by VISX, who were kind enough to send me a copy of the complaint. It basically asks for the Superior Court of California to declare that the provisions of the License-Back portion of the Pillar Point agreement does not obligate VISX to pay a per-procedure royalty to Pillar Point on account of LASIK procedures performed prior to its (VISX's) receipt of Pre-Market Approval of LASIK! (And if they never file for such approval, they can continue to keep the $250 procedure fees paid by physicians and laser owners by their purchase of keycards!)

On Tuesday, December 16th, I heard back from Summit that they strongly deny that they have ever withheld any procedure fees, even for LASIK, from Pillar Point (as alleged in the anonymous message). Summit claims that the message I received is blatantly false as far as its references to Summit. Further, Summit claims that the algorithms used in the U.S. are identical for PRK and LASIK, as demanded by the FDA, although they may be different outside the U.S., and that Summit has no way of knowing what procedures have been done on their machines, nor do they believe can VISX distinguish between procedures. In fact, if VISX has a different algorithm for LASIK, its use would be in violation of FDA regulations, since VISX's lasers are only approved to perform PRK (and PTK).

Summit also claims that it was unaware until about November that VISX had been withholding procedure fees from Pillar Point. When questioned about the decline in procedure fees, Summit was told by VISX that the procedure level performed on VISX lasers was slowing down. Summit learned via a telephone call the day before the November 12th VISX complaint was filed, that VISX had decided to withhold LASIK procedure fees. Today, Summit filed a cross-complaint against VISX, claiming among other things, that LASIK is a licensed PRK procedure, performed on the cornea after a "flap" has been made, and that further, VISX, to Summit's knowledge, has no way of distinguishing between LASIK and PRK. Therefore, they

have no legal right to withhold procedure fees from Pillar Point. The complaint also claims that since VISX has withheld LASIK fees in breach of the VISX License Back portion of the Pillar Point agreement, Summit is entitled to the full $250 fee, without it being split between the partners. Also, since VISX sought legal action before asking for mediation, as called for by the agreement, a penalty is due Summit.

Finally, late on December 16th, VISX released a statement announcing publicly that it had stopped making the royalty payments to Pillar Point for LASIK, and had filed the November lawsuit seeking the declaratory judgement about its interpretation of LASIK being unapproved. The announcement went on to state that if the declaratory judgement was denied, it would be liable to submit to Pillar Point all of the royalties not paid since October 1997. (According to Summit's interpretation of the Pillar Point agreement, it [Summit] would be paid all of the royalties, without the normal split, because of the legal action taken by VISX.)

On the following day, **Hambrecht & Quist** dropped its rating of VISX to "buy" from "strong buy".

12/14 *The Chicago Tribune* ran a feature story on eye laser surgery stating that consumer interest for the procedure continues to grow. According to the analysts contacted for the story, the U.S. procedures could rise to 200,000 this year, and 400,000 in 1998. The story goes on to describe the differences between PRK and LASIK, with LASIK becoming more and more popular.

12/15 *OSN Intelligence Report* notes that the first LASIK for hyperopia using a **Summit Technology** Apex Plus laser, was performed by Stephen Brint, MD, in New Orleans as part of the **CRS-USA** clinical trial. The +4 patient was treated bilaterally with Summit's disc technology and reported seeing 20/20 within 10 minutes after the procedure.

12/17 **Pharmacyclics** announced that it had signed an agreement with **Alcon Pharmaceuticals, Ltd. (APL)** for worldwide marketing rights to its Lu-Tex photosensitizer for ophthalmic indications, including its use in treating age-related macular degeneration. Under the terms of the agreement, Alcon will conduct and bear all of the costs for worldwide development and drug registration for ophthalmic indications of Lu-Tex. Pharmacyclics received an up front payment and will receive payments based on completion of certain milestones, as well as a royalty on product sales. APL is an affiliate of **Alcon Laboratories, Inc.**, a wholly owned subsidiary of **Nestle S.A.**

12/17 **Premier Laser Systems** announced that it had submitted data on laser cataract emulsification, using its Centauri erbium:YAG laser, to the FDA for review and preliminary consideration. The company is awaiting a response from the FDA as to the sufficiency of the data for a final submission.

12/17 **Laser Vision Centers** announced that it had signed its 100th agreement for excimer laser access. With the agreement, LVC now services sites in 33 states with more than 200 surgeons. The company said that it expects another 25 sites to be signed before April 30, 1998, the end of its fiscal year. The agreements with the six newest sites were signed within the last 15 days and are for locations in North Carolina, Michigan, Illinois, Wisconsin, and two sites in Florida. The new sites will enable the company to tighten its routes and improve operating efficiency. LVC also announced that it had acquired a laser from the Richmond Eye and Ear Hospital in Richmond, VA, which will be mobilized and serve additional sites in the Southeast, including Richmond Eye and Ear.

12/17 **TLC The Laser Center** held "Doctors Only Day" at its Indiana Laser Center in Indianapolis on December 12th, and 10 eye doctors associated with the center underwent laser vision correction on their own eyes. All the doctors underwent LASIK, performed by TLC Indiana co-medical directors Dr. Michael Orr and Dr. Kevin Waltz. Dr. Orr who previously had one eye corrected, had his second eye done at the end of the day. Both doctor's wives have also had their eyes done with the excimer laser. The ten doctors treated join over 500 medical doctors, including more than 200 eye doctors, who have had their vision corrected through TLC.

12/17 **Coherent Inc.** announced the international introduction of its EPIC portable three-in-one ophthalmic laser system. (Note: I wrote about this system in my article about the new lasers introduced at this fall's AAO meeting.) According to Coherent, the EPIC extends the ophthalmologist's capabilities to perform capsulotomies, trabeculoplasties, or photocoagulation procedures in one device, that used to require multiple lasers to perform. The EPIC contains a YAG laser photodisruptor module that clips onto the physician's slit lamp for clearing up secondary cataracts, an argon laser for retinal photocoagulation procedures, and a doubled YAG for performing Selective Laser Trabeculoplasty for the treatment of primary open angle glaucoma.

12/18 **VISX** announced that its "Beyond Glasses! The Consumer's Guide to Laser Vision Correction", which premiered recently in Denver, begins airing nationally on PBS stations. (See the December 8th brief above.) Produced by Denver's KBDI-TV, the station has made the program available free to all interested PBS affiliates via satellite.

12/22 **Autonomous Technologies** said it is preparing for an FDA advisory panel meeting during the first quarter of 1998, that will review its submitted PMA. The company said it had cleared clinical site audits with no citations, and had received foreign regulatory approval to ship its LadarVision system to Italy and the UK. The company has shipped one laser to Italy and is planning to ship another to the UK in the near future.

12/24 **LaserSight** announced that it had reached agreement with holders of its Series B Preferred stock to extend the date by which the company is required to obtain

approval of its common shareholders of the conversion and other terms of the preferred stock. The extension now runs till February 28, 1998. (The preferred stock had been issued to finance the acquisition of the **IBM** UV patents.

12/26 Today's *New York Times* contained an article about the changes going on at **Bausch & Lomb**. The focus of the article is what B&L's focus will now become. According to the author, David Morrow, B&L is "rapidly selling off several noncore divisions and replacing them with companies that compliment its eye-care businesses." William Carpenter, CEO, is betting that the company's retooling will remedy five years of flat sales and halt a serious erosion in its eyewear division. Earlier this month, B&L sold off its Thin Film Technology coating business, sold its sports optics business in 1995, and last year sold its oral care and dental implant divisions. This fall the company announced it would buy both the **Storz Instrument Company** and **Chiron Vision Corporation**, pushing its eye-care sales to more than $2 billion, 5% more than in 1996. "While Wall Street Analysts believe that B&L is on the right track by narrowing its focus, neither they nor investors are likely to show much enthusiasm until earnings improve."

12/26 *The Society for Excellence in Eyecare* said that it had delayed its intention of supporting a physician suit against the FDA for the seizure of an excimer laser due to the sudden death of ophthalmologist Albert Neumann, who was a prime candidate for the legal suit. SEE would have intervened on behalf of Dr. Neumann's suit challenging FDA's interpretation of the custom device exemption under the FDA's Cosmetic Act. The society's board has asked counsel to ascertain if there are other viable options for this action.

12/26 I received a copy of the business plan for **American Healthcare International**, founded in 1995 as **American Laser Vision**. The company, which owns and manages laser vision correction and eye surgical centers in emerging international markets and the U.S., is seeking at least $2.5 million in expansion capital to establish six additional eye centers internationally, prior to further expansion, exiting the business, and/or an IPO. The company currently operates facilities in Manila, in the Philippines; Lahore, Pakistan; and in Binghamton, NY, and is developing urology, liposuction, aesthetic surgery, oncology, ENT, and telemedicine services. The center in the Philippines generated over $1.1 million in revenues in its first year of operation, while the Pakistan center reached break-even within six months. Anyone wanting additional information should contact either Mac Fadra, CEO or Ken Moadel, MD, Medical Director, at 212-734-3457.