OPHTHALMIC LASER UPDATE -- JANUARY 1998

12/15 *Ophthalmology Times* has an excellent writeup about Ken Taylor's presentation, given at the last AAO meeting, about his model for the refractive surgery market. The accompanying graph depicts his conclusions about the number of RK, LASIK, and PRKs that have been done since 1996, and his projections out to the year 2000, at which time most of the 500,000 annual surgeries done will be LASIK. Ken still believes that the initial pool of refractive surgery patients consists of only 12 million myopes, and that only about 2% will convert to refractive surgery, and that the conversion could be closer to only 1%.

12/22 According to *The Gray Sheet*, **Summit Technology's** Apex Plus laser system has begun clinical trials for hyperopic correction using LASIK. The first procedure was done by Stephen Brint, MD, on December 10th or 11th, as reported in our 12/15 brief in last month's newsletter. Summit expects to have twenty investigators perform hyperopic LASIK on up to 2000 eyes under the **CRS** LASIK Study Expansion for Hyperopia, using the Apex Plus in conjunction with the Emphasis laser disc. Summit anticipates filing for approval of hyperopia and astigmatism combinations within the first half of 1998.

12/29-
12/31 **Bausch & Lomb**, after receiving the necessary regulatory approvals, completed its acquisitions of both **Chiron Vision** and **Storz Instruments** on successive days. The Chiron acquisition, as noted in our October Briefing, was for $300 million, while the Storz acquisition was for $380 million. This now makes B&L a global leader in the "eye vision correction" market, with more than $2 billion in sales in the $25 billion global market. (**Alcon Laboratories** is in second place, with global sales of about $1.8 billion, followed by **Ciba Vision**, **Essilor**, and **Allergan**, according to the *Associated Press*.)

Both Chiron and Storz will become part of a new **B&L Surgical** business unit.

12/31-
1/9 In the ongoing saga of **BeaconEye** -- see our briefs in both the November and December issues -- the company announced on December 31st that it had committed to negotiate exclusively with **TLC The Laser Center** through January 7th, to settle the terms of agreement pursuant to which Beacon and certain shareholders would support a transaction with TLC. The announcement contemplated that TLC would offer to acquire Beacon for $10.6 million payable in TLC stock, the conversion price to be based on the weighted average price for the 20 day trading period up to December 23rd. The agreement was also conditional on the termination of employment agreements with certain senior officers.

However, on January 8th TLC and BeaconEye announced that they had been unable to reach an agreement. BeaconEye said it was continuing to hold discussions with its

shareholders and TLC concerning a transaction, but was also considering other alternatives. Some of those alternatives included preliminary proposals from **ICON Vision Centres, Inc.** and from **LCA-Vision Inc.** Beacon also announced that it had extended the payment period for many of its accounts payable and had deferred payment of certain capital and operating lease obligations, and would require additional financing by early February.

On January 9th, TLC said that it intended to make a take-over bid for BeaconEye at a price of 40 cents cash per common share, with the bid being made without the support of Beacon. The take-over bid is subject to the requirement that at least 90% of Beacon common shares are validly deposited and not withdrawn, and no material adverse change occurs in the business and affairs of Beacon. TLC requested a list of Beacon shareholders and expected to mail a formal take-over bid circular as soon as the list was received, with the bid being open for 21 days from the date it was mailed. TLC retained **RBC Dominion Securities** to act as its financial advisor and to form a soliciting dealer group to gain acceptance of the bid. (It is our understanding that the bid for about $4 million for the common stock, with about 10 million shares outstanding, also includes a takeover of debt and assumption of executive "golden parachutes", which brings the total to about $9.5 million, down somewhat from the original $10.6 million offer.)

I will keep you posted as the story continues to unfold!

12/31 The *Los Angeles Times* reported that **Premier Laser Systems** had acquired 28% of the outstanding shares of **Ophthalmic Imaging Systems** for about $1.53 million, and that Premier had also hired **Josephthal & Co.** to help it decide whether to pursue a seat on the OIS board of directors, "or take any other actions", including buying more shares. Josephthal told Colette Cozean, CEO of Premier, that its options included a tender offer or a formal proposal to acquire control of OIS. In its fiscal year, ended August 31, OIS lost $2.1 million on revenues of $6.6 million, in its business of supplying diagnostic imaging products and services used in eye care.

Following the newspaper story, OIS announced the adoption of Rights Agreement, effective that day, to provide the board of directors with the opportunity to develop and pursue actions that promote the best long-term interests and short-term interests of its shareholders. The board also declared a dividend of one Preferred Share Purchase Right on each outstanding OIS common share, payable on January 2nd, to holders of record on that date.

12/31 **LaserSight** announced that it had sold two subsidiaries, **MEC Health Care** and **LSI Acquisition**, to **Vision Twenty-One**, for approximately $13 million, including $6.5 million in cash and approximately $6.5 million in Vision Twenty-One common stock. The deal closed effective on December 1st. MEC Health Care administers HMO and self-insured vision plans, while LSI Acquisition is a practice management company that manages the ophthalmic business known as the **Northern New Jersey Eye**

Institute. According to *Dow Jones*, MEC had 1997 revenues of $8.7 million, while LSI did approximately $4 million in 1997. LaserSight estimates it will have an after tax gain of between $1.5 to $2 million from the transaction. The sale improves LaserSight's current liquidity and will allow management to focus its resources on its technology division. A total of $3.5 million from the net proceeds will be used to repay **Foothill Capital** part of the company's loan, used in the acquisition of the **IBM** patents.

1/1 The first issue of the year of *Ocular Surgery News,* its annual ophthalmic laser issue, has my writeup about the new ophthalmic and cosmetic lasers on exhibit at this fall's AAO meeting. It also contains a nice writeup about the refractive surgery survey I conducted last August, recapped by Rochelle Nataloni, along with some quotes about the refractive surgery market by analyst Michael Lachman of Hambrecht & Quist. Mr. Lachman is an advocate of nearly 700,000 refractive procedures to be performed annually by the year 2000. In addition, staff writer Ryan DuBosar looks at the potential LASIK market and updates the FDA status of the various refractive laser systems. Sara Smith of OSN has an interesting article on surgical glaucoma management, including the options of selective laser trabeculoplasty (SLT), the technique of selectively targeting the melanin cells in the trabecular meshwork.

1/5 **Summit Technology** said that it expects its 1997 fourth quarter results will be "marginally profitable", despite **VISX's** decision to withhold royalties due to **Pillar Point Partners** when LASIK is performed in the U.S. on VISX equipment. Summit also noted that it had adopted a similar reporting position with respect to LASIK procedures performed in the U.S. (Although, according to company sources, it doesn't know whether PRK or LASIK is performed when its laser is used.)

The news release goes on to state that it is interesting that VISX's interpretation that LASIK is not a PRK done on the eye after the flap is created is in contradiction to the sworn testimony of VISX CEO Mark Logan, given in a Pillar Point-related deposition in June 1997, wherein M. Logan stated, "LASIK is just a form of PRK". Robert Palmisano, VISX CEO said, "We are confident that VISX's interpretation of the Pillar Point agreement is wrong. In the event we prevail on our cross complaint, we should be entitled to recover the entire amount that VISX failed to pay Pillar Point, i.e, a full $250 for each LASIK procedure for which VISX withheld payment from Pillar Point...We estimate that our recovery in this action would exceed $5 million to date, and is accruing at a rate in excess of $1 million a month."

1/6 **LCA-Vision** reported a total of 11,268 laser eye procedures were performed at its U.S. locations in 1997, a 281% increase over the previous year. The firm's affiliated ophthalmologists performed 7246 more surgeries to correct nearsightedness or astigmatism than in 1996. Commenting on the procedure results, CEO Dr. Stephen Joffe noted that close to 98% of LCA-Vision patients had 20/40 or better vision after the procedure, and that LASIK represented over 40% of the procedures performed,

and that well over 20,000 successful procedures have been performed at LCA-Vision's 30 worldwide facilities.

1/6 **TLC The Laser Center's Partner Provider Health, Inc.** announced that it had signed a contract with **Three Rivers Health Plans, Inc.** to provide eye care services to Three Rivers' 56,000 Medicaid-eligible customers. Three Rivers currently provides health care to Medicaid-eligible individuals in fourteen western and central Pennsylvania counties, and plans expansion into an additional 18 counties servicing 200,000 people, within the next 12 months.

Under the agreement with PPH, coverage for routine eye exams and eye wear will be provided through local independent practice association partnership subsidiaries of PPH, called VisionMeds which, in Pennsylvania, consists of a network of more than 200 optometrists.

1/7 **Laser Vision Centers** said that its U.S. surgical case volume for December rose 455% over December 1996, and 20% over November 1997. Commenting on the results, CEO Jack Klobnak said, "Since December is normally a slow month for surgeries, we believe the growth which we experienced is indicative of the overall acceptance of this procedure and clearly shows that this is an industry with strong growth potential." Beginning in February, the company will announce U.S. laser revenues rather than growth in case volumes, because it feels that the revenue numbers would more accurately reflect the growth the company is experiencing.

1/7 **Summit Technology** announced that its board of directors had authorized the repurchase of up to 250,000 shares of common stock.

1/8 **Autonomous Technologies** has filed a resale registration statement on Form S-3 with the SEC, related to a total of 3.8 million shares of common stock that are issuable upon exercise of certain outstanding warrants, or that are held by certain shareholders who acquired the shares prior to the company's initial public offering in May 1996. Upon the registration becoming effective, certain of the selling shareholders will be able to sell their shares without restriction. The company does not stand to receive any proceeds from the sale of these shares.

1/12 Dr. Stephen Joffe issued a statement concerning inquiries about **LCA-Vision's** unusually high trading volume for the past week. Dr. Joffe noted that during a typical trading day, less than 15,000 LCA shares normally trade, but during the past week, more than 3 million shares traded, with over 1.5 million shares on Friday alone. This high trading volume comes on the heels of the **Summit Technology** distribution of 9 million shares to its shareholders, under the acquisition of Summit's laser vision centers agreement. And, other than the distribution of shares, Dr. Joffe knew of no other reason for the increase in trading volume, except for the recent announcement of laser vision surgical volumes and the excellent results obtained. (See the January 6 brief above.)

1/12 Both **Laser Vision Centers** and **VISX** announced that they would be presenting at the January 14 16th Annual **Hambrecht & Quist** Healthcare Conference. In its news release, VISX noted that its stated goal is to grow earnings per share at an annual rate of 25% to 30%, based on its unique combination of technology, market position, and an intellectual property portfolio containing over 120 issued patents and 60 pending patents in the field of laser vision correction. The company also noted that it expected to obtain approval for high myopia in the first quarter of 1998, and to be the first company to file for approval to correct hyperopia.

1/13 **Autonomous Technologies** announced that it would appear before the FDA's Ophthalmic Devices Review Panel on February 13th, to present its PMA application for its LadarVision excimer laser. The PMA encompasses myopia with astigmatism of up to -10 diopters of myopic vision, the largest range of correction yet presented before an FDA panel.

1/13 **TLC The Laser Center** announced its results for the quarter ended November 30. Gross revenues for the quarter were $26.2 million, with net revenues reaching $18.2 million. Over 6400 refractive laser procedures were performed during the quarter at TLC clinics, compared to 1980 for the same quarter a year ago. TLC's net loss for the quarter was $2.8 million (10 cents/share), which included $2.8 million in amortization and $820,000 in interest. As a result, TLC generated positive EBITDA of $943,000 in the quarter, the first time in the company's history.

1/13 **BeaconEye** announced that it continued to work with its financial advisor, **CIBC Wood Gundy Securities** to explore options for maximizing shareholder value, including financing alternatives, potential mergers and acquisitions, and a sale of the company. Beacon noted the January 9th takeover bid made by **TLC The Laser Center**, and said that it had provided a list of shareholders, as requested, to TLC. The Board of Directors intends to consider TLC's offer once it has been received, as well as other offers from **ICON Vision Centers** and **LCA-Vision**. Beacon reported that 2578 procedures were performed in its laser vision correction centers in the three month period ended December 31st. The number of procedures performed were an increase of 28% over the prior quarter and 2.6 times the number done in the same period of 1996. During December alone, despite the holidays, 930 procedures were performed.

1/13 **Sunrise Technologies International** announced the initial closing of a private placement convertible note and warrant offering in the amount of $5.9 million. The money will be used to complete the final phase of its hyperopic clinical trial and for continuation of its clinical trials for treating presbyopia. The money should carry the company well into 1999, by which time it plans to file its PMA for the treatment of hyperopia.

1/13 **LaserSite** held its second annual meeting, and the venture's managing entity, **Nexus Healthcare**, announced the following highlights: total laser vision correction

procedures increased by 265% over the previous year, to 2395; LaserSite was one of 20 sites selected to perform hyperopic LASIK, using an upgraded **Summit** Apex Plus laser system; and outcome studies continue to confirm results consistent with or favorable to national and international experiences. The Dallas firm, organized as a cooperative by 36 physicians and Nexus Healthcare, and operational since late January 1996, is presently affiliated with over 125 ophthalmologists and optometrists.

1/14 **TLC The Laser Center** mailed an all cash offer to the shareholders of **BeaconEye** to acquire all of the outstanding common shares at a price of $0.40 per share. The offer remains open until February 4th, and is subject to certain conditions set forth in the offering circular.

1/15 This issue of *Ocular Surgery News* contains my writeup of the pre-AAO meetings that I attended last fall. I discussed the VISX University, and Shareef Mahdavi's talk about what drives the refractive surgery patient; the new microkeratomes presented at the ISRS; and the talks about new treatments for hyperopia and presbyopia, along with the new RS modalities at the RSIG meetings.

1/15 **BeaconEye** said that it had received the offer from **TLC The Laser Center**. The company's board of directors is asking shareholders not to tender their shares or complete a letter of transmittal until it can mail a circular relating to TLC's offer to them, by January 23rd. Beacon is continuing to assess other alternatives to the TLC offer.

1/16 **Premier Laser Systems** announced that it had submitted a proposal to the board of directors of **Ophthalmic Imaging Systems** to acquire OIS for $1.75/share in cash, in a friendly transaction, for the approximately 2.7 million shares that the company currently does not own. Under the terms of the proposal, OIS must modify its recently adopted shareholders rights plan to permit the transaction to proceed. The all cash proposal is at a 30% premium to the current bid price of $1.34 for OIS shares, and it will be withdrawn if it is not accepted by 5:00 pm PST on January 22nd. Premier has purchased approximately 29% of the outstanding shares of OIS over the last several months.

1/16 **Iridex Corporation** announced that its subsidiary, **Light Solutions Corporation** had recently been issued a patent for Fiber Stub End Pumping. The company said that this patent along with earlier patents, helps protect the core technology enabling the company's semi-conductor-based green laser system to be used for ophthalmology and dermatology applications. The patent, which describes a new type of end-laser pumping, allows such laser systems to use semiconductor diodes from a variety of manufacturers and thereby reduce sole-source risks which may occur with other designs.

1/17 This month's issue of *Refractive Market Perspectives* contains an overview of how the various laser refractive centers are doing. According to Market Scope's David

Harmon, although the number of procedures doubled last year, the number of laser centers only grew by 6%, as most operators concentrated on making their centers operate more profitably, by increasing the number of procedures per laser system. Harmon believes that there was a net increase of 20 lasers in the corporate centers for the year, while physician and institution owned lasers grew only slightly. In a table accompanying the article, Harmon puts the number of corporate center lasers at 165 by year's end, 109 in institutions and 95 in physician's offices, for a total of 365 lasers in operation. (I personally think the number is low, believing that over 400 lasers are in operation in the U.S., and possibly closer to 500.) It should be noted that **Laser Vision Centers** owns 23 lasers, but only 5 are at fixed sites. The remainder are roll-on or are truck mounted mobile, and can service nearly 100 additional locations. The only other companies with announced mobile lasers are **True Vision Laser Centers**, and I do not know if their mobile laser is operational yet, and **Pacific Cataract and Laser Centers** which, according to Market Scope, operates 3 mobile lasers in the northwest. Harmon expects that with increased procedural growth and the potential of new, lower cost lasers coming to market, the number of corporate laser centers could grow significantly in 1998. The newsletter will report on 1997's procedure volume and the forecast for 1998 in its next issue.

1/19 **Gimbel Vision International** announced it had entered the Oregon market through its purchase of a 50.4% interest in the **Oregon Laser Eye Center LLC**, located in Eugene, Oregon, effective on December 31st. The Oregon Laser Eye Center has been in operation since April 1996, and serves all of southwest Oregon, as well as eastern portions of the state. The investment was $48,000 and Gimbel will also provide a guarantee in the amount of $700,000 to purchase new laser equipment.

1/20 The January issue of *EyeWorld* contains an interesting and chilling cover article by Leslie Sabbaugh, To speak or not to speak? That is the question. The story covers the controversy about the free exchange of information about "off-label" procedures at scientific and society meetings. In a landmark case heard in Philadelphia, three societies that held talks on "off-label" uses of the pedicle screw in spine stabilization are included in a class action suit brought against the manufacturers and physicians that used them and supposedly caused patient injuries as a result of their "off-label" use. As noted by Nancey McCann, ASCRS director of governmental relations, "Societies may become so fearful of being involved in a lawsuit that they will not allow any discussion of off-label uses." Leslie Sabbaugh states that, "Ultimately, how this litigation may affect ophthalmologists using the excimer laser for an off-label use such as LASIK remains to be seen. One thing is certain, however, in the future, medical societies must be even more vigilant in monitoring their educational meetings -- meetings that were always considered to be the free exchange of information among peers."

1/20 **LaserSight Patents, Inc.**, a wholly owned subsidiary of **LaserSight Inc.**, announced that it had signed definitive patent-related agreements with **Nidek Co., Ltd.** of Japan, which would yield LaserSight $7.5 million in cash at the closing, subject to a

withholding of up to $340,000 for Japanese taxes. Under the agreements, LaserSight will retain all patent ownership rights within the United States, of the **IBM** patents related to UV light used to ablate tissue, but would transfer ownership of the related non-U.S. rights to Nidek. LaserSight will also grant Nidek a non-exclusive license to use the U.S. patents. Nidek's acquisition does not affect any outstanding license agreements relating to non-U.S. patent rights that have been previously granted to LaserSight and other companies. The agreements also provide for LaserSight to continue to have the exclusive right to use and sublicense the non-U.S. patents in all fields other than ophthalmic, cardiovascular, and vascular. LaserSight transferred an exclusive license for cardiovascular and vascular uses to another company for $4 million in September 1997.

The transactions are expected to close later this month, and are subject to the approval of the holders of LaserSight's Series B Preferred Stock, and of **Foothill Capital Corporation**, its secured lender. Upon closing, Nidek will hold ophthalmic patent rights in Australia, Austria, Belgium, Brazil, Canada, France, Germany, Italy, Japan, Spain, Sweden, Switzerland, and the United Kingdom. Nidek will be entitled to receive certain future royalties relating to these patent rights. The transaction will also result in approximately $1.2 million in prepaid royalties to LaserSight, that will be amortized to income over time.

1/20 *The Sacramento Bee* ran a story today about **Premier Laser System's** bid to purchase **Ophthalmic Imaging Systems**. Premier bid $4.73 million for the remainder of OIS that it didn't already own -- see the January 16 brief above. A spokesperson for OIS said that company directors would consider the proposal during an upcoming board meeting, and would respond promptly. Premier's bid came three weeks after it announced that it had purchased 29% of the company's stock and might decide to acquire the whole company. OIS sales were $6.6 million with losses of $2.2 million in fiscal 1997.

1/20 **Ophthalmic Imaging Systems** announced that it had received the unsolicited bid from **Premier Laser Systems**. OIS's board said that it would evaluate and consider the Premier bid in due course and announce its response following that evaluation. The company also said that it had retained **Cowen & Co.** to assist it in evaluating the Premier bid and any other alternatives available to it, including the possibility of remaining independent.

1/20 *The Federal Register* notes that the agenda for the upcoming February 12/13 meeting of the Ophthalmic Devices Advisory Panel will discuss the PMA for a broad-beam excimer laser for correction of myopia with astigmatism using LASIK, and the PMA for a scanning excimer laser for correction of myopia with astigmatism using PRK. I know the latter is for **Autonomous Technologies** -- see the January 13th brief above, but I am not sure whose PMA is for the LASIK procedures. It might be either a re-consideration of the **Emory University** PMA (see the July 11th brief in the July 1997

issue), or it might be the **Kremer** PMA being presented by **LaserSight**. I will pass along the word on PMA's sponsor as soon as I learn it.

1/21 **LaserSight Technologies** announced that it had received 510(k) clearance to market its Automated Disposable Keratome. The company had previously said it would begin shipping the keratomes by the end of January, but it is in final manufacturing validation and anticipates shipping orders in February. Shipments on orders taken this month might take till June to fill. Future orders will be prioritized and shipped according to the date of receipt. Revenues from ADK sales will be reported quarterly, along with regularly scheduled financial information.

1/21 **LCA-Vision** is projecting fourth quarter and year end results to be up 78% for the quarter and 27% for the year. The results reflect strong internal growth from original centers and the additional revenues generated by the centers acquired from **Summit Technology** during the fourth quarter. For the year, the company expects revenues to be more than $17 million. Patient volumes continued to expand in 1997 to a record 11,268 performed in U.S. centers, an increase of 281% over 1996.

OPHTHALMIC LASER UPDATE -- FEBRUARY 1998

1/26 **Bausch & Lomb (B&L)** announced the new organizational structure for the recently acquired cataract, refractive, and retinal surgical businesses, formerly operated as **Chiron Vision** and **Storz Instrument Company**. The major product lines of the businesses were combined into a single unit known as **Bausch & Lomb Surgical**. Haken Edstrom, former president and COO of Chiron Vision and Robert Blankemeyer, former president of Storz Instruments, will lead the new business unit. Both Edstrom and Blankemeyer have been elected corporate vice presidents of B&L, with Edstrom named president and Blankemeyer COO of B&L Surgical.

Edstrom is responsible for the unit's global strategic marketing, business development, R&D, scientific affairs, finance, information management and technology, and human resources. Blankemeyer will be responsible for global manufacturing and product supply, sales, and customer marketing and service. Edstrom will continue to be based in Claremont, CA, while Blankemeyer will remain in St. Louis.

The Storz pharmaceutical product lines will be combined with the B&L pharmaceuticals business, headquartered in Tampa, FL, and headed by Tom Riedhammer, president of **B&L Pharmaceuticals**.

1/27 **VISX** announced that it had received another fundamental patent in the laser vision correction field. U.S. 5,711,762, Laser Surgery Apparatus and Method, contains apparatus claims that cover both broad beam and scanning laser systems used to ablate corneal tissue. VISX believes that the patent covers the technologies of all manufacturers currently moving through the FDA approval process. (The patent seems to cover the delivery of 193 nm UV energy with the use of a mask comprised

of a slit, circle, crescent or other opening, including an ablatable plastic mask (ala Summit's ablatable mask), but my reading of the claims does not seem to cover the use of scanning systems, and especially scanning systems operating above 25 Hertz.)

1/27 **Sunrise Technologies** announced the completion of its private placement of 12% convertible notes and warrants, for a total of $9.35 million.

1/28 **LaserSight** said that its PMA for an excimer laser to perform LASIK will be reviewed by the FDA Ophthalmic Review Panel on February 13th. The application is for a single site use of Dr. Kremer's home-built laser for the treatment of myopia and myopic astigmatism using LASIK. The company is preparing a separate PMA for its scanning laser system for PRK. There will also be a special shareholder's meeting in St. Louis on February 27th. (The advance word is that the company's corporate office will be moving to its Orlando, FL site.)

1/28 **VISX** announced its financial results for the fourth quarter and year end, with revenues for the quarter of $19.3 million, composed of system sales of $6.9 million and royalties, service, and other revenues of $12.4 million. This compares to system sales of $13.8 million and royalty and service revenues of $5.1 million in the fourth quarter a year ago. Net income for the quarter was $7.0 million (44 cents/share). For the year, system sales were $34.4 million and royalty and service revenues were $34.2 million, for total revenues of $68.6 million. Last year's sales totaled $69.7 million, composed of system sales of $53.1 million and royalty and service revenues of $16.5 million. For the year, net income was $14.1 million (89 cents/share). The company fell slightly short of our estimated $70 million revenues for the year.

I estimate that the system sales resulted in the sales of about 86 units in 1997, compared to sales of 133 systems in 1996. In a teleconference about the financial results, chairman Mark Logan noted that he expected 300,000 procedures to be performed in 1998, with just under 200,000 done (on approved systems) in 1997. The downturn in the Asian economy, especially in Korea -- where some laser sales have been canceled -- will have some negative impact on 1998 system sales. Commenting on the Pillar Point dispute, VISX believes that since LASIK has not yet been approved for its systems, it does not have to forward the royalty fees to Pillar Point. (I still don't understand how VISX knows which procedures are being performed on its machines! Apparently, it is guessing the percentage, based on a market study it had conducted by an industry analyst [not me, but I do know who, and he is a reliable source].) Logan would not release percentages for LASIK procedures, although it was speculated that it could be as high as 80% in 1998. Logan also noted that in the prior week, one physician had performed 120 procedures in a day -- probably bilateral LASIKs, with the previous one-day totals being 90 and 110.

1/28 **MedJet** announced that the FDA had granted 510(k) clearance for its HydroBrush to remove the epithelium from the cornea. This is the first clearance for a waterjet product. The company is also investigating the use of the HydroBrush for the removal

of pterygiums, a fleshy overgrowth on the surface of the eye, with approximately 5 million people in the U.S. suffering from this affliction.

1/29 **VISX** announced that it had received the first FDA approval for the use of its excimer laser system for the correction of higher myopia with astigmatism. The additional approval allows for the Star laser to be used to correct myopia up to -12 diopters with up to -4 diopters of astigmatism. No changes in the laser are required, the changes will be incorporated into the key card used with the laser. Certification for the new use will be accomplished via UPS for current users. Greater than 99% of nearsighted consumers can now be accommodated with laser vision correction.

Laser Vision Centers, commenting on the approval the following day, noted that "industry sources" (this time me) had estimated that more than 2 million people fall into the high myopia category, needing correction of over 6 diopters, and up to 12 diopters. The company also noted that during December, it had provided access to over 200 U.S. ophthalmologists and had trained well over 30% of all U.S. surgeons who are currently certified to use the excimer laser.

1/29 With its acquisition of **Chiron Vision** and **Storz Instruments**, we will begin covering **Bausch & Lomb's** activities, especially of its newly formed surgical business unit. B&L announced its fourth quarter and year end results, with revenues from ongoing product lines in the quarter reaching $469.4 million, up 10% from a year ago. Adjusted for changes in currency exchange rates, these revenues were up 15% from 1996's quarter. These results exclude fourth quarter revenues generated by its former Thin Film Technology division, which was divested in December 1997. It also excludes revenues from its dental implant business, also divested in 1997. For the year, the company recorded sales of $1.9 billion from ongoing operations, about the same for the previous year.

The company recorded a restructuring charge of $9.4 million after taxes in the fourth quarter, as part of the strategic restructuring program announced last April. In addition, a fourth quarter charge of $13.2 million after taxes was recorded in connection with the proposed shareholders litigation settlement agreement, announced in November. Excluding those charges, and the 1996 fourth quarter gain on the divestiture of the dental implant business of $8.5 million after taxes, the company reported net earnings of $30.0 million (54 cents/share) in 1997, compared with $7.4 million (14 cents/share) in 1996. For the quarter the earnings were $7.4 million (13 cents/share).

1/29 **Summit Technology** released its fourth quarter and year end results, with fourth quarter net revenues of $21.6 million (or about $9.0 million for laser-related activities), and net income of $307,000 (1 cent/share). For the year, total revenues were $88.8 million (or about $37.5 from laser-related activities), with net income of $8.9 million (28 cents/share), including a one-time gain of $10.7 million from the sale of its Vision Center subsidiary. Net income from continuing operations was $1.5

million (5 cents/share). The company fell short of our estimate of $40 million for laser-related activities for the year.

1/29 **Iridex** announced its fourth quarter and year end results, showing net sales for the year up 46% to $18.1 million, and net income of $2.1 million (31 cents/share). For the quarter, sales were $5.8 million and net income was $803,000 (12 cents/share). According to CEO Ted Boutacoff, 1997 was a record year, with net sales up as a result of the strong market acceptance of its OcuLight GL and DioLite 532 laser systems. (Iridex is composed of three business units: **Iris Medical Instruments**, selling lasers to ophthalmologists; **Light Solutions**, providing lasers and fiber optics for photodynamic therapy; and its dermatology division, **Iriderm**, providing lasers to dermatologists.)

2/2 The *Orlando Sentinel* reports that **LaserSight** is poised to make its Orlando, FL **LaserSight Technologies** division the focus of its business again. More importantly, LaserSight's CEO, Michael Farris will move to the Orlando area later this month. However, the formal headquarters of the company will probably stay in St. Louis. According to the newspaper, the company currently has 55 employees in its Orlando facility, doing research and design on eye-surgery systems; 30 people in its St. Louis headquarters working in health care consulting; and 20 employees in Costa Rico in manufacturing.

2/3 **LASIK Vision Canada** has broken the price line, by offering laser eye surgery for US$1995 for two eyes. According to president and CEO Hugo Sutton, MD, "Our market research indicates that safety concerns are no longer a deciding factor in a person's decision to correct their vision problems by surgery. The issue is strictly one of affordability. By reducing the price, our goal is to make this medical procedure available to the many thousands of people for whom its has been previously unaffordable." The price reduction is supported by an international advertising campaign throughout Canada and in the U.S. west coast states of Washington, California, and Alaska through television and radio commercials, newspaper and magazine advertisements, and billboards. In Canada laser correction can be used for myopia, hyperopia, and astigmatism. The outpatient procedure takes about 15 minutes and has been used to correct the vision of over 3 million worldwide to 20/40 or better since first introduced in the late 1980s. LASIK Vision Canada was founded by Dr. Sutton in 1991, and has treated thousands of patients since opening. The company's website is: www.laser-eye.com.

2/3 **Standard & Poor's** has assigned its triple B/triple B- preliminary ratings to **Bausch & Lomb's** $500 million shelf registration. The investment-grade ratings for the company reflects its important global positions in diverse businesses, including contact lenses, lens solutions, and premium sunglasses. Recent acquisitions further diversify the company's operations within the eyecare industry and mark an aggressive entrance into the high margin cataract and high growth eye surgery businesses. The acquisitions also bolster the company's ophthalmic pharmaceutical product portfolio

and are expected to enhance its relationship with ophthalmologists. Still the company's financial flexibility is limited by the increased debt burden associated with the December 1997 acquisitions of **Storz Instrument Company** and **Chiron Vision**. The company has also suffered earnings erosion in its formerly high-margin premium sunglasses business as the need to quickly respond to fashion trends has accelerated. The recent acquisitions mark an entry into new business lines that are susceptible to reimbursement and technological changes; however, the outlook is stable and its outstanding ratings are affirmed.

2/4 Both **TLC The Laser Center** and **BeaconEye** commented on the expiration of TLC's takeover bid, which expired at 4:00 PM today. TLC said that since the 90% minimum tender offer was not satisfied, it would not take up any of the shares tendered, nor would extend its offer. BeaconEye announced that its board of directors had been advised by holders of more than 50% of its outstanding shares that they did not intend to tender their shares. Beacon also announced that it had received a proposal from **New Venture Equity Limited**, a wholly-owned subsidiary of **Dundee Bancorp Inc.** relating to a financial transaction. That transaction could, if implemented, provide up to $5.25 million in debt and equity financing to Beacon. The company and significant shareholders are in the process of reviewing and negotiating the terms of the proposed financing.

2/4 **LCA-Vision** announced the opening of the chain's 31st laser vision correction center, its third in Maryland, and first such laser vision correction facility in Annapolis. The new center will be affiliated with the company's successful Baltimore center, a joint venture with the **Greater Baltimore Medical Center**. The Baltimore center is among LCA's busiest, with over 1800 procedures performed since its opening in the spring of 1996. Dr. Stephen Joffe, chairman and CEO, expects the Annapolis center to be profitable within a year. Dr. Anthony Kameen, medical director of the Baltimore center, will serve in the same capacity at Annapolis.

2/4 **VISX** announced that monthly system operator training programs will begin on February 24th in Santa Clara, CA, at the company's headquarters. The programs are designed to provide certification and continuing medical education (CME) credits to professionals who operate VISX lasers. The program costs $500 per person.

2/6 1997 U.S. refractive surgery volume, as reported by *Market Scope*, grew 27.2% during the fourth quarter and reached 215,000 procedures, including procedures done on U.S. citizens in Canada, and on unapproved systems. This represents a 105% increase over 1996 volume. With another record for procedures set in January, it appears that 1998 procedure volumes will grow another 60% and reach between 345,000 to 350,000! Market Scope projects an increase of 80 new laser centers to open this year, along with additional excimer laser approvals for myopia and astigmatism towards the end of the year, which will drive the market. According to Dave Harmon, about 3000 surgeons now claim to perform refractive surgery, with a few hundred performing about 80% of procedures. A chart in the February issue shows that the number of lasers in place will increase from the 340 at the end of 1996 and 369 at year end 1997,

to 439 by the end of 1998. This represents an increase of 80 new lasers, with about 10 lasers falling out of use. Market Scope also notes that about 16,500 procedures will be done internationally on U.S. citizens, as part of the 345,000 volume forecast. (However, with the price cut announced by Dr. Hugo Sutton --see the Feb. 3 brief above -- the international number may be higher!)

2/6 **TLC The Laser Center** announced the formation of a joint venture in the State of Michigan, called **TLC Michigan, LLC**, which will be 50.1% owned by TLC, and 49.9% owned by Drs. Paul Ernest, Anthony Senoli, Marcus Rhem, and Kevin Lavery. The venture owns ophthalmology practices in Chelsea, Lansing, Battle Creek, Ypsilanti, and Jackson, MI. In addition, it will provide a refractive laser center in Detroit, and one soon to be established in Lansing. The venture is expected to increase TLC's secondary care revenues by more than $5 million and to generate more than 1000 extra refractive procedures over the next year. Dr. Ernest is one of the highest volume cataract surgeons in North America, and Drs. Senoli, Rhem, and Lavery, along with being top cataract surgeons, collectively have one of the largest refractive surgery practices in the state, currently performing laser vision correction procedures at a rate of more than 2000 per year.

2/9 **Autonomous Technologies** reported its fourth quarter and year end results, with a net loss of $3.3 million (33 cents/share) for the quarter on sales of $26,000. For the year, the net loss was $11.6 million ($1.43/share), on revenues of $37,000. With cash on hand of $7.3 million, another round of financing for the anticipated third or fourth quarter launch of its U.S. marketing effort will be required in the second half of the year. The company will appear before the FDA on February 13th seeking approvability of its PMA for myopic correction.

In a teleconference held the following day, in conjunction with the release of the company's financial results, CEO Randy Frey said that the company currently has 11 systems in the field, 8 at clinical sites, and three in operating sites or performing hyperopic clinicals. Autonomous expects to ship up to 50 systems by year's end, with 10-15 units going to international locations, and the remainder to fulfill U.S. marketing obligations after the anticipated FDA marketing approval. The company expects to ramp up to producing 12-15 laser systems per month after approval. Frey also expects that its revenue sharing model, rather than direct outright sales, will offer the most appeal to physicians wanting to obtain his laser system. (The model calls for an upfront payment and a per procedure payment based on volumes.) Commenting on its "custom cornea" trials, the initial experiments on 100 eyes were very successful, and Frey expects to have data to present to both the FDA and ophthalmologists at the upcoming AAO meeting this fall in New Orleans. Commenting on the market for his lasers, Frey said he believes that the top 150 sites are doing in excess of 1200 procedures per year, and with the demand increasing, it is likely that these sites will be interested in purchasing/obtaining another laser to meet the demand. As for the company's Pillar Point litigation, Frey believes that Autonomous is in good shape but will escrow the Pillar Point fee just in case the lawsuit goes against the company.

The *Orlando Sentinel* reported on the release of financials stating that the company "was bleeding heavily", with losses of $11.6 million in 1997 and $9 million in 1996. However, Autonomous is not alone in losses in the medical laser business, according to a quote from Kathy Kincade, editor of *Medical Laser Report*. "A recent survey showed that two-thirds of the nation's surgical laser companies are currently unprofitable. One of the problems in the medical laser industry is that expenditures often outweigh profits. That's the nature of the beast, unfortunately." The story goes on to state that despite the big losses, Autonomous and its backers remain confident that better days are ahead. (And that prophecy looks good with the February 13th "approvability" of its laser system.) The newspaper notes that Autonomous employees 60 people in the Orlando area.

2/10 **TLC The Laser Center** announced that it had acquired the secondary care and laser correction practice of Drs. Joseph Anderson and Michael Shapiro in Madison, Wisconsin. The acquisition is expected to increase TLC's secondary care revenues by $4 million annually, and to contribute significantly to the growth of TLC's Madison laser center, already in operation. Drs. Anderson and Shapiro are leaders in laser vision correction, performing more than 2000 procedure a year.

2/11 **LaserVision Centers** announced that revenues for same U.S. laser vision centers for January 1998 were up 420% from January 1997, and 25% from December, a record for surgical cases.

2/11 **TLC The Laser Center** reported that its shares trading are being added to the Toronto Stock Exchange's Composite 300 Index and the TSE 200 Index, in the Biotechnology/Pharmaceuticals subgroup.

2/12 **KeraVision** said it remains on track to apply for FDA marketing approval this year. The company reported its fourth quarter and year end results, with 1997 revenues totaling $355,000, primarily from sales of its "rings" in Germany and France. This compared to 1996 revenues of $137,000. The net loss for the year was $19.4 million. Revenues for the quarter were $94,000, compared to $91,000 for the previous quarter.

Highlights of the year included building a platform for growth based on the KeraVision Ring for myopia, adjusting the strategy in Europe, taking the first steps towards commercialization in Canada, achieving several milestones in its U.S. clinical trials, and using the rings for the first time to treat hyperopia. Additional markets the company intends to enter in 1998 include Greece, Netherlands, Scandinavia, Spain, and the United Kingdom, relying primarily on overseas distributors to sell the product.

2/12 **LaserSight** announced that it had concluded the business transaction that granted **Nidek** certain patent rights (the **IBM** patents) in exchange for $7.5 million in cash, including $200,000 being withheld for Japanese taxes. (See the January 20th brief last month for the original announcement.) Under the transaction, LaserSight retains U.S. patent ownership and has transferred to Nidek, the ownership of the ophthalmic-

related non-U.S. patents. In addition, Nidek has been granted a non-exclusive license to the use of the U.S. patents. Nidek now holds the ophthalmic patent rights in Australia, Austria, Belgium, Brazil, Canada, France, Germany, Italy, Japan, Spain, Sweden, Switzerland, and the United Kingdom. Nidek will be entitled to receive certain future royalties relating to the patents rights from LaserSight, **Summit Technology**, and **VISX** within Nidek's territories. The Nidek acquisition does not affect any licensee's rights under outstanding license agreements relating to non-U.S. patents that have been previously granted to LaserSight and other companies by IBM. LaserSight will continue to hold exclusive rights to use and sublicense the non-U.S. patents in all fields other than ophthalmic, cardiovascular, and vascular -- the latter two previously granted to an unnamed party.

An agreement was also reached for the partial redemption of up to $3.5 million of LaserSight's Series B stock, from $4.2 million of the proceeds from the Nidek transaction.

2/13 **Premier Laser Systems** announced that it had entered into an agreement with **Ophthalmic Imaging Systems** to provide the company the opportunity to negotiate a friendly acquisition of the latter. The "standstill" agreement, which expires on March 6th, limits Premier's ability to engage in certain acquisition-related activities and restricts OIS ability to solicit other acquisition proposals.

2/13 The FDA's Ophthalmic Advisory Panel reviewed two PMA applications: rejecting the **Kremer Eye Center** PMA presented by Dr. Kremer and **LaserSight** for LASIK to treat nearsightedness and astigmatism; and recommending approval for the PMA from **Autonomous Technologies** for PRK treatment of myopia up to 8 diopters, and astigmatism up to 4 diopters. The Kremer PMA was turned down for lack of sufficient data proving the laser was safe and effective for use in LASIK. The panel requested that the applicant reorganize the data and collect new information for resubmission to the FDA. The primary panel reviewer said she was unable to determine the laser's safety and effectiveness for certain patient groups due to inconsistent or missing data and the small patient populations. In response, Dr. Kremer said, "I never understood how people could be ahead of their time and not accepted, but I do now. I always thought that if you could invent something that did things better it would be accepted. I guess I was wrong." Although the application was sponsored by LaserSight, it would have been for a single site (Dr. Kremer's office), and for his home-built wide beam excimer laser system. The panel's decision is not a tremendous blow to the company, which is in the process of preparing a PMA for its own scanning laser system, which will be submitted to the FDA separately. (I have a copy of the question list taken from *Federal Filings*, that details the areas of concern, if anyone is interested in seeing it.)

Regarding the Autonomous Technologies application, the FDA panel voted to recommend approval with certain conditions; the scanning laser system was recommended to treat up to 8 diopters of myopia and up to 4 diopters of astigmatism,

rather than the 10 diopters and six of cylinder sought by the company. In addition, the PRK laser treatment was recommended for patients age 21 and over, rather than the 18 and over sought by Autonomous. Finally, the panel asked the company to note on its labeling that it should be used with caution on women undergoing hormone therapy. One of the panel reviewers said that the benefits of the eye tracker function of the laser system was not proven and asked the FDA to prevent the company from placing a benefit claim on its label. The reviewer said that this claim would require a comparison trial with a PRK laser that does not contain a tracker.

During testimony earlier in the day, medical monitor Marguerite McDonald, MD, said that six months after treatment, more than 93% of patients had 20/40 vision or better, and 70% had 20/20 or better. Dr. McDonald also noted that 20% of patients had uncorrected vision six months after treatment that was better than their vision before surgery. The following Tuesday (February 17th), the company released the multicenter clinical results that had been presented to the panel. It showed 71% 20/20 uncorrected visual acuity for 398 myopic eyes; 86% 20/25; and 97% 20/20 or better. For 172 astigmatic eyes, 59% had 20/20 UCVA; 80% 20/25; and 92% 20/40 or better. (I also have a copy of the questions considered by the panel for Autonomous.)

2/16 The **Oklahoma Academy of Ophthalmology** issued a news release concerning a bill passed by the Senate Business and Labor Committee that seeks to amend the Oklahoma Optometry Act, making Oklahoma the only state in the country to allow optometrists to perform surgery on the eye with a laser. If the bill is passed by the legislature and signed by the governor, it could set a dangerous precedent for the rest of the U.S. by lowering the standard of quality health care, according to the Oklahoma Academy. In an unprecedented maneuver, Oklahoma optometrists are pushing a bill which will allow them to become surgeons through legislation rather than medical education. Last July, an Oklahoma District Judge rules that only licensed physicians are authorized to perform surgery on the eye, and that surgery performed with lasers is indeed surgery. Despite aggressive lobbying by optometrists, legislatures in Texas and Connecticut have opposed giving optometrists authority to perform surgery, and New Mexico Governor Gary Johnson vetoed a similar bill in 1997. Similar bills were introduced in all three states but failed when legislators and elected officials were not willing to jeopardize the quality of healthcare in their states.

2/17 **Gimbel Vision International** announced that it would acquire an interest in **Laser Ocular Brasil-Canada Ltda.**, located in Rio de Janeiro, Brazil, effective March 1st. Gimbel Vision's Brazilian partner, **Gimbel Guimares Vision Centers S/C Ltd.** will own 51% of Laser Ocular Brazil-Canada Ltd., with the remaining 49% owned by several Brazilian doctors and **IBOL-Instituto Brasileirode Oftolmologia Ltda.**, the largest institute of ophthalmology in Rio de Janeiro. The company expects that the new laser center's surgeons will perform in excess of 2400 procedures annually, and will include LASIK surgery. To date the company's physicians have performed over 20,000 refractive eye surgeries.

2/19 **LaserSight** said that the FDA has scheduled a meeting with Dr. Frederic Kremer for February 24th, to seek resolution on issues identified by its Ophthalmic Devices Panel during the February 13th presentation on his excimer laser for use in LASIK. LaserSight owns worldwide rights to manufacture and commercialize the laser, should FDA approval be granted.

2/19 *The Sacramento Bee* carried a story about **Premier Laser System's** negotiations with **Ophthalmic Imaging Systems**. A spokesperson for Premier said that OIS "would make a wonderful acquisition...we're in a cash position to make strategic acquisitions." Officials at OIS declined to comment. OIS directors have been studying an unsolicited $4.73 million cash buyout offer from Premier, which already owns 29% of the company.

2/19 *Dow Jones* carried a story about **LaserSight's** stock rebounding 12%, after dropping for three straight sessions following the release of the FDA's turndown of the Kremer LASIK application. Apparently, some company followers thought that the turndown was for LaserSight's scanning laser system. But, as pointed out in the February 13th brief above, the PMA application was for Kremer's home-built wide area ablation excimer laser, and not for LaserSight's systems. LaserSight has said that it would submit the PMA for its laser system later this year.

2/20 **Gimbel Vision International** announced that it had completed the previously announced public offering in which it raised $1.7 million on the issuance of 1.5 million units at a price of $1.10 per unit. (See the August 26th brief in last September's newsletter for more details.)

2/20 **Miravant** announced that the results of a Phase I/II trial, presented at the 21st Annual Meeting of the Macula Society in Boca Raton, suggests that PhotoPoint may help to increase visual acuity in patients diagnosed with exudative ("wet") macular degeneration. Patients treated with optimal doses were able to read up to an additional 4½ lines on a standard eye chart, a significant improvement in vision. The "wet" form of macular degeneration is the leading cause of vision loss in older adults, affecting over 1 million people. According to Robert Murphy, MD, co-director of the Glaser Murphy Retina Center in Baltimore, and an investigator for the study, "Although these results are from early trials and more study needs to be done, the vision improvements seen in some PhotoPoint patients were nothing short of astonishing."

2/21 *The American Academy of Ophthalmology's* board of trustees passed a resolution at its winter meeting, opposing a far-reaching laser eye surgery bill being considered by the Oklahoma State Legislature, which would grant open-ended surgical privileges to health care practitioners who were not surgeons, specifically optometrists. (See the February 16th brief above.) A spokesperson for the Academy said, "Although laser surgery has a high-tech public perception, it is surgery. The laser is a surgical scalpel that permanently cuts, burns, and vaporizes tissue. If the Senate bill passes, Oklahoma

would be the only state to allow health care practitioners who are not surgeons to perform surgery.

2/23 **TLC The Laser Company** said that it had sent a letter to **BeaconEye's** board on February 20th, indicating that it was prepared to make an offer for all outstanding shares, by way of amalgamation between BeaconEye and a subsidiary of TLC. The offer is conditional on prior receipt of the support of the BeaconEye board and an indication from shareholders of at least two-thirds of the common shares of their support for the offer. The purchase price contemplated is $1.00 per share of TLC stock, the conversion price based upon the weighted average price for the 20 day trading period up to and including February 20th.

OPHTHALMIC LASER UPDATE -- MARCH 1998

2/23 *The Gray Sheet* reported some additional details of the FDA's Ophthalmic Devices Panel meeting of February 13th, which voted 6-0 to recommend approval of the **Autonomous Technologies'** PMA, with conditions. Because the data only included 21 eyes between -8 and -9 diopters, and 10 eyes between -9 and -10 diopters, the range of correction requested was "not justifiable or supported by the data". Therefore, the approval only covered up to -8 diopters of myopia, and -4 diopters of astigmatism. The panel also conditioned its approval on labeling specifying that at least 250 microns of the corneal stroma be preserved during the procedure, a conservative approach, "until we (the panel) knows that encroaching on the 250 micron thickness impairs the cornea's structural integrity". Also, citing only a small number of patients under the age of 18 in the data presented, the panel restricted the age limit to patients 21 years or older.

The major reason the Kremer PMA application was turned down was because there was less than 90% patient accountability at the six month follow-ups, and inadequate standardization of post-operative patient evaluations. The panel recommended against approval by a 4-2 vote. Of the two cohorts presented, the first had only 86.6% accountability, while the second had 77.4%. Kremer argued that accountability below 90% shouldn't negate his PMA, because his large sample size of 2500 eyes assures the data's validity. He also noted the difficulty of getting patients to return for followup when they feel they are not experiencing any problems. As for standardization of patient examinations, "several hundred" physicians were involved in the followup exams. According to the Panel, having several hundred practitioners follow the patients contaminates the purity of the data. A followup meeting with the FDA was scheduled to resolve these issues.

LaserSight, the sponsor of the Kremer PMA, issued a news release after the meeting, stating that Dr. Kremer had met with senior staff members of the FDA to clarify issues about his clinical data in the PMA submission. Based on that meeting, both the FDA and Dr. Kremer believe that any remaining issues can be resolved.

2/24 **Sunrise Technologies International** announced that it had received conditional approval from the FDA to treat the fellow eye on the same day as the initial laser thermal keratoplasty (LTK) treatment in its hyperopia study, using its CorneaSparing non-contact LTK system. Previously, the company had to wait six months to treat the fellow eye.

2/24 Dr. Kenneth Lipstock, of Richmond, VA, and Dr. Luis Ruiz of Bogota, Columbia have formed the **International Center for Refractive Surgery**, located in the British West Indies, to treat patients and to train other ophthalmologists in advanced refractive surgery techniques, such as LASIK. The center was established to allow Americans to take advantage of "third generation" excimer lasers, still being clinically evaluated in the U.S. For more information, the center's web site is www.ilvc.com.

2/24-
2/25 Several stories were published in the Toronto press about the pending merger of **TLC The Laser Center** and **BeaconEye**. (See last month's February 23rd brief for the details of TLC's latest offer.) *The Financial Post* reported that TLC had made another run at BeaconEye, a financially weak eye surgery chain that had received a new merger, takeover, or financing proposal nearly every week this year. The latest being TLC's offer of $1/share for the 8.7 million outstanding shares as of last September 30th, plus the issued convertible debentures. The story notes that the **Icon Vision Centers** rescue plan, worth about $5 million, was followed by an offer from **Dundee Bancorp**. The latter was withdrawn last week, when BeaconEye said it was negotiating with a mystery U.S. investor of unknown affiliation, named Jack Hunter.

The following day, *The Financial Post* said that BeaconEye was considering the TLC offer, worth about $10.2 million, along with an offer from **ClearVision Laser Centers, Inc.** of Colorado, which was also interested in a merger, including bridge financing deal that would keep the company afloat until a definitive merger could be negotiated. In the meantime, Icon Vision Centers said that it and its partners had bought more than 1.1 million BeaconEye shares (about 11%) and might seek a board seat. Apparently, both the withdrawn talks with Dundee Bancorp and U.S. investor Jack Hunter were both Icon deals, according to BeaconEye president Keith Moore. According to TLC spokesperson Stephen Kilmer, it wants to merge with BeaconEye because TLC believes that the company can be turned around just by changing the business model and cutting overhead.

An investment opinion column also appeared in the February 25th *Financial Post* about the proposed merger of BeaconEye and TLC. According to author Barry Critchley, the new bid by TLC for competitor BeaconEye appears to be a classic example of Economics 101. "TLC's renewed effort to buy all BeaconEye for $1 a share reflects consolidation in the business, from which the spoils -- super profits -- would tend to flow to the biggest company or the one with some advantage." Critchley noted that TLC's bid hadn't gone unnoticed by Vancouver-based **LASIK Vision Canada**, a relatively new entrant, which had adopted another classic

Economics 101 strategy; get into what is effectively a commodity business and offer the service at a lower price providing a reasonable return. The usual result is that super normal profits get whittled down to more normal levels. At LASIK Vision, started earlier this month by Vancouver eye surgeon Hugo Sutton (see our February 3rd brief last month), patients pay C$2995 for both eyes, compared with the C$4800 fee charged when he was with **Broadway Eye Centre** and the C$4000 TLC "generally" charges for what's known as PRK and the C$4800 charged for LASIK. With the lower price, LASIK Vision is doing about 15 procedures a day, up from 3 or 4. According to spokesperson Michael Henderson, the company has picked 16 cities across Canada for possible expansion, and at least two brokerage firms have been approached about raising some capital for expansion.

TLC's Kilmer does not agree people are sensitive to price for these operations. "They just want the best care". Nor does he believe that laser refractive surgery is a commodity business. "A surgical procedure takes place. The laser is a high-tech replacement for the scalpel, but the technique still comes down to the skill and experience of the surgeon." Another competitor, Calgary-based **Gimbel Vision International** is not going to get into the price war. "To maintain the quality of care that patients require and to maintain the latest technologies available for refractive eye surgery, it is necessary that prices stay where they are," said CEO Ed Belanger. The firm charges C$4800 for LASIK and C$4400 for PRK for both eyes.

2/25 **Sight Resource Corporation** announced that William Sullivan, president and CEO had purchased 41,290 shares of common stock from the company at a cost of $120,000. The shares are subject to a two-year lock-up provision, which allowed Mr. Sullivan to acquire the shares at 75% of fair market value. In addition, the company granted Mr. Sullivan employee stock options to purchase 300,000 shares at a price of $3.938, the closing price on January 22nd, the date on which his employment agreement was approved by the board of directors.

2/26 **Premier Laser Systems** announced that it had acquired approximately 51% of the outstanding shares of **Ophthalmic Imaging Systems** through private purchases. The company had previously purchased approximately 29.5% of the shares of OIS. As part of the acquisition, Premier has agreed with OIS to commence a tender offer within five business days to acquire the remaining outstanding shares of OIS stock. Premier intends to offer $1.75 in cash, $0.25 in Premier stock and two warrants, each of which permit the holder to acquire $0.25 worth of stock for a nominal purchase price if OIS meets certain future revenue goals. The directors of OIS have unanimously approved the transaction and recommend that OIS shareholders offer to tender their shares.

The following day, Premier issued a release announcing that it had agreed with OIS that Premier's tender offer would commence promptly following the effectiveness of Premier's related registration statement, which would be filed next week. An account of the agreement was also published in *The Sacramento Bee*, and put out by *Knight*

Ridder Tribune Business News. In the story, analyst John Doss of **Dominick & Dominick** said that OIS would be a good fit for Premier.

2/27 **BeaconEye** and **TLC The Laser Center** announced that they had entered into an agreement pursuant to the TLC takeover bid. The price to be paid by TLC will be $1.50 per share (valuing the offer at about $16 million), payable in common shares of TLC which will be valued at the weighted average closing price during the 20 days ending on the last trading day prior to take up of Beacon under the offer. The TLC shares will be valued not higher than $18.75 or less than $17.50. TLC has said that they are in receipt of irrevocable lock-up agreements and/or commitments from Beacon shareholders owning approximately 75% of Beacon's shares, these shareholders agreeing to tender such shares to the offer. The formal offer will be mailed on or before March 16th. TLC has agreed to take over management of Beacon immediately and provide the necessary funding of Beacon's operations until the offer is completed.

When the acquisition is completed, the TLC network will include 45 refractive laser centers (two of which are also secondary care clinics) and 15 secondary care facilities, operating in 29 states and provinces across North America. The Beacon chain is expected to increase TLC's refractive revenues by more than 20%, and will be supported by strong synergies and cost savings generated by combining the two operations. TLC has retained **RBC Dominion Securities** as its financial advisor.

The Financial Post kicked in with its comments, prior to the actual announcement, noting that unlike the past deals (at 40 cents and $1.00), Beacon's main shareholders, **Hawker Siddeley** (32%) and **Icon Vision Centers** (11%) are likely to back this offer. Editorial writer, Barry Critchley wrote that some Beacon shareholders feel let down by even the newest offer, believing that **CIBC Wood Gundy Securities**, hired by Beacon last year to maximize shareholder value, could have done even better.

Following the newest offer, *The Financial Post* reported that TLC has promised to cut the rich severance agreements, worth up to $6 million, that BeaconEye signed with its three top managers. Details of the reduced package had not been released, and Keith Moore, one of the recipients said he was unaware of the role the cuts played in getting institutional shareholders to back TLC's offer, but that management was committed to some reduction. TLC took over management of Beacon's 11 eye surgery centers and will pay its creditors, whose patience had kept the company afloat.

2/27 **LaserSight** announced that its shareholders had approved the three proposals presented at the company's special meeting held today. Shareholders approved the future issuance of share of the company's common stock resulting from conversion of LaserSight's Series B Preferred Stock and the exercise of related stock purchaser warrants. LaserSight sold these securities in a private placement last August to fund the purchase of the **IBM** patent portfolio. The shareholders also approved an increase in the number of authorized shares of common stock from 20 million to 40 million.

And finally, they approved a proposal that would have allowed the company to adjourn the special meeting to another date if there were not enough votes to approve the first two proposals.

3/2 **Laser Vision Centers** reported that revenues for its third quarter, ended January 31st, increased 216% over the same quarter a year ago, and were up 21% over the previous quarter. Revenues for the quarter were $6.4 million, with a loss of $913,000 (10 cents/share) compared to a loss of $2.3 million for last year's quarter. Revenues for the nine month period were $15.7 million with a loss of $3.6 million (42 cents/share). This compared to revenues for 1997's nine months of $5.4 million with a loss of $6.7 million (83 cents/share). The company also noted that its EBITDA (earnings before taxes, depreciation and amortization) remains positive, both for the quarter and for the nine month period.

3/4 **TLC The Laser Center** announced its third quarter procedure results. Over 9300 procedures were performed at the company's centers in the quarter ending February 28th, up 165% for the same quarter a year ago, and up 46% from the 6420 procedures performed in the previous quarter.

3/5 According to this month's *Refractive Market Perspectives*, laser center operators are expecting 1998 to be a "good" year. "With relatively stable pricing, flat or decreasing operating costs, and increasing volumes, most centers will generate positive cash flow during 1998, many for the first time." **Laser Vision Centers**, **TLC The Laser Center**, and **LCA Vision** are all predicting positive earnings at some point this year, with LVC and TLC achieving positive EBITDA during 1997. David Harmon expects average laser procedure volumes to reach 68 procedures per laser per month vs. 47 during 1997. About 75 centers are doing more than 100 procedure per month (with 5 of these doing more than 250 procedures per month), while 110 are doing between 50 and 100, and about 180 centers are doing less than 50 procedures per month.

The other lead story this month is about the microkeratome market, especially with the conversion from PRK to LASIK continuing strong. Although most units sold today are designed for single use, using the same disposable blade for both eyes in a bilateral procedure is commonplace and, it appears, based on limited data on disposable blade sales, that multiple reuse appears to also be common practice. According to *Market Scope*, **Chiron Vision** (now **Bausch & Lomb Surgical**) remains the market leader, but with the proliferation of new products, their dominant position could erode.

3/5 **Sight Resource** reported its fourth quarter and year end results. For the quarter the company had revenues of $11.4 million, up 33% from the same period a year ago, and a net loss of $1.5 million (17 cents/share). For the year, the company had revenues of $44.6 million, up 49% from a year ago, and a net loss of $2 million (23 cents/share). EBDITA for the year was $204,000 compared to a loss of $1.2 million a year ago. The $2 million net loss included a non-recurring provision of $400,000 for the write-

off of software associated with the company's point-of-sale system and a provision of $110,000 for store closings. New president William Sullivan noted that the positive EBIDTA was a first for the company, and the goal for 1998 is to make even more dramatic improvements. The company also intends to pursue the acquisition of strong regional operations which will be accretive to earnings.

3/9 **Sunrise Technologies International** announced fourth quarter and year-end results. The company had fourth quarter revenues of $300,000 and a net loss of $2.5 million (8 cents/share). For the year, revenues were $2.8 million with a net loss of $6.6 million (23 cents/share). The company continues to have positive results from its clinical trials to treat hyperopia, now in Phase III, and is beginning to clinically test the treatment of presbyopia with its CorneaSparing LTK system.

3/9-
3/10 In a series of announcements, a number of people, including a malpractice attorney, an OD, and the head of the Academy of Ophthalmology, all came out against the proposed bill before the Oklahoma legislature proposing to give laser surgery rights to optometrists in that state. Oklahoma attorney Blake Virgin believes that the bill will increase the number of medical negligence and malpractice suits dramatically, although optometrists lobbying for the bill claim that there have been no complications or malpractice suits filed against those optometrists that have been performing laser surgery. Darrel Heck, OD has urged the legislature to oppose the bill and, if passed, for the governor to veto it. Heck noted that the laser surgery training he had received consisted of one weekend course. Elliot Finkelstein, MD the AAO's president said, "Although laser surgery has a high-tech public perception, it is surgery. The laser is a surgical scalpel that permanently cuts, burns, and vaporizes eye tissue. I strongly urge Oklahoma citizens to contact their state representatives immediately and voice opposition to Senate Bill 1192."

3/10 "Technology and innovation are factors that will drive above-market returns in healthcare stocks over the long term", according to Mike Yellen, portfolio manager of the **GT Global Healthcare Funds**, and keynote speaker at the **Informed Investors Healthcare Forum**, held on March 7th in Sacramento, CA. Yellen pointed to refractive laser surgery company **VISX**, one of the presenting companies, noting that VISX was a company with virtually monopolistic patents, royalty streams that drop almost to the bottom line, and a market that's just begun to be tapped. Also on the program, and responding to a question about the impact of refractive surgery on the contact lens market, CEO Tom Bender of **Cooper Companies** (a contact lens manufacturer and marketer), said, "We complement each other. No way are they (VISX) going to do procedures on a 125 million people, but it'll damn sure be more than the 200,000 they did last year."

3/12 **Summit Technology** announced that the FDA had approved the Summit SVS Apex Plus excimer laser and the emphasis disc for treating low to moderate astigmatism, boosting dramatically the utility of Summit's equipment for its customers. (Current

users of the Apex system must purchase an upgrade -- for about $50,000 -- to be able to use the emphasis disc technology. This approval puts Summit still one step behind its main competitor, **VISX**, who, in addition to astigmatism approval, also has approval for high myopia.) Summit also said it was pursuing FDA approval for the treatment of hyperopia with the SVS Apex Plus and emphasis disc, and is awaiting FDA action on its PMA for the treatment of high myopia.

3/12 **Staar Surgical** in announcing its fourth quarter and year-end results, noted that it was very pleased with the progress of its FDA clinical trials for the Implantable Contact Lens (ICL). John Wolf, chairman and president said, "Phase II of the study for myopia is going well, with initial clinical results that are very encouraging. The Phase I study for hyperopic patients has been completed, again with very positive data, and we are hopeful to begin Phase II within 30-60 days." (The ICL will compete with both excimer lasers and the LTK holmium laser for treating patients with high myopia and with hyperopia.)

3/12 **Vision Twenty-One**, an eye care management company, noted along with its release of fourth quarter and year-end results, that during the quarter the company had completed acquisitions of three managed care companies, including **Block Vision**, **MEC Health Care**, and **Florida Eye Care Associates**. These acquisitions resulted in an addition of approximately 2.8 million managed eye care lives. Also, during the period, the company acquired 9 ophthalmology clinics and 2 ambulatory surgery centers, it opened 5 optometry clinics located inside retail optical centers, and gained 3 new managed care contracts representing an additional 63,000 lives. Since the end of the fourth quarter, the company announced the closing of a $50 million bank credit facility and the pending acquisitions of 12 optometry clinics. Today, the company announced it had entered into letters of intent to acquire 6 ophthalmology clinics, 35 optometry clinics, and 1 ambulatory surgery center within existing or developing Local Area Delivery Systems (LADS). The LADS are expected to close in the first quarter of 1998. The estimated revenues of the new acquisitions were $38 million for the year ended December 31st. In the first quarter of 1998, the company has also completed the opening of a refractive laser surgery center in the Phoenix LADS, and initiated a new managed care contract for the provision of ophthalmology services to 250,000 existing vision care lives.

Vision Twenty-One provides a wide range of management and administrative services to its LADS, designed to provide for integrated networks of optometrists, ophthalmologists, ambulatory surgery centers, and retail optical centers which offer the full continuum of eye care services in local markets served by the company. Vision Twenty-One provides its services to 39 LADS located in 26 states through which approximately 5800 affiliated providers deliver eye care services. In addition, the company has approximately 6200 eye care professionals available for potential managed care business in future markets.

3/13 **LaserSight Inc.** reported its fourth quarter and year-end results. For the quarter, revenues were $6.3 million, compared to $6.4 million for the same quarter a year ago. The company sold 13 lasers in the quarter, bringing the total units placed throughout the world since 1994 to nearly 200. They had a net loss in the quarter of $1.8 million (20 cents/share). Revenue for the year was $24.4 million, vs. $21.5 million for 1996. For the year the net loss was $7.3 million (80 cents/share). In 1997 there were increased costs for R&D and regulatory matters, related to new products and clinical trials, including the company's Automated Disposable Keratome (ADK), which is now expected to begin shipping in May, rather than the previously announced target date of February. New orders being taken are scheduled for shipment in July or August.

The company said it expects to file its PMA for the LaserScan LSX within a week, and continues to work with Dr. Frederic Kremer on his PMA submission for LASIK, using his home-built wide area beam excimer laser. As previously noted, Michael Farris, president and CEO has relocated from St. Louis to Orlando, now considered the official company headquarters.

3/13 **Atlantic Pharmaceuticals** said that it believed the high volume of trading activity in its stock was the result of a story in the March 23rd issue of *Business Week* concerning its Catarex technology, being developed through **Optex Ophthalmologics, Inc.**, its majority-owned subsidiary, for the removal of cataracts through small incisions. Atlantic is developing proprietary technologies in antisense therapy, cataract removal, prevention of restenosis following coronary angioplasty, and anti-inflammatory/analgesic drugs.

3/13-
3/16 More on the Oklahoma optometric laser use controversy. The Oklahoma State Medical Association authorized a state-wide poll related to the controversial Senate bill seeking to allow optometrists to perform laser eye surgery. The Bill has now passed both the Senate and the House and has been sent to the Governor for his signature. The opinion poll, conducted by RT Nielson Co., to provide an objective analysis of public opinion, resulted in an overwhelming majority of Oklahomans who declared that they would choose an ophthalmologist over an optometrist it they had to have laser eye surgery. According to the poll results, over 60% of Oklahomans would choose an ophthalmologist as compared to approximately 6% that would choose an optometrist for surgery, an almost 10:1 ratio in favor of ophthalmology. The poll also indicated that many people do not clearly understand the difference between the two groups of eye care professionals. After being told that optometrists were not medical doctors, the ratio in favor of ophthalmologists increased to almost 15:1.

This week's issue of *EyeWorld Week* says that Governor Frank Kesting would decide early this week whether to sign or veto the Senate bill. No other state permits optometric surgery and most expressly prohibit it, so Oklahoma is being closely watched across the country by both optometrists and ophthalmologists.

3/16 *Ocular Surgery News Intelligence Report* says that **VISX** will launch its Star S2 SmoothScan excimer laser system at the upcoming American Society of Cataract and Refractive Surgery meeting in San Diego. The S2 extends the capability of the existing platform to offer smoother ablation, scanning capability, and ease of use, according to the company. Company spokesman Stephen Trokel, MD, said, "Smoother ablations should reduce the problem of minor surface irregularities which diminish acuity and create glare problems. Contrast sensitivity should be enhanced as well." (This is almost a selling mantra for the companies introducing scanning systems.) The smoothing capability is achieved through a reconfiguration of the seven-beam scanning system, resulting in a smoother, nearly featureless ablation. International users will receive a scanning module that will allow them to treat hyperopia and astigmatism. U.S. users will be offered upgrades for myopia and astigmatism.

3/16 **Laser Vision Centers** announced that it had been served with a subpoena from the Department of Justice, which LVC believes is investigating the so called "international card" software that enabled excimer laser operators to perform laser eye surgeries for higher myopia than had initially been approved by the FDA. Higher myopia correction was approved for the VISX system in January 1998. According to the news release, many ophthalmologists have taken the position that FDA restrictions on physician's use of laser equipment through software control, rather than the traditional means of labeling, deny physicians the flexibility to treat individual patients as the physician deems medically necessary, and represent an unwarranted intrusion upon physician's rights to practice medicine according to their best medical judgement. The subpoena requests that LVC produce several specified categories of documents. Laser Vision intends to cooperate fully.

3/16 **Paradigm Medical Industries** announced the completion of a private placement offering that raised $2.96 million, allowing the expansion of its marketing efforts for the new glaucoma detection system, the Blood Flow Analyzer, and for the anticipated expansion of its clinical investigational trials for the Photon Laser Cataract system. The company also released its year-end financial results with net sales of $566,200 and a net operating loss of $2.6 million (68 cents/share).

3/16 Governer Frank Keating of Oklahoma signed the legislation legalizing the use of lasers by optometrists in that state, the first in the nation. In a statement issued from his office, he said, "There were strong arguments on both sides, but when all was said and done, I was left with no material reason not to concur with member of the House and Senate who overwhelmingly supported this bill." The legislation, which takes effect in November, permits optometrists certified by the Board of Examiners in Optometry to perform laser surgery, including YAG capsulotomies, argon trabeculoplasty, and PRK. The legislation, however, restricts optometrists from performing LASIK, retina, and cosmetic eye lid surgery.

The following day, the president of the AAO said that the Oklahoma legislation was fundamentally flawed and potentially damaging to public health and safety, and that all avenues were being explored to challenge the action by the Academy, in cooperation with the medical community in Oklahoma.

3/17 **TLC The Laser Center** announced that it intends to mail its offer to the shareholders of **BeaconEye** by Friday March 20th, rather than the 16th as originally expected. TLC has requested the extension of both BeaconEye and it shareholders, with whom it had entered into a lock-up agreement. Consistent with the BeaconEye offer, TLC is managing BeaconEye and has put approximately $2.3 million into the operations to date to pay past due obligations.

3/17 **LaserSight** announced that it had entered into a new agreement with holders of its Series B preferred stock. The preferred holders have agreed to limit their conversion to no more than 1 million shares of common stock between March 13th and September 14th, provided the agreement receives approval from a majority of shareholders at the annual meeting on June 12th. Additionally, LaserSight has the option to purchase any or all of the remaining Series B preferred stock at a 20% premium, provided the company has the resources and approval from the company's secured lender, and that the overall agreement receives shareholder approval. The agreement also uses a new formula for conversion that is lower than the original $6.68/share, and a lower exercise price of the warrants previously issued. Just prior to the conversion restriction becoming effective, the preferred holders submitted notice for the conversion of 244 shares of preferred stock into 1.4 million common shares, bringing the total outstanding to 11.4 million, with 700 shares of preferred stock worth $7 million outstanding.

3/18 **TLC The Laser Center** announced that it had completed the acquisition of two secondary care practices in the state of Washington, and that it had acquired a 25% interest in a secondary care practice in Oklahoma. The Washington acquisitions includes the practices of Dr. Armin Mohr in Burlington, and Dr. Ronald Ullman in Sequim, increasing TLC's coverage in the Northwestern region of the state. The new practices will be consolidated in TLC's Northwest Eye Practice, working closely with its laser vision correction center in Seattle. The Oklahoma acquisition is the practice of Dr. Bradley Britton in Oklahoma City. Dr. Britton is also a medical director at TLC's Oklahoma City laser vision correction center, and one of the high volume refractive surgeons in the country. The acquisitions, along with the proposed takeover of **BeaconEye**, will bring the company's refractive laser centers to 45, and secondary care clinics to 16, operating in 29 states and provinces across North America.

3/18 **Laser Vision Centers** announced that same U.S. laser revenues for February increased 375% compared to February 1997, and decreased by 5% from January 1998. The latter was probably due to the fewer days in the month, which reduced the number of available surgery days. The average revenue per calendar day in February actually increased by 5% versus January.

3/18 **TLC The Laser Center** announced the filing of a multi-jurisdictional registration statement containing a preliminary prospectus with the Ontario Securities Commission and the SEC. The filing relates to a proposed public offering of 4.6 million common shares plus 690,000 for an over allotment to the underwriters, **PaineWebber**, **RBC Dominion Securities**, **SBC Warburg Dillon Read** and **First Marathon Securities**.

On the following day, the company also announced that it had mailed an offer to the shareholders of **BeaconEye** to acquire all of the outstanding shares at the previously announced price of $1.50 per share, payable in TLC common stock.

3/19 **LCA-Vision** reported its fourth quarter and year end results, showing revenues for the quarter of $6 million, compared with revenues of $3.3 million for the same quarter a year ago. The net loss was $2.6 million (7 cents/share). For the year, revenues rose 27.5% to $17.6 million, up from $13.8 million in 1996. Due, in part, to one-time charges related to the acquisition of the 19 **Summit** vision centers, the company posted a net loss of $8 million (30 cents/share) for the year. This compared with a net loss of $4.1 million (21 cent/share) for 1996. Commenting on 1997 results, CEO and chairman Dr. Stephen Joffe said, "As anticipated, the Summit acquisition added $2.6 million in revenues and greatly increased our size, but also produced losses of $1.9 million, or 5 cents per share. A previously announced restructuring reserve of $1.1 million, or 4 cents per share, also impacted 1997 earnings...Nearly every one of our original centers is now either profitable or very close to profitability...we expect to turn them [the Summit Centers] around in 1998." Dr. Joffe also noted that overall patient volume is currently exceeding projections. In 1997 11,268 surgeries were performed, compared to 4,022 in 1996. He also said that LASIK now represents over 50% of all procedures done in the company's 31 centers. This also allows ophthalmologists to treat both eyes at the same time. LCA operates 28 laser vision correction centers in the U.S., 2 in Canada, and 1 in Helsinki, Finland. Close to 25,000 successful procedures have now been performed at the company's centers, which have more than 600 physicians and 800 referring optometrists affiliated with them.

3/19 **QLT PhotoTherapeutics** and **Ciba Vision** announced that patient enrollment has begun for their Phase IIIb clinical trial using verteporforin (BPD-MA) as a treatment for various forms of macular degeneration. The study, known as the VIP (Vertepoforin in photodymanic therapy trial), complements the companies' pivotal Phase III trials which focus on the effectiveness of verteporforin as a treatment for age-related macular degeneration (TAP trial). The new VIP trial is designed to treat patients with an earlier stage of AMD who were originally excluded from the TAP investigation, as well as patients with a similar but distinct condition resulting from progressive near sightedness known as pathological myopia. Approximately 400 patients will be enrolled in the randomized, placebo-controlled, double masked VIP trial, scheduled for 28 centers across North America and in Europe.

Submissions for regulatory approval are on track to be filed in mid-1999 based on the results of the initial TAP studies.

3/23 **LaserSight** announced that it had submitted its PMA for the company's scanning laser system to the FDA. The submission contains data from multiple investigators at multiple sites within the U.S., encompassing the treatment of myopia in the range of -1.5 diopters to -10 diopters, with less than or equal to 1 diopter of astigmatism.

3/24 **Sunrise Technologies** said that it had received conditional approval from the FDA to begin a study to treat patients with LTK who were overcorrected after having a myopic excimer laser procedure (PRK or LASIK) that resulted in induced hyperopia. Studies conducted outside of the U.S. have demonstrated that LTK can correct hyperopia induced by the excimer laser procedures, and provides minimal trauma to the patient. The new study will begin on 10 patients at one investigational site; 5 patients will be post-PRK, and 5 will be post-LASIK. Dr. Daniel Durrie of the Hunkler Eye Center will be the first U.S. site to perform the procedure. Russell Trenary, president and CEO of Sunrise, noted that, to his knowledge, this is the first refractive laser approved for study to treat a complication caused by another laser. Dr. Donald Johnson of Vancouver, has been using this procedure to correct post-PRK hyperopia for the past four years, with good results.

3/24 **Gimbel Vision International** announced the opening of the new Gimbel Eye Centre-Toronto in the Edison Centre. Refractive surgeons joining GEC-T are Drs. Richard Bains, David Rootman, and Allan Slomovik. Drs. Bains and Rootman will be associate medical directors, while Dr. Slomovik will be director of research and quality assurance. Dr. Kar Sakhichand will serve as the Centre's optometrist. (To date, the company's surgeons have performed over 20,000 refractive eye surgeries in Canada alone.)

3/24 **VISX** announced that the FDA had approved the VISX Star S2 excimer laser system for the treatment of myopia and astigmatism (see the March 16th brief above). The S2 will be introduced at the April meeting of ASCRS in San Diego. According to VISX, the new laser extends the capabilities of the existing Star technology platform, offering smoother ablations, the widest demonstrated range of clinical applications, flexible software, and a number of other important features. The smoothing capability is achieved through reconfiguration of the unique seven-beam system which results in nearly featureless ablations. Other highlights of the approval is laser removal of the epithelium, and better ergonomics for intrastromal microkeratome procedures, improved patient fixation, and variable pulse frequency up to 10 Hz. The new system is marketed internationally as the VISX Star S2 Smoothscan, and is capable of treating hyperopia and hyperopic astigmatism.

3/24 **LaserSight** announced that Dr. Charles Casebeer of **CRS Clinical Research**, has received approval from the FDA to incorporate LaserSight's ADK disposable microkeratome into his national study of LASIK. The CRS LASIK study

encompasses more than 250 surgeons and is the largest FDA IDE study ever undertaken in the U.S. It is in its second year of research, and includes the treatment of myopia, astigmatism, and hyperopia.

It turns out that CRS had obtained FDA approval for the use of several additional keratomes in addition to the Chiron ACS, including the ADK, including the **Moria** Classic I and the Hansatome from **Chiron Vision**, now **B&L Surgical**. Further, CRS has also received approval to enroll surgeons as hyperopia investigators without the requirement that they participate in the study for high myopia and astigmatism. They can now participate in the hyperopia protocols directly from the general study group, saving at least three months time.

3/24-
3/25 Today's *Wall Street Journal* broke the story that **Summit Technology** and **VISX** were the targets of an investigation by the Federal Trade Commission, about whether or not they conspired to fix prices by interlocking their patents in **Pillar Point Partners**. According to the story (probably taken from the FTC news release embargoed until today), the FTC has found evidence to support that charge. One industry spokesperson quoted, James O'Shaughnessey, chief intellectual property counsel for **Rockwell International**, told a recent forum that, "As recently as five years ago, the entry fee [royalty on the use of a patent] was reasonable -- 1% to 2% of revenues. Now we are seeing royalties exceeding 6% to 7% of revenues." In fact, royalties charged by Pillar Point (on behalf of Summit and VISX), exceed the 10% range -- $250 on a $2000 procedure cost.

Both the official FTC news release and the full complaint were posted on the FTC's web site (www.ftc.gov), which I accessed. The news release alleges that the two laser companies conspired to control the market for laser eye surgery with price fixing, resulting in overcharging consumers $30 million last year. William Baer, Director of the FTC's Bureau of Competition said, "Summit and VISX sought to exempt themselves from the forces of competition by monopolizing the market for laser eye surgery and increasing the price of this important new procedure. The antitrust laws respect legitimately earned patent rights. But where the rights are abused or fraudulently obtained, we will act aggressively to protect consumers." The latter charge, of fraud, pertains to the FTC's charge that VISX acquired a key patent by fraud before the patent office. VISX is charged with "purposely identifying the wrong person as the first to invent PRK in order to conceal fraudulent conduct by the original inventor". In addition, VISX broke the law when it did not disclose previously published patents or publications that might prove that the claimed invention wa not "novel", a requirement of patent laws.

The Commission vote 5-0 to issue the administrative complaint, which contains 10 pages of detailed background and charges. Notice is given to both respondents to appear in the Commission offices on April 16th, before an Administrative Law Judge

of the FTC, to answer the charges and show cause why an order should not be entered requiring them to cease and desist from the violations of law charged.

Both VISX and Summit issued news releases the same day denying any wrong doing. VISX said it "strenuously denies the price fixing and other allegations." The company also said that it had worked hard to resolve the Pillar Point issues by mutual consent with the FTC (and had also filed on February 14th to disolve Pillar Point), and was disappointed that the commission decided to commence administrative proceedings while discussions were ongoing. Mark Logan, chairman and CEO also said that in respect to the patent issue, "We are puzzled by the challenge to VISX's patents by the FTC. The complaint challenges the 1990 resolution of complicated patent interference proceedings and asserts that certain documents were not cited to the PTO (Patent and Trademark Office). Those claims are unfounded. The interferences were resolved in full compliance with PTO procedures...VISX is confident that its fundamental patents cite all prior art relevant to the invention."

Summit said it believes now, as it did then (when Pillar Point was formed), that the Pillar Point arrangements were lawful and pro-competitive. Robert Palmisano, CEO of Summit, said, "We are disappointed that the FTC has elected to bring this action just as laser vision correction procedures are beginning to grow rapidly. One must ask what effects this step will have on other startup ventures who must risk capital in hopes of an often distant and uncertain reward. Defending against these charges will certainly be burdensome for a company of our size, but we firmly believe that the FTC's allegations are without merit and that we have done nothing wrong."

The following day, VISX issued a follow up news release stating that the five patents at issue in the FTC charges, are only a small portion of VISX's intellectual property portfolio. VISX currently has 36 issued U.S. patents in the field of corneal refractive surgery, including fundamental patents covering LASIK and scanning technology. Outside of the U.S., VISX owns 80 issued patents in the field, and receives royalties from six leading manufacturers of refractive lasers. VISX reiterated that the FTC's claims against the five patents were unfounded. (The five patents at issue are the original patent issued to Francis L'Esperance, contested by Stephen Trokel, including the one issued to Dr. Trokel in place of the L'Esperance patent wherein the lawyers representing Trokel failed to disclose prior art; and three patents the subject of an interference action between L'Esperance and Charles Munnerlyn, one of which became a Munnerlyn patent.)

In a *Boston Globe* story on the subject, published on the 25th, it was revealed that the FTC had came up with the $30 million overcharge figure from background material it had uncovered during its investigation. Contained in that information was the fact that one company (VISX) had proposed to make the royalty $100 and the other (Summit) proposed $250. As established by the Pillar Point agreement, the higher figure prevailed. The FTC took the difference -- $150 -- and multiplied it by the number of

procedures last year to come up with the $30 million overpayment (and $10.5 million for 1996!).

The American Academy of Ophthalmology (AAO), the Society for Excellence in Eyecare (SEE), and Outpatient Ophthalmic Surgery Society (OOSS) all come out in support of the Government's action against Summit, VISX, and Pillar Point. The AAO said it applauds any actions that further the reduction of price fixing, while SEE and the OOSS said that the government's action must be cheered by all eye surgeons and their current and future patients.

3/25 **Staar Surgical** said that it had received FDA approval to begin Phase II of its clinical trials for the implantable contact lens (ICL) to correct hyperopia. The approval will allow Staar to implant 62 ICLs in patients and to increase its investigator base from 4 to 10 surgeons. According to chairman and president John Wolf, the results from the Phase I trials and from ongoing international clinicals were even better than the Phase I myopia results. Worldwide, surgeons have now implanted more than 3000 ICLs.

3/26 **Nidek Inc.** announced that the FDA had approved the company's new MC-7000 Multi-wavelength ophthalmic laser system for global sales and distribution. The MC-7000 is designed to treat a diverse set of patients suffering from glaucoma, age-related macular degeneration, and retinal disease. The MC-7000 krypton laser combines four wavelengths of laser therapy into one system. According to a company spokesperson, the laser allows red, yellow, yellow-green, and green light to be produced independently. The laser will list for about $80,000 with a slit lamp.

3/26 As could almost have been predicted, a class action lawsuit has been filed by a consumer who believes he was overcharged for PRK. BJ Snyder of Los Angeles has filed a $40 million lawsuit, based on the FTC complaint that consumers overpaid $30 million in 1997 and $10.5 million in 1996. The suit was filed on behalf of consumers by the law firms of Prongay & Borderud (Pacific Palisades) and The Alexander Law Firm (San Jose).

3/30 This week's *U.S. News and World Report*, contains a look at who profits from refractive surgery. It discusses the fees charged by a **TLC The Laser Center** clinic in Fairfax, VA, who apparently charges $2750 for LASIK and $2250 for PRK. The story breaks out some of the referral fees and the Pillar Point fee, as well as laser service, etc., quoting from information obtained from **RBC Dominion Securities**, to show that low volume and medium volume clinics aren't doing very well, while high volume clinics -- performing 2400 procedures per year (although the article reads per month!) can make money, in this case pretax earnings of $1.8 million.

OPHTHALMIC LASER UPDATE -- APRIL 1998

3/31 A pretty good news story about laser eye surgery managed to hit the front page of *USA Today*. Author Robert Davis did a nice job describing this "hot" way to correct vision.

4/2 I received a copy of the **RBC Dominion Securities** report on **TLC The Laser Center**, published in February, and the prime source for the story on refractive surgery published in the March 30th issue of *U.S. News and World Report*, mentioned in last month's newsletter. It notes that "TLC should benefit significantly from the anticipated 84% annual growth in the North American laser vision Correction marketplace." The author, Doug Miehm, forecasts that 648,000 procedures will be done annually by the year 2000. They rate TLC as a "strong buy".

4/3 **Iridex** announced that it had received ISO 9001 and EN 46001 certification for its laser products.

4/6 This issue of the *AOA News* provides a few more details about the suit/motion filed by **VISX** to dissolve the **Pillar Point Partnership**. (See last month's 3/24-3/25 brief about the FTC action against **Summit Technology**, VISX, and Pillar Point.) Apparently, the documents in the suit were filed under seal, and few additional details about the action are available. Neither company is willing to talk about the suit, except Lola Wood, of VISX, said that there were several issues over which the participants disagree, but she would not be specific.

4/8 **LCA-Vision** reported that its first quarter volume of laser vision corrections rose 98% to 4451, up from 2248 performed for the same quarter last year at the same 30 centers. Excluding the centers acquired from **Summit Technology** in August, the volume at its original 11 centers grew 206% to 2759 versus 903 done during the first quarter of 1997. Nearly 25,000 successful procedures have now been done at the company's 30 sites.

4/8 **The Society for Excellence in Eyecare (See)** said that its board of directors was considering various options in support of individual member physicians to refrain from making royalty payments of $250 per eye when using either Summit or VISX lasers for PRK. According to their news release, there have now been at least two consumer class action suits filed against the companies and Pillar Point for allegedly overpaying for PRK. Among the actions SEE is considering are instituting a lawsuit to seek a declaratory judgement that the license fees are illegal; instituting a suit to seek a judgement that the license fees do not apply to LASIK; and suggesting as an adjunct to either suit that the court establish an escrow account to which Pillar Point fees could be paid pending the outcome of the suit, and/or recommending that eye surgeons use International or "Bermuda" cards rather than pay the $250 royalty. (Some sort of key card is required to operate both the Summit and VISX lasers.)

4/9 **TLC The Laser Center** announced its third fiscal quarter results with record gross revenues of $36.5 million, up 258% from the same period a year ago. Net revenues

were $24.1 million (after adjustments for revenues retained by physician groups and contractual allowances). The increased revenues were primarily from the continued growth in procedures, with over 9300 done in the quarter, compared to 2209 last year. The net loss for the quarter was $3.3 million (12 cents/share), which included $3.1 million in amortization, $654,000 in taxes, and $618,000 in interest, resulting in a positive EBITDA of $1.1 million for the quarter.

TLC also announced that all of the terms and conditions of its offer for **BeaconEye** had been satisfied or waived, and that TLC had taken up and paid for 10.5 million shares, giving it 97% ownership of the outstanding shares.

4/13 **Sight Resource** announced that it had acquired **Eyeglass Emporium**, a privately-held primary eye care chain in Indiana. This fifth acquisition of an eye care chain brings the number of eye care centers to 95. Terms were not disclosed. Eyeglass Emporium was established in 1981 and operates nine eye care centers with total annualized revenues of about $5 million.

4/13 **Gimbel Vision** announced that 1997 earnings before interest, depreciation, and taxes were $4.5 million, up 108% from 1996. Consolidated net earnings were $1 million (5 cents/share), with cash flow from operations of $2.1 million. Revenues for the year were $17.8 million, compared to $7.7 million in 1996. During the year, surgeons performed 9322 procedures an 85% increase over 1996. To date, the company's surgeons have performed over 20,000 refractive procedures in Canada alone.

4/14 **Laser Vision Centers** announced that same U.S. laser revenues in March were up over 310% compared to March 1997, on 23 excimer laser systems. LVC also said that it had performed over 3000 cases in the U.S. in March, the best month to date. Two hundred and fifty five surgeons used its services in March and the company now serves over 115 sites in 33 states. According to John Stiles of LVC, about 75% of the procedures done on its lasers are LASIK.

4/15-
4/16 **VISX** released its first quarter results, showing total revenues of $24.3 million, up substantially from both its first quarter and fourth quarter last year. The revenues were made up of $7.6 million in system sales (representing the sale of 27 units -- 2/3 domestic and 1/3 international, and including 9 system trade-ins), and license and service revenues of $16.8 million, up from $5.6 million (+200%) in last year's first quarter and up from $12.4 million (+35%) from the fourth quarter. (The company noted that the number of key cards (procedures) had increased by 240% over last year's first quarter.) Net income for the quarter was $9 million (58 cents/share). Management noted that the new Star S2 upgrades can be field retrofitted, and would cost $50,000. With the smoother ablations obtained with the new S2 design, VISX expects that most of its established base installations would convert over to the new configuration. All new machines being shipped are the S2 model. Commenting on the Japanese market, Mark Logan said that he expected to obtain PTK approval by year's

end, and PRK approval sometime next year. He also noted that the company expected to be able to collect procedure-based revenues in that country. Logan indicated that he expects that about 200,000 procedures would be done on VISX lasers in 1998, with an industry total of about 300,000. He expects that they will obtain hyperopia approval in late 1998.

Appearing on CNBC the following day, Logan said that the refractive laser market was "on the brink of exploding". As reported by *Dow Jones*, Logan said that industry analysts estimate about 70% of procedures in the U.S. are done on VISX machines. He also stated that they may have reached a saturation point, at least temporarily, on equipment sales, with ongoing revenues from licensing royalties becoming more and more important.

4/16 **Iridex** announced its first quarter results with revenues of $5.9 million and net income of $655,000 (10 cents/share).

4/16 **Sunrise Technology** announced that it had received conditional approval from the FDA to begin a study to expand the hyperopic treatment range up to 4 diopters with its Cornea Sparing LTK laser. The company is currently in Phase III trials for treating hyperopia from 0.75 to 2.5 diopters. The new study will enable treatment between 2.75-4.00 diopters. Clinical results on procedures performed outside of the U.S. indicate that the Sunrise LTK procedure may achieve correction of up to 4 diopters after 3-6 months, using a modified algorithm, which can be programmed into the current laser. The new study will begin on 20 patients at two investigational sites in the Dominican Republic. The expanded range should cover up to 80% of all hyperopes over the age of 40.

4/17 **Atlantic Pharmaceuticals** will present its new endocapsular vortex emulsification technology at the ASCRS meeting in San Diego beginning tomorrow. Atlantic's consultant, Dr. Richard Kratz believes that the Catarex method could make cataract removal faster -- requiring just 1-3 minutes -- compared to 4-15 minutes for phacoemulsification. The new procedure can be performed using a 2 mm incision in the cornea and a 1.25 mm incision in the lens capsule. The company is in discussions with several potential licensees for major world markets to help speed introduction of the technique into the marketplace.

4/17 **Autonomous Technologies** announced that it had arranged for a total of $24 million in financing, as part of an ongoing financing plan to enable it to participate in the laser vision correction market. The company said that it had executed a letter of intent with an unnamed financial institution to provide a $15 million credit facility to support U.S. commercial placement of the company's LaderVision systems for at least one year. The credit facility provides cash to the company approximately equal to the manufacturing cost of each system shipped and accepted under a per-procedure placement contract between Autonomous and the physician. The plan is expected to be completed in May.

The second instrument was a private placement of convertible preferred stock with an institutional investor for an expected $9 million, to be funded in two parts, with initial closing and funding of the first $5 million within a month.

4/17 **TLC The Laser Center** announced that it had completed a follow-on offering of 4.6 million shares at $14.50, raising $66.7 million.

4/20 A new, free newsletter that follows companies and stocks in the growing vision care industry can be obtained weekly by e-mail. **OptiStock**, can obtained by signing up at the company's website, www.optistock.com.

4/20 Two U.S. analysts have initiated coverage of **TLC The Laser Center**. Paine Webber analyst Charles Olsziewski initiated coverage with a "buy" rating, but further details weren't immediately available. SBC Warburg also initiated coverage with a "buy" rating. According to a TLC spokesperson, only RBC Dominion and First Marathon Securities, two Canadian brokerages, who were part of the underwriting group for the share offering, had reports on the company before the two U.S. companies began coverage. The spokesperson also believes that Gordon Capital is preparing a report.

TLC also announced that it had formed an association with the University of Wisconsin Medical School Department of Ophthalmology. The department will continue to operate and market its own program, but the new association will consolidate the use of lasers and staff at TLC's Wisconsin laser center located in Madison, and UW patients will be able to go to the Madison location for refractive surgery.

4/21 **Sunrise Technologies** reported that its investigational LTK program for hyperopia has resulted in an 84% success rate in restoring 20/40 or better vision after six months in its Phase II/III clinical trials.

4/22 **Bausch & Lomb** reported first quarter results with revenues of $553.1 million, up 24% from the first quarter a year ago. The revenues include $91.2 million generated by the pharmaceutical and surgical product lines of the former **Chiron Vision** and **Storz Instruments**. Including a $100 million restructuring charge, and $61.2 million related to the buyouts, net earnings were $14.2 million, along with a net loss of $49.4 million (89 cents/share).

4/23 **Gimbel Vision International** reported that the number of procedures at its 14 centres rose to 3281 for the quarter, up 101% from the number performed a year ago.

4/24 **Sight Resource** reported revenues of $13.6 million for the first quarter, an increase of 31% from last year, and net income of $13,000 (0 cents/share), compared to a loss of $387,000 in last year's first quarter.

4/24 **Sunrise Technologies** reported first quarter revenues of $102,000 and a net loss of $154,000 (11 cents/share). This compared to last year's quarterly revenues of $1 million, which included dental laser revenues in that time frame. (The company sold its dental laser business in June.)

4/24 A Michigan outpatient surgery center, **Metropolitan Eye Center and Outpatient Surgery Facility Inc.** said it was suing **VISX**, and **Summit Technology**, accusing the two companies of price fixing in the laser vision correction industry. The clinic is seeking treble damages for the licensing fees paid to **Pillar Point Partners**, and is awaiting a judges decision on whether the suit can proceed as a class action.

4/26 This month's issue of *Review of Ophthalmology* contains an interesting article by James Salz, MD, on how to use the **Autonomous Technologies** LadarVision scanning excimer laser. Because of the tracking system, Dr. Salz suggests that alignment for tracking should be done during the pre-op exam, to lock in the sites which will be used for tracking, a 3-4 minute procedure. Removal of the epithelium cannot be done with the laser, because it is too slow, and the actual ablation is about 50% slower than with a wide-area beam device for the same correction. The investigational system ran at 30 pulses per second, while the post-approval system will run at 60 pulses per second, taking about 10 seconds per diopter of correction.

4/27 According to *EyeWorld Week* the first formal hearing in the FTC investigation of **Summit** and **VISX** was held, with no substantive issues discussed. However, a trial date was set for October 13th, and it is expected that a protective order will be issued in the interim to keep certain documents in the trial confidential. VISX attorneys plan to ask for a stay pending a re-examination of its Trokel patent by the Patent Office, contending that a stay would benefit the case because the determinations of the PTO, which could take a year to conclude, should be included in the testimony. FTC lawyers said that the case should not be delayed by the re-examination, and would oppose the action.

OPHTHALMIC LASER UPDATE -- MAY 1998

4/27-
4/28 **TLC The Laser Center** announced that all of the terms and conditions of its offer to purchase common shares of **BeaconEye** had been satisfied or waived. Accordingly, TLC has obtained and paid for 10.6 million shares, or approximately 98% of the outstanding shares. With the acquisition, TLC's network now includes 45 laser centers (two of which are also secondary care clinics) and 16 secondary care facilities in 25 states and provinces across North America.

The following day, TLC announced that the underwriters of its recent follow-on offering have exercised their over-allotment option, purchasing an additional 690,000 shares at a price of US$14.50.

4/28 **LCA-Vision** reported 161% growth in first quarter revenues, on a 98% increase in procedure volume. For the first quarter, the company had total revenues of $7.2 million, up from $2.8 million for the same quarter a year ago. Corresponding patient volume nearly doubled to 4,451 from 2,248 in the first quarter of 1997. LCA had a net loss for the quarter of $1.6 million (4 cents/share), down from $1.8 million in 1997. EBITDA also demonstrated dramatic improvement over both the prior quarter and a year ago, cutting losses to $359,000 from $1.2 million and $1.1 million respectively. According to chairman Dr. Stephen Joffe, "The big jump in revenues reflects swelling demand for laser vision correction and a clear signal to us that our industry is about to move into high gear." The company currently operates 27 laser centers in the U.S., two in Canada, and one in Helsinki, Finland.

4/29 **Summit Technology** announced improved revenues for its first quarter, with total revenues of $21.8 million and net income of $177,000 (1 cent/share). Revenues from its vision correction business increased 53% to $10.1 million, which represented $3.3 million in laser system sales and $6.8 million in royalties and service fees. The remainder, $11.7 was revenues from its Lens Express subsidiary. The company noted that its financial performance continued to be impacted by VISX's failure to pay Pillar Point Partners procedure fees for LASIK procedures performed on VISX equipment, which Summit believes it is entitled to recover 100% because of VISX's failure to live up to the Pillar Point agreement. Summit also noted that the Santa Clara County Superior Court had summarily denied VISX's motion to dissolve Pillar Point, based on a suit filed last February.

4/29 **LaserSight** said that its booth at this year's ASCRS meeting was one of the busiest at the show, with particular interest in its wet labs for the ADK disposable keratome, attracting nearly 1000 surgeons for hands on practice with the device. Orders were secured from surgeons around the world. Special demonstrations were held for several laser center companies, including **ClearVision Laser Centers** and **LaserVision Centers**. Attendees also heard new clinical data regarding patients in Italy who had received planned topography-guided ablations with the LaserScan laser system.

4/30 According to *NewsPage*, **Premier Laser Systems** was awarded a patent on a corneal sculpting system for reshaping the eye. The system includes a laser delivery system coupled to a filter positioning system and a corneal topography system.

The same source reported that **VISX** also received a new patent for its excimer laser or other source of 193 nm UV energy with pulsed energy densities of greater than 20 mj/cm^2 at a rep rate up to 25 Hz, to direct its radiation through a mask. (See the 5/5 brief below for more information about this patent.)

5/4 **Autonomous Technologies** reported first quarter results with a net loss of $3.8 million (38 cents/share). The loss was in line with company expectations as it prepares to launch its LadarVision system in the U.S. later this year once PMA approval is obtained. (The company got an ophthalmic panel recommendation for approval on

February 17th.) Revenues from the sale of systems amounted to $59,000. Randy Frey, chairman and CEO noted that interest was high in the laser system at the recent ASCRS meeting.

5/4 A series of articles about **Summit Technology**, **VISX**, and **Pillar Point Partners** crossed the *Dow Jones Newswire*. Written by Louis Hau, they are presented in abridged form below:

--With refractive surgery forging new inroads in the vision-correction market, companies making money from the procedure would appear to be facing a bright future. But a complicated web of patent and regulatory concerns is clouding the outlook for some industry players. Lasers made by Summit Technology and market leader VISX have been approved by the FDA to perform PRK, to correct myopia and astigmatism. But neither has yet been cleared by the FDA to perform LASIK, which now accounts for the majority of refractive surgery procedures performed in the U.S.

Unapproved, "off-label" usage of a medical device is legal and not uncommon. What is unusual is to have an unapproved use of a device outstrip the approved use in the marketplace, as has happened with LASIK in refractive surgery. In a further twist, it isn't in VISX's financial interests to get its laser approved for LASIK. The reasons are related to VISX and Summit's patent-sharing partnership called Pillar Point, through which the two companies share a royalty fee of $250 on every refractive surgery procedure performed. The partnership was set up in 1992 as a way to resolve a number of patent disputes between the two companies. Last October, VISX stopped remitting royalty fees to Pillar Point for LASIK procedures performed on its lasers. It has argued that the partnership can only collect royalties on FDA-approved -- i.e. PRK -- procedures. Summit disagreed, saying it believes Pillar Point should collect fees on both LASIK and PRK.

The issue is crucial for both companies. First, VISX Chairman and Chief Executive Mark Logan estimates that LASIK accounts for close to 90% of the procedures performed on his company's lasers. Second, it is procedure fees, not laser sales, that are projected to make up the bulk of both companies' future revenue. Both report that fees already generate more revenue than equipment sales.

Another, more ominous cloud hanging over VISX and Summit is a Federal Trade Commission complaint filed in March against the two companies. The complaint argues that Pillar Point's patent-pooling arrangement is anticompetitive. The FTC has also charged VISX separately for allegedly acquiring a key patent fraudulently. The agency is seeking to dissolve Pillar Point and to prevent VISX from enforcing its claim on the disputed patent. Ironically, VISX itself is seeking the dissolution of Pillar Point in a lawsuit it filed in February in California Superior Court in Santa Clara County. Market observers note that the partnership is effectively costing VISX money, because it commands a far larger share of the refractive laser market than Summit. Analysts expect that Pillar Point will eventually be dismantled, whether by

the FTC or VISX. How that positions VISX and Summit for the future is still not clear.

If and when Pillar Point's patents revert back to VISX and Summit, **Hambrecht & Quist Inc.** analyst Michael Lachman believes the two companies will still be able to command royalty fees for procedures performed on their lasers. While other observers are predicting a drop in fees to $150 or $100, Lachman said that he can't foresee any market forces that could force a decline much below $200.

PaineWebber Inc. analyst Charles Olsziewski said he believes the procedure fees will fall over time but noted that growth in procedure volume should help to more than make up the difference.

Another question facing VISX and Summit is whether they will be able to charge royalty fees on competing laser makers entering the market. **Autonomous Technologies** is awaiting market clearance of its laser system, which an FDA advisory panel recommended for approval in February. Other laser makers winding their way through the regulatory process include **Nidek** of Japan, **LaserSight**, and **Bausch & Lomb**, which acquired **Chiron Vision** in December.

John Klobnak, chairman and chief executive of **Laser Vision Centers**, which uses only VISX lasers, said that while he expects the fees will eventually come down, he is concerned that a sharp drop could jeopardize VISX's financial health. "If these companies are to do business, they'll need those fees," he said. "It certainly isn't in our interests for VISX to go out of business."

Laser Vision Centers relies on VISX not only for capital equipment but supplies and service as well, Klobnak said. In addition, with procedures growth up sharply despite prices ranging anywhere from $1,500 to $2,500 per treated eye, "price does not appear to be a major driver," he said. Similarly, **TLC The Laser Center** Chief Financial Officer Peter Kastelic said royalty fees aren't a top concern for his company because the market for LASIK and PRK doesn't appear to be particularly price-sensitive.

"Obviously we'd love to see it go away," Kastelic said. "But our business model is working even with that fee there." Because of the uncertainties surrounding VISX and Summit, investors who want to play off growth in laser vision correction should avoid those names and look at companies like Laser Vision Centers and TLC, which don't face any negative risks from the FTC complaint, said Anne Anderson, president of **Atlantis Investment Co.**

Olsziewski and Lachman still like VISX's prospects. Olsziewski is maintaining a buy rating on the company. Lachman has a strong buy on VISX. He has a hold on Summit, which he notes is contending with shareholder lawsuits that were filed after the company's stock tanked in 1996, a weaker patent portfolio than VISX and a laser that hasn't been as well-received by doctors as VISX's laser.

--After an overhyped and disappointing launch just a few years ago, things are finally coming into focus for laser vision-correction surgery. Physicians and market observers say positive word of mouth from a critical mass of satisfied patients and a new surgical technique that delivers faster and less painful results have persuaded a rapidly growing number of prospective patients to try refractive surgery, as the laser procedure is known.
Precise industry wide figures aren't available. But operators of laser vision-correction centers, such as Laser Vision Centers, **LCA-Vision** and TLC The Laser Center, are reporting sharp rises in year-over-year procedure growth, pushing them closer to profitability. This growth also helped VISX, the leading manufacturer of refractive surgical lasers, vault over first-quarter earnings estimates.

"We're getting to the point where this is a big enough industry that people are making money, and I don't mean just VISX," said PaineWebber Inc. analyst Charles Olsziewski.
VISX Chairman and Chief Executive Mark Logan agrees, saying that he believes the number of Americans opting for refractive surgery could eventually reach about 30 million, about the same number that currently use contact lenses. Olsziewski expects the number of refractive procedures in the U.S. to reach 350,000 in 1998, between 500,000 and 550,000 in 1999 and about 1 million in 2000. Those are significant numbers, but they're still a far cry from the more aggressive forecasts that had circulated a few years ago. During the months before Summit Technology became the first company to get FDA approval to market a refractive surgical laser in October 1995, some industry experts (me, and Jonathan Cohen then with **SmithBarney**, using my forecasts) had projected 5 million procedures performed by the end of the decade.

5/5 **VISX** announced the award of another U.S. Patent, 5,735,843, relating to apparatus claims covering the removal of corneal tissue with a mask and an aperture that provides energy to the cornea, that is graded with more in the center than at the edge for myopia, or more at the edge for hyperopia corrections.

5/7 **VISX** announced that the Ministry of Health and Welfare in Japan had approved the VISX excimer laser system for PTK in that country to treat corneal scars and dystrophies of the eye. VISX is the first and only U.S. company to receive such approval, and it is the first step to obtaining PRK approval in that country. The approval was obtained in conjunction with **Alcon Laboratories**, Japan, which was VISX's marketing partner when the approval was first sought. Alcon will transfer the approval to VISX which will undertake the distribution and servicing of the approved excimer laser systems. VISX continues to work with the Ministry for approval of other vision correction procedures for Japan.

5/7 *The Federal Register* announced that the upcoming June 5th meeting of the Ophthalmic Devices Panel of the FDA would review a PMA for an excimer laser for

the correction of myopia using LASIK. (Perhaps this is the **Chiron Vision** (**B&L Surgical**) application?)

5/7 I received a research report on **Gimbel Vision International**, prepared by James Coulter of **McDermid St. Lawrence Securities**. The author believes that Gimbel Vision is well positioned to benefit significantly from international growth in the laser vision correction market and rates the company a "buy". The report notes that Gimbel has only limited expansion plans for the U.S., whose market the company believes is almost "saturated" and, therefore, is concentrating on growth in South America, Canada, and Asia-Pacific (including Australia and China).

5/8 An article in the *Rochester Democrat and Chronicle* outlined **Bausch & Lomb's** strategy for the future. According to writer Leslie Sopko, "Neither sunny skies nor sandy beaches were enough to inspire B&L last week to view its future through Ray-Ban sunglasses. When CEO William Carpenter gathered his troops at the pharmaceuticals division for the annual shareholder's meeting, his enthusiasm was for the company's less glamorous but more profitable side. Vision care, prescription eye medications, and ophthalmic surgery stole the show, and for good reason. Vision care...the manufacturer of contact lenses and sterile solutions is the company's largest, contributing 47% of revenues...pharmaceuticals revenues climbed slightly, while operating earnings jumped 28%...the surgical unit has already begun adding to B&L's revenues, which are expected to climb above $2 billion in the $25 billion eye-care market." Sixty-percent of revenues and 90% of operating earnings come from the vision care and pharmaceutical businesses -- without sales of the new surgical products. (No specific comments were made about refractive surgery except to note that industry analysts say that the growth potential for eye surgery products was staggering. And that B&L, through Chiron, will eventually compete in this arena, once it obtains FDA marketing approval. The company currently sells its surgical lasers only outside of the U.S.)

5/11 *Market Scope's* current issue reported that laser vision correction volume was up nearly 22% during the first quarter, reaching roughly 83,000 procedures in the U.S., and nearly 90,000 counting U.S. patients traveling to Canada and those procedures done on unapproved lasers and in clinical studies. This compares to about 74,000 for the fourth quarter. If the volume accomplished during the quarter holds up and increases occur in line with current increases for the rest of the year, the total volume should easily exceed early forecasts of 350,000 and could reach 400 to 450,000 procedures for 1998.

Market Scope also reported on the latest developments in the FTC/Summit/VISX/Pillar Point saga. VISX has requested a postponement of the FTC action pending having the Patent Office review the charges made by the FTC of fraudulent actions taken by VISX in obtaining several PRK patents. Although no official word about the request has been announced, the trial date of October 18th was

set for an administrative hearing. In the interim, the Patent Office has begun the process of re-examining the patents identified as fraudulent in the FTC complaint.

As noted by Summit in its latest quarterly release (see the 4/29 brief above), VISX's suit to dissolve Pillar Point was denied by a California court, but according to VISX, only an immediate dismissal was ruled upon. More action may be forthcoming on this suit. In related matters, two new lawsuits were filed against Summit and VISX accusing them of price fixing. One suit was filed by Metropolitan Eye of Clair Shores, Michigan, while the other was a class action suit filed by a Californian consumer.

Based on early information coming out of the recent ASCRS meeting held the end of the month in San Diego (as published in the May 15th issue of *Ocular Surgery News*), Summit and VISX CEO's said that they may jointly decide to abandon Pillar Point and just license their separate patents, maintaining some sort of a per-procedure fee.

Market Scope also presented a good review of the recent ASCRS meeting, picking up on the refractive surgery highlights on LASIK, LTK, intrastromal corneal rings, phakic IOLs, and the latest on PRK. As David Harmon put it, "With few dissenting opinions, LASIK, by consensus, is the procedure of choice for correction of low to moderate levels of myopia and astigmatism. The buzz surrounding LASIK was strong enough to overshadow interest levels in intrastromal rings, LTK, and phakic IOLs. Excimer lasers and microkeratomes attracted most of the interest in the exhibit halls."

5/11 **Sterling Vision** announced the acquisition of the assets and business of an ambulatory surgery center located in Garden City, NY, which contains four surgical operating rooms and is one of only 24 such licensed facilities in the state of NY, only 2 of which are located in Nassau County.

The company is also profiled in the May 11th issue of *Vision Monday*, which discusses 1997 results as contained in its 10-K report. The report details recent changes in Sterling Vision's approach to the laser surgery market, noting that at the end of 1997 the company had leased six excimer lasers; five of which were installed in ophthalmologists' offices and used by affiliated ophthalmologists who pay Sterling a fee for each PRK procedure, while the sixth laser was installed in the Sterling-owned **Insight Laser Center** in New York city. Sterling had originally planned to establish a chain of company-owned Insight Laser Centers, but found that revenues from such centers were modest and that the company was better served by collecting laser-use fees rather than administering complete programs. Therefore, the new strategy was to develop affiliations with refractive laser surgeons who pay to use the lasers installed in ophthalmologists offices, and to use the New York city laser center. Sterling expects its wholly-owned center will continue to operate at a loss for 1998, but at a lesser amount than was lost in 1997.

5/12 **LaserSight** announced that its PMA application for its scanning laser system had been accepted for filing by the FDA. This means that the FDA has conducted a preliminary

review and found the filing to be in order for full review. The PMA, submitted in March, contains data from multiple investigators at various sites within the U.S. The company further stated that FDA had determined that the PMA would not require review by its Ophthalmic Devices Advisory Panel, which should speed up the review process.

As a result of a telephone discussion with FDA personnel, I learned that placing a PMA before its review panel was up to the discretion of the FDA. And since they had recently reviewed a similar scanning laser (from **Autonomous Technologies**), unless some particular problems cropped up, the review would be conducted internally without panel review. LaserSight now joins Autonomous, **Chiron** (**B&L Surgical**), and **Nidek** in the que for PRK myopia approval.

5/12 **QLT PhotoTherapeutics** announced the preliminary data from two of its pivotal Phase III trials of verteporfin (BPD-MA) as a treatment for age-related macular degeneration. Based on an interim review of patient data, no significant safety concerns have been identified to date for the drug, based on the experience of 335 patients at 3 months, and 122 patients at 6 months. The drug is being co-developed with **Ciba Vision Corporation**. The randomized, double-masked, placebo-controlled studies -- known as the TAP investigations -- are underway at 22 sites throughout Canada, the U.S., and Europe. Since the studies are double-masked, efficacy data from the studies is not yet available. However, patient safety is being closely monitored by an independent Data and Safety Monitoring Committee, appointed for the TAP investigations. QLT and Ciba expect to conclude the one-year followup evaluations for the TAP trials this fall, with results analyzed for regulatory review in 1999. Pending approval, the companies project a commercial launch of verteporforin in 2000.

5/13 **LCA-Vision** announced the private placement of $10 million in convertible preferred stock with a group of institutional investors. Proceeds will be used to pay down debt and for general corporate purposes.

5/13 **Laser Vision Centers** announced that same U.S. laser revenue for April increased 180% over the same month a year ago, and that case volume was the best ever. For the quarter ending April 30th, case volume was up 30% over the previous quarter and 375% over the same quarter a year ago. Jack Klobnak, chairman and CEO, speaking at the Prudential Securities Small Cap conference in NY, that the company continued to see strong surgeon and patient acceptance of excimer laser procedures and the company's strategy of serving small and medium-sized markets with mobile lasers. Over 250 surgeons used the company's services during April.

5/13 **Gimbel Vision International** said that it had extended the exercise date of its warrants to August 26, 1999. Each whole warrant, as extended, entitles the holder to purchase one common share for $1.50.

5/14 **LaserSight** announced that it recently became one of only two laser manufacturers able to sell excimer lasers in Russia, when it received official registration from the Russian Ministry of Health. Geoff Clark, managing director of **BCK Medical Ltd.**, a LaserSight distributor, believes that Russian ophthalmologists are eager to gain knowledge about LaserSight's scanning laser systems. "As the largest country in the world, with 40-50 truly concentrated population centers, we're looking forward to working with surgeons to explore their various needs."

5/14 According to *Federal Filings*, **Autonomous Technologies** has run into a snag in its attempt to gain marketing approval for its vision correction system. News disclosed in its latest quarterly report to the SEC states that the FDA conducted a quality systems regulation (QSR) audit of the company's manufacture of the device in January which found various deficiencies. Autonomous said that it had submitted data it believes supports correction of the deficiencies, and anticipated a re-audit on May 11th. However, because the company had not completed all of the QSR process validation procedures, the audit was postponed to a later, undetermined date. The company believes that the process validation procedures will be completed in less than three months.

Autonomous issued its own news release announcing that it had signed an agreement with **DSR Optronics**, a subsidiary of **DRS Technologies**, as its exclusive manufacturer, to assemble, align, and test the electro-optical module of its LadarVision system, excluding the excimer laser component. The electro-optical module consists of all laser and optical elements, including the excimer laser device and narrow-beam shaping elements of the lower optics module, and the eye tracking and microscope elements of the upper optics module. DRS Optronics specializes in manufacturing complex military fire control and laser systems in compliance with stringent process controls meeting military product quality standards. Autonomous has ordered 50 electro-optical modules from DRS and has received three to date. Autonomous will integrate the modules with the separately sourced electronic assembly, and will conduct final acceptance testing at its Orlando headquarters.

Autonomous also acknowledged that the followup audit of its FDA QSR had been postponed while it completes further process validation procedures, which were expected to take less than three months. The company still believes it is on track to receive final marketing approval by late summer.

5/14 **LaserSight** released its first quarter results with revenues of $4.2 million, below the $6-6.5 million run rate for the previous two quarters. The company reported the sale of 14 laser systems, compared to 15 systems in last year's first quarter. Net loss from operations for the quarter were $1.96 million and the total loss, reflecting the effect of premiums and accretion on the redemption of Series B Preferred Stock, was $3.1 million (30 cents/share). The company also announced that **Vision Twenty-One** had provided most of the February payment (approximately $1.5 million) related to the purchase of two LaserSight subsidiaries in December 1997, but had not liquidated any

portion of the March and April installments, with remaining obligations of approximately $4.5 million through April 30th. LaserSight is entitled to receive at least $6.5 million, but not more than $7.475 million from the liquidation of all Vision 21 shares.

5/14 **Bausch & Lomb** and **Atlantic Pharmaceuticals** signed an exclusive worldwide licensing agreement for B&L to complete the development and commercialization of Atlantic's subsidiary **Optex Ophthalmologics'** Catarex cataract removal technology. The Catarex system involves a rotary device that operates at high speeds of 30,000 to 70,000 revolutions per minute, creating a vortex which draws the cataractous lens material to the probe and liquifies it for easy removal. The probe remains stationary at the entrance to the lens capsule, not requiring movement within the capsule as does a phacoemulsification or laser probe. The stationary positioning is expected to reduce the risk of damage to the lens capsule, and since early studies show that little heat is generated, it should also reduce the risk of tissue damage from burns. The Catarex technique has the potential to speed up the procedure, from about 4-12 minutes for phaco, to 1-3 minutes for the new procedure.

Under terms of the multi-year agreement, B&L Surgical and Optex will jointly complete the final design and development of the Catarex system, with B&L assuming responsibility for commercialization. Atlantic will receive an up-front and milestone payments and ongoing royalties on sales of Catarex products. Terms were not disclosed.

5/15 **LaserSight** announced that it had signed an agreement with **Humphrey Systems** that enables the two companies to develop and market software to be used for corneal-topography-planned ablations to correct refractive errors. The agreement establishes an exclusive arrangement between the two companies, and allows for the line of topography-planned software for Humphrey Systems to be available only on LaserSight's laser platform that is sold throughout various countries in international markets. (Humphrey Systems is a company of the **Carl Zeiss Group**, an international optics and technology firm.)

Senior managers at Humphrey and LaserSight believe that topography-planned ablations are imperative to having the best outcomes and will revolutionize refractive surgery. The majority of refractive patients and especially those with irregularities, could benefit from this type of surgery according to Dr. Jack Holladay, a researcher in topography-planned systems. "I'm enthused about what LaserSight and Humphrey are doing, because the best combination for surgeons would be topography-planned ablation implemented on a small-diameter scanning laser. The system would be the ultimate tool in tailoring refractive treatments".

5/15 This issue of *Ophthalmology Times* contains an easy way to distinguish between the myriad of microkeratomes available on the market. Dr. Ronald Krueger has put together a chart, shown below, that catagorizes the various microkeratomes. As can be

seen, he has split them up into mechanical and non-mechanical; further split the mechanical into oscillating or not; the oscillating into disposable and non-disposable; and the non-disposable into how they are hinged! I believe this is a worthwhile excercise and I applaud his efforts.

5/18 **Keravision** said it had received regulatory approval in Canada, the company's first market opportunity in North America, to sell its Keravision Ring to treat nearsightedness. The company intends to begin sales in the third quarter at a limited number of surgical sites across the country, to be followed by a broader distribution in the fourth quarter. The company plans to apply later this year for FDA approval for sale into the United States.

5/18 **LaserSight** announced that it had participated in Yale University's first-ever refractive surgery symposium, demonstrating the company's ADK disposable keratome, and by helping to sponsor guest speakers through an educational grant. The symposium, attended by approximately 100 ophthalmologists, optometrists, and technologists from the Northeastern U.S., coincided with the opening of the Yale New Haven Eye Laser Center. The company noted that it continues with final manufacturing and clinical evaluation of the ADK, and still expects to begin shipments to fill orders during the second quarter.

5/20 *Dow Jones* reported that **VISX's** share price continued their ascent, reaching a 52-week high of 50½ on reports of robust laser sales that should help it beat second quarter earnings estimates. In a meeting with Wall Street analysts, VISX executives said that hardware sales have been stronger than expected, according to **Hambrecht & Quist** analyst Michael Lachman. Lachman said that strong laser sales also bode well for the company's long-term outlook because they will translate into greater procedure fee revenue.

5/20 **Paradigm Medical Technologies** said that it had received FDA approval to expand into its Phase II clinical trials for its Photon laser cataract removal system. The expanded trials should begin in June. According to the company, the number of cataract removals passed the 2 million mark in the U.S. in 1997, and the volume continues to increase with the aging of the population. The company expects to file its PMA for marketing approval as soon as late 1998 for the system.

5/20 *Same Day Surgery* contains an interesting article about the use of mobile/roll on-roll off excimer lasers for use in settings that cannot support a full-time laser. The article discusses the advantages of the MobileExcimer and roll-on roll-off laser programs provided by **Laser Vision Centers** as an alternative to investing in a fixed system.

5/27 **TLC The Laser Center** announced that **Partner Provider Health, Inc. (PPH)** had signed a contract with **PHP Healthcare Corporation** to deliver integrated eye care services to military families and retirees in 10 Northeastern and mid-Atlantic states. **Sierra Military Health Services** serves as the primary contractor for **TriCare Managed Care Support** in Region 1, where more than 600,000 beneficiaries reside. PHP Healthcare is the subcontractor to SMHS for medical/surgical network delivery for 10 of the 12 states within the region.

5/27 **Paradigm Medical Industries** announced that it had received a Certificate of Exportability from the FDA, allowing the export of its Photon laser cataract removal system. The company has signed exclusive contracts with dealers specializing in distributing ophthalmic surgical equipment in 21 countries.

5/28 **Gimbel Vision International** announced its first quarter results with revenues of $6.2 million, up from $2.9 million for the same quarter a year ago. Earnings before interest, depreciation, and income taxes increased from $775,400 in 1997, to $1.1 million, while net earnings were $251,300, up from $121,200 in 1997.

5/28 At the **Summit Technology** annual meeting, shareholders re-elected two directors and heard an upbeat message about the firm's prospects from Robert Palmisano, CEO. He told shareholders that a new management team is tightly focused on a clear strategy to regain industry leadership and capture a rising portion of accelerating procedure volume. The company has largely completed a turnaround and should post solid profitability this year if it maintains its 30% market share and laser vision correction procedure volume reaches 350,000 in the U.S., as analysts predict. Palmisano also noted that, "Of the approximately 7000 refractive surgeons in the U.S., only approximately 1500 currently practice laser vision correction. That number will grow and our intent is to be their preferred partner." He also said that Summit would establish a new independent organization, the LASIK Institute, to act as an unbiased information source and bridge between clinicians and consumers. It would be directed by an independent advisory board of leading ophthalmic surgeons, some of whom will not be Summit users. At the meeting, shareholders re-elected Jeffrey Bernfeld and Richard Traskos to serve until the 2001 annual meeting.

5/28 **Laser Vision Centers** said that its options will begin trading on the Pacific Exchange and the Chicago exchanges on June 1st.

5/29 **LCA-Vision** announced that it had prepaid its term loan and re-negotiated its line of credit with the Fifth Third Bank of Cincinnati. The reduction in interest for the remainder of the second quarter was expected to exceed $75,000.

6/1 **Nidek** announced that the Ministry of Health and Welfare had approved its EC-5000 refractive laser system for performing PTK in Japan. It becomes the second company to win such approval, following last month's approval of **VISX**. The company also said that its PRK PMA for myopia had been accepted for filing by the FDA and was

currently under review, with final approval expected this year. The application for PRK covers myopia up to -15 diopters and PARK (astigmatism) for up to -4 diopters, representing a significant range of visual correction capability. The company claims to have over 300 systems installed worldwide.

6/2 *NewsPage* notes that a U.S. Patent was recently awarded to **Refractec** for a thermokeratoplasty system and method for locally heating and reshaping the cornea for visual correction.

6/3 **TLC The Laser Center** reported its fiscal fourth quarter and year-end procedure results. Over 13,900 refractive procedures were performed at TLC centers in the quarter, which includes just 6 weeks of **BeaconEye** activity, or 1301 procedures. The total was up 48% from the last quarter and 268% from last year's same quarter. The increase was primarily from same store growth, as only one new center opened in May. For the fiscal year, more than 35,800 paid procedures were performed, up 258% from fiscal 1997.

6/5 As speculated on last month (see the May 7th brief), the FDA Ophthalmic Devices Advisory panel reviewed and recommended the **Emory Vision Correction Center** LASIK technique for approval, not the **Chiron Vision** PMA. The Emory PMA application for treating up to -15 diopters of myopia, had originally been reviewed last July, at which time the review panel had requested additional followup information before giving their final recommendation. After reviewing the additional information, the review panel voted to recommend approval. The system includes the **Chiron** ACS microkeratome and the **Summit Technology** excimer laser with customized, proprietary software. The final approval from the FDA, once labeling is worked out, will enable the Emory Vision Correction Center to practice LASIK and to teach other ophthalmologists their technique. This will allow those trained ophthalmologists to advertise, for the first time, the availability of LASIK, that up to now has been available only as an "off label" technique, which cannot be advertised. The Emory researchers plan to file supplemental PMA's to cover the use of other lasers, including their **Nidek** system.

6/5 *NewsPage* noted that **Autonomous Technologies** had obtained a U.S. Patent for its "System for Automatically Inhibiting Ophthalmic Treatment Laser", which provides for automatic shutoff of the laser beam when a set threshold of eye movement is detected.

6/8 **VISX** and **Summit Technology** jointly announced they had reached agreement to dissolve the patent holding company they had formed in 1992, Pillar Point Partners. Each company will cross-license the other, on a world-wide royalty-free basis, to existing and future patents that would have fallen into the Pillar Point purview, which can be passed on to each company's laser users. VISX agreed to pay Summit a one-time charge of $35 million to settle all disputes between them. Both companies hope the dissolution of Pillar Point will allay further FTC legal actions, although disputed

VISX patents, also part of the original complaint, may still be pursued by the FTC. In addition, each company retains the right to license other manufacturers to all of their own patents.

In a telephone conference call held by VISX after the announcement, Mark Logan, CEO, responded to my questions about further action by the FTC by saying that VISX expects to sit down with the FTC and discuss and resolve any remaining concerns. He doesn't expect any changes in the per procedure fees currently being charged, as they include the rights to the **IBM** patents, the **Patlex** patents, use of proprietary software for the laser, and all of the VISX (and Summit) patents. As for licensing of other manufacturers, VISX already has six international agreements and expects to license its patent portfolio to others practicing vision correction in the U.S. as well. On another aspect of the agreement, the transfer of the cross license would cover acquired new technologies, if it would have generally been covered under the Pillar Point agreement. Logan also noted that VISX is looking into filing for LASIK approval. Their study protocol is ready to go as soon as they get questions about how to cover more than one microkeratome as part of their filing cleared up.

6/8 **LaserSight** and **TLC The Laser Center** made joint announcements about TLC making a strategic $8 million investment in LaserSight to create a mobile excimer laser business to open access to individual doctors and networks throughout North America. TLC, through its purchase of 2 million convertible preferred shares, now holds about 15% of LaserSight's outstanding shares. LaserSight will focus on providing and servicing advanced technology, while TLC will provide value-added services, including training, education, marketing, and information systems which include outcome analysis and database management. TLC's investment is intended to allow quick implementation of the mobile services and ready access to TLC's more than 6000 affiliated surgeons across North America.

LaserSight also announced that it had repurchased all of its existing Series B preferred stock and that it had received $4.3 million on June 5th from **Vision Twenty-One**, of which $2 million was used to pay off all of the company's outstanding indebtedness to Foothill Capital Corporation.

(It should be noted that LaserSight's original business plan, upon its formation, included the development of a mobile laser system, with more than 200 physicians signing on to have access to the mobile system. This part of the business plan had been put on the shelf, with the physicians under contract moved into the **Laser Vision Center** network, while other aspects of the business were developed.)

6/8 Anne Anderson of **Atlantis Research** held a telephone conference call for her clients, commenting on both the **Pillar Point** breakup and of **TLC's** investment in **LaserSight**. She mentioned that she now believes that there will be 330,000 procedures done in 1998 and 580,000 in 1999. She further feels that the market will level out at around the 600,000 level and that per procedure fees will come down, led by **Summit**, with

refractive procedure fees dropping from $2000 to $1200 for PRK and from $2400-$2800 to $1800 for LASIK as the volume picks up.

6/10 This month's issue of *Refractive Market Perspectives* says that corporate laser centers share of procedures is approaching 50% (now at 48%), even though they own less than 43% of all lasers. (Institution-owned lasers have a 21% share and surgeon-owned lasers have 31%.) David Harmon believes that the corporate centers are rising in procedure share because they are quick to relocate slow performing lasers and are able to attract additional surgeons to increase utilization, whereas individual surgeons and institutions are typically locked into a community and offer limited access to other surgeons in an area. He also notes that **Laser Vision Centers** moves the majority of its 23 lasers from site to site, leaving them in one location just long enough to service surgeons in that area. Apparently, **Clear Vision** has risen quickly in procedure market share. Although operating only seven lasers, it has a 13% share of corporately done procedures, beating out **LCA-Vision** with a 10% procedure share. **TLC The Laser Center** leads the field with a 27% share, followed by Laser Vision with 18%. Other corporate centers control 32% of the procedure market.

The newsletter also notes that George Mack of *Microsoft Investor*, an on-line magazine, published an extensive analysis on and recommendation for **VISX** on May 15th. Harmon believes that the recommendation helped propel the company's stock to an all time high, reaching $50 per share on May 20th. James Coulter of McDermid St. Lawrence published a research report on **Gimbel Vision International** (see my brief of May 7 in last month's newsletter), but his report didn't have the same impact as the one above.

6/16 **LaserSight** announced that it had completed an $8 million equity financing with Dawson Samberg Capital Management's Pequot Private Equity Fund L.P., and certain affiliates. The financing is a private placement of 2 million shares of Series D preferred stock, purchased at $4 per share, and convertible on a one-for-one basis into an equal amount of common shares, and is subject to certain anti-dilution adjustments. Over the past two weeks, the company has raised $16 million, and received approximately $4 million in cash from selling the **Vision Twenty-One** stock received last December in conjunction with the sale of two of its health care subsidiaries to Vision Twenty-One. The Series B preferred stock has been eliminated for $6.3 million, and $2 million of secured debt has been repaid to **Foothill Capital**. The balance of $11.7 million positions the company to bring its products into the U.S. market and continue international expansion.

The company also announced that it would reconvene its annual meeting on June 30th, which was adjourned on June 12th. As of June 12th, votes from only about 40% of outstanding shares had been received, as a large majority of the company's shares are held in retail brokerage accounts and delays occurred in delivering the proxy material to shareholders. At the meeting held on June 12th, company managers presented updates on several products and industry issues:

- All clinical data questions posed by the FDA for the Kremer PMA single-site LASIK laser have been answered, and the company is awaiting a response from the FDA.
- The FDA's clinical data review of the LaserSight LSX scanning laser PMA is near completion, with approval possibly expected later this year. The company is conducting internal quality system audits of its manufacturing facilities in preparation of the FDA's upcoming inspection, required for PMA approval. (And failed initially by **Autonomous Technologies**.)
- The company continues to work through the clinical and manufacturing validation process with Dr. Luis Antonio Ruiz for its ADK microkeratome, to ensure the highest quality in future mass production and to be prepared for anticipated recurring demand from refractive surgeons.
- The company successfully completed a feasibility study of its patented glaucoma treatment (with the excimer laser) and anticipates filing an IDE application in August to begin long-term clinical trials in the U.S.

6/16 **Autonomous Technologies** announced that it had received ISO 9001/EN 46001 certification. This followed rigorous inspections and audits of the design, manufacturing, installation, and servicing of the company's laser vision correction systems.

The company also announced that it had arranged for an additional $3.1 million in equity financing, completing a private placement of 600,500 shares of unregistered stock for $5.166 per share to four European institutional investors. The company will file a registration statement in the near future on behalf of the investors.

6/17 Today's *Boston Globe* reported that **Summit Technology** expects to settle price-fixing charges brought by the FTC shortly. According to a statement from Robert Palmisano, chairman and CEO, "We have had discussions with the FTC. This is not going to be a long-term issue for our company." However, even if the FTC suit is settled, Summit also faces several lawsuits filed by patients, relating to overcharges of the Pillar Point fee, and shareholders and ophthalmologists over other Pillar Point issues.

6/17 The *American Academy of Ophthalmology* released its first call on the upcoming annual meeting to be held at the Convention Center in New Orleans at the beginning of November, on the 8th through the 11th. The AAO expects over 26,000 people to attend, making it the largest ophthalmic meeting in the world, and the third largest medical meeting held in the United States. Some of the highlights:

- More than 400 companies will be presenting their latest and most innovative products and services;
- This year's Technology Pavilion will be a combined facility featuring presentations on the use of technology with corresponding hands-on exhibits and demonstrations;

- During the opening session, ophthalmologist Rubens Belfort of Brazil will discuss the global impact of the AIDS epidemic in this year's Jackson Memorial Lecture;
- In a combined meeting with the U.S. Eye Injury Registry, experts will discuss topics ranging from "shaken baby syndrome" to surgical considerations and vision rehabilitation in "Pediatric Eye Trauma Update"; and,
- Computer microchips and ablating lasers have made refractive surgery a possibility for millions of people around the world. Where will the field go from here? Refractive surgery experts will discuss safety issues, managing complications, and the next wave in refractive surgery in "Overcoming the Obstacles: The Quest for Perfect Refractive Surgery Correction."

Prior to the annual meeting, 3500 people are expected to attend the Academy's Subspecialty Day 1998, held on November 6 and 7. Four programs highlighting the latest developments in retina, refractive surgery, glaucoma, and practice management will be held.

6/18 Canada's *Financial Post* "Buy & Sell" columnist Sonita Horvitch reported that Denis Ouellet, senior vice president at Montreal's TAL Investment Counsel likes the outlook for **TLC The Laser Center**. He is quoted as saying, "TLC is very well managed...is the North American leader in this type of care (laser vision correction)...laser eye surgery should grow to be a substantial business."

6/22 *EyeWorld Week* reported that researchers in London, specifically John Marshall, PhD, chairman of the Department of Ophthalmology at St. Thomas Hospital, have reported that experiments using a low-energy diode laser retinal photocoagulation treatment, along with the Odyssey Optical Systems S2LO scanning laser ophthalmoscope, show that these very light thermal treatments can visualized, a breakthrough in retinal treatment. According to Dr. Marshall, incorporating a treatment diode laser into the Odyssey system permits visualization of the treatment areas using a corresponding imaging wavelength, which does less harm than with higher-energy treatments. Research associates Greg Heacock and Helen Cook plan to publish result of their ongoing work with the S2LO device. (Marketing rights to the device are held by Boston's **Mile Creek Capital LLC**.)

6/22 **Autonomous Technologies** announced that it had received permission from the FDA to conduct LASIK hyperopic astigmatism trials for up to +6 diopters of sphere and -6 diopters of cylinder. The clinical trials are scheduled to begin immediately and will include up to 150 patients, subject to certain conditions required by the FDA.

6/22 Seven Chester County firefighters underwent LASIK laser vision correction at the Plymouth Meeting's **TLC The Laser Center**, under the capable hands of Steven Siepser, MD, a leading laser eye surgeon in the Greater Philadelphia area. The six men and one woman were treated in less than four hours, and can now fight fires without eyeglasses or contact lenses.

6/22 Richard Burnett of *The Orlando Sentinel* wrote a feature story entitled, "Laser Firms Keep Eyes on the Future: Two Orlando Companies are Racing to get Federal OKs for Laser Eye Surgery Technology on a Bet the Winner will Reap Big Awards." The story was about the two excimer laser firms located in Orlando, **Autonomous Technologies**, and **LaserSight**. The thrust of the article was about which of the two companies would make it through the FDA first. Although Autonomous appears to be in the lead, with the FDA's panel's recommendation for approval in February, it has run into some problems with its manufacturing quality control audit, while LaserSight's PMA has been accepted for filing and apparently will be able to forgo the panel review. However, both expect to receive marketing approval by later this year. A second question is will there be a market for their devices once approved? But, since both companies have advanced technologies including a unique tracker and the ability to perform "custom corneas" for Autonomous and topography-controlled high scan rate-ablation for LaserSight, there appears to be technology advantages for each that should provide a healthy market for their devices.

6/22-
6/23 **Laser Vision Centers** announced that it had achieved profitability for its fourth fiscal quarter, ending April 30th, becoming the first publicly traded excimer access company to report a profit. Revenues for the quarter increased 179% to $7.8 million, from $2.8 million a year ago, with net income of $127,000 (1 cent/share), compared to a loss of $5.3 million (60 cents/share) in last year's fourth quarter. Revenues for the fiscal year were $23.5 million, up 185% from $8.2 million in 1997. The net loss for the year was $3.5 million (40 cents/share), down from $12.1 million ($1.45/share) in 1997. CEO and chairman Jack Klobnak said, "Laser Vision was the first company in this business and it has become the first company to report a profit...Just over a year ago we changed our business model and the fact that we are profitable within a year is remarkable...this industry is finally starting to live up to its potential." During the quarter, the company reported performing over 9900 cases worldwide, and subsequent to the quarter, it has done 3600 cases in May, of which 89% were done in the U.S.

The following day, Klobnak appeared on CNBC and attributed the company's success to both the technology and its accessibility, he said that the industry's success was due to referrals from satisfied patients. "We now have several hundred thousand people in America who've has this treatment. They're telling their friends, and word of mouth is really what's driving this business now." He mentioned that the company hopes to gain FDA approval for its lasers to treat hyperopia in the fall, adding the potential of an additional 54 million consumers domestically.

6/23 **TLC The Laser Center** announced the formation of a joint venture in Pennsylvania, called **TLC-Allsight The Laser Center**, located in Pittsburgh. The company is 51% owned by TLC and 49% by **Allsight, Inc.**, a private company owned by approximately 100 optometrists. TLC's investment is approximately $200,000 plus the proportionate assumption of equipment leases. Upon the holders of Allsight recouping

their investment, TLC has the right to acquire an additional 20% of the venture for $1, increasing its stake to 71%.

6/25 *The Financial Post* carried a story about **TLC The Laser Center**, saying that the company was executing its business plan with 20/20 vision. Although the company may still be in the "red", Keith Damsell, the Post's technology reporter, said that hasn't stopped the company's shares from "zapping their way to the top of the Toronto Stock Exchange. A rising number of patients and a rapid series of acquisitions have sent the shares...climbing." The stock has risen from a 52-week low of CDN$9.50 on October 27th, to a record high of CDN$27.75 on June 4th on the TSE. (And doing the same on NASDAQ, climbing from a low of $7.25 to a high of $19.125 during the same period.)

Several analysts have expressed similar opinion. "The laser correction market is growing hand over fist," says analyst Mike Jams of the Montreal office of **Levesque Beaubien Geoffrion Inc.**, and at least three Wall Street brokerages have "buy" ratings on stock:
PaineWebber Inc., **SBC Warburg Dillon Read Inc.** and **Hornblower & Weeks Inc.** "There is still tremendous room to grow," says Hornblower president John Rooney. By the end of 1998, Rooney expects the shares to hit US$20 and top US$25 in 1999. In the fourth quarter ended May 31, the company performed 13,900 procedures, more than triple the number performed one year earlier. PaineWebber had forecast only 11,200 procedures during the three-month period. In a June 8 update, the brokerage says TLC "is particularly well positioned to capitalize on dramatic industry growth." It has a 12-month target price of US$21 to US$22 on the stock. Despite the huge patient volumes, analysts do not expect TLC to make a profit until the first or second quarter of 1999. The company's continuing losses are due to rapid revenue growth through acquisitions. The resulting growing pains have slowed earnings momentum.

Although competition may be fierce among the various laser centers, analysts say the laser trade has a long way to go before it peaks. For example, Toronto has nine eye laser surgery clinics and none have suffered from direct competition, said one New York analyst who asked not to be identified. "We're not seeing a lot of pricing pressure," the analyst said. "The getting is good for everyone right now."

6/27 I received a package of information about **MedNet International**, a company founded in 1996 to develop eyecare centers in China. (This certainly was timely, considering the President's visit to China taking place as I was reading the MedNet material!)

MedNet had set up and was operating 9 eye centers in partnership with local hospitals in densely populated areas in China by the end of 1997, and expects to open an additional 3 centers in 1998. All of the centers are equipped to provide eye exams, argon laser treatment for glaucoma, and conduct cataract surgery, while 4 centers are equipped to handle retinal and refractive surgeries. The company is run by Dr. Craig Beyer, president and CEO (and formerly associated with **LaserSight, Inc.**); Jimmy

Lee president and CEO of **Mercer International**, as chairman; with Eugene Chen, vice president and COO, a former director of operations at **Johnson & Johnson** in Shanghai; and William McCartney, CFO.

According to a report from **MEC Merchant Bank, SA**. provided by the company, MedNet had net income of CDN$33,600 in 1997, on revenues of CDN$4.7 million. The analysts estimate that the company will grow to revenues of CDN$9.1 million in 1998, providing net income of CDN$374,700. Analysts Jacques Frehner and Edouard Seligman of MEC say that at an average of US$400 per procedure (cataract and/or excimer laser surgery), the Chinese market could represent over $2 billion in revenues with just a 1% penetration of the 1.2 billion who suffer from eye disorders. The 4 laser centers operated by MedNet performed 1338 refractive procedures during the fourth quarter of 1997 (averaging 111 cases/laser/month during that period).

Apparently, the company has little direct competition in China. Although there are over 100 excimer lasers operating in China, most are run by individual investors, and are located in government hospitals or clinics, with the original purchaser of the equipment receiving a per procedure fee for the equipment's use. Generally, according to the MEC report, these operators suffer from a lack of range of services, management, training, infrastructure, and organization, all of which are provided by MedNet. The only organized competitive approaches are those of **Shooting Star Technologies**, who claimed they would open 6 eye care centers in Asia by the middle of 1997, and have announced memos of understanding with hospitals in Beijing and Jinan; and **Thaiko Corporation**, a private Taiwanese company that operates 8 eye centers in Taiwan, and currently participates in two Chinese eye center joint ventures, one at the Tongren hospital in Beijing, and the other at a military hospital in Xian. Thaiko is primarily funded by Taiwanese ophthalmologists and has limited financial resources and management.

OPHTHALMIC LASER UPDATE -- JULY 1998

6/29 **Paradigm Medical Industries** and **National Healthcare Manufacturing** announced that they have formed **Ophthalmic Product Alliance** and signed a co-distribution agreement with **Pharmacia & Upjohn**, covering a range of ophthalmic products. Under terms of the agreement, the three companies will offer a comprehensive package of products to cataract surgeons, including surgical equipment, IOLs, pharmaceuticals, surgical instruments and sterile procedure packs. Paradigm will provide a turnkey ordering and delivery of its cataract extraction equipment line of products from its Salt Lake City headquarters; National Healthcare will employ its fully automated production facility to package a line of standard and custom sterile procedural packs; and Pharmacia & Upjohn will provide Healon viscoelastics and its CeeOn line of IOLs to the alliance.

6/29 **LCA-Vision** announced that it had secured an $8 million line of credit with the Provident Bank of Cincinnati, to bolster its financial strength and its ability to take

advantage of attractive growth opportunities. The new covenant carries a more favorable interest rate.

6/29 *Dow Jones* reported that **SBC Warburg Dillon Read** analyst James Lane had downgraded **Laser Vision Centers** to "buy" from his previous "strong buy" rating.

6/29 *Ocular Surgery News Intelligence Report* reported that it will be **VISX** appearing before the FDA's Ophthalmic Device Advisory Panel July 23rd, seeking to gain approval to perform hyperopic correction using PRK. The newsletter said that the company would not discuss the specific range of correction sought.

6/30 **LaserSight** reported that its shareholders approved two proposals presented at its annual meeting, as well as electing all of the nominated board of directors, and ratifying KPMG Peat Marwick LLP as its auditor. The two proposals approved included amending the conversion terms of the company's former Series B Convertible Participating Preferred Stock and reducing the exercise price of the warrants issued to the Series B Preferred stockholders in August 1997. Shareholders also approved an amendment to the company's 1996 Equity Incentive Plan to increase the number of shares available and to implement certain technical changes to the plan.

6/30 **Sunrise Technologies** said that it had completed enrollment for the Phase III study for the treatment of low to moderate hyperopia. To date, the company has treated over 650 eyes with its holmium laser, and have found zero adverse events, sight threatening complications, and loss of best corrected visual acuity at the stability endpoint. The company has placed 40 lasers internationally where there also has been no reports of problems or complications.

7/1 **LCA-Vision** reported that second quarter correction procedures rose 103% to a record 5,677, up from 2,971 procedures for the same centers a year ago. Through the first half of the year, LCA centers have performed a record 10,127 procedures, versus only 6,271 for the first six months of 1997. If the centers acquired from **Summit Technology** last year are excluded, LCA's original wholly-owned centers grew at a 141% pace for the quarter, and were up 166% for the year. Commenting on the results, Dr. Stephen Joffe, chairman and CEO said, "We continue to foresee operating profitability in the third quarter. Our free-standing business model has demonstrated that we can achieve and sustain profitable growth...our progress in turning around the former Summit centers has been significant." (In a separate letter to shareholders and other interested parties, Dr. Joffe reiterated the good news and noted that "with losses steadily declining, we expect to be cash flow positive in the third quarter.")

7/1 This issue of *Ophthalmology Times* contains a story about the dissolution of **Pillar Point Partners**. In the story, San Francisco attorney John Alioto, who had filed a class action suit against Pillar Point, said he felt vindicated but still seeks triple damages of whatever amount a court deems has been overcharged because of Pillar Point in accordance with antitrust laws. Both **VISX** and **Summit Technology** have previously

expressed skepticism that Alioto's clients will collect any damages from them, but Alioto plans to continue his action, which he says could take a year or more to resolve.

7/6 **LaserSight's** board of directors announced the adoption of a "shareholder rights plan" and declared a dividend distribution of one preferred share purchase right for each outstanding share of common stock. Michael Farris, president and CEO, said, "The rights are designed to assure that all LaserSight shareholders receive fair and equal treatment in the event of a proposed takeover of the company, and to guard against partial tender offers, squeeze-outs, open market accumulations, and other abusive tactics to gain control of LaserSight without paying all shareholders a control premium. The rights will not prevent a takeover, but should encourage anyone seeking to acquire the company to negotiate with LaserSight's board of directors prior to attempting a takeover." The rights will be exercisable only if a person or group acquires 15% of the company's stock, or announces a tender offer which would result in ownership of 15% or more.

7/7 **TLC The Laser Center** announced that it had been chosen to take part in the **CRS Corneal Research** IDE for hyperopia study in the U.S. (Both **VISX** and **Summit Technology's** lasers are being evaluated in the CRS hyperopia study.) A total of 7 TLC centers will be involved in the study, including centers in Atlanta; Boca Raton, Florida; Rocky Mountain, Colorado; Houston; Manhattan; Rockville, Maryland; and Tulsa, Oklahoma. According to the news release, some 70 million Americans are hyperopic, potentially doubling the market for laser vision correction in the United States. TLC is currently upgrading all of its excimer lasers in the U.S. in anticipation of future FDA approval for the treatment of hyperopia. (See the note above, about VISX seeking hyperopic approval at the upcoming FDA device panel meeting.)

7/8 This month's *Refractive Market Perspectives* contains an interesting story about **Autonomous Technologies'** attempts to avoid **VISX's** allegedly blocking patents, once Autonomous obtains FDA marketing approval. Autonomous had filed suit to obtain an opinion that it does not violate the VISX patents but, according to Autonomous chairman and CEO Randy Frey, "VISX has done everything in its power to prevent the case of merit from coming before the court", claiming Autonomous has not yet begun marketing its laser in the U.S. and, therefore, has yet to violate its patents. Obviously, this delaying tactic will dramatically slow down Autonomous once it does get approval if VISX's position is upheld by the courts. Frey contends that his company's system does not infringe VISX patent claims, but would like to get the situation clarified prior to getting marketing approval.

(The updated 1998 Market Scope Refractive Market Directory will become available on July 20th, for $195. If it is anything like the previous 1996 version, it will be well worth your money. Call Dave Harmon at 888-806-4015 to obtain your copy.)

7/8 Both **Summit Technology** and **VISX** announced that they had signed separate consent agreements with the FTC, resolving all charges brought by the FTC against the companies concerning their formation of **Pillar Point Partners**. The consent agreement was entered into after both companies agreed to dissolve Pillar Point in June. The consent orders both companies to provide various rights and information to their respective customers and prohibits them from entering into licensing fee agreements with each other. It does not prevent them from charging a per procedure fee for use of their equipment, nor is it an admission or finding of wrongdoing on their parts.

For VISX, the consent agreement does not address the patent portion of the FTC's complaint, but reduces the remaining issues to technical matters involving the prosecution of one patent and the way in which VISX resolved interferences in 1990 on several of its patents. VISX believes it can resolve the remaining issues with the FTC.

7/10 The July issue of *Ophthalmology Management* contains an interesting article about how the new **VISX** Star S2 laser accomplishes smoother ablations. According to the story, the scanning system splits the laser beam into seven smaller diameter beams which rotate while expanding in size and moving across the cornea during the ablation cycle.

7/14 **Iridex** announced that sales and earnings for its second quarter will not meet consensus analyst's expectations. The company expects sales to be approximately $6 million, below analyst's estimates of $6.1 to $6.6 million. As a result, the company expects second quarter earning of approximately 8 cents per diluted share, which is flat compared to last year, and below analyst expectations of 11 cents. According to president and CEO Ted Boutacoff, "While we set another quarterly sale record for the company, softness in international orders, particularly from Asia, could not be offset by additional domestic orders and shipments...This quarter we shipped additional diode laser systems to **Miravant**...(for) use by research centers for a Phase III clinical study...for the treatment of age-related macular degeneration...The recent grant of fast track status...for this treatment is another opportunity for use of our products in leading edge medical technologies."

In a separate announcement, the company said it had successfully completed CE assessment and had received CE certification for its laser products, allowing sales to the European Union countries.

7/15 **Sunrise Technologies International** announced that it had entered into an agreement with Harrison Wilson & Associates and Ketchum Public Relations of **Omnicom Group** for work associated with the U.S. launch of its Sunrise LTK system for the treatment of low hyperopia, which is in clinical trial in the U.S., but currently in use in Europe and the Americas.

7/15 **Laser Vision Centers** announced that U.S. laser revenue for same systems increased over 120% in June compared to the same month a year ago. The company said that June was the best month to date for U.S. surgical volume and that over 230 surgeons used its laser services during the month.

7/15 The May issue of *Review of Ophthalmology* reports of new developments disclosed at the recent ARVO meeting. In the section on refractive surgery, written by Dr. Sadeer Hannush, in addition to clinical updates on both PRK and LASIK, Dr. Hannush notes that the 1.9 micron diode laser from **Rodenstock** may work better than the holmium laser in LTK. According to the report, researchers using the Rodenstock diode said that they were able to correct up to 5.5 diopters of hyperopia and up to 3.75 diopters of astigmatism, which stabilized after 120 days and remained stable throughout the 440 day follow-up period. As with the **Sunrise Technologies** laser, the procedure works best on older people.

There is also a report on the 450 femtosecond intrastromal laser being tested by researchers from the University of Michigan and from Heidelberg University. The laser was used to create stromal flaps and also to ablate stromal tissue without affecting the corneal surface. The work was done on rabbits. There was also a paper on an infrared optical parametric oscillator laser that is said to produce equivalent results to an excimer, but with less haze; and an ultraviolet 213 nm laser which researchers say also compares favorably to the excimer.

7/15 **VISX** reported its second quarter results with record revenues and operating profit. The revenue for the quarter was $31.7 million, up from both the second quarter last year $15.6 million, and from the first quarter this year of $24.3 million. Income from operations was $14.4 million, but net income was a loss of $15.3 million ($1.01 per share), primarily because of the $35 million payment to **Summit Technologies** as part of the deal for dissolution of **Pillar Point Painters**. Revenues for the six months were $56 million, up from $31.3 million last year. The revenue for the quarter was made up of $9.4 million in system sales and $22.2 million from license and service revenues. For the six month period, system sales accounted for $17 million and license and service revenues for $39 million. (My "back of the envelope" calculations work out to about 54,000 procedures for the quarter and 124,800 for the half year. If VISX systems account for approximately 70% of all procedures done, then the latter figure works out to a 360,000 procedure year for the industry.

During the teleconference following release of the quarterly results, Mark Logan, president and CEO, and Tim Meyer, CFO, noted that the company shipped 33 lasers during the second quarter, about 21 lasers domestically, 8 to Asia, 3 to Europe and 1 to South America. According to Meyer, the average price of the systems sold during the quarter was about $300+, because of the mix of leased machines, trade-ins, and new system sales. (Actually, the average price was closer to $286,000.) And Logan expects to sell about 35 systems next quarter, with demand slackening off after that. The company has about 220 lasers operating in the U.S. and roughly the same number

outside of the U.S. Logan believes that there are about 450 lasers currently operating in the U.S. (Summit's 170 and about 50 investigational devices). He also believes that saturation will occur with about 600 systems in operation, after which it will be very difficult to place new units. (I believe that saturation will be about 800 units.)

VISX will appear before the FDA's Ophthalmic Review Panel on July 23rd for review of its hyperopia application. If they are successful in obtaining panel recommendation for approval, Logan expects to be able to offer the service before the end of the year. It will involve an equipment upgrade, in addition to software upgrades. Logan doesn't believe that hyperopia approval will have much of an effect on procedure volumes, as evidenced in other countries where it is already being done.

7/15 According to the current issue of *Laser Report*, **Schwartz Electro-Optics** (SEO) had sold its Orlando, FL solid-state division to **LaserSight** last April. An inquiry to LaserSight brought the response that the transfer occurred on April 15th, with LaserSight acquiring essentially all of the assets and assumed liabilities of SEO's medical products division for 305,820 shares of common stock, with the value of the acquisition placed at $1.25 million. The division develops, tests, manufactures, assembles, and sells solid-state lasers and their related equipment, accessories, parts and software, for medical and medical research applications, with its primary focus on erbium:YAG lasers used in dermatology. (**Does this mean that LaserSight is going to expand into the dermatology/plastic surgery cosmetic/aesthetic arena?** We will have to wait and see what the company says.)

7/16 **Sight Resource** said that it's **SightCare** managed care division had been selected to offer vision care services and products to a group of non-union state employees and their dependents covered by the Commonwealth of Massachusetts Group Insurance Commission. Under terms of the agreement, SightCare will provide vision care benefits to approximately 8000 employees and their dependents, which amounts to approximately 18,000 individuals.

7/16 **Gimbel Vision International** reported that the number of refractive procedures performed at its 14 centers rose to 4119 during the second quarter, an increase of 87% from last year's second quarter, and up 25% from this year's first quarter. (The results include volumes from the company's Australian subsidiaries for April and May.) President and CEO Glenn Gimbel attributed the increases to same-store growth as well as start-up volumes in the company's new center in Rio de Janeiro.

7/16 **Summit Technology** announced the launch of its "Elite Athlete Vision Correction Program". The program was designed to offer laser vision correction to world class amateur athletes who are Olympic hopefuls and will be directed by Dr. Barry Seiller, medical director of the Visual Fitness Institute of the Eye care Center of Lake County, Vernon Hills, IL, and director of visual performance for the U.S. Ski, Bobsled, Snowboard, and Luge teams. He will perform laser vision correction on two of the

Olympic medal winning members of the U.S. Luge team and members of the U.S. Ski team and their coaches and trainers.

7/17 This month's issue of *EyeWorld* contains several interesting articles. Paul Gerber and Marjolijn Bijlefeld write about how PPMCs approach refractive surgery, with three different models emerging; access to outside lasers for their physicians, operating an open facility, or creating a closed facility only for its managed equity partners. Among the PPMCs mentioned are **Omega Health Systems**, **NovaMed Eyecare Management**, **Vision Twenty-One**, and **MedSynergies** and **Pioneer EyeCare**.

Maxine Lipner writes about "Sleuthing the sands of Sahara", about the sometimes present powdery substance noted in some cases of LASIK, and how no one seems to understand where they may come from. Maxine also has an interesting article on new treatments for age-related macular degeneration, noting the photodynamic therapy approaches and some others, including radiotherapy. And finally, a group of doctors at the Retina and Vitreous Associates of Alabama discuss a new laser treatment for the prevention of retinal detachment in those people who may be susceptible to that phenomenon. The procedure is called "laser cerclage" and consists of a 360° band of laser spots around the peripheral retina, from the equator or vortex veins to the ora serrata. A pattern-type treatment is applied using the indirect ophthalmoscope laser. No mention is made of laser type, but I assume they are using a "green" laser, either an argon or doubled YAG.

7/20 **Medjet** announced that it had extended the expiration date of its publicly traded Class A Stock warrants until November 6, 1998.

7/20 *Dow Jones Online* had a story about the upcoming FDA Ophthalmic Panel review of **VISX's** hyperopia application. According to analyst Michael Lachman, the demand for the procedure won't be as high as it is for nearsightedness. In markets where the procedure is already approved, which includes Canada and European countries, Lachman estimates hyperopia makes up about 10% to 30% of the market. Although Lachman said estimates show about 20% of the population is farsighted and 25% are nearsighted, many of the people considered to have hyperopia just need reading glasses. "That has similarities, but it is age related and not directly treated with a laser," he said. Lachman expects demand for the laser procedures to continue its upswing, taking Visx's 1997 sales of $69 million to $117 for 1998. He also projects in 1999 sales to hit $128 million, but only about 7% of the procedures will be on hyperopia, which he assumes will be approved by the end of this year. Since most of the people with hyperopia are older than those with myopia, or nearsightedness, Lachman expects age to be a factor in sales. "The people with hyperopia are more affluent," Lachman said. "But they are also a more conservative group."

Dow Jones Online also reported that last week, **Summit Technology** submitted its application to the FDA to have its hyperopia laser approved.

7/21 **Bausch & Lomb** reported its financial results for the second quarter, with its net income increasing 21%, to $55.5 million (98 cents/share) from $20.3 million (36 cents/share) for the same quarter a year ago. The latest quarter included a restructuring charge of $5.1 million, a gain on divestiture of $33 million and costs of $10.2 million on purchase accounting adjustments for inventories acquired with the **Chiron Vision** and **Storz Instruments** purchases. Sales for the quarter rose to $635 million, including $629.5 million form ongoing product lines. Revenues from its pharmaceutical/surgical businesses, which include products from Chiron and Storz, were $162.9 million, compared to $54 million a year ago, reflecting sales of the new companies' products. $104.1 million of the total $162.9 million in the ophthalmic drug and surgical businesses were revenues generated by the pharmaceuticals and surgical product lines of the former Chiron Vision and Storz Intruments.

OptiStock reported that B&L is restructuring to cut $100 million in costs by next year and eliminate 1,900 of its 15,000+ jobs.

Several days later, B&L priced a multi-managed deal covering $500 million in debt. According to *Capital Markets Report*, The deal was remarkable due to the variety of underwriters for the four-part offering. $100 million thirteen year notes were underwritten by **Morgan Stanley Dean Witter**, another $100 million 15 year note was done by **Warburg Dillon Read**, **J.P. Morgan Securities** underwrote a 27 year note for $100 million, and 30-year notes were also led by Morgan Stanley Dean Witter. Proceeds from the deal will be used to pay down short-term debt associated with Bausch & Lomb's acquisition of Chiron Vision and Storz product lines last year.

7/22 Dr. Robert Maloney, of the **Maloney Vision Institute** in Los Angeles, announced that the FDA had approved the results of Phase I clinical trial for a revolutionary implantable lens to correct nearsightedness. The Artisan Myopia Lens, a 5 mm iris claw-type acrylic anterior chamber IOL, is implanted directly behind the cornea and in front of the natural lens, in the anterior chamber. The procedure takes about 25 minutes, and is similar to IOL implantation during cataract removal and replacement surgery. The procedure involves only mild discomfort, according to Dr. Maloney, and results in perfect vision in as little as 24 hours. The lens, developed by Dr. Jan Worst of the Netherlands in 1978 for aphakic correction, and formerly known as the Worst Iris-Claw lens, was adapted for myopia (phakic correction -- the Worst Myopia Claw lens, and now renamed as the Artisan Myopia lens) in 1986. It has been successfully implanted in more than 5000 Europeans over the last ten years. Maloney is one of two U.S. eye surgeons who participated in the first phase trials, which are now approved for expansion into Phase II to include 110 additional patients this year and, once approved for Phase III, will include 550 people, hopefully in 1999. The cost of the procedure is $2500 to $3500 per eye, depending on whether the procedure is done in an ambulatory surgery center or in a hospital OR (and also varies with geographical area), compared to $2500 for laser eye surgery. Dr. Maurice Johns of Jeffersonville, Indiana was the other Phase I investigator. Eight additional doctors, including Richard

Lindstrom, will be involved in the Phase II trials. The U.S. clinical trials are sponsored by **Ophtec USA** of Boca Raton, FL.

7/23 **TLC The Laser Center** reported its fiscal fourth quarter results, for the period ending May 31, 1998. Gross revenues for the fiscal year were $90.6 million, up 276% from last year's $32.8 million. For the fourth quarter, gross revenues were $32.3 million, compared to $14.1 million a year ago. Net revenues for the year were $59.1 million, up 294% from last year's $20.1 million, while net revenues for the quarter were $20.6 million up from $8.6 million last year.

More than 35,800 paid procedures were performed in fiscal 1998, up 258% over fiscal 1997. Over 13,900 procedures were done during the last fiscal quarter. The vast majority of TLC's revenue growth came from the company's core business -- refractive surgery, with more than 90% of fourth quarter revenues derived from the provision of laser vision correction services.

The net loss for the fiscal year was $9.5 million (34 cents/share), with the fourth quarter contributing a loss of $2.8 million (9 cents/share). (The fourth quarter loss included a non-recurring charge of $1.5 million against secondary care operations. The company generated positive earnings before interest, taxes, depreciation, and amortization (EBITDA) of $4.5 million for the fiscal year, and reflects a positive swing of $9.6 million over the 12-month period.)

Of the net revenues for the quarter, $18.7 million of the $20.6 million came from refractive procedures. For the year, $51.1 million of the $59.1 million came from laser vision correction revenues. (If I have done the math right, the average net amount collected by TLC for PRK/LASIK during the fourth quarter was about $1345 per eye, and for the fiscal year, was $1427 per eye. It looks like procedure charges are on the way down! However, during a teleconference following the press release, Elias Vamvakes, president and CEO stated that the retail pricing for PRK/LASIK was holding strong and that TLC was getting between $2400 to $2750 per eye, depending upon the market. TLC is typically the price leader in its markets.)

Other interesting items gleaned from the teleconference:

- With the strong procedure growth -- its centers are averaging between 115 to 120 procedures per month, with some centers averaging 130 procedures per month -- the company intends to add an additional 12 to 15 clinics this year.

- The company focus is on increasing patient flow and penetration rates in the markets it serves.

- If Canada serves as an example, hyperopia approval should add an additional 20% to procedure growth. All of the TLC centers are being upgraded in

anticipation of hyperopia approval in the next several months. (VISX won ophthalmic panel approval for hyperopia -- see the brief below.)

- As with its competitors, TLC expects to reach profitability in 1999, achieving positive cash flow during this past quarter. The company was able to bring **Twenty-Twenty** profitable within six months of acquisition, and expects to do likewise with **BeaconEye**.

- Canadian centers are doing 85% to 90% LASIK and U.S. centers are getting there. Some high volume surgeons are at 80%.

- About the LaserSight deal, it was a strategic investment in both the new laser scanning technology as well as building a mobile capacity.

- About the $250 procedure fee that TLC pays to VISX, they are in ongoing negotiations about reducing it, and are currently paying more than $1 million per month, so any reduction would be significant.

- Mr. Vamvakes expects that there will be more consolidation in the marketplace, with many of the single doctor operations joining in with corporate entities to gain the marketing clout that the corporate centers can achieve.

7/23 *Federal Filings* released a question list posed by the FDA to its Ophthalmic Devices Advisory Panel for consideration of this afternoon's presentation by VISX regarding its supplemental application for the Star S2 laser for treating hyperopia. Among the questions was one about whether the data supported the full range of +1 to +6 diopters of correction? Another questioned the differences in results (apparently significant) between the Canadian and U.S. clinical trials. And finally, the FDA questioned whether the existing data was sufficient to establish the time course of post-operative refractive changes and the time to relative stability, or whether additional analyses and/or followup data was needed.

7/23 Later in the day, *Federal Filings* announced that the FDA's Ophthalmic Devices Advisory Panel had recommended to approve Visx's Star S2 Excimer Laser System for the treatment of hyperopia for patients with certain conditions. However, the panel was split on its recommendation of use of the laser for the full range of patients for which the company was applying, because the sample size of those with high degrees of hyperopia was very small. Although the effectiveness of Visx's Star Laser System was established, the panel members were split on the issue of the stability profile of the device for certain patients. Panel members also indicated that changes should be made to the device's label.
The company had asked the panel to recommend approval of the Visx Star Laser System for the full range of hyperopia, +1 to + 6 diopters. The Visx clinical trials included 13 eyes in Canada with the worst form of hyperopia, in the four to six range.

The FDA panel split over whether that was enough information to recommend the laser for patients with the most severe form of hyperopia.

Dow Jones Online wrote that the FDA' review panel had given VISX "conditional backing" for its system to correct farsightedness for correction of hyperopia of +1 to +6 diopters. The panel recommended approval under the following conditions:

- the company continue to follow patients who have undergone the procedure;
- that the laser's label indicate that women undergoing hormone replacement therapy and people taking antihistamines may heal more slowly; and,
- that the company continue to gather long-term patient satisfaction information.

This announcement followed a presentation by VISX spokesperson Dr. James Salz, who presented the panel members with the efficacy data for the laser system to treat hyperopia. Salz pointed out that, along with the effectiveness of the device, predictability, stability and patient satisfaction were assessed. He concluded that by three months of treatment with the laser system, patients reached a stable refraction of hyperopia to normal vision. Patient satisfaction rated 97.3% at six months and 93.5% at 12 months.

Regarding the safety profile, the company spokesperson noted that some adverse events were noticed, such as haze, intraocular pressure (IOP) and induced astigmatism, however, only in small percentages, indicating that there were none that posed overall safety concerns. Adverse events such as intra-operative corneal bleeding, lid edema, posterior vitreous detachment and foreign body sensation, were also minor. During a two-year follow-up, there were no new adverse events recorded.

In its studies, Visx said the average time for healing after the laser surgery was less than five days. The Santa Clara, Calif.-based company's clinical trials looked at the procedure performed on 222 eyes in the U.S. and 53 in Canada. VISX also noted that U.S. Census data from the 1980s showed 22% of Americans had hyperopia, or nearsightedness.

The following day, **Laser Vision Centers** said that it had begun upgrading all of its existing VISX Star S2 lasers in anticipation of the approval for hyperopia, which analysts believe will come by fall. The release noted that some analysts had estimated the U.S. hyperopia market to include a population of between 50 to 55 million, the vast majority of whom would fall under the recommended parameters. Jack Klobnak, chairman and CEO noted, "Even if only a very small percentage of the farsighted population chooses to have this procedure, it could have a dramatic impact on the industry and Laser Vision."

LCA-Vision also noted that all of its wholly-owned U.S. centers were equipped with VISX lasers and would begin performing hyperopia corrections as soon as it was approved by the FDA. Dr. Stephen Joffe, chairman and CEO noted, "We already have

a backlog of hundreds of farsighted patients awaiting the treatment and that number should rise appreciably as we get closer to a final OK."

7/23 **Medjet** and **Alcon Laboratories** announced an agreement, granting Alcon an exclusive worldwide license for the use of Medjet's proprietary microjet technology for corneal refractive surgery. Under terms of the agreement, Alcon will register, manufacture, promote, and market microjet devices and consumables. Financial details were not disclosed. Eugene Gordon, chairman, CEO, and founder of Medjet said, "When we started Medjet, we aspired to establish the microjet as a superior cutting and shaping instrument for surgery. Our initial focus was corneal surgery for vision correction. We have achieved much in the laboratory. Bringing the technology to the operating room will be the next critical part of the process. This strategic alliance with Alcon is a major step towards making this dream a reality." Medjet's technology uses a hair-thin, circular jet of sterile balanced salt solution delivered at supersonic speed to reshape the cornea. The HydroBlade Keratome is being developed as a tool to cut the corneal flap during LASIK surgery; the companies aim is to develop the device as a primary tool in correcting many vision problems, including myopia, hyperopia, and astigmatism.

7/23 The July issue of *Review of Ophthalmology* contains a couple of interesting articles. In the "News and Trends" section, the magazine reviews the breakup of **Pillar Point** stating that several questions linger. On the question of the $250 procedure fee, both **Summit Technology** and **VISX** said that they will continue, but the author mentions that VISX's side of the fee may be affected by questions over the validity of its patents questioned by the FTC. As Michael McNealy of the FTC stated, "The dissolution doesn't touch the patent fraud issues."

Another issue is what licensing fees competitor laser companies will have to pay. Both companies (VISX and Summit) say that they intend to require competitors to pay a per procedure fee once their technologies arrive on the market. "Depending on what they get approval for, most companies will have to get licenses," said Robert Palmisano of Summit. According to the story, however, some of the competitors have their own ideas. **Nidek's** David Yeh said that his company feels its technology did not infringe on the patents (held by both Summit and VISX) and thus will owe no royalties. VISX believes the opposite and will sue if Nidek refuses to obtain a license. **Autonomous Technologies** also believes its technology does not infringe, but will escrow $250 per procedure in case they don't win in court. If they do prevail, they intend to split the fee with the surgeons using their equipment. Bill Kelley of **Aesculap Meditec** said his company is definitely not interested in charging a per procedure fee. Aesculap will seek a one-time license fee or royalty to be built into the price of its laser. There was no comment from **Bausch & Lomb**.

There was also an update on the photodynamic therapy treatment of age-related macular degeneration written by an expert in the field, Joan Miller, MD of Boston, at Massachusetts Eye and Ear Infirmary. She is working with at least two of the systems

in clinical trial, the **QLT PhotoTherapuetics/Ciba** Vision study, using diode lasers produced by **Coherent Medical** and **Zeiss**, and the **Miravant** study, using the **Iris Medical** diode laser.

7/23 **Iridex Corporation** announced results for its second quarter, with net sales increasing to $6 million from $4.4 million a year ago, and net income increasing slightly to $525,000 (8 cents/share) compared to $514,000 (also 8 cents) for last year's second quarter. For the six-month period, sales were $11.9 million, up from $7.7 million a year ago, while net income was $1.2 million compared to $700,000 for last year's half. According to president and CEO Ted Boutacoff, "Strong sales from domestic ophthalmology and dermatology businesses...were offset by continued weak sales from the economically troubled Asian region...and sales from Europe were lower than expected, primarily due to delays in attaining the CE mark, not secured until late in the quarter...As a result...overall worldwide sales and earnings were less than the company expected."

7/23 **KeraVision** reported second quarter results with revenues of $112,000 for the quarter and $264,000 for the half year. This compared to sales of $114,000 and $170,000 for the same periods a year ago. The net loss for the quarter $5.6 million (65 cents/share) and for the half year, $11.1 million ($1.09 per share). KeraVision explained the loss increase was due to costs of expanded patent coverage and to market development. The company also noted that its KeraVision Ring for myopia is taking part in the FDA's pilot program that streamlines the review of premarket approval applications. Under the program, a company can submit sections of its application as soon as they are ready, instead of all at the same time. This means the FDA can begin its evaluation sooner.

OPHTHALMIC LASER UPDATE -- AUGUST 1998

7/28 **Sight Resource** reported its second quarter results with revenues of $14.5 million, an increase of 45% from its second quarter a year ago. Net income was $77,000 (1 cent/share), compared to a net loss of $205,000 a year ago. For the six month period, the company had revenues $28.1 million and net income of $90,000 (1 cent/share). According to a company source, Sight Resource currently operates only 3 excimer laser centers, having sold off the remainder of its lasers/centers over the past year. Approximately 5% or less of revenues is now associated with refractive surgery. The company contracts access for its patients in markets where it does not have its own center.

7/28 **LCA-Vision** reported its second quarter results with revenues of $9 million, up from $3.8 million for the same quarter a year ago. Revenues from laser vision correction procedures rose 244% to $8.4 million, up from $2.4 million. Corresponding patient procedure volume more than doubled to 5,677 from 2,791 for the second quarter last year. To reflect the remaining costs involved in closing 7 under-performing centers, including related goodwill, and to write down certain equipment to net realizable

value, the company took a special restructuring charge of $10.5 million, of which $9.9 million is a one-time, non-cash charge. This resulted in a net loss for the quarter of $11.5 million (32 cents/share). Excluding the one-time charges, the company's second quarter loss was $972,600 (3 cents/share), compared with a loss of $981,800 (5 cents/share) a year ago.

LCA produced positive cash flow in the second quarter, ahead of its third quarter goal, and second quarter EBITDA also indicated improvement in operating performance, with a positive $352,200, versus negative EBITDA for both last year's second quarter and this year's first quarter. According to chairman and CEO Dr. Stephen Joffe, the company expects better than break-even performance for the balance of 1998, with profitability from that point on.

For the half year, revenues rose to $16.2 million, up from $6.6 million a year ago, with revenues from laser vision correction rising to $14.9 million versus $4 million. Including the one-time charges, the company reported a loss of $13.1 million (36 cents/share) for the half year.

7/28 **Omega Health Systems** announced that its physicians planned to offer the **VISX** procedure for hyperopia as soon as final marketing approval is obtained. Refractive procedures for myopia and astigmatism currently account for over 10% of the total surgical procedures performed by affiliated surgeons, who did 1,876 refractive procedures during the first half of 1998, compared with 850 procedure last year. 1,069 procedures were done in the second quarter alone. Thomas Lewis, president and CEO noted that the majority of affiliated surgeons currently use the VISX laser and look forward to treating those with hyperopia. Laser vision correction services are now performed by surgeons affiliated with 19 of Omega's 21 locations, in cooperation with local optometrists.

7/28 **Sunrise Technologies International** reported that its PMA application for treating hyperopia should be submitted to the FDA in the fourth quarter of this year, with patient enrollment completed on June 30th.

7/29 **Autonomous Technologies** announced that the FDA had completed review of the company's PMA, and that it was approvable. The correction range of the approvable letter is for up to -10 diopters of sphere and -4 diopters of cylinder. The range of sphere is broader than the -8 diopters recommended by the Panel this past February and is based on additional data provided to the FDA by Autonomous. Final PMA approval cannot occur until the FDA determines that Autonomous' manufacturing facilities, methods and controls comply with the FDA Quality System Regulation (QSR). Randy Frey, CEO stated "This news brings Autonomous one step closer to the starting line for commercialization in the highest growth laser vision correction market: the United States. The Autonomous team is on track and prepared for its upcoming manufacturing inspection which is the final hurdle in the FDA approval process."

7/29 **Summit Technology** announced revenues for the second quarter increased 11% to $23.4 million, with system sales increasing to $5.4 million from $1.9 million a year ago. Subtracting contact lens and related product sales, revenues associated with refractive surgery amounted to $12.9 million for the quarter, up from $10.1 million for the first quarter, and $9.3 million a year ago. Net income for the quarter was $30.5 million (97 cents/share), which included the $35 million settlement from **VISX**. Excluding the settlement, net income was $0.9 million (3 cents/share).

Revenues for the six month period were $45.2 million with net income of $30.7 million (93 cents/share). Excluding the settlement, net income was $1.1 million (4 cents/share). Excluding contact lens product sales, refractive surgery revenues for the half year amounted to $23 million, compared to $16 million for last year.

In a teleconference accompanying release of the quarterly results, CEO Bob Palmisano noted that the company had placed 12 systems (all in the U.S.) during the quarter giving the company an installed base of greater than 200 systems. He noted that Summit had achieved astigmatic approval and expected high myopia and hyperopia approvals shortly. CFO Bob Kelley noted that license fees were flat because of the erosion of systems in place and in use, which should last for another quarter. (Apparently, because of this erosion, procedures done on Summit systems represented only about 25% of all U.S. procedures, up about 5% from the first quarter, but down from the 30% previously announced by Palmisano.) Palmisano also said that no companies had yet approached Summit about licensing their patents, but that he expected this would occur as others came closer to approval for marketing. He also noted that the **Emory Vision Correction** LASIK approval, when it comes, would only be for a single site and was not transferrable without a supplementary PMA application, and since Summit has its own PMA in with the FDA, they would probably run with that. (See the 8/3 brief below.)

7/30 The **American Academy of Ophthalmology** said that it had found iris scanning, a new and increasingly popular identification system, safer and less invasive than other ocular identification systems. Iris scanning is a non-invasive, non-contact process that utilizes a stereo camera and regular light to locate a person's face, find the eye, and take a digital image of the iris. The entire process takes about two seconds and accommodates glasses as well as contacts. Because the human iris is distinctly unique from person to person, with 250 differentiating features (compared to just 40 different features in a fingerprint), it is ideal for identification purposes. The chance that two different irises could have the same code is one in 1078. Recent advances in eye surgery such as refractive surgery, cataract surgery, and cornea transplants do not change the iris' characteristics. In fact, it is impossible to modify the iris without risking blindness.

8/1 *The Globe and Mail* ran a lengthy article entitled "Ophthalmology: A little laser for your eyes' sake. To correct their fading vision and rid them of glasses and contact lenses, North Americans are paying up for laser eye surgery. Is it worth it?" Author

Barbara Wade Rose wrote about her recent laser vision correction surgery. She opted for PRK, performed by the Bochner Eye Institute because she felt that LASIK might be riskier.

"Excimer laser eye surgery has the virtue of being a genuine home-grown trend. Canada is a world leader in the procedure, having approved laser treatment in 1990, five years before the United States did. Indeed, many U.S. doctors headed north to learn how to program vision correction into the excimer laser computer, operate the $500,000 machine and provide patient follow-up.

In the mid-1990s, financial analysts were predicting that 375,000 laser eye treatments would be performed each year in North America. The figure turned out to be more like 75,000, which some say was a result of excessive regulation by the U.S. Food and Drug Administration. Today, however, the numbers are decidedly on the rise. An estimated 350,000 procedures will be performed in North America this year and 500,000 in 1999."

"In Canada, prices and techniques vary from province to province. In British Columbia, for example, the treatment can cost about $2,500 per eye and is frequently done one eye at a time so patients can get on with their lives while the eye heals. In Ontario, competition has pushed the price down to $2,000 per eye, and both eyes are done at the same time. The largest outfits in Canada are St. Louis-based **LaserVision Centres**, which opened six Canadian clinics in 1991 and operates 50 centres in the United States; and **TLC The Laser Center** of Mississauga, Ont., which operates more than 30 clinics in Canada and the United States."

Barbara confesses that even before her surgery, she decided to buy shares in TLC because she knew that one Canadian in four wears glasses and that laser eye surgery is projected to earn $2.9-billion (U.S.) annually by the end of the decade.

8/3 **Ion Laser Technology**, better known for its laser tooth whitening BriteSmile technology, announced that it had reached an agreement to acquire all of the assets of **Excimer Vision Leasing**, a company that leases ophthalmic lasers to doctors and manages the marketing aspects of certain laser vision correction centers. EVL, founded in November 1995, has entered into 15 separate leases for ophthalmic laser devices, for which the lessee pays EVL a fee for each vision correction procedure performed using its lasers. In addition, EVL has marketing agreements with two ophthalmic offices to manage the marketing aspects of their laser vision correction centers. Under these agreements, EVL receives a per procedure marketing fee for its services. In the first six months of 1998 EVL generated cash flow of more than $600,000, and expects to achieve $1.2 million by the end of the year. For the year, 5,549 procedures have been performed on EVL lasers, compared to 1,812 last year.

The terms of the deal call for ILT to issue EVL 1,533,000 share of its common stock and a Zero Coupon $7 million promissory note for a term of five years, which will

accrue interest of 8.5%. EVL is 80% owned by **CAP America Trust**, set up by Tony Pilaro, a director of ILT, with the balance of EVL owned by Richard Braddock, who served as chairman of ILT from April 1996 to May 1998.

Richard Trefz, president and CEO of ILT said that the acquisition would enable ILT to expand its market presence and capabilities into the ophthalmic laser area. With laser vision correction growing at exponential rates, ILT would also benefit from the cash flow generated by the acquisition. This will be important as the company continues to invest in the development of new tooth whitening technologies. The agreement is expected to be completed in the second half of 1998.

8/3 *EyeWorld Week* reported that **VISX** must submit 1-year post-treatment follow-up data on 80 of 124 primary eyes to the FDA's Ophthalmic Devices Panel as one of the panel's conditions for recommending approval of the Star Excimer Laser System for the treatment of hyperopia last week. VISX said the data had not been included in its PMA supplement submitted in March because those subjects wouldn't complete a year of post-treatment until August. The panel also requested that the remaining 44 eyes that had had a year of post-treatment at the time of submission continue to be monitored until the rest of the follow-up was complete.

The newsletter also reports that the FDA has taken issue with an **Emory Vision Correction Center** advertisement that states an FDA advisory panel unanimously had recommended approval of the laser in situ keratomileusis procedure. In a letter made public on July 28, the agency stated, "The advertisement misrepresents the facts of the advisory panel's recommendation and implies that the advisory panel recommends and the FDA will approve the laser for the LASIK procedure at Emory." While an advisory panel did back approval of the procedure, performed on Summit Technology's already-approved Apex laser, it recommended approval for *one specific serial numbered unit only* (emphasis added by me). (I guess my idea that Emory would be able to teach others how to do the procedure, which they could then advertise, is also off the table.)

8/3-
8/4 In federal court in Brooklyn, New York, **Mercacorp, Inc**., a Swiss investor, has sued **LaserSight** (LASE), its CEO Michael Farris, **Wall & Broad Equities**, a Brooklyn-based investment concern, and its principal, Isaac Weinhouse, for stock fraud, manipulation and insider trading. Mercacorp alleges it suffered $5 million in actual damages and seeks $50 million in punitive damages based on a continuing scheme by Farris and the other defendants to artificially inflate and manipulate the price of LaserSight's common stock in violation of Section 10(b) of the Securities Exchange Act of 1934 and for common law fraud. Mercacorp alleges that in May 1997 the defendants fraudulently induced it and others to invest over $5 million in LASE. At the time, Mercacorp and others bought approximately 850,000 shares of LASE common stock from another private investor, **Maslo Funding**, for approximately $6.50 per share. Mercacorp claims it was tricked into buying those

shares; that another 500,000 LASE shares were bought in the open market at over $6 per share shortly thereafter, and that it later secured $16 million in additional funding for the company. Mercacorp claims it was manipulated and defrauded by Farris, with the assistance of Weinhouse, based on a series of false and misleading statements they repeatedly made about LASE, its then pending contract with **IBM** and the company's funding plans and requirements.

According to Mercacorp's action, **Shoreline Pacific International Finance** ("Shoreline") received a bonanza from Farris and LASE when it acted as placement agent for the company's Series 2 preferred stock last year. The action alleges that Farris and Shoreline must have been in cahoots because Farris and LASE ignored at least five offers made at the time by Mercacorp and **Swartz Investments, LLC**, a large investment banking concern, that were far better for the company and its shareholders than the deal closed through Shoreline. Specifically, the lawsuit alleges that Mercacorp was defrauded on five separate occasions in 1997 and 1998. First, when it bought the Maslo Funding shares. Second, when others it knew purchased an additional 500,000 LASE shares in open market purchases. Third, Mercacorp claims it was defrauded in July 1997 when it secured $16 million in financing for LASE and was falsely led to believe it would participate in the issuance of the company's Series B convertible preferred stock. Finally, Mercacorp asserts it was defrauded in late 1997 when that convertible stock was redeemed and again in February 1998 when the time to redeem that stock was extended.

(It sounds to me that Mercacorp didn't do a good job on its "due diligence" before getting involved with LaserSight. Perhaps, another case of "he said, she said!")

I have obtained a copy of the complaint filed by **Zeigler, Zeigler & Altman LLP**. It makes for interesting reading but, as noted above, someone didn't do a good job of determining what was really going on during the time LaserSight was seeking financing to pay IBM for the UV patent package.

LaserSight and its CEO Michael Farris deny the reported allegations made against them and said that they will vigorously defend against the allegations.

The company also reported that the **Kremer Laser Eye Centers** PMA for LASIK had received approval by the FDA, the first LASIK approval. The approval is for a single device and single site and will require supplemental manufacturing approval by the FDA for LaserSight to manufacturer and commercially distribute additional lasers.

The approval is for performing LASIK with a 6-millimeter ablation zone to treat myopia from -1.0 to -15.0 diopters, with or without astigmatism from 0 to 5 diopters, on Dr. Kremer's home-built excimer laser system. This is the only excimer laser approved to date to treat high myopia up to -15 diopters. FDA staffers acknowledge that additional data will have to be submitted to demonstrate that LASIK is safe and

effective at other sites before broad commercialization of the device can be done. LaserSight stated that it intended to seek such approval.

With the approval, LaserSight and Dr. Kremer will begin to execute the "so-called" unwind provisions related to the approval as part of their agreement to acquire his technology in July 1997.

8/10 **VISX** announced that it was expanding its "Ambassadors Program" that allows the waiver of the license fee for any ophthalmologist, optometrist, and their staff who wish to have laser vision correction, and who will serve as "ambassadors" for the procedure. The extension runs until September 30th. The company encourages laser owners to waive their professional or facility fee, allowing the ambassador to have the procedure at little or no cost.

8/10 **Sunrise Technologies International** announced that it had been approved for trading on the NASDAQ, and would begin trading on August 13th.

8/11 **Autonomous Technologies** reported its second quarter results with a net loss of $4.2 million (39 cents/share). The loss was in line with company expectations as it prepares for the launch of its LadarVision laser in the U.S. once the anticipated PMA approval is obtained. The company had revenues from sales of LadarVision systems of $45,000 in the quarter. Autonomous also announced that it had closed on its previously announced equity financing with OZ Master Fund for $5 million. The fund has an option to purchase an additional $4 million of convertible stock by November 10th.

The company had said in May that it expected a three-month delay in completing the quality audit before obtaining full marketing approval. Autonomous now feels it has taken the necessary steps to prepare for this FDA audit, and is just awaiting the inspection by the FDA audit team.

8/12 **Laser Vision Centers** reported that same U.S. laser revenue for its first fiscal quarter ended July 31, 1998, was up over 130% over the same quarter last year. The company said that in July it performed over 3,550 surgical cases in the United States and it was the best month to date for U.S. case volume. The company also reported that over 10,200 revenue generating cases were performed on its U.S. laser systems during the quarter, a 190% increase over the same quarter a year ago and a 17% increase over the previous quarter. In addition, the Company said that 378 surgeons used its services during the quarter compared to 357 the previous quarter. "We have now seen nine consecutive quarters of increased case volume. We believe this demonstrates the growing interest and enthusiasm patients have for this procedure," LaserVision chairman and CEO Jack Klobnak said. "The addition of new surgeons to our network is an indication of continued growth for this industry and our company."

8/12 A study published in the August 1998 issue of *Ophthalmology*, the Journal of the American Academy of Ophthalmology, concludes that both photorefractive

keratectomy (PRK) and laser in situ keratomileusis (LASIK) "seem to be relatively safe and effective procedures for the correction of moderate to high myopia," and that outcomes "are generally similar."

This randomized, prospective, clinical trial treated 220 eyes of 220 patients using an excimer laser for both PRK and LASIK procedures at seven clinical centers. Attempted corrections ranged from -6.00 to -15.00D, and patients were followed for up to six months. The study compared uncorrected visual acuity after the procedures and found that although an early advantage was seen in the LASIK group, after one month the difference disappeared. For the outcome of uncorrected visual acuity worse than 20/40 at the six-month follow-up visit, a trend toward superior outcome for PRK was seen, though this was statistically insignificant. However, Robert K. Maloney, MD, one of the authors of the study, points out that "there was a higher loss of two Snellen lines of spectacle corrected visual acuity with PRK for high myopia." Although this also is not statistically significant, the study suggests "a trend toward a lesser likelihood of loss of spectacle corrected visual acuity with LASIK compared with PRK."

In its conclusion, the study states: "It should be stressed that this study assesses one laser using a particular ablation algorithm and looks only at the correction of higher degrees of myopia. The relative results of PRK and LASIK using other lasers and for lower degrees of myopia await future clinical investigations."

8/13 **Medjet Inc.** which had granted **Alcon Laboratories, Inc.**, the world's leading ophthalmic surgical company (with annual sales in excess of $2 billion), an exclusive worldwide license to register, manufacture, promote and market Medjet's corneal refractive surgery microjet devices and consumables (see our July 23rd brief last month), now believes that, based on the growing number of laser-based vision correction procedures (an estimated 350,000 procedures to be performed in the U.S. alone during 1998), it should derive significant license fees and accelerating royalties from the deal.

Alcon Laboratories is a wholly-owned subsidiary of **Nestle S.A.**, and its products are sold in 170 countries. (It should be noted that Alcon is the former international distributor for the **VISX** laser, and did a dismal job with that product.)

8/13 **Gimbel Vision International** announced revenues of $12.4 million for the second quarter, representing a 66 percent increase over last year's $7.5 million and an increase of 99 percent from the first quarter of 1998. The increase in revenue reflects strong growth in the number of primary procedures at existing locations as well as higher than targeted surgery volumes at the company's new center in Rio de Janeiro, Brazil. Primary procedures increased to 4,119, up 87 percent from the same period last year and increased 25 percent from the previous quarter which brings the six month surgery volumes to 7,464.

The company generated earnings before interest, taxes, depreciation and amortization (EBITDA) of $2.4 million for the second quarter compared to $1.8 million in the same period of 1997 representing a 37 percent increase. EBITDA increased 111 percent from the first quarter of 1998. Net earnings were $0.4 million (2 cents/share) which is a 67 percent increase over the first quarter and a 13 percent decrease from the second quarter of 1997.

Gimbel Vision is continuing its current expansion plans in South America and the United States. The Company continues to monitor the status of its Australian subsidiaries and hopes to have a positive resolution to the situation before the end of the third quarter. The second quarter financial results include the operations in Australia through June 11, 1998.

8/14 **Premier Laser Systems** announced that due to the unavailability of its financial statements, it will be unable to proceed with its previously proposed acquisition of the remaining 49 percent interest in **Ophthalmic Imaging Systems** by the Aug. 21, 1998 termination date of its acquisition agreement with OIS. OIS and Premier are in the process of discussing various alternatives including the possible restructuring of the transaction. Premier continues to maintain a 51 percent stock ownership of OIS.

OIS officials commented that it was in the process of considering various alternatives available to it, including the possible restructuring of the transaction with Premier.

8/14 **Sunrise Technologies International** announced financial results for the second quarter and year-to-date, with revenues for the three and six-month periods totaling $222,000 and $324,000, respectively, compared to $1.5 million and $2.5 million, respectively, for the same periods in 1997. The vast majority of the revenue decline was due to a lack of revenue from dental operations in the first half of 1998 after the sale of the dental assets in the second quarter of 1997. In addition, ophthalmic revenues for the first half of 1998 were approximately 34% lower than the same period in 1997. This reduction was primarily due to the deferral of revenue recognition of certain international shipments with trade-in rights. The net loss for the three and six-month periods were $5.6 million (17 cents/share) and $9.4 million (28 cents/share), respectively, and was primarily due to the lack of revenue from the company's ophthalmic products to offset the expenses associated with the development and regulatory approval of the Laser Thermal Keratoplasty System (the "LTK System").

Russell Trenary, president and CEO, said, "We continue to have very positive results from our clinical trials. We have successfully completed patient enrollment in the clinical trial for low hyperopia of .75 to 2.5 diopters, and we expect to submit our pre-market approval application (PMA) for low hyperopia later this year."

8/14 **LaserSight** reported its second quarter results with revenues of $4.9 million compared to $2.5 million of adjusted revenues for the same quarter in 1997. Revenues for the six month period were $9.2 million, compared to $6.3 million of adjusted revenues in

1997. The unadjusted revenues for the three- and six-month period ended June 30, 1998, was $5.4 million and $11.9 million. Revenues for the three and six month periods ended June 30, 1998 rose 96 percent and 46 percent from the corresponding 1997 periods (adjusted for the sale of two of LaserSight's former health care subsidiaries).

The company reported a net loss of $1.8 million for the second quarter, as compared to $2.4 million in 1997. Reflecting one-time charges for conversion discounts on and premiums and accretion on the redemption of preferred stock, the loss attributable to shareholders was $4.2 million, or 34 cents per share. Without the one-time charges of approximately 20 cents per share, the adjusted loss per share for the second quarter of 1998 was 14 cents as compared to the 1997 second quarter loss of 26 cents.

For the six month period, the company's net loss was $3.7 million compared to $3.1 million for the 1997 period. Including the one-time charges, the loss attributable to shareholders in the 1998 period was $7.3 million, or 64 cents per share. Without the one-time charges of approximately 31 cents per share, the adjusted loss per share for the six months ended June 30, 1998, was 33 cents, as compared to 34 cents for the 1997 period.

The company sold 15 laser systems during the second quarter compared to eight systems during the second quarter of 1997. The average sale price of the laser systems rose approximately 7 percent compared to the same period last year. A total of 29 laser systems have been sold during the six-month period, compared to 23 systems sold during the same time in 1997.

In other news, the company said that it had completed the validation of the manufacturing processes for its ADK (automated disposable keratome), and had begun to build product for commercial shipments. LaserSight is expanding the number of surgeons who are treating patients with the ADK as part of the company's ongoing quality assurance and clinical validation procedures. Continued positive clinical validation should allow commercial shipments to begin sometime during the third quarter.

8/15 This month's issue of *Refractive Market Perspectives* reports that refractive laser volumes were up 23.6% in the second quarter, with over 107,500 procedures performed at U.S. refractive laser centers. If those traveling internationally are included, over 111,000 procedures were performed on U.S. patients. Year-to-date, approximately 201,500 procedures have been performed, compared to 82,100 for the six months last year, a 145% increase. Dave Harmon goes on to note that the increase in procedures per laser center are expected to continue at their current pace in the coming months. With new laser sales on the upswing, he believes that as many as 25 new systems are scheduled to begin operating during the third quarter, most in new laser centers. On average, 89.3 procedures per laser per month were done during the second quarter, up from 75.1 for the first quarter.

At corporate centers, average monthly volumes increased 19.6% over first quarter volumes; while the average increased 20.8% for surgeon and institution-owned systems. Collectively, corporately-owned centers performed 42,385 procedures. Based on the procedure volumes for the first six months, and assuming a 20% average growth rate, David estimates that procedure volumes for this year could be as high as 500,000! However, more conservative forecasts of single digit growth would bring the number in at about 450,000. This is still higher than nearly all analysts and companies have been projecting (including me, still holding at 368,000 -- for the time being!).

8/15 This month's issue of *Review of Ophthalmology* contains an interesting article entitled, "What Went Wrong in Oklahoma?", detailing the approach taken by the optometric lobby in obtaining laser rights in that state. The author, Dr. Jeffery Shaver, explains what went wrong and offers suggestions on how other states can avoid the same fate. A very interesting read!

Also this month, *Ophthalmology Management* offers two interesting articles. First, Dr. Ronald Krueger expands on his scheme for deciding which microkeratome doctors should buy -- illustrated again with an updated version of his chart of microkeratome categories that I included in the May issue of this newsletter -- and describing each of the major brands in detail. The second article describes the laser/topography link being promoted by **LaserSight**, in conjunction with **Humphrey Systems**. The combination laser and topography system, to be known as ScanLink, will be offered along with the services of LaserSight's newest consultant, Dr. Jack Holladay, an expert in topography systems.

8/18 **Innovative Optics** announced that it had completed initial shipments of its FDA-approved InnovaTome microkeratome to domestic and international customers. Additional units are on backorder, as the company ramps up production volume. As of mid-August, the company reported a significant sales backlog. According to industry analysts, worldwide, some 500,000 LASIK procedures will be done in 1998.

8/21 *NewsPage* reports that **VISX** was assigned another U.S. Patent, this one for a surgery station provided for refractive eye surgery by laser photoablation, with the patient in a normal and comfortable upright seated position.

8/21 **Premier Laser Systems** and **Ophthalmic Imaging Systems** jointly announced that they had terminated their acquisition agreement of February 25th. The parties continue to discuss a variety of potential business arrangements, and Premier continues to hold a 51% stock ownership share.

8/21 The FTC announced that both **VISX** and **Summit Technologies** had settled Federal Trade Commission charges that they violated antitrust laws by creating a patent pool that raised prices and eliminated competition. Instead of competing with each other, the firms placed their competing patents in the patent pool in order to share the proceeds each and every time a Summit or VISX laser was used. The result of this

illegal activity was higher prices and limited choice for consumers, the FTC said at the time the charges were announced (last March). Under the proposed settlement, Summit and VISX would be prohibited from fixing prices in the future or agreeing in any way to restrict each other's sales or licensing of their PRK lasers and patents.

The proposed consent orders would settle all of the allegations of the complaint against Summit and settle part of the allegations against VISX. In addition to charges of price-fixing, the Commission has charged that VISX fraudulently acquired a key patent from the United States Patent & Trademark Office. VISX continues to litigate this charge. An announcement regarding the proposed consent agreement will be published in the Federal Register shortly. The agreement will be subject to public comment for 60 days, after which the Commission will decide whether to make it final.

(I have a copy of the FTC order, taken from their website. Anyone wishing a copy should call or email me.)

8/25 **LCA-Vision**, responding to a decline in its stock price, attributed the drop to an SEC filing that proposed a possible reverse split at some unspecified future date. The company said its fundamentals remain strong and reiterated that earnings would be better than break-even over the balance of 1998.

8/25 A Toronto-based physician, Dr. Sheldon Herzig announced that he was conducting training sessions for U.S., Korean, and Canadian ophthalmologists on the Schachar method for reversing presbyopia. The controversial method involves the placement of scleral expansion bands, and takes about 45 minutes to accomplish. Four small molded acrylic plastic strips are surgically placed into the sclera, and supposedly restores the ability to accommodate for those who have lost that ability. (I sat in on a presentation of the procedure at last year's AAO meeting, and was not convinced that it works.)

8/25 **Xomed Surgical Products' Solan Ophthalmic Products** unit announced that it had received FDA approval for the FlapMmaker microkeratome, made by **Refractive Technologies**. The FlapMaker is distributed in the U.S. and Central and South America through the Solan distribution network. Solan plans to market the product in the U.S. within its CleanField Surgical system product line.

OPHTHALMIC LASER UPDATE -- SEPTEMBER 1998

8/26 After seven years of clinical study and more than 1,500 treatments of nearsighted patients, **KeraVision** said that its "ring" for correcting myopia has cleared a major regulatory hurdle. The FDA has accepted for filing the company's PMA application, triggering the final phase of regulatory review for possible commercial approval in the United States. Following an ophthalmic panel review and its recommendation for

approval, the KeraVision Ring will become the first surgical treatment designed to treat myopia without permanently altering the optical zone.

8/26 *The Wall Street Journal*, in a lengthy article, reported that "Eye Diseases are Starting to Attract Attention of Pharmaceutical Companies. Noting that age-related macular degeneration is ocurring in an estimated 400,000 people in Europe and the U.S. each year, several pharmaceutical companies, including **Novartis**, **Pharmacia & Upjohn**, and **Alcon Laboratories** are looking into PDT techniques to stop this sight-threatening disease. Novartis (and its **Ciba Vision** subsidiary) has teamed up with **QLT PhotoTherapuetics** which is expected to complete a clinical trial involving 600 patients at 28 hospitals around the world later this year and, if successful, could win regulatory approval sometime next year.

Other drug treatments for glaucoma and retinopathy were also noted.

8/31 Both *EyeWorld Week* and *OSN Intelligence Report* reported that **VISX** and **Coherent** have entered into an accord for Coherent to service VISX excimer lasers installed in Japan. **VISX KK** has been established with headquarters in Tokyo. (VISX recently received PTK approval in Japan, and expects PRK approval shortly.) Also, both note that VISX has introduced two new programs for acquisition of its Star S2 excimer laser system. The Automatic Capacity Expansion program will offer Visx laser owners a price discount and no added maintenance costs for 3 years on the acquisition of a second (or third) system to accommodate growing procedure business, and the extension of its Competitive Laser Trade-In program for those who own non-Visx lasers. In addition, all new S2 systems have been upgraded for the treatment of hyperopia, approval of which is expected shortly.

9/1 **Summit Technology** joined many other companies in announcing the authorization of an up to 1 million share buyback program.

9/1 *NewsPage* reported that Russell Trenary, president and CEO of **Sunrise Technologies International** was interviewed by *Wall Street Corporate Reporter*. The lengthy interview discussed how Trenary rose through the ranks of **American Hospital Supply** and **Allergan** before assuming his current role with Sunrise. It goes on to describe the Sunrise turnaround from a dental laser company into today's focus on ophthalmic refractive surgery, through its LTK program. As Trenary put it, "We are in the final stage of the study on low hyperopia... the treatment of hyperopia between three-quarters and two and a-half diopters...We would expect to submit our pre-market approval application with the FDA in the fourth quarter of this year. We have sub-studies pertaining to the treatment of higher levels of hyperopia between two and a-half diopters and four diopters as well as sub-studies for the treatment of presbyopia and over-corrected excimer laser cases. These are cases where the doctor used an excimer laser to treat myopia and ended up making the patient hyperopic...Our goal is to expand it to include higher levels of hyperopia, presbyopia, and the treatment of over corrected excimer laser procedures. Beyond that, our

strategy is to meet as many needs of the refractive ophthalmic surgeon as we can with our technology."

Trenary (and Sunrise) are still overestimating their potential market to include the myopic as well as the hyperopic markets (estimating that their are 200 million Americans and Europeans with low hyperopia) and figuring that about 5% could have both eyes treated -- forgetting that others, including both **VISX** and **Summit** (and others) are also targeting those same people with their excimer lasers! His true market will only be a fraction of the hyperopes and some presbyopes who don't want to wear reading glasses, or aren't interested in monovision -- either with contact lenses or excimer correction of one eye for near and the other for distance vision. (I have a copy of the interview for those interested in seeing it.)

9/2 **Laser Vision Centers** announced that it had acquired **Refractive Surgical Services**, a privately-held Minneapolis-based provider of mobile microkeratome access. RSS had been a joint venture between its management and **Chiron Vision**, which was recently acquired by **Bausch and Lomb**. Under the agreement, LaserVision acquired 100% of RSS for a combination of cash and notes. RSS operates 33 ACS microkeratomes and has 16 employees. LaserVision operates six additional microkeratomes and 38 excimer lasers worldwide. LaserVision also announced that its executive vice president and CEO, Jim Wachtman, has been named president of the company. The position had been vacant for over a year. Wachtman will continue to report to Jack Klobnak, chairman and CEO. Nick Curtis, president of RSS will become a vice president of LaserVision, reporting to Wachtman. LVC clients currently account for more than half of RSS's capacity. LaserVision said that in the last quarter, close to 90% of its cases were performed using LASIK.

In a conversation with a spokesperson for LVC, I was told that the acquisition will accomplish several things: allow LVC to operate more efficiently as the laser scheduler can also book a microkeratome; help prevent cancellations as some LVC customers don't own their own keratomes, and it will also provide backups in case something goes wrong with the device on site; allow LVC to take a larger portion of the fee, as much as an additional $250; and finally, shore up its surgeon base, as some surgeons may have the volume to obtain their own laser, but be 200th on someone's microkeratome waiting list!

9/2 **TLC The Laser Center** announced its procedure results for the first quarter of fiscal 1999. Over 17,700 paid refractive procedures were performed at the company's centers in the three month period ending August 31, 1998. This is up 28% from last quarter and 291% from last year's first quarter. Elias Vamvakas, TLC's president and CEO, commented that the company "was very pleased that sequential and annual procedure growth exceeded all expectations. This is the 10th consecutive quarter since...that TLC has reported record procedure volumes, and is an excellent start for fiscal 1999. TLC benefits from a strong U.S. dollar, as more than 88 percent of refractive revenues are generated from the U.S. Tremendous clinical results and word

of mouth continues to drive the growth in our centers while demand and pricing for the procedure remain strong."

9/3 **Paradigm Medical Industries** announced completion of the first laser cataract cases under its expanded Phase II clinical study approved by the FDA in May 1998. The Phase II study will be conducted at seven sites in the U.S. and the company expects to have all sites trained and performing laser cataract removal by mid-September.

9/3 **LCA Vision** said it had filed an amended proxy rescinding the original request to give its board the authority to consider a stock split in the future. Apparently, the original announcement had raised many questions and concerns about the reverse split and had affected its stock price.

9/3 The SEC announced that it had filed a complaint in the U.S. District Court for the district of Columbia against JT Lin, the former president and CEO of **LaserSight Inc.**, Mrs. Lin, his wife, and Mrs. Lin's brother, Kuo-chang Wong, were charged with diverting corporate funds to themselves through certain consulting agreements and other arrangements and concealing their interests in those transactions. The complaint also alleges that the Lins and Wong orchestrated a sham offshore transaction as part of the scheme to sell unregistered LaserSight stock the Lins owned. Without admitting or denying the allegations, Dr. and Mrs. Lin consented to the entry of a final judgement of permanent injunction against them and agreed to give up their wrongful gains from the sales of LaserSight stock together with prejudgment interest, and to pay civil penalties of $100,000 and $50,000 respectively. In a related matter, the Commission issued a cease and desist order by consent against Wong, finding that he was a cause of the Lin's violations of the antifraud and securities registration provisions.

As reported by *The Orlando Sentinel*, the Lins have agreed to pay more than $200,000, including almost $60,000 in profits, to settle the complaint of secretly funneling money and stock from LaserSight to offshore companies that they controlled. Apparently, they had obtained a total of $1.36 million through improper cash transfers or disbursements in 1992 and 1993. When challenged by the company's board of directors, Lin characterized the transfers as loans and agreed to pay back almost $1.2 million, including interest. Although the Lins agreed to pay certain penalties, they still contest the allegations. "We have agreed to settle this, but there is no basis for many of these findings", said Lin. "It's a complicated issue, and we don't fully agree with what the government says."

9/5 This month's edition of *Refractive Market Perspectives* reports that institution and surgeon-owned laser vision centers have gained market share at the expense of corporate centers. According to the newsletter, surgeons and institutions now comprise 54% of procedures performed, compared to 52% during the first quarter. Corporate centers now have 46% of procedures, down from 48% last quarter. As shown in an accompanying graph, surgeon-owned centers are now doing 32% of

procedures, while institutions are doing 22%. Dave Harmon accounts for the surge by surgeons to an increase in surgeon-owned lasers, as well as the general increase in procedure volumes, with a handful of surgeon-owned centers now doing greater than 250 procedures per month. Institution centers are also reporting strong growth, in part due to significant marketing efforts by their established surgeon clients, as well as the addition of new surgeons as clients. Among the corporate centers, according to Harmon, the top five companies each gained market share, while a variety of the smaller centers and physician management companies lost share. The top five corporate centers with their current market shares are **TLC** (29%), **Laser Vision** (19%), **LCA** (11%), **Clear Vision** (14%), and **Vision Correction Centers** (7%).

Commenting on the **VISX** second laser purchase discount program, Harmon notes that the program, while likely to appeal to only a few high volume centers, may preclude the purchase of an **Autonomous**, **Chiron**, **Nidek**, or **LaserSight** laser, all of which are expected to clear the FDA shortly.

9/7 This week's issue of the *AOA News* contains a report on developments from the *International Society of Refractive Surgery* meeting held in Orlando in July. Harvey Bonner, OD, and a member of the AOA New Technology Committee reported on several topics. According to his report, hyperopia approval is expected by the end of the year and results from around the world have been very positive with several laser platforms. LASIK hyperopia correction up to +6 diopters and up to 3 diopter of astigmatism have been very good, while LTK is being used on a small fraction of patients. However, LASIK remains the primary treatment mode.

Advances are being made in infrared and holographic topography, leading ever closer to topography-controlled ablations. Apparently, **LaserSight's** joint venture with **Humphrey Instruments**, according to Bonner, holds perhaps the most flexibility. Biocompatible gels are being used with PALM (photoablative lenticular modification) as an approach to corneal irregularities, with the cornea masked with the gel and ablated to eliminate the irregularities.

There are now at least 19 conventional microkeratomes available or in development, with three disposable keratomes now available, two water jet approaches and two laser microkeratomes under development. The **Chiron** ACS and Hansatome remain the worldwide leaders, but LaserSight's ADK is gaining acceptance in low-volume laser centers as a backup device. Bonner notes that LASIK is gaining dominance among laser refractive surgeons worldwide, but that PRK is enjoying something of a resurgance with the emergence of new laser technologies that create smoother ablations and result in lower incidences of haze. He noted that the ICRs fill a narrow niche, as being most effective with low amounts of myopia. Also, Bio-optics, the use of a phakic IOL and LASIK together is gaining popularity as an approach for high myopia and high hyperopia which cannot be treated with LASIK alone.

9/8 **TLC The Laser Center** announced that it has signed a letter of intent with Dr. Thomas S. Tooma to form a joint venture in California. Dr. Tooma, an experienced laser eye surgeon, is currently running one of the largest refractive practices in North America, based out of Newport Beach, California. The venture, designed to expand the California market, will be 50.1% owned by TLC and 49.9% by Dr. Tooma. It will include TLC's existing centers in Brea, Irvine, and the newly opened San Diego center, along with Dr. Tooma's practices in Newport Beach, Riverside/San Bernardino Counties and Northern California.

9/8 **Laser Vision Centers** announced that revenues for its first fiscal quarter were $9.1 million, compared to $4.1 million for the same quarter last year, a 122% increase. Net income for the quarter was $333,000 (3 cents per share) compared to a net loss of $1.5 million (18 cents per share) for the same period a year ago. The company reported that it had performed more than 10,200 surgical cases in the U.S. during the quarter and a total of almost 11,300 worldwide, noting that it was the fifth consecutive quarter of both increased revenue and improved operating results and the second consecutive quarter of profitability. In addition, 378 U.S. surgeons accessed LaserVision's services during the quarter, 89 of whom were using LaserVision for the first time. The company said that 89% of its U.S. surgeon customers averaged fewer than 20 procedures per month for the quarter. LaserVision chairman and CEO Jack Klobnak said, "We are moving closer to having a national presence providing vision correcting services in every state...We continue to see same laser growth...Our recent acquisition of **Refractive Surgical Resources** (RSS) should help us achieve future growth objectives and improve our operating efficiencies."

9/8 **Iridex Corporation** announced that it had introduced its next generation slit lamp adaptor at the European Society of Cataract and Refractive Surgeons (ESCRS) tradeshow in Nice, France. When combined with the company's **Iris Medical** OcuLight lasers, the portable Slit Lamp Adapters add the therapeutic capability of laser photocoagulation to most standard diagnostic slit lamps. The company claims that the new product design includes parfocality at all spot sizes, tint-free viewing, unrestricted working space to accommodate contact lenses, as well as a self-centering micromanipulator that adds precision beam-steering capabilities.

9/9 VISX announced that it had settled the patent infringement suit filed by **Pillar Point Partners** against the **Barnett Dulaney Eye Center** and **Sun Valley Acquisition Corp.** Pillar Point had alleged in its complaint, filed in the U.S. District Court for the District of Arizona, that an excimer laser system previously used by Barnett Dulaney infringed patents held by Pillar Point. The terms of the agreement were not disclosed, but prior to the settlement Barnett Dulaney purchased a Visx Star excimer laser system.

9/10 *NewsPage* reports that **Nidek** has been issued a new U.S. Patent covering an apparatus for use in operating upon a cornea comprising a light delivery optical system for delivering an ultraviolet laser beam from a laser source onto the cornea.

9/10 **TAL Investment Counsel Ltd.** said that as a result of purchases of **TLC The Laser Center** common shares during August, it now held 3.7 million shares or a 10.96% stake.

9/15 **Gimbel Vision International** announced plans to discontinue the operations of its ophthalmic distribution business unit, formerly known as **IC Medical Inc.** This business unit was previously made part of a subsidiary of the company in November 1997. Glenn Gimbel, president and CEO said, "IC Medical was formed in 1995 to serve ophthalmic teaching institutions, hospitals, ophthalmologists, optometrists, and ophthalmic dispensers through the sale of high technology equipment. However, the company has determined that it will concentrate on its core business of operating world-class eye surgery facilities worldwide on a go-forward basis."

9/16 **Iridex Corporation** announced it has received 510K clearance from the FDA for a Dermatology Kit which allows the **Iris Medical** OcuLight GL laser photocoagulator to treat vascular and pigmented skin lesions. The Dermatology Kit expands the versatility currently available with the OcuLight GL (532 nm) portable photocoagulator by increasing the number of delivery devices available to physicians purchasing the laser system as well as adding to the clinical procedures that can be performed in the ophthalmologist's office. The Dermatology Kit will allow ophthalmologists to treat facial telangiectasia, rosacea, angiomas, lentigines, keratoses, and freckles. These procedures can be performed in an office setting, take only several minutes, can typically be performed without anesthesia, and require minimal postoperative care.

9/20 **VISX** announced that it would expand it Business Development Managers program to provide customers with the expertise needed to significantly increase procedure volumes. The mission of BDM is to identify issues that prevent high patient volumes and tailor solutions to increase practice growth. To help in the program expansion, the company has added two experienced professionals, Heather Ready, formerly a co-founder of **Vision Correction Centers** and Sherry Bennet formerly with **Physician Resource Group**, and also a co-founder of Vision Correction Centers.

9/23 Dr. Howard Gimbel was the first Canadian doctor to implant a **Staar** ICL at his Gimbel Eye Centre last December. He has now implanted more than 20 lenses. He said, "We believe the Staar Surgical ICL will represent a viable alternative to all of the current treatments for refractive error...unlike the excimer...the shape of the patient's eye is not altered."

9/23 *NewsPage* reports that **VISX** has been awarded another U.S. Patent, for an ophthalmic method and apparatus for laser surgery of the cornea. The abstract states, "The invention contemplates a method for making a disposable element adapted for selective placement in the path of a laser beam delivery to the cornea." (This sounds an awful lot like the **Summit Technology** ablatable mask!)

9/24 **VISX** shares climbed after analysts told investors that, based on conversations with management and industry contacts, the company's per-share third-quarter earnings will be ahead of expectations. After a conversation with VISX's management, **Warburg Dillon Read LLC** analyst Matthew Dodds told investors the company plans to be "significantly ahead in the third quarter." Although the company didn't provide exact numbers, Dodds said the company's guidance pointed toward earnings per share of about 60 cents for the third quarter. If that guidance is on track, then Visx's earnings would be 8 cents a share higher than a **First Call Corp.** analysts' consensus estimate. VISX reported net income of 32 cents in the year-ago third quarter.

PaineWebber analyst Charles Olsziewski also took the positive news to the Street. In a research note, Olsziewski said "we believe that our recently revised September-quarter estimate of 53 cents per share (up 140% year to year) may prove to be at least 5 cents too low." Olsziewski, who reiterated his buy rating on the refractive laser technology maker's shares, explained that both laser vision correction procedures and laser system sales were running ahead of his forecasts during the quarter. According to the analyst, sales of Visx's laser systems could exceed his estimates of 35 units by 10% and procedures in the industry could climb to 100,000 in the quarter, of which Visx will have conducted about 75% to 80%.

Both Olsziewski and Dodds said they will not be revising their estimates for the year until after the company reports its third-quarter earnings in mid-October.

9/24-
9/25 And the patent wars continue. In joint announcements, **Autonomous Technologies** announced it had won a moderate victory in its two-year-old lawsuit against **VISX** in the District Court of Delaware. After switching trial counsel for a second time, VISX abandoned its motion to dismiss the Autonomous suit against it and filed a counterclaim.

Autonomous brought the original suit in October 1996 seeking a declaratory judgment that VISX's L'Esperance U.S. Patent No. 4,718,418 ('418) was not infringed by its laser system, that the patent was invalid, and that all VISX's patents that were pooled in the **Pillar Point Partners** were unenforceable based upon fraud and inequitable conduct before the United States Patent Office. By filing the counter claim in this suit VISX has now enabled Autonomous to directly seek the invalidity and unenforceablity of the L'Esperance Patent No. 4,665,913 ('913) as well.

Randy Frey, CEO of Autonomous commented, "We welcome this action. Finally, we will be able to get these VISX patents before a Court of law, where we believe that they will be found invalid and unenforceable. I continue to maintain that Autonomous does not infringe on any of VISX's patents. Our technology is very unique. After hearing VISX repeatedly talk about the importance of the Warner, Trokel, and Munnerlyn method patents, it appears that VISX has decided to keep them out of the counterclaim against Autonomous to protect their validity."

In its announcement, VISX said that it had filed a patent infringement lawsuit in Federal Court in Delaware against Autonomous Technologies Corporation aimed at enforcing VISX's patent rights in the U.S. relative to the use of ultraviolet lasers to correct vision problems. The patents asserted in the suit were the L'Esperance 4,718,418 "Apparatus for Performing Ophthalmic Laser Surgery" and 4,665,913 "Method for Ophthalmological Surgery" patents. VISX is seeking injunctive relief to prevent Autonomous from manufacturing, promoting and selling its infringing equipment in the U.S.

In early 1997, Autonomous and VISX entered into a patent license agreement in which VISX granted Autonomous a license to VISX's patents for laser vision correction outside the United States. In return for this license, Autonomous pays royalties to VISX on all sales of their systems worldwide, excluding the U.S. Commenting on this action, Mark Logan, chairman, president, and CEO of VISX, said, "VISX pioneered laser vision correction and has spent tens of millions of dollars making this technology available to physicians and their patients. We will enforce our intellectual property rights to protect the investments we and our customers have made, and will continue to make, in this industry."

In a related matter, VISX continues to be involved in an FTC action alleging inequitable conduct and willful fraud on the Patent Office, including fabricated, backdated, and falsified scientific records by Dr. L'Esperance in the '418 and '913 patents.

9/25 **Sunrise Technologies International** announced that **Pennsylvania Merchant Group(PMG)** had issued a research report on the company. In its report, analysts Christopher Perry and Michael Mortorelli rated Sunrise as a "speculative buy." Russell Trenary, Sunrise's CEO and president stated, "We are delighted that PMG has elected to issue research reports on Sunrise. We believe our investors, potential investors and the capital markets will be well-served by PMG's financial analytics and industry-savvy analysis. We welcome their scrutiny and interest." In its report, PMG states that Sunrise's holmium Laser Thermal Keratoplasty (LTK) System "surpasses today's excimer laser in many respects. Excimer lasers actually involve the removal of the corneal tissue to reshape the eye, while the holmium laser does not remove tissue and thus is less invasive to the cornea...(also) the holmium LTK System is more affordable (and thus should generate more income) for ophthalmologists...(Sunrise's) LTK System is also expected to be virtually maintenance free while it costs between $20,000 and $100,000 per year to maintain an excimer system. These advantages convince us that the LTK System should enable Sunrise to quickly become a leading participant in the rapidly growing laser vision correction market."

The news release doesn't go into details, but no mention is made of the limited capabilities of the Sunrise LTK system compared to the excimers. I have requested a copy of the report and will comment further upon its receipt.

9/28 This month's issue of *EyeWorld* contains two interesting items. In a story about how Dr. Frederic Kremer won FDA approval for his "homemade" laser for LASIK, I learned that the reason that **Emory Vision Correction** didn't get its approval was that it no longer had/used the **Summit Technology** Apex laser for which the recommendation for approval was granted! As noted by Emory researcher, Dr. Doyle Stulting, "The process was so long, so slow, and so cumbersome, that by the time we moved toward approval, the technology was outdated!" Apparently, Emory principals had anticipated a broader approval than being limited to a single serial-numbered laser. Emory will apply for a substitution to the laser in an ammended PMA.

EyeWorld also contains an article on laser phaco, discussing the various laser techniques being evaluated and clinically tested to accomplish removal of cataracts. Emphasis is on the two erbium -- from **Premier Laser Systems** and **Aesculap Meditec,** and the two YAG systems, from **Paradigm Medical Industries** and **ARC Laser** (the Dodick system) -- in the pipeline. (What ever happened to the YAG laser system developed by Dr. Patricia Bath?)

OPHTHALMIC LASER UPDATE -- OCTOBER 1998

9/20 Last month, I missed a cover story that ran in the *Baltimore Sun*. Jonathan Bor wrote about refractive surgery in a story entitled, "Surgeons sculpt imperfect eyes:Making cuts with a laser has usually proved effective in correcting nearsightedness". The positive story relates the experience of two local ophthalmologists, Dr. Anthony Kameen, who does about 100 procedures a week now, and Dr. Terrance O'Brien of Johns Hopkins Wilmer Eye Institute.

9/28 I received the **Pennsylvania Merchant Group** report on **Sunrise Technologies International**. It is a fairly balanced report, describing the opportunities for LTK to treat hyperopia, presbyopia, and over-corrected PRK patients (who have been made hyperopic). My disagreement is with the section on market potential. The authors, Christopher Perry and Michael Martorelli, have used a figure of over 200 million people for the Americas and Europe, who are over the age of 40 and are hyperopic between +.75 and +2.5 diopters, given to them by Sunrise. After speaking to Russ Trenary, CEO of Sunrise, I understand where the 200 million figure comes from, and while technically correct for the over 40 age group with between +1 to +3 diopters of hyperopia, that number includes North America (Canada, the U.S. and Mexico), Western and Eastern Europe, and South America.

However, if you look at just the U.S., in the year 2000, there will be 118 million Americans over the age of 40 and, according to the so-called "Baltimore Eye Study" (conducted by the people at Johns Hopkins in Baltimore), about 31% of those fall within the Sunrise treatable zone of +1 to +3 diopters, or 37 million people. Using my consultant's prerogative, between 15% to 20% of the total are prime candidates, being older, more motivated, and probably economically able, giving the prime treatable population at between 5.6 to 7.4 million people in the U.S., or 11.2 to 14.8 million

eyes (assuming both eyes will be treated). By applying similar assumptions to the 163 million population in the rest of the world areas noted above, an additional 24.4 to 32.6 million people (assuming they have the right financial resources) or 48.8 to 65.2 million eyes are potential prime candidates. This provides a large cornucopia of potential for Sunrise (and the other laser companies) that are seeking hyperopia approval.

Perhaps an even bigger potential market exists with the presbyopes. I haven't worked out the details, but 100% of all people over the age of 40 are, or will become, presbyopic! And, Sunrise appears to be able to treat this affliction (as will some of the other laser companies) by correcting one eye for near and the other for distance, i.e., monovision. (I know this works for some, because that's how my eyes are corrected -- with contact lenses.)

The report notes that only 45 LTK lasers have been placed Internationally since September 1996, and that sales have been stagnant over the last several quarters, with the authors believing that sales would pick up upon FDA marketing approval. They further predict that the approval would come sometime during the summer of 1999, and first domestic sales of LTK lasers during Sunrises' fourth quarter of that year. They forecast that 250 lasers will be sold in 2000 and 375 in 2001. Based on my target market population assumptions above for hyperopia (without presbyopic approval), this may be somewhat optimistic. However, with the ability to treat presbyopes, Sunrise may be able to reach those lofty goals!

9/28 In response to the August 26th article in the *Wall Street Journal* about "Eye Diseases are Starting to Attract Attention of Pharmaceutical Companies" (see the 8/26 brief last month), Dr. David Septel, executive vice president of the Macular Degeneration Foundation, wrote a letter to the editor that pointed out that there are two types of AMD, the wet and dry types. "A third of the 30 million people in the U.S. over the age of 65 have varying degrees of AMD, with the dry type accounting for over 90%. Photodynamic therapy approaches could compete to treat, in a purely palliative, non-curative way, only the wet form...Patients with wet AMD are those for whom PDT could be indicated. However, even for this small market, competition will be fierce. Experts agree that effective therapies will likely come from the rapidly expanding pharmacological stable of angiogenesis factor inhibitors, significantly diminishing the chances of the billion-dollar photodynamic returns predicted by industry analysts and pharmaceutical company touts."

I disagree with Dr. Septel. As pointed out last month, anyone that can be helped by this fairly innocuous treatment, to prevent a loss of sight, is worth the effort being put forth by the various companies mentioned. And, because PDT is easy to administer, it will be widely used once approved.

9/28 *The Gray Sheet* reports **Alcon Laboratories** had a recall of its Series Ten Thousand Endodiode Laser systems. The problem was that the system might inadvertently emit

a full power beam while in the "ready" mode, regardless of the footswitch position. The FDA approved the firm's corrective action on September 8, with a field correction ongoing of the 129 units distributed.

10/1 **Wavelength Laser Technologie GmbH** sent me an announcement of its new ergonomically designed excimer laser for refractive surgery, the Allegretto. (I assume that this laser will be on display at the upcoming AAO meeting in New Orleans at the beginning of November.) The laser operates at 200 hz and is a spot scanning system with an active eye tracker. More information will be forthcoming in my report from the AAO.

10/1 **Summit Technology** announced that it had entered into a definitive agreement with **Autonomous Technologies**, to acquire all of Autonomous' outstanding shares for a combination of Summit stock and cash valued at approximately $86.6 million. The actual deal calls for 11,650,400 shares of Summit stock at the time of closing and an equal amount of value in cash, up to a maximum of $50 million in cash. Assuming that the Summit stock is valued at $4.00 per share (the average closing price for the ten trading days to and including September 30), and making certain assumptions about stock options and warrants, each share of Autonomous common stock will be exchanged for approximately .94 shares of Summit stock and approximately $2.50 in cash. The actual amounts will be based on the average closing price at closing. As part of the transaction, Summit has agreed, pending closing, to lend Autonomous up to $5 million on a revolving credit line basis, not to exceed $1.5 million per month. The amount of cash consideration in the merger will be reduced by one half of the amount borrowed under this credit line at the time of closing.

Since Summit has a cross licensing agreement with **VISX**, this deal, when it goes through, allows Autonomous to get out from under the VISX patent lawsuit currently pending.

I think basically that the acquisition of Autonomous was a good move for Summit, as it gives them fast entry into third generation laser technology and advanced eye tracking, especially with Autonomous' approval expected shortly. However, with LASIK taking the bulk of procedures, I'm not sure that scanning technology is appropriate for LASIK, as wide area ablation does just fine under the flap! But, for those ophthalmologists who still do PRK, and especially for producing "custom corneas", the Autonomous system, with its high performance eyetracker, is among the best of the scanning small spot technologies coming down the pike. (Although it operates at a much slower repetition rate -- giving appreciably longer ablation times -- than the faster rep rate **LaserSight** system.)

For Autonomous, this is a fortunate move, as it gives the company much needed cash and widespread distribution -- without having to put on a sales force -- and, if everything goes as planned, puts them out of "harms way" as far as the VISX patent lawsuit goes. We will have to wait and see on that part.

Robert Palmisano, Summit CEO said, "We believe Autonomous Technologies' system advances the state-of-the-art, a view corroborated by outstanding clinical results. The Autonomous' LADARVision System integrates narrow-beam shaping with high-speed tracking, which offers the potential for superior patient outcomes. The future of laser vision correction must encompass customized corneal ablation for each individual patient's eye and the Autonomous technology platform coupled with the highly advanced eye measurement technology currently in development will provide the market a powerful technology for the future,". Randy Frey, chairman and CEO of Autonomous commented, "We are excited about merging with Summit. Summit was the first company to have a laser system approved by the U.S. FDA for laser vision correction and has an installed base of approximately 200 lasers (in the U.S,) with an outstanding service organization. The combination of Summit and Autonomous will make for a powerful team in the laser vision correction business offering the Summit Apex Plus system and the Autonomous LADARVision System. I look forward to joining the talented management team at Summit."

Autonomous will continue as a separate operating unit under the direction of Randy Frey, currently Chairman and CEO of Autonomous. He will report directly to Robert Palmisano at Summit. It should also be noted that **Ciba Vision** holds approximately a 15% share in Autonomous, and thus upon completion of the acquisition, would become a part owner of Summit.

In a teleconference accompanying the announcement, it was noted by Frey that since Summit's Ireland facility is running straight out, the Autonomous lasers will continue to be produced in Orlando, where the company is ramping up to produce 4 units a month, growing to 8, over the several months following final FDA marketing approval. The current top capacity of the Autonomous facility is about 12 systems per month. Palmisano hopes that the acquisition will help Summit to double its market share of systems, from its current 24-25%. (However, this is highly unlikely, according to my scenario noted above.)

10/1 The Glaucoma Research Foundation said that it would release the results of a 10-year study later this month. The study addresses the questions of treatment for one of the most puzzling forms of glaucoma, normal tension glaucoma. Glaucoma's increased eye pressure may lead to optic nerve death and ultimate blindness, but in normal tension glaucoma, the optic nerve deteriorates even though eye pressure remains in the normal range. It is estimated that between 25% to 30% of American glaucoma patients never experience an elevation in eye pressure. In Japan, the number is as high as 70%. The Normal Tension Glaucoma Study set out to answer the question of whether eye pressure, even at normal levels, plays a role in NTG, and whether it is clinically feasible to lower the eye pressure in people with NTG. The NTG study is a collaborative effort of 24 research and medical centers in North America and Europe.

10/1 HCFA published a notice in the Federal Register announcing its intent to delay the implementation date of its proposed ASC regulation until an undetermined date in

2000. Outpatient Ophthalmic Surgery Society (OOSS) President David McIntyre, MD, said "This is a huge victory for OOSS and the ASC community, which has been vigorously lobbying HCFA and Congress to delay the scheduled October 1st implementation." The Agency's notice says that it will defer implementation of the rebased ASC rates, the APC groups, the additions to and deletions from the ASC list, and other technical policy and regulatory changes proposed in the June 12, 1998, notice until such time as it implements the hospital outpatient prospective payment system, which will be "as early as possible after January 1, 2000."

10/5 According to the *Orlando Sentinel*, laser-maker **Summit Technology** soon may find itself back in court with **VISX**, its chief rival in the vision-correction business. Earlier this year, Summit reached a settlement with Visx over patent rights to certain vision-correction laser equipment. But Summit's proposed buyout of **Autonomous Technologies**, could put Summit back into the legal arena with Visx. That's because Autonomous has a suit pending to establish that its technology does not infringe on Visx patents. (But I expect that this suit will never see the light of day because of the legal expenses involved. Also, see the October 12th brief below.)

10/5 **LCA-Vision** reported that procedure volume at its centers rose again in the third quarter to a record 6,093 procedures, up 122 percent from the 2,749 procedures performed a year ago in the same quarter. Through the first three quarters of 1998, LCA-Vision centers have performed a record 16,280 procedures versus 6,412 procedures for the first nine months of 1997.

Excluding the centers acquired in August, 1997 from **Summit Technology**, third-quarter volume at LCA-Vision's original, wholly-owned U.S. locations grew at an even faster pace, up 144 percent to 3,523 procedures compared with 1,445 procedures for the same centers a year ago. Commenting on the sustained quarterly growth in procedure volume, Dr. Stephen Joffe, LCA chairman and CEO added, "Despite the summer vacation break for patients and physicians alike, we again maintained the strong upward trend in procedure volume growth. Demand for laser vision correction is being fueled by the popularity of LASIK and enthusiastic patient word-of-mouth advertising."

LCA-Vision operates laser vision correction centers in the U.S., Canada, and Europe, and is supported by network of 600 physicians and 800 referring optometrists. Since inception, more than 38,000 laser vision correction procedures have been performed at the company's centers.

10/7 **IRIDEX Corporation** announced that the company expects sales for the third quarter ended October 3, 1998 will be approximately $5.3 million, an increase of approximately 14% as compared to the prior year equivalent quarter, but below consensus analysts' range of sales expectations of $6.0 to $6.6 million. In addition, the Company expects third quarter earnings to be between break-even and slightly

profitable as compared to the analysts' range of earnings estimates of $0.08 to $0.10 per share.

The Company attributes the third quarter revenue shortfall to softness in international ophthalmic and dermatology sales, particularly from the Asian region. In addition, the Company delayed the shipment of the new higher-powered visible light OcuLight GLx product until the fourth quarter. President and CEO Theodore Boutacoff stated, "International orders for our ophthalmology products from the Asian region were off more than 50% from prior year equivalent periods, both on quarterly and year-to-date levels. This slowdown has continued longer than we had anticipated and is likely to continue. As a result, we are updating our fiscal spending controls to adjust to a delayed economic recovery in Asia."

10/9 **LaserSight** announced that its wholly-owned subsidiary, **LaserSight Technologies** had received European CE Mark approval for its LaserScan LSX. This approval allows the company to begin sales into the European Union countries. CEO Mike Ferris noted that with the European market experiencing an increase in the number of laser refractive procedures, primarily due to the emergence of LASIK, the LSX should do extremely well as it has been utilized almost exclusively for LASIK procedures.

10/11 **VISX** reported details of its Global Advisors Forum held at the recent *European Society of Cataract and Refractive Surgeons* meeting in Nice, France. Attended by some of the leading ophthalmologists from around the world, and key VISX executives, the Forum provided a venue for VISX customers to discuss details of their clinical experiences with the new Star S2 Smoothscan laser, and for VISX officials to report on enhancements to the Star platform that VISX is currently planning. New features under development include larger optical zones with blending, mixed astigmatism algorithms, eye tracking, and topographically-directed LASIK procedures.

10/11 *EyeWorld Week* reported that ophthalmologists at the **Stanford Laser Vision Center**, led by Dr. Edward Manche, have begun a clinical trial for hyperopic LASIK using the **VISX** Star S2 laser under an IDE from the FDA. The study will enroll patients who are naturally farsighted, with or without astigmatism, as well as those who have become farsighted because of earlier refractive procedures such as radial keratotomy and PRK.

The same newsletter also notes that **CRS Clinical Research** has finished its 2-year IDE study for LASIK. CRS will submit the results to the FDA in an attempt to have the lasers used in the study relabeled for LASIK. Fifty-two participants submitted approximately 2,000 eyes. **Summit** Apex, Apex Plus, and **VISX** Star lasers were used. "We validated LASIK as a safe and effective procedure and made it possible for the American ophthalmologist to use state-of-the-art technology," said Charles Casebeer, MD, senior medical monitor for CRS. The protocol was the first CRS study

undertaken as an IDE study under the FDA's supervision; several other studies evaluating hyperopia, astigmatism, and high myopia remain under way.

10/12 *Ocular Surgery News Intelligence Report* notes that **Refractec** has received approval from the FDA to begin clinical trials using its Corneal Shaping system to perform radio-frequency keratoplasty (RFK). The Phase 3 hyperopia study will include 50 eyes from +1 to +4 diopters at four clinical sites. The study should get under way in November.

10/12 Two more briefs of note from the *Orlando Sentinel*. In the first, the newspaper reports that **LaserSight** has gone from unknown to well-known, as far as **Value Line** is concerned. The investment-rating service, which has not followed the laser maker until now, recently listed it as one of the top performers among technology stocks.

The newspaper also corrected its story of October 5, noting that the pending buyout of **Autonomous Technologies** by **Summit Technology** may have a welcome side benefit: the end of patent lawsuits between Autonomous and laser giant **VISX**. The acrimonious, 2-year-old legal battle will effectively end the day Autonomous becomes part of Summit. That's because a prior patent settlement between VISX and Summit will also cover Autonomous, VISX officials said. Until the deal is done, however, VISX plans to press the lawsuit.

10/13 **Laser Vision Centers** announced that same U.S. laser revenue for the month of September increased 49% compared to the same month a year ago. Same U.S. laser revenue compares the revenue generated on 23 lasers that were in operation in September 1997 to the revenue generated by those same lasers in September 1998. The company also said that September was its best month to date for U.S. surgical case volume, increasing 6% over the previous best month. The last two full weeks of September were the company's best weeks ever. 278 surgeons used its laser services during the month of September compared to 179 in September, 1997.

10/13 **TLC The Laser Center** announced its financial results for the three months ended August 31, 1998. Results were characterized by continuing record revenues and first-time generation of net profit as a public company. All were driven primarily by strong growth in the number of refractive laser procedures performed. For the quarter, gross revenues almost tripled to $42.5 million, with over 17,700 paid refractive laser procedures performed at TLC clinics, compared to only 6,100 in the same quarter a year ago. The company's net profit for the quarter was $400,000 (1 cent/share) versus a net loss of $2.6 million (9 cents/share) a year ago. Revenues from refractive surgery totaled $32.1 million, or 76% of total revenues -- and $26.4 million or 91% of net revenues. (The bulk of the remainder was from secondary care facilities.)

During an accompanying teleconference, Elias Vamvakis, president and CEO noted that the company had growth plans of adding 12 to 15 new centers in this fiscal year, and 10 to 12 over the next three to four years. These will include both acquisitions and

startups. He also noted that on average, TLC's centers were performing 123 procedures per month, with established TLC centers doing 145 procedures, while the recently acquired **BeaconEye** centers were only performing about 85 procedures monthly. (Some clinics, like the flagship Toronto center have accomplished as many as 500 to 600 procedures per month.)

The following day, **PaineWebber** analyst Charles Olsziewski raised his earnings estimate for TLC to $0.18 a share for the year ending May 30, 1999, from $0.16 a share, after the company beat expectations with its first-quarter results.

10/14 **LaserSight** announced that it had completed a patent license agreement with a subsidiary of **TLC The Laser Center**. Under the agreement LaserSight has been granted an exclusive license under U.S. Patent No. 5,630,810 relating to a treatment method for preventing the formation of central islands. Central islands are a problem generally associated with laser refractive surgery performed with broad beam laser systems used to ablate corneal tissue. In exchange for the grant of the exclusive license, LaserSight has agreed, during the term of the patent license agreement, to pay TLC 20% of the aggregate net royalties LaserSight receives in the future from licensing of the TLC patent and *certain other patents owned by LaserSight* (italics added). (A management spokesperson would not identify which other patents are included.) The term of the patent license agreement extends for the life of the TLC patent which expires in February 2016.

"The acquisition of this patent license is part of our ongoing strategy to add to LaserSight's intellectual property portfolio and strengthen our patent position", said Michael Farris, CEO of LaserSight. "This license further demonstrates the benefits of the ongoing relationship between LaserSight and TLC, the world's largest provider of refractive laser services." (TLC is the owner of approximately 264,800 shares of LaserSight common stock and 2,000,000 shares of LaserSight Series C convertible participating preferred stock. Gary Jonas, TLC executive vice president of strategic development, is a member of LaserSight's board of directors.)

It appears that LaserSight is putting together a "patent portfolio" similar to those owned by both **Summit Technology** and **VISX**. LaserSight now has the "IBM" patents on the use of UV energy, the "Kremer" patent on a "pivoting head" microkeratome, two "Lin" patents on scanning laser technology, rights to the "Ruiz" and "Lenchig" patented technology for a disposable microkeratome design, an "O'Donnell" patent on a method for treating glaucoma, and now the "Machat" patent on the treatment of central islands.

10/14 **VISX** announced its financial results for the third quarter with revenues of $35.8 million, up from $18.0 million for the same quarter a year ago. Income from operations was $15.8 million, up from $4.5 million in last year's third quarter, with net income reaching $14.7 million (89 cents/share). Pro forma net income was 62 cents/share.

System sales during the quarter accounted for $12.2 million, while revenues from royalties and services reached $23.7 million. Assuming that 85% of this total was from royalties, about 78,000 key cards were sold during the quarter and VISX sold 39 lasers (at an average selling price -- with tradeins -- of $312,000), 26 in the U.S. and 13 overseas. Over the first nine months of 1998, VISX has sold more than 80 lasers and nearly 205,000 key cards! Its domestic laser base now exceed 250 systems. (If VISX procedures represents 70% of the U.S. total, and the fourth quarter equals the third, the industry will easily exceed 400,000 procedures this year!)

For the nine month period, revenues reached $91.8 million, up from last year's $49.3 million. Net income was $8.4 million (51 cents/share). Pro forma net income, excluding the $35 million settlement with **Summit Technology** was $1.65 per share.

During the accompanying teleconference, Mark Logan, chairman and CEO noted that he didn't see any changes in the per procedure fee that his company charged, especially in light of procedure fees rising to the $2300 to $2500 per LASIK eye. As for the new U.S. laser placements, Logan said that most went to new accounts -- new doctors getting into refractive surgery. Logan also indicated that the FTC hearing on the remaining patent issues will be held on November 17th, unless a settlement is reached before then.

10/14 This month's *Refractive Market Perspectives* relates a survey done by Market Scope in looking at several high-volume cities (and one low-volume city) and comparing the number of procedures done in 1997 as a percentage of the population, then projecting the average percentage rate across the U.S. population. According to Dave Harmon's calculations, about .09% per hundred population had refractive surgery in 1997 (at a 250 million population, about 225,000 procedures), and he believes that the percentage will double in 1998, or 450,000 procedures. He also notes that if the saturation level across the U.S. could reach an equivalent percentage to the highest U.S. city (Denver, CO), the number of procedures in the U.S. would total 2.1 million per year!

In another survey done by Market Scope, Harmon polled refractive surgeons on their choice for low to moderate myopia and for high myopia. Results from 300 responses indicated that LASIK was the procedure of choice (68%) for low myopia, and for high volume surgeons, that number jumped to 98%. His survey also indicated that, as could be expected, LASIK was more popular for surgeons located in the Rocky Mountain, Western, and Midwestern states, while less popular in the Northeast and the Mid Atlantic. It is also most popular with office-based surgeons, compared to doctors operating at local hospitals. (Also see the survey conducted by ASCRS reported below.)

10/15 Mark Logan, chairman and CEO of **VISX** was interviewed on CNBC. He indicated that although system sales had been good during the last quarter, the future of his company lies with procedure revenues. Logan noted that since his lasers had been in

use, about 750,000 procedures had been done, and with over 100 million people as future candidates, only a small percentage of potential candidates have been treated. He also commented about LASIK not yet being an approved procedure, but being done in over 75% of total procedures, as a practice of medicine issue. As for liability of this off-label use, Logan commented that most of the problems are in creating the flap, so the microkeratome manufacturers would most likely be held liable.

10/15 **ZEVEX International**, announced that it had entered into an agreement with **KeraVision** to manufacture an electro-mechanical positioning instrument used with the KeraVision Ring. The KeraVision Ring has been cleared for sale for the treatment of myopia in Canada and Europe and a PMA for this indication was filed with the FDA in August 1998. "With this agreement, ZEVEX becomes an important supplier to KeraVision as we launch our pioneering new vision correction system this year in Canada and prepare for a possible launch next year in the U.S.," said Ted Newill, KeraVision vice president for sales and marketing - North America. "We chose ZEVEX to provide the vacuum source used in the surgical procedure due to their reputation for quality and delivery."

10/15 **Bausch & Lomb** announced third quarter results with a profit of $36.5 million (65 cents/share) on sales of $575.6 million. Eyewear sales fell 3 percent, hurt by the dollar's strength abroad and an unexpected cutback in orders by its largest sunglasses customer, **Sunglass Hut International**. Sunglasses sales rose 1 percent in the United States but were dragged down by the economic turmoil in Asia and Latin America. Vision care (contact lenses) revenues rose 3 percent, driven by double-digit growth in the disposable and replacement lenses businesses, while sales in its ophthalmic drug and surgical instrument business more than tripled to $151.5 million from $43 million a year ago. Last fall, Bausch & Lomb catapulted ahead of **Alcon Laboratories** as the world's largest eye-care company by acquiring **Storz Instrument Co.** and **Chiron Vision Care** for $680 million. The newcomers contributed $100.6 million in third-quarter sales.

10/15 I meant to report on an interesting story in the September issue of *Review of Ophthalmology*, on "The Pros and Cons of Disposable Microkeratomes". Walter Bethke writes about what's available, or about to be available, the **LaserSight** ADK, the Flapmaker from **Refractive Technologies**, and the One from **Moria**, which is still in development. Bethke notes the pros of dispoable keratomes use as: minimizing the possibility of error during assembly (as they are pre-assembled); requiring no maintenance -- after all they are already put together and are disposable; being relatively economical for low volume surgeons; being good for beginners, as a risk-free way to train surgeons in a multi-surgeon practice; and as a backup for surgeons who own reusable keratomes. The cons include: the economics -- they cost $60 to $125 per use for two eyes compared to $25 to $50 per blade, and some high volume physicians use them for up to four eyes (after autoclaving) with reusable keratomes. And some surgeons have questioned the reliability of disposables, especially with their short history of use and the need for high precision molding of their plastic parts.

10/15 The October 15th issue of *Ocular Surgery News* has the results of a survey of ISRS and ASCRS members about their preference for performing refractive surgery. There is a big difference between ISRS and ASCRS members, with 5% of ISRS members performing more than 75 surgeries a month while only 1% of the ASCRS members (responding to the survey) doing that many. And LASIK is clearly the winner among all, even for low myopia, with nearly 50% of respondents chosing that modality, and 76% of ISRS and 54% of ASCRS respondents choosing LASIK for moderate myopia, and even for high myopia. The survey also noted that of the respondents -- 41% of ISRS members and 28% of ASCRS members responded -- the **VISX** laser was preferred two to one over the **Summit** device, with all others trailing far behind.

10/16 *NewsPage* reports that **Nidek** had been issued another U.S. patent, covering a laser indirect ophthalmoscope. The scope has an improved delivery system for a laser treatment.

10/16 According to an interview conducted with **Laser Vision Centers** chairman and CEO Jack Klobnak by *Dow Jones News Service*, the second quarter and fiscal year consensus earnings estimates are achievable. A First Call consensus of five analysts estimates that LVC will earn 5 cents for the second fiscal quarter, ending October 31st, and 23 cents in fiscal 1999, both compared against losses for last year. The decision to make some of its lasers mobile turned the company around said Klobnak. After its executives realized that 1996 PRK procedures would be less than industry estimates, they decided to take some of the lasers out of its centers and put them on motorized undercarriages, making them easier to get in and out of trucks and medical offices. This gave more patients and doctors access to the lasers. The company saw an immediate jump in surgery volumes, which increased to 5180 in fiscal 1997, from about 500 in 1996. By fiscal 1998, LVC had 18 roll-on/roll-off lasers and two self-contained surgery centers on 48-foot trailers, that could relocate from town to town. Each unit services as many as 12 cities a month. In fiscal 1998, LVC performed more than 24,500 refractive procedures, and in the first quarter of fiscal 1999, more than 10,200 procedure were done on company-owned equipment. Nearly two-thirds of LVC's U.S. procedures are done by mobile lasers.

Laser Vision plans to add six more roll-on/roll-off lasers during fiscal 1999 but has no plans to add more fully equipped surgery centers on trailers. The company has 10 fixed-laser surgery center sites and almost 160 mobile sites in 40 states. Laser Vision has several other goals for fiscal 1999, including increasing revenue more than 80%, earning an operating profit of between 7% and 8%, and increasing institutional holdings to more than 50%. CEO Klobnak said the company is working on reaching more urban doctors but will continue focusing on small- and medium-size towns where patients often don't want to drive a long distance for a surgical procedure. "Doctors are more efficient when they manage their own time in their communities than driving somewhere else. Surgical volume increases when you provide it in a hometown than when people are driving one or two hours." Ophthalmologists pay Laser Vision an average of $800 a procedure and an average of an additional $200 a

procedure if they need a microkeratome for performing a Lasik procedure, which accounts for about 90% of the treatments at Laser Vision centers and on their mobile equipment.

It's possible that Laser Vision's potential patient pool will expand before the end of the year. **VISX**, the company that manufactures the excimer laser that Laser Vision uses, thinks that the FDA could approve the instrument for treating farsightedness before 1999. Klobnak said when that occurs, about 45% of the U.S. population could be potential surgical candidates.

10/19 **Sunrise Technologies International** announced it has received conditional approval to expand the number of patients to be treated for its monovision clinical trial for the treatment of presbyopia. This investigation is a substudy of the primary hyperopia study. Currently, the substudy for presbyopia allows for a maximum of 60 patients to be enrolled at five sites, with 47 patients having been treated to date. This new expansion will allow an additional 20 patients to be enrolled, for a total of 80 cases to be treated at up to five sites. Russell Trenary, president and CEO, stated, "This group of patients might best be categorized as `emmetropic presbyopes' and, according to peer reviewed studies, approximately 20% of the over 40-year-old population is `emmetropic.' This is in addition to our initial study group of hyperopes in the +.75 to +2.5 diopter group that comprises approximately 31% of those over the age of 40."

According to Daniel S. Durrie, M.D., from the Hunkeler Eye Institute in Kansas City, Mo., "Our goal with this procedure is to get the patient to read their watch, dial the telephone, read a menu and to be able to engage in the normal daily activities that require good near vision. This is in contrast to the hyperopia study we are involved in with Sunrise where we are treating distance vision." He added, "I really like this procedure because it is much easier to define what these patients want to achieve with their vision." According to a company spokesperson, "Early data from the first phase of our presbyopia substudy is very encouraging. The goal is to increase patients ability to see well with their treated eye for tasks performed up close and still have satisfactory distance vision from their untreated eye. We will continue to follow these patients for six months and longer."

10/19 **VISX** announced that its European Patent, 0151869, covering scanning laser technology was found to be valid and enforceable in a patent lawsuit brought by VISX against **Nidek** in the UK. The court has rejected Nidek's contentions that the scanning invention claimed in the patent was obvious and not novel. In coming to that conclusion, the court noted the testimony of Nidek's own expert witness who described the invention as "a creative jump" from what was previously known. The court issued its ruling following a trial devoted almost entirely to determining the validity of the patent.

The trial judge also found that Nidek's broad-beam scanning slit laser did not infringe the scanning patent. This finding, that VISX believes to be in error, is restricted to

Nidek's systems in the UK. Mark Logan, chairman and CEO of VISX stated, "Although we disagree with the decision on infringement, we are extremely pleased that the judge recognized the strength and validity of the scanning patent.

Nidek was found to have infringed VISX's European Patent 0207648 covering broad beam laser technology. However, in light of public disclosure of elements of the invention shortly before the filing date of the patent, the infringed portion was found to be invalid, and required VISX to pay a portion of Nidek's legal fees from the suit. Since UK law differs significantly from U.S. law, VISX believes the disclosure will not effect the validity or enforceability of U.S. counterparts of this patent.

VISX said it would continue to vigorously enforce its patents against Nidek in the infringement actions pending in Canada and France. VISX has more than 140 patents issued worldwide, covering scanning and broad beam lasers, tracking, LASIK, and numerous other technologies in the field of laser vision correction.

10/19 **TLC The Laser Center** passed on the word that **Leerink Swann** analyst James Molloy had initiated coverage of TLC with an "attractive" rating. I was able to obtain a copy of the Leerink Swann report, and found it very well done. Molloy has obtained a good grasp of the laser vision correction market and has prepared a good overview of what is happening, particularly for TLC. My only criticisms are that he doesn't even mention the competition in the service side of the industry, as TLC has only about a 14% share of the market -- even though apparently the largest share -- who are the others? And what are their potential strengths (or weaknesses)? I spoke with Molloy and there is the possibility that he will write about some of the others, perhaps **Laser Vision Centers**, in another report. (By the way, as noted in last month's newsletter in the September 5th brief, Dave Harmon's *Refractive Market Perspectives* has TLC with a 29% share of the corporate center's share of laser vision correction procedures. As reported, this is now about 46% of the total, so TLC's overall share is a little over 13% by Harmon's reckoning.)

And, I do not agree with Molloy's projections for the potential number of procedures likely to be performed over the next several years. He projects 600,000 in 1999 and only 700,000 for the year 2000. I think he is low on both years, especially if this year goes well over 400,000 procedures, possibly 450,000, as it now appears it will. My projections of 650,000 for 1999 may now be on the low side, but I will stick with my 943,500 for 2000!

10/20 The October issue of *EyeWorld* contains an ad for **Telco Medical Technologies**, the Australian excimer laser producer, that states the company will also introduce a solid-state UV laser at the upcoming AAO meeting. The new laser is called the Eye Q Solid-State Refractive laser, and apparently uses doubling crystals to bring a YAG or YLF system down into the UV. I'll find out more about this interesting device at the AAO and report on it -- as well as any other new lasers -- next month.

10/20 *NewsPage* reports that **Chiron Vision**, now a part of **Bausch & Lomb Surgical**, has been issued a U.S. patent for an apparatus for resecting corneal tissue. The way the abstract reads, I assume this is for one of their microkeratomes.

10/21 *The Orange County Register* carried a positive article on LASIK in its Accent section. The story told about the experiences of two patients undergoing the procedure and getting good results.

10/22 **KeraVision** reported its financial results for the third quarter. Revenues totaled $239,000 for sales of the company's KeraVision Rings and related surgical instruments. This compared to $91,000 for the same period a year ago. The net loss for the quarter was $5.7 million (48 cents per share), versus $4.6 million (36 cents per share) a year ago. The increase in losses was primarily due to market development costs associated with opening the Canadian market, and expanded paten coverage for the ring technologies. The company has established six "alpha" sites across Canada to lead the commercial roll-out. The plan is to roll out one region at a time, apparently, from the brief below, beginning in western Canada.

For the nine month period, revenues were $503,000 and the net loss was $19.8 million ($1.57 per share). (It is becoming clearer that the KeraVision Ring is and will remain a "niche" product with limited sales to those surgeons who wish to offer their patients an option for a reversible procedure.)

10/22 **Gimbel Vision International** announced that Dr. Hamza Khan of its Gimbel Eye Centre in Edmonton, Alberta, became the first surgeon in western Canada to offer patients the KeraVision Ring. According to the company, Dr. John van Westenbrugge, of the Gimbel Eye Centre in Calgary, is the only other Alberta surgeon trained in the procedure.

10/26 *Ocular Surgery News Intelligence Report* noted that **Ophtec USA** had received FDA approval to expand its Phase 2 clinical investigation of the Artisian Myopia Lens, to include a design with a 6 mm optic. The 5 mm design is currently under clinical investigation in the U.S. and Canada for the treatment of high myopia in phakic eyes from -8 diopters to -20 diopters. The company also said that the FDA has permitted expansion of parameters for its clinical trials to -5 diopters. Company president Rick McCarley said that since its introduction in Europe, the 6 mm model has become the preferred choice for patients up to -15 diopters, while the 5 mm model is the choice for between -16 and -20 diopters.

10/26 The current issue of *Optistock: The Newsletter of Vision Care Investing"* notes that **First Venture Capital** of Vancouver intends to buy all outstanding shares of **Lasik Vision Canada**. After the transaction, which will probably close in December, the company plans a name change to **First Vision Corp.** Lasik Vision operates clinics in Vancouver, British Columbia and Mississauga, Ontario and wants to expand in Canada as well as enter the U.S. market.

10/26 *EyeWorld Week* notes NASA's upcoming space shuttle launch will include early-stage research that could lead to the construction of three-dimensional collagen-based cornea in space. Dale DeVore, chief scientific officer for **Collagenesis** said that the shuttle mission will specifically study the effects of microgravity on collagen fibril formation. (Collagenesis is also developing injectable collagen that it hopes will someday replace today's intraocular lenses -- as written up in *EyeWorld* last August. I have a copy of the article if anyone is interested.)

10/26 **Odessy Optical Systems** announced that it would introduce a unique product line of Scanning Laser Ophthalmoscopes (SLO's) during the American Academy of Ophthalmology annual convention in New Orleans (November 8 - 11). The initial product, approved by the FDA in August 1998, is the first of three new models which utilize diode lasers and advanced imaging technologies for diagnosing, monitoring, and treating retinal disease before it can destroy a patient's vision. It is also the lowest-price SLO ever commercialized -- making this sight-saving instrument available to thousands of eyecare providers that could not afford the high-priced systems currently on the market. Odyssey will also introduce a hand-held Ophthalmoscope, and a PocketScope device at the AAO convention. The hand-held ophthalmoscope is expected to sell for less than $2,500. And the PocketScope, a battery-powered miniaturized replacement for direct ophthalmoscopes, could sell for less than $600. FDA approval is pending on these two devices.

10/26 **Innovative Optics** announced that it had signed an exclusive agreement with **Sigmacon** of Ontario, Canada for distribution of its FDA-cleared Innovatome microkeratome. Sigmacon, the largest distributor of surgical ophthalmic equipment in Canada, placed an initial order for 25 of the Innovatome systems.

OPHTHALMIC LASER UPDATE -- NOVEMBER 1998

10/26 **Nidek** finally came out with its version of the court results in response to the **VISX** spin about their supposed victory in the English Courts (see the October 19th brief in last month's newsletter). Nidek hailed the court's decision as a "landmark" legal victory "which may have profound implications for the U.S. and other excimer laser markets." In Nidek's response, they claimed to have defeated VISX's attempt to enforce two of its patents against Nidek, its distributor, and a clinic using the Nidek laser. The Justice found that Nidek's EC 5000 excimer laser did not infringe VISX's scanning beam patent, and that even if the broad beam patent did cover Nidek's system, it was invalid and unenforceable. Apparently, a third patent was also involved in the litigation (not mentioned by VISX). This was a patent for masking technology EP 0207648, which was also found invalid because it was "obvious" in the light of prior art publications and an oral prior disclosure at a medical meeting. As a result of these findings, VISX was required by the judge to pay a significant proportion of Nidek's legal costs.

Apparently, Nidek came close to invalidating the VISX scanning technology patent completely, on the basis of some evidence the judge described as "powerful". However, the judge upheld the patent with what he said was some "hesitation", and despite his opinion that one of VISX's witnesses, Dr. Trokel, was not a "wholly reliable witness".

Nidek hopes to achieve similar success in other litigation brought against it by VISX in France (where the patent law is similar to that in the UK) and in Canada.

10/27 I received the recently completed **Dain Rauscher** report on the laser vision correction industry. If you liked Michael Lachman's (**Hambrecht & Quist**) industry report, you'll love this one. It is the most complete, comprehensive report on the industry since my reports for **Summit Technology** and **LaserSight** back in 1992 and 1994 respectively. The authors, Parice Halbert and David Therkelsen have taken analyst reporting on the industry to the next level, giving a thorough overview of what's happening and who's doing it, industry financial reviews and forecasts for the various major players, including the three companies that Dain covers, **Bausch & Lomb**, **Iridex**, and now **VISX**, as well as brief overviews of other public participating companies including **Autonomous**, **KeraVision**, **LaserSight**, **Staar Surgical**, **Summit**, and **Sunrise** -- as well as the major public, center service companies, **LCA-Vision**, **LaserVision Centers**, and **TLC The Laser Center**.

Parice and David project the laser vision correction market to reach $1.4 billion in revenues by the year 2000, on 775,000 procedures annually by then; with laser company revenues reaching $260 million. They attribute the growth to the "wow" factor of LASIK, which they say is driving the market.

The report is fact-filled and is based on a comprehensive knowledge gained about the industry. It is a "must read" if you haven't already done so. As is clearly evident, I really liked this report, having had the opportunity to consult with them on their analysis.

10/27 **Sight Resource Corporation** reported financial results for its third quarter and nine months. Revenue for the third quarter was $14.3 million, an increase of 13% from revenue of $12.7 million for the third quarter of 1997. Net income was $143,000 (2 cents per share) compared with net income of $78,000 (1 cent per share) for the third quarter of 1997. EBITDA (earnings before interest, taxes, depreciation and amortization) was $825,000 for the three month period compared with $641,000 for the same period in 1997. Third quarter results include the operations of **Eyeglass Emporium**, an Indiana based chain which was acquired on April 1, 1998. Results for the third quarter included a gain of $251,000 from the sale of ophthalmic equipment (Summit lasers).

For the nine-month period the company reported revenue of $42.4 million, an increase of 28% from revenue of $33.1 million for the same period in 1997. Net income was

$233,000 (3 cents per share), compared with a net loss of $514,000 (6 cents per share) for the first nine months of the prior year. EBITDA was $2.2 million for the nine months compared with EBITDA of $955,000 for the same period in 1997.

10/27 **Staar Surgical** announced that the FDA had given the go-ahead to begin Phase III of its clinical trials for the Implantable Contact Lens (ICL) to correct myopia. The FDA's release will allow the company to implant 278 additional ICLs in patients and to increase its investigator base to 15 sites nationwide. In addition, this allows the company to expand the study to include patients with as little as 3 diopters of myopia, and to reduce the waiting period for patients to receive the ICL in the second eye to 45 days from six months.

10/28 **Sunrise Technologies** announced financial results for the third quarter and year-to-date. Revenues for the third quarter were $180,000 compared to $76,000 for the same period in 1997. The net loss was $3.6 million (10 cents per share) compared to $1.6 million (6 cents per share) in the third quarter of 1997. Revenues for the nine-month period were $504,000 compared to $2.5 million for the same period in 1997. This decrease was primarily due to the lack of revenues from the dental operations that were sold in June 1997. The net loss was $12.9 million (38 cents per share) compared to a net loss of $4.1 million (15 cents per share) in the comparable period of 1997.

"Our third quarter results were in line with our expectations and reflect the accelerated milestones we are achieving and the investments we are making in the exciting and fast growing ophthalmic refractive surgery industry," explained Russell Trenary, president and CEO. "Our spending was similar to last quarter and occurred in several important areas. In the product development arena, we completed our first prototype of the new Hyperion LTK System. This new technology performs the Sunrise LTK procedure in approximately three seconds, and relative to our current machine the doctor will now have access to a system that has enhanced characteristics, like our proprietary eye tracking system, as well as increased convenience through automation and sophisticated computer user interface features...The Hyperion LTK System, which possesses a small footprint designed for offices or surgery centers, represents the system we plan to launch in the U.S. in 1999."

10/28 **IRIDEX** announced that third quarter sales increased 12% to $5.2 million from $4.6 million in the corresponding 1997 quarter. Net income for the quarter decreased to $43,000 (1 cent/share) compared to $596,000 (9 cents/share) in the corresponding quarter in 1997. President and CEO Ted Boutacoff commented, "Our net sales performance for the third quarter was well below our expectations for a number of reasons. Sales orders from the Asian region continue to be weak, we postponed the initial shipment of the new OcuLight GLx product, and dermatology product sales growth was less than expected. Despite these factors, we were able to generate modest overall sales growth, due to strong sales growth for our ophthalmology products domestically and in Europe when compared to the prior year quarter. As a result of

the weak sales order activity from the Asian region, we instituted additional spending control measures to minimize or reduce expenses and capital purchases in areas that do not directly affect our sales and new product development efforts."

Boutacoff further commented, "We believe a number of factors will help us going forward. We expect an increase in dermatology activity during the fourth quarter due to the recent addition of sales personnel dedicated to dermatology. We expect to begin shipment of the OcuLight GLx during the fourth quarter and to generate additional sales from our new Slit Lamp Adapters with Micromanipulator and UltraView Optics and Dermatology Kit products. In addition, we believe the activity from the American Academy of Ophthalmology meeting in early November will also create product demand in the fourth quarter and into 1999."

10/28 **Summit Technology** announced that revenues for the third quarter increased 10% to $22.3 million from $20.3 million for the same quarter a year ago. Income from continuing operations were $698,000 (2 cents/share), as compared to $24,000 (24 cents/share) for the third quarter of 1997. Net income for the third quarter of 1997 included a favorable impact of $7.4 million related to discontinued operations.

Revenues for the first nine months of 1998 were $67.5 million, an increase of 13% compared to $59.8 million for 1997. Net income was $31.4 million ($1.00 per share) compared to net income of $8.6 million (28 cents per share) for the same period a year ago. The results of the first nine months of 1997 include the impact of discontinued operations. In the second quarter of 1998, Summit received a $35.0 million payment from **VISX** pursuant to a settlement agreement, under which Summit and VISX agreed to dissolve **Pillar Point Partners** and settled all pending litigation between the two companies. Excluding the $35.0 million settlement and related taxes and expenses, income from continuing operations for the nine months were $1.8 million (6 cents per share) compared to $1.2 million (4 cents per share).

Eliminating contact lens and related product revenues, revenues for systems and service and royalties totaled $11.2 million for the quarter, with systems accounting for $2.8 million -- including the sales of 11 lasers in the U.S. and 1 internationally. Of the U.S. sales, 9 were outright sales, and 2 were on a rental basis. (The average ASP for Summit's lasers currently runs at about $250,000.) For the nine month period, system sales included 36 systems sold in the U.S., 6 internationally, and 63 system upgrades. System revenues were $11.5 million, nearly double over last year, while service and royalties accounted for $22.7 million, up from $19.6 million a year ago.

During the accompanying teleconference, Bob Palmisano, CEO, noted that Summit had just acquired a microkeratome, the **Krumeich-Barraquer** device, from **EyeTech Vision A.G.**, a Lichenstein corporation, which was designed and produced in Germany by Dr. Jorg Krumeich. Palmisano said that approximately 25 refractive surgeons in 14 countries currently use the device. Summit intends to immediately begin marketing the microkeratome in international markets and will market it in the

U.S. once 510(k) clearance is obtained. According to the recently published **Dain Rauscher** report on the refractive industry, microkeratomes represent a $20 million market opportunity.

Summit anticipates closing on the previously announced **Autonomous Technology** deal in January 1999, and also expects hyperopia approval in 1999. High myopia and LASIK approvals are pending. Palmisano also said that production of Autonomous' lasers would be constrained at the beginning of the year, but should clear up towards year's end. He also cleared up some misconceptions about what Summit charges for its per procedure fees; those surgeons using the Emphasis disc are charged $200 plus $75 for the disc, while all others are charged a straight $250. He sees no changes in the immediate future, or at least until some further competition enters the market.

10/29 **BancBoston Robertson Stephens** senior medical devices analyst Wade King initiated coverage of **VISX** with a buy rating and a $68 price target. King said that VISX currently trades at 18 times 1998 EPS estimates of $2.31. By the end of 1999, he looks for shares of the company to trade at 20x his 2000 EPS estimate of $3.38. This yields a price target of $68. Investors at current levels have the potential for over 60% ROI.

King's report notes that laser vision correction is currently one of the fastest growing surgical markets and that VISX dominates with over a 70% market share. He believes that 393,000 procedures will be done domestically in 1998, 524,000 in 1999, and 604,000 in the year 2000. Most of the report is a straight run through about VISX and its products and regulatory status, but his competitive analysis is somewhat lacking. He believes that **Autonomous'** LadarVision laser will quickly become **Summit's** flagship product "since it appears technically superior to the Apex Plus". (I have asked him what the basis for this remark is, but have yet to hear back.) And although mentioning **Nidek** and **Bausch & Lomb/Chiron** as competitors, doesn't mention **LaserSight**! (How long has he been following this industry?) King notes that he expects VISX to introduce a new generation laser system in 2000, which should fuel increased systems sales. He also expects that the per procedure fees will drop to $220 by the end of 2000.

10/29 **VISX** attempted again to put its spin on the recent patent ruling versus **Nidek** in the UK. They announced that there had been no business development that would account for the recent volatility in its share price other than the press release from **Nidek**. The company believes that, contrary to information released by Nidek (see the October 26th brief above), the ruling in the U.K. leaves VISX in a strong position to enforce its patents, when necessary, in other actions throughout the world. U.S. law differs significantly from the U.K. law in determining patent infringement and validity, and is generably more favorable to the patent holder. According to VISX, Nidek's statement that the ruling may have "profound implications for the U.S. and other excimer laser markets" is inaccurate and highly misleading. VISX believes Nidek was deliberately attempting to mislead VISX's customers and the investment community by making

such a statement. The fact that a major portion of the U.K. trial was devoted to Nidek's unsuccessful attempts to invalidate VISX's scanning patent, in combination with the court's determination that Nidek infringes VISX's broad beam patent, supports VISX's continued confidence in the strength and breadth of its patent portfolio. (However, my read of the judgement doesn't necessarily uphold this spin.)

10/29 Toronto's *Globe and Mail* contained a story about several analyst's forecasts for **TLC The Laser Center** based on recent results issued by the company. Analyst Cameron Groome of **First Marathon Securities** had his eyes zapped on a Wednesday afternoon, was off work most of Thursday, and was on a plane on Friday. "I thought the best way to understand what the word-of-mouth factor would be [about TLC] was to go in and have the procedure done." Mr. Groome isn't alone. TLC recently reported that refractive laser procedures at its 48 clinics in Canada and the U.S. nearly tripled to more than 17,700 in its fiscal first quarter ended Aug. 31. That gave the company its first quarterly profit since going public in March, 1996, with results that beat street estimates by about 5 cents a share. TLC posted a profit of $403,000 (1 cent per share) in the first quarter, compared with a loss of $2.6 million (9 cents per share) in the same period a year ago. Most analysts weren't expecting TLC to move into the black until its third quarter this year. As a result, several TLC stock watchers have boosted their forecasts for the fiscal year, which ends May 31, to between 18 and 23 cents a share, an increase of 2 to 5 cents. Hot on the heels of the profit revisions, TLC's stock began a new assault on its 52-week high of $27.75 on the Toronto Stock Exchange. It closed Tuesday at $24, up 50 cents. **PaineWebber** analyst Charles Olsziewski said the bottom line in the first quarter "was even more impressive given the losses posted by BeaconEye [which was acquired in April], the company's secondary care business and its managed care subsidiary, **Partner Provider Health**." Mr. Olsziewski rates the stock a buy for "aggressive, risk-tolerant accounts" with a 12-month target of $21 to $22.

Mr. Groome said he was impressed with same-store sales growth of more than 100 per cent in the quarter. Moreover, sales in the past three quarters have grown an average of 26% quarter-over-quarter. He said a recession would have to be "vicious to turn the company into zero or negative territory."

10/30 **LCA-Vision** reported record revenues and a sharp decline in losses for the third quarter. Revenues from laser vision correction increased sharply, up 116% to a record $8.5 million, versus $3.9 million a year ago. Procedure volume for the period grew to a record 6,093 procedures, up 122% from 2,749 procedures for the same quarter last year. Total revenues for the period rose 84% to $9.1 million, up from $5.0 million a year ago. The company was again cash flow positive, with EBITDA rising to a positive $16,000, up from a deficit of $657,000 a year ago. The company also trimmed its third-quarter net loss to $759,000 (2 cents per share), compared with a net loss of $2.6 million (8 cents per share) a year ago. Commenting on the results, LCA-Vision CEO Dr. Stephen Joffe said: "Procedure volume continues to accelerate

at a healthy pace. We look for further progress in the fourth quarter and remain confident that we can achieve positive earnings per share in the first quarter of 1999."

11/2 **Orbtek** disclosed that it has implemented a plan designed to meet the structural and capital requirements of the company's plan to accelerate growth. In March 1998, the company retained the services of John Williams, a capital structure and finance specialist who has since been appointed to the board of directors, to assist in planning and implementing financial strategies to meet the needs of the company as it undergoes its anticipated rapid growth. In the ensuing seven months the following accomplishments have been achieved:

-- $3.75 million of corporate debt has been eliminated.
-- $2.5 million of Class "A" preferred stock, along with their associated warrants, has been retired.
-- A $1.5 million private placement of convertible debt was offered and sold-out during the second quarter and a $600,000 private placement is currently being offered to further bolster the company's financial position.

The company's products include the innovative ORBSCAN diagnostic imaging systems, as well as surgical instruments, and software linking its diagnostic imaging systems directly to therapeutic systems such as the excimer lasers used to perform LASIK. LASIK is the fastest growing procedure for the surgical correction of myopia and other vision problems. To date, over 300 ORBSCAN Systems have been sold in over 36 countries throughout the world.

11/2 **Autonomous Technologies** reported its third quarter results with a net loss of $4.6 million (40 cents/share) on revenues of $30,900, versus a loss of $2.7 million (27 cents per share), for the same quarter last year. The quarterly loss of $4.6 million was in line with analyst and company expectations as the it continues to ramp-up for commercial production of its LADARVision System.

As of September 30, 1998, the Company had cash on hand of $2.8 million. In addition, **OZ Master Fund, Ltd.** has an option to purchase an additional $4 million of Convertible Preferred Stock from the Company no later than November 10, 1998. If the option is exercised, OZ Master Fund, Ltd. will also receive a stock purchase warrant for 300,000 shares of common stock. The Company has also obtained a $5 million line of credit from **Summit Technology** as a result of its pending acquisition by Summit. Autonomous believes that its current cash position combined with the expected additional investment of $4 million will provide sufficient cash resources for operations for the period prior to the closing of the acquisition without the need to draw from the Summit line of credit.

11/2 **Gimbel Vision International** reported the number of paid refractive procedures performed at its centres rose to 4,272 for the three month period ended September 30, 1998. This is up 67% from the 2,555 procedures performed during the same period

last year. Same-store growth continues to increase with volumes from those centres in operation during the past twelve months increasing 53% during the third quarter of 1998 compared to 1997. Of special note is the significant growth at the recently added centres in Rio de Janeiro, Brazil; Sacramento, CA; Eugene, OR; and Toronto, Ontario. The procedures performed during the third quarter at these centres increased an average of 72% over the second quarter of 1998.

11/2 *Wall Street Corporate Reporter* interviewed Robert Palmisano, CEO of **Summit Technology**. The interview covered much ground, including Mr. Palmisano's background with **Bausch & Lomb**, and how he perceives he has turned Summit around, including rebuilding the management team by replacing 9 of the previous 12 vice presidents and establishing a new direction for the company. Summit now has two major divisions; the laser vision surgery business and **Lens Express**, which sells contact lenses by direct mail to consumers. Soon, a third division, **Autonomous Technologies**, will be added.

Palmisano noted that Summit has two manufacturing locations, with the Emphasis Discs being produced in Waltham, MA and Summit's lasers produced in Cork, Ireland. When Autonomous comes on board in late January, its lasers will continue to be produced at its Orlando, FL location. Discussing the target market for laser vision correction, Palmisano noted that its target was 35 million people with currently less than a 1% penetration of that market.

11/3 **The Society for Excellence in Eyecare (SEE)** has written the FTC to express its strong opposition to the proposed acquisition of **Autonomous Technologies** by **Summit Technology**. "Our members, who represent large, progressive eye surgery practices around the country -- including many of the ophthalmic surgeons who have been pioneers in refractive surgery -- are distressed at the prospect that antitrust enforcement authorities might permit this anti-competitive merger." Pointing out that the excimer laser industry is in great need of an infusion of competition from a new entrant like Autonomous, SEE says equipment prices remain high, and there is no sign that, notwithstanding the proposed **Pillar Point** settlement, patent license fees will come down. "The result of these high costs is that the price to the patients of refractive eye surgeons in the U.S. is considerably higher than it is in other countries, such as Canada and dramatically higher than in South America."

(I emailed SEE that if the proposed merger were stopped, Autonomous would suffer immensely, as they could ill afford to go through a legal battle with **VISX**, and it could result in their folding, thus effectively limiting competition rather than enhancing it.)

SEE also sent a letter to the FTC commenting on the proposed consent orders with Summit and VISX regarding the dissolution of the Pillar Point Partners agreement. In a strangely worded letter, the organization stated, "The proposed consent order does not redress the harm the laser purchasers or lessees have suffered. Indeed, it may have

the perverse effect of leaving them with a piece of costly medical equipment, for which they typically paid in excess of $350,000 and *which they cannot ever use for PRK procedures*. (Italics added) To address this problem, the orders should be modified to give the owners of Summit and VISX excimer lasers the option to rescind their laser purchase or lease, as well as their Pillar Point license agreement."

11/3 Two FDA approvals of merit were announced; **Autonomous Technologies'** approval of its LadarVision laser system came through for -1 to -10 diopters of myopia, with up to -4 diopters of astigmatism, and **VISX's** approval for hyperopia from +1 to +6 diopters, with up to 1 diopter of astigmatism.

In a followup telephone call, Randy Frey of Autonomous noted that his company would commence marketing right away (at the upcoming AAO meeting), taking sales orders, but would put off shipments amd collecting on sales until the deal with **Summit Technology** was finalized, "to avoid mischievous behavior" (by VISX). Frey also claims that the newest version of his laser "has been speeded up" (to about 55 Hz) to accomplish ablation rates of 1 diopter per 8 seconds, so that a standard 4 diopter correction would only take about 30 seconds, equivalent to the wide area ablation machines.

Several of the laser vision centers chimed in on the VISX announcement, claiming that they had updated VISX Star S2 machines and would commence offering hyperopia corrections immediately. This included **TLC The Laser Center**, **LCA-Vision**, and **Laser Vision Centers**. All said that they had been compiling names of those requesting hyperopic correction and would be notifying them that it was now available.

11/3 **Premier Laser Systems** announced that **Data.Site**, its majority-owned joint venture, has debuted OnTarget Network, an addition to their Web site, where ophthalmologists, optometrists, and especially patients can retrieve statistical data on thousands of eye procedures. Previously, ophthalmologists around the globe have been able to compare their refractive and cataract surgical outcomes with the Data.Site worldwide database of similar procedures, helping them to keep abreast of the most successful surgical techniques, evaluate their own surgical recommendations and guide treatment decisions. Now, patients and others will be able to access top-line data on various eye procedures and related outcomes to make intelligent decisions about possible surgeries. The Web site can be accessed at www.datasite1.com.

11/4 **LCA-Vision** announced an exclusive agreement to purchase a quantity of Innovatome microkeratome systems from **Innovative Optics**. LCA-Vision operates 22 refractive surgery centers throughout the world including 19 in the United States. Thomas Wilson, COO for LCA-Vision said "after an extensive evaluation of several microkeratomes, LCA determined that the Innovatome was the instrument of choice for our immediate and future needs. This determination was based on surgical results,

features and benefits, cost effectiveness, and availability." He also stated that "we feel the Innovatome is an excellent choice for our needs, since it can be easily employed with consistent results by experienced as well as beginning LASIK surgeons."

The same day, the **Hillside Group** and Innovative Optics announced that they too had signed an agreement for Hillside to obtain 50 Innovatome microkeratomes in a transaction valued at approximately $2.5 million. The Hillside Group is a medical industry leader in patient financing and medical project/equipment financing, and within the ophthalmic area is the single largest financing source for VISX STAR SmoothScan excimer lasers. Under the terms of its agreement with Innovative Optics, Hillside is guaranteed a priority delivery of Innovatome microkeratomes. William Curtis, Managing Director of The Hillside Group, said, "We are placing numerous VISX excimer lasers through our rental and lease programs. Innovative Optics' commitment that Hillside will receive a guaranteed priority delivery is a significant benefit to our lessees, and means we can now provide simultaneous delivery of an Innovatome microkeratome with each laser we finance."

11/4 This month's *Refractive Market Perspectives* reports that procedure volumes continue to rise dramatically. Dave Harmon reports that, including procedures performed on Americans travelling internationally, over 123,500 procedures were performed on U.S. patients during the last quarter. Year-to-date, approximately 324,800 procedures have been done, as compared to 140,235 for the first nine months last year, a 132% increase. Assuming a 10% increase for the fourth quarter, Dave is now forecasting **470,000** procedures for the year!

Commenting on **VISX's** hyperopia approval, Dave notes that about 35 million Americans have hyperopia, but that many are over 50 years of age. Of those falling between age 40 to 50, many suffer from presbyopia as well; while those under age 40 are typically able to naturally accommodate to bring objects into focus. Many with low to moderate levels of hyperopia go undiagnosed until after age 40, when they begin to lose the ability to accommodate. He goes on to note that an additional procedure increase of 5%, the percentage of contact lenses sold with a plus correction, is a good estimate of the long term impact of hyperopia on laser refractive surgical volumes. (However, as I learned at the RSIG meeting prior to the Academy meeting, the approval opens up the opportunity for monovision correction of presbyopia, by correcting one eye for near and the other for distance vision. A large number of refractive surgeons are already doing just this for their over 40 myopic patients. It should be noted that some patients -- as many as 20% -- find it difficult to adapt to monovision and some loss of stereopsis, and should be tried with monovision contact lenses before surgery is attempted.)

Dave's newsletter also contains an in-depth review of the patent litigation between **Nidek** and VISX (see the press release briefs from both companies, above and last month), discussing the elements of the decision reached recently in the UK court. The judges conclusions were: EP 051869 is valid, but Nidek's laser does not infringe it, but

were Nidek's laser to infringe the patent, it would be invalid on the grounds of insufficiency; EP 0207648 is invalid on grounds of obviousness, because of the Trokel article, the Puliafito article and the disclosures made at the Interlaken conference, but if it were valid, the Nidek laser would have infringed it. I won't go into further detail here, but anyone interested can either contact me or Dave (817-514-0702) for the in-depth details. (For a look at the complete judgement, see my November 16th brief below.)

11/4 A coalition of 11 national medical societies, including the AAO, ASCRS, and SEE filed suit in federal district court in Chicago challenging the government's just-released rules for phasing in the new practice expense component of the Medicare physician fee schedule. The lawsuit was brought against the Secretary of HHS and HCFA, and asks the U.S. District Court for the Northern District of Illinois to declare HCFA's practice expense transitions formula unlawful and invalid.

According to the plaintiff's, HCFA's formula for phasing in resource-based practice expense relative value units (PE-RVUs) is in direct conflict with the transition formula required by the plain language of the Balanced Budget Act of 1997. They also contend that the unlawful transition formula will lead to $495 million in unauthorized fee reductions for certain physician services over the 1999-2001 transition period. The implementation of the unlawful regulation will cause great confusion and injure patients and the public interest, said the plaintiff's court papers. "If the unlawful regulation is permitted to take effect, hundreds of millions of Medicare reimbursement dollars will be misdirected, leading to under-payments for hundreds of thousands of reimbursement claims involving services for which PE-RVUs were reduced in 1998 and over-payments for hundreds of thousands of claims involving services for which these units were increased in 1998. These incorrect payments will be made to both physicians and Medicare beneficiaries."

At last word, this challenge was successful in delaying implementation of the HCFA expense transitions.

11/5 **VISX** announced that it had initiated collaborative efforts with several leading topography companies to develop customized ablation planning systems for laser vision correction. **EyeSys Premier** is the first company to test a system which will allow users of the VISX Star S2 laser with the EyeSys VISTA or System 2000 corneal topographers to create customized ablations. (Other laser companies also working on topographically-linked ablation include **LaserSight**, **Aesculap-Meditec**, **B&L Surgical/Chiron**, **Nidek**, and **Schwind**.)

11/5 **Staar Surgical** announced that, as a result of continued competition in its cataract business, it expects to report revenues and results of operations below analysts' estimates for its third quarter ended Oct. 2, 1998. The company plans to announce its third quarter results on November 13. In a separate announcement, Staar also announced that the FDA had given marketing approval for its STAAR TORIC IOL,

the only intraocular lens designed to reduce pre-existing astigmatism in cataract patients.

11/6 According to *Federal Filings Newswire*, **Summit Technology** and **Autonomous Technologies** held merger talks in late 1997 and early 1998, which were broken off until mid-1998 when a minority shareholder of Autonomous contacted Summit's CEO about re-opening deal talks. This was done during July until a confidentiality agreement was entered into on August 3rd. On August 4th, Summit's board of directors authorized the company to pursue a deal with Autonomous, and the company retained **Hambricht & Quist** on August 21 to be its financial advisor in connection with a possible deal. Four days later Summits and Autonomous' financial advisors held a meeting to discuss information and exchange ideas. A general agreement was reached on September 9th and Summit conducted on-site due diligence over the next three days. The deal was approved on October 1st, and announced later that day.

11/6 **Autonomous Technologies** announced that it had received a Medical Device License from the **Canadian Therapeutic Products Directorate** for the company's LADARVision System. The Canadian license was granted after the Medical Devices Bureau determined that the company's clinical study data satisfied the requirements for safety and efficacy. The license application was for visual correction between -1.0 and -10.0 diopters of nearsightedness and up to -6.0 diopters of astigmatism. Based on the new Medical Device Regulations, the LADARVision System is considered a Class III medical device.

11/6 **Premier Laser Systems** announced that it, along with its subsidiaries and joint venture affiliate companies, will introduce eight new advanced technology products and systems for eyecare professionals at the annual AAO meeting in New Orleans, Nov. 8-11. Featured products will be demonstrated by Premier Laser, its wholly-owned subsidiary **Eyesys Premier**, its majority-owned joint venture **Data.Site**, and 51 percent-owned **Ophthalmic Imaging Systems**.

Among the products to be featured are a Digital Fundus Imager from OIS; a new software package that simulates the PRK/LASIK procedure for the **VISX** Star S2 lasers, the VISX Refractive Planner; the Data.Site OnTarget Network; the Premier dERbium system for skin resurfacing; EyeSys Vista, a handheld corneal topography system; and a digital Slit Lamp Imager.

11/9 **Orbtek** reported that it had active working relationships with **VISX** and **Aesculap Meditec**, two excimer laser manufacturers, to complete and provide systems which link surgical ophthalmic lasers directly to the topographic information gathered and analyzed by the ORBSCAN Systems. "We are extremely pleased to be collaborating with these upper echelon companies to provide even more capability and accuracy to the procedures being performed in the ophthalmic surgical arena," said Jack Savage, Orbtek CEO.

Using Orbtek's initial linking technology, the CIPTA system (Corneal Interactive Programmed Topographic Ablation), a **LaserSight** excimer laser has performed over 150 LASIK procedures in Europe with excellent results. The next generation of laser-linking technology is Orbtek's revolutionary Wavefront Ablation Vision Enhancement W.A.V.E. system which provides for even more accurate surgical ablations and predictable outcomes to vision enhancement procedures. Orbtek's cooperative relationships with industry leaders such as VISX, **Bausch and Lomb**, Aesculap Meditec, and **STAAR Surgical** are key ingredients in the company's future as it continues to implement strategies to fuel its projected rapid growth. Over 300 ORBSCAN systems have been sold in over 36 countries throughout the world.

11/9 KeraVision announced that it planned to expand its hyperopic clinical study to the U.S., Canada, and Europe. With 85% of farsighted (hyperopic) patients able to see with 20/20 vision or better and all 100% having vision of 20/40 or better after being treated with its KeraVision Rings. Clinical results from the hyperopia study were reported at the AAO meeting in New Orleans. The company intends to launch additional hyperopia studies at clinical sites in the U.S., Canada and Europe next year.

KeraVision has developed a similar non-laser KeraVision Ring treatment for nearsightedness (myopia). That product is currently sold in Canada and in several European countries and is under final review by the FDA for possible commercial use in the United States.

11/11 **TLC The Laser Center** was featured in a news story in *Investor's Business Daily* discussing the opportunity for treating farsightedness with the recent approval of the **VISX** laser for treating hyperopia.

It sounds like something out of a science-fiction novel -- using lasers to reshape the surface of the eye, making once-blurry vision crystal clear. But laser vision surgery is a very real option. And the market has grown in the blink of an eye. U.S. ophthalmologists will perform 400,000 laser vision correction procedures this year, up from 195,000 in '97, says analyst Charles Olsziewski of **PaineWebber Inc.** By '00, some industry observes say, more than 1 million procedures may be done each year. The reason? Laser surgery is producing solid results, and that's fueling positive word-of-mouth. "It's been like that old shampoo commercial," Olsziewski said. "You tell two friends, and so on."

North America's largest provider of laser vision surgery, TLC The Laser Center Inc. stands to reap the rewards of that market boom. The Canadian company already enjoys strong business from correcting nearsightedness and astigmatism. TLC received more good news last week, when the FDA approved Visx Inc.'s laser to treat farsightedness. TLC believes adding that procedure to its lineup will greatly expand its business in the U.S. "In effect, it doubles our potential market," said chairman, president, and CEO Elias Vamvakas. The company now holds 18% to 20% of the U.S. market for laser surgery.

Most of TLC's business comes from performing laser in-situ keratomileusis, or LASIK. Lasik has been used in Canada to correct farsightedness for more than a year. Such procedures account for 20% of business at TLC's Canadian centers. "At least 50 million people are farsighted," Olsziewski said. "While not all patients are going to be candidates for laser vision correction, TLC had a 15% to 20% incremental boost in procedures in Canada when it began treating farsightedness."

11/12 The unique non-laser surgical approach being developed by **KeraVision** to treat low to moderate myopia resulted in 20/20 vision or better for 74% of patients and at least 20/40 vision for 97% of those in a U.S. clinical trial, that was reported at the AAO annual meeting in New Orleans. Clinical results for the KeraVision Ring, the most extensive so far, are based on data submitted earlier this year to the FDA as part of KeraVision's PMA application for the product. The results were from 410 KeraVision Ring treatments that were included in the U.S. Phase II and Phase III studies, performed at 11 clinical sites. Patients were monitored for at least one year to assess the safety and efficacy of the treatment. Fifty-three percent of the study group improved to at least 20/16 -- in other words, better than 20/20 vision. "The KeraVision Ring appears to safely and effectively correct myopia, with the added benefit that we can reverse the effect," reported George O. Waring, MD, professor of ophthalmology at Emory University. "Reversibility means that people can have permanent correction without making a permanent choice."

In August, the FDA accepted for "filing" the company's PMA application for the KeraVision Ring. That action triggered the final phase of regulatory review for possible commercial approval in the U.S. Final FDA review Is pending.

11/13 **TLC The Laser Center** reported that Al Kildani, an analyst with **Pacific Growth Equities** has initiated coverage of TLC with a "buy" rating and a 12-18 month target price of $28 per share. (The same analyst also issued a report on **Laser Vision Centers**, terming that company a "long-term-buy", with a 12-18 month target price of $14-16.)

Both reports thoroughly analyze the strategies that each company is pursuing, TLC following a co-management optometrically-fed network system, which feeds its metropolitan-area located centers, while LVC follows the mobile approach, moving lasers to doctor's offices in smaller markets, providing them access on an as-needed basis.

11/13 **Staar Surgical** reported revenue of $12.9 million for the third quarter which compares with revenue of $11.8 million for the third quarter of last year. Prior to some accounting charges, net income for the quarter was $398,000 (3 cents per share), compared with $2.1 million (15 cents per share) for last year's third quarter. Including the effect of an accounting charge of $1.7 million (12 cents per share), the net loss for the quarter was $1.3 million (9 cents per share).

The company also noted that it had begun shipment of its newly approved toric IOLs in the U.S.

11/13 **Eyemakers, Inc.**, an operator of 34 eye retailing shops in the Southwest under the names **Eyemakers** and **Budget Optical** and a provider of practice management services for optometrist-owned eyecare practices, announced that it had signed a letter of intent to acquire **Icon Laser Centers of Canada** and **Icon Laser Centers of the Southwest, Inc.** Under the proposed transaction, Eyemakers would acquire all the issued and outstanding capital stock of Icon of Canada and that of its affiliate, **Vista Laser Centers of Southwest, Inc.**, which does business under the name of Icon Laser Centers.

Icon Canada has a Laser Vision Center in London, Ontario and is planning to open a center in Toronto before year end 1998. Icon (USA) has a LVC center in Scottsdale, Arizona. According to the November 23rd *Vision Monday*, once the deal closes in late January, Eyemakers will sell most of its company-owned Budget and Eyemaker stores to their associated optometrists, retaining practice-management agreements. A few high-volume units will be retained and converted into Eyemakers Laser Vision Stores, bringing laser vision correction into the retail environment. (It seems to me that **Sight Resource** tried this, and found it difficult to pull off.) Jim Mellon, Eyemakers president and CEO expects the company will operate at least six laser superstores in the U.S. and Canada by year-end 1999.

11/15 *EyeWorld Week* reported that the FTC hearing on the **VISX** patent improprieties, that was scheduled for later this week, has been put off until December 14th.

11/15 This month's *EyeWorld* magazine contains several interesting articles in its coverage of lasers and refractive surgery. The first is a piece describing the **Refractec** radio frequency approach to corneal shaping. A second article discusses the "crowded" microkeratome market, with a table listing 17 different systems, including the two water jet systems. The third piece is an updated table listing the four laser phaco systems, including the Dodick Laser Lysis system, which had been inadvertently left out of the table accompanying the September article on laser phaco.

11/16 **LaserSight** reported that revenues for the third quarter and nine month period rose 73% and 54% from the corresponding 1997 periods after adjustment for the sale of two of LaserSight's former health care subsidiaries. Revenues for the quarter were $5.3 million, compared to $3.0 million of adjusted revenues in 1997. Revenues for the nine months were $14.5 million, compared to $9.4 million of adjusted revenues in 1997. Before such adjustment, revenues for the three and nine-month periods were $6.2 million and $18.1 million respectively. The company reported a net loss of $2.2 million (17 cents per share) for the third quarter, as compared to a net loss of $2.4 million (25 cents per share) in 1997. For the nine month period the company's net loss before a one-time preferred stock charge, was $5.9 million compared to $5.5 million for the 1997 period. Including the one-time preferred stock charge, the loss

attributable to common shareholders in the 1998 period was $9.5 million (79 cents per share).

International sales of the company's refractive laser products increased over previous quarters with corresponding increases in laser system gross revenues. During the quarter the company received approval to apply the CE Mark to its LaserScan LSX excimer laser system, a requirement for sale of that system into all European Community member countries. LaserSight also consolidated its corporate office and Technologies division into a new facility located in Winter Park (metropolitan Orlando), Florida. The company sold thirteen laser systems during the third quarter of 1998, compared to ten being sold in the third quarter of 1997. A total of 42 laser systems have been sold during the nine month period, compared to 33 systems sold during the corresponding period in 1997. The average sale price of the refractive laser systems rose approximately 14% during the nine months as the result of the product mix shifting towards a larger proportion of LaserScan LSX system sales.

The company also announced that **Mercacorp, Inc.** had agreed to dismiss its lawsuit filed last August, with a release of all claims. In a simultaneous transaction, LaserSight issued Mercacorp a warrant to purchase 750,000 shares of the company's common stock at a price of $4.00 per share (the closing bid price of the common stock on November 10, 1998), and a warrant to purchase 750,000 shares of the company's common stock at a price of $5.00 per share. Both of these warrants terminate if the $4.00 warrant is not exercised in full within fourteen days after the effective date of a registration statement covering the shares of common stock to be issued upon exercise of the warrants. In addition, prior to the exercise of the $5.00 warrant, LaserSight has the option, but no obligation, to repurchase the $5.00 warrant by paying $1.00 per share. The $5.00 warrant will expire in three years if not exercised. Michael Farris, CEO, said, "We are pleased to resolve this dispute in a manner which does not require any cash payment and may result in a capital investment in the company at or above the market price at the time of resolution. This resolution allows the company to more clearly focus its efforts on important ongoing strategic business initiatives."

11/16 After a request at the AAO meeting, I received a note from **Nidek** providing the web address to access the judge's decision in the case between Nidek and **VISX** in England. I was able to download the October 19th judgement, which is available at www.courtservice.gov.uk/highhome.htm, under the patents judgements section. (I can provide a copy -- with some of the drawings missing -- for anyone who is interested, but cannot access the website. I believe, however, that David Harmon's explanation in his current newsletter is quite complete -- see the November 4th brief above.)

11/16 The FDA announced that it had reached a consent decree with **Photon Data, Inc.** for the condemnation of 10 excimer lasers and numerous components valued at nearly $13 million, and to the reconditioning of various laser components. The reconditioning will be conducted by the firm under FDA supervision. PDI has agreed

to pay all costs incurred as a result of the disposition of the lasers and reconditioning of components. The laser systems will be disposed of by the government. Further, the firm has agreed to pay civil fines for potential future violations of the injunction in the amount of $25,000 per violation. The firm has agreed to put $100,000 in escrow to pay such fines. In addition, it has agreed to execute a $100,000 penal bond to insure that they comply with all the conditions of the consent decree.

11/17 **KeraVision** announced that the Ophthalmic Devices Advisory Panel of the FDA would review the company's PMA application on January 12, 1999. If approved, the KeraVision Ring would become the first non-laser, surgical approach in the U.S. for treating nearsightedness (myopia), opening the way for a new category of vision correction surgery that is designed especially for treating low to moderate myopia.

11/17 **Staar Surgical** announced that the FDA had given permission to expand its clinical trial of the Implantable Contact Lens (ICL) for hyperopia to a total of 14 sites nationwide and 350 patients. On Oct. 27, 1998, the company got approval to begin Phase III clinical trials for the ICL for myopia. With this current expansion for hyperopia and the release to Phase III for myopia, the company can now enroll a total of 350 patients, which includes patients with refractive errors from 3 to 20 diopters in each study.

11/18 **Bausch & Lomb** announced that it had undertaken an evaluation of strategic options for its eyewear business. Alternatives to be considered include joint ventures, sale, spin-off, or other business combinations. The company has engaged the investment banking firm of **Warburg Dillon Reed LLC** to provide assistance in this process. This evaluation is consistent with the company's focus on leveraging the opportunities and capabilities of its three eye-related healthcare businesses - Vision Care, Pharmaceuticals, and Surgical products, and with its stated objective to maximize the value and profitability of its eyewear business lines.

William Carpenter, president and CEO stated, "...it is apparent to us that Bausch & Lomb's greatest potential for accelerated growth in the future lies in our healthcare businesses for the eyes...Those businesses share common professional customer bases and distribution channels, similar engineering and manufacturing platforms, comparable R&D needs and capabilities, and similar infrastructure needs. Because they provide the greatest opportunities for leveraging our core competencies and the greatest potential for future growth, they will be the primary focus of our attention going forward."

11/19 **Laser Vision Centers** announced that same U.S. laser revenue for its fiscal second quarter ended October 31, 1998, was up over 60% over the same quarter last year. LaserVision operated 30 excimer lasers in U.S. during the quarter, however same U.S. laser revenue only compares the revenue of 23 lasers which were in operation in the second quarters of both years. The company said that in October it performed over 4,300 surgical cases in the United States and it was the best month to date for U.S.

case volume. The company also reported that over 11,600 cases were performed on its U.S. laser systems during the quarter, a 109% increase over the same quarter a year ago and a 14% increase over the previous quarter. In addition, the company said that 408 surgeons used its services during the quarter compared to 378 the previous quarter.

11/19 **LCA-Vision** Inc said it had begun performing laser surgery to treat hyperopia. The company's Dayton and Cincinnati facilities were the sites of the initial procedures -- the first performed on farsighted patients in Ohio outside of clinical FDA trials. Dr. Stephen Joffe, chairman, said, "This is a genuine milestone. Since all of our centers are equipped with **VISX** lasers, a growing backlog of farsighted patients, eager for the procedure, plus a staff of well-trained and credentialed physicians enabled us to get off to a quick start tapping into this major market. We see hyperopia as a very important segment of our future patient volume." Dr. Joffe added that the big impact of hyperopia approval will probably begin to be felt in 1999 as awareness of the procedure's availability rapidly spreads.

11/19 I received the latest report, on "Scanning Excimer Lasers", from *Grassroots Research*, written by the esteemed Lynne Peterson. Her conclusions are:

● Refractive surgeons are interested in scanning lasers, but there does not appear to be much pent-up demand. Interest will increase once scanning lasers link corneal topography and ablation.

● As the next generation in excimer laser technology, scanning lasers are likely to capture a significant share of new laser sales. Laser owners would switch to a scanning laser if it lowered the per-procedure fee to $100 or less.

● **Summit** already appears to be lowering its per-procedure fee from $250 to $170-$200, (but see Summit's explanation in the October 28th brief above) and pressure is mounting for **VISX** to follow suit.

● **Autonomous** is not considered a major threat to VISX since the Autonomous laser is slower (not anymore, as the company has speeded up its rep rate to 55 Hz), not substantially cheaper, and will be a niche product for both high- and low-volume doctors. However, it could capture 8%-9% market share by the end of 1999.

As usual, Lynne has written an excellent report, with, however, a few facts behind the times. In a comparison table, she showed the older MEL 60 scanning slit laser from **Aesculap Meditec**, rather than their newer small spot scanning MEL 70. She also bought the VISX "spin" on the **Nidek** UK legal battle, rather than the true story wherein Nidek won the patent war! And, other than the higher rep rate Autonomous laser, which was only announced at the AAO meeting, the report is quite good. Grassroots Research can be reached at 415-954-5493.

11/20 Members of the senior management team of **Bausch & Lomb** updated the investment community on the company's strategic plans at a New York City meeting. The company announced that it is well on its way to transforming Bausch & Lomb into a technology-based healthcare company for the eye. In prepared remarks, president and CEO William Carpenter reviewed the company's progress in reengineering the company so that it could focus its full attention on leveraging the growth potential and tremendous synergies among its vision care, surgical, and pharmaceutical businesses. After reviewing the turnaround in the company's sunglass business and the rationale for the decision announced earlier to evaluate strategic alternatives for that product line, Carpenter turned to the future. Following a brief review of current trends in the eye care market, Carpenter explained how Bausch & Lomb is uniquely positioned to take advantage of those trends.

The company:

-- enjoys a strong competitive position in every market in which it competes;
-- has a global infrastructure unsurpassed by any competitor; and,
-- has the broadest product line in the eye care field.

Carpenter said that Bausch & Lomb's future success will be driven by breakthrough new products based on technological innovation, and by leveraging the significant strength of the Bausch & Lomb name with consumers around the world.

(For more about B&L's strategy for the future of its surgical business, see my writeup from the AAO, Part 2, accompanying this edition of the newsletter.)

11/23 According to a new strategic research study by **Frost & Sullivan**, "U.S. Refractive Surgery Devices Market", this market will experience unprecedented growth in the next few years. In 1998, the U.S. market for refractive surgery devices was $63.8 million, and it is expected to grow an astounding 72% in 1998-99. The increase in LASIK procedures will lead to increases in sales of excimer lasers, microkeratomes, and blades. In particular, blade sales have been gaining tremendous market shares and revenue growth since 1996 due to the requirement of using a new blade for each patient undergoing the LASIK procedure.

The entrance of two new devices, intrastromal corneal ring segments (ICRS) and phakic intraocular lenses (IOLs), are expected to cause major stirs in the market. Laser-based eye surgery will face stiff competition from both technologies. (The author must be a dreamer!) ICRS are expected to gain FDA approval by late 1999, and are likely to enter the market in 2000. ICRS have the advantage of being reversible. However, the present generation technology is not suited to the treatment of astigmatism. Phakic IOLs will enter the market in 2001-2002. Like the ICRS technology, implantation of phakic IOLs is reversible. More importantly, phakic IOLs address a segment of the market where laser surgery falls short: patients with high

levels of refractive error. However, phakic IOLs can result in higher risks of cataracts and glaucoma.

According to Frost & Sullivan Medical Analyst Sharmila Shankarkumar, "Many researchers and managers at leading firms strongly believe that the future of refractive surgery lies in phakic IOLs. **Bausch & Lomb** acquired all three technologies for all three procedures (lasers, corneal rings [(?) -- as noted in my AAO writeup, **Storz Ophthalmic**, now a part of B&L Surgical has given up on GIAK, which is rink-like, and I am not aware of any other "ring" technology possessed by B&L Surgical], and phakic IOLs). However, the company decided to pursue only lasers and IOLs. Such strategic decisions reflect the beliefs that major participants have about the success of different technologies."

Major trends in the market include companies adopting aggressive marketing techniques in order to gain market share. For example, Bausch & Lomb (the market leader) is under pressure due to an excess demand for microkeratomes. They recently announced that they have a back-log of six to nine months of orders. Competitor **Moria** has taken advantage of this situation by propositioning those on Bausch & Lomb's waiting list.

Competition is expected to heat up in the next few years due to the entry of several new firms hoping to reap generous profits from this lucrative market. New entrants in the refractive surgery market include laser market leaders like **Nidek** and **Coherent** (what about current market leaders **Summit** and **VISX**?), and smaller firms like **Ophtec**. Well-established firms, such as **Alcon** and **Allergan**, are carefully watching small entrants with pioneering technologies to see what proves to be most successful in the market. According to Shankarkumar, "These smaller firms are ripe targets for acquisition. Mergers and acquisitions provide established firms with access to new technologies which the market has approved. Summit Technology's acquisition of **Autonomous Technologies** and Alcon's alliance with **Medjet** are examples of the manner in which established firms seek new technologies." Furthermore, Bausch & Lomb's acquisition of **Chiron Vision** and Storz Ophthalmic gave Bausch & Lomb access to all the leading devices.

Other market participants noted include: **Aesculap-Meditec**, **Eye Tech Ltd.**, **Eye Technology Inc.**, **Herbert Schwind GmbH and Co.**, **Innovative Optics, Inc.**, **International Vision Inc.**, **IntraLase Corporation**, **KeraVision, Inc.**, **LaserSight Technologies Inc.**, **Mastel Precision Surgical Instruments**, **Med-Logics**, **Micra USA Inc.**, **MicroOptix**, **Novatec Laser Systems Inc.**, **Ophthalmic Innovations International**, **Ophthalmic Technologies Inc.**, **Refractive Technologies Inc.**, **STAAR Surgical Company**, **Sunrise Technologies Inc.**, **Visijet Inc.**, **Advanced Corneal Systems Inc.**, **Howard Instruments Inc.**, **Microtech Inc.**, **Pharmacia Ophthalmics Inc.**, and **Refractec, Inc.**

11/24 In a major move reflecting confidence in the long-term efficacy and visual stability of laser vision correction, **LCA-Vision** introduced its new "Continuum of Care" program that provides lifetime care to most patients undergoing laser treatment to correct myopia, astigmatism, or hyperopia. Commenting on the ground-breaking program (which is similar to one initiated by **TLC The Laser Center** last year), LCA-Vision Chairman and CEO Dr. Stephen Joffe said, "Our willingness to make this commitment, extending care from the usual 12-month post-operative period to a patient's lifetime, underscores the excellent results LCA-Vision has achieved performing nearly 40,000 procedures over the last seven years. The `Continuum of Care' is a powerful incentive that will give a significant boost to our marketing efforts and give potential patients greater confidence to undergo laser vision correction."

To participate in the program, Dr. Joffe explained, the patient and the LCA-Vision medical team will agree on the level of correction to be achieved and which laser refractive technique will produce the best results. In those very few instances when the desired correction is not achieved in the initial procedure, and the team believes a second procedure is likely to improve the visual outcome, the patient will be re-treated. The program also provides that, if at any time during a patient's lifetime, his, or her, vision drops below the desired level, re-treatment will be provided as long as the patient has had the necessary annual check-up and the problem "is related to myopic regression or refractive error caused by natural physiological conditions." The decision to re-treat will be made jointly by the treating LCA-Vision surgeon, the patient, and the co-managing doctor. To maintain eligibility in "Continuum of Care", patients must return to their affiliated physician (MD or OD) for an annual eye examination. Patients with extreme degrees of pathological myopia and astigmatism may not qualify.

11/26 **Gimbel Vision International** announced revenues of $16.1 million for the nine months ended September 30, 1998, representing a 56% increase over last year's $10.3 million. The increase in revenue reflects the 67% growth in the number of paid refractive procedures from the same period last year. Gimbel Vision generated earnings before interest, taxes, depreciation and amortization (EBITDA) of $4.4 million for the nine month period compared to $3.3 million in the same period of 1997 representing a 32% increase. Earnings were impacted by the costs associated with discontinuing operations of the ophthalmic distribution business unit, as well as the estimated impact from the sale of the Australian subsidiaries. The sale of the Mackay, Australia centre has been completed, and offers for the Brisbane eye centre are being tendered. Earnings per share at the end of the nine months were 4 cents before the loss on discontinued operations. To date, the company's surgeons have performed over 30,000 refractive eye surgeries in Canada alone.

11/30 **TLC The Laser Center** announced that two new vision correction treatment options are now commercially available at select TLC Canadian refractive centers. The first new procedure, the ICL (Intraocular Contact Lens), is designed to correct the vision of people who have extremely high prescriptions in their eyeglasses or contact lenses

and for those who may not have enough corneal thickness to have their vision corrected with the excimer laser. Patients with Lupus or other diseases may also be candidates for the ICL procedure. Sometimes referred to as a phakic intraocular contact lens, the ICL is a contact lens which is custom-made for each patient and surgically implanted in front of an individual's own natural lens. While now available in Canada, the ICL is not expected to be approved by the U.S. FDA for several more years.

The second procedure introduced at select TLC Canadian refractive centers is the KeraVision ring. First performed more than 3 months ago by Dr. Simon Holland, TLC Vancouver's Medical Director, this procedure provides patients with low levels of myopia another option to laser vision correction. It is the first surgical procedure that is intended to reshape the eye by adding material to it and has the potential benefit of future reversibility. The KeraVision ring is also not yet approved by the U.S. FDA.

OPHTHALMIC LASER UPDATE -- DECEMBER 1998

11/30 **Laser Vision Centers** announced that revenues for its fiscal second quarter were $10.4 million, up 99% from the same quarter a year ago. For the six-month period, revenues were $19.5 million, ahead 109% from last year. Net income for the quarter was $958,000 (9 cents/share), compared to a net loss of $1.2 million for last year's second fiscal quarter. Net income for the six-month period was $1.3 million (12 cents/share), compared to a net loss of $2.7 million (31 cents/share) last year.

For the quarter, the company performed 11,600 surgical cases in the U.S. and over 12,600 worldwide. 408 U.S. surgeons used its equipment during the quarter, 30 of whom were using the services for the first time.

"All of us at LaserVision are pleased with the second quarter results. We believe these numbers clearly show a business model that is both flexible and full of potential leverage," LaserVision chairman and CEO John J. Klobnak said. "We believe this industry is poised for continued robust growth and we feel our company is well positioned to grow."

The company also announced that it had agreed in principle to acquire **Midwest Surgical Services**, a privately-held, Minneapolis-based provider of mobile cataract services to 146 surgeons located at 185 sites in 24 states. Approximately 20% of these surgeons currently work with LaserVision. The company will acquire all the stock of MSS for an initial payment of $3.5 million in cash and notes, with potential additional consideration of up to $8.25 million in cash and LaserVision common stock based on the performance of MSS through July 2001. The acquisition is expected to be completed by December 31. LaserVision believes MSS is the largest U.S. provider of mobile cataract services.

"We see the proposed acquisition as a positive event for our customers. MSS has a tremendous reputation for excellence centering on quality products and impeccable customer service consistent with LaserVision's," Tom Eakins, president and CEO of MSS said. "This relationship will enhance our nationwide expansion of cataract services and continue our ability to provide development opportunities to the ophthalmologists' practices and community hospitals."

12/1 Less than a week after the award of two cornerstone technology patents, US 5,829,448 covering the photoactivation of molecular agents, and US 5,832,931, a method for improved selectivity in photo-activation and detection of molecular diagnostic agents (see the December 2 surgical brief), **Photogen Technologies**, through its subsidiary, **Photogen, Inc.**, signed its third research agreement with a teaching affiliate of **Harvard Medical School**. The first two agreements were signed just over a month ago. This agreement, with **Massachusetts Eye and Ear Infirmary (MEEI)**, will evaluate the company's multi-photon excitation (MPE) technology for the treatment of ocular melanoma. Currently, the most common form of treatment for ocular melanoma is radiotherapy, which presents a range of local complications. This research agreement will evaluate MPE as the basis for an alternative treatment that could offer advantages over current treatments options. Photogen intends to use the data gained through this evaluation to determine whether MPE is effective in the destruction of choroidal melanoma, the most common primary cancer of the eye in adults. Photogen expects the work conducted under this agreement to help move the company toward the first commercial MPE-based product for the treatment of diseases of the eye. Success here will be determined by the favorability of research results and the company's ability to secure suitable production and distribution collaborative manufacturing and marketing agreements.

Photogen's agreement with MEEI comes on the heels of two research agreements with Harvard Medical School affiliates signed approximately one month ago. An agreement with **Massachusetts General Hospital** for work to be carried out at its **Center for Imaging and Pharmaceutical Research** will evaluate treatment of prostate and lung cancer using Photogen's simultaneous two-photon excitation technology. Another agreement with MEEI will initially evaluate the technology for treatments of age-related macular degeneration of the eye.

12/3 **Innovative Optics** announced that **HyeKwang Technologies** of Seoul, South Korea received KAITEC approval for sale of the Innovatome microkeratome system in South Korea. This government approval was obtained via a lengthy testing and review process conducted by the Korean KAITEC agency. HyeKwang Technologies is the exclusive distributor of the Innovatome microkeratome in Korea.

12/3 **TLC The Laser Center** announced that over 18,000 paid laser procedures were performed at the company's refractive centers in the second quarter of fiscal 1999. This is a 181% increase from last year's 6,420 second quarter total, and is the 11th consecutive quarter of record procedure volumes. The increase this quarter was

primarily driven by 124% same-store procedure growth. In the same 33 centers that TLC operated in both Q2-98 and Q2-99, paid procedures more than doubled from 6,420 to 14,402 respectively. These results do not include the more than 1,200 procedures performed by Dr. Tooma of California, which TLC has agreed to acquire sometime in calendar 1999. Elias Vamvakas, TLC's president & CEO, commented that the company "was very pleased with its second quarter procedure growth...September is traditionally the weakest month of the year and, even though our first two quarters have always been weaker than the second two, we have already performed more procedures than we did all last year."

12/4 **Sunrise Technologies International** announced it had successfully completed a private placement of approximately $11.8 million in common stock, priced at $3.50 per share; approximately $6.8 million of which was paid in cash with the remainder paid in notes due on March 15, 1999. The proceeds will be used in part to continue the company's efforts to secure pre-market approval from the FDA for the treatment of hyperopia of +.75 to +2.50 diopters, to plan the launch of the Sunrise Hyperion LTK System, and to continue the company's product development expansion. In addition, the company plans to expand clinical trials for higher levels of hyperopia, presbyopia, and treatment for certain unsuccessful excimer laser procedures for myopia. According to Russell Trenary, president and CEO, "Nearly two-thirds of the money raised came from ophthalmologists who have seen our clinical results or who have used our system in clinical studies to treat hyperopia. We are delighted to receive this continuing support from ophthalmic surgeons."

12/4 Tooting its own whistle, **Summit Technology** claimed it stole the AAO show with live laser surgeries (during the ISRS meeting -- along with **Autonomous Technologies** and **VISX**), strategic acquisitions (true, the Autonomous acquisition was certainly the "buzz" of the show, but the **Krumeich-Barraquer** microkeratome announcement met with somewhat less excitement), and ophthalmic innovations (?). Summit claims that it unveiled a number of modular upgrades to its Apex Plus platform, including a new microscope with projected illuminated reticle (Ho-hum).

12/5 I received the first AAO review, this one put out by **Dain Rauscher**. Some of the highlights reported include: "The age of refractive surgery is here. The combination of increasing consumer word of mouth, an expanding range of FDA approved indications, and improving technology is translating into a strong procedure volume growth in LVC and, therefore, the potential for investment profits."

The authors Parice Halbert and David Therkelsen have also revised their volume projections for 1998. They now estimate that between 100,000 to 105,000 procedures were performed during the third quarter in the U.S., and with the suggestion that fourth quarter volume will also be strong, they believe that at least 400,000 procedures will be done this year. Their estimates remain conservative in light of recent developments. (They appear to be holding with their predictions of 562,000 procedures in 1999 and about 765,000 to 775,000 for 2000.) Another note, they

believe that procedure pricing is increasing, rather than declining. They estimate that roughly 20%-25% of the physicians they spoke to at the AAO have raised their prices during the past 12 months, especially for LASIK. They believe that patients are willing to pay a "premium" price for LASIK if they perceive that they will be treated with the best technology and by the best surgeon.

The only disagreement I have with the authors is their perception that **Nidek**, whose approval is very close, will not fare well in the U.S. market. Based on how Nidek has done in Canada, Europe, and Asia/Pacific, I expect that once they clear up their possible patent infringement problems with both **Summit Technology** and **VISX**, they should compete strongly with the other players.

12/7 According to *NewsPage*, a company called **ParTech Inc.** has gained a U.S. Patent for simulating corneal laser surgery. The abstract reads in part, an apparatus and method for simulating a predicted post-operative topography of a cornea based on a pre-operative topography and a proposed laser ablation procedure.

12/7 This month's issue of *Refractive Market Perspectives* claims that the corporate laser vision correction centers showed a slight share gain for the third quarter. According to Dave Harmon, they accounted for 47% of the procedures performed during the quarter, with surgeon owned laser centers accounting for 32%, and institutions down to 21%. Among the laser centers, **TLC** still ranks first with a 27% share, followed by **Laser Vision Centers** at 19%, **Clear Vision** at 15%, **LCA-Vision** at 12%, and **Vision Correction Centers** with a 7% share of third quarter vision center procedures.

In commenting about the AAO meeting, Dave Harmon noted that **Novatec** was not in attendance, and attempts to call their phone number resulted in a telephone disconnected message. I ran into Shui Lai, president of Novatec, at the meeting, and learned that his company funding was running low. He was seeking to partner with another company to continue his solid-state refractive laser program.

12/8 In a major news story, David Segal of *The Washington Post* wrote about how the FTC was poised to add a new weapon to its arsenal, the demand for allegedly illegal profits. He used the recent settlement between **Summit Technology** and **VISX** to illustrate the "classic" methods of the Federal Trade Commission in becoming more aggressive in demanding money from companies charged with antitrust violations.

The FTC was expected to demonstrate its new remedy powers by filing an antitrust suit against Mylan Laboratories Inc., demanding allegedly illegally obtained profits. The article noted that some legal experts say the agency might be pushing the envelope of its congressional mandate when it demands that companies turn over illegal profits. Although the FTC routinely collects fraud fines and civil penalties from companies that violate its consent decrees, it rarely asks for paybacks in antitrust cases. The article describes how the FTC accused Summit and VISX of colluding by forming a joint venture, **Pillar Point Partners**, which collected royalties on

photorefractive keratectomy procedures. That settlement, Segal wrote, "was a classic bust, FTC style. Neither company acknowledged wrongdoing and neither paid a fine, but simply agreed not to fix prices in the future." Segal reported that there are more than 20 lawsuits against Summit and "a smaller number" against VISX, many of which may be joined into one class action to be heard in a district court in Phoenix.

"Still, it could have been even more expensive," he continued. "Companies sued by the FTC for antitrust violations in the future may find that it's not just plaintiffs' attorneys that come calling for money, but the new, more aggressive FTC."

12/11 In an interesting press release to sports editors, and football writers and columnists, **Summit Technology** noted that with the debate continuing about the return of instant replay in the National Football League, following the many missed plays over the past several weeks, it has offered to provide all of the 112 NFL referees an eye exam and, if any are appropriate candidates, corrective laser surgery for free. In an email message to his news media release list, Charlie Sonneborn of SEE (Society for Excellence in Eyecare) noted that perhaps Summit ought to extend the program to Congress!

12/15 **Laser Vision Centers** announced that it had completed the acquisition of **Midwest Surgical Services, Inc.**

12/15 **Sunrise Technologies International** announced it had completed and submitted its PMA for the treatment of hyperopia (+.75 to +2.50 diopters) to the FDA for its LTK system. The company had previously submitted sections of a modular PMA application which allowed the FDA the opportunity to begin review of modules of the application prior to the submission of the final module containing clinical data. This final module, just submitted, included the results of the company's clinical studies on 345 cases, which was the population of cases that underwent extensive statistical analysis.

12/15 This week's issue of *Ophthalmology Times* contains a letter to the editor disputing a news brief concerning the patent infringement lawsuit between **Bausch & Lomb Surgical/Chiron** and **Moria**, previously published by the magazine. In the October 15th issue, OT had said that B&L Surgical had seized evidence to be used in support of its patent infringement lawsuit, which allegedly involves a patent by Luis Ruiz and Sergio Lenchig of Columbia and licensed to B&L Surgical (covering one of Chiron's microkeratomes). Alain Duprat, CEO of Moria disputed this claim. He said in his letter to OT that B&L Surgical was "not entitled to confirm that it had seized evidence to support a patent infringement suit. Only Luis Ruis, MD requested and obtained a court order to buy and seize a Carriazo Barraquer microkeratome from Moria." He went on to say that the Ruiz Automated Corneal Shaper patent, licensed to B&L Surgical, "involves a specific structure of a microkeratome that the Carriazo Barraquer microkeratome does not reproduce. Moria's position is that the Ruiz patent holds no merit against the Carriazo Barraquer and that this action is an attempt to slow

down the strong world-wide market penetration by Moria's variety of microkeratomes." Further, according to Duprat, the action is only pending in France and does not affect practitioner's right to use the Carriazo Barraquer microkeratome. (And you thought the excimer laser patent wars were exciting!)

12/15 This week's issue of *Ocular Surgery News* contains two interesting articles. The first is about a new holmium laser filtering technique that has been found to lower both IOP and complication rates for glaucoma patients. Developed by Drs. Svend Vedel Kessing and Jannik Boberg-Ans, in Denmark, the technique, called intrastromal holmium laser keratostomy (ILK), involves the creation of an intrastromal laser canal anterior to Schwalbe's line in the floor of a corneoscleral tunnel incision formed by a knife. The laser probe is inserted into the tunnel and used to create an opening into the anterior chamber through a combination of tissue damage and shrinkage, creating an intrastromal cavity. In a group of 39 patients, followed for over 24 months, the success rate for ILK patients with or without medications was 88%, and for those without medications, 69%. This compared to a control group treated with subconjunctival sclerostomy with a success rate of 30%. The complication rate for the ILK treated patients was only 13%, compared to 54% for the SLS group.

The second article is a report and update on the **Refractec** Corneal Shaping System. This decive uses radiofrequency keratoplasty (RFK) to reshape the cornea to treat hyperopia, astigmatism, and presbyopia, by selectively shrinking corneal collagen in a series of spots placed in rings in the periphery of the cornea. (Similar to the way the **Sunrise Technologies** holmium laser system reshapes the cornea, but using radiofrequency rather than laser energy.) The Refractec technique was pioneered by the father and son team of Drs. Antonio Mendez G. and Antonio Mendez N., refractive surgeons in practice in Mexico. The Refractec technique, which has gained marketing approval in much of Europe and Latin America, is scheduled to begin Phase 3 clinical trials in the U.S. this month. Hyperopia of up to 3.5 diopters was treated successfully in early trials in Mexico. When the device becomes available in the U.S., company officials say that the power unit will sell for $35,000, and that disposable probes will cost about $125 each.

12/17 **VISX** announced that its board of directors had approved a two-for-one stock split, payable in the form of a 100% stock dividend to shareholders of record on December 28th. Upon completion of the stock split, the number of shares outstanding will be approximately 31 million, which company officials hope will increase the stock's liquidity and broaden its marketability and contribute to improved shareholder value.

12/17 **LaserSight** announced that it was adding to its microkeratome business, by offering both blades and a durable microkeratome in addition to its disposable single use device. The complete system will offer the surgeon the option to use either the disposable or the durable devices, based on his/her clinical preferences. The LaserSight blades will be sold internationally through its current distributors, and directly to U.S. surgeons.

12/20 **Medarex**, a company developing the drug MDX-RA, for the prevention of secondary cataracts during cataract surgery, ran into a problem with its Phase 3 clinical trials. The problem caused the trials to be suspended and the company's stock to lose approximately one quarter of its value. Enrollment for the clinical trial was halted after 13 of 565 patients experienced sight-limiting events. Medarex president and CEO Donald Drakemen, said that since seven of the affected patients were being given the placebo, MDX-RA appears not to be at fault. "We have focused now on things common to the placebo and the drug, such as the formulation, and we're reviewing that," Drakemen said.

12/21 **Laser Vision Centers** announced that same U.S. laser revenue for 23 lasers that were in operation in November 1997 increased 43% in November 1998. Total company growth achieved a higher percentage, as the company operated a total of 30 lasers during November 1998.

12/22 **Nidek** announced that its EC-5000 excimer laser system had received FDA marketing approval for the PRK correction of myopia ranging from -0.75 to -13.0 diopters. Supplemental applications will be submitted in the near future, for the correction of astigmatism up to 4.0 diopters. A clinical study for the correction of hyperopia is also underway. (This approval, for up to -13 diopters of myopia, is the widest single approval to date.)

The approval marks the culmination of a four year process to obtain regulatory approval and the right to sell in the United States. Nidek is the first non-U.S. based company to successfully navigate the demanding FDA regulatory process, and the first to bring rapid, linear beam scanning technology to market. The company's patented beam delivery system -- well known and highly respected by international excimer surgeons -- uses a rotating, rectangular beam of ultraviolet light to quickly modify the optical power of the cornea.

Nidek Co. Ltd. is a 27 year-old, privately held company located in Japan, with subsidiary offices in the United States and France. The company manufactures intraocular lenses and surgical & diagnostic instrumentation, including a full line of ophthalmic and cosmetic lasers, for eye care and other specialists in over 90 countries. The company's EC-5000 excimer laser system has been in development since 1985.

(Now that Nidek has obtained U.S. FDA marketing approval, it will be interesting to see how quickly both **Summit Technology** and **VISX** pursue the company to take a license to their U.S. patents covering the ablation of the eye. The company already is a licensee of the **IBM** UV patents, in a deal struck with **LaserSight** in January of this year -- see the January 20th brief in the January issue of this newsletter. Nidek has won one patent license battle with VISX in the UK, and faces additional challenges in France and Canada.)

12/23 **Summit Technology** announced that it had received a 510(k) concurrence letter from the FDA permitting it to begin marketing the Krumeich-Barraquer microkeratome in the United States. "When we acquired the Krumeich-Barraquer microkeratome we knew that we had an exciting new product to offer refractive surgeons and we are pleased that the FDA has responded so quickly to our 510 (k) application," stated Robert Palmisano, CEO of Summit. Summit plans to commercially launch the Krumeich-Barraquer microkeratome during the first quarter of 1999. With this approval, Summit is now the only FDA approved laser manufacturer to also offer a microkeratome.

12/23 **KeraVision** said it had entered into a definitive merger agreement to acquire **Transcend Therapeutics, Inc.** and its anticipated net cash balance of about $8 million. Under the agreement, Transcend will wind down its operations as a drug development company and no Transcend employees will be retained after the closing of the transaction. According to the terms of the agreement, Transcend will become a wholly owned subsidiary of KeraVision. Transcend stockholders will receive shares of KeraVision common stock with a value equal to the amount of net cash of Transcend as of the closing date plus a premium of between 20% and 30%, depending on the price of KeraVision stock prior to the closing of the merger. Certain stockholders of Transcend holding approximately 51% of the outstanding common stock of Transcend have agreed to vote in favor of the merger. In addition, KeraVision will be entitled to a breakup fee of $500,000 if the agreement is terminated for certain reasons.