

PRK UPDATE -- AUGUST 1995

- 7/? -- LaserVision completes acquisition of Vision Correction Inc.
- 7/25 -- VISX enforces Canadian Excimer patents by offering all infringers (manufacturers and users) a license to the technology.
- 8/3 -- Summit Technology wins German patent infringement suit against Chiron and Coherent for sales of PRK laser systems.
- 8/7 -- Industry analyst, Michael Moretti, predicts 450,000 PRK procedures in 1996.
- 8/8 -- Chiron Vision purchases additional 25% equity interest in Technolas, raising ownership to 75%.
- 8/21 -- VISX files suit against Schwind in Germany claiming patent infringement.
- 8/24 -- WSJ covers refractive surgery center business in front page story; one analyst (Irv Arons) projects 18 million people will be treated by 2005, while another analyst (Gil Kliman) believes that only 300,000 procedures will be done annually 5 years after approval.
- 8/24 -- NewVision acquires second optical chain, Vision World.
- 8/24 -- LaserSight announces development of first totally solid-state laser for PRK.
- 8/25 -- LaserSight also announces completion of 50% of Phase 2a clinical trials.
- 8/28 -- LaserSight responds to Barron's comments about it being considerably behind leaders Summit and VISX in reaching U.S. market.
- 8/29 -- Summit files suit against VISX charging patent infringement for all laser systems made in U.S. for sale outside the U.S. Suit is in retaliation for VISX suit against Summit in Canada (see above). ("What hath David Muller wrought!")

PRK UPDATE -- SEPTEMBER 1995

- 9/5 -- Summit Technology enforces injunction against Chiron/Technolas, prohibiting Chiron from manufacturing and sales of its Keracor 116 laser system.
- 9/6 -- LaserSight to acquire MEC Healthcare, a managed eyecare corporation with contracts with several HMOs to provide total vision service.

- 9/15 -- Summit receives "approvable" letter from FDA for its Apex (formerly Omnimed) laser to be used on up to 6 mm optical zones and for up to 7 diopters of myopia. (Final approval for marketing should occur within 30 to 90 days.)
- 9/18 -- NewVision, LaserVision Centers, 20/20 Laser Centers, and others comment on Summit's approvable letter.
- 9/18 -- Summit sends "Dear Doctor" letters to ophthalmologists informing them of "approvable" letter and status of competitors in the FDA que in accompanying brochure, "Excimer: What you Need to Know".
- 9/19 -- Summit registers 2.2 million shares to fund development of U.S. refractive surgery centers, to provide marketing for consumer acceptance of PRK, to provide capital to expand manufacturing capabilities, and for R&D and working capital.
- 9/25 -- VISX would neither confirm nor deny that they are the laser company whose PRK PMA will be reviewed by the FDA at its October 20th Ophthalmic Advisory meeting.
- 9/25 -- As reported in "The Gray Sheet", David Muller, President and Chairman of Summit Technology, appearing at the Septber 20th Bear Stearns health care conference stated that his firm plans to open "20-30 laser vision centers within 12 months after FDA marketing approval.
- 9/26 -- VISX announces that it has signed a worldwide (except for the U.S.) patent license agreement with Chiron Vision for use of the VISX patents for laser vision correction. The company has also extended its agreement with Aesculap-Meditec to cover Canada. With that agreement (and the Chiron one), the company claims that 80% of the excimer lasers used in Canada are now licensed. (Unsaid is that Summit's lasers are still not part of any agreement.)
- 9/26 -- Analyst Irv Arons revised his forecast for the refractive surgery market stating that 1.1 million procedures would be performed 5 yrs after FDA approval of PRK, and 2 million people will have been treated by that time.
- 9/27 -- Richard Capozza, an ophthalmic industry vetran, joins Autonomous Technology as Chief Operating Officer.
- 10/2 -- VISX announces receipt of PTK approval for its Models B & C (STAR) excimer laser systems. Marketing and sales via Alcon Labs to begin immediately.
- 10/3 -- Laser Vision Centers comments on the VISX PTK approval, stating that the approval will allow the company to offer a choice of excimer lasers to its Center doctors.

- 10/5 -- LaserSight announced completion of its acquisition of MEC Health Care for \$9 million. The company intends to replicate the MEC business concept of arranging HMO vision care contracts across the country.
- 10/6 -- VISX announces it has filed a registration statement with the SEC to sell 2.5 million shares of common stock via Dillon, Read and PaineWebber. Although not stated, the money raised will probably be used to gear up manufacturing facilities in expectation of shortly gaining FDA marketing approval of its STAR excimer laser for performing PRK.
- 10/6 -- NewVision announces the placement of its first laser in the Boston area at the Mass Eye and Ear Infirmary. Initially, the laser will be used for PTK procedures. The placement doubles NewVision's installed lasers, with the other at Hahnemann Medical Center in Philadelphia.

PRK UPDATE -- OCTOBER 1995

- 10/2 -- As reported in "The Gray Sheet", Chiron's royalty payments to Visx, under the patent license agreement signed September 25th, will be a "single digit" percentage of future unit sales. The agreement also applies to Chiron's Keracor 117, an advanced model of the Keracor 116, which was introduced in Amsterdam at the ESCRS meeting this week. Chiron believes that between 250 to 350 excimer lasers will be sold worldwide (outside of the United States) in 1995, at an average selling price of \$300,000. The company believes that it will have a 25% share of these sales. The report further noted that the Chiron laser was in Phase 3 trials, with an expected late 1996 or early 1997 PMA filing date.
- 10/5 -- Vision 21 and Columbia/HCA sign exclusive agreement to provide managed eye care services throughout Florida for the next 20 years. Columbia/HCA Eyecare Providers of Florida will become part of Vision 21's network of ophthalmologists and optometrists.
- 10/9 -- This issue of The Gray Sheet states that Visx will begin shipments of its STAR excimer laser system for PTK this month. As noted last month, the company is hopeful of having its PMA for myopia reviewed at the FDA's Advisory Panel Meeting of October 20th.
- 10/9 -- Escalon Ophthalmics announced an agreement to be acquired by Intelligent Surgical Lasers, with the surviving company to be called Escalon, Inc., and to be controlled by the Escalon officers. The \$10.3 million stock transaction has to be approved by both companies shareholders, and is expected to be completed before the end of 1995. The combined company will be headquartered in Skillman, NJ. At this

time it is not known what the ongoing status of ISL's refractive surgery program will be.

- 10/10 -- Summit Technology reports third quarter financial results, with revenues of \$13.8 million and net income for the quarter of \$0.3 million, or \$0.02 per share. For the nine months of this year, revenues are \$30.2 million, with a net loss of \$3.7 million or \$0.22 per share.
- 10/10 -- Hawker Siddeley Canada's Beacon Eye Institute will benefit from a recent ruling by Health Canada, declaring that the Visx Twenty/Twenty excimer laser is no longer investigational, allowing the expansion of its laser-PRK vision correction services throughout Canada.
- 10/11 -- Kaiser Permanente of the Mid-Atlantic States awarded a vision services contract to LaserSight's subsidiary, MEC Health Care. The contract calls for providing vision care services within the Greater Baltimore Metropolitan service area, adding 40,000 new lives to MEC's base of approximately 350,000 lives across a four-state region, cared for by a network of 100 ophthalmologists and 150 optometrists.
- 10/13 -- Vision 21 expanded its managed care network with the addition of two more leading ophthalmic surgical teams, The Eye Institute of Central Florida, and the Johnson Eye Institute. This brings Vision 21's managed care provider network to 300 practitioners in Florida, 180 ophthalmologists and 120 optometrists.
- 10/16 -- NewVision Technologies announces it will change its corporate name to Sight Resource Corporation on October 30, 1995. The company states that the new name reflects its expanded corporate mission as it continues to develop its vertically integrated eye care business. The company will continue to use its former NASDAQ symbol of VISN for its common stock.
- 10/16 -- Summit Technology and Visx both announced that they were the target of an FTC probe, looking at whether Pillar Point Partners and/or its partners (Summit and Visx) had engaged in any unfair methods of competition in violation of the FTC Act. Both companies believe that the formation of Pillar Point was in compliance with such laws. According to The Boston Globe, the action may have been precipitated by the court filing of LaserSight in conjunction with the action taken against it by Pillar Point.
- 10/18 -- Summit Technology has established three "Centers of Excellence" in conjunction with its launch of its own refractive surgery centers. The first three Centers are Rush-Presbyterian-St. Luke's Medical Center in Chicago, The George Washington University Medical Center in Washington, DC, and the Jules Stein Eye Institute at the UCLA Medical Center in Los Angeles.

- 10/18 -- Laser Vision Centers received \$14.1 million by closing of a private placement of its convertible preferred stock. The company continues to negotiate with other investors to round out the \$18 million private placement.
- 10/20 -- Following a ten-year quest, Summit Technology receives final approval to market its SVS Apex excimer laser system for the correction of myopia. It is ironic that the Summit approval comes on the day that Visx appears before the FDA Advisory Panel seeking its approvable status.
- 10/20 -- At the FDA's Advisory Panel meeting, Visx was given conditional approvalability for both the Model B (Twenty/Twenty) and Model C (Star) excimer laser systems for the treatment of low myopia. The company will have to provide the Panel with additional updated followup data on 95% of the patients who have had the PRK procedure done in trials over the past two years, in addition to several other conditions. According to company officials, they expect to be able to provide the additional data quickly, and unofficially, anticipate obtaining marketing approval within three to six months.
- 10/24 -- In a series of announcements, NewVision Technology signed agreements to open two excimer laser centers in Rhode Island, the first at the Rhode Island Eye Institute in Providence, and the second at Koch Eye Associates in Warwick. On the 26th, the company announced it had changed its name to Sight Resources Corporation, effective on October 30th, which better reflects the company's expanding corporate mission.
- 10/26 -- Summit Technology's 2.2 million share public offering was priced at \$41.50 per share, expected to raise just under \$100 million. The company announced on October 30th that it had indeed raised over that amount from the sale of 2.5 million shares.
- 10/27 -- Following the approval of Summit's laser, LaserVision Centers announced that it had purchased 15 lasers from Summit, bringing the total of lasers it owned to 45. The company stated that it planned to add the 15 new lasers to the six already in the States as part of its plans to open up to 50 excimer laser centers over the next twelve months. On November 2nd, the company placed what is probably the largest medical laser order, by reaching an agreement with Visx to purchase 20 Star lasers for immediate delivery, and to purchase an additional 20 laser systems over the next twelve months. The total purchase has a value of over \$20 million.
- 10/28 -- In a surprise announcement, Visx and Alcon Laboratories stated that they had settled their \$2.5 billion legal battle with Cap Advisors Ltd, by agreeing to dissolve the marketing agreements between them. This, in essence, gives the marketing rights for the excimer laser systems back to Visx. Alcon will continue to provide service for

the Visx laser sold to Alcon International customers, but will allow Alcon to market any excimer laser system, including the Visx system.

- 10/31 -- In a presentation to the ophthalmic media, Summit Technology outlined its plans to open 6 to 8 Summit Vision Centers next year, based on a hub and spoke concept that will have academic institutions as the hub, and a total of 20 to 30 satellite laser centers operating around the hubs. The first four hubs are Presbyterian-St. Lukes Medical Center in Chicago, George Washington University Medical Center in Washington, DC, UCLA-Jules Stein in Los Angeles, and Tufts New England Eye Center in Boston.
- 10/31 -- Summit Technology announced that it had prevailed in an European Patent Office opposition to a Visx patent, concerning an apparatus for analysis and correction of abnormal refractive errors of the eye. Visx countered the following day by stating that the patent in question was one of 102 international patents and involved comparative topography apparatus which was not the source of any revenue and not commercially significant.

PRK UPDATE -- NOVEMBER 1995

- 10/30 -- Summit Technology gears up for opening 20 to 30 Summit Laser Vision Centers centered around 6 to 8 hubs. According to the "Gray Sheet", three of the management firms have ordered at least 24 SVS Apex lasers at \$500,000; 20/20 Laser Centers for 7, LaserVision Centers for 15, and Sight Resources plans to order an additional 12 lasers over the next 18 months.
- 11/2 -- LaserVision Centers places what could be the largest ever order for medical lasers by purchasing 20 Visx "Star" laser systems for immediate delivery, and optioning for the purchase of an additional 20 systems for delivery over the next 12 months. The total price tag is worth over \$20 million. Once the systems are delivered, LaserVision Centers will have over 85 laser systems for its European and U.S. operations. (The company plans to open at least 50 laser vision centers in the U.S.)
- 11/6 -- LaserSight announced that Michael R. Farris, formerly President of The Farris Group, had been elected President and CEO of the corporation, replacing Robert Qualls, who remains President of its LaserSight Technologies subsidiary.
- 11/7 -- Drexler Technology (Mountain View, CA), the producer of optical memory LaserCards, announced that it had received a follow-on order from Visx for another six months worth of memory cards. The cards permanently record and store Visx system parameters for each eye surgery, and function as a "one user" ticket to activate the Visx system.

- 11/8 -- Visx announced that it had completed a public offering of 2.5 million shares at \$23.75 per share, raising \$55.6 million, to be used for R&D, ongoing clinical trials, and establishment of marketing and sales operations (in light of the October 28th legal settlement, returning marketing rights to Visx).
- 11/8 -- Hawker Siddeley Canada's subsidiary Beacon Eye Institute (Ft. Worth, TX) announced the purchase of 20 Visx Star excimer laser systems (worth \$10.5 million) for delivery over the next 15 months. Beacon plans to open the first six U.S. laser centers in Texas, Colorado, and Michigan during the first half of 1996. According to the company, over 4300 eye doctors have requested and received Beacon's educational information.
- 11/9 -- LaserSight announced the issuance of U.S. Patent #5,460,623, covering its Excalibur disposable excimer laser calibration system. The system provides a quantitative simulation of the proposed laser treatment pattern before each eye is treated, providing the surgeon with detailed information on the proposed ablation size, shape, homogeneity, depth, and centration. The company plans to market the system worldwide and charge between \$25 and \$50 per test.
- 11/10 -- Intelligent Surgical Lasers reported its first quarterly results for the period ending September 30th, with no revenue and losses of \$902,147. (As noted previously, the company is in the process of doing a reverse buyout of Escalon Ophthalmics, with Escalon becoming the surviving company.)
- 11/10 -- LaserSight announced third quarter results of revenues of \$6.8 million, and net income of \$759,000. Nine month results were revenues of \$17.3 million and income of \$3.6 million.
- 11/14 -- LaserSight announced an agreement with the University of Southern California to commercialize a device that allows the precise removal of the corneal epithelium layer with the laser prior to PRK. In conjunction with the device, LaserSight is developing an integrated tracking/laser delivery system, which will virtually automate the PRK process, called Auto-PRK.
- 11/14 -- Summit Technology announced it will issue a stock dividend of one share for every two shares held, to shareholder of record on November 24th.
- 11/15 -- Visx announced its third quarter results, showing revenues of \$3.95 million and a net loss of \$2.4 million for the quarter. For the nine month period, revenues were \$10.4 million and a net loss of \$10.7 million, which included a charge of \$2.25 million for settlement (pending court approval) of a securities class action lawsuit against the company.

- 11/18 -- Alcon and Visx announced that Visx received its "letter of approvability" for treating myopia, the final step before final marketing approval. The company expects to respond immediately to complete the FDA's requirements for final approval of its PMA.
- 11/21 -- Global Vision announced plans to open the Harrisburg, PA LaseRx Center, in partnership with 35 local ophthalmologists and optometrists. Site selection for the center is in progress and the laser for the center is scheduled for delivery.
- 11/29 -- Sight Resources (formerly NewVision Technologies) raises \$6.1 million from exercise of warrants and begins scheduling vision correction treatments at its laser center in Boston. According to the company, the Summit laser at the Boston center has been upgraded and will begin treating patients on December 15th. Sight Resources expects to have seven excimer laser centers treating patients by the end of the year and will continue to install lasers at the facilities of its medical partners throughout 1996.
- 11/30 -- LaserSight's subsidiary, The Farris Group, will pursue physician practice acquisitions and management opportunities in the areas of ophthalmology and primary care specialties. The company will offer its key consulting clients, including Deaconess Health system (St. Louis, MO), and Aetna Professional Management Corporation, operating in eight major U.S. metropolitan areas, the opportunity to participate in the acquisitions.
- 12/4 -- Francis E. O'Donnell, Chairman, purchased 5,200 shares of LaserSight, Inc. at \$14.25 on December 1st.

PRK UPDATE -- DECEMBER 1995

- 11/28 --Dillon Read puts out major report on Visx, recommending a buy. This report follows the November 20th "approvable" letter received by Visx from FDA. Based on a "pessimistic scenario", the company's revenues could increase from \$20 million in 1995 to as much as \$82 million in 1996, and nearly three-fold over the next four years reaching \$236 million, according to analysts Raul Esquivel and Matthew Dodds. The analysts expect Visx to ship 57% of the laser systems installed in 1996 and 50% thereafter. Under an "optimistic scenario", the company's revenues could jump to \$88 in 1996 and leap to \$330 million in 2000! (And I thought I was bullish!)
- 12/1 --The "red herring" for Sterling Vision was issued by Fechter, Detwiler and Burnham Securities, with an IPO for this optical retailing chain that has announced its intention to enter the PRK market under the name Insight Laser Centers, planning to open three PRK centers by the end of the first quarter of 1996, including one to be located at the Trump Towers in NYC. According to the prospectus, the company plans to open an

additional four to seven additional centers within 12 to 18 months, in metropolitan NYC and northern California. (For a chart of the plans of more than 20 of the "center" companies, see the synopsis of the Vision Monday story of December 11th below.)

- 12/11 --Vision Monday published the second of a planned three article discussion of the PRK market. (The first article appeared in the November 27th issue, providing an overview of the current situation and market estimates from yours truly and other market analysts.) This article discussed the plans for more than two dozen management companies planning to enter the centers business. According to Jeff Black of VM, more than 300 centers are planned to be open by the end of next year, with each company planning to open as few as 5, and some as many as 50! (LaserVision Centers). (It will be interesting to see how many centers get opened, and how many are still in business a few years out.) According to VM, there are now 18 centers open in the United States. (The next article in the series will focus on the various laser companies, where they are in the regulatory and marketing race, and what's next for laser surgery.
- 12/11 -- A story in the December 1995 Optometric Management states that Idaho ODs can perform PRK. According to the Idaho Board of Optometry, one of the few state boards that sets the scope of practice, Ods can perform PRK. The article goes on to say that Summit will train both ODs and Mds at St. Alphonso Hospital in Boise, and that certified ODs could be performing PRK by late January. ODs in Oklahoma, already can use YAG lasers to perform post cataract capsulotomies, and probably will be certified to do PRK with the excimer according to the president of Oklahoma's board of examiners.
- 12/11 -- WSJ publishes a cautionary story about PRK, with Health Journal columnist advising readers to "wait for the prices to come down" before having vision correction surgery performed.
- 12/12 -- Fahnestock analyst Daniel Lewis publishes his report on Visx, with a buy recommendation. He believes that Visx is at the beginning of a period of strong earnings growth, resulting, mainly, from royalty payments (Pillar Point and license agreements with other manufacturers), and direct sales of excimer lasers. (In his report, he quotes my conservative estimates for the market, as well as his own even more conservative numbers, ramping procedures from 130,000 in '96 to only 600,000 in 2000.)
- 12/13 -- Summit Technology announced that it had prevailed in its European patent opposition against the Visx patents. The EPO had found that claims 1-8 of Visx's patent on Apparatus for Ophthalmological Surgery (EP 0218427) to be invalid for the reason of lacking novelty, with the remaining claims held allowable. In a second action by the EPO, they limited the scope of Visx's patent entitled Method and

Apparatus for Performing Ophthalmic Laser Surgery (EP 0257836B). In Summit's opinion, the remaining claims of the Visx patents are limited in nature and do not cover any products manufactured or sold by the company. The Company had previously announced that the EPO had upheld Summit's opposition to another Visx European patent, Apparatus for Analysis and Correction of Abnormal Refractive Errors of the Eye, and revoked the patent because the subject matter had been disclosed in Summit's own patent, Surface Erosion Using Lasers (EP 0224322).

- 12/14 -- Two stories about PRK appeared in this day's San Francisco Chronicle's paper. In one, the paper commented on the Dillon Read report on Visx (see above), quoting from the report that "the market potential for vision correction is enormous", and commenting on the potential revenues for the company. In the second story, the paper focused on the ongoing FTC investigation of Pillar Point Partners over the per-procedure fee issue. A statement attributed to Mark Logan, Visx CEO, said, "The two companies could have increased the price of their machines, rather than create a per-procedure fee, but the sticker shock would have been too much for laser users." (Since Mark wasn't around when the Pillar Point agreement was agreed to, I can't imagine how he could have reached that conclusion.)
- 12/14 -- WPRK in Pittsburgh, a collaborative laser center of over 150 ODs and MDs in western Pennsylvania, has changed its name to AllSight, Inc. (Allegheny Laser Sight). The consortium has selected a center location in Pittsburgh, PA and has a guaranteed delivery date for its Summit laser. They expect to be up and running by February 1st. The company will conduct its first doctor/staff AllSight affiliates practice management training session on January 21st.
- 12/15 -- Sight Resources announced that three of its U.S. excimer laser centers were beginning to treat patients. The three are located at the Mass Eye and Ear Infirmary in Boston; The Rhode Island Eye Institute in Providence; and the Koch eye Associates in Warwick, RI. A fourth laser center in Philadelphia is scheduled to begin treating patients in a few weeks. The company currently owns 16 Summit lasers.
- 12/15 -- LaserVision Centers reports that its revenues were up 22% to \$960,000 for its second quarter (ended October 31st), and up 7%, to \$1.7 million, for six months. The net loss for the quarter was \$1.5 million, compared to a loss of \$848,000 for the same period a year ago. For six months, the loss was \$2.5 million, compared to last year's loss of \$1.4 million. The company has set in motion its plan to enter the U.S. market with its partner Columbia/HCA, by contracting for the purchase of 55 lasers in addition to the 6 lasers already in place in locations throughout the U.S.
- 12/15 -- Two interesting tidbits in the current (December) issue of Review of Ophthalmology: Technolas is back, discussing the new scanning software in the Keracor 117 excimer laser, to get around the Summit Azema patent suit in Germany;

and a story about an FDA spokesperson (Sharon Snyder) stating that the FDA regulates devices, not procedures, thus opening the way for surgeons to (supposedly) perform LASIK on approved Summit machines. Ms. Snyder went on to be quoted as saying, "MDs can use the laser as they see fit in the best interest of their patients. It's perfectly legal!"

- 12/15 -- Also, in the current November/December issue of the Journal of Refractive Surgery, Lisa Kearns reports on the FDA investigating injuries reported from the use of a "homemade" laser. Without stating whose laser or who the surgeon was, Lisa talks about the case of a 32 year-old female patient who was functionally blind more than 3 months after undergoing simultaneous bilateral LASIK with a custom-made non-FDA approved excimer laser. Experts familiar with the case say the damage done to the patient's eyes was directly related to problems with the laser. Instead of the energy being distributed over the entire ablation zone, it was concentrated in one small spot, resulting in a 1-2 mm optical zone with an estimated ablation depth of 400 mm, creating a pit, which is extremely hard to correct. Several subsequent operations were attempted to correct the problem, with the patient now able to read and drive, but still with a loss of visual acuity.
- 12/18 -- LCA-Vision opened its first U.S. medical center for PRK in Cincinnati, to serve the tri-state area. Training and certification of ophthalmologists will be done by the Ophthalmology Department of the University of Cincinnati. Designed as an "open access" facility, the LCA-Vision Center will be available to many of the 90 MDs and 200 ODs operating in the tri-state region. LCA-Vision plans to open as many as 20 additional laser eye surgery centers during the next year, in cities across the U.S., including New York; Chicago; St. Louis; Lexington (KY); Sarasota (FL); Montgomery (AL); Dallas; Pittsburgh; Cleveland, Dayton, and Toledo (OH); Baltimore; Savannah (GA); and Scranton (PA); among others.
- 12/18 -- In a note from Bill Kelley, General Manager, North America for Aesculap-Meditec, he says that Aesculap has established its initial 5 clinical sites for the FDA trials in the U.S. In addition, he mentioned that the parent company, Aesculap, had formed a joint venture with Jenoptik, the original Zeiss optical company in Jena, East Germany. Meditec's laser technology and manufacturing will move to Jena, combining the company's manufacturing and office facilities in that city. The new company will serve dermatology, dentistry, and general surgery specialties, as well as ophthalmology. The company is about to introduce a new erbium laser for dermatology, to compete with the Ultra-Pulse CO₂ laser for skin resurfacing. Clinical studies are underway in Europe and will soon expand to other world areas.
- 12/21 -- LCA-Vision opened New York city's first laser eye surgery center devoted to performing PRK. Crystal Vision Associates, will occupy temporary quarters at 800A Fifth Avenue, prior to moving into new space at the same location in early February.

The site is jointly sponsored by Cabrini Medical Center, LCA-Vision, and a group of prominent NYC ophthalmologists. The enterprise will use a Summit laser. As noted above (12/18) LCA-Vision plans to open as many as 17-20 additional sites over the next year.

- 12/21 -- Visx and Schwind jointly announced a patent license agreement between them. The agreement allow Schwind to use Visx patents in its Keratom laser system for photorefractive vision correction. Added to the Visx release was a note from CEO Mark Logan, commenting on the recent Summit/Visx litigation in the European Patent Office (see 12/13 above). According to Mr. Logan, "This licensing news comes on the heels of our successful defense of two patent oppositions filed in the EPO by Summit...the challenged patents remain in force with all primary claims in place." (This seems to be contrary to Summits claims above. Does anyone know who won this fight?)
- 12/21 -- Sight Resource also announces the opening of a NYC laser center. This center, the fifth to be opened by Sight Resources in the U.S., and the second outside of New England (the other in Philadelphia), will be under the direction of Dr. Herbert Gould. He will treat Sight Resource's patients, as well as providing training for other NY-based ophthalmologists. The center is expected to be operational in early January.
- 12/21 -- LaserSight claims it is in exclusive negotiations with a major (unnamed) managed care company, having signed a memorandum of understanding. The joint venture would combine the physician practice acquisition expertise of The Farris Group (a LaserSight subsidiary) with the managed care company's physician practice management and managed care expertise.
- 12/21 -- Steve Joffe, MD, and president of LCA-Vision, answered the WSJ article of Dec. 11 with a letter, stating that his center in Toronto had achieved a 98% success rate in getting 20/40 vision or better, and that the pain associated with the first 24 hours "is simply not supported by our clinical experience." He goes on to state that, "Success in laser eye surgery, like any other surgical procedure, is a function of the skill and experience of the attending ophthalmologist and proper patient selection."
- 12/21 -- Sterling Vision's IPO goes off at \$7.50 per share for the 2.2 million share offering.
- 12/26 -- LaserSight signs letter of intent to acquire the first of at least 12 to 15 major ophthalmic practices, in a stock swap for unrestricted shares of LaserSight, Inc. If completed, the acquisitions could generate almost \$29 million in revenues and approximately \$3.2 million in income, according to the company.

PRK UPDATE -- JANUARY 1996

- 12/28 -- **LaserVision Centers** applies for NASDAQ National Market System listing. The company currently trades on the "Small Cap" market.
- 12/29 -- **Everen Securities** puts out its initial report on **LaserVision Centers**, with a strong buy recommendation. The recommendation is based on LVC being the largest operator of excimer laser centers, with 23 centers in Canada and Europe, and its joint venture with **Columbia/HCA**. The report states that Columbia/HCA's 135 ambulatory surgery centers account for roughly 10% of all ophthalmic procedures performed annually in the U.S., and that LCA has identified 35 of Columbia/HCA's outpatient centers as possible sites for excimer laser vision correction, hoping to capture approximately 14% of the PRK market in the U.S. over the next 5 years.
- 1/1 -- According to the Gray Sheet (and later in the Jan. 15 edition of Ocular Surgery News), argon laser trabeculoplasty is acceptable as a "first-line" glaucoma treatment. This is supported by a seven-year National Eye Institute study comparing the use of the laser to medications for the treatment of newly diagnosed primary open angle glaucoma. The results of the Glaucoma Laser Trial Follow-up Study is published in the December issue of the American Journal of Ophthalmology.
- 1/2 -- **LaserSight** launches PRK services strategy, with an agreement with **Greater Baltimore Vision Laser Center, (jointly owned by Greater Baltimore Medical Center and LCA-Vision)**, to provide access to the Center's laser to LaserSight's optometric network throughout the greater Baltimore area. As part of the agreement, LaserSight's optometric network will be the exclusive network affiliated with the Center. The network will be administered by **MEC HealthCare**, with approximately 150 optometrists in the Baltimore area.
- 1/4 -- **AllSight, Inc. (formerly WPRK in Pittsburgh)** will hold a training seminar for affiliates and their staffs on January 21st at the Sheraton Inn Pittsburgh North. (As previously announced, their Pittsburgh PRK center is expected to open on February 1st.
- 1/10 -- **Autonomous Technologies** has received its IDE to begin Phase II U.S. clinical trials for its T-PRK tracker assisted excimer laser. The Phase II clinicals will begin in February at the Eye, Ear, Nose & Throat Hospital in New Orleans, under the direction of Dr. Marguerite McDonald, Director of the Refractive Surgery Center, and medical director for the company. The IDE contained data on the blind eye and Phase IIa studies conducted by Dr. Ioannis Pallidaros at the University of Crete in Greece.
- 1/10 -- **LaserVision Centers** announced at the Hambrecht & Quist health care conference, that it would meet with the FDA in the "next few days" to discuss certification

requirements for the company's MobileExcimer to do PRK. Once the FDA OKs the MobileExcimer, it would provide the company access to smaller markets and increase surgical users.

- 1/11 -- **LCA-Vision** announced plans to open its third refractive surgery center in the Beachwood suburb of Cleveland during the week of January 22nd. This center would join centers already open in Cincinnati and New York. In addition, the company has signed contracts with groups of ophthalmologists to open eye-treatment centers in Baltimore (see LaserSight announcement above) and in Savannah, GA. The company also expects to move from the NASDAQ Bulletin Board to the Small Cap Market during the first quarter.
- 1/11 -- **VISX** announced that the California Superior Court had approved the settlement of the **CAP Advisors Ltd** derivative suit against **Alcon Laboratories** and VISX.
- 1/11 -- **The Cleveland Clinic Eye Institute** and **Summit Technology** have formed an alliance for the clinic to become a regional "hub" for Summit's Center of Excellence program.
- 1/12 -- According to the St. Louis Business Journal of January 15-21, both **LaserVision Centers**, and **EyeShapers Laser Center of St. Louis** have plans to open refractive surgery centers in west St. Louis County. LaserVision is seeking a Certificate of Need for its center, while EyeShapers does not believe it will need one, as it plans to move a laser used by Washington University's School of Medicine to its new site. Also, LaserVision is moving into a new headquarters building in the St. Louis area, double the size of its previous office space.
- 1/12 -- The current issue of MedPro Month has a short squibb about a start-up company involved in a new approach to changing corneal shape. **Advanced Corneal Systems** of Laguna Hills, CA, started by people formerly with **Allergan Medical Optics**, is in Phase II clinical trials with a technique based on an injection of a drug to soften the cornea, followed by the placement of a rigid gas permeable contact lens to mold the new corneal shape until the cornea re-hardens. According to my sources, the clinical trials are being conducted in Mexico. This technique is similar to one I knew about in the early 1980s. While at Arthur D. Little, I had licensing rights to patents issued to Charlie Neefe of Big Spring, TX, who proposed adding certain drugs to the corneal surface to soften it, while reshaping the surface with (then) a hard contact lens, and hardening the corneal surface with vitamin C. (I have copies of the patents if anyone is interested.)
- 1/12 -- On one of the week's most widely watched television program, 20/20 (the Barbara Walter's interview of Hillary Clinton), the program devoted a positive segment to PRK. Other than disparaging remarks by George Waring about some pain (and his

optimism for RK and LASIK), the segment gave a fair picture of the benefits of the procedure.

- 1/12 -- The January 15th issue of Fortune gives a favorable review of the prospects for **Sight Resources**, even giving me credit for a potential \$2 billion (service) market if only 1% of the population opts for laser vision correction.
- 1/12 -- **LaserSight** announced the completion of a private placement of Series A Convertible Preferred Stock, yielding gross proceeds of \$5.8 million. The funds will be used to retire acquisition-related debt, pursue strategies related to PRK services and ophthalmic practice acquisitions, and improve working capital.
- 1/15 -- **Summit Technology** sends out "The Summit Report" to all ophthalmologists (?) stating that, based on the clinical results reported to the FDA (clinical trial data submitted by **VISX**), the Summit excimer laser gives better results than does the VISX laser. "In U.S. clinical trials, the chances of seeing 20/20 or better were greater with the Summit Technology excimer laser system. More patients were also corrected to 20/25 or better or 20/40 or better with the Summit laser." Reading between the lines, one has to take into account the poor results obtained by VISX in the first half of their studies when they were still using N₂ blowby. The real question is, are the results with the two lasers comparable now, with today's systems, and I think they are.
- 1/17 -- **Sunrise Technologies** announced that an additional patent of Bruce Sands had issued and was assigned to the company. U.S. 5,484,432 relates to a collagen treatment apparatus by applying infrared energy to the tissue in which the threshold shrinkage temperature is substantially reduced by applying reagents such as lysozyme to the tissue prior to heating. (A patent on the method had issued previously in May of 1994.)
- 1/19 -- First excimer laser PRK procedures in Minnesota were performed on Jan. 17 at the Phillips Eye Institute by Drs. Richard Lindstrom and David Hardten. Other doctors will be performing the procedures over the next few weeks.
- 1/18 -- **Global Vision** announced plans to open its fourth laser vision correction center in Knoxville, TN. The Knoxville LaseRx Center, a partnership with over 45 local ophthalmologists and optometrists is expected to be operational in early February.
- 1/22 -- **Summit Technology** announced that Stanford University Medical Center in Palo Alto, CA, the Cleveland Clinic Foundation Eye Institute in Cleveland, and the New England Eye Center at the Tufts University School of Medicine in Boston, have joined the Company's Centers of Excellence program for providing physician education, clinical research, and patient care. The company now has six centers established across the country, the others being Rush Presbyterian-St. Lukes Medical

Center in Chicago, the George Washington University Medical Center in Washington, DC, and the Jules Stein Eye Institute at the UCLA Medical Center in Los Angeles.

- 1/22 -- **LCA-Vision** announced that its shares have begun trading on the NASDAQ Small Cap Market, under the symbol LCAV. The company's third center, in Cleveland, is expected to open this week. During February, additional openings are scheduled for Savannah, GA; Toledo and Dayton, OH; and in Baltimore, MD.
- 1/22 -- **LaserSight Technologies**, a subsidiary of **LaserSight, Inc.**, announced that it had opening its new manufacturing facility in San Jose, Costa Rica, on January 15th. The company plans to fill the majority of its future orders at the Costa Rico facility, which has a capacity to produce and ship up to ten lasers per month.

OPHTHALMIC LASER UPDATE -- FEBRUARY 1996

- 1/26 **LaserSite**, a privately-held venture formed by two Dallas refractive surgeons, Drs. Harvey Carter and Jeffrey Whitman, announced that it had opened its first Center for Laser Correction, in Dallas, and had treated its first patients. The company claims it plans to operate excimer laser centers throughout north Texas. To date, they have been joined by 43 other prominent ophthalmologists from the greater Dallas-Fort Worth area. Nexus Healthcare, a health services development and management company assisted in forming the LaserSite venture and will oversee daily center operations. The principals of Cornea Associates of TX will act as LaserSite Medical Directors.
- 1/30 **LaserSight** and **Par Technology** have formed a joint venture to commercialize the Ex-CaliPar (renamed from Ex-Calibur) excimer laser calibration system. Ex-CaliPar is claimed to be the only clinical system that confirms centration, homogeneity, depth, and contour for each laser procedure. LaserSight will market the device worldwide to all excimer laser users, while the partnership proposes to sell a software module for calibration in conjunction with single-use, disposable plastic targets. (An excellent writeup about Ex-Calibur/Ex-CaliPar, and Dr. Peter McDonnell's epithelium laser removal procedure/device, by Kathy Kincade, appears in the January 22-28 issue of *Ophthalmology Times*.)
- 2/1 **LCA-Vision** announced that it had opened its fourth laser eye surgery center in Savannah, GA, with 7 patients expected to be treated. The center is a joint venture among Memorial Medical Center, Candler Hospital, and LCA-Vision. A fifth center, of the twenty planned for this year, in Baltimore, is expected to open later this month.
- 2/1 **LaserSight** has appointed Peter McDonnell, Professor of Ophthalmology, Doheny Eye Institute, University of So. California, as its Medical Director, replacing Dr.

Craig Beyers, who has gone to China to open refractive surgery centers. Dr. McDonnell, Director of Refractive Surgery at Doheny, was a principal investigator for the VISX excimer laser. (He is also the inventor of the epithelium removal device noted above in the 1/30 brief.) Dr. McDonnell will become involved in clinical studies for both the Mini-Excimer and the solid-state LaserHarmonic.

2/5 I received the January 16th prospectus for **Iridex Corporation**, formerly known as **Iris Medical Instruments**. (The company changed its name to Iridex in January 1996.) Iridex is the manufacturer and distributor of the OcuLight Diode Laser Photocoagulator system, composed of the diode laser and various endoprobe and contact probe delivery systems, as well as a slit lamp delivery system. With more than 1000 systems sold worldwide, has plans to introduce a new semiconductor-based visible-light laser photocoagulator system later this year. The company is also collaborating in the development of a diode-based photodynamic laser therapy system with **PDT, Inc.** The company is planning to offer 1.6 million shares at an IPO price of \$9.00 per share, to raise approximately \$12.6 million, primarily for working capital.

2/6 In an inquiry to *Ocular Surgery News*, I received, via e-mail, the statement released by the FDA at its January 22nd meeting regarding LASIK and its use with approved PRK lasers. Basically, the FDA states that LASIK has not been approved for safety and effectiveness, nor has any laser been approved to perform LASIK. Therefore, companies may not market or promote lasers for LASIK; physicians may not market or promote lasers for LASIK; physicians use of a laser approved only for PRK is a practice-of-medicine issue, as long as the physician does not market or promote the laser for LASIK. (An interesting aside to the notice about LASIK is the Agency's statement that it "has no position with regards to whether the individual (using the laser ?) is an optometrist, ophthalmologist, or other kind of practitioner. This is a matter for the States to decide.")

Am I missing something? I thought that LASIK was still investigational and only two companies, **Chiron** and **Summit** had IDEs to conduct clinical investigations. That also means that the six or so firms selling microkeratomes also need to sell them only under an approved IDE, or so I thought. Therefore, all the FDA has to do to stop unauthorized LASIK (or ALK for that matter) is to clamp down on the companies selling the microkeratomes!

2/6 **Summit Technology** released its fourth quarter results, with revenues of \$15.0 million, compared with \$8.2 million for the same quarter last year. Revenues for the year were \$45.1 million, up from \$24.2 million for 1994. The company had a net income of \$186,000, or \$0.01 per share for the quarter, and a net loss of \$3.5 million or \$0.14 per share for the year.

- 2/6 **VISX** finally hired the key sales personnel from **Alcon Laboratories**, to head its own sales and marketing efforts, with Jim McCollum joining the management team as VP of Marketing and Sales. Ric Tiplady and Steve Parks also transferred from Alcon to VISX with Jim.
- 2/7 **Global Vision** announced plans to open its fifth laser center, The North Texas LaseRx Center, in Dallas, TX, in conjunction with the over 50 local ophthalmologists and optometrists. Site selection is completed and the center is expected to be operational by the end of February.
- 2/7 I finally was able to get to Arthur D. Little and visit the Healthcare Library to get my fix of "*The Gray Sheet*". In the January 8th issue, **Nidek Technologies** claims that it expects to file its PMA for its EC-5000 PRK laser in 1997, following completion of its U.S. studies of the device in late 1996. The company is awaiting approval to begin its 700 patient, 10-site Phase 3 study. (Since the Phase 3 study requires a two-year followup, I don't understand how they can expect to obtain approval and come to the market any sooner than the end of the decade!) The firm completed its Phase 2 trials last summer, and preliminary data from the U.S. trials show comparable data to those seen in overseas trials, which involved 1,684 patients as of September. That data shows 97% of myopic eyes treated achieved 20/40 or better after one year followup, with 89% having 20/25 or better, and 79% having 20/20 or better. The company also notes that it has not yet resolved the legal issue of whether it needs to obtain a license from Pillar Point Partners prior to U.S. commercialization.

In the January 15th issue of "*The Gray Sheet*", there is an analysis of the "meteoric rise" of **VISX's** stock in 1995, gaining 28½ points, or 271.4% to 39 over the year. The newsletter attributed the rise to the various approvals obtained by the company in its race to catch up with **Summit Technology**. Summit also did well in the year, gaining 76.5% to reach 33.75 (adjusted for a three-for-two stock split), after a 36.9% gain in 1994. The story goes on to say that, "As investors look ahead to the future of Summit and VISX, they no doubt are enticed by the potential market size that awaits if PRK procedures become popular. **Irving Arons**, managing director of Massachusetts-based **Spectrum Consulting**, has estimated that 1,100 laser systems will be in operation in the U.S. by the year 2000. Arons also projects that 1.1 million to 2.7 million procedures will be conducted annually by that time." (This comes from the news release I put out last September.) The story goes on to discuss the fiasco that occurred with laser company stocks (Candela, Laserscope, and Surgical Laser Technologies) back in the early 1990s, following the collapse of the laser market for cholecystectomies, and for Trimeddyne in angioplasty and urology in 1992 and 1993. However, Candela, up 3¼ points, on the strength of its diversification strategy (cryogenic surgical devices and cosmetic skin care service centers) has staged a comeback.

- 2/8 **LaserSight** announced that it had received notice from the U.S. Patent Office that its patent application for its scanning delivery method and apparatus for PRK had been approved for issue. The patent covers LaserSight's photo-polishing method and galvanometric scanning delivery system designed for ultraviolet (excimer and solid-state) and infrared wavelengths for PRK. According to Robert Qualls, president of LaserSight Technologies, Inc., "This patent represents the only PRK method and delivery system not covered by the Pillar Point Partnership. Moreover, unlike the UV patents in Pillar Point, it covers all wavelengths for PRK."
- 2/9 **Intelligent Surgical Lasers** announced that its shareholders had approved a proposed acquisition of all of the assets and liabilities of **Escalon Ophthalmics**. Completion and closing should occur shortly. As noted in the November Briefing, this is really a reverse buyout, and Escalon will be the surviving company.
- 2/10 Over the weekend, I got caught up with some of my accumulated reading. In the January 8-14 issue of *Ophthalmology Times*, is another note about ISL. We can finally put to rest the possibility of using ISL's picosecond laser for intrastromal ablation. According to investigator Mark Speaker, the results in both rabbits and cats looked promising, but the animal results could not be reproduced in blind human eye tests, perhaps because of a thicker Bowman's layer. According to Speaker, "Basically what we found is that in the human cornea, the effect takes much longer to evolve. We didn't begin to see refractive changes until after six months." This leaves only the use of the picosecond laser as a microkeratome for removal of a disc of tissue, or in combination with the excimer, by creating the flap with the picosecond laser and doing the refractive ablation with the excimer.
- In line with the above note, in the January/February issue of *Journal of Refractive Surgery*, there is an interesting article about the use of a waterjet keratome for cutting corneal tissue. The so-called Lipshitz-Bass knife (LBK) is used to make lamellar corneal incisions, using a suction ring to partially deform the anterior corneal surface, make the corneal cap cut with a 4000 psi saline water jet, and realize a re-curved surface when the suction ring is released. The work, done on rabbit eyes, showed a smooth surface quality, with epithelium healing within 48 hours. The procedure takes only 1 to 2 seconds, compared to 20 to 80 seconds for the excimer laser. According to the authors, the equipment should be about half as expensive as the laser.
- 2/12 **LaserSight** confirmed that **Pillar Point Partners** and LaserSight were in discussions to settle the alleged patent infringement claims brought by PPP against LaserSight, over a scanning patent (L'Esperance) licensed to PPP by **VISX**.
- 2/12 **Intelligent Surgical Lasers** announced the completion of its acquisition of **Escalon Ophthalmics**. Upon closing of the transaction, ISL will file to change its name to

Escalon Medical Corporation. The company will continue to trade on the NASDAQ under the symbol ISLS. (For more on this, see the 2/9 brief above.)

- 2/13 **Sight Resource** announced it was beginning to treat patients at its Chicago and Philadelphia excimer laser centers. The Chicago site, at the St. George Eye Center, is the fifth operational center opened by the company, and the first outside of the Northeast. A sixth center is slated to open in New York City before the end of the month. The patients at the St. George Eye Center were treated by Dr. Nicholas Caro, while those in Philadelphia were treated by Drs. Karen Heffler and Myron Yanoff, the medical director of Sight Resource.
- 2/14 **Intelligent Surgical Lasers**, reported its quarterly and year end results. For both the quarter and the year, the company had no revenues, sustaining a net loss of \$737,000 for the quarter and \$1.2 million for the year.
- 2/15 **VISX** announced its fourth quarter and year end results. The company had revenues of \$6.3 million for the quarter, and \$16.7 million for the year. The net loss for the quarter was \$4.1 million or 30 cents per share, including a charge of \$3.1 million (23 cents per share) for settlement of a shareholder derivative suit. For the year, the company had a net loss of \$14.8 million or \$1.20 cents per share, including \$5.4 million or 44 cents per share for the suit and a securities class action lawsuit against the company.
- 2/20 **LaserSight** reported substantial increases in 1995 and fourth quarter earnings. On sales of \$8.7 million for the quarter, and \$26.0 for the year, net income jumped to \$973,000 for the quarter (13 cents per share) and \$4.6 million for the year (64 cents per share). The increase was attributed to increased international acceptance of the company's excimer laser, of which the company reported it had sold 64 compared to 30 in 1994.
- 2/22 **LCA-Vision** continued its national rollout with the opening of its fifth refractive laser center in Baltimore, the Greater Baltimore Vision Laser Center, jointly owned by with the Greater Baltimore Medical Center, the city's largest hospital, and two ranking Baltimore-based ophthalmologists. The company plans to open two additional centers, in Dayton and Toledo, Ohio next month.

PRK UPDATE -- March 1996

- 2/26 I believe that I have been perceived as an eternal optimist in the field of refractive surgery, and especially in PRK. Well, I have just met my opposite number. This morning, I received a copy of Anne Anderson's (**Atlantis Research**) report on Summit Technology, issued on February 7th, and probably the reason for the 20% drop in Summit's stock price. Nearly every comment that Anne made is negative, or at least on the downside, as evidenced by some of the following comments.

"Early years of PRK Procedure likely to disappoint investors." She noted that she was one of the early analysts to have the procedure done, with a positive experience, but believes the early years will not develop as analysts (like myself) have projected.

"Machine placements could be less than expected." Commenting that most estimates have called for 1200 to 2000 placements, she cannot see much more than 700! Or if one looks at the likely number that can be supported by U.S. cities, less than 1000 units should suffice.

"International experience with PRK unpromising." I guess we can all agree with that. And I have told those of you who have asked, my reasons for greater optimism for the U.S. market, while the foreign markets are not good examples of what will happen here.

"Competing refractive therapies." I guess she thinks that RK will remain viable after PRK takes its hold. I disagree. LASIK still uses the excimer laser, and LTK has not shown particularly good results due to regression. The ICR, while promising, is still a surgical intervention.

"Ophthalmic surgeons ambivalent about PRK." Yes, unless the doctors affiliate with a laser center, the economics, especially for the marketing required, may make this look unfavorable. But, with a connection with a laser center, although less rewarding, the docs can make a buck!

"Offers for secondhand equipment circulating." I really don't believe that the "gray" market will have much of an impact, at least for the foreseeable future.

"High breakeven point limits profitability of Laser Centers." According to her analysis, it only takes 50-60 eyes per month to break even. That's about half what most laser centers were planning on. An interesting table accompanying this section shows how much money 9 of the 16 largest have raised. (Give me a call if you want a copy faxed to you.)

"Summit's strategy of owning centers creates additional risk." I guess I have to agree. In the long run, it will influence potential purchasers to think VISX!.

"Early signs of market share loss to VISX." According to Anne, there is apparently a preference for VISX machines, and many laser centers are counting on a VISX approval early in 1996, and will shift their center's laser to the VISX Star.

"Summit financial model dependent on procedure fees." No question, PPP procedure fees figure into Summit's financial planning. The only real question is the viability of the Pillar Point Partnership, and what the ongoing FTC investigation will uncover. In

any event, if the partnership unfolds, there is nothing to prevent each company to demand a per-procedure fee based on its own patent portfolio. It will then come down to who places the most machines.

- 2/26 To counter the above, Jonathan Cohen of **Smith Barney** issued a "buy" rating in his flash report (which incidently raised Summit's stock temporarily), giving his price target of \$38, and countering many of the points raised in Anne's report. He states that, "From Summit and VISX's perspective, Pillar Point Partners remains inviolate...while unable to predict what the FTC may or may not choose to do...we note that PPP was specifically designed to survive a challenge from the FTC on an anti-trust basis."

He goes on to state, that if the partnership does breakdown, Summit and VISX would compete for equipment sales on the basis of price and performance (a war that VISX might win, I believe), and also by offering rebates or more favorable terms in regards to a per procedure royalty payment. He does not believe that that outcome is at all likely. His models for both Summit and VISX are both highly sensitive to the total number of procedures performed in the U.S. and his estimates remain unchanged, predicting 200,000 during 1996, 500,000 during 1997, 800,000 in 1998, and 1.2 million by 1999. (I have picked that number for the year 2000!)

He goes on to comment on Summit's offering PRK services directly to the U.S. market, with Summit committed to opening 25 PRK centers during the first six months of 1996. He agrees basically with their strategy, but states that the strategy may place the company at some disadvantage by competing against their customer base and the academic centers lack marketing expertise. He notes that Summit is aiming to capture only 5% of the total U.S. PRK market. Although some practitioners see Summit as a competitor, he believes that Summit's generic advertizing and marketing will contribute to expanding the business more than their proprietary role will hurt it. That is the basis for his continued recommendation of the stock.

- 2/28 **LCA-Vision** reports 1995 operating results, stating that the company is in a major transformation to a laser eye surgery provider. The company reported net income of \$178,764 for 1995, equal to one cent/share, on revenues of \$13.7 million. These numbers for 1994 were \$1.7 million in earnings (26 cents/share) and \$16.9 million in revenues. The earnings decline was attributed to a decrease in the number of hospital-based contracts for laser and MIS surgery programs as they geared up for conversion to the new business sector of eye laser surgery, establishing free-standing laser refractive surgery centers. LCA-Vision has opened eye surgery centers in five U.S. locations: Cincinnati, New York, Cleveland, Savannah, and Baltimore. They plan to open two more centers in Ohio next month (March), and as many as 20 centers around the country by the end of 1996. The company also owns and operates the Toronto LaserSight Centre, where nearly 4000 laser eye surgeries have been successfully

performed since 1991. LCA-Vision currently has management contracts with 38 hospitals in 18 states providing cost-effective management, training and marketing support programs.

- 2/28 **Summit Technology** announces openings of first Summit Vision Centers and begins its national marketing campaign. The first Summit Vision Center was scheduled to open March 4 in the Minneapolis/St. Paul metropolitan area, with 18 additional centers scheduled to open during the next three months. During March, centers were expected to open in Bethesda, MD; San Bernadino, CA; Agoura Hills, CA; Glendale, CA; Schaumburg, IL; Vernon Hills, IL; and West Palm Beach, FL. For April, centers are scheduled for Torrance, CA; Costa Mesa, CA; San Francisco, CA; Concord, CA; Chicago, IL; Towson, MD; and Columbus, OH. In May, centers are anticipated in San Jose, CA; Tyson's Corner, VA; Miami, FL; and Fort Lauderdale, FL.

The company also announced its plans for a category development consumer advertising campaign. It will consist of a 30 second TV spot that will air nationally, as well as print placements in consumer magazines. The program is scheduled to begin in mid-April and will contain an 800 number for consumers to obtain additional information, and the location of the nearest Summit laser to their zip-code. (This will be **any** Summit laser, even those in the hands of private ophthalmologists not associated with the Summit Vision Center program. A separate ad campaign in support of the Summit Vision Centers began in selected markets on January 29th.

In another announcement, Summit stated it intended to close its New Image center operation in the United Kingdom, for which it recorded a \$400,000 charge related to the closings in its fourth quarter.

- 3/7 **Sight Resources** opened its sixth U.S.-based laser center in New York City. The company now services four of the largest seven markets and intends to open additional sites in other major markets by the end of the year. Currently operating centers are in Boston; Providence, RI; Warwick, RI; Philadelphia, PA; Chicago, IL; and now, in New York City.
- 3/11 **LaserVision Centers** intends to install eight additional excimer lasers in markets in the U.S. The schedule calls for at least one laser per week to be installed over the next eight weeks at sites in CA, NV, OH, FL, MO, and IL. The company already has six excimers installed at sites in NC, FL, MN, MO, and LA. In another announcement, the company headquarters has relocated to a larger space in the St. Louis area.
- 3/11 According to the *Ocular Surgery News Intelligence Report* of March 11th, optometrists in Idaho have begun performing PRKs. Acting with the full support of the Idaho Optometric Association, 3 ODs performed PRKs at the Idaho Refractive Laser Center. According to OSN, the AAO is preparing a challenge to the IOA position, and

working with the State Board of Medicine and the State Society of Ophthalmology, will challenge the right to this surgical use of lasers by optometrists.

In another breaking story, a U.S. district judge in California has dismissed the efforts brought by Summit Technology to stop importation of its lasers into the U.S. by Hi-Line Medical and three eye surgeons, William Ellis, Kenneth York, and Paris Royo. (According to my sources, along with the right to import these lasers, they apparently are not subject to Pillar Point Partner procedure fees, as the lasers were originally sold to parties outside of the U.S., and therefore are exempt from PPP royalty fees! One of my friends claims to have rights to approximately 30 of these lasers, both Summit and VISX machines, and told me on 3/14 that they were for sale.)

- 3/11 As most of you are aware, **Ciba Geigy** and **Sandoz** will combine and form a new super drug company, **Novartis**. According to the March 11th issue of *C&E News*, the combined company will focus on several drug-related areas but will maintain its markets in vision care, with contact lenses, lens care products (Ciba Vision) and ophthalmic products (Ciba Ophthalmics). Left unstated, was the relationship with Chiron (and Chiron Vision), which is 49% owned by Ciba Geigy.
- 3/11 I got caught up with my ophthalmic literature reading over the weekend. I would like to call your attention to several articles that appeared in the last two issues of *Review of Ophthalmology*. In the January issue, Judith Lee has an excellent article, the first in a series, about the international experience with PRK, entitled "PRK Planner: 5 Lessons from Canada". The story, meant for individuals or groups who install excimer lasers, includes information like "anticipating slow growth", "expect high costs", (the need for) "planning aggressive marketing", "its harder than it looks", and "it can work". This story is followed by an article by Guy Kezirian, "What Europe Can Teach Us". He goes on to discuss the European PRK market, showing the myopic population broken down by country, the patient pool, and the number of patients that are likely to have PRK per year. The article also shows some profiles of "name" European surgeons (Danielle Aron-Rosa, Theo Seiller, Ioannis Pallikaris, etc.), and the ratio of how many LASIK to PRK procedures these doctors are performing.

The February issue contains three stories of interest: the second installment of Judith Lee's series, "PRK Planner: Write a Business Plan that Works for You", including plans for two ophthalmologists; "Taking it to the Street", by Stan Herrin and Kristine Morrill, on what's involved in selling ophthalmic practices to publically owned management companies; and finally, Fred Kremer's column describes how both the Aesculap-Meditec and Nidek excimer lasers work.

The February issue of *The BBI Newsletter*, contains Larry Haimovitch's writeup of last fall's AAO meeting. Included in the article are tables describing the PPP royalty split between VISX and Summit; and Larry's estimates for refractive surgery for 1996

through 2000. Larry also discusses the status of the Staar Surgical implantable contact lens (ICL), research into the correction of hyperopia, using the holmium laser (Summit and Sunrise), and the new player, Refractec, using an RF probe for reshaping the cornea, in a process called conductive keratoplasty. He also discusses the latest results with the intracorneal ring from KeraVision, and a novel approach to reshaping the cornea from Advanced Corneal Systems, using an injectable drug to break down the molecular structure of the proteoglycan bonds, without affecting the collagen, followed by applying a gas permeable contact lens to bring the new shape to the corneal surface. (Kind of like wiring teeth or using hard lenses to reshape the cornea.) I recently received a package of information from this company if any of you are interested in knowing more about what they are doing.

3/15 **LaserVision Centers** reported its third quarter and nine months results, for the period ending 1/31/96. For the quarter, the company had revenues of \$852,000 and a net loss of \$1.6 million (-32 cents/share), while for the nine months period, revenues were \$2.6 million, with a net loss of \$4.1 million (-76 cents/share). Revenues for fiscal 1995 were \$2.5 million, with a net loss of \$2.1 million, or -54 cents/share. According to Chairman Jack Klobnak, the company opened its first LaserVision Centers and performed its first PRK procedures during the third fiscal quarter. Subsequent to the close of the third quarter, the company has installed five additional excimer lasers, for a total of six, and plans to install one laser a week for the next 8 weeks, as previously announced (see the 3/11 announcement above). The company noted that the slight decrease in revenues for the third quarter were due to lower international revenues, which were partially offset by higher U.S. revenues. As a result of the company's MobilExcimer to service two of the company's English centers, the lasers at these centers were taken out of service as of January 1, and are available for relocation to other potential international locations.

3/18 The March issue of *Review of Ophthalmology* checked in, with several interesting articles, beginning with the editorial by Stan Herrin, advising those involved in PRK to "Just Say No to PRK Price Wars". Stan went through the economics of running a laser and concluded that dropping prices from \$2000 or \$2500 to \$1500 just didn't make economic sense, based on the costs involved in establishing a laser business. With the typical surgeon netting only \$350 to \$400, cutting the price by \$200 (from \$1500 to \$1300) could halve the surgeon's take-home, because of all the upfront costs involved. Fred Kremer's column on Refractive Surgery describes how the LaserSight and Novatec lasers work. (Both are scanning spot ablaters.)

A roundtable with Charles Casebeer (Phoenix), Stephen Brint (New Orleans), Don Johnson (Vancouver, BC), Bruce Jackson (Ottawa, Ontario), Harold Stein (Toronto), and Patricia Teal (Ft. Erie, Ontario) discussed how to make a profit with excimer PRK. One of the major points brought out is the high cost of acquiring a patient, and the length of time it takes to convert a potential customer into a patient (in some cases,

up to two years). Guy Kezirian, a contributing editor, has an excellent article in the continuing PRK Planner series, "What to Look for in a Laser Center Contract". He raises a lot of interesting questions that should be investigated before signing an agreement. An interesting sidebar discusses, "Why Not Buy a Pre-Owned Laser?". It discusses a scenario where there could be a glut of used lasers available due to obsolescence, the coming approval of VISX (thus putting several Summit lasers on the market), the approval of other manufacturer's machines over the next several years, and with price wars and declining margins, the forcing out of business of several of the smaller, less well financed laser centers. A pipe dream? Who knows.

Judith Lee continues with her excellent series in the PRK Planner series, with "A Comprehensive Guide to PRK Centers". She interviewed the principals at many of the laser center companies, and provides a good overview of what each is planning, and how they operate. There are also several clinical articles about PRK combined with ALK (LASIK), how to minimize complications, and touching up with RK after PRK.

(Anyone who doesn't have access to this magazine and would like a copy of any of the above should give me a call.)

- 3/19 **Summit Technology** announced an affiliation with **Davis Vision**, the second largest managed vision care provider in the United States, with over 6000 active OD and MD providers across the country. (Who is the largest?) The affiliation will allow Davis providers to participate with their patients in the Summit Vision Center access plan.
- 3/21 **LCA-Vision** continued its national rollout with the opening of its sixth laser eye surgery facility in Dayton, OH. The company plans to open one more center this month, on its way to 20 for the year, in Toledo, OH.

Ophthalmic Laser Update -- April 1996

- 3/15 First some catchup news that I didn't get to last month. The March 15th issue of *Ocular Surgery News* ran the results of a faxpoll of its ophthalmic panel about refractive surgery. In summary, about 3% of the respondents' income was derived from RS (this will be an important statistic to track if OSN continues to ask the question); 58% have a positive attitude towards RK; 70% toward AK; only 23% toward ALK; 67% toward PRK; 10% toward LTK; 50% toward LASIK; 9% toward the ICR; 16% toward the ICL; 8% toward the use of aphakic IOL; and 19% toward clear lensectomy followed by an IOL. In an interesting sidebar question, only 19% would submit for a Summit PRK if they were an eligible candidate, while 66% said no.
- 3/18 *Vision Monday* had two interesting news pieces that I forgot to add last month; first the newspaper noted that **Global Vision** opened its fifth vision correction center in Dallas

(which I reported last Feb. 7 in the February Briefing), and that **Summa Health Systems**, an Akron, OH non-profit healthcare network, had opened the Summa Laser Eye Center in Akron. The second item was an excellent profile on **Sterling Vision**, providing everything you ever wanted to know about this eyecare chain and its entry into laser vision correction via its **Insight Laser Centres**. (Anyone wanting a copy of the writeup, give me a call.)

- 3/20 In the March 15th issue of OSN, I spotted an ad for a new-to-me excimer laser company, **Kera Technology, Inc.**, operating out of Orlando, FL. I faxed a request for more information and received it today. It is a company founded by George Huang, president of **UniData, Inc.**, a former **LaserSight** subsidiary. George was showing his own laser scanning device at last fall's AAO meeting, and apparently decided to build a complete laser system. The laser, called IsoBeam D200 LASIK System features dual beam delivery to provide "central island and lateral island-free symmetrical ablation". According to the literature package I received, the system was specifically designed to provide "nomogram for the LASIK procedure". If you want to see the interesting literature, call me.
- 3/20 I received the Cowen & Co. report on **KeraVision** and its' intracorneal ring developments. Much to my surprise, analysts Ann Barber et al believe that the ICR will be a big winner! All of this based on the results on just 39 patients! The analysts included an interesting table comparing RK, PRK and the ICR, which I have reproduced and attached for your review. (I wrote a recent OSN column on KeraVision. Call me if you would like a copy.)
- 3/27 **The Bochner Eye Institute**, of Toronto, announced the installation of the first Nidek EC 5000 excimer laser in that city.
- 3/27-
3/28 As I reported to you on 3/28, **VISX** won FDA approval for its Models B (Twenty/Twenty) and C (Star) systems. (I have obtained a copy of the FDA memorandum and letter to VISX, if anyone is interested in reading them.) The background memo announces that the FDA has approved the second laser for correction of mild to moderate nearsightedness, based on a review of the clinical, engineering, and statistical data submitted by the manufacturer, and on the recommendation of the Ophthalmic Device Panel which met on October 20, 1995 and gave it approvable status. As I noted to you, the approval was for people 18 years or older with 1.0 to 6.0 diopters of myopia and astigmatism of less than 1.0 diopter. Summit's approval was for patients older than 21, with myopia of from 1.0 to 7.0 diopters, and astigmatism up to 1.5 diopters.

The April 1st issue of *The Gray Sheet* discussed the VISX approval, quoting a VISX spokesperson as saying that the March 27th approval "allows treatment of the largest patient population yet". The company went on to say the the potential patient population for its Star laser was 9.7% larger than for the Summit system, with an additional 6.6 million people eligible for treatment.

News releases of congratulations were issued by several firms, including **Sight Resources** (a positive impact on the industry); **20/20 Laser Centers** (announcing it will place VISX lasers along with previously approved Summit systems in each area it serves); **LaserVision Centers** (FDA's decision enables LaserVision to increase U.S. market penetration); **The New Jersey Eye Center** (Joseph Dello Russo claiming his efforts led to the approval -- he was one of the investigators); **LCA-Vision** (stating that it would add a second (VISX) laser into its busy Baltimore center); and **Mattan's Medical Laser Institute of America** (stating that it had been using a VISX system in its **Vision Sculpting** centers in Canada, and that the company could now move aggressively in opening 12 clinics over the next year in major metropolitan areas across the U.S.).

3/28 **Intelligent Surgical Lasers** officially changed its name to **Escalon Medical Corporation**, and began trading on the NASDAQ under the symbol ESMC, instead of ISLS.

3/28-

4/1 **Sterling Vision** had two announcements; first it has opened the first two Insight Laser Centers in the New York metropolitan area, in the offices of Nassau Ophthalmic Services in Garden City and Hauppauge, Long Island. Sterling anticipates opening six to eight additional centers in major U.S. cities throughout 1996. Secondly, it announced the company's year-end results, showing revenues of \$112.3 million (combined retail sales of both company owned and franchised stores), with net income of \$767,000.

4/1 The April 1st *Ocular Surgery News Intelligence Report* asks the question, "Do excimers have bad (sic) effect on high-volume surgeons?" The newsnote poses the question about whether a connection exists between high volume PRK surgeons and bronchial irritations. Steve Klyce of New Orleans, believes that there may be the potential for serious concern from the carcinogenic effect of frequent exposure to the smoke generated during PRK procedures. According to Richard Lindstrom, Luis Ruiz of Bogota has installed a fan-like device to blow the smoke away from him during operations, after developing significant health problems from exposure to the excimers plume while performing LASIKs. (Also in the same issue was the first announcement of the Court finding the Pallin method patent on "frown incisions" invalid, in Pallin's case against Dr. Jack Singer.)

4/3 **Vision 21 and Eye Care Centers of America (ECCA)** enter into a managed care alliance. Together they will operate as a managed care organization, offering services in 24 states, with more than 350 locations and a network of more than 700 optometrists and ophthalmologists and 50 surgical facilities. ECCA, doing business as EyeMasters and Binyons, is the third largest superoptical retailer, with 153 locations in 17 states, while Vision 21 is a leader in Florida's managed care markets. In the March 1995 issue of *Eyecare Technologies*, the magazine noted that Vision 21 had temporarily closed the doors of its RK refractive surgery center, deciding to wait and see before expanding into PRK. According to president Ted Gillette, "The company will decide whether to reopen a center when second-generation laser become available and after the fallout in PRK centers has occurred".

(The same story also profiles **Sterling Vision's** entry into the PRK arena. According to the story, Sterling has leased five lasers and is in negotiation for others. Within the next 12 to 18 months, the company anticipates having 7 to 10 centers operational. Note that the number keeps changing -- see brief for 4/1 above.)

4/8 ASCRS, who provided the bulk of the defense funds for Jack Singer (see brief for 4/1 above), will defend anyone against enforcement of the Pallin patent (US Patent 5,080,111) by Pallin or anyone else.

The same issue notes that the FDA hopes to have a final *laser vision correction guidance document* published in the Federal Register by Labor Day, according to the proceedings of the April 1 Advisory Panel meeting. The discussion included a proposal from the Division of Ophthalmic Devices to expand the guidance to address high myopia, hyperopia, astigmatism, and laser in-situ keratomileusis (LASIK). (I have a copy of a February 28 FDA document, entitled "Refractive Surgery Lasers Consensus on Clinical Issues", developed by the Clinical Issues Committee, coordinated by Morris Waxler, which may be the proposal noted in the OSN story.)

Also in the same issue, **Summit Technology** president David Muller says that reports that laser vision correction is off to a slow start "is completely unfounded, and probably perpetuated by parties concerned about the possibility of increased competition". Since FDA approval, Summit has sold 13,000 software key cards, which means an equivalent number of eyes have been treated, "give or take a few hundred". At the rate of uptake, and assuming the laser business continues to ramp, Muller expects that more than 100,000 procedures should be performed this year. (And that is only with **his** machines. Now that VISX has approval, additional procedures will be done on those machines, but probably still less than the 375,000 procedures I had forecast last September. I intend to conduct a survey of laser vision correction centers in the next few months, to get a more accurate count of the actual number of procedures and center operators' expectations.)

- 4/8 *The New York Times* had a first page story on the "clash between optometrists and eye surgeons over laser process". The story details the "war" between the two "Os" over the rights to use lasers and, more specifically, the right to perform PRK. (By the way, I first wrote about this problem in my OSN column back in April 1993, "First Shot fired in MD-OD Laser War!")
- 4/8 *The Gray Sheet* comments that the **Autonomous Technologies Corp.** IPO is expected to net \$18.1 million with the offering of 2.5 million shares, expected to be priced between \$7-9. In June 1994 ATC entered into a strategic alliance with **Ciba Geigy** subsidiary, **Ciba Vision Group**, for the worldwide co-promotion of the T-PRK laser system. To date, Ciba has invested an aggregate of approximately \$5 million in cash and \$220,000 in services. Following the offering, Ciba will own approximately 18.6% of the company's common stock. (I have a copy of the prospectus.)
- 4/9 **Escalon Medical Corporation** announced that effective March 31, ISL's former chairman Heinz Gisel, and former executive vice president Edward Lake had resigned from the company to "pursue other interests". Sterling Johnson, president of Escalon also announced that the company was seeking a corporate partner to collaborate on the refractive laser program originally started by ISL. (I told Sterling back at the AAO meeting that he was 'kicking a dead horse', and I still feel that way. The ISL picosecond laser only has limited applications for precision surgery within the eye, and, in my opinion, that does not include refractive surgery. If any of you are interested in the ISL laser let me know, and I will find out what Escalon's real interest is.)
- 4/9 A letter of intent has been signed between **The Laser Center (TLC)** and **Columbia/HCA Healthcare**, in which TLC will provide certain management services for Columbia's Miami refractive surgery center. According to TLC, it will provide training and education for the doctors using the center. TLC will receive revenue from patients and doctors using the center, in return for paying a facility fee to Columbia.
- 4/10 The April issue of *Review of Ophthalmology* contains, as usual, several interesting articles. Another story about **Sterling Vision**, in which it is said that the chain says it is acquiring ophthalmic practices and converting them into PRK centers. Sterling says it will open 3 centers in New York this month, including one in the Trump Tower, one in San Francisco, and 4 to 7 more over the next 12 to 18 months. (See above for other versions.) Sterling is following in Sight Resources' steps, by taking advantage of its retail optical customer base as a marketing tool for acquiring PRK patients.

Frederic Kremer's column this month explains how the **Autonomous Technology** and Chiron/Technolas lasers work (both the Keracor 116 and the newest 117 models).

Judith Lee continues her excellent series on PRK Planner with a discussion of "Why and How Incision Procedures Still Fit In", advising ophthalmologists not to throw away their diamond knives quite yet. (The main thrust of the piece is the cost differential that still exists between RK and PRK.)

Associate Editor Walter Bethke adds a piece about how elective (cosmetic) procedures are gaining ground, discussing PRK, laser skin resurfacing, cosmetic laser blepharoplasty, LASIK, RK, AK, ALK, and traditional blepharoplasty. (I will be getting back to you shortly about how Palomar Medical Technologies/Spectrum Medical Technologies is planning to develop "turnkey" cosmetic laser centers, for incorporation into a laser refractive center practice. I am currently working out the details on what will be involved, and will be sending you packages of information when they are finished.

Also, a group of the editors and invited writers preview what's new at ARVO, with chapters on Cataract Research, Corneal and External Disease, Refractive Surgery, Contact Lenses, Retina, and Glaucoma. Some of the new techniques in the refractive surgery chapter include performing LASIK with the picosecond laser (an very expensive microkeratome!), the use of enzymes to reshape the cornea (remember **Advanced Corneal Systems?**), and PRK without the P, using the corneal contouring blade device that used to be owned by **Optical Radiation** before its breakup.

Finally, there is a writeup on "How and When to Use the Laser Endoscope", detailing the use of the **EndoOptics'** unique endoscopic laser diode device for treating glaucoma.

- 4/11 **Sterling Vision** announced that Francis L'Esperance, one of the pioneers of laser vision correction, had been appointed to the position of chairman of the Board of Directors of **Insight Laser Centers**, Sterling's wholly owned subsidiary for providing laser vision correction. Dr. L'Esperance was a co-founder of **Taunton Technologies**, which later merged with **VISX** and was renamed **VISX**.
- 4/12 **Gaines Berland** analyst Richard West issued his latest putdown of **LaserSight**, with his continuing recommendation to sell. His analysis is based on his reading of the financial "paper" on the company in which he found several items not to his liking. (I don't pretend to understand what Richard is writing about, so anyone who wishes to see the full text of his report, give me a call.)
- 4/12 On the same day, coincidentally, **LaserSight** announced that Robert Qualls, president of its LaserSight Technologies subsidiary, had resigned. William Kern, vice president of sales and marketing, has been appointed acting president. LaserSight Technologies was responsible for 77% of the company's \$26 million in revenues in 1995. (In private correspondence and a telephone conversation with Bob Qualls, he told me that the

parting with LaserSight was amicable and that he was now pursuing other interests in ophthalmology.)

4/12 **Summit Technology** announced it had appointed a new president, Verne Sharma, who will join the company on April 22nd. Mr. Sharma previously served as general manager of stand-alone business units of Rohm & Haas (a specialty chemical company) and General Electric's Medical Systems subsidiary. Most recently he was a vice president of marketing at US Surgical. David Muller will continue as CEO and chairman.

4/15 In the article announcing the **VISX** approval in *Ophthalmology Times*, Shareef Mahdavi, director of marketing, notes that there are 35 to 40 VISX lasers in operation across the United States, including investigational units, and that the company had 100 orders for systems at press time for the article.

4/15 The April 15th *Ocular Surgery News Intelligence Report* notes that Hampton Roy, a high volume excimer user, in response to the April 1st story about possible bronchial irritation when using the excimer (see above), said that he will probably wear a specialized micropore laser mask when performing PRK procedures.

In the same issue, Ken Taylor of Arthur D. Little performed his own analysis of the **VISX** claim of its approval giving it access to "more myopes" than Summit's approval (see the 3/28 brief), and found that based solely on the number of viable myopes in the -1 to -1.5 diopter range, that VISX probably did have access to approximately 10-11% more patients than Summit. As Ken stated, "The bottom line is that both companies are approved to treat the majority of patients out there."

(For those of you interested, the same issue refers to a 1991 study of IOLs and cataract surgery that I wrote while with Arthur D. Little.)

4/15 **Sunrise Technologies** announced that it had received FDA approval to expand its Phase 2 clinical trials for hyperopia with its LTK corneal shaping holmium laser. The study will expand to include 5 sites and 100 additional patients.

4/17 **EquiMed** announced the acquisition of two additional ophthalmology practices, Ronald Salvittis in Washington, PA and Thomas Abell in Campellsville and Lexington, KY.

4/18 **LaserVision Centers** has signed an agreement with **New Image Laser Centres, Ltd.**, the subsidiary of **Summit Technology** that had operated laser vision correction centers in the U.K. LaserVision's European subsidiary, LVC (Europe) will take over operation of the two New Image centers in Birmingham, England and Edinburgh, Scotland. In addition, LaserVision will take over the patient base from the New Image

London center, which was closed in March, and combine it with the three U.K. centers that it owns. LaserVision expects to make the consolidation work by using its MobilExcimer system in the U.K., and re-deploy several of its fixed excimer systems to be installed into the two former New Image centers. In addition, David Newlove, the former managing director of New Image Centres, will join LaserVision as president of its European Subsidiary.

- 4/18 **LaserSight** announced that it had reached an agreement to acquire the assets of the ophthalmic practice of John Norris of South Orange, NJ, known as the Northern New Jersey Eye Institute, which includes three ophthalmologists and an ambulatory surgery center. LaserSight said it was in negotiations to acquire similarly positioned practices in over a dozen key markets.
- 4/19 **VISX** reported its first quarter 1996 results, with revenues of \$11.6 million and net income of \$2.7 million (8 cents/share). (At approximately \$500,000 per laser system, this represents the sale of more than 20 systems in the first quarter. Some of the income has to be attributed to PPP fees and service fees for installed systems.)
- 4/22 **EquiMed** refuted what it called a "misleading" *New York Times* article which appeared in the Sunday April 21st edition. (Since I didn't see the *Sunday Times* article I can't comment on the news release, but it apparently had to do with lawsuit claims made against the company's chairman Douglas Colkitt. According to the release, the company had, in the past 45 days, completed the acquisition of 6 physician practices and two ambulatory surgery centers.
- 4/22 **KeraVision** announced that 95% of the nearsighted patients participating in its corneal ring clinical trials had experienced 20/40 or better vision with the device, according to results announced at the World Congress of Ophthalmology meeting in Orlando. Seventy four patients in the Phase 2 trials had received a simplified version of the corneal ring (segments ?), using 5 ring thicknesses gauged to patient requirements. The three month results showed the ring's effectiveness in decreasing nearsightedness, with 76% of patients achieving improvement to 20/25 or better. The Phase 2 trials are ongoing.
- 4/22 **Paradigm** says that it will submit the data from a randomized trial of 20 patients comparing the data for its laser system with phacoemulsification by the end of September, according to a brief in the April 22nd issue of *The Gray Sheet*. The FDA requested the additional information following the filing of a 510 (k) application by the firm. Paradigm expects that the treatment phase of the study will be completed by June and the three month follow-up data submitted in September.
- 4/22-

4/23 **Summit Technology** announced that it had agreed to purchase **Lens Express** (Deerfield Beach, FL), the largest mail-order contact lens business in the U.S. According to *The Boston Globe*, the deal, an exchange of Summit stock for that of Lens Express, was worth at least \$34.3 million. Lens Express had sales of \$50.6 million in fiscal 1995, and was profitable according to Summit. According to David Muller, "joining the companies offers synergies in both marketing and operations...there is a great deal of similarity between the target audiences for laser vision correction and contact lenses. Our research indicates that contact lens wearers are more than twice as likely to be interested in laser vision correction than those who wear only glasses. As a result, we anticipate that the Lens Express database of over 4 million people who require vision correction will provide a cost effective method of marketing laser vision correction." Lens Express will become an operating division of Summit, with no personnel changes anticipated, and senior management remaining in place. Mendo Akdag, CEO of Lens Express will report directly to Muller. (According to knowledgeable sources affiliated with the contact lens business, Lens Express had "topped out" in sales, so this source didn't see much advantage to Summit, except for the acquisition of the Lens Express patient list.) In the *Globe* article, John Rooney of Baker Weeks & Co., is quoted as saying that the acquisition is "a bad sign for the buyer (Summit). If they're trying to diversify already, they must be in trouble."

In a media teleconference held April 23rd, David Muller gave additional details about the forthcoming acquisition of Lens Express. As he explained, Summit is in the "vision correction business" and this is just another way of accomplishing that end. They expect that 75-80% of the names in the Lens Express database are potential candidates for PRK. They know they are going to get some resistance from the professions over the acquisition. They intend to work first with their advisory panel to come up with reasonable solutions and then meet with professional groups to hear their concerns and attempt to overcome them. Basically, Summit intends to run Lens Express in an ethical manner and intends to clean up their act. Summit expects that a synergistic advertising campaign (both print and TV) will have crossover messages expressing the benefits of both laser vision correction and the wearing of contact lenses.

In discussing the recent news release about the number of PRK procedures to date (see our 3/26 brief last month), David Muller explained that 9000 of the 13,000 eyes had been done since the first of this year, with 4000 of them in the last month (March ?). Some 90 lasers were in place at January 1, and 175 by the end of the quarter, with many of these still in the training phase, and not yet treating patients. According to David, it takes 90 to 120 days from installation before the machines are used to begin patient treatments. And now with VISX in business, the numbers will begin to add up. He is comfortable with the low end of the analysts projections, of between 100,000 to 150,000 procedures by the end of this year.

4/23 **Summit Technology** released its first quarter results, announcing revenues of \$12.7 million, and an operating loss of \$4.5 million (11 cents/share). \$3.3 million of the loss was attributed to the company's vision correction center's segment, with the investment of a considerable amount of time and money to prepare an efficient and effective consumer marketing program designed to increase awareness of laser vision correction in the U.S. A nation-wide TV advertising campaign, intended to benefit all Summit laser owners (and VISX owners as well) is scheduled to begin on or around May 1st. Ten Summit Vision Centers and six Centers of Excellence are currently operating and treating patients. Additional centers are scheduled to open during the remainder of the year.

(Using the same analogy that we did for the VISX results, the \$12.7 million revenues represent the sale of at least 25 laser systems in the first quarter -- at an approximate sales price of \$450,000. The two companies combined to sell more than 45 laser systems in the first quarter of 1996. Next quarter should start to tell the difference, if as we believe, the VISX Star system is the preferred excimer by both practitioners and laser centers.)

4/24 Alan Jenks sent a copy of his April 24th newsletter, *Jenk's Healthcare Business Report*, which contains a front-page article on the Summit-VISX battle for laser vision correction.

4/25 **Sterling Vision** announced that it plans to acquire three **Coherent** Ultrapulse CO₂ lasers to be placed at selected Insight Laser Centers in New York and San Francisco. The company will contract with dermatologists to perform skin resurfacing procedures within its laser vision correction clinics.

4/26-

4/27 The story of the controversy within the FDA about the approval of the VISX laser and the alleged leaking of confidential data about the VISX system to David Muller, CEO of Summit Technology, broke across the pages of the *Wall Street Journal*. Several of us in the industry were aware last February that there had been a big shakeup at FDA over the VISX situation, but the facts were difficult to come by. In the 4/26 WSJ article, it was stated that "confidential" documents were sent to David Muller, allegedly by someone inside the FDA, and that the FBI was investigating the FDA leak. The unanswered question is what did David Muller do with the information? According to the story, Wall Street analysts who had been in touch with Summit officials in the months before the VISX approval, said that Summit appeared to possess "an unusual amount of information about where VISX stood in the FDA approval process, information that wasn't readily available to others."

In a follow-up piece the next day, *The Boston Globe* said that Muller read the documents that appeared in his mailbox last November "to understand what it was",

and then "promptly" turned the material over to its Washington-based attorneys, Hogan, Hartson, for return to the FDA. The Globe story also mentions that Mark Stern, the principal reviewer of the VISX application was no longer with the agency.

It will be interesting to see what the real story is when all the facts are known.

OPHTHALMIC LASER UPDATE -- MAY 1996

- 4/29 **Sight Resource** releases its first quarter results, showing net revenues of \$5.7 million and a net loss of \$648,000 (10 cents/share). These results compared to net revenues of \$4.2 million and a net loss of \$1.1 million for the same period last year.

- 4/29 In a follow-up story about **Summit Technology** and the leak of confidential data about **VISX**, *The Wall Street Journal* reported that David Muller didn't solicit the confidential information that he received, nor does he know who sent him the data. Eric Hecht, an analyst for **Morgan Stanley** downgraded Summit from a 'strong buy' to 'neutral'. The combination caused Summit's stock price to drop nearly 2 points.

- 5/1 **Sunrise Technologies** has appointed Russell Trenary as president and COO of **Laser Biotech**, its wholly owned ophthalmic subsidiary, whose current products include the gLase 210 ophthalmic (holmium) laser for treating glaucoma and the Sunrise Corneal Shaping System (also a holmium laser) for performing laser thermal keratectomy (LTK) in to correct or improve hyperopia.

- 5/1 **LaserSight** released an estimate for its first quarter results, stating that it expected to incur a loss estimated at \$0.15 to \$0.20 per share. The company attributed the estimated loss primarily to a tightening of credit policy for South American sales of lasers, and start up costs associated with opening its Costa Rica manufacturing facility for its Technologies subsidiary.

- 5/3 A new partnership has been formed between **The University of California at San Francisco Department of Ophthalmology** and the **University of California Berkeley School of Optometry**. The partnership will combine top refractive surgical techniques from UCSF with pre- and post-operative patient care at UC Berkeley. The schools hope to have a model alliance for showcasing cooperation between ophthalmologists and optometrists in the field of refractive vision correction.

- 5/3 **Escalon Medical**, formerly **Intelligent Surgical Lasers**, reported the results for its third fiscal quarter ended March 31st. The company reported revenues of \$964,000 as compared with \$170,000 for the same period last year. The new revenues now include sales for Escalon Ophthalmics, acquired on February 12th. The combined companies had a net loss of \$2.0 million (24 cents/share), including a one-time charge of \$1.2 million associated with the accounting treatment of the acquisition and restructuring.

Without these charges, the company would have had a net loss of \$724,000 for the quarter.

- 5/5 **Summit Technology** was the focus of an Emerging Business article in *The Boston Sunday Globe*, which related the recent troubles encountered by the company with both the FDA leak and the FTC investigation into the **Pillar Point Partnership** relationship with arch rival **VISX**. The rather lengthy article points out that the company's stock has dropped from \$33 per share last February, to a close of \$17 per share the previous Friday (May 3). (The story does not raise any new points that haven't been disclosed previously, but anyone wishing a copy please call me.)
- 5/6 **LCA-Vision** reported its first quarter results with a net loss of \$524,000 (1 cent/share) on net revenues of \$3.7 million. This was an increase for revenues of \$3.3 million for the first quarter of 1995. The company said the increase was from the opening of new free-standing laser eye surgery centers and the acquisition, in August 1995, of the minority shareholder's interests in the Toronto Laservision Centre. The anticipated decline in earnings due to the opening of the surgery centers and the reduced number of hospital-based surgery programs that LCA-Vision manages, was offset by a \$545,000 gain from the sale of stock in an investment(?). In addition to the "thriving" Toronto center, the company has opened an additional seven eye surgery centers along the East Coast. LCA-Vision currently directs laser surgery programs in 31 hospitals and medical centers across the U.S.
- 5/8-
- 5/9-
- 5/11 More news on the **Summit Technology** ongoing saga. On Monday May 8, *The WSJ* broke another story, describing a second leak of data about Dr. Fred Kremer's homemade excimer laser that apparently was also sent to David Muller, reportedly in the same "inch-high" package of data. (What is not clear, is why anyone, including Summit, would be interested in this homemade machine!) Summit's response was that there was only the one package of information, and that David Muller does not remember seeing the Kremer information.

The following day (Tuesday, May 9) *The Boston Globe* broke a story that Summit had "violated federal regulations by marketing and selling laser machines that were not yet approved by the FDA", according to a warning letter sent to Summit in October 1994, nearly a year prior to its receiving FDA marketing approval. The company told the *Globe* that "the FDA was satisfied with our response...it was not a big issue...we received FDA approval after this letter so clearly it didn't affect the approval process."

Two days later, in unrelated news, the *Globe* reported that a Superior Court judge had refused to issue a temporary restraining order sought by Summit to stop **Field Service Engineering Company**, who services medical lasers in the field, from performing any

maintenance or service on older Summit laser systems. Apparently, the excimer laser service company had hired two engineers and was working on laser equipment imported from Europe, Canada, and South America. Summit had claimed that Field Service had "misappropriated our proprietary technology and that the employees who once worked at Summit are violating their employment agreements". Field Laser Engineering services 50 medical lasers produced by 15 different manufacturers.

- 5/9 **Sunrise Technologies** reported that a clinical paper delivered at *ARVO* had demonstrated that patients treated for low-level hyperopia with its LTK laser, as part of the Phase 2a clinical study, had benefitted from a lasting improvement in vision 18 months after treatment. The 18 month followup data showed minimal regression for those with a mean of 2.2 diopters of hyperopia treated with a double ring of eight spots.
- 5/13 *American Medical News*, the newsletter of the American Medical Society, reported on the "Eye treatment revolution", with a front page story about "the birth of a billion-dollar market", relating the unfolding of the laser vision correction market. In addition to the stories about both Summit Technology and VISX, the newspaper also discusses the formation of vision correction centers and networks, and the fight between ODS and MDs about who will have the right to 'push the button' in the future.
- 5/13 **LCA-Vision** said that it will ask its shareholders to approve a one-for-four stock split at its annual meeting on June 3rd. The split would simplify compliance with NASDAQ's minimum bid price requirements and would make the shares available for margin credit at major brokerage houses, as well as attracting institutional investors.
- 5/13 According to *Medical Industry Today*, medical organizations in Idaho are attempting to win a court ruling against the Idaho Board of Optometry to stop optometrists from performing PRK in that state. The Idaho Medical Association, Idaho Society of Ophthalmology, and the American Academy of Ophthalmology said in their complaint that "the performance of such a surgery by optometrists poses serious risk to patients...optometrists are not qualified to perform ophthalmic surgery." The medical organizations seek to overturn the judgement that has allowed four optometrists to date to perform the procedure, while "no other optometrist has done so in the nation", according to the Ophthalmology group.
- 5/14 **LaserSight** announced its first quarter results, with, as anticipated, a \$1.2 million loss (\$0.19 per share) on revenues of \$4.6 million, up from \$4.5 million from a year ago. (See the 5/1 brief above for the reasons behind the reported loss for the quarter.)
- 5/14 **LaserVision Centers** announced some changes in its management staffing, with the naming of James Wachtman, formerly with CAPS, a hospital pharmacy division of McGaw, Inc., as executive VP and COO of North American Operations, supervising

the day-to-day operations of LaserVision Centers' excimer laser centers in the U.S. and Canada. Alan Gillam, who had been president and COO, will remain president and will concentrate on new business development, mergers, and acquisitions, and the development of the company's MobilExcimer program, as well as overseeing European operations. The company now has 15 lasers installed in the U.S., of which 11 are fully operational. The first two U.S. sites, in Minneapolis and Greensboro, NC have performed over 560 PRK surgeries since the first of the year. Close to 200 surgeons have completed the LaserVision training program.

- 5/14 **Equimed** announced its first quarter results, reporting net revenues of \$20.7 million, with net income of \$0.4 million or 2 cents/share. During the quarter the company incurred extraordinary charges related to the early retirement of debt and a non-recurring item from the change from an S corporation to C corporation tax status. Without those items, net income would have been \$1.8 million and 7 cents/share. The company owns or operates 36 oncology centers, 22 ophthalmic centers with 9 ambulatory surgery centers and 131 treatment locations in 17 states.

5/16-

- 5/17 **Summit Technology** announced that it had completed the acquisition of **Lens Express**, for approximately 1.7 million share of Summit stock. For the fiscal year ending June 30, 1995, Lens Express had revenues of \$50.6 million and an operating income, on an adjusted basis, of \$2.4 million. Lens Express will become an operating division of Summit.

On the day following the closing of the Lens Express deal, a story broke on the *Dow Jones News Service* that two lawsuits had been filed against Summit. The first suit, filed by a former employee of Lens Express, optician Harry Hammett, alleges that the company shipped lenses before checking whether the prescriptions were valid. An action that mirrors complaints made by eye doctors around the country, and which was spotlighted on NBC's *Dateline*. In the second suit, filed against the company in April, was amended this week to include Summit as a defendant, Joseph Seriani, currently of Fort Lauderdale, alleges that the founders of Lens Express forced him out of business (he had the first mail-order contact lens business, operating out of Columbus, Ohio) and used both companies -- Lens Express and Seriani's -- to distribute cocaine and launder drug money. (Spectrum Group member Roger Mummert, a former contact lens beat reporter for *Vision Monday*, has written extensively about this scandal. Anyone interested can contact me for more details.)

- 5/17 **LaserSight** announced that it was beginning its Phase 2b clinical trials with its LaserScan 2000 mini-excimer laser. The company plans to treat 125 patients with up to 10 diopters of myopia at five sites throughout the U.S. LaserSight is also currently involved in clinical trials in Canada and Europe, with the Canadian trials in Phase 3 testing at up to 10 sites. The company will also begin Phase 2 trials for

photoastigmatic refractive keratectomy (PRK), for the correction of astigmatism up to 6.5 diopters, in conjunction with the correction of up to 10.5 diopters of myopia.

- 5/17 I received two analyst's reports on **Iridex Corporation** (the old Iris Medical) from *Pacific Growth Equities*. The first comprehensive report is dated March 18th, and the follow-up is April 26th. Iridex is a world leader in providing diode laser photocoagulation systems for treating diseases such as macular degeneration and diabetic retinopathy. The lasers are also used to treat glaucoma, retinal detachments, and ocular tumors. The solid-state lasers can replace the installed base of over 15,000 out-dated argon gas lasers, used for many of the above applications. (The primary report contains a table of the U.S. incidence of blindness causing diseases, showing a total of over 23 million Americans with diseases such as AMD, glaucoma, etc.) Some new products under development include a visible light photocoagulator (unspecified, but which will be introduced at the upcoming ASCRS meeting) and a diode laser being developed in cooperation with **PDT, Inc.**, for activation of that company's photosensitizer.
- 5/22 The National Eye Institute has awarded **Atlantic Pharmaceuticals** (Half Moon Bay, CA) a \$100,000 grant to develop a technology, known as Catarex, through which cataracts can be removed within about 10 minutes through a single, one-millimeter incision. The device employed uses a directed mechanical energy source (not further described). This technique would replace (?) phacoemulsification, which normally uses a 3-5 millimeter incision for removal of the lens cortex. According to company officials, Catarex could lead to the use of advanced polymer lens substitutes currently under development by a number of companies. The research will be performed by **Optex Ophthalmologies**, a subsidiary of Atlantic Pharmaceuticals. (I have written about the possibility of extracting the lens through a 1-millimeter hole, and the possibility of injecting a liquid polymer to fill the lens membrane. I believe that this is a long way from reality! Anyone interested in my old column on this subject give a call.)
- 5/23 In a related story to the brief above, the May issue of *Review of Ophthalmology* has an article entitled, "Cataract Extraction at the Speed of Light", describing the mechanism of the **Paradigm** Photon LaserPhaco probe. This device uses a YAG laser delivered through a quartz fiber enclosed in a phaco-like probe to shatter cataractous lens particle into small pieces that can then be sucked out of the eye via an aspiration mechanism. The device sells for \$80,000 outside of the U.S. As far as I can tell, this device is still in the pre-clinical stages in the U.S.

A supplement to the magazine, "Understanding PRK: Techniques & Technology", contains an interesting article authored by Drs. Jeffrey Machat and Marguerite McDonald, "What You Need to Know About PRK Lasers". The overview contains useful information about all of the PRK laser except the Coherent/Schwind.

- 5/23 The May issue of *Argus* contains an interesting overview of the status of the OD push for excimer laser surgery privileges across the U.S., with a summary table of legislation on a state-by-state basis. A second article discusses the expanding role and status of LASIK, astigmatism, and hyperopia in excimer surgery.

OPHTHALMIC LASER UPDATE -- JUNE 1996

- 5/20 The FDA issued a statement in response to "the widespread and sometimes misleading promotion of excimer lasers to treat nearsightedness", basically stating that two laser systems had been approved for the treatment of mild to moderate nearsightedness. The FDA and FTC's Bureau of Consumer Protection recently notified the eye care community that all advertising and promotion of PRK should be truthful and substantiated and that consumers should be given sufficient information about the procedure to make an informed decision, i.e., advertising should contain enough information about the risks and limitations of PRK to prevent deception. Unrealistic claims such as "throw away your glasses", and unsubstantiated claims about success rates could be misleading. Also, use of the laser for treating both eyes at the same time is not recommended. A three month interval to allow the treated eye to stabilize is recommended. Performing LASIK has not been evaluated by FDA and is outside of approved use. At their discretion, individual doctors may chose to treat both eyes and/or perform LASIK. This would fall under the "practice of medicine" which is not regulated by FDA. Moreover, promotion and advertising of these indications do not fall within the approved uses in the labeling for the approved laser systems. Use of lasers for PRK is restricted to those practitioners trained in laser refractive surgery and in the calibration and operation of the laser.
- 5/24 **Sterling Vision** released its first quarter results, showing systemwide sales of \$30.9 million for the 231 stores, of which 160 were franchised. Net income was \$263,000, down from the \$930,000 for the same period in 1995. The decrease was primarily the result of continuing expenses from the acquisition of 32 stores at the end of 1995 and the startup costs related to the establishment of **Insight Laser Centers**.
- 5/28 After **Mattan** declined to purchase **Vision Sculpting** in January, the company decided instead to expand a joint venture agreement with a group of U.S. physicians who will open a string of **Medical Laser Institute of America (MLIA)** clinics over the next three years. The expansion involves addition of an ophthalmologist group to provide laser vision correction. Construction will begin on the Oak Brook Medical and Surgical Centre in Chicago, slated to open in July. Two California clinics are in the planning stages.
- 5/28 Jay DeCaire, formerly of **Summit Technology**, and Christine Oliver, formerly with the laser refractive surgery division of **Alcon Labs**, have joined **Autonomous**

Technologies. Mr. DeCaire will be Vice President of Manufacturing, and Ms. Oliver will be Director of International Marketing and Sales.

- 5/29 **VISX** announced a comprehensive marketing program in support of its customers. The Gateway Support Program will make a series of services available to each laser system owner, the goal of which is to help increase patient demand on a local level. The program includes in-depth customer and staff training; an analysis of local market demographics; and customized communications materials. (I was shown the in-depth analysis of local market demographics and strategic marketing recommendations at ASCRS and was very impressed with the detail included. The program was put together for VISX by **Fearon Hepner & Rhodes**, a research and marketing company. They have prepared a MarketFocus report of the Kraff family practice in Chicago which includes an analysis of their marketing area and strategic recommendations for targeted marketing. This analysis will act as a model of what can be done for other VISX customers. As I recall, the detailed analysis will cost the practitioner about \$20,000 (about half of its actual cost), but based on what I was shown, is well worth the money.)
- 5/29 **PDT Inc.** and **Iridex**, the parent of **Iris Medical**, have signed an agreement for the co-development and distribution of light devices for use in photodynamic therapy as a treatment of eye diseases. Under the agreement, Iridex will collaborate exclusively with PDTI on the development of diode light devices and will pay royalties to PDTI on their sales. The first device, a portable, solid-state diode laser light source, is being used in Phase I/II clinical trials of age-related macular degeneration. (Although it was not clear from the news release whether the device being used was laser-based or just a diode array, company officials confirmed that it is a diode laser device.)
- 5/29 **Sterling Vision** announced the acquisition of 90 retail optical stores, of **Vision Centers of America**, better known as **D&K Optical**. The acquisition brings Sterling's store count up to about 330.
- 5/31 I received a copy of Bart Chapman's (Arnhold and Bleichroeder) March 15th report on **VISX**. (This report was written just prior to VISX's March 27th FDA approval for marketing.) The report is bullish on VISX, as would be expected, and strongly recommends purchase of VISX shares, with the expectation that the shares will trade above \$40 within 6 months of approval. The report notes that in addition to laser sales and Pillar Point domestic royalties, VISX has signed separate agreements internationally with Chiron Ophthalmics/Technolas, Aesculap-Meditec, and with Schwind on the distribution of its laser systems in the European Union. The VISX earnings model shows estimated revenues of \$74 million in 1996, ramping up to \$229 million in 1999! (A combination of laser sales/service and royalty payments on procedures.)

- 5/31 **TLC** reported that it had opened two new refractive laser centers on the West coast, **TLC Northwest** in Vancouver, and **TLC Northwest** in Seattle, with plans to open an additional 5 centers in the next quarter. These will be in Piedmont, SC; Oklahoma City; Denver; San Bernadino, CA; and Madison, WI.
- 6/2 Bound into the June 1st issue of *Ocular Surgery News*, was a Baker Weeks research report, dated May 3rd, on the Laser Vision Correction Industry. The report discusses the projections of earnings for both **Summit** and **VISX**, based on Pillar Point revenues, and the outlooks for both Summit's laser centers and for **Vista Technologies** and its parent **PharmaPatch**. (The report is very complimentary to Vista, and, in my opinion, was written expressly to tout this company. It is my belief, although the report is unsigned, that it was written by Joe Rooney, the son of Pat Rooney, who holds a major interest in **Vista Technologies**.) The report contains several interesting tables: one on the public LVC Center companies showing their purported market caps and the odds of their success (with Summit, PharmaPatch and Vista ranking highest!), along with the unknown author's reasonings; a table of how many LVC centers will be in place by the year 2000 along with the number of procedures to be done and the PPP revenues, to be shared between VISX and Summit; and a table of U.S. laser sales and revenues for VISX and Summit out to 1988. All in all, a very interesting report. Too bad it is so slanted.
- 6/3 I received a copy of the final prospectus for **Autonomous Technologies**. Two and a half million shares were sold at \$8.00 per share, raising \$20 million (of which the company collected \$18.6 million after underwriting expenses). (See the April 8th brief in the April issue for more details about the IPO.)
- The company also announced that it had completed patient entry for its Phase 2 clinical trials with 75 patients at two overseas locations and 33 patients enrolled at its clinical site in New Orleans. A total of 181 eyes have been treated, including an earlier Phase 2A overseas study. The initial overseas Phase 2B results show that 80% of the patients achieved 20/20 uncorrected visual acuity at six months, and the recent U.S. data indicating even greater percentages are 20/20 at the 1 month followup exams completed last month.
- 6/3 **LCA-Vision** shareholders approved the 1-4 reverse stock split at the annual shareholders meeting. Dr. Stephen Joffe, president and CEO told the meeting attendees that the national rollout of new centers is well ahead of projections in all areas. The company expects to open its eighth and ninth facilities (in Columbus, OH and Charlotte, NC) within the next 60 days, with up to 20 centers in operation in metropolitan areas by the end of 1996.
- 6/3 **LaserVision Centers** has submitted an application to the FDA seeking approval to operate its MobilExcimer self-contained refractive surgery center, using the VISX

Star excimer laser, in the United States. The MobilExcimer concept has been tested for the past five years, with two units now in operation, one in the UK serving twenty locations, and the other in Canada, serving five locations.

- 6/4 A new newsletter aimed at the refractive surgery center market was unveiled at ASCRS this month. *MarketScope* is published by David Harmon, formerly with the Alcon laser business, and more recently involved with **EyeShapers** of St. Louis. The newsletter contains very interesting information about what's happening in the laser center business, with articles on global fees, the rapid pace of center openings, Canadian companies aggressive U.S. plans, and the UK centers reorganization and consolidation. The publishers are also offering a market report on the U.S. refractive market. I have subscribed to the newsletter and have requested a copy of the table of contents of the market report. Anyone interested in subscribing (\$350/yr) or learning more about the market report can call Dave at 888-806-4015. (This is the new toll-free exchange being added to the old "800" exchange.)
- 6/4 The quarterly newsletter of the Ballistic Missile Defense Organization had several items of interest to ophthalmology. The lead story was about the adaption of LADAR (laser radar) by **Autonomous Technology**, originally developed for the BMDO in an SBIR program, in their eye tracking system for their T-PRK excimer laser system. Another BMDO spin-off is the deformable mirror developed by **Xinetics** (Littleton, MA), and incorporated in a novel camera imaging system for the retina, by the **University of Rochester**, for enhancing retinal resolution. This was developed as part of the "free electron" laser program sponsored by BMDO. Another spin-off of the same program is work underway at **Massachusetts General Hospital's Wellman Laboratories of Photomedicine** in developing a pulsed laser technique for treating glaucoma that is less destructive to surrounding tissue than argon laser trabeculoplasty. (Some of these developments from the BMDO newsletter were picked up by *The Wall Street Journal* in their June 6th edition.)

By sending away for more information about the above, I received a copy of a brochure entitled "BMDO Technology Applications in Biomedicine". Under a section called Fiber Optics and Lasers, several of the above were described as well as several other programs sponsored by BMDO. These included a two year CRADA between **Beckman Laser Institute** and **Lawrence Livermore National Labs** to develop laser-based medical systems; an optical biopsy system based on light-induced fluorescence under development by **The City College of New York's Institute for Ultrafast Spectroscopy and Lasers**; fast lasers for molecular snapshots, developed by **Clark-MXR** (Dexter, MI) and by **Meadox Research** under an SBIR; and the work on laser thrombolysis by a consortium consisting of **Los Alamos National Labs**, **Palomar Medical Technologies**, and the **Providence St. Vincents Hospital** in Portland, OR.

- 6/4 **Sight Resource** announced that they had placed a laser at the Lahey Hitchcock clinic in Burlington, MA, which will provide laser vision correction for Lahey's New England network. This is the seventh laser center opened by Sight Resource, and the fourth in New England. (The Lahey location is right around the corner from Sight Resource's Burlington, MA headquarters, so the company can keep a close watch on its operations!)
- 6/4 **Premier Laser Systems** unveiled what it believes to be the industry's first fully integrated erbium:YAG laser system designed for ophthalmic surgical procedures. The new Centauri system incorporates the erbium laser and the option of either a bi-manual or coaxial, uni-manual hand piece to accommodate the individual physician's technique. A new irrigation/aspiration product for use with the laser was also introduced. This product also features vitrectomy and coagulation modules. In addition, the Centauri's fiber optic delivery system can be used in performing anterior capsulotomies and certain FDA approved cosmetic procedures, including ocuplasty and blepharoplasty and potentially dermabrasion. Cataract removal, glaucoma filtration procedures, and removal of vitreous bands with the erbium laser, as well as its use in refractive surgery, currently remain investigational.
- 6/5 **LaserSight** announced the expansion of its managed care vision plan, with a national rollout. The plan is being expanded in terms of products offered and geography. They are contacting over 35,000 optometrists and ophthalmologists for participation in the plan. Currently, LaserSight is focused on 16 targeted markets, representing over 30 million insured lives enrolled in HMOs and PPOs. Separately, the company announced that its **MEC** subsidiary had signed an agreement with Healthplan Southeast, located in Tallahassee, FL, to provide and arrange the care for 60,000 contracted lives. MEC is also in discussions with health plans in TX, MO, MD, CA, PA, and NJ.
- 6/6 **Hawker Siddeley** has raised \$25 million from institutional investors in a private placement of special warrants, convertible into common shares on a one-for-one basis. Proceeds of the offering will be used in the expansion of the **Beacon Eye Centers** in the U.S. and Canada. Beacon has opened two U.S. centers in San Antonio and Dallas/Ft. Worth, with three more centers in Austin, and Houston, TX, and Denver, CO, near completion and expected to be operational in August. Five additional laser centers are currently scheduled for opening by year's end. In planning for this expansion, the company has ordered an additional 18 **VISX** Star Excimer laser systems for near-term expansion, in addition to the 4 systems in operation. Company officials stated that more than 210 laser PRK procedures were performed at their Toronto center in May alone.
- 6/7 **Sight Resource** has issued a "red herring" (dated May 29) for a secondary offering of 1.6 million shares. If the offering is priced at \$7, approximately the trading range for

the company's stock, Sight Resource should raise about \$11.2 million. The prospectus states that the proceeds will be used for working capital and general corporate purposes, including acquisitions.

- 6/10 **LaserSite** (of Dallas, TX) announced it had initiated two clinical research initiatives to evaluate effectiveness of the laser procedures for correction of nearsightedness. The first study will collect data of patients undergoing PRK for pooling with other providers data, while the second study will compare results of PRK with LASIK. The latter study will be part of the nationwide study of LASIK being conducted by the **International Society of Refractive Surgery**.

- 6/10 The June 17th issue of *Forbes* contains an article entitled, "Seeing-Eye Ads", in which the author discusses the new ad campaigns for the various centers promoting PRK. The piece describes the **Summit Technology** national TV campaign, running on cable TV stations from April through June; the **Beacon Eye Institute** TV campaign running in Canada and Texas; Summit's purchase of **Lens Express** with its telemarketing and newspaper ads; and also mentions **Sight Resource**, whose spokesman states that PRK isn't an impulse buy. The average patient takes from six months to a year to decide whether to have PRK.

- 6/11 **LCA-Vision** says that it will open three new laser eye surgery centers in major metropolitan areas during the next 60 days, as its national rollout continues. (For more on this, see the 6/3 brief above.) Dr. Stephen Joffe, LCA-Vision CEO notes that the seven centers already operating are meeting or exceeding the company's projections for procedures performed.

- 6/12 **Sight Resource** announced that it had opened its eighth laser center at the International EyeCare center in McAllen, TX, and the first out of the Northeast. The McAllen center is the only excimer laser site in the Rio Grande Valley, an area with an international population approaching 1 million.

- 6/15 Michael Moretti, writing in the June 15th issue of *Ocular Surgery News*, states that the FDA has lost control of the approximately 50 "black market" excimer lasers that have been brought into the U.S. from foreign sources. By not taking any action against these operators, The FDA has almost given them explicit rights to operate. However, these operators face possible legal action from Summit and/or Pillar Point, and face higher exposure to possible malpractice suits if anything goes wrong with procedures performed with the black market machines. Also, the U.S. Customs Department may step into the fray, as importers may have misrepresented the lasers when they were brought into the country.

- 6/15 Talking about malpractice suits, the June issue of *Review of Ophthalmology* checked in with two interesting articles, one on "11 Ways to Avoid Malpractice", and the other a

letter to the editor from Summit Technology antagonist Bill Ellis, owner of one of the "black market" excimer machines noted above (and a response from Summit). In the malpractice article, Gregory Tiemeier discusses how a laser/center owner can develop a strategy to avoid malpractice suits, or at least minimize the risks. (This is must reading for laser/center owners. For a copy, give me a call.)

Bill Ellis' letter questioning whether the Summit laser should have been approved makes a lot of half-truth charges and innuendos about the data submitted and the approval process. (These same charges were made at the "Pillar Point and the Law" seminar that I attended during ASCRS, and are addressed in my writeup included with this edition of the briefs.) A reply from Michael Barra, director of marketing of Summit, answers most of the half-truth points made by Dr. Ellis. (What amazes me is that Dr. Ellis' attorney, Joe Alioto, allows his client to make these remarks, knowing full well that most are only half-truths or are misapplied!)

6/17 I received a copy of a faxed edition of a *Stockbrokers Society Research Report on LCA-Vision*. The report describes the operation of LCA-Vision, stating that, "At some point...revenues from established Centers should exceed start-up and other costs, and the company will become highly profitable. Dr. Joffe isn't predicting when that will happen, but...he and his family continue to hold more than 90% of the outstanding stock -- dramatic evidence of their confidence in PRK and LCA-Vision."

6/17-

6/18 **Summit Technology** in a news release stated that "it is unaware of the reason for the recent weakness in the company's stock price." This was followed by an article in *The Boston Globe* the next day, surveying five analysts about the reasons: multiple federal investigations, increasing competition, and "a confused strategy". One telling note, Anne Anderson of **Atlantis Research** believes that Summit may be losing ground to **VISX**. She stated that "VISX sold about 20 machines last quarter and Summit sold much fewer than that. The market place seems to have shifted towards VISX." (In some conversations I had at ASCRS, I learned that Summit was having a hard time selling any lasers into the U.S. marketplace, while VISX was "flying high!")

In an attempt at "spin control", Summit also released data about sales of its keycards, indicating the number of PRK procedures that are being performed. During the first 11 weeks of the second quarter, approximately 11,600 laser vision correction procedures were performed on Summit lasers, a 51% increase over the first 11 weeks of the first quarter. According to the company, sales of its Omnicards, used for monitoring purposes had been averaging approximately 1200 per week for the last three weeks. The company estimates that about 25,000 procedures have been done on Summit lasers since approval in October. (If we estimate that an additional 15,000 procedures have been done on VISX lasers, although this may be high, then the total

since approval should be close to 40,000. I am still holding out for about 150,000 procedures for 1996!)

- 6/17 I received a copy of the *Burnham Securities* report on **Sterling Vision**, dated June 5th, but not released until late last week. Author George Koo discusses both the retail optical and the laser centers businesses, as they relate to Sterling Vision, in detail. In addition to the information about Sterling's Insite Laser Centers, several exhibits at the back of the report provide insight into the operations of nearly all the public and privately held laser center companies, including the author's analysis of how many centers he believes were open in the U.S. by the end of May; comparable financials for both retail optical and laser/eyecare service companies; and a table of the status of competing refractive surgery techniques. A very interesting report.
- 6/17 **TLC The Laser Center** announced the opening of its eighth North American laser center in Greenville, SC. TLC Piedmont Laser Center is the second U.S. clinic that offers total ophthalmic surgical care. The 6000 sq. ft. center houses a VISX excimer, along with both YAG and argon lasers, allowing TLC to perform refractive as well as cataract removal and glaucoma management. TLC now has four centers operating in Canada and four in the U.S.
- 6/17 I received the second issue of *Market Scope* (although marked issue 3, the first, according to the author was only a trial issue). (See the June 4th brief for information about the issue I picked up at ASCRS.) Highlights include articles on financing plans for excimer lasers, with a listing of the various firms in that business; progress at 20/20 Laser Centers; a discussion of the number of firms buying physician practices; the formation of SALT (The Society for the Advancement of Laser Surgery), and the Pillar Point meeting held during ASCRS sponsored by that group; and a brief review of the highlights of the ASCRS meeting. I also received a copy of the table of contents for the market report, "The U.S. Refractive Surgical Market". Anyone wishing a copy of the brochure describing the study can contact me.
- 6/17 I also received a sample copy of another newsletter, *MarketSight*, a look at the financial side of the excimer laser industry. This newsletter is published by Bill Baumner of Boca Raton, FL, and discusses financial performances and insider transactions of people connected with companies involved in the laser vision correction markets. Subscriptions are \$149/year and can be obtained by calling 800-688-6262.
- 6/17 The June 17th issue of *Ocular Surgery News Intelligence Report* had the story of the expanded capabilities of the new VISX keycards that have been shipped since the first of June. I learned about this at ASCRS, but was waiting for confirmation. OSN says that Dick Lindstrom found that the new cards were capable of treating up to 25 diopters of myopia and 15 diopters of astigmatism. I asked the VISX people about this

at ASCRS, and got no response. I was told by others that these are the cards that were used during the clinical trials, and as long as VISX doesn't say anything about them, owners of VISX machines can use them as they please ("practice of medicine" issues, again). Apparently, the laser is only capable of removing a limited amount of tissue -- approximately 200 microns -- thereby limiting somewhat what can be done in terms of high myopia and more than moderate amounts of astigmatism.

- 6/17 **Global Vision** said that it had raised an additional \$2.5 million in capital from a California group, **Crosspoint Venture Partners**. No terms were released, but Crosspoint will hold a minority interest in Global. According to the release, Global currently operates 8 laser vision correction centers and plans to have 20 by year's end.

- 6/17 **Vision 21** has selected **Summit Medical Systems** to exclusively provide a clinical outcomes database for negotiations with third-party payors. Data gathered from Vision 21 practices will be incorporated within the national database of ASCRS, also managed by Summit Medical. This will allow a comparison of Vision 21 data with the national and area-specific standards and outcomes.

- 6/18 **LaserSight Inc.** said that it had been granted an important new patent for "scanning" technology, U.S. 5,520,679. The company said it was notifying other manufacturers of scanning refractive laser systems about the new patent (just about everyone who uses scanning technology was listed, including the two LaserSight ex-employee spin-offs **Photon Data** and **Kera Technology**, and **Summit** and **VISX** (?), who don't. Perhaps they are included because of the Pillar Point controversy between them and LaserSight). I assume the notification was for licensing purposes. I have requested a copy of the patent and will comment on it when it is received.

- 6/18 **PDT Inc.** has received an SBIR grant for \$100,000 for the study of PDT to treat glaucoma. The grant from NEI funds a study of PDT's SnET2 in forming a patent hole. This is accomplished by destroying the cells that normally cause the fistula to close.

- 6/19 **Equimed** announced the acquisition of the urology practice of David Nehme, MD, in Stuart, FL, the first acquisition in the urology field. (Equimed is a national physician practice company providing for oncology and ophthalmology services in selected geographical markets through its network of specialty medical providers.)

- 6/20 I received the "red herring", dated June 6, 1996, for **Vista Laser Centers of Michigan**". Nine hundred thousand shares are offered at \$5.00 per share to start up a refractive laser center in the metropolitan Detroit area, as well as operate a laser center in Windsor, Ontario, Canada. The company has an option to acquire a Summit holmium laser system for the Detroit center, and for a Summit excimer and Sunrise holmium laser for the Windsor location. Drs. Donald Johnson of Vancouver and

Charles Casebeer of Phoenix are directors of the company, while Dr. Fouad Tayfour of Windsor, will render consulting services to the Windsor operation.

- 6/21 **LaserVision Centers** released its operating results for its fourth quarter ended April 30th. Revenues were \$1.3 million with a net loss of \$4.7 million (81 cents per share). Revenues for the fiscal year increased 18% to \$3.9 million, while the net loss was \$8.8 million of \$1.75 per share. Jack Klobnak, chairman and CEO commented that the "strong increase in revenues for the quarter was primarily due to limited, early U.S. operations...from two U.S. based LaserVision Centers which were open for the full quarter as well as an additional five centers which began operation in the quarter." The company noted that the net loss for the quarter and fiscal year was impacted by a significant increase in general and administrative expenses and related expenses due to the substantial increase in staffing level to continue with U.S. expansion activities.

OPHTHALMIC LASER UPDATE -- JULY 1996

- 6/26 **Sight Resource** announced that it had completed its \$11 million offering, with the sale of 1.7 million shares, collecting \$9.6 million after expenses. The proceeds will be used for working capital and general corporate purposes, including acquisitions. The company currently consists of 30 eyecare centers, a centralized optical laboratory and distribution center, two management service organizations, and 8 laser vision correction centers.

The May issue of *Medical Laser Insight* had a profile of the company, providing a flattering overview of its history and approach to the laser vision correction market.

- 6/27 The *Boston Globe* broke the story about the lawsuit filed by John Alioto on behalf of Dr. Robert Burlingame of Sherman, TX, against both **Summit Technology**, **VISX**, and their **Pillar Point Partnership** arrangement. Alioto, as I have previously written, claims that "Summit and VISX have imposed a new "tea tax" on the American Public, and it should be dumped into Boston Harbor like the old one"...alleging that the partnership amounts to a "nationwide price fixing". (In discussing how she was able to "break" the story, Alex Pham told me that John Alioto had sent her a copy of the complaint he had filed in the federal District Court in San Francisco!" The story didn't appear on the Dow Jones newswire until after her story appeared in the morning Boston Globe.) While only one doctor is named in the current suit, a number of ophthalmologists have begun protesting the PPP fees and may join in on the suit. (See my account of the "Pillar Point and the Law" writeup, enclosed with last month's briefing.)
- 6/28 The *Wall Street Journal* entered into the PRK fray again, by disclosing that Verne Sharma, president of **Summit Technology** had sent a June 24th letter to the FDA charging that **VISX** was widely distributing software that provides users of its lasers

with the capability of treating astigmatism and high myopia. (As I reported in my ASCRS writeup enclosed with last month's briefing.) Sharma accuses VISX of "flagrant, intentional, and egregious violation of federal law." Mark Logan, chairman and CEO of VISX denied that his firm had done anything improper. They were selling a software package that did allow treatment of astigmatism and high myopia as well as less serious conditions, but didn't promote the use of its laser for unapproved uses and that the company cannot control how doctors use the machine. Susan Alpert, director of the FDA's Office of Device Evaluation would not comment on the specific allegation, but told the Journal that, "We're looking at the entire industry." The Journal story also discussed the above suit filed by Alioto, with a comment from Logan that denied antitrust violations and argued that the (PPP) fees "merely allow us to recoup a large initial investment in developing the technology."

Both VISX and Summit finally replied to the Alioto suit on July 2nd, by releasing duplicate releases from Pillar Point Partnership's New York-base attorneys stating, "Summit and VISX have spent hundreds of millions of dollars developing excimer lasers for use in vision correction...each held patents which could have enabled it to prevent the other from making its excimer laser system available to U.S. ophthalmologists...formed Pillar Point in 1992 to provide a patent environment in the United States in which laser vision correction could some day become a reality...the partnership holds patent rights which give Summit and VISX the means for recouping the investments which were necessary to commercialize the patented technology." The releases went on to state that PPP had initiated a program to enforce the Pillar Point patents against unlicensed users of the patented technology and had engaged counsel for that purpose.

- 7/1 *The Gray Sheet* elaborated on the **VISX** astigmatism and high myopia controversy by stating that these capabilities were part of the Star laser system approval from the FDA last March, although the agency did not approve the two indications. VISX pointed out that the FDA approved labeling manual stated that an operator of the system is required to enter calibration values "between -25.0 and +25.0 diopters, and cylinder parameters of -20.0 to +20.0 diopters, with an axis range between 0 to 180 degrees." The company also said that approximately 70 Star systems would be installed by the end of the quarter. (This would include at least 20 clinical trial units.)
- 7/2 **LCA-Vision** announced that it would revert to its original NASDAQ Small Cap Market symbol of LCAV, effective at the start of trading on July 3rd. The company had been trading under a temporary symbol for 20 days following a 1-4 reverse split on June 5th.

I also received a copy of a brief two-page company profile research report on LCA-Vision issued by *Glaser Capital*, issued on June 19th.

7/2 The *American Academy of Ophthalmology* issued a notice that both the *American College of Surgeons* and *The American Medical Association* had joined with the AAO, the Idaho State Medical Association, and the Idaho Society of Ophthalmology, in opposing the Idaho Board of Optometry in allowing optometrists in that state to perform laser surgery, and specifically PRK. According to the letter, no other optometrists in the nation are known to have performed this surgery. (I don't have the facts to substantiate it, but I believe that other optometrists have performed PRK under the guidance of ophthalmologists.)

7/3 **Physicians Resource Group** announced that it had acquired the assets of five eye care practices and had entered an agreement for a sixth. The practices are located in Lakewood, FL; Houston; Paducah, KY; Kingman (near Phoenix), AZ; and Rockford (near Chicago), IL. The sixth practice is in Corpus Christi, TX. Total cost of the acquisitions is approximately \$17 million, and includes 14 ophthalmologists, 10 optometrists, 18 locations, and one ambulatory surgery center.

7/3-
7/5 **Summit Technology** released its estimate for second quarter results, expecting to have an overall \$11-12 million loss for the quarter, on revenues of \$18 million (which includes an estimated \$12.5 million of revenues for Lens Express! If that is so, and figuring on about \$3 million for PPP fees -- both for its own share and that from VISX procedures, than the company only had revenues of about \$2.5 million from sales of lasers and service charges!) (We understand, although have not yet seen a hard copy, that Jonathan Cohen issued a flash report on July 3rd, downrating the company's stock to a neutral rating, and the market responded by dropping the share price. **VISX** also got caught up in the downwind, and its stock also dropped, prompting it to issue a statement that it expected its second quarter earnings to be in line with previously published (?) analyst's expectations.)

The Summit release stated that during the quarter, approximately 13,600 laser vision correction procedures had been performed on its equipment, compared to 9,400 in the prior quarter, with over 27,000 procedures performed since last October's approval. The company went on to state that revenues from equipment sales were "substantially lower" than those for last year's quarter due primarily to the large number of systems installed (approximately 200 of which are Summit machines) and (strong) competition from VISX. The release also reiterated the allegation that VISX was distributing key cards without the software locks that prevent the use of its systems for treating astigmatism and high myopia.

The Summit story was picked up both by the *Boston Globe* on July 4th, that also noted that John Rooney of *Baker Weeks* had issued an 11 page report on the 3rd, that among other things, urged Summit to get out of the laser manufacturing business and

concentrate on its Vision Correction Centers; and *The Wall Street Journal* on July 5th. Nothing new was reported in the Journal article.

7/8 According to *The Gray Sheet*, a single-site study of Laser-K (LASIK) by Dr. Frederic Kremer of King of Prussia, PA, will be allowed by the FDA under an investigational device exemption (IDE). The study will allow Dr. Kremer, with his home-built excimer laser, to perform LASIK on myopic patients between -0.75 diopters to -20 diopters, with or without astigmatism. Dr. Kremer would not comment on the number of patients that he would be allowed to treat, but he said "it paves the way for eventual submission of a PMA for his system." He also plans to submit an IDE to treat patients with between +1 to +5 diopters of hyperopia. Dr. Kremer believes that he is one of the first physicians to receive an IDE for a self-constructed laser for performing LASIK surgery.

7/8-

7/9 **LaserSight** announced that it had acquired a New Jersey ophthalmic practice and surgery center, the Northern New Jersey Eye Institute. The deal was for an exchange of unregistered stock and a \$340,000 promissory note payable on or before September 13, 1996.

The next day, the company announced its preliminary second quarter estimates, expecting an increase in revenues of approximately 30 percent over first quarter results, to between \$6.0 to 6.2 million, up from \$4.6 million. According to CEO Michael Farris, "The second quarter represents a dramatic improvement over the first quarter in both bottom line results and positive impact to the Company's balance sheet. This balance sheet impact stems from the more stringent credit policy implemented in April associated with laser sales during the second quarter. Over 80% of the laser sales have either been collected or are due within the next 90 days...Demand for our technology remains strong. "

7/9 **LCA-Vision** announced that it would open its eighth U.S. laser vision correction center in New York's Westchester County on Friday, July 12th. Based in Mt. Kisco, the site is a joint venture with LCA-Vision as a major partner, and will operate under the name of Crystal Vision Associates. Another Crystal Vision center in Manhattan, opened last December, is a joint venture with Cabrini Hospital Medical Center and a NY ophthalmological practice group.

7/11-

7/12 **Summit Technology** announced a major restructuring of its business, with the layoff of 55 employees, 9% of its workforce, and moving practically all of its manufacturing to its Ireland plant. In addition, the company took a one-time restructuring charge of \$500,000 in the second quarter.

The next day, *The Boston Globe* picked up and expanded on the story, noting that 43 of 196 Massachusetts' employees were let go, including Vice President of R&D Howard Apple, who was replaced by Alex Sacharoff, formerly director of product development.

- 7/11 I received Anne Anderson's (**Atlantis Research**) second report on the PRK industry (see the March Briefing for my analysis of her first report), dated July 2nd. Anne remains pessimistic about the outlook for both Summit and VISX, and for the number of procedures that will be done over the next two years. As usual, I don't agree with all her conclusions about why the industry will not grow, but do agree with her assessment of Summit's problems (especially in light of the announcement above). Much of her pessimism has to do with the problems that might face the Pillar Point agreement. What she doesn't realize is, if it does fall apart, both Summit and VISX will merely charge their owners a "users fee" for use of their patented technology, and will not lose much in income (especially VISX, with the stronger patent base and "better" laser system). Yes, Summit may be the big loser in this battle.

Specifically, Anne has reduced her estimates of the number of PRK procedures to be done this year to 70,000, down from 172,000, and for 1997 to 160,000 from 408,000. (I believe she is wrong, as close to 100,000 procedures will be done in 1996, as the slow decision time of 9-12 months will start to come into play, as will the additional centers that are coming on line. Dave Harmon of Refractive Market Perspectives -- in the next item -- agrees with my thinking.) Anne has also reduced her estimates of the number of laser systems that will come on line in the U.S. from 800 in the year 2000, to only 625, although she hedges that bet somewhat with her comment that the replacement market might be better than she now thinks. (I will hold with my 1200 laser system projection for the time being.) The one good point she raises about Pillar Point is that legal fees to protect their position is going to eat into projected revenues for both VISX and Summit, especially if Alioto follows through with multiple suits (and they don't get combined into a class action suit). As for financial results, Anne doesn't believe that Summit will ever make a profit, unless they exited the laser vision correction market (?), while she projects that VISX will top out in 1997. As usual, a very interesting analysis.

- 7/11 As I mentioned, I also received the July issue of David Harmon's *Market Scope*. It contains a number of very interesting stories, including his analysis of the PRK volume growth to date, and his projections for the year. For the year-to-date, he has PRK volume at 30,800 procedures, translating to about 79 procedures per installed laser in centers (for the quarter) for the average of 262 operating laser centers as of June 30th. Based on these trends, and with procedures on VISX systems starting to kick in during the second half of the year, he projects 108,000 procedures for 1996, and as high as 300,000 for 1997. David also has an analysis of the global fees being charged. On a weighted basis, he arrived at a global fee of \$1860 for the quarter, with

a range of \$1500 to \$2250. It is also interesting to note that VISX's market cap of \$517 million on June 28th was higher than Summit's at \$423 million (based on a stock price of 14 1/2). This is a turn around from the early days of PRK! (It should be noted that Summit's stock plummeted to a low of 8 3/4 following the announcement of the restructuring above!)

Last but not least, Dave is offering a "Refractive Surgical Market Directory" in August for \$195. It will contain the names, addresses, and phone numbers for 2000 refractive surgeons, 200 operating laser centers, information on laser center operating companies, laser manufacturers, and key industry suppliers. Call 888-806-4015 for further information.

- 7/12 **Sight Resource** announced that preliminary second quarter results will show a 38% increase in revenues over the same period last year. (This is primarily due to additional eye care centers and laser vision correction centers now in operation by the company.) The company expect to post a net loss of \$689,000, down from the \$1.1 million loss for 1995's second quarter. The company intends to use the money recently raised to acquire additional multi-site eye care centers and ophthalmology practices, as well as use its inventory of fully owned excimer lasers to add additional laser vision correction centers.
- 7/12 The July issue of *Medical Device & Diagnostic Industry* relates the **Summit**/FDA story from the Dr. Ellis viewpoint, as told by columnist James Dickinson. The story appears to be written from the notes provided by Dr. Ellis at the "Pillar Point and the Law" symposium that I attended (and reported on last month). There doesn't appear to be any new ground covered in the article, although Summit was given a chance to respond to some of the allegations and issued a written statement through its Washington, DC law firm. (Anyone wishing to see the material can give me a call.)
- 7/15 The July 15th issue of *The AOA News* contains a story about the Australian PRK market, as a foreshadow of the way the U.S. market may progress. Refractive lasers have been available in Australia for five years, with about a dozen systems in operation. About half of these are owned or operated by networks with strong optometric involvement. Since advertising of laser procedures was banned until recently, referrals was the only method of obtaining patients. Sydney, with a population of 3 million has three lasers, while Brisbane, with 1.5 million residents, has two, with another system about an hour away up the coast, and a fourth about an hour away in the other direction. Apparently, with the ban on advertising broken, laser centers are opening so rapidly, it is becoming hard to keep track.

- 7/16 **LaserVision Centers** announced that it was postponing its public offering of 2.5 million shares due to the unsettled market conditions. The company expects to proceed with the offering when the market is less volatile.
- 7/16 I received a research report issued by **Commonwealth Associates** on its initial coverage of **Sight Resource**. Analysts Ed Vanacore and Vince Calicchia state that they believe the company to be a short-term strong buy and more speculative over the longer term. They liked the company's fully-integrated approach to the vision care market, believing that it gives the company many competitive advantages, including cost savings associated with marketing and providing optometric care for laser vision correction, especially as compared with LVC centers only. In their earnings model, they are assuming that Sight will acquire one primary eye care chain per year over the next several years, helping to increase revenues from an estimated \$25 million (just primary eye care) in 1996 to \$52 million in 1988. The analysts also expect that LVC revenues will jump from an estimated \$3.1 million in '96 to nearly \$15 million in '98, giving a total revenues increase from \$28.6 million to \$66.9 million by that time. (This is from a starting point of \$18.2 million, all from optical, in 1995.)
- 7/17 **Autonomous Technologies** announced that Dr. Richard Keates had joined its board of directors, and Dr. George Petit had been appointed to the position of Vice President of Research. Dr. Keates has been Chairman of the Ophthalmology Department at UC/Irvine, while Dr. Petit was a medical research officer with FDA.
- 7/18 **VISX** announced record second quarter and six-month results, with revenues increasing to a record \$19.6 million for the quarter, and \$31.1 million for the half-year. Net income for the quarter was \$4.6 million (28 cents/share) and \$5.8 million (36 cents/share) for the half-year. The company also announced that it was releasing a hyperopia correction module for use in international markets. (Our model, based on the announced Summit results, estimate that VISX earned about \$3.5 million from the combined PPP fees, leaving laser sales of about \$16 million, or the sale of about 30 laser systems in the quarter! The rest being service fees.)
- 7/18 Jane Freedman's research report (J.Freedman & Associates) on **LCA-Vision** came out with a strong buy recommendation, based on the company's management strength and successful track record of both the surgical laser program, and the results obtained with the Toronto PRK center. Ms. Freedman expects revenues to increase from \$13.7 million in 1995, to \$58.4 million in 1988. She agrees with me that there will be a shakeout in the laser center industry over the next 12-18 months, and that by the end of that time the number of companies involved sharing the market should stabilize. She expects LCA-Vision to be one of the dominant player/survivors.
- 7/19 **KeraVision** said that increased expenses related to its ongoing clinical trials for its KeraVision Ring, magnified second quarter losses, which increased to \$3.2 million.

7/22 According to *The Gray Sheet*, the July 26th Ophthalmic Devices Panel will have a busy schedule. Dr. Susan Alpert will speak about excimer regulatory issues, and at least 13 others are slated to make presentations during the open public segment of the meeting. These include officials from **Summit Technology**, and Dr. William Ellis, who is in a court battle with Summit over importation of a European Summit laser.

In second notice in *The Gray Sheet*, **VISX** said it will adjust the software in its Star excimer laser system so that physicians cannot perform high myopia. This announcement followed a July meeting between VISX officials and FDA personnel. VISX will now ship keycards to laser users limiting the correction of myopia to their approved -6 diopters or less. However, in a July 18 letter to eye care professionals, the company said that the FDA's position to limit use of the laser "is the first attempt to restrict physicians through software control of the device rather than through strictly enforced labeling." Although the company is not scheduled to speak at the July 26th FDA meeting, the company further states that "practice of medicine is going to be a major topic of discussion."

7/23-

7/24 Two announcements from **Sight Resource Corporation**; first the company plans to adopt a share repurchase program which may include the repurchase of up to 800,000 shares over the next 12 months and, secondly, the company announced the opening of its ninth laser center and the second in Texas, at International EyeCare in Houston. According to the company, Houston has a metropolitan population of 3.3 million people, making it the 8th largest market in the country. The company now has placed six of its nine lasers within the top eight markets; 2 in Boston, Chicago, Houston, New York, and Philadelphia. With this latest placement, the company estimates that it can provide access to laser vision correction to approximately 30 million people in the United States.

7/24 **LaserVision Centers** announced that the FDA had accepted its filing for pre-marketing approval for the excimer laser that will be used in its MobilExcimer system. The PMA was submitted in June as part of a two-step plan to win FDA approval of the MobilExcimer. If the FDA approves this first PMA, it will serve as the basis for the second step, obtaining a supplemental approval of the MobilExcimer system itself. (Acceptance of the filing indicates that there is sufficient information to allow the FDA to make a decision about the filing.) The company indicated that it intends to use the MobilExcimer to serve smaller market surgery facilities owned by **Columbia/HCA**, with whom it currently operates 17 domestic fixed locations.

The company said that the MobilExcimer went through a series of intensive road tests last week at the Transportation Research Center, near Columbus, OH, overseen by personnel from LaserVision, **VISX**, and **Calumet Coach**, the manufacturer of the MobilExcimer vehicle. According to Alan Gillam, LaserVision president, "After

undergoing hours of rigorous testing, the laser required absolutely no recalibration, attributed to the Company's patented mounting system for the laser." The test results are being compiled for submission to the FDA within the next few weeks.

- 7/25 **Iridex Corporation** announced that its subsidiary, **Iris Medical Instruments**, had received FDA approval to market the DioPexy Probe for use by ophthalmologists to treat conditions such as retinal detachments. The probe treats retinal problems through the sclera, employing a technique known as transscleral retinal photocoagulation, which appears to have fewer side effects than cryotherapy. The probe is an accessory to the OcuLight diode lasers models SL and SLx.
- 7/26 **Premier Laser Systems** announced that it had entered into a strategic development/manufacturing program with Mission Viejo-based **Circuit Tree Medical Inc.**, for an ophthalmic irrigation/aspiration system that integrates with Premier's erbium:YAG laser system under development for cataract removal, vitrectomy, and diathermy procedures.
- 7/26 Ronald Rosenberg of *The Boston Globe* writes that Congress is launching a probe into how confidential FDA files found their way into David Muller's hands, chairman of **Summit Technology**. According to source to the congressional probe, "We've gotten nothing from the FDA to explain how the documents went to Summit last November...why is it taking so long...the FDA is conducting its own internal investigation...and there is tremendous incentive to control and contain it (the investigation)". The House Commerce Subcommittee on Oversight and Investigations is conducting the hearing, which is set for Wednesday, July 31st. A Summit spokesperson acknowledges that Summit has been invited to testify, but "has not yet determined what they will do with the invitation". (Summit has issued a 20 page white paper explaining its side of the scandal, which I have requested. I will keep you posted about this matter, as well as the FDA panel meeting being held this day.)
- 7/27 According to an *Associated Press* brief in today's *Boston Globe*, the FDA issued a warning against the use of "gray" lasers, by the 50 or so doctors who have imported them into the country. In the case of home-built lasers, the FDA is urging them to get government permission to study their use while informing patients that the devices are experimental (as Dr. Fred Kremer of King of Prussia, PA has done -- see the July 8th brief above).
- 7/29 **LCA-Vision** was the first to respond to the FDA warning above, by issuing a notice that all of its Summit and VISX lasers in use at its centers were FDA approved.
- 7/29 An awaited story about **Summit Technology**, **VISX**, and the FDA scandal finally hit the front page of *The Wall Street Journal*. Reporters Laura Johannes and Laurie McGinley wrote a long diatribe about the strained relations between Summit and

VISX, with some rather strong jabs thrown against David Muller and the direction he has taken his company. The story also relates the charges against VISX for shipping keycards capable of permitting the correction of astigmatism and higher degrees of myopia, and the leaks of confidential information from someone within the FDA to David Muller of Summit. (You just have to read the story yourself!)

OPHTHALMIC LASER UPDATE -- AUGUST 1996

- 7/24 **Cowan & Joseph**, a full-service healthcare marketing, advertising and public relations firm, announced that **VISX** had become its newest account. C&J will assist in the design and marketing of SightLine, a consumer awareness program available to physicians purchasing the VISX excimer laser system. SightLine includes a detailed map of the physicians trade area, demographic and population trends, competitive analysis and strategic marketing recommendations tailored to the specific practice. (See my note about this program in the ASCRS writeup, included with your June newsletter.)
- 7/29 **LaserSight** released its second quarter results, reporting significant improvements over the first quarter. Revenues increased 30 percent to \$6.0 million, while the net loss was only \$25,000 (2 cents/share). The company said it had sold 13 lasers in the second quarter, compared to 7 in the first quarter. For the half year, revenues were \$10.6 million, about the same for last year, while the net loss was \$1.3 million (22 cents/share), compared to a net income of \$2.9 million (43 cents/share) for the first half of 1995.
- 7/29 The American Academy of Ophthalmology held a meeting with the FTC, ASCRS, ISRS, OOSS, and SEEC on July 22nd, to discuss advertising guidelines for PRK. (It is our understanding, according to *EyeWorld Week* of August 5th, that the FTC guidelines had already been sent to the printer and that the attendees were quite upset that they weren't going to have the input that they expected. Further, the guidelines had "an overly negative" connotation toward refractive surgery and refractive surgery marketing!)
- 7/31 I received a copy of the **Summit Technology** "white paper", prepared by the company in its defense of allegations about the FDA leak. (I expect that this is the document that Summit submitted to the House Oversight Committee during its July 31st meeting -- more about that below.) The paper goes into the background of PRK, including how a typical procedure is performed, and a chronology of the FDA milestones to approval for both Summit and **VISX**. It discusses the "leaked documents" including how David Muller received the package at his home on the day after Thanksgiving, opening the package at the airport on the way to his holiday destination, and did not realize what

the documents were until later in the day after his arrival. He says that he reviewed the documents during the weekend and sent them to his attorney in Washington the following Monday. He claims not to know who sent the documents. (And he threw away the mailer package at the airport.) The paper claims that Summit has not disclosed or discussed the contents of the documents with anyone other than legal counsel and the FDA, giving VISX written assurance of the same. It goes on to say that Summit has cooperated with FDA investigators and there is no indication that Summit or Dr. Muller are targets or subjects of the investigation and, to Summit's knowledge, the FBI is not involved in the case. (I understand that the FDA, late in July, the FBI was asked to look into the internal workings of the FDA, and how the leak may have occurred.)

The white paper also discusses the reimportation of unapproved export lasers and the allegations of FDA collusion with Summit over the approval of a 6.0 mm ablation zone for the Apex laser, and the purported evidence of overseas reports of retinal damage using the Summit laser in Malta, the UK, and in Israel. The paper states that "there simply is no credible evidence of causation...Dr. Susan Alpert, Director of FDA's Office of Device Evaluation, indicated that the agency believes that these reports are isolated and probably reflect poor patient selection rather than problems with Summit's laser." Also, Dr. Roger Steinert, Summit's Medical Monitor for the clinical trials states, "There is no evidence to suggest a causal relationship between (laser vision correction) and retinal detachment."

As for homemade lasers, Summit believes that these pose a threat for the public health and to the vision correction industry, primarily because they are not likely to operate "reliably or safely". (This situation was taken up by the July 31st FDA Ophthalmic Panel Meeting discussed below.)

The last item in the white paper is a discussion of the allegations of preapproval commercialization of the Summit laser. Summit claims it did not presell excimer lasers, although it does admit that it did sell a holmium laser workstation designed to accommodate an excimer laser upgrade, once approval for the excimer was obtained.

(Please call if you want a copy of the white paper.)

- 7/31 **Sight Resource** reported an increase in revenues and a narrowing of losses for the second quarter. Net revenues were approximately \$5.9 million, an increase of 40% over last year, while the loss for the quarter was approximately \$697,000 or 11 cents/share, versus a loss of \$1.1 million for 1995's second quarter. The increase in revenues was attributable to additional eye care centers and laser vision correction centers now operated by the company, which were not in operation during the second quarter of 1995.

7/31 **Chiron Corporation** released second quarter results, which included ophthalmic product sales by **Chiron Vision** of \$59.5 million, up from \$52.4 million for the comparable quarter last year. The increase was primarily due to increased sales of intraocular lenses and viscoelastic products used during cataract surgery, and the first full quarter's sales of Vitasert Implant for treating CMV-retinitis, which alone accounted for \$4.8 million in sales in the quarter. (No breakout of sales of excimer lasers was provided.)

7/31 **LaserVision Centers** announced that it had withdrawn its registration statement for an offering of up to 2.5 million shares due to unfavorable market conditions.

7/31-

8/5 A series of stories appeared in both the local and national press about the ongoing saga of **Summit Technology's** troubles and of the FDA Ophthalmic Panel meeting held July 26th, and the Congressional Hearing held on the 31st. Our report starts with the *Boston Globe* of July 31st, in which staffer Ron Rosenberg tells of the mounting crises affecting the company. (This followed the *WSJ* article that was on page 1 of the July 29th issue -- see our brief last month.)

The *Dow Jones Newswire* of July 31 carried excerpts of both Mark Logan's and Dr. Mark Stern's testimony before the Congressional Hearing looking into the FDA leak of data to Summit. Dr. Stern testified that he was forced to resign from the FDA over his questioning of the leaking of proprietary VISX material to Summit. Dr. Stern said he did not know who leaked the material. Mark Logan, VISX CEO testified that the information Summit received could have a material impact on the companies competitive and legal positions. Although the FDA has been investigating the incidents for over 8 months, no one from the agency or FBI has interviewed him or any other VISX employee. (For more on the testimonies, see the *EyeWorld Week* brief below.)

The Wall Street Journal and *Boston Globe* of August 1st carried more on the Congressional Hearing results. Of note, according to the *Journal* reporter Laura Johannes, Rep. Joe Barton said that he considers Dr. Emma Knight as a "major suspect" in the leak. As reported in the *Journal*, Dr. Stern testified that a superior in the agency told him in the fall of 1995 that Dr. Knight had prematurely released a copy of a letter outlining the approval conditions for the company's (Summit) laser. Such approvability letters are routine precursors to final approval, but aren't disclosed by the agency. Dr. Stern said he didn't know to whom the letter was released, but people familiar with the matter said it was a reporter from a trade publication. Dr. Stern's testimony appears to place one of the major leaked documents in Dr. Knight's hands just before Thanksgiving. He testified that another FDA official sent Dr. Knight a confidential letter outlining approval conditions for the VISX laser, with a cover

sheet wishing her a happy Thanksgiving. This document, showing Dr. Knight's outgoing fax number indicated that she, or someone using her fax machine, had sent it to someone else after receiving it.

Ron Rosenberg, who also attended the Congressional Hearing, wrote up his impressions in the next day's *Boston Globe*. He revealed that Dr. Stern had been shown the leaked documents by Louis Caputo, the FDA's chief of internal affairs, and that Jan Callaway, an FDA team leader in charge of the VISX evaluation, was the one who sent the proposed approval letter to Dr. Knight just before Thanksgiving. According to Dr. Stern, Callaway objected to sending the VISX documentation to Dr. Knight, but was ordered to do so by Nancy Brogden, acting director of the Center of Ophthalmic Devices at FDA. (The intrigue just continues to build!) Dr. Stern also raised questions about the link between Summit and some FDA members (without giving any details).

- 8/1 **VISX** stated today that it was unaware of any business development that would account for the recent decline in its share price. According to Mark Logan, Chairman and CEO, "VISX is currently better positioned to capitalize on the burgeoning market for laser vision correction...procedures are being performed at a rate greater than our internal projections...the Star system has been extremely well received by both U.S. and international ophthalmic surgeons."
- 8/1 I received a copy of a June 25th confidential letter from the FDA's Lilian Gill, Director, Office of Compliance, to William Appler, attorney for **Hi-Line Medical** related to the importation of "gray" lasers into the U.S. Ms. Gill's letter calls for certification by Hi-Line describing how each imported laser is identical in all relevant aspects to the approved version of that excimer laser. The certification will indicate where the unit was originally manufactured, serial number, date of manufacture, each of the specifications and characteristics on which Hi-Line based their certification, plus a signed statement that the device's operating capability is limited solely to approved uses, and a certification that the device will not be advertised, promoted, or used for indications other than those identified in the approved version's application for premarket approval. Hi-Line will also have to demonstrate that the laser was adequately maintained and calibrated according to the requirements of the approved PMA. Upon receipt of such information, FDA will evaluate and determine whether it is adequate, and is so determined, whether it is covered by the approved version's PMA. (From the tone of the letter, it appears that the FDA is willing to work with Hi-Line to bring imported machines into compliance for re-sale.)
- 8/1 The August 1st issue of *Refractive Market Perspectives* contains a number of interesting articles. It reports on the July 26th Ophthalmic Panel meeting (see the 7/29 brief above), wherein Susan Alpert of FDA said that the FDA would release a plan during the next few weeks to address concerns over custom built and imported

excimer lasers. The plan will call for custom built and unapproved laser owners to contact the agency to negotiate a protocol for obtaining pre-market approval. The plan will be administered by the FDA's Division of Small Manufacturer's Assistance, and through professional associations. The plan will include a grace period allowing the continued use of the devices while data is collected to support a premarket submission. After the grace period, the agency will exercise its enforcement authority against any individuals, groups, or companies using or promoting the unapproved lasers. Current users will have to weigh the costs associated with bringing their systems into compliance versus the cost of just purchasing an approved system. Also in the equation is whether Pillar Point will attempt to sue any user of a non-Pillar Point paying system, which is in operation in violation of the manufacturer's valid patents.

The newsletter also noted the highlights of the mid-summer ISRS meeting in Minneapolis during July. According to RMP, there were 460 attendees and 65 company exhibits. Dan Durrie gave the keynote address, "Refractive Surgery: Re-Engineering Ophthalmology", and a live surgical presentation was made from the Codet Eye Institute in Tijuana, Mexico, with Dr. Arturo Chayet performing several procedures including PRK with a **Novatec** laser, LTK with a **Sunrise** laser, LASIK with the **Nidek** laser, and implantation of a **Keravision** intra-corneal ring.

In news that I hadn't picked up from the newswires, **TLC-The Laser Center** announced the opening of what it called "network centers" in eight locations. The centers serve to screen prospective patients and provide pre- and post-operative care for patients who are then referred to affiliated TLC Laser Centers. The location of the network centers was not disclosed, however, the company disclosed that it had opened five U.S. laser centers in Greenville, Houston, Indianapolis, Tulsa, and Seattle. An additional six centers are under construction in Denver, Johnson City, Oklahoma City, Madison, Miami, and San Bernardino. Another nine centers are in the planning stage for opening by year's end.

True Vision Laser Centers has opened its first laser center in Albuquerque, NM.

- 8/2 **LCA-Vision** reported second quarter results, showing revenues of \$3.5 million and a net loss of \$952,561 (6 cents/share), compared with a pro forma net income of \$112,626 (11 cents/share) for the second quarter of 1985. The decline in earnings reflects the costs associated with the stepped-up build-out of new centers, which are expected to total 13 by the end of September. New centers in Buffalo, NY, Charlotte, NC, Columbus, OH, and Ft. Erie, Canada are slated to open toward the end of the third quarter.
- 8/3 On August 3rd, *The Boston Globe* broke the story about the first shareholder suit filed against Summit, alleging that top company officials sold \$55 million in stock at

inflated prices without disclosing the company's problems. (I have read the 31 page complaint and found it riddled with errors, innuendos, and half-truths. It is a wonder that the attorneys who prepared the suit had the gall to file it with so many errors.) The suit alleges, among other things, that somehow David Muller or Summit officials had some complicity in the FDA leak of VISX documents; or used the information contained in the documents to maintain the company's share prices; the company specifically directed the company's sales force to sell its laser for uses broader than allowed by FDA (?); presold the excimer laser before final approval; and that the secondary offering just prior to receiving final approval in October 1995 enabled the company to raise more than \$100 million of desperately needed cash but contained misleading statements and omitted material facts. (This lawsuit, filed in Boston by the firm of Berman, DeValerio & Pease, is the first of at least three class action suits, the second was filed in Massachusetts District Court on August 8th -- the August 9th brief below, and the third, also filed in Massachusetts District Court, on August 13th -- the August 13th brief.)

- 8/5 The August 5th issue of *EyeWorld Week* tells a bit more of what happened at the July 31st Congressional Hearing looking into the FDA leak of **VISX** information to **Summit Technology**. The hearing chairman, Joe Barton of Texas believes that the FDA's internal inquiry was "haphazard and flawed". He believes that the FBI, which apparently was not formally asked to investigate until July 22nd, should have been brought in sooner. No one from FDA would testify, but Mark Logan, VISX CEO said that the detailed drawings and test information that was give to Summit could give Summit a tremendous advantage in ongoing patent litigation between the companies. Dr. Mark Stern, a former FDA reviewer, raised concern about the role Dr. Emma Knight, also a medical reviewer, might have played in the leak.

The issue also notes that eyewear firm **OPSM Protector Ltd.** will establish refractive surgery centers throughout Australia, starting first in Melbourne and Sidney.

- 8/5 The August 5th issue of *The Gray Sheet* discussed some of the material covered at the July 26th FDA Ophthalmic Panel meeting. The panel recommended that clearance for additional indications for the excimer lasers approved for PRK could be based on studies with as few as 100-200 patients followed up for six months. Both **VISX** and **Summit** are collecting data for high myopia and astigmatism and plan to seek FDA approval for expanded PRK uses. "By recommending studies with relatively low patient populations for expanding PRK indications, the panel indicated an eagerness to see wider excimer laser use while sustaining the regulatory principle that new indications must be supported by at least a minimum of clinical data. The panel's recommendations also tacitly supports FDA's position that off-label excimer laser use for the unapproved PRK indications is not a practice-of-medicine issue because it generally requires altering the laser system's software." The panel members stressed

that indications for hyperopic PRK or LASIK surgery would require full clinical data to support an original PMA.

- 8/6 I received a copy of the July 3rd **Baker Weeks** report by John Rooney on **Summit Technology**, in which Rooney calls for the splitting of the company into two parts (as reported in the 7/4 *Boston Globe* article noted in last month's briefs). Rooney suggests that Summit's investment bankers, Morgan Stanley and Smith Barney, are advising the company to split off the laser vision center business and Lens Express under David Applegate. Verne Sharma would head up Summit Technologies consisting of the selling of laser equipment and collecting the Pillar Point royalties. (Rooney suggests that the French Riviera might look good to David Muller at this time!) The bottom line is that he still suggests that Summit is a good buy, with a reconstructed share price of \$22!
- 8/6 **MedNet International Ltd.** (Hamilton, Bermuda) reported its second quarter results, the establishment of a teaching advisory board, and the opening of its first eye centers to treat cataracts, retinopathy, and glaucoma in China. The company said that in the second quarter it had shipped the equipment necessary to open four eye centers in major hospitals in China, that began operation in the latter part of June. MedNet intends to establish six additional centers by the end of the year. The first four centers are located in major hospitals at Wuxi; Zheng Zhou; Chong Quing; and at Dalian. The additional centers will be opened in Nanjing; Pudong; Shanghai; Haung Zhou; Shengdu; and in Beijing. Some leading U.S. ophthalmologists will form the advisory/training board, including Dr. Robert Maloney of the UCLA Laser Refractive Center of the Jules Stein Eye Institute; Dr. Harry Grabow of Sarasota, FL; and Dr. Gholam Peyman of LSU Eye Center in New Orleans. The company's initial focus is in the correction of cataracts, retinopathy, and glaucoma, but will expand into the rapidly growing treatment of nearsightedness and astigmatism using laser procedures. For the six month period ending June 30th, the company had revenues of \$508,755 and a net income of \$110,919. The company is in the process of applying for listing on the NASDAQ national marketing system to broaden investor awareness.
- 8/7 **LaserVision Centers** Chairman and CEO Jack Klobnak, commented that he was unaware of any business development that would account for the recent decline in share price. The company now operates in twenty domestic locations, with the installation of lasers in Arcadia and Fresno, CA; Nashville, TN; and Mobile, AL. Commenting on the roll-out of excimer lasers, the U.S. case volume increased approximately 26% from May to July, and he expects the trend to continue as more doctors are trained and begin performing laser vision correction. The company has trained 67 surgeons in the last 90 days, with a total of 281 U.S. surgeons trained so far. Now that training is moving smoothly, marketing campaigns have begun in five markets and more are scheduled to begin in the next several months. Conversion levels from calls to screenings is currently more than 50%, and the company expects

to begin carefully measuring the levels from screenings to surgery. The process from inquiry to surgery is currently running at three to six months.

- 8/8 I received a new analyst report on **Sight Resource**, written by Edward Vanacore of **Commonwealth Associates**, and published on July 31st. Ed believes that the company is a strong short-term buy, and a speculative longer-term buy. The reasons given included stronger than expected quarterly results, with a lower than anticipated quarterly loss. Although revenues were below his forecast, gross margins and operating margins were improved beyond expectations.
- 8/8 **Summit Technology** confirmed its previously announced second quarter results (see last month's July 5th brief), with revenues of \$18 million and an operating loss of \$13.2 million. Net loss for the quarter was \$12 million (39 cents/share). For the six month period, revenues were \$43.4 million, compared to \$42.6 million last year, and the net loss was \$15.5 million (50 cents/share) as compared to a net loss of \$4 million or 15 cents/share for the six month period in 1995.
- 8/9 The law firm of Milberg Weiss et al of New York filed a class action shareholder suit against Summit Technology on August 8th, charging Summit and David Muller with misrepresenting or omitting to disclose material facts relating to, among other things, the expected size of the market for laser vision correction, the superiority of a competitive excimer laser system manufactured by VISX, and Summit's inability to develop a cost effective advertising program to promote the LVC procedure. After receiving a copy of the complaint, this suit appears to be much better researched than the other two. (See both the August 3rd and 13th briefs.)
- 8/12 As noted in the August 12th edition of *EyeWorld Week*, copies of the testimonies of Mark Logan of VISX and Mark Stern, former FDA reviewer, as well as Summit's submitted statement, are available at the ASCRS address on the World Wide Web, <http://www.ascrs.org>.
- 8/13 **Sight Resource** announced that it had opened its tenth U.S. laser vision correction center, located at the Center for Advanced Eyecare in Lake Villa, IL, the second LVC established by the company in Illinois. The Center, with offices in both Villa and Cary, provide ophthalmic services to the heavily populated areas of Northern Illinois and southern Wisconsin. (Illinois is the fourth state for Sight Resource, the others being Massachusetts, Rhode Island, and Texas.)
- 8/13 Another class action law suit was filed by the law offices of Dennis Johnson of South Burlington, VT, charging that **Summit Technology** began selling its excimer laser prior to receiving FDA approval, and used improper and flawed data to gain approval. Further, David Muller received proprietary and confidential information about its competitor's laser, and he and other top officers sold millions in stock without

revealing this information. After receiving a copy of the complaint, I discovered that it was a copy of the Berman, DeValerio & Pease complaint, so apparently Attorney Johnson has joined forces with the Boston law firm. (According to a spokesperson for this firm, it is likely that all the class action suits will be combined into one suit, led by the firm that represents shareholders holding the most shares of the company.)

- 8/13 **Sunrise Technologies** announced that it had completed a private placement of equity financing resulting in net proceeds of approximately \$2.25 million. The placement was facilitated by Pennsylvania Merchant Group and consisted of the sale of approximately 2.3 million shares of common stock. The proceeds will be used to support the ongoing clinical trials for the Sunrise Corneal Shaping System, which is currently in expanded Phase 2 clinical laser thermal keratoplasty (LTK) trials for the correction of hyperopia.
- 8/14 **Sterling Vision** released its second quarter results showing a systemwide sales increase of 13% to \$32.6 million, and a half-year increase of 11.4% to \$63.5 million. During the period, the company increased the number of stores within the Sterling family to approximately 110. Because of the level of expenses required for the expansion, the company showed a slight loss of \$147,000 (1 cent/share) for the quarter, but was marginally profitable for the six-month period. The company opened its first Insight Laser Center in New York city in June and anticipates having 5-7 centers operating or under development by year's end.
- 8/14 **EquiMed, Inc.** announced its second quarter results with net revenues at \$29.4 million and net income of \$2.7 million (10 cents/share). For the six months, revenues were \$50.1 million and net income was \$3.1 million (12 cents/share). Currently EquiMed employs 114 physicians, owns or operates 35 oncology centers, 21 ophthalmic centers with 10 ambulatory surgery centers, and has 130 treatment locations in 20 states.
- 8/15 **LCA-Vision** marked the fifth anniversary of its Toronto Laser Sight Centre, which has performed 4600 laser eye surgeries since its opening in 1991. A total of 991 surgeries were performed in the last six months. The company noted that its facility, which houses three excimer lasers, is now the busiest and most profitable of the eight centers operating in Toronto. It enjoys a 98% success rate in achieving 20/40 vision or better.
- 8/15 **Escalon Medical Corporation**, formerly **Intelligent Surgical Lasers** announced its fourth fiscal quarter results, with revenues of \$1.4 million and a net loss of \$470,637 (4 cents/share). Investment in the ISL Picosecond Laser System for refractory surgery is continuing, but on a controlled basis. The company is seeking strategic partnerships to achieve its corporate goals.
- 8/22 **LCA-Vision** announced that it intended to enter the European laser surgery market with a 43% investment in a major new laser eye surgery center scheduled to open in

Helsinki, Finland on September 1st. The new center will be jointly owned by LCA-Vision, Professor Tom Schroder, founder and director of Laseri, a well known Helsinki medical center specializing in minimally invasive surgery, and Dr. Juha Lehtosalo, one of Finland's leading eye surgeons. The center will occupy space within the Laseri Medical Center located in downtown Helsinki, and be known as the Laseri Eye Surgery Center. It will be equipped with a state-of-the art Japanese (Nidek?) excimer laser system, featuring a patented computerized eye movement tracking system.

- 8/26 **VISX** said that it had submitted a PMA supplement to the FDA requesting approval to treat -1.00 to -6.00 diopters of myopia with -0.75 to -4.50 diopters of astigmatism. (The approval to treat astigmatism, which can be accomplished by a software change in the keycards supplied to physicians, could significantly increase the number of people eligible for PRK.)
- 8/26 **20/20 Laser Centers** released its second quarter results with revenues for the quarter higher than had been projected. The company reported revenues of \$3 million for the six month period, with \$2.1 million of that occurring during the past three months. The two laser center locations that opened in January have shown a 112% increase in the number of procedures done in the second quarter of the year.

OPHTHALMIC LASER UPDATE -- SEPTEMBER 1996

- 8/15 An interesting editorial by editor Dick Lindstrom in the August 15th issue of *Ocular Surgery News* asked the question, "Where are the PRK patients?". Dick went on to speculate on the reasons for the slow start and the "budding signs that things are about to improve". As he put it, most analysts' assumptions of the size of the myopic market were significantly inflated due to astigmatism and the range of the population between -1 to -6 diopters, giving a potential market of only about 10.4 million patients. (I had said about 10 million prime candidates in my 1992 report!) However, when you remove young people and older than 65 years, only 5.2 million remain. Then comes the question of affording the procedure, further reducing the pool to only 2.6 million, of which, at least 600,000 (or more) have had RK, or PRK/LASIK in clinical trials or gone to Canada or some other offshore center. Further reducing for those with ocular pathology, reduces the number to no more than 2 million potential patients, according to his analysis. Finally, lasers are only available in the larger cities (so far), and since half the population lives in smaller communities or rural settings, you have to divide again by two, leaving at best only about 1 million potential patients within the FDA guidelines.

He also relates the better side of things. The limiting factor for PRK, to date, is not the lack of patients, but rather the lack of an adequate installed base of lasers and trained surgeons. By looking at some of the Summit clinical sites, where the doctors were

trained and ready to go, he found that these doctors were doing quite well, with each doing more than 100 eyes per month. He also notes that many surgeons and centers were waiting for the VISX laser to be approved, and this delayed their entry into the marketplace. Now that that has occurred, the pace over the next year will accelerate. He believes that most concerns will meet their business plans, but 18 to 24 months later than originally planned. As he states it, "The kick-off is really first quarter 1997, not fourth quarter 1995, as it will take that long to obtain critical mass of installed lasers and trained surgeons." (I would add, and to get marketing programs into high gear.) His bottom line was that there would be only between 50,000 to 75,000 laser procedures in 1996, and 250,000 in 1997, reaching 1 million eyes annually by the year 2000. He adds, "Don't lose faith yet!" He predicts, "In the United States, refractive surgery will challenge cataract surgery for primacy of impact on ophthalmology and the industry that supports it in the next century."

(Anyone that missed the editorial can call me for a reprint.)

- 8/19 The August 19th issue of *The Gray Sheet* reports that the 'summary of safety and effectiveness' for **Summit's** SVS Apex excimer laser PMA is available through the FDA's Dockets Management Branch, according to a notice in the 8/15 *Federal Register*. Publication of the summary allows for submission of petitions challenging the approval. FDA officials expect that the Summit PMA as well as that for VISX's Star laser, when available, will be challenged. More information can be obtained from Debra Lewis, head of the Center for Devices and Radiological Health's Staff College at 301-827-3623.

- 8/26 According to the August 26th issue of *EyeWorld Week*, a new startup company, **IR Vision, Inc.** of San Jose, CA, is building a prototype solid-state infrared laser for refractive surgery. According to company officials, the laser is expected to retail for 1/3 the market price of FDA-approved excimer lasers, and will have 1/10 of the operating costs. Primate studies are expected to start this fall. (I believe that the laser may be a 3 micron device, and I think Bill Telfair, formerly of **Taunton Technology**, may be involved.)

- 8/27 The summer 1996 issue of *The Update*, published by the **Ballistic Missile Defense Organization**, contained several stories of relevance to ophthalmology. One story relates the work being funded by BMDO in neural network technology as part of a diagnostic device for monitoring eye disease, including cataracts, by ophthalmologist Hutson Hay of Huntsville, AL, along with **Nichols Research Corporation** and **Applied Information Movement and Management**. The group is collaborating on a method of reading light signatures reflected from the eye and correlating the optical signatures with specific eye conditions. The device may eventually be able to detect and track, for example, the extent of cataract and measure its progression.

In another program, researchers at **Massie Research Laboratories** in San Ramon, CA are developing a high-resolution retinal camera based on adaptive optics, which could be used in the early detection of glaucoma. At the **Wellman Laboratories of Mass General Hospital**, BMDO's Medical Free Electron Laser program support is being used in the photodynamic therapy research to reduce tissue damage during ocular neovascular surgery. Under the program, BPD from **QLT PhotoTherapeutics** is being used to treat neovascular vessel growth, with some impressive results. A multi-center clinical program, co-sponsored by QLT and **Ciba Vision** is underway.

Finally, in another BMDO funded research program, **The Charles Stark Draper Laboratory** at MIT is developing a retinal implant chip that may someday offer vision to many who are blind. So far, a prototype microchip and a laser-based CCD detector have been developed, and animal studies continue.

8/28 In another program for correcting eye disease using PDT techniques, **PDT, Inc.** and **Pharmacia & Upjohn** have joined forces for the co-development of PDT's lead PDT drug, SnET2 to selectively destroy diseased cells in serious eye disease, such as advanced age-related macular degeneration. PDT is also testing SnET2 in preclinical studies for other vision-threatening eye diseases. Under the agreement, Pharmacia & Upjohn will reimburse PDT for incurred ophthalmology development expenses and will fund future clinical and preclinical studies. P&U will also make milestone payments and will pay royalties to PDT upon commercialization of SnET2 for these applications.

8/29 **Summit Technologies** troubles continue to multiply, this time from a suit by its partner in **Pillar Point Partners, VISX**, that claims Summit has underpaid royalties on the sales of refractive lasers by some \$4.5 million. In addition to the split from the \$250 fee paid for each use of a Summit laser, Summit is supposed to pay a 6% royalty on the sale of each machine. The dispute centers on the method Summit uses to calculate the selling price for its laser system, according to *The Boston Globe*, and on the failure of Summit to pay a royalty on those systems sold prior to FDA marketing approval. The \$4.5 million is the amount that VISX claims is owed for the sale of Summit's lasers. Both companies said that efforts to settle the disagreement amicably had been unsuccessful.

The September 2nd *Gray Sheet* provides some elucidation on the law suit, stating that Summit has not paid royalties on the holmium work stations and excimer laser systems it sold prior to FDA approval last October. Also, the complaint asserts that Summit has refused to pay interest on any unpaid equipment royalties and, by refusing to pay royalties based on a formula referring to the full net selling price of the subject equipment disposed of by Summit (?), has **breached** the licensing agreement!

- 8/29 **LaserSight** announced that it had signed two distributorship agreements which expand international sales efforts for its excimer laser system. The distributors are **Marwell Laser Systems** of Scandinavia, and **Dos Santos Medica** of Venezuela, formerly a Summit Technology laser distributor.
- 8/29 **Iridex Corp.** announced that its **Iris Medical Instruments** subsidiary had received FDA clearance to market its new OcuLight GL semiconductor-based green laser photocoagulator (a diode-pumped, frequency-doubled YAG). According to the company, the OcuLight GL is the only CW solid-state laser photocoagulator capable of treating a variety of eye diseases. The laser can replace traditional argon gas-tube lasers, at a fraction of the size and weight. (At the ASCRS meeting last June, I was told the laser would sell for about \$30,000.)
- 8/30 This issue of *InSight Focus/InSight Washington* contains an interview of Dr. Mark Stern by editor Bob Gatty, conducted on August 15th, following last month's testimony by Stern at the Congressional Hearing which was held to look into the FDA's handling of the Summit and VISX approvals. According to Stern, the FDA's limiting the capabilities of the excimer lasers through software lockouts poses a risk to the public health. "By limiting the treatments to simple myopia, the FDA has overlooked the creative solutions that will be employed to treat the majority of other refractive conditions not covered by the FDA's approval order." Stern goes on to question why the "approved" lasers need to have key counters to collect Pillar Point fees, since the investigational machines did not, and how that adds to the "safety and efficacy" of the devices? If a doctor uses an approved PTK device for LASIK, that should not be a concern to the agency. (For a full copy of the four-page interview, give me a call.)
- 9/2 According to the September 2nd *Market Scope*, **TLC-The Laser Center** has reported revenues for the quarter ending 5/31/96 of \$7.3 million, and a loss of \$1.5 million. The revenues are an almost four-fold increase, and represent the opening of new laser centers and acquisitions during the past year, while the losses were due to the startup expenses of the new centers.
- 9/5 **Sunrise Technologies** announced that it was accelerating enrollment in its Phase II hyperopia trials with its Corneal Shaping LTK holmium laser. The company said it has been able to show sustained control of regression, along with excellent long-term clinical results in trials conducted to date. With several years of data from studies in Italy, Mexico and Argentina indicating how successful the FDA trial results might be, the company has decided to push ahead with the FDA clinical studies. In addition, the company has retained **Bio-Reg Associates**, an experienced FDA clinical trial agent, to help manage its FDA clinical trials. This creates an arms-length situation that adds substantial credibility to the trial. The company anticipates that the clinical trials will require approximately three to four years to complete, including submission and

approval of the PMA. The Corneal Shaping laser is currently being used in 15 countries outside the U.S.

- 9/6 The September issue of the AAO's *Argus/Ophthalmology's World News* contains a frightening article about the dangers of RK for high mountain climbers. Two years ago, in preparation for this spring's Mt. Everest climb, Dr. Beck Weathers, a Dallas pathologist, had RK performed to enhance his vision while climbing. He underwent RK specifically so he could climb high altitudes without having to wear glasses which tend to fog or ice over during a climb. (It is not clear from the writeup whether this was for one or both eyes.) He said he informed his refractive surgeon that he planned to climb to high altitudes, and was told there should be no problem. But on two preparatory climbs, to as high as 20,000 feet. Dr. Weathers noticed that his vision -- which at sea level fluctuates predictably over the course of a day -- was changing more and more, and wasn't helped by his three different pairs of glasses. "It wasn't so bad that I had trouble doing the things I needed to do, though", he said. However, the difference between 20,000 feet and 26,000 feet, the altitude of the final base camp on the 29,000 foot Everest climb, proved catastrophic. On May 10th, tragedy struck eight climbers, including several of the world's most accomplished climbers. Within a few hours after his group began an overnight climb to the summit, he knew he was in trouble. "By about the middle of the night it was apparent I had lost my depth perception. I really couldn't see anything out of my right eye, and the left eye was pretty blurry", he said. He couldn't continue the ascent, but also couldn't descend back to the base camp without help. "When you can't see to plant your foot on what you think is going to be part of the mountain, and it's just thin air -- so you fall", he explained. It took several hours for an expedition leader to arrive to help the shivering Dr. Weathers down the mountain, and they had to be roped together. According to the guide, Beck was hopelessly blind so that every 10 meters he'd take a step into thin air and I'd have to catch him with the rope. Because of severe frostbite, Dr. Weathers lost his nose, all of one hand, and most of the other hand. He claims that if he hadn't been blinded by his RK, he wouldn't have lost his hands. His vision problems at high altitude has had a dramatic effect on his life, including his ability to go back to work as a pathologist. (According to ophthalmologists who have studied the phenomenon, RK treated eyes react with a strong hyperopic shift at high altitudes. PRK would not effect the eyes in the same way.)
- 9/6 **LaserSight** appointed Richard L. Stensrud, a director of the company since June 1995, to the newly created position of chief operating officer. According to Mike Farris, LaserSight's president and CEO, this appointment will allow him to focus on implementation of the company's strategic plans of securing more managed care contracts, acquiring practices, and looking for strategic opportunities to build a company focused exclusively on vision care. Mr. Stensrud formerly operated a consulting firm serving companies in the health care field.

9/6-

9/7 Turmoil struck **Summit Technologies** twice again today, first with the company announcement that its board of directors had terminated its founder and chairman, David Muller, and secondly with the announcement of yet another shareholder suit -- see below. As reported in the September 7th *Boston Globe*, Dr. Muller was ousted following a sometimes acrimonious meeting, at which, according to witnesses, Muller reminded the board how he built the company from scratch and how he gained political support that led to the firm's winning government approval for its laser. The *Globe* reported that "combined with a current FBI probe into the company's practices, a congressional probe, and at least four shareholders lawsuits, some directors felt Muller's tirade left them feeling that he had raised significant legal questions, leaving them no alternative but to fire him". (The political support referred to above may have been the large political contributions Summit made to Senator Edward Kennedy and the Democratic Party, when the firm was seeking approval for its laser.) A lengthy writeup about the firing also appeared in today's *Wall Street Journal*. (Copies of the two newspaper articles were faxed to clients on September 7th. Anyone wishing hard copies can call me.)

The fourth in a series of shareholder's suits against David Muller and Summit was announced by the law firm of Wechsler Harwood Halebian & Feffer, of New York city, as having been filed for plaintiffs, Shear et al, on August 29th. (It should be noted that after receiving the complaints for suits 1 (Boston) & 3 (Vermont), they turned out to be identical, and apparently combined.) I have requested a copy of this complaint and, if it is received, will determine if it is similar to any of the others, or different.

And Attorney John Alioto announced that the **Shepherd Eye Center** of Las Vegas has become the second ophthalmic practice to join in the antitrust action against Pillar Point Partners, joining ophthalmologist Robert Burlingame of Sherman, TX.

The September 9th *Gray Sheet* speculates that cost-cutting efforts at Summit likely will be concentrated in the company's refractive laser treatment centers. "The firm may halt or slow down the opening of additional centers in the short term and eventually may consider exiting the business altogether to concentrate solely on laser manufacturing and sales.

9/9 *EyeWorld Week* reports that **Shooting Star Technologies**, which operates vision centers under the **Gimbel Eye Centre** name, has announced the suspension of financing plans through **First Centennial Securities Laser Corporation**.

9/9 **Escalon Medical Corp.** said that it will move its laser R&D lab from San Diego (the former home of Intelligent Surgical Lasers) to Irvine, CA, closer to the home base of many of its key scientific staff.

- 9/10 **Pillar Point Partners** today filed two law suits to stop the practice of using excimer lasers to perform PRK without paying the per procedure fee of \$250. One of the suits was filed against **Barnet Dulaney Eye Center** of Phoenix; the second was against consultant **William Appler**, a disbarred Washington, DC lawyer according to *Insight Washington*, for aiding and encouraging others, including eye clinics and medical personnel to infringe the patented technology of Pillar Point. (Appler, if you recall, was one of the presenters at the "Pillar Point and the Law" seminar that I attended, and wrote up for the September 15th issue of *Ocular Surgery News*.)
- 9/13 The September issue of *Ocular Surgery News International* reports on the growth of refractive surgery in India. **Better Sight Center** opened its fourth refractive surgery center in Madras, India. **Gainwell Medimart, Ltd.**, promoters of the centers, announced that 10 additional centers would be opened before the end of this year. They said that as of January 1997, they will be one of the largest refractive surgery centers in the world. India currently has 21 excimer laser installations and this number should reach 35 by year's end, fourteen of which will be Better Sight Centers. The first three centers were opened in Bangalore, Calcutta, and Cochin between November 1995 and February 1996, and more than 1100 procedures have been performed. According to Amit Bagaria, CEO of Gainwell, "Surprisingly, most excimer laser manufacturers and laser center companies have ignored the Indian market. Perhaps they don't realize that India is a country of 950 million people, of whom at least 200 million can afford the cost of the PRK procedure." Gainwell plans to open 19 additional center in India in 1997 and 5 or 6 international centers in the Middle East and Southeast Asia. The three opened centers use **LaserSight's** Compak 200 mini-excimer, and the Madras center will use the new LaserScan 2000 PhotoPolishing System. At its centers, Gainwell sells access time on a time-share basis to area ophthalmologists on payment of a small entry fee and a larger refundable deposit. The company believes it has India's largest referral network of optometrists and ophthalmologists for the Better Sight Centers.
- 9/16 **Autonomous Technologies** announced that it had received clearance on September 13th to proceed with its Phase 3 clinical trials of its T-PRK laser. ATC had submitted clinical data on 180 patients from its Phase 2 A/B trials conducted at the University of Crete and at the Eye, Ear, Nose & Throat Hospital in New Orleans. The Phase 3 trial will include treatment of up to 500 subjects at seven investigational sites for between -1 to -7 diopters of myopia. The company expects to complete Phase 3 enrollment by mid-1977. The company also reported that the six month results for its Phase 2 B study showed 77% of the patients achieved 20/20 vision, while 100% attained 20/40. In the New Orleans subgroup, 83% reached 20/20 by three months. Also, no patients showed a loss of 2 lines or more of best corrected acuity at six months.
- 9/16 **Laser Vision Centers** released its quarterly results with revenues increasing by 95% to \$1.5 million, and a net loss for the quarter of \$2.3 million (32 cents/share). Non-cash

and non-recurring items of \$973,000, including expenses associated with the canceled stock offering accounted for 42% of the loss for the quarter. Another big part of the loss was an increase in general and administrative costs related to the addition of personnel to operate its U.S. centers. According to the company, PRK volume in the U.S. increased 67% in the quarter, with revenues from PRK increasing 62%. Also, the company noted a continued strong performance of its European operations, and an 184% increase in revenues over the same quarter last year.

- 9/16 **EquiMed** reported it had acquired the assets of the radiation oncology practice of Tri County Regional Cancer Center Partners in Upper Southampton, PA., raising to 34 the number of radiation oncology centers it runs, along with three other cancer-related centers. The company also announced the acquisition of eight optical shops located within **Venture Stores** in Missouri and Illinois from **Comprehensive Eyecare Ltd.**, as well as the right to develop 92 other optical shops within the Venture chain. Venture currently operates 111 optical stores in nine states, 32 of which are in the Chicago area. EquiMed now operates 36 optical shops.
- 9/17 Kim Doney, the architect of **Summit Technology's** successful attempt to obtain FDA approval of its excimer laser systems, announced her resignation from the firm, effective September 30th. Doney, executive VP of clinical and regulatory affairs, was responsible for oversight of the exceptional FDA filing of data that resulted in the FDA approval. According to company officials, Doney's decision to leave the company was made prior to the removal of chairman David Muller by the board of directors.
- 9/17 **LaserSight** announced the results of clinical trials underway in the labs of Dr. Daniele Aron Rosa in Paris, France, with its mini-excimer. Thirty patients with myopia ranging from -1.5 to -6.5 diopters were treated through December, and have completed 10 months followup. The results show better than 91% have retained visual acuity of 20/40 or better. These results will be submitted for CE Mark approval for commercial marketing of the company's excimer laser in Europe, and as supplemental data to the FDA in conjunction with clinical trials underway in the U.S. LaserSight is currently in Phase 2B, treating 128 patients with up to -10 diopters of myopia. The company noted that it currently had lasers placed in 28 countries and has active sales agreements with 19 international distributors.
- 9/17 According to *The Wall Street Journal*, **Grand Metropolitan** is moving closer to selling its **Pearle Vision** chain of 860 company-owned and franchised optical outlets, mostly in the U.S. and the Netherlands. Apparently there is more than one suitor. It seems to me that this would be a perfect opportunity for another of the refractive laser center companies, like **Sight Resources** and **Sterling Vision**, to acquire an optical chain that could provide a feeder network for refractive surgeries, as well as providing ongoing

cash flows with its traditional eyeglass and contact lens businesses. Who knows, perhaps one of the vision center companies **is** in the bidding!

- 9/17 Also in the September 17th issue of the *WSJ* was an interesting article about the quest to create images within the eye, for a type of "heads-up" display. Besides military and commercial applications, this could possibly be useful for surgery, by presenting a patient's x-rays to the surgeons view, while he/she was operating on his/her patient. The device is being funded by **Microvision** in Seattle and developed by researchers at the **University of Washington's Human Interface Technology Laboratory**. (Call if you missed the piece and I will send/fax it to you.)
- 9/19 **Sight Resource** announced it had acquired another eye care provider, with the purchase of **E.B. Brown Opticians Inc.**, a chain of eye care centers in Ohio and Western Pennsylvania, with annual revenues of greater than \$14 million. According to *The Boston Globe*, the acquisition was for \$9 million in a combination of cash, notes, and stock. With this first acquisition outside of New England, Sight Resource now provides eye care services in eight states.
- 9/19 **LCA-Vision** announced the opening, today, of its ninth U.S. facility, in Charlotte, NC. Some two dozen prominent Charlotte area ophthalmologists are affiliated with the site, which will be operated as an open-access facility. The company plans to open an additional five centers by the end of October: in Columbus, OH; Buffalo, NY; Ft. Erie, Canada; Palo Alto, CA; and Helsinki, Finland.
- 9/19 **LaserSight** announced some executive changes in its **Farris Group** subsidiary and its board of directors. Patrick Devereux was named president of the Farris Group, replacing David Pieroni, who retains his position as a consultant to the company and was named to the board to maintain a majority of outside directors. Pieroni replaces Richard Stensrud on the board, who was recently named executive vice president and COO of LaserSight, Inc. (A round of musical chairs' music, please!)
- 9/20 *Insight Washington* says that Congressional investigators have no intention of dropping their probe of the circumstances surrounding the FDA approval of both Summit's and VISX's PMAs, even if the ongoing FBI investigation fails to uncover criminal violations. According to the counsel to the House Commerce Committee, the subcommittee must determine how and why an FDA staff member sent proprietary and confidential information about the VISX laser to David Muller of Summit.

Also, the newsletter states that Mark Stern, ex-FDA reviewer, has joined forces with ophthalmologist Bill Ellis in asking the FDA to temporarily withdraw Summit's PMA for its laser system until the company can explain the potential problem of retinal complications when using the SVS Apex laser system, and other allegations of deficient or misleading data used in the submission. (Stern was originally on the Ellis'

program, "Pillar Point and the Law", held during the ASCRS meeting, but did not show up, supposedly because of illness.)

9/22 According to *The Boston Globe* and sources at the company, **Sight Resource** has shifted its priorities from opening new refractive surgery centers, to acquiring ophthalmology practices to broaden its scope of practice. It will still open new laser centers but, according to the company and the newspaper, that is now a third priority, after buying retail optical chains and acquiring ophthalmic practices. Based on the company's European experience, it learned that "stand-alone laser centers is the wrong approach". By acquiring ophthalmic practices, the company hopes to link these practices to its retail outlets and laser centers, to provide total vision care, including primary care and surgical services. The company currently operates 10 laser vision correction centers around the country, including four in New England and two in Illinois. They will add an eleventh laser center later this year to serve the E.B. Brown Opticians retail optical business in Cleveland that it recently acquired (see the 9/19 brief above).

9/23 This week's *EyeWorld Week* tells of the second ophthalmologist to obtain an IDE for performing LASIK. Dr. Francis Price of the Price-Whitson Center for Refractive Surgery in Indianapolis joins Dr. Frederic Kremer, along with an academic group at Emory University with IDEs for LASIK. Dr. Price has a **Chiron Technolas** excimer that he couldn't use, and the IDE gives him the right to use the laser.

The same issue also contains the news that **Medjet, Inc.** had obtained a U.S. patent for a method of removing corneal tissue using a water jet in conjunction with a template to shape and guide the cuts. Also, **Shooting Star Technologies** has signed an agreement with the Air Force General Hospital of Beijing, to develop a **Gimbel Eye Center** at the hospital. The eye center will provide both cataract and refractive surgery and represents the first in a series of planned projects in Asia for the company.

9/25 **LCA-Vision** announced that its Helsinki, Finland laser eye surgery center had begun operations. As noted in the August 22nd brief, the center is 43% owned by LCA-Vision, with the remainder owned by two prominent Helsinki physicians.

9/25 I received the first edition of **Market Scope's** "Refractive Directory" for 1996. The directory is a wealth of information about the location of refractive laser centers and of refractive surgeons, each broken down state-by-state. In addition, there is information about the laser companies, laser center operators, instrument suppliers, and of analysts and newsletters that follow the field (including this one). In a fast count, I noted 204 laser sites, and editor Dave Harmon acknowledges that he may have missed at least 100 laser sites! The directory costs \$195 and is available by calling 888-806-8015.

- 9/25 **BeaconEye** said it plans to open five of its Beacon Laser Centers by year-end, and to double the number of centers to 22 in 1997. The company now has five U.S. laser centers operational, in San Antonio; Austin; Dallas-Ft. Worth; Houston; and in Denver. The next five centers are expected to be in Fort Lauderdale and Tampa, FL; Atlanta; and Beverly Hills and Irvine, CA.
- 9/26 The other shoe finally dropped on **Pearle Vision Centers** (see the 9/19 brief above), with the announcement that **Cole National Corporation** had agreed to purchase Pearle from **Grand Metropolitan** for \$165 million. The move will almost double the number of outlets operated by Cole National, which operates vision centers within **Sears Roebuck, Montgomery Ward** department stores, as well as **Sears Optical Stores**.

OPHTHALMIC LASER UPDATE -- OCTOBER 1996

- 9/15 The September 15th issue of *Ophthalmology Times* contains several articles about PRK around the world. In Canada, the magazine reports that there are 55 excimers in operation, and of the 1080 ophthalmologists, 11% perform PRK. Thirty seven private physicians and 18 corporations are involved, with the majority of lasers being VISX systems (20), with Chiron (12) and Summit (6) next. There are also some Meditec, Nikek, and Novatec systems in operation. The mean cost of surgery is \$1500.

In Australia and New Zealand, there are about 15 lasers in use, 12 in Australia, with more on order, and three in New Zealand. There is also a short writeup about Asia, that basically states that PRK is the treatment of choice over RK, where the incidence of myopia can run as high as 70%.

- 9/23 *The Gray Sheet* reports that regulatory consulting firm **C.L. McIntosh** has petitioned the FDA to halt the use of unapproved excimer lasers (both home-built and reimported systems) for ophthalmic surgery, stating that FDA should initiate selected seizures or consider other enforcement actions. The petition also asks FDA to reconsider single-site IDEs and to withdraw any IDE approvals that have occurred.

The same issue contains additional information about William Ellis' petition requesting the FDA to hold a public hearing to review Summit Technology's approval for PRK. Ellis asks that an independent advisory committee of experts be constituted to review the premarket approval application for the SVS Apex laser. (Also see the 9/20 brief in the last issue.)

- 9/27 *Dow Jones* reports that two Canadian eye-care companies are focusing expansion plans into the United States. Executives at both **TLC The Laser Center** and **Beacon Eye**, 49% owned by **Hawker Siddeley Canada**, which runs the **Beacon Eye Institutes**, are hoping that laser vision correction becomes as common a part of growing up in North America as orthodontics. Elias Vamvakas, president and CEO of TLC sees a

time when laser eye surgery will be a "rite of passage" for teenagers, they'll get a car at 16, and get their eyes done at 19! TLC has 12 centers open, including four in Canada, five under construction, and 8 more being developed for construction next year. By the end of 1997 the company should have 26 centers, with all the new ones in the U.S. They then expect to expand by about six centers a year. Beacon currently has six centers, including one in Canada, with five more U.S. sites identified in the U.S., and expected to be open before January 1997. By the end of 1997, there should be a total of 22 Beacon Laser Centers open.

9/30 *EyeWorld Week* reports that **VISX** was granted a patent for a method and system for using a rotating mask and lens to scan a desired portion of the cornea, enabling wide area ablation with a laser having a narrower beam. The newsletter also notes that **RBC Dominion Securities** is leading a group of underwriters who will buy 3.5 million shares of **TLC The Laser Center** for C\$25.3 million.

9/30 Two items of note for this day. First, I received a letter from Dr. Robert Dotson, MD, of Oak Ridge, TN, president of SALT, the Society for the Advancement of Laser Technology, berating me for spreading "false information" about SALT in my column about Pillar Point and the Law that was in the September 15th issue of *Ocular Surgery News*. I did mention that it was later denied that SALT was an official sponsor of that meeting, but apparently that wasn't enough for Dr. Dotson. Along with the letter was a video in which he appeared, done by what may be a right wing organization called American Investigator for National Empowerment Television (NET). The video was entitled, "Eye on the FDA", and is an alleged expose of the influence David Muller of **Summit Technology** had on the FDA's granting approval of his company's excimer laser by contributing funds to the campaign of Senator Edward Kennedy. All sorts of allegations are made on the tape, which includes interviews with James Fallon, former employee of Summit, talking about third-hand information he heard about the alleged "holmium hoax" and the Kennedy contributions; with Mark Logan, president and CEO of **VISX**, discussing the value of the information sent to Muller by an employee of the FDA; and with VISX PMA FDA reviewer Dr. Mark Stern about irregularities within the FDA. What was really galling about the piece, besides the innuendos, purported accusations, and finger pointing, was the use of the so-called "Blinn memo" supporting the holmium hoax. This has been shown to be a forgery following investigation by the FBI. (Anyone desiring to obtain a copy of the tape can call NET at 1-800-NET-0660.)

The second item was the appearance the same day of a story, apparently taken from the NET video program, that ran in *Investor's Business Daily*, describes many of the same points made by the video. The major point of the article was again the alleged influence that Senator Kennedy may have had on the speedy (?) FDA approval of the Summit laser, following campaign contributions made by David Muller and others at Summit. (In reality, the approval took nearly ten years from the start of human testing

to final approval, so I wouldn't call it quite "speedy".) Call me if you want a copy of the text of the Investor's Business Daily article.

- 10/1 I received a comprehensive profile of **Shooting Star Technologies**, comparing this company to other laser eye surgery providers, with specific comparisons to **TLC The Laser Center**. The document also compares the company with **LaserVision Centers**, **Beacon Eye**, and **LCA-Vision**, providing market cap valuation; latest twelve month revenues; revenues for the latest quarter; and a figure for total value/revenues which describes market cap plus debt minus cash. A second table gives a direct comparison to TLC, while three pages of text provides a detailed profile of the company. Anyone wishing to see the six-page profile should call me.
- 10/1 **LaserVision Centers** announced that it has completed the conversion of all of the company's Convertible Preferred Stock into share of common stock. The release also notes that U.S. case volume for its centers had increased 67% in the quarter ending July 31st, from the quarter ended April 30th.
- 10/2 **Iridex Corporation** announced its revenues and earnings for the third quarter will not meet consensus expectations of analysts following the company. The company expects revenues to range between \$2.5 million to \$2.7 million. The shortfall is primarily due to the company's inability to obtain an adequate and timely supply of a sole-source component for its new OcuLight GL laser until late in the third quarter, delaying shipments of the product.
- 10/3 The October issue of *Market Scope* states that PRK volumes are up in the third quarter according to a survey conducted by author David Harmon. He estimates that since approval in October 1995, more than 61,000 procedures have been performed and the monthly rate has risen to over 12,000, with additional laser centers open and advertising programs starting to "kick in". David estimates that approximately 330 excimer centers were operational at the end of the third quarter, compared to 275 at the end of the second. He believes that 10 U.S. and several Canadian centers are doing in excess of 100 procedures per month, while an additional 90 centers are doing at least 50 procedures, while the remaining 240 centers, mostly startups, are still doing less than 50 procedures a month. The average U.S. center performed approximately 34 procedures per month during the third quarter, compared to 25 in the second. "Despite a slow start, which created a severe disillusionment in the financial markets, the market has shown steady growth both in the number of laser centers and procedures performed per laser. A solid infrastructure of centers, advertising and referral networks are being established for 1997 and the years to come."
- 10/3 **Sterling Vision** has entered into a master franchise agreement with **Eye-Site Inc.** of Toronto, following the sale of four **IPCO** optical stores in Toronto to the company, owner and operator of five retail optical stores in that city. The combined nine stores

will be converted to Sterling Optical stores and operate as Sterling franchises. In addition, Eye-Site has contracted to open, over time, an additional 40 Sterling franchises within the province of Ontario.

10/3-

10/4 A *Federal Filings* of October 3rd notes that two employees of **Summit Technology** -- Kimberley Doney, Executive VP for Quality, Regulatory, and Clinical Affairs, and Andrew Jones, VP of Manufacturing -- have recently resigned. (See last month's 9/17 brief for more on Kim Doney.)

The following day, another *Federal Filings* notes that on October 1st, Summit was served with another shareholder suit claiming that the price of the company's stock was artificially inflated due to public statements made by the company and its former president and founder, David Muller, who was terminated by the company in early September. Summit expects that the most recent suit will be combined with the other ten such suits. The company believes that the actions are without merit and will vigorously defend the lawsuits.

10/4 Dillon Read & Co. announced that it had initiated coverage of **LaserVision Centers** with an outperform rating. In a research note, the firm said there are near-term announcements that could cause LaserVision to move toward positive cash flow, including the approval of excimer lasers to treat patients with astigmatism and the approval of its MobilExcimer system for performing PRK in areas of the U.S. not currently covered by laser vision centers. Another strength is the company's relationship with **Columbia Healthcare**. These latter two points differentiates LaserVision Centers from its competition.

The firm is bullish on the PRK market despite the recent spat of bad corporate news, which the analysts, James Lane and Shahreen Islam, don't believe will have an impact on PRK procedure volume. They are looking for at least 25% annual growth in procedures over the next several years, to more than 400,000 procedures by the year 2000.

10/4 The October issue of *Medical Laser Report* contains an in-depth interview of Bill Telfair of **IR Vision** (see the ophthalmic laser brief of 8/26). Bill, along with Paul Yoder, another founder of Taunton Technologies, and industry veteran Carston Becker (formerly of SLT, Laserscope, and Coherent), are all involved in the IR Vision startup. Pre-clinical trials of their 3 micron erbium laser system are about to begin, with some animal studies having been completed. According to Telfair, he is developing a small beam scanning system, with eye tracking, for refractive surgery. Once animal studies are completed and financing is in place, the company expects to begin clinical trials next year, with a system ready for the international market within two year.

10/7 **Physicians Resource Group** announced that it had signed definitive agreements to acquire two of its largest competitors, **American Ophthalmic, Inc.**, a privately held company, and the ophthalmic division of **EquiMed, Inc.**, for a combined equity value of about \$124 million. When the acquisitions are completed, PRG's annual revenues will increase to about \$378 million, up from the current \$248 million. With the acquisitions, PRG will provide management services to 136 practices, incorporating 586 professionals and 44 ambulatory surgery centers. American Ophthalmic will be acquired for about \$70 million, \$35 million in cash and the rest in PRG shares, with about \$10 million contingent upon delivery of letters of intent relative to acquisitions during the next several months. The acquisition of EquiMed's eye care division will be a cash transaction valued at \$54 million, plus assumed liabilities of another \$15 million. In addition, PRG will pay EquiMed additional funds for other acquisitions delivered to PRG through March 1997, which could bring the total deal to about \$100 million.

Separately, EquiMed said it would now concentrate on its more lucrative medical facility management business, including its oncology and image enhancement divisions. (The latter is the joint venture with **Cosmetic Technologies International**, a division of **Palomar Medical Technologies**, to open a series of laser cosmetic centers. For more on this joint venture, see the July 19th brief.)

10/7 According to the October 7th issue of *EyeWorld Week*, one of the major refractive laser suppliers is abandoning its U.S. clinical trials for PRK. Attempts to verify that this is **Chiron Vision**, and its trials with its Keracor 116/117 lasers have not yet been successful. Allegedly, the FDA has told the company that it would have to re-start its clinical trials because of the change in delivery mode of the newer model 117 (and the even newer model 217, just introduced in Europe), from wide area ablation to small spot scanning. This would be a major blow to Chiron, which had already entered Phase 3 trials. The newsletter also states that many companies feel that the regulatory process may soon change, greatly accelerating the approval process. However, no revised guidelines have yet been issued. More on this important issue as I get it.

10/7 An announcement from the *American Academy of Ophthalmology* states that an Idaho court has ruled that optometrists in that state are not authorized to perform PRK to correct myopia and/or astigmatism. This ruling effectively shuts down the Idaho Board of Optometry's ruling allowing laser use as within the scope of optometry in that state. The judge ruled (on October 4th) that PRK is surgery and that the scope of optometry does not encompass surgery, and that the Optometric Board does not have the power to enlarge the scope of practice to include surgery. The judge further stated that PRK is an "invasive procedure...the use of a 'light knife' instead of a steel surgical knife to achieve this result does not alter the analysis."

- 10/7 **TLC The Laser Center** announced the signing of a letter of intent to acquire all the outstanding shares of **20/20 Laser Centers, Inc.**, based in Bethesda, MD. 20/20 operates nine laser centers in the northeast corridor of the U.S. and in Florida, with 875 contracted optometrists and ophthalmologists. The acquisition will significantly strengthen TLC's expansion into the United States. 20/20's projected revenues for fiscal 1996 were expected to be around \$7.5 million, which is close to TLC's center revenues for fiscal 1996. The acquisition will cost approximately \$33 million, and is expected to close in late January 1997. TLC currently operates 12 laser centers, and with the acquisition and centers currently under development, expects to have 36 clinics operating by the end of 1997, covering 23 states and three provinces.
- 10/8 **LaserVision Centers** has signed a letter of intent to use the refractive surgical outcomes analysis program developed by **Data.Site LLC** (formerly Dan Durrie's RSS Outcomes-Based Info Management Systems, introduced at last year's AAO meeting), based in Kansas City. Data.Site provides quality and risk management, marketing analysis, and co-management programs for ophthalmic practices. By signing on, LaserVision will be able to compare surgical results from its centers to a global database, to help its surgeons improve both surgical outcomes and patient satisfaction.
- 10/8 **Shooting Star Technologies** sent out an update of the extensive corporate profile detailed in the October 1st brief above. The company notes that it is poised for growth in 1996/97, intending to add fourteen new sites by the end of 1997. These will include 2 in Canada; 1 in the U.S.; 3 in Australia and in Brazil; 2 in China; and 1 each in Thailand, Japan, and Taiwan.
- 10/9 **Pillar Point Partners** announced that it had filed another in a series of patent infringement suits aimed at enforcing its patent rights relative to the use of UV lasers to correct vision problems. The latest lawsuit was filed against Dr. Jon Dishler and the Laser Institute of the Rockies, located in Denver, CO.
- 10/9 **Escalon Medical** announced that the U.S. Patent Office had issued two new patents and a notice of allowance for a third patent related to the company's novel picosecond laser technology under development for refractive eye surgery and other applications in medicine. The three patents, when all issued, will bring the total to thirteen, covering ultrafast (picosecond and femtosecond), solid-state lasers for refractive surgery.
- 10/10 **LaserSight** announced that it had signed letters of intent to acquire two additional physician practices; the practice of St. Louis-based Dr. Loren Schrenk (The Eye Consultants of St. Louis), and the practice of Dr. James Pizza of West Caldwell, NJ.
- 10/14 The *Gray Sheet* stated that the FDA announced on October 10th, that users of unapproved excimer lasers have until January 15, 1997 to submit IDEs covering their

devices. Under the IDEs, users of custom-built and reimported laser will be expected to gather clinical data to support PMA applications. The IDE deadline applies to lasers being used both for PRK and LASIK. Under the policy, users of reimported lasers who are able to demonstrate that their device is identical to an FDA-approved Summit or VISX laser will have the option to submit a certification form to the agency in lieu of an IDE. The certification form will contain information needed to demonstrate that the reimported laser is "identical in all relevant aspects to the approved ones". Estimates of the number of lasers falling into the two categories, subject to the policy, are between 50 and 100 systems.

The October 18th issue of *InSight Washington*, in an interview with Susan Alpert of the FDA, states that the physicians eligible for the moratorium will be those who have not been warned to stop using unapproved lasers. Those who have received warnings are ineligible!

According to the new policy, as stated by both *EyeWorld Week* and *Ocular Surgery News Intelligence Report*, custom-laser owners may choose to submit an IDE application as an individual or jointly with others who own comparable lasers under a single sponsorship. Owners of Summit and VISX lasers approved for PRK can also become involved with LASIK, sponsored by **CRS-USA (Comprehensive Refractive Surgery-USA)**, a private company which recently obtained a "master IDE" for studying LASIK. Surgeons with the proper training and equipment can join the study for a fee of \$2500, which will enable them to gain access to a secure online database, run by **DataSite (formerly RSS)**, of their own results as well as from a core of 39 surgeons for comparison.

The same issue of the *Gray Sheet* states that **KeraVision** gained FDA approval to begin Phase 3 clinical trials of its KeraVision Intrastromal Corneal Ring on 360 myopic eyes at up to 10 U.S. locations. The study will investigate use of three different versions of the ICR to treat myopias ranging from -1.0 to -3.5 diopters. The company is currently engaged in Phase 2 trials using larger rings to treat -3.5 to -5.0 diopter myopes.

- 10/14 According to the October issue of *Pharmaceutical Approvals Monthly*, **Ciba Vision's** Voltaren Ophthalmic supplemental NDA covering its use in ocular pain associated with PRK is nearing FDA submission, while its claim for use in photophobia after RK was approved on July 23rd. (As is well known, both Voltaren and Acular (Allergan) are widely used *off-label* for reducing pain associated with PRK. Sales for both products are up 12-14% over last year.)
- 10/14 *The BBI Newsletter's* October issue has a major article on refractive surgery, with an emphasis on LASIK. The newsletter attributes the slow start of the PRK market to the relatively few physicians trained to date; the small installed base of excimer lasers,

especially the VISX Star; and the typical charge of between \$1500 to \$2000 per eye which represents a significant financial commitment for most patients. In addition, potential patients are carefully mulling over the decision to have refractive surgery and are taking several months before deciding to proceed. BBI is predicting that PRK procedures will reach between 75,000 to 100,000 this year. Looking ahead, the newsletter believes that procedural growth will be robust, but that it will be fueled less by PRK than by LASIK, primarily because of the absence of procedural and post-op pain and a virtually immediate improvement in vision. BBI believes that LASIK will account for between 5% to 10% of the refractive procedures this year, and that share will grow as more surgeons are trained and when final FDA approval is obtained. (I disagree with my good friend Larry Haimovitch, who wrote the BBI article, primarily because of the very high surgeon skills required, and the reliance on performing a good cut of the corneal flap with not so good equipment. Only when an automated microkeratome is perfected, may I change my mind. By the way, it should be noted that Larry had bi-lateral LASIK performed this summer by Dr. Richard Lindstrom.)

- 10/15 **LaserSight** was granted a certificate of free sale by the Ministry of Health of Costa Rica, enabling the company to sell its LaserScan 2000 commercially in that country. The company also announced that Howard Apple had joined as vice president of product development and engineering. Howard was formerly VP of R&D at Summit Technology.
- 10/15 **VISX** announced that the FDA had completed its initial review of the company's PMA supplement requesting approval to treat 0.75 to 4.50 of myopic astigmatism with -1.00 to -6.00 diopters of myopia. The company was also informed that in the interest of public health, its application will receive expedited processing. (In Canada, according to Dr. Raymond Stein of the Beacon Eye Institute, they routinely perform between 300 to 400 PRK procedures each month, 90% of which require some degree of astigmatic correction to attain maximum visual acuity.) When approved, all VISX systems sold in the United States will be capable of correcting astigmatism with a simple software change, which will be incorporated in the key card supplied to system owners.
- 10/17 **Iridex Corporation** announced its third quarter results with sales increasing 26% to \$2.6 million and net income of \$0.24 million (4 cents/share), an increase of 11% over the same quarter last year. For the nine months, revenues were \$7.5 million and net income was \$0.62 million (10 cents/share). The company reported that it was recovering from a shortage of a sole-source component for its OcuLight GL, and with CE certification, it can begin shipping the product into Europe. In addition, the company was awarded a Phase I SBIR grant from NIH to study new methods to detect age-related macular degeneration.

- 10/17 **VISX** announced that the U.S. Navy had purchased a VISX Star excimer laser to treat nearsighted military personnel. The laser has been installed at the Navy Medical Center in San Diego. The Navy decision followed an extensive investigation of the effect of PRK on military personnel which measured combat activities such as rifle shooting both before and after excimer treatment.
- 10/17 **Summit Technologies** announced that **Herbert Schwind GmbH** had agreed to pay Summit 1.23 million German marks (approximately \$800,000) in satisfaction of a judgement obtained against Schwind's Keratom excimer laser for infringing Summit's Azema patent. Summit has also obtained a separate German judgement against **Chiron/Technolas** that its Keracor 116 laser also infringes the same patent, and has brought separate actions against **Nidek** in Japan and **VISX** in the United States on the applicable counterparts of this patent. According to the October 18th *Boston Globe*, Mark Logan, VISX chairman said that his company has a similar patent that was approved by the U.S. Patent Office two years before the Azema patent was issued.
- 10/18 **Vision 21** announced that Richard Lindstrom had accepted the position of National Medical Director of this eye care physician management company, and was also named to its board of directors.
- 10/21 **LaserSight** announced that it had granted a license to **Photon Data, Inc.** for the scanning patent, U.S. 5,520,679, recently issued. PDI is the first company utilizing scanning technology to receive a license from LaserSight. Under the agreement, PDI will pay to LaserSight a 7.5% royalty fee based on gross sales of PDI's Scan-190 SmartScan laser. LaserSight is currently in discussions with other manufacturers regarding licensing agreements. (It should be noted that J.T. Lin, founder of PDI, and former founder and president of LaserSight, is the inventor of the scanning patent, which was assigned to LaserSight.)
- 10/21 **VISX** announced record third quarter and nine month financial results. The company reported third quarter revenues of \$19.7 million, with net income of \$5.6 million (35 cents/share). For the nine month period, revenues were \$50.8 million, up from only \$10.4 million for the same quarter last year, while net income rose to \$11.4 million or 72 cents/share. This compared to a net loss of \$10.7 million for the first nine months last year. Product sales for the quarter were \$14.5 million, representing the sale of about 29 laser systems, while service and other revenues accounted for \$5.2 million, which includes Pillar Point receipts. (If we estimate that \$4.5 million of that total was from PPP fees, it would represent about 18,000 procedures in the quarter, however, some of that was from fees collected by Summit and represents the share paid to VISX under the PPP agreement. Thus, the total number of procedures performed in the quarter is greater than 18,000, and as much as double that number.)

- 10/21 **TLC The Laser Center** announced results for its first fiscal quarter, with gross revenues of all managed clinics totaling \$8.1 million. Net revenues were \$4.9 million, with revenues from its refractive clinics at \$3.6 million. The company sustained a net loss for the quarter of \$764,000 (5 cents/share). The company also announced the acquisition of a secondary care clinic in Chicago (the Horn Eye Centers), bringing the total number of clinics offering eye care services to three. This practice will be enhanced to provide laser vision correction services shortly. The company has also signed a letter of intent to acquire the assets of Midwest Eye Institute with two locations in the greater Chicago area. TLC currently operates 14 refractive clinics with another 13 expected to be operating by the end of the year.
- 10/22 **Shooting Star Technologies** announced that it will complete a private placement for \$100,000, which is expected to close on November 1st.
- 10/23 **LaserSight** and **LaserVision Centers** have reached an agreement that calls for LVC to provide excimer laser and necessary technical personnel to locations serviced by the approximately 200 ophthalmologists under contract with LaserSight. The contracted ophthalmologists are required to provide a minimum number of PRK treatments on a given day to access the excimer laser. The physician schedules the patients through LaserSight, which in turn provides billing, collection, and financing services. LaserSight pays the physicians a professional fee and LaserVision a facility fee and retains the balance for services. LaserSight also announced that its wholly owned managed vision care subsidiary **MEC Health Care** is now offering PRK as a covered benefit in selected markets, as a result of its relationship with LVC. With PRK costing between \$1800 to \$2000 per eye, the new benefit allows members to reduce their out-of-pocket expense to between \$1000 and \$1200.
- 10/23 **Vision 21** and **For Eyes Optical** of Hialeah, FL, have formed a strategic alliance to pursue managed eye care contracts. The two companies will operate as a managed care organization (MCO) under the name Vision 21, offering services in seven states, with more than 100 locations and a network of more than 400 optometrists, ophthalmologists, and surgical facilities.
- 10/24 **Sight Resource** released preliminary third quarter results, with net revenue estimates of \$9.7 million, an increase of 86% over revenues for the same quarter last year. The net loss for the quarter is estimated to be \$590,000 (7 cents/share). The third quarter results include revenues from the recent acquisition of **E.B. Brown Opticians**. The company is estimating that 1996 revenues will reach \$38 million, up from \$19 million in 1995, and will be operating 10 laser vision correction centers, compared to only one in 1995, and 72 eye care centers, compared to 29 last year.
- 10/24 **Global Vision** announced that it had raised an additional \$1.5 million from Pacific Venture Group, a California-based venture capital firm. This is in addition to the \$2.5

million recently raised from another California-based venture capital company, Crosspoint Venture Partners. The proceeds will be used to fund the ongoing operations as well as establishing new laser vision correction centers in strategic areas throughout the U.S. The company currently operates eight laser centers in the U.S.

- 10/24 **LaserSight** announced that it had reached an agreement to acquire the exclusive licensing rights to neural networks and other artificial intelligence information technologies developed by **MindSight, Inc.** MindSight has been a pioneer in developing neural network technologies to various eye surgeries, including IOL surgery, RK, and now PRK (and LASIK). The neural net technology allows fine tuning surgical outcomes as the program "learns" the laser's nuances and helps the surgeon to adjust his treatment accordingly.
- 10/25 **Vision 21** has developed an integrated eye care delivery system for the Chicago area with its strategic affiliations with **Alliance for Eye Care**, which provides ophthalmological services, and two optometric groups that will operate in conjunction with optical retailers, **For Eyes Optical** and **Uhlemann Optical**.
- 10/25 **Paradigm Medical Industries** has signed a multimillion dollar manufacturing agreement with **Zevex International**, of Salt Lake City, to design and manufacture the company's ultrasonic phaco system and its Photon Laser cataract removal system. The contract is expected to result in more than \$30 million in revenues over its three-year period, and allow Paradigm to accelerate its market launch. The initial phase of the manufacturing program will allow Paradigm to begin filling its initial backlog of more than \$6 million of its phaco systems, with the delivery of 20 units by the end of March 1997. (In a private conversation with President Tom Motter at the AAO meeting, I learned that the company expects to file its 510 (k) application for its laser cataract device early next year. I wonder if the FDA will allow this device to be filed under a 510 (k), since it is a new application for a laser device, and other companies working in this area have had to file PMAs!)
- 10/25 **Autonomous Technologies** announced two developments. First, the company said that it had filed legal actions seeking a declaratory judgement of non-infringement, invalidity, and un-enforceability of certain patents owned or licensed by **Pillar Point Partners** in the United States and **VISX** in Canada. The U.S. action alleges that all patents controlled by Pillar Point are unenforceable. Autonomous intends to aggressively assert and protect the rights to produce its T-PRK laser system in the United States and to sell the systems worldwide. The company also announced that it intends to defend against other allegations of infringement, including action taken against it in the United Kingdom by VISX. Autonomous had placed a laser in a **LaserVision Center** location in London, but was forced to remove it after VISX alleged infringement. Despite requesting a European license to avoid the cost of litigation, VISX nevertheless initiated legal action forcing the laser removal. The

company also stated that it does not infringe the recently issued **LaserSight** scanning laser patent, despite allegations that have been reported in the media. Randy Frey, CEO, said that there are no pending legal actions between Autonomous and LaserSight.

The company also announced the results of its Phase IIb six-month follow-up on uncorrected visual acuity. As reported by Dr. Marguerite McDonald during the AAO meeting, in the U.S. trials, 90% of the 39 patients treated achieved 20/20 vision, while 97% had 20/25, and 100% had 20/32 vision! Eighty eight percent of the patients were corrected to ± 0.5 diopters, and 94% to within ± 1.00 diopters. Similar results were obtained by Dr. Pallikaris in Greece in his Phase IIb trials. (This is the best results that this author has ever seen reported.) The company had previously announced FDA approval to proceed with its Phase III clinical trials and has placed laser systems with Dr. Jonathan Frantz in Ft. Myers, FL, and with Dr. James Salz of Los Angeles. Additional sites are planned for a total of 7 sites. The company has also recently begun its trials to treat astigmatic patients with Dr. Ioannis Pallikaris and Dr. Konstantina Koufala in Crete, Greece.

- 10/28 **LaserVision Centers** announced at the AAO meeting that it will begin offering a Refractive Management Service Organization (RMSO) program to ophthalmologists performing refractive surgery. LVC will buy the assets of the refractive service practice and provide various management services designed to increase same-store/practice sales and provide superior surgical results. The program, called a "mini carve-out", will help refractive practices better position themselves for the expected entry on managed care into the refractive surgery market. The first practice to sign a letter of intent is Lindstrom, Samuelson, & Hardten Ophthalmology Associates of Minneapolis, one of the leading refractive practices in the country.
- 10/28 **LCA-Vision** announced that it had acquired the privately-held **Eye Laser Center** of Ft. Erie, Ontario, Canada, from a group of U.S. and Canadian ophthalmologists. Dr. Patricia Teal will serve as medical director of the center, which will be the company's 12th; nine in the U.S., two in Canada, and one in Europe. Complimenting the Ft. Erie facility, LCA also announced that it will open an LCA-Vision Center in Buffalo, NY, just across the border from the Ft. Erie center, in early December, under the medical directorship of Dr. Joseph Beradi, a partner in the Ft. Erie center group.
- 10/28 **Coherent, Inc.** announced at the AAO meeting that the company will begin shipping outside of the U.S., a new laser specifically developed for the treatment of primary angle glaucoma. The Selecta 7000, a doubled YAG laser, has successfully been used for selective laser trabeculoplasty (SLT), and according to the company, has the potential to become the standard of treatment for this condition. Pilot studies with the laser, conducted at the Wellman Laboratory of Photomedicine at MGH by Dr Mark Latina have shown a 30% drop in average IOP, beginning the first day of treatment

and lasting through one year of followup. Trials for FDA marketing clearance in this country are underway.

- 10/30 I was provided with a copy of the FDA's October 20th instruction sheet for owner certification of lasers as PMA approved devices by Kent Williams of **Field Service Engineering**. The simple form merely states that the owner certifies that the laser he/she owns is identical in all relevant aspects to a PMA approved device. If the owner can answer that the computer hardware, firmware, and software of the device is identical to that distributed in the PMA device and that he/she has a copy of the approved labeling, the appropriate operator's manual and other relevant material, then along with the model name, number, serial number, etc., he/she can request certification for use. If the FDA agrees, they will so notify the owner. If the FDA believes the information provided is inadequate, it will require an IDE application. There is no mention of a Pillar Point counter anywhere!
- 10/31 **Summit Technology** reported its third quarter results, with revenues of \$21 million, an increase of 17% over its second quarter results. The net loss for the quarter was \$3.9 million (13 cents/share), a decrease of 6%. The company also announced that approximately 15,200 procedures were performed in the U.S. using Summit lasers, up from about 13,600 procedures in the second quarter. Since approval, approximately 42,000 procedures have been done. (In a speculative mood, if we figure that Lens Express contributed about \$12.5 million in revenues, and the PPP fees generated about \$3.5 million, with service and refractive procedures at the 19 centers another \$2 million, then the \$3 million left means that the company probably sold about 6 lasers in the quarter.)

OPHTHALMIC LASER UPDATE -- NOVEMBER 1996

- 10/21 *The Gray Sheet* reported on the changes promulgated in the October 10th "Guidelines" for excimer laser refractive surgery (which I received on November 5th, thanks to Lou Charleton of **LaserSight**). The important changes are that a laser manufacturer can make design/modification changes in its laser during late-stage clinical trials, as long as it receives approval for the changes from FDA and, the FDA has effectively eliminated study phases, allowing study expansion requests before the end of the current study period. This means that there will not be a stop in the study while awaiting FDA review and approval of the results before beginning the next phase of the study. Under the new guidelines, a sponsor can request expansion of the study before all of the current study subject's data have been collected, as long as there has been timely submissions of adequate data/progress reports that has demonstrated reasonable safety and effectiveness and prior agency approval of all changes in the investigational plan and in the device submitted in the original IDE.

- 11/1 **Sight Resources** announced that it is taking a leadership role in screening pre-verbal children for amblyopia (lazy eyes -- a muscular disorder), affecting about 5% of children and which is 95% preventable if detected early. Through its wholly-owned subsidiaries **Cambridge Eye Doctors** and **Vision World**, the company has purchased five of **Medical Technology & Innovations'** PhotoScreeners, which will be installed in selected locations and will be used to initially provide the service at no cost to the public, through its "We Care About Your Kids" photoscreening campaign, which will run through the end of the year. If the response is as great as anticipated, the company may consider putting photoscreeners in all its 72 eyecare centers.
- 11/1 **Sunrise Technologies** announced that it had signed a memorandum of understanding to acquire privately-held **EyeSys Technologies**, a leader in the corneal topography field with over 3000 installed systems (about a 40% share of the market), for 12.5 million newly issued shares of common stock. The companies hope to complete the transaction before the end of the year. Sunrise hopes to be able to incorporate the EyeSys system into its Corneal Shaping system.
- 11/3 The November issue of *Market Scope* provides the first coverage of last month's AAO meeting, with highlights of "what was hot" and "what was not". Among what author Dave Harmon thought "was hot" included LASIK for high myopia, laser removal of the epithelium, phakic IOLs for extreme myopes and hyperopes, intrastromal rings and PRK for low myopes, polymer-based posterior chamber phakic IOLs (the Staar ICL), using someone else's excimer, scanning, low power and small beam excimers, and selling your practice to PRG or some other management company! Dave also gave a recount of the Pillar Point controversy that took place at the refractive surgery sub-specialty session, where Liz Davilla of VISX was bombarded by questions and comments from angry ophthalmologists. (I have covered all of the rest of the news in either this issue or last month's issue of the briefing.)
- 11/4 This issue of *EyeWorld Week* states that **Coherent** will begin shipping its Selecta 7000 Q-switched doubled YAG laser, specifically designed for selective laser trabeculoplasty, outside of the U.S. while it seeks FDA approval for marketing here and in Japan. Conceived by Dr. Mark Latina of the **Wellman Labs at MGH**, the laser targets melanin-containing cells in the trabecular meshwork using low-energy pulses that reduces ocular pressure without damaging the meshwork. The method may prove beneficial for the early treatment of open angle glaucoma.

The same issue also contains an interesting short item about **IBM** and its PRK patent. *EyeWorld Week* states that IBM has put a moratorium on further licensing of its basic patent for PRK, and that it might be considering entering the market. In a conversation with the director of business development in the office of intellectual property and licensing, I was able to confirm the former and obtain a categorical denial of the latter. (More on this situation as it develops.)

- 11/4 **Beacon Eye Inc.** reports that for the nine months ended September 30th, the company generated revenues of \$3.5 million, compared to \$0.5 million for the same period last year. The net loss for the period was \$17.7 million (compared to \$8.7 million), which included \$12.4 million in business development expenses during the nine month period. For the quarter, revenues were \$1.8 million, with a loss of \$8.2 million (including business development costs of \$5.7 million). The company presently operates three laser centers in Texas in addition to the Toronto center, and has plans to open five additional centers in the fourth quarter and early in 1997, in Ft. Lauderdale and Tampa, FL; Atlanta, GA; and Orange County and Beverly Hills, CA.
- 11/4 **LaserSight** announced that its LaserSight Technologies subsidiary had received ISO 9002 certification, and it is seeking the CE mark so that it can market its laser products into Europe. The company has established distributor agreements with companies that will market the LaserScan 2000 excimer laser throughout Europe, including the Benelux countries, the UK, Germany, Portugal, Eastern Europe, France, Italy, Spain, Greece and Scandinavia.
- 11/6 **Equimed** announced that it had completed the sale of its ophthalmic division to **Physicians Resource Group**, with an effective closing date of November 1st. The company will now execute its strategy of pursuing its medical facilities management businesses relating to oncology and image enhancement.
- 11/7 **Sunrise Technologies** announced some management changes, with David Light becoming chairman of the board of directors (in addition to remaining CEO) and Russ Trenary being named president and COO of Sunrise, and becoming a member of the board of directors. The company also reported its third quarter results with revenues of \$1.8 million and a net loss of \$1.0 million (4 cents/share). For the nine month period, revenues were \$4.3 million and a net loss of \$4.0 million (16 cents/share). Mr. Light commented that dental revenues were beginning to reflect the hard work done in the first half of the year, with dental laser sales picking up in Europe, especially in Germany, and also in the Pacific Rim countries. In the ongoing LTK clinical studies with its Corneal Shaping laser, the five sites conducting the expanded Phase II studies should complete the treatment of the 100 patients by December.
- 11/8 **LCA-Vision** reported its third quarter results with revenues of \$3.2 million, down from the \$3.6 million for the same period last year, and a net loss of \$1.1 million (6 cents/share), compared with a loss of \$91,745 last year. The decline in earnings was attributed to the ongoing retail build out of new laser eye surgery centers, with the company expecting to have a total of 17 centers operational by year's end. The company also noted that it was retaining the services of a large NY-based investment banking firm to assist it in implementing its strategic objectives.

- 11/11 This week's issue of *EyeWorld Week* notes that Liz Davilla of **VISX** noted in her presentation to over 1000 ophthalmologists attending the pre-AAO refractive surgery meeting, that it was "too early for us to spend money on PRK category development through national advertising, but that rather practices should develop internal sales and marketing skills first". At a November 27th press conference, Mark Logan reiterated what Liz had said, and said that patient word of mouth was the most effective current marketing tool. "National advertising is not the way to go."
- 11/12 **KeraVision** reported that it had cleared the last major regulatory hurdle in Europe, allowing it to begin commercializing the KeraVision Ring for the treatment of myopia. The company received the CE mark along with ISO 9001 certification opening the way for marketing the product in all European Union countries. The company has targeted France and Germany for initial commercialization, for selling five ring sizes to correct -1 to -5 diopters of myopia. KeraVision estimates that there are 8 million adult myopes falling into the treatable range in Germany, and an estimated 5.1 million in France. The company recently received FDA approval to initiate a Phase 3 study of three ring sizes for the treatment of -1 to -3.5 diopter myopes, plus approval for an extended Phase 2 study for two ring sizes to treat -3.5 to -5 myopes.
- 11/13 **LaserSight** announced its third quarter results and that it had engaged A.G. Edwards to "explore and evaluate strategic business opportunities". Revenues for the quarter were down to \$4.5 million (down from \$6.8 million last year's third quarter), resulting from a higher allowance for sales returns, a lower per unit price for laser sold during the quarter (some of the older "mini-excimer" were sold off for \$200,000, compared to the average sales price of \$300,000 for the LaserScan 2000 systems that were sold), and a reduction in the number of systems sold. The net loss for the quarter was \$2.1 million (28 cents/share), compared to \$759,000 or 11 cents/share a year ago. Revenues for the nine month period were \$15.1 million, down from \$17.3 million last year, while the net loss for the period was \$3.3 million or 51 cents/share, compared to a net income of \$3.6 million and 53 cents/share. In a teleconference following release of the third quarter results, president and CEO Mike Farris noted that the fourth quarter looked promising, with orders taken at the recent AAO meeting for 10 laser systems, compared to only 1 sale at the same meeting a year ago.
- 11/13 **Escalon Medical** reported its first fiscal quarter results with revenues of \$1.4 million, compared to no revenues in the same quarter last year. The net loss for the quarter was \$348,200 (3 cents/share) compared to \$902,000 (16 cents/share) last year. (It should be noted that none of the revenues came from sales of lasers, but were from the products that Escalon was selling prior to its acquisition by **ISL**, and the renaming of the company as Escalon. The company is seeking strategic partnerships for the ongoing development of the ISL picosecond laser for refractive surgery (primarily its use as precise microkeratome in performing LASIK).

- 11/13 **Sight Resource** third quarter results showed an 87% increase in revenues to \$9.8 million. The net loss for the quarter was \$594,000 (7 cents/share), compared to \$1.1 million (21 cents/share) last year. (Third quarter results include the operations of E.B. Brown Opticians, acquired effective July 1st.) Company president and CEO Bill McLendon noted that, "for the first time in the company's history there were earnings before depreciation and amortization."
- 11/14 **Laser Vision Centers** said that it had been approved for listing on the NASDAQ National Market. The company expects that its stock will begin trading on the big board starting Monday, November 18th.
- 11/14 **Physicians Resource Group** released its third quarter results with revenues of approximately \$60.5 million and net income of approximately \$3.5 million (13 cents/share). For the nine months, net revenues were \$163.4 million, and net income was \$0.3 million (1 cent/share). Excluding the non-recurring expenses and related tax effects of recent transactions, income would have been \$5.9 million (22 cents/share). The company also announced the closing on November 5th of the eye care division of **Equimed**, for approximately \$54 million, which may be increased if EquiMed delivers additional acquisitions to PRG prior to the end of the first quarter next year. With the expected closing of **American Ophthalmic** later this month, PRG will provide management services to 140 practices in 24 states, including 600 physicians at 388 locations, together with 45 ambulatory surgery centers and 169 optical dispensaries, all of which represents an annual revenue rate of approximately \$350 million.
- 11/14 **Autonomous Technologies** announced its third quarter results with an operating loss of \$2.9 million for the quarter (43 cents/share) and \$6.2 million for the nine month period (\$1.19/share). The net losses are due to the planned expansion of clinical trials, which entered into Phase III in October, for low to moderate myopia; and the expansion of a production organization in preparation for anticipated commercialization of its products early next year. The company has opened a protocol for treating astigmatism and expects to begin hyperopia and LASIK trials early next year.
- 11/15 **Sterling Vision** reported that system wide sales for the three month and nine month periods has increased 18% and 13% respectively. For the three month period, sales were \$33.6 million, while nine month sales were \$96.8 million. President Robert Greenberg commented that expenses incurred in connection with acquisitions as well as development costs for its ophthalmic laser center business led to a loss for both periods. The third quarter loss was \$760,000 (6 cents/share), while the nine month loss was \$749,000 (also 6 cents/share). The company operates approximately 350 company-owned and franchised retail optical stores.

- 11/18 The November 18th issue of *EyeWorld Week* notes that surgeon Bobby Maddox of El Paso, TX has seen inflammation in 15 consecutive patients who received LASIK with the Summit laser and the Chiron microkeratome. The inflammation was severe in three of the patients. He has reported the problem to CRS-USA, the sponsor of an international LASIK study. He believes the problem may be related to residual polishing compound on the microkeratome blades, but is awaiting a final report from a laboratory to which he sent the blades for analysis. Chiron Vision is aware of the problem and is preparing a report on the subject.
- 11/18 A memorandum of understanding has been signed with the **Pacific Eye Centre** of Brisbane, Queensland, Australia and **Shooting Star Technologies**. The joint venture will provide both cataract and refractive surgical services to the more than 3.3 million people living in the Queensland state. Revenues for the site are expected to exceed \$5 million in 1997. The agreement will allow Shooting Star to purchase a 75% interest in the Pacific Eye Centre's existing practice in Brisbane, and allow equal participation in a new surgery center opening in Mackay, Queensland in January 1997. Shooting Star owns refractive surgery centers across the Asia-Pacific and North and South American areas.
- 11/19 **Laser Vision Centers** announced it had received approval of its PMA for the **VISX** model C (Star) laser, and the company would immediately submit a supplemental PMA for approval to use the system in its MobilExcimer units. The company noted that more than 350 eye surgeons have expressed interest in having access to the MobilExcimer system once it is approved in the United States. The company currently operates successful MobilExcimer units in both Canada and Europe.
- 11/19 **Premier Laser Systems** has signed a letter of intent to form a joint venture with privately held **Refractive Surgical Services (RSS)** of Kansas City, KS. RSS is a leading provider of on-line refractive surgical data analysis for ophthalmic practices worldwide. The joint venture, to be named **Data Site**, will further develop the ophthalmic analysis services and market them to ophthalmologists, as well as cooperatively sell Premier's products to networks of ophthalmologists. Data Site will also develop outcomes analysis programs for the dental and surgical markets that will be distributed worldwide. Premier will own 51% of the joint venture, while RSS will retain 49%. RSS currently has service contracts with leading managed care networks such as **Laser Vision Centers** and serves as an electronic bulletin board for the ISRK. It also performs surgical analysis for refractive surgery studies for manufacturers **Nidek**, **Chiron Vision**, and **KeraVision**, and has initiated the first comprehensive LASIK study approved by the FDA with members of the ISRK.
- 11/20 **EquiMed** reported its third quarter results with net revenues of \$29 million and net income from operations of \$2.5 million (9 cents/share). With a non-cash writedown of \$24.2 million of goodwill associated with the sale of its ophthalmology division, effective November 1st, the company reported a net loss of \$21.7 million or 76

cents/share. For the nine month period, net revenues were \$79.2 million and the net loss was \$18.6 million (68 cents/share). The sale of the ophthalmology division allowed the company to reduce its debt by approximately \$14 million. It is in a strong cash position which will enable it to further reduce debt and support its ongoing oncology business and introduce image enhancement centers in select markets around the country. The company now owns or operates 36 oncology centers in 10 states.

- 11/21 **Sunrise Technologies** announced that the U.S. patent office had issued a patent (5,431,646) for an optical fiber probe and laser sclerostomy procedure for treating glaucoma.
- 11/22 **LCA-Vision** announced the opening of its tenth U.S. refractive laser surgery center in St. Petersburg, FL, to serve the Tampa Bay/St. Petersburg metropolitan area. The St. Petersburg site will be a temporary location until early 1997, when the company expects to move to a much larger permanent location, now under construction in nearby Clearwater, FL. The company plans to open an additional four U.S. centers before the end of the year, bringing the total to 17 worldwide.
- 11/23 I received **LaserSight's** 10Q and the only thing of interest that has not previously been covered in the brief about their third quarter results above (see November 13 brief) is the fact that the company sold 13 laser systems in the third quarter, compared to 18 for the same period last year. For the year to date, the company has sold 33 laser systems, which compared to 44 systems last year through September. (It must be noted that some of the systems sold this year, as reported by CEO Mike Farris, were the old "mini-excimers", which were sold for close to \$200,000, rather than the \$300,000 that the newer Scan 2000 sells for.)

I also received **Summit Technology's** 10Q and other than listing all of the legal actions both being taken by Summit and Pillar Point, and the actions against Summit, there was nothing striking in this report. Of note, there are now at least 15 shareholder suits filed against the company, which eventually will be combined into one action. Also, the company notes that it is "evaluating its operations and strategies, which may result in the total or partial disposition of one or more of the company's businesses, or the acquisition by the company of one or more additional businesses." The other item was that at the end of the quarter the company had 19 Vision Correction Centers, of which 14 were open at the beginning of the quarter, and they had revenues of \$1 million. (The only breakout of revenues for its operating divisions.)

- 11/25 **Summit Technology** announced that it had successfully completed its first field upgrade of an Apex laser into an SVS Apex Plus. The field modification was done in only three days. The news release notes that the company has sold more than 75 Apex Plus systems outside the U.S., and has an installed base of over 200 Apex lasers in the U.S. that can be converted upon receiving FDA approval to do so. The first field

conversion was done on the system owned by Dr. Bobby Maddox in Juarez, Mexico (who reported at the Summit meeting held during the AAO, that he was charged \$85,000 for the conversion -- supposedly Summit's cost).

- 11/25 In a followup to last week's announcement of the problems he had with the **Chiron** microkeratome blades (see the November 18th brief), *Eyeworld Week* reports that Chiron has contacted all surgeons who received blades from the lots identified by Maddox, and although many of the blades have been used, no other cases of interface inflammation have been reported. Final test results on the blades received by Maddox are expected next week.
- 11/25 According to a news release sent out by the AAO, the American Medical Association's Board of Trustees has approved a statement defining laser surgery as surgery and restricting the performance of surgery to qualified physicians. The Board's decision backs up the AAO's position that PRK (and LASIK) are surgery and should not be performed by non-physicians (i.e., optometrists).

OPHTHALMIC LASER UPDATE -- DECEMBER 1996

- 11/11 The November 11th *Vision Monday* ran a story about how both Verne Sharma, president of **Summit Technology** and Mark Logan, chairman and CEO of **VISX** were optimistic about PRK in 1997. The article noted that Ken Taylor of Arthur D. Little thought that about 70,000 to 75,000 PRKs would be performed in 1996, with both gentlemen agreeing with that projection, and Logan believing that their would be triple that number in 1997. (Both men were sent my updated projections for 1996 and beyond in November, which I sent to most of you early in the month. I am still holding out for 110,000 procedures in 1996, 84,000 of which would be performed on licensed lasers, with the remainder being done on "gray" and "black" machines. Anyone wishing a copy of my projections for 1996 out to 2000, please call.)
- 11/18 I missed the release sent out by **TLC The Laser Center**, which noted that they had signed a letter of intent with **Duke University Medical Center** to establish a laser center. This would be TLC's first academic medical affiliation in North Carolina. The company is building two other laser facilities in the state, at Winston-Salem, and in Charlotte.
- 11/25 This week's *Gray Sheet* notes that the FDA intends to respond to custom laser IDEs within 10 days, compressing its normal 30 day response time. The quick turnaround is intended to prevent a backlog and to ensure that review times for other submissions do not lag. The notice applies to physicians using custom-built devices to perform PRK and LASIK, and also to those physicians who are using re-imported lasers that were exported before gaining FDA approval. FDA estimates that fewer than 20 physicians

nationwide are currently using custom-built lasers, and states that the notice is not intended for "engineers" to get more lasers onto the market. As for re-imported lasers, FDA has "documented" evidence of about 25 such devices, although the number is estimated to range between 50 to 150.

- 11/28 **Shooting Star** released its third quarter results showing revenues of \$5.6 million, an increase of 68% over the preceding quarter. Net income before taxes for the nine month period increased 81% to \$1.3 million. In management commentary sent with the statement, the company notes that it intends to develop 14 new centers by year end 1997, with the majority of these centers in the Asia-Pacific region. Other centers are expected to be developed in Brazil and in China.
- 11/29 The FDA has tried to get the attention of all owners of either "gray" or "black box" lasers. As a member of the American Society of Lasers in Medicine and Surgery, I received a package of information sent by Susan Alpert of FDA for distribution to the ASLMS membership. The cover letter accompanying the October 10th letter to manufacturers and users of refractive lasers, asks for its dissemination to membership to ensure that the American Public is assured that all lasers used for refractive surgery are safe and effective, in other words, approved by FDA.
- 12/1 As a result of my urging, Ron Rosenberg of *The Boston Globe*, finally wrote an encouraging story about **Summit Technology**. In the story, Ron related the "good news" about partnering with its customers that Verne Sharma related at the meeting held at the Summit conference held as part of the AAO meeting in Chicago last month. (I had called Ron after the meeting and told him what Verne had said to the gathering, and how I felt that it signaled a "turnaround" for the company.) The story gives a balanced view of both the troubles encountered by the company and the hopes for the future. Anyone wishing a copy should call.
- 12/2 Another update on the FBI investigation into the **Summit Technology** data leak is reported in this week's issue of *The Gray Sheet*. According to the story, an update of its investigation is expected to be given to the House Commerce/Oversight Subcommittee within the next few weeks. The subcommittee is said to have reached an understanding with the FBI that it would report to Congress to discuss its progress in investigating the leak of data. Under the agreement, the FBI would provide an accounting of the case, even if it determines that it does not have enough evidence to warrant criminal prosecution of an individual or a group of individuals responsible for the leak. The FBI were called in in July after the FDA's Office of Internal Affairs failed to bring the case to a conclusion. Some FDA staffers express doubt that the FBI investigation will be any more fruitful than the OIA's effort, noting that OIA employs former law enforcement officers well versed in conducting criminal investigations.

- 12/2 **Shooting Star** announced that it had signed a memorandum of understanding on November 29th with **Asoke Sin Co. Ltd.** in Bangkok, Thailand. The two companies agreed to enter into a joint venture agreement that would see Shooting Star acquire a 45% interest in a new laser refractive surgery center in Bangkok, built in conjunction with Asoke's Rutnin Eye Hospital. The two companies also plan to open other centers in Thailand that will offer a full range of ophthalmic services, including cataract surgery.
- 12/3 **KeraVision** announced that after a ten-year research effort, the company had initiated sales of its ICR (intracorneal ring) for the treatment of nearsightedness with the inaugural order shipped to Germany. Commercialization in France and Austria is expected to begin in early 1997, and will be expanded to three more European countries by the end of the year. This comes after the November 5th EC certificate allowing the CE Mark allowing the sales of the product into Europe. (See the 11/12 brief in last month's newsletter.) The ring sells for about \$600 and, with implantation charges, will cost about the same as laser refractive surgery.
- 12/3 **TLC The Laser Center** announced that a group of underwriters, led by **RBC Dominion Securities**, and including **Gordon Capital Corporation**, and **Midland Walwyn Capital, Inc.** has agreed to purchase 525,000 share of common stock at \$7.25 per share, for gross proceeds of \$3.8 million. The release did not specify what the funds would be used for. TLC operates 16 clinics in North America, four of which are in Canada.
- 12/3 **Summit Technology** announced that it had received approval to expand its clinical trials for the treatment of hyperopia, using the company's Apex Plus excimer laser system. The multi-site trials will use the company's erodible mask for correcting mild to moderate hyperopia (+1 to +4.0 diopters) with ≤ 1.0 diopter of astigmatism. The clinical data collected from these trials will be used in support of the PMA supplement application, expected to be submitted to the FDA in late 1997. The Apex Plus system has been used successfully to treat myopia, hyperopia, and astigmatism for two years outside of the United States.
- 12/4 **LCA-Vision** said it had completed conversion of \$1.2 million of existing debt to a private placement of Class B preferred stock. The company also announced that it had issued \$100,000 worth of new common stock, in connection with the company's pending West Coast expansion. The shares were issued to a group of physicians who have invested in LCA-Vision's soon-to-be-opened first facility in California. In addition to the California location, the company plans to open new centers in Buffalo, Albany, New York, and Columbus, Ohio before the end of the year.
- 12/5 **Sight Resource** today commented on Summit's announcement of obtaining approval to expand its hyperopia trials. Steve Blinn, COO, stated that they have followed

Summit's progress in the treatment of farsightedness in the international market with great interest and applauds the latest approval. He said that as Summit gains approval to expand treatment parameters, and expand the patient population, they believe that laser vision correction will grow significantly. "The prospect of 54 million farsighted people being added to the potential laser vision correction pool is truly exciting."

- 12/5 This month's issue of *Market Scope's Refractive Market Perspectives* has a lead story about how, despite the "doom and gloom" prevalent in the industry, as stated by David Harmon, there are several points of light which reflect market potential for refractive surgery. He says that while most laser centers struggle to build volume, a few North American centers have managed to consistently produce 100 plus procedures per month. The busiest of these deploy a variety of strategies ranging from co-management, to intensive advertising, while most are built around one or two key surgeons with a strong local, and in some instances, national reputation. Six of the centers are highlighted and they include: **TLC** in Windsor, BC and in Toronto; **London Place Eye Center** in Westminster, Ontario; **Ophthalmology Ltd.** in Sioux Falls, SD; the **20/20 Laser Center** of Rockville, MD; and the **Hunkler Eye Center** in Kansas City, MO, and the surgeons associated with each center. (Anyone wishing a copy of this interesting article, give me a call.)

David also states that **Summit Technology** is still in the laser business, commenting on the first in-the-field upgrade of an Apex to an Apex Plus, done on Bobby Maddox's laser in Juarez, Mexico.

- 12/9 **LCA-Vision** opened its 11th U.S. laser center in the Columbus, Ohio suburb of Pickerington. This will be temporary location until larger permanent quarters in a new building under construction are completed in Columbus. As previously noted, the company plans to have a total of 17 centers -- including the two in Canada and the one in Finland -- opened before the end of the year.
- 12/10 **Paradigm Medical Industries** continues to move forward toward the production and delivery of the Precisionist Thirty Thousand and the Photon Laser Cataract Removal System in early 1997. The company claims it has a backlog of over \$6 million in orders worldwide. The company recently completed a multimillion dollar manufacturing agreement with **Zevex International**, a designer and manufacturer of ultrasonic and electronic processing components for the medical industry. Zevex will make both the ultrasonic and laser phaco devices for Paradigm. The first 19 system are expected to be ready by the end of March next year, to be shipped during the second quarter.
- 12/11 **VISX** announced that it has been notified by the FDA that its PMA supplement for treating astigmatism will be on the agenda of the January 14th Ophthalmic Devices Advisory Panel. According to the release, the company has sold over 200 excimer

laser systems worldwide, with the international systems successfully treating astigmatism since 1990. Based on that experience, nearly two-thirds of the patients undergoing PRK have been treated for astigmatism. Once U.S. FDA approval is obtained, it would dramatically increase the total number of procedures performed. All U.S. VISX systems sold are capable of treating astigmatism with a simple software change via the keycard. No additional hardware or disposables are required (as with the Summit Apex, converting it to the Apex Plus).

The company also notes that it received approval in October for the expansion of its U.S. clinical trials for treating hyperopia with the Star excimer laser system. According to chairman and CEO Mark Logan, "The early results being seen from the controlled hyperopia studies appear significantly better than those published for other available technologies." (I assume he is referring to the Sunrise holmium laser LTK trials.) Unlike the Summit Apex Plus laser, the Star will require a hardware upgrade for treating hyperopia, which according to VISX, will require a field upgrade taking about four hours.

- 12/12 **QLT PhotoTherapeutics** and **Ciba Vision** announced that they have treated the first patient in their co-sponsored multi-centered Phase 3 clinical trials with BPD-MA (verteporfin) for treating age-related macular degeneration (AMD). Trials on 540 enrolled patients will begin over the next few months at 19 clinical sites throughout Canada, Europe, and the United States. Results of the Phase 1/2 clinical trials released last spring showed partial or complete closure of diseased blood vessels associated with AMD, and no loss in visual acuity after a single treatment with BPD-MA. Researchers who took part in the study expressed optimism that the treatment will provide a selective modality for the treatment of this disease condition, which is the leading cause of blindness in persons over the age of 50, with approximately 200,000 new cases of the severe form diagnosed annually. Currently, there is no adequate treatment available for 80-90% of the patients.
- 12/13 **Global Vision** also commented on the December 3rd Summit announcement of expansion of its hyperopic trials. Jerry Maida, chairman, said that he was pleased not only for what the announcement meant for Summit, but the impact the approval (for the treatment of hyperopia) would have on the industry as a whole. He believes that the approval would expand the laser vision correction market from its current 70 million nearsighted people, to approximately 150 million for both nearsightedness and farsightedness. Global owns both Summit and VISX lasers, but five of its seven centers' lasers are Summit devices.
- 12/13 According to a *Dow Jones News Release*, **Paradigm Medical Industries** signed an agreement with **Johns Hopkins University Applied Physics Laboratory** to collaborate on R&D projects, to develop a laser probe that will have surgical applications for the back (retina) of the eye.

- 12/15 This week's *Barron's* has a story about some of "the small fry" newly public companies that were going unnoticed in a year of 692 companies going public. Among the companies discussed was **Iridex**, the parent of **Iris Medical**, whose September quarterly earnings were disappointing to Wall Street, in part due to the late shipment of a key component for the company's newly introduced Oculight GL laser. According to the story, deliveries of that late component have improved recently.
- 12/16 **Laser Vision Centers** released its results for its second quarter, ending October 31. Revenues were \$1.9 million, compared to \$960,000 for the same period last year, while six-month revenues were \$3.4 million compared to \$1.7 million. The net loss for the quarter was \$2.1 million (25 cents/share), compared to \$1.5 million last year. For the six months, the loss was \$4.4 million (57 cents/share) compared to \$2.5 million last year. The company also noted that revenues had increased 28% from the first to second quarter, while the net loss had decreased 7%. The company attributed the higher revenues to continued growth in the U.S. excimer laser surgery market, with case volumes for the quarter increasing by more than 40% over the previous quarter. (Beginning in March next year, Laser Vision will begin announcing same laser (procedure) sales on a monthly basis.)
- 12/16 **Paradigm Medical Industries** announced that it had completed its human clinical trials, on ten patients, for its laser cataract removal system. The patients will be followed for six months before the company submits the data to the FDA for review. (Thirty percent of the patients have completed the six-month review and that those patients show excellent post-operative results, with eyesight restored to normal visual acuity. The system, with its Nd:YAG laser energy delivered through a fiber optic delivery system, to vaporize tissue in a chamber at the distal end of the probe, is claimed to cause no heat or vibration and use less energy than conventional ultrasound phacoemulsification devices. Because of the modular nature of the system, the laser phaco device, the Photon Ocular Surgery System, can be added as a "plug-in" upgrade to the company's Precisionist ThirtyThousand ultrasound phaco system. The laser phaco system is based on a patented invention by Dr. Daniel Eichenbaum of Murphy, NC. Initial domestic shipments of the ultrasound phaco, and both the systems internationally, are expected to begin next March.
- 12/16 The cover story of the December issue of *Review of Ophthalmology* is all about "Whatever Happened to Summit Technology?" In the story, authors Judith Lee and Stan Herrin relate the history of Summit, from its founding in 1985, to its high flying days just after approval of the excimer last October, to the troubles that followed that led to the firing of its founder, David Muller, by the board of directors that he had appointed. The story goes over familiar grounds that have been highlighted in this newsletter, including some misleading and untrue information about Mr. Muller's stock sales. It concludes with some hopeful quotes from the authors and Dr. Dan Drurrie that with its legacy of regulatory success and with the history of helping to

start an industry from scratch, "the house that David Muller built may still be a force with which to be reckoned." According to Drurrie, "I wouldn't count them out."

12/18 **VISX** announced that the FDA had approved the company's protocol to expand its study of hyperopia with the Star laser. The study will be carried out at several U.S. sites and will include up to 4 diopters of hyperopia. According to Walter Stark, a clinical investigator for the study, "Approximately 61% of the worldwide population is affected by hyperopia and this could open the door for many of them." (The VISX system will require a hardware change/upgrade for the treatment of hyperopia, unlike the software change that will allow the correction of astigmatism.)

12/18 *The Wall Street Journal/California* carried an upbeat story on **VISX**, commenting that the company makes excimer lasers to correct vision for the more than 100 million Americans who suffer from farsightedness, nearsightedness, and astigmatism, which presents a potentially huge market. And despite the company's past problems, it "may be the right stock for investors willing to take a risk on that potential". According to Zack's Investment Research, five analysts rate the stock a "buy", two are "neutral", and one bear rates it a "sell"! Some of the analysts quoted included Beverly Berman of Hanifen Imhoff, "An increased number of procedures will drive earnings, and that will boost the stock"; Michael Yellen of GT Global Health Care Funds, "**Summit's** stock has been a disaster, and I think it has tainted VISX by association"; and PaineWebber analyst Charles Olszewski said that there are important differences between the two companies. Although it was first to win approval for marketing, its technology is now viewed by doctors as inferior to that developed by VISX. (Obviously, he needs to see the update I wrote about the Summit Apex Plus!) The story goes on to comment on the problem faced by both companies in their inability to meet the "unrealistic projections" for the number of laser vision correction procedures to be performed in the U.S. this year. "Analysts say that a variety of industry sources led them to believe earlier this year that as many as 125,000 procedures would be performed (that sounds vaguely familiar!). When it became clear that the actual figure would be closer to 70,000 (Ken Taylor of ADL), the market soured on both stocks". (My newest analysis, as you know, is closer to 110,000 procedures for 1996 -- for both approved and "gray" and "black box" numbers.) Ms. Berman projects that VISX will collect \$27.2 million on Pillar Point fees alone in 1997, based on her prediction that about 200,000 procedures will be done. "If the eye-zapping procedure catches on, as bullish analysts predict, the royalty stream could increase to more than \$54 million by 1999". The biggest "bear" on the Street is analyst Anne Anderson of Atlantis Research, who downgraded VISX to a "sell" from a "hold" in April. In a recent report, she doesn't believe royalties will meet expectations, and she expects sales of equipment will decline from third-quarter levels, heading into 1997. Mark Logan, VISX chairman and CEO, disagrees, stressing that royalty fees will increasingly drive the company. (Anyone wishing to see a complete copy of the story, give me a call.)

- 12/18 **Autonomous Technologies** announced that the FDA had approved the inclusion of higher myopia and astigmatic patients as part of its existing T-PRK Phase 3 trials. The expansion will allow inclusion of patients with myopia up to -10 diopters and up to -6 diopters of astigmatism, for a maximum spherical equivalent of -10 diopters. The higher myopia/astigmatism investigation may be conducted in up to 7 sites, on 500 patients. Autonomous entered Phase 3 trials in October. According to Randy Frey, chairman and CEO, the new expansion will allow the company to stratify the data for broader indications. Consequently, it will allow Autonomous to be in a stronger competitive position, without extending the anticipated timeline for completion of clinical trials.
- 12/19 **LCA-Vision** announced the opening of its 12th U.S. facility in Buffalo, NY. The new center will be operated in conjunction with the company's second Canadian site, opened two months ago in Ft. Erie, Ontario. The company's planned 1997 rollout schedule remains on pace. According to Dr. Stephen Joffe, CEO, "The fast pace of recent LCA center openings keeps our rollout program on target and gives us a significant lead in localities where research indicates demand for procedures is building steadily. The number of surgeries performed in our existing centers is also accelerating as promotional activities and positive word-of-mouth increase acceptance of the procedure's effectiveness." (It should be noted that patients of the Buffalo center requiring the treatment of astigmatism, higher myopia, and far sightedness can be treated at the nearby Ft. Erie center.)
- 12/19 **EquiMed** announced that its board of directors had approved a plan to repurchase shares of its stock over the next six months. The announcement followed the November 6th sale by the company of its ophthalmology division to **Physicians Resource Group** for an initial closing consideration of \$54.6 million in cash and the assumption by PRG of \$15.3 million in related liabilities. In connection with the sale, EquiMed used \$14.8 million of the proceeds to pay off and terminate long-term debt.
- 12/20 Author James Dickinson, writing in *Medical Device and Diagnostic Industry*, continues to beat a "dead horse" by revisiting the "FDA Document Leak" story, commenting on the fact that after a seven month internal investigation by the FDA that failed to turn up who may have leaked the secret documents to (then) Chairman David Muller of Summit, the investigation has been turned over to the FBI. Dickinson does raise some interesting questions concerning the FDA's internal investigation: Why wasn't the obviously criminal leaking of documents immediately referred to the FBI? Why did the OIA (office of internal affairs) wait five months before beginning serious field investigations, such as taking fingerprints of people who might have handled the stolen documents and interviewing those outside of the agency who had knowledge of events (such as Mark Logan and Summit's vp of regulatory affairs, Kim Doney? And others of the same nature.

12/20 **Summit Technologies'** third quarter report to shareholders noted that while management was happy with the increase in procedures performed on Summit lasers during the third quarter compared to the second, "representing a growing acceptance of laser vision correction by the U.S. consumers...our equipment sales remain slow and are not likely to pick up until procedure volumes increase significantly." The company also noted that it had announced that it would not open any additional Company-owned vision centers, and was "evaluating its options for this (the centers) business".

12/20 **LaserSight** announced that its subsidiary, **LaserSight Technologies** was now certified to apply the CE Mark to its LaserScan 2000 excimer laser, allowing the company to expand European sales efforts into Germany, France, Switzerland, and Austria; well in advance of the 1998 requirement of CE Mark for marketing into the EU (European Union of countries). The company also announced that it had retained **De Ceunynck** of Belgium as its distributor for the Benelux (Holland, Belgium, and Luxemborg) countries. De Ceunynck is the oldest ophthalmic company in the region and boasts an excellent reputation for service standards according to the company. LaserSight also noted that De Ceunynck was formerly the **Meditec (Aesculap Meditec)** laser distributor, but "recognized the demand for scanning technology of LaserSight's LaserScan 2000". (Apparently, they were not told about Aesculap Meditec's new dual use excimer laser, the Model MEL 70 Multiscan, which can operate in either a moving slit or scanning mode, simply by throwing a switch!)

The company said that it was now represented by 20 distributors and have laser installations in 29 countries worldwide.

12/23 **TLC The Laser Center** announced that it had signed a definitive agreement for the acquisition of all outstanding shares of **20/20 Laser Centers**. 20/20 had operated nine laser centers in the north-east corridor of the U.S. and Florida. Final approval is expected in mid-January, for the acquisition valued at approximately \$25 million, rather than the originally reported \$33 million. The purchase will be funded through the issuance of TLC common shares based on a price per share of C\$7.25. Elias Vamvakas, TLC's CEO, said that the acquisition would make TLC the largest provider of excimer laser correction in North America.

12/30 The December 30th issue of *Eyeworld Week* notes that Dr. Stephen Hollis, of Columbus, GA, has decided to trade in his custom-made excimer laser for a VISX Star, according to a letter he sent to other custom laser owners. He decided that the hassle of filing a custom IDE and eliminating the risk of legal action with Pillar Point were among the reasons. VISX offered him a trade-in value of \$175,000 for his laser against the Star, which was confirmed by VISX. Hollis also noted that if five or ten other custom laser owners turn in their lasers, VISX may up the ante.

The newsletter also notes that Dave Harmon's year-end analysis of the laser centers market shown 341 U.S. centers operating at year's end. The ownership is roughly one third corporate owners, and one third each institutions and individual or groups of physicians, with the highest volume centers operated by individual physicians or by corporate laser centers with an affiliated surgeon. David goes on to say that physicians, either individually or in partnership, operate 98 excimer lasers in the U.S.