MEDICAL/SURGICAL LASER UPDATE -- JANUARY 1997

12/13 According to the *American Society of Plastic and Reconstructive Surgeons*, vanity is no longer gender-specific. The percentage of men undergoing cosmetic surgery is increasing every year.

12/16 *The Gray Sheet* reports that the FDA is targeting three to four device categories for intensive compliance scrutiny in 1997, under its "risk-based" surveillance initiative. One of the categories listed in the 15 item priority list is surgical lasers. According to FDA officials, the next step is to go over the list of 15 devices and evaluate which has the highest number of recall and adverse events reports, to see which has a significant problem, and then instruct its field personnel to hold public meetings so that inspections, based on risk tiering can take place.

12/23 The FDA is proposing the early use of investigational devices. The proposed rule would give device manufacturers the ability to provide a product to a targeted population prior to full approval.

12/30 **Premier Laser Systems** announced that it expected to report record sales, in the range of $1.4 to $1.6 million for its fiscal third quarter, ending December 31st, more than double its sales for the comparable quarter in 1995. According to President Colette Cozean, the rising sales include substantial increases in orders of diode, erbium, and argon lasers, principally for dental applications. The company also expects a record backlog of orders entering its fourth quarter, including for its argon laser which are expected to reach approximately $1 million by January 1st. "The rapid acceptance by dentists of our Arago and MOD argon lasers for teeth whitening has been a significant vector in our sales increase, and accounts for much of the anticipated backlog going into January". Because of the inability to purchase sufficient argon laser heads from its current source, the company is bringing in a second source of argon lasers, that will begin shipping production quantities during the March quarter. The company is also experiencing shortages of its portable Arago lasers, which is completely outsourced, with its contract manufacturer lagging seriously in "agreed to" shipments. Premier will accelerate development of a replacement product that will be manufactured at the company's facilities, with expected shipping also to begin during the March quarter.

12/30 **Iridex** announced that its **Light Solutions** subsidiary had been awarded a contract from Department of the Navy's Naval Research Laboratory, to improve the performance of semi-conductor-based high repetition rate infrared lasers. Awarded under the SBIR program, the Phase II contract has a value in excess of $500,000.

12/30 **Trimedyne** announced its fiscal fourth quarter results with slightly lower revenues and a reduced loss. For the quarter ending September 30th, revenues were $3.2 million with a loss of $1.7 million (16 cents/share). Included in the results were a write-down

of inventories and prepaid royalties totaling $1 million, compared with $1.2 million for the same quarter a year ago, primarily due to factors in the urology market, connected with the ongoing litigation with **C.R. Bard**. Revenues for the company's fiscal year were $12.5 million, down 4% from revenues of $13.0 million a year ago. According to president Peter Hyde, "The fiscal year...was a disappointment for Trimedyne. No shipments of urology products were made to C.R. Bard in the past year. The failure of Bard to perform its obligations as Trimedyne's exclusive distributor under our agreement and other matters are being addressed in a lawsuit filed against Bard in October 1995...Despite our receiving FDA clearance to market the company's lasers and sidefiring laser devices for the treatment of BPH in March 1996, sale of these products have been less than anticipated...In addition to the incursion of a variety of sidefiring laser devices made by competitors into the U.S. market, when Bard ceased marketing the company's device, new electrovaporization devices, which are considerably less expensive and more familiar to urologists than our laser products, were introduced and are being widely used for the treatment of BPH." (According to my information, lasers and sidefiring devices are being used in less than 10% of BPH procedures, the bulk of non-TURP procedures are being done by rollerball electrocauteries.) Hyde also commented that revenues increased slightly for orthopedic products and accounted for the bulk of the company's medical business.

Marvin Loeb, chairman, commented on three significant development efforts underway: first, the development of a new type of laser for use in plastic surgery, cosmetic surgery and dermatology, procedures that cannot be done with conventional lasers (my speculation is that the company will use its holmium laser technology for collagen shrinkage, similar to what **New Star Laser's** subsidiary **Laser Aesthetics**, and **Coherent Medical** are doing); secondly, acquiring patents and developing a new cardiovascular laser system and related disposables for use in TMR to treat severe cardiac disease, using the company's superpulsed holmium laser and AutoFire automated firing system and proprietary Channel Maker optical fiber devices (see our November 11, 1996 brief for more information); and thirdly, the acquisition of a license to a U.S. Patent covering a proprietary device for delivering and releasing coils in brain aneurysms, and an exclusive license to a U.S. Patent covering a new laser device for treating menhorragia (excessive uterine bleeding). According to Loeb, brain aneurysms are diagnosed in approximately 90,000 persons annually in the U.S., and an estimated 200,000 surgeries are performed annually to treat menhorragia.

There was no mention of the proposed sale of **Poly-Optical**, the optical fiber company acquired in 1983; in the press release but, apparently, the company has said it will sell a majority interest in the company.

1/2 **Spectranetics** announced that it had received notification from the FDA that its excimer sheath removal procedure for imbedded pacemaker leads was receiving expedited review. This means that the technique could be granted market approval at

a faster pace than originally projected. The company applied for expedited review in November 1996, based on results on more than 300 patients at 14 U.S. sites. The expanded clinicals will continue during the FDA review process.

1/3 **LaBarge** and **Venisect** announced that Venisect has submitted additional data on human clinical trials to the FDA for their Laser Lancet perforator system for drawing blood samples. The test results submitted further confirm that the device is safe and effective as an alternative to needles and lancets for puncturing the skin to draw blood. The request for additional information was the third such request by the FDA for the device. A second indication, and subject of another application, is for its use in transdermal drug delivery, to enhance the percutaneous transport of many pharmaceuticals, employing molecules of any size, according to company officials.

1/7 **Laserscope** and **Medical Alliance** announced that they have entered into a strategic alliance for the further development of the office-based vascular lesion market, using the Laserscope Aura laser system as its centerpiece. Under the agreement, Medical Alliance will become the exclusive fee-for-service, mobile provider of the Aura laser system in the U.S. and, over the next several months, will purchase more than $1 million worth of the laser systems, for markets which MA currently serves. In addition, Laserscope will receive a portion of the per use equipment fees, which MA will charge physicians and/or patients. Currently, approximately 2500 physicians perform 6000 procedures monthly using MA's services. The Aura will be used for treating spider-like leg and facial veins. The StarPulse technology incorporated with the Aura allows it to be used either for dermatology or surgical applications, making it exceptionally versatile, according to MA officials. It is also much smaller and lighter in weight than competitive systems, and it is a low-maintenance, solid-state device. The alliance will allow Laserscope to penetrate both the fee-for-service as well as those that purchase or lease systems for office-based procedures.

1/7 **Pharmacyclics** said that it had completed its Phase 1 clinical trials of Lu-Tex in the PDT treatment of advanced local or metastatic cancer. Based on the results of the study, the company intends to initiate the Phase 2 testing in the second quarter of 1997. Of the 35 patients enrolled in the dose esculation study, 15 had breast cancer, 7 melanoma, and 13 other types of tumors. Overall 127 lesions were treated, all of which were either in the skin or subcutaneous tissues and readily evaluable by physical examination. Light was applied either with a laser or light-emitting diode device. The reponse rates for treated lesions were 36% complete responses and 16% partial responses, for a total tumor response rate of 52%. Of those patients with breast cancer, there were 55% complete response and 23% partial, for a total response rate of 78%. Among melanomas, the total response rate was 50%. The company was happy with the results, since the trial was designed primarily to test drug safety. A multi-center Phase 2 trial in patients with breast cancer recurrent to the chest wall will be launched, which occurs in about 25% of breast cancer patients.

1/8 **Palomar Medical Technologies** announced that it is an equity partner in the formation of a new company, **LaTIS, Inc.**, created to use Palomar's laser thrombolysis technology to develop a pulsed-dye laser system for treating stroke, one of the more debilitating human diseases. For the past four years, Palomar has been conducting research with St. Vincent's Hospital and Medical Center in Portland, OR, to develop a laser-based approach to treat arterial blood clots. This research was recently expanded to include the laser treatment of stroke, caused by blood clots in the brain's circulatory arteries, and affecting approximately 500,000 people annually. As part of the formation of LaTIS, Palomar has transferred rights to its patent to LaTIS. Also involved in the formation of LaTIS is **Advanced Cardiovascular Systems**, **Hillman Medical Ventures**, **Shaw Venture Partners**, and St. Vincent's. Palomar will become the potential laser supplier when the technique is approved for marketing.

1/8 **Ion Laser Technology** announced that it had signed an exclusive agreement with trading partners in Korea, India, and Singapore, to distribute the BriteSmile Laser Tooth Whitening Systems. **Sewon Trading Corp.** in Korea, **American Institute Hospital of Laser Surgery** in India, and **SmileInc PTE Ltd.** in Singapore will be shipped their first systems during the first quarter this year. The distributors will be responsible for obtaining all governmental approvals for distribution of the ILT lasers and BriteSmile tooth whitening chemicals within their respective countries. Approvals are pending and expected in due course. The new agreements are in addition to an exclusive agreement with **Laser Estetica S.I.**, to place systems in Spain. Laser Estetica is developing an advertising and public relations program for 1997, and has place two BriteSmile systems within the country. Up to ten additional locations are expected to open during 1997, and a training site in Barcelona will be established. Systems have been placed with individual dentists in Canada and in Japan.

1/8 **PLC Medical Systems** announced that it had reached its goal of shipping 31 Heart Lasers in 1996, a 35% increase over the 23 lasers that were shipped in 1995. Of the 31 laser systems, 17 were placement contracts, and 13 were sales. One Heart Laser was shipped to Eastern Europe for laboratory research only. The shipments were broken down as follows: 13 lasers to Europe; 1 to the Middle East; 7 to Asia/Pacific; and 9 systems within the Americas, including lasers to Mexico, Venezuela, and Columbia. Furthermore, in 1996, hospitals in 12 new countries began offering TMR using the PLC systems. The majority of lasers shipped in 1996 were under the placement contracts, which provide the company with recurring revenues of $3500 for each patient treated, with yearly minimums specified by a multi-year contract, rather than a one-time sale of the device.

1/8 **QLT PhotoTherapeutics** and **American Home Products**, a wholly owned subsidiary of **American Cyanamid Company**, have revised certain agreements that define AHPC's contractual relationship with QLT, and its role as the primary manufacturer of Photofrin, QLT's PDT drug, and also its exclusive distributorship in Japan. The

new agreement includes the following: a new five-year manufacturing and supply agreement and commitment to manufacture QLT's global requirements of Photofrin, including QLT's right to contract with a backup manufacturer to ensure continuity of supply; a revised agreement that removes AHPC's right to appoint two directors to QLT's board of directors; an agreement to remove certain preferential grandfathering rights provided to AHPC under the QLT Shareholder Protection Rights Plan; and an agreement to appropriate compensation to be paid to AHPC for QLT's decision in 1994 and 1995 to reacquire certain Photofrin marketing rights.

1/8 **PDT, Inc.** announced that its subsidiary, **PDT Cardiovascular, Inc.** had entered into a co-development agreement with privately-held **Ramus Medical Technologies** of California, an innovator in the development of autologous tissue stent-grafts for coronary and peripheral artery bypass surgeries. The agreement gives PDT Cardiovascular exclusive rights to co-develop its photodynamic therapy with Ramus Medical's RapidGraft, a proprietary technology for building suitable blood vessel grafts made from the patient's own non-vascular tissue. Combining the two technologies may help overcome problems with traditional grafts to maintain post-surgical patency of the vessel grafts. In conjunction with the co-development agreement, PDT Cardiovascular made a $2 million equity investment in Ramus Medical and secured an option to acquire additional shares of the company in the future. RapidGraft is constructed in less than five minutes, is easily implanted, stent-supported, and made of non-vascular tissue from the patient's own body, which may reduce complications of rejection and infection. The grafts, now in clinical trials, are intended for both open chest bypass surgery, and the newer, minimally invasive bypass procedures, such as MIDCAB and/or keyhole procedures. By using PDT's light activated drugs, it is the hope to selectively control hyperplastic or fast growing cells in blood vessels newly opened by angioplasty, and to expand the program in conjunction with the Ramus' products to investigate PDT as an adjunct to bypass surgery to potentially improve the patency and extend the life of bypass grafts.

1/8 **Coherent, Inc.** announced that it has concluded an agreement for the acquisition of the assets of **Micracor, Inc.**, a manufacturer of semiconductor-based solid-state microchip lasers for the telecommunications market. The acquisition includes two semiconductor-based laser technologies, diode-pumped microchip lasers and optically-pumped semiconductor (OPS) lasers. Both technologies play vital roles in many commercial, scientific, and medical applications, according to the company.

1/9 A four-year collaboration between researchers at the **University of California, Irvine's Beckman Laser Institute**, and **Lawrence Livermore National Laboratory** has led to a new way of individualized treatments tailored just for a particular person, for the removal of port wine stains. Based on a computer code developed to improve astronomical imaging, a diagnostic tool has been developed that helps doctors pinpoint the precise laser parameters needed to remove port wine stains on an

individual basis. Clinical trials of the technique are underway, combined with a new laser to treat port wine stains developed by an unnamed Palo Alto company.

1/14 **Rare Earth Medical** announced that it had received two 510(k) approvals to market its Lightstic 180 fiberoptic medical laser diffuser for urological procedures, and its Lightstic 360 for general surgical use. Rather than emit the laser light out of the end of the fiber, both Lightstic diffusers direct the light laterally, in a cylindrical pattern, over an area called the "diffusion region". SBIR grants from the National Cancer Institute funded the development of both the Lightstic 180 and 360 products. The Lightstic 180 can be used to treat BPH, while the 360 might be used for destroying cancerous or benign tumors. Physicians in the Netherlands are researching the use of the latter for treatment of liver cancer.

1/15 **Candela Corporation** announced that it had received FDA clearance for its erbium laser for dermatology. The laser is the SkinLight system for which Candela is exclusive distributor in the U.S., Canada, the Far East, South America, and parts of Europe, from **Fotona d.d.**, based in Slovenia. The prime application for the laser is for the gentler skin ablation treatment. (For a table of currently known erbium lasers being marketed for skin resurfacing, give me a call.)

The laser joins Candela's product line of cosmetic lasers that includes the SPTBL-1b Vascular Lesion Laser for the treatment of port wine stains, stretch marks, scars and facial veins; the ScleroLaser for the treatment of leg veins; the ScleroPlus, which treats both vascular lesions and leg veins; the AlexLazr for blue, black, and green tattoos and pigmented lesions such as freckles and Nevus os Ota; and the YAGLazr for pigmented lesions and red, yellow, and blue tattoos.

1/15 **PDT Inc.** announced that Phase 2/3 clinical trials are now underway in both France and Australia to investigate its SnET2 PDT photosensitizer in the treatment of certain cancers. The studies, funded by PDT's pharmaceutical partner, **Pharmacia & Upjohn**, focus on basal cell carcinomas in Australia, and on cutaneous (skin) metastatic breast cancer in France. The new trials are in additions to the Phase 2/3 trials in the U.S. for cutaneous metastatic breast cancer and basal cell carcinomas, following the previously released results of earlier Phase 2 trials showing good response rates and a favorable preliminary safety profile for these treatments. The Phase 2/3 trials are underway to determine safety and efficacy in a larger patient population.

1/16 **Premier Laser Systems** released results for its fiscal third quarter and nine months ending December 31st. The company reported revenues of $1.5 million and $3.9 million respectively, with losses of $1 million (15 cents/share) and $2.7 million (46 cents/share) for the periods. According to CEO Colette Cozean, "Sales have escalated quickly, especially due to the strong demand for our entire family of dental lasers...orders are considerably stronger than sales revenues...(due to) difficulties in

obtaining sufficient quantities of components and outsourced systems to meet the increasing demands of the market...systems with the highest order levels continue to be diode laser, argon lasers, and erbium lasers, especially for use in dentistry...and for use in ophthalmology." Cozean said that she expects FDA action during the fourth (fiscal?) quarter with regard to its erbium laser for hard-tissue dentistry.

1/18 **Big Sky Laser** announced that it had recently completed a major facility expansion at its Bozeman, Montana headquarters. According to Greg Smolka, Director of Sales and Marketing, "1996 was the fifth straight year of record laser sales and (the company) simply needed more room to keep up with the demand." Big Sky is projecting an 80% increase in sales for 1996 on top of a 40% increase in 1995. Medical laser OEM sales, particularly YAG and erbiums have fueled much of the growth, but the company also has seen continued strong growth in lasers for scientific, military, and industrial applications. If you happen to be in the Bozeman area, you are cordially invited to visit the facilities. Call 1-800-224-4759 to arrange for a tour.

1/20 **Cool Laser Optics**, manufacturer of the cutaneous skin cooling system for cosmetic laser applications, announced that it had finalized North American distribution rights with **Unimedix** for the United States, and **Instrumed Surgical** for Canada. Last September, the company signed a patent licensing agreement with **Coherent**. The company expects to announce its arrangements for international distribution shortly.

1/21 **Candela Corporation** announced that it had received U.S. Patent 5,599,342 for an innovative elongated spot handpiece useful for laser treatment of linear lesions, such as leg veins, stretch marks, and facial veins, as well as tattoos. The handpiece will allow physicians to treat linear lesions and tattoos more precisely, with a reduction in temporary discoloration by avoiding unnecessary exposure to surrounding uninvolved tissue. The handpiece was introduced to the market in mid-1996 and has been embraced by the medical community, according to the company.

1/21 **Sharplan**, the fully owned subsidiary of **Laser Industries**, has launched its SilkTouch laser for hair transplantation. The SilkTouch is the first and only FDA approved laser for this indication. In addition to the FDA clearance, the company noted that it had recently received notice of allowance of a key patent application covering the use of the SilkTouch laser for hair transplantation. According to the company, there are an estimated 350 hair transplantation centers in the U.S., and according to the American Academy of Cosmetic Surgery, 197,276 Americans underwent the procedure in 1994 (without the use of lasers).

1/22 **Laserscope** announced that it had received FDA clearance to market its new erbium laser system for applications in dermatology, plastic surgery, general surgery, gynecology, oral/maxillofacial, ophthalmology, podiatry, and ENT surgeries. The laser is manufactured by Laserscope's new joint venture partner, **NWL Laser-**

Technologie, GmbH, in which Laserscope currently holds a 32% equity interest. The company expects to increase its interest in NWL to a majority position during the third quarter of this year. Robert McCormick, president and CEO said that Laserscope expects to make other submissions to the FDA in the months ahead, as it is in the early stages of investigating such new procedures as hair removal, hair transplantation, and chronic urethral syndrome.

1/22 **Boston Scientific Corporation** announced that it had entered into an exclusive international distribution agreement with **CardioGenesis Corporation**, a leader in transmyocardial revascularization. Under the agreement, Boston has the exclusive rights to sell and distribute the full range of TMR products and technology of CardioGenesis in all international markets, excluding the United States. Boston Scientific is a worldwide leader in the marketing of medical devices that are used in a broad range of interventional medical specialties. A dedicated direct sales force is expected to be formed by Boston Scientific for the marketing of CardioGenesis's laser and accessories in Europe.

1/22 **Medical Alliance** announced it had completed an exclusive agreement with **ThermoLase Corporation** to allow Medical Alliance to offer the SoftLight laser technology for hair removal to physicians in the U.S. and Canada. The company also announced that it had acquired the **Stone Treatment Center of New England**, which provides mobile laser lithotripsy equipment to hospitals and surgery centers on an "as needed" basis. In addition to the lithotripter market, Stone Treatment has subsequently entered the arthroscopic and urologic business by providing holmium lasers and the ultrasonic aspiration system for the removal of tumors. The company had also entered the aesthetic market by providing the Coherent Ultrapulse laser for skin resurfacing, hair transplantation, and blepharoplasty. Acquisition of the Stone Treatment Center business increases the geographic reach of Medical Alliance' coverage for aesthetic procedures to include 46 states and Canada, while providing product diversification.

1/23 **Eclipse Surgical Technologies** announced that it had received FDA IDE approval to begin the first clinical study in the U.S. of a new minimally invasive surgical procedure approach for TMR. Minimally Invasive Direct Coronary Artery Bypass surgery (MIDCAB) uses smaller incisions between the ribs than conventional CABG surgery, which requires cutting through the sternum. By combining Eclipse's laser TMR approach with MIDCAB, the surgeon can treat additional areas of the heart which MIDCAB alone cannot revascularize.

1/23 According to *Dow Jones*, analysts said that **QLT PhotoTherapeutics'** stock was up because of the good results being obtained with the use of BPD for treating age-related macular degeneration, which will be released in May. Further, the company plans to appear before the FDA in June for its Photofrin treatment of lung cancer, which could lead to ultimate approval for that indication. Analysts said the rumor that

Novartis (the combination of **Ciba Geigy** and **Sandoz**) stemmed from QLT's partnership with a Novartis unit, **Ciba Vision Corp.** for the development and marketing of BPD for vision problems. Any takeover action would likely wait until the outcome of ongoing Phase 3 clinical trials for BPD, which won't be completed unit next year.

1/24 **Palomar Medical Technologies** said that the U.S. District Court for the Southern District of NY had granted a motion of the plaintiff, **Commonwealth Associates**, for a partial summary judgement as to the issue of liability on the first claim in its complaint against Palomar for breach of contract. Commonwealth had agreed to serve as Palomar's financial advisor for a period of nine months beginning in January 1995, and to provide services in connection with possible merger and acquisition transactions. In return, Palomar agreed to pay certain fees, furnish certain warrants, and pay a premium if Palomar consummated an acquisition identified by Commonwealth. No acquisitions were consummated pursuant to the contract. Commonwealth alleges that it suffered up to approximately $2.7 million in damages, which Palomar claims it will vigorously contest at trial.

1/24 The January issue of *Lasers & Optronics* contains a story about a new method of destroying breast tumors without surgery, developed by researchers at the Oak Ridge National Laboratory. The approach uses PDT and a mode-locked Ti-sapphire laser tuned in the deep red to selectively destroy the tumor without affecting surrounding tissue. The photosensitizer drug used was 8-MOP, a derivative of psoralen.

1/27 **Ion Laser Technology** announced that it had filed a 510(k) application for marketing clearance on a patent-pending dental composite curing device, which will cure composites significantly faster than any device used in dentistry today. According to company officials, the qualities of the cured composite materials equal or exceed those cured by either xenon lamp or argon lasers. The nature of the new device was not revealed, except to state that it will be priced thousands of dollars less than the least expensive argon curing lasers presently available to the dental market.

1/27 The January issue of *Medical Device & Diagnostic Industry* contains a thorough overview of advances in photodynamic therapy, providing information about the programs underway at both **PDT, Inc.** and **QLT PhotoTherapeutics**, with some mention of **Pharmacyclics**. No mention of the work underway at **DUSA Pharmaceuticals** is mentioned.

1/27 **Candela Corporation** reported its fiscal second quarter results, ending December 28th, with revenues of $9.4 million, up 19% from last year's same quarter, and net income of $736,000 (13 cents/share). For the six month period, revenues were $17.0 million, up 23%, and net income was $1.2 million or 22 cents/share. The figures include results for **Spa Management**, now operated as **Candela Skin Care Centers**.

Two major openings are imminent for Candela Skin Care Centers, and an additional center should be in operation by the end of the company's fiscal year (June 30th).

1/27 **ESC Medical Systems Ltd.** announced its record fourth quarter results, with net sales increasing to $11.6 million, from $3.7 million from the same quarter last year, and net income increasing 264% to $4.4 million (25 cents/share). Net sales for the year were $32.9 million, up from $8.4 million, and net income, excluding non-recurring expenses associated with the acquisition of **LBT Ltd.**, increase to $12.7 million (74 cents/share). Including the one-time acquisition charge of $3.5 million, net income for the year was $9.2 million or 54 cents/share. The record fourth quarter reflects the strong worldwide acceptance of the PhotoDerm VL and PhotDerm PL systems, and the incremental revenues internationally of the EpiLight hair removal system and the Derma 20 erbium laser system and the Topaz 30 YAG laser.

1/27 **Trimedyne Inc.** announced that it had received FDA clearance to market its new cosmetic laser for aesthetic surgical use and therapeutic use in dermatology and plastic surgery. Field evaluations of the new laser will be conducted during the next few months at multiple locations in the U.S., with introduction at plastic and aesthetic surgery association meetings in May and shipments expected to commence in June or July. Until the market release, the company is not disclosing the nature of the laser, but speculation is that it probably is based on holmium technology, a strength of the company. (For more information about new developments at Trimedyne, see our December 30th brief in this issue.)

1/27 **The Gargiulo Group**, a Division of **Oscar Gruss & Son** has issued a "buy" recommendtion with its initial coverage of **Laserscope**. Justin Tang views Laserscope as a turnaround story and forecasts robust revenue growth over the next three years. Successful reorganizationand acquisitions are the basis behind this view, especially the acquisition of **Heraeus Surgical** to form a major laser company with size and breadth of product line, to position the company in the competitive and over-populated industry.

MEDICAL/SURGICAL LASER UPDATE -- FEBRUARY 1997

1/21 Minimally invasive heart surgery is beginning to make news. Two California companies are pioneering the development of instruments and techniques for a number of minimally invasive procedures, including repair of damaged valves and multiple bypass procedures, all done through small openings in the chest, between the ribs, rather than creating large chest openings. **Heartport Inc.** and **CardioThoracic Systems** have been locked in a high-profile rivalry since both went public within days of each other last year. I have two lengthy stories, from the January 21st *San*

Francisco Chronicle, and from the February 17th *Boston Globe*, for anyone who would like to read more about the procedures and the rivalry.

1/24 **American Dental Technologies** was awarded a preliminary injunction against **Kreativ Inc.**, ordering them to stop making false statements about the ability of ADT's KCP dental air abrasive to perform several classes of cavity preparations.

1/28 **Coherent Inc.** reported record first fiscal quarter results, with sales of $93.9 million, 12% higher than for the same period last year. Medical division sales for the quarter were $41.3 million, about on par with the same quarter last year, but down $2 million from the previous quarter. During the quarter, the company acquired **Tutcore OY** of Finland and **Miracor** of Massachusetts, and wrote off $9.3 million of purchased in-process technology from the acquisitions. Current quarter pro-forma net income before the write-off was $8.5 million (73 cents/share), but a net loss of $0.5 million (5 cents/share) with the write-offs.

1/30 **ThermoLase** announced that it had signed a 10-year lease for retail space in Newport Beach, CA, where the company plans to open a Spa Thira salon. Eight Spa Thiras are currently open, with the newest, located in Greenwich, CT and Manhasset, NY, scheduled to open in early February. In addition, a spa has just opened in suburban Minneapolis, and another is under construction in Palm Beach, FL.

1/30 **Lasermedics** completed the acquisitions of **Gatti Medical Supply**, a provider of equipment and supplies to the physical and rehabilitation marketplace, and **T.E.N.S.** a marketer of electrotherapy medical equipment. (Lasermedics seems to be re-inventing itself into a physical therapy company, while awaiting the possible approval of its low energy biostimulation laser for treating carpel tunnel syndrome.)

1/30 **Laserscope** reported its fourth quarter results with revenues of $16.1 million and a net income of $73,000 (6 cents/share). Revenues were up 130% over the same quarter last year, and represent the pooling of sales from the acquisition of **Heraeus Surgical**, the sales growth in the elective aesthetic surgery market, and continued improvement in international operations. Revenues for the year were $42.6 million and net income, excluding third quarter charges associated with the acquisition, were $1.6 million (17 cents/share). With the acquisition charges, the company reported a loss for the year of $1.7 million (19 cents/share).

The company believes that it is now the market leader in the treatment of leg veins with its Aura Laser with StarPulse. Its strategic partnership with **Medical Alliance** underscores the opportunity for the Aura laser. According to Robert McCormick, president and CEO, the acquisition of Heraeus, and that company's Paragon CO_2 laser, enables Laserscope to participate in another key area of the aesthetics market. He also believes that the PDT market continues to show promise, with approvals in place for

Photofrin from **QLT PhotoTherapeutics**, its pharmaceutical partner, in Japan, Canada, the Netherlands, France and the United States.

2/4 **Palomar Medical Technologies** announced that its **Tissue Technologies** subsidiary had received both the CE Mark and ISO 9001 registration for its TruPulse laser for skin resurfacing. The approvals allow the product to be marketed freely into the European Community of countries. According to Steve Georgiev, chairman and CEO, the company is already shipping the laser worldwide and has commitments from 14 international distributors to purchase approximately 180 systems, worth $8 million.

2/4 **ThermoLase** announced its results for the quarter ending December 28th. Revenues were $8.6 million, compared with $7.4 million for the same period last year. The net loss for the quarter was $1.4 million (3 cents/share), compared with a loss of $82,000 last year. The calendar year was completed with seven spas open and 70 physicians licensed to provide SoftLight services. (Each physician agrees to pay the company a minimum of $16,000 per month in service fees.)

2/4 **Spectranetics** announced its fourth quarter results with revenues of $5.0 million, up 17% from last year. The net loss for the quarter was $331,000 (2 cents/share). For the year, revenues were $20.7 million, a 20% increase, and the net loss was $1.4 million (7 cents/share). The revenue increases for the quarter and year were due primarily to growing sales of the company's laser catheters for angioplasty procedures, as well as investigational products for use in clinical trials.

2/5 **CardioGenesis** reported its fourth quarter results with sales of $1.0 million. This resulted from sales of the company's intraoperative TMR system (ITMR) to international customers and into clinical sites in the U.S. Net losses for the period were $3.1 million (26 cents/share). For the year, sales were $4.0 million and a net loss of $8.8 million (97 cents/share). Highlights of the year included performing the first percutaneous myocardial revascularization (PMR) to treat patients with severe angina; achieving the CE Mark and commercial launch of the first product, the ITMR system in Europe; reporting of favorable preliminary results from the ITMR feasibility study in "no option" patients, and subsequent FDA approval to enter Phase 2 clinical trials; and FDA approval of a new trial to study ITMR as an adjunct to CABG. Additionally, the IPO in May 1996 provided the financial resources to pursue strategic initiatives and to fund additional clinical trials. The year culminated in the international distribution agreement with **Boston Scientific Corporation**, signed on January 22, 1997 (see our brief in last month's issue).

In its clinical programs, the company has successfully performed seven PMR clinical procedures in patients with severe angina at two clinical sites in Europe; and is conducting two multi-center prospective, randomized studies of ITMR, one in "no option" patients with ITMR as the stand-alone procedure, and the other a study of

ITMR as an adjunct to CABG. A total of up to 650 patients and 45 clinical sites are approved to be included in the two ITMR trials. A request to begin a U.S. clinical trial of the company's PMR system should be submitted during the first quarter of this year.

2/5 **Cell Robotics** announced that it had submitted a 510(k) application for the use of its erbium laser for skin resurfacing. According to the company, clinical studies have shown that the erbium laser causes less burning of the skin, resulting in faster healing times. The company has completed a first-generation prototype erbium skin resurfacing laser and plans to introduce it to the market by mid-1997. Additional lasers for other aesthetic applications, such as hair removal and tattoo removal, may be added to the product line. The company, with **Big Sky Laser**, has completed pre-production units of its Lasette laser skin perforator for the clinical blood sampling market, and is awaiting a response from the FDA on its 510(k) application which was submitted on December 23, 1996.

2/5 **Atlantic Central Enterprises, LTD.** announced its entry into the cosmetic surgery center business. The company holds a controlling interest in subsidiary company **ICON Centers for Cosmetic Surgery**, which will focus on the acquisition and mangement of existing cosmetic surgery practices, to establish an international network of plastic surgeons and dermatologists. ICON's strategy is to target successful plastic surgery and dermatology practices and bring them into their network, as part of the Physician Practice Management industry.

Atlantic Central Enterprises is an international company dedicated to building a group of companies directed toward capitalizing on the changing and aging worl population, through strategic acquisitions of lifestyle companies that are mainly health care related. Atlantic is currently the controlling shareholder of **Vista Technologies Inc.**, whose subsidiaries, **Vista Laser Centers**, perform laser vision correction; and also a significant shareholder in **Technical Chemical Products**, a company with leading edge diagnostic technology.

2/6 **Premier Laser Systems** announced that it had received a letter from the FDA containing a brief list of queries regarding its pending submittal to market its erbium laser for certain procedures in hard-tissue dentistry. Colette Cozean, chairman and CEO said that the company responded in straightforward fashion to all the queries within 48 hours of receipt of the letter, which informed the company that the FDA considers the submittal to have a very high priority. If the company receives the approval, it will then be able to claim the broadest line of dental lasers in the world. The company already markets several lasers to the dental marketplace, including its diode and erbium systems for soft-tissue applications, and individual and multiple-operatory argon lasers for teeth whitening and composite curing.

2/7 **Surgical Laser Technologies** announced its fourth quarter results with sales of $3.0 million, up from $2.4 million in the third quarter, but down from the $3.8 million for the same period last year. The net loss for the quarter was $263,000 (3 cents/share). The fourth quarter net income included a net gain of $5.9 million from the settlement of patent litigation (with **Laser Industries/Sharplan**) (60 cents/share). Additionally, the fourth quarter results included a non-recurring charge of $1.5 million (16 cents/share) for reserves on certain inventories and write-off of certain intangible assets. Sales for the year were $11.0 million, compared to $14.8 million in 1995. The net loss for the year was $4.5 million (46 cents/share), which included a non-recurring charge of $1.5 million in the third quarter for severance and related expenses, as well as the write-off of certain leasehold improvements at the company's former manufacturing facility. President Keith Stoneback stated that the fourth quarter's operating loss of $169,000 compares favorably with operating losses for the first three quarters which averaged $700,000 to $800,000 per quarter, and he believes that the turnaround has started. Over the next two quarters the company will focus on supporting the expansion of its international distribution, placing a greater emphasis on surgical specialties beyond urology, which has been the focus in recent years.

2/7 **Cell Robotics** announced that it had submitted an IDE application for a clinical trial of its in vitro fertilization workstation. If approved, the company will conduct a clinical trial of the workstation, which functions as a diagnostic tool with a standardized method of embryo examination and documentation. The workstation will also offer laser-assisted hatching of embryos before implantation into the mother. (I believe the company is referring to weakening or creatomg a hole in the egg cell wall to enable a sperm to invade more easily, to form an embryo.) In Austria, a member of Cell Robotic's board of technical advisors has shown considerable improvement in pregnancy rates after laser-assisted hatching. The clinical study is planned for five prominent IVF sites, three in the U.S., one in Belgium, and one in Israel. The novel sperm injection techniques was developed at the clinic in Belgium.

In addition, the company has been awarded an SBIR grant of $100,000 from NIH to allow the development of an integrated laser module, and to research various effects of laser light on biological samples, such as determining non-damaging shock wave and thermal gradient parameters. The grant also covers the development of a specialized objective lens for the laser-assisted hatching process.

2/7 **Candela Corporation** announced the opening on February 11th, of what it believes is the world's first combination spa, salon, and cosmetic laser treatment center. The new facility is located in Scottsdale, AZ. The spa is a 7500 sq. ft. facility situated in one of Scottsdale's best locations. It will house a full-service spa and salon, which will offer therapeutic body treatments, weight training, cardiovascular training, diet programs, and health club memberships, among other amenities. State-of-the-art dermatology lasers will be installed and available to treat a panoply of skin conditions, such as

wrinkles, leg and facial spider veins, stretch marks, sun spots, and tattoos. Candela operates a pilot cosmetic skin care center in Framingham, MA, opened in October 1995; and plans to open a combination spa, salon, and cosmetic laser center in Boston in April 1997.

2/10 **Coherent Inc.** announced that a multi-center clinical study has shown that skin resurfacing with its UltrPulse laser increases the body's own collagen in resurfaced skin. The study also confirms that skin resurfacing with the UltraPulse is an effective treatment for moderate to severe wrinkles and furrows. The laser is the first to be granted marketing clearance by the FDA for increased collagen during skin resurfacing. Fourteen physicians at five sites treated over 100 patients with the UltraPulse and were able to demonstrate significant improvement in the appearance of patients with moderate to severe wrinkles. Microscopic examination confirmed that the laser resurfaced skin showed increases in healthy appearing collagen. According to the company, the market for resurfacing lasers has grown rapidly over the past three years to over $180 million per year, and an estimated 150,000 procedures are expected to be performed this year.

2/10 An interesting article by Dr. Harvey Wigdor of Ravenswood Hospital Medical Center in Chicago, appears in the current issue of *Lasers in Surgery and Medicine* (Volume 20, #1, 1997). The article is a survey of 100 dental patients concerning their perception of lasers used in dentistry. The results showed that 69% of the responding patients thought that lasers would make their visit to the dentist easier. Dr. Wigdor concludes that dental patient's perception of the laser is positive, and that patients feel that lasers can make their visit to the dentist less traumatic. Some of the reasons cited include less pain, faster, no drilling, and no noise. Fifty-six percent said that they would be willing to pay an additional fee if the laser could be used instead of a drill, and 48% said they would be willing to participate in a study of lasers in dentistry. (Give me a call if you would like a copy of the article.)

2/10 Fulfilling our comments about the proposed sale in the last issue (December 30th brief), **Trimedyne** announced that it had completed the sale of its **Poly-Optical Products** subsidiary, in an all cash transaction to privately-held **Remote Source Lighting International**. The sale will add approximately $1.4 million to Trimedyne's working capital and will result in a gain of approximately $700,000 to the present quarter. Poly had revenues of approximately $3 million for its last fiscal year, and income from operations of $252,000. Remote is a developer and manufacturer of fiber optic lighting systems for use in a variety of industrial and commercial signage and entertainment applications.

2/10 **Medical Alliance** announced exclusive agreements with **Valleylab** and **Imagyn Medical**. The agreements will give MA preferential access to new technology and products and will increase the breadth of medical and surgical procedures that can be

provided in OB-GYN offices that utilize the company's services. The strategic relationships also provide the manufacturers of such technology and products a non-traditional distribution channel through which they can market their products directly to third party payors and physicians, thereby enhancing market acceptance and recongnition of products and services. The Valleylab agreement enables MA to facilitate microlaparoscopic procedures that can be performed by OB-GYNs in their offices. The agreement with Imagyn allows the company to offer OB-GYNs new microhysteroscopy technology which enables the physician to not only provide diagnostic procedures, but to also provide therapeutic hysteroscopic treatment.

MA provides a broad range of services used to create temporary surgical sites in physician's offices in 46 states and Canada. The company has over 125 managed care contracts covering approximately 16 million lives, and provides its services along two primary business lines -- medical surgical, and aesthetic elective services. The company's surgical services allow physicians to perform approximately 25 different insurance-reimbursible, office-based procedures, across numerous specialties, including gynecology, podiatry, urology, and otolaryngology. Its aesthetic services are utilized primarily by plastic surgeons and dermatologists for cosmetic procedures such as skin resurfacing, laser hair removal, tattoo removal, and vascular and pigmented lesion treatments, which include leg vein treatment. Currently, approximately 2600 physicians perform 6500 procedures monthly using Medical Alliance's services.

2/11 **QLT PhotoTherapeutics** announced that it had submitted a supplemental new drug application (NDA) for approval of Photofrin as a treatment for specific types of lung cancer. The application is the result of clinical trials involving 650 patients in the U.S., Canada, and Europe, whose treatments are extremely encouraging for certain early and late-stage lung cancers, according to Dr. Julia Levy, President and CFO. According to the American Cancer Society and the American Lung Association, lung cancer killed approximately 159,000 people in the U.S. last year, 27% of all cancer deaths in the country. About 41% of lung cancer patients survive the first year after diagnosis, but only 13% survive for five years. The mortality rate has not improved significantly over the past 20 years. The supplemental NDA is for the use of Photofrin PDT to be used for the reduction of obstruction and palliation of symptoms in patients with obstructing endobronchial nonsmall cell lung cancer(NSCLC), and also for the treatment of endobronchial carcinoma in situ or microinvasive NSCLC in patients for whom surgery and radiotherapy are not indicated. Three-quarters of all lung cancers are identified as NSCLC. In two multicenter randomized controlled studies comparing Photofrin PDT and YAG laser therapy for the palliation of patients with advanced disease, Photofrin PDT was reported to be equal or better than YAG therapy for objective tumor response, palliation of symptoms, and time to local progression. In those patients with early stage superficial lung cancer, results from three single arm studies showed Photofrin PDT to provide durable complete tumor responses while preserving normal lung tissue.

Following preliminary review by the FDA, the supplemental NDA will be evaluated by the Oncological Drug Advisory Committee. The submission is part of a four-part application for the components of a combination product, consisting of QLT's Photofrin and Optiguide cylindrical diffusers and of **Coherent** and **Laserscope** PDT laser systems. Photofrin has already been approved as a treatment for lung and esophageal cancer in France and the Netherlands; for esophageal cancer in the U.S.; for esophageal and bladder cancer in Canada; and, in Japan, for early-stage lung cancer, superficial esophageal cancer, superficial and early-stage gastric cancers, early-stage cervical cancer, and cervical dysplasia, a pre-cancerous condition.

Photofrin was launched in October 1996 into the U.S. by QLT's strategic partner, **Sanofi Pharmaceuticals**, for the palliative treatment of esophageal cancer patients with totally obstructing tumors and certain partially obstructing tumors. Sanofi will promote Photofrin for the new indications for treating certain lung cancers, following FDA approval. According to Sanofi Pharmaceuticals, currently more than 40 hospitals across the U.S. are equipped to perform photodynamic therapy procedures utilizing Photofrin. Information about therapy using Photofrin and a list of active sites is available from Sanofi by calling the company's product information service department at 800-446-6267.

Laserscope announced that it had filed a supplemental PMA with the FDA for its laser system for activation of Photofrin for the above mentioned lung cancer applications. According to Robert McCormick, president of Laserscope, "177,000 new lung cancer cases are reported annually in the U.S. The potential of being able to treat certain early and late-stage lung cancers with our portfolio of lasers and fiberoptic products adds a new dimension and direction to our business." In addition to the use of the laser, each treatment will require one or two doses of Photofrin (at $2000 per dose), and the consumption of at least one Optiguide fiberoptic delivery device, priced in the range of $500 to $600. Laserscope's PDT system includes a model 630 or 630XP PDT Dye Module, powered by a Laserscope 700 or 800 series KTP/532 or KTP/YAG Surgical Laser System.

2/11 **Ion Laser Technology** announced record revenues for its third quarter and nine-month periods ending December 31, 1996. Sales for the quarter were $2.1 million, up 107% compared to the same period last year, and were primarily due to laser tooth whitening sales which accounted for $1.3 million for the quarter, and $3.5 million for the nine month period. Sales for the nine months were $5.5 million, up 92%. The company's gross margin percentage rose from 32% to 53% for the quarter, and from 33% to 51% for the nine month period. The increases are due to margins associated with the sales of tooth whitening products. The company had net profits of $91,100 (2 cents/share) for the quarter and $306,300 for the nine months (6 cents/share). During the quarter, the company signed a multiple-site laser tooth whitening deal for the

Dallas/Ft. Worth area, which calls for 15 systems to be installed in the first year and an additional 15 system to be installed in the second year.

2/11 **Eclipse Surgical Technologies** announced fourth quarter results with revenues increasing to $2.9 million, up from $1.0 million in 1995. The net loss for the quarter was $2.8 million (18 cents/share). For the year, revenues were $9.8 million, up 260% over the same period last year. Net loss for the year was $4.2 million (28 cents/share). During the quarter, nine new patent applications were filed and 18 new laser installation sites were equipped. The company now has an installed base of 62 TMR laser systems, and filed 29 patent applications covering laser technology, fiberoptic handpieces, and TMR-related methodologies and apparatus during the year. The company completed Phase 2 clinical trials comparing TMR to drug therapy for patients with Class IV angina with no surgical option, and await the six to twelve-month data. During October, the first minimally invasive surgical TMR procedure was performed on a patient in Europe utilizing the Eclipse holmium laser and thoracoscopy. In addition, the company has received IDE approval to begin Phase 1 investigational trials studying TMR in combination with minimally invasive direct coronary artery bypass surgery (MIDCAB), which uses smaller incisions between the ribs rather than cutting through the sternum as in conventional bypass surgery.

2/12 **EquiMed** announced that it had purchased several related support companies from its chairman, Douglas Colkitt, to increase internal efficiencies. The purchases and subsequent consolidations were all approved by EquiMed's independent directors. The companies involved include **Nixon Equipment Corporation**, which leases medical equipment to many EquiMed affiliated oncology centers; the **George Washington** and **Thomas Jefferson** real estate companies, which own eight buildings, seven of which are leased to EquiMed in connection with oncology centers; **Russell Data Services** billing services; and **Trident International** accounting services. All of the acquisitions will now fall under EquiMed's Management Services Organizations Division.

2/12 **Laser Industries** opened its first aesthetic laser treatment center in Tel Aviv. The center will serve as the flagship model for other centers that the company plans to open in North America and Europe later this year. The centers are operated under a separate subsidiary, **International Medical Laser Clinics Ltd.**, headed by Naomi Barsilay, who holds worldwide experience in the establishment and operation of medical centers. The Tel Aviv center, **Laser Clinics Israel**, will offer a variety of aesthetic laser surgery procedures including skin resurfacing, blepharoplasty, hair transplantation, hair removal, and removal of tattoos and pigmented lesions.

2/12 **Trimedyne** reported its first fiscal quarter financial results with revenues down 3% to $2.9 million, and a net loss for the quarter of $924,000 (8 cents/share). The loss for the current quarter includes approximately $200,000 of expenses incurred by Trimedyne's newest subsidiary, **Cardiodyne, Inc.**, in its development of a new TMR

laser for treating severe cardiac disease. Commenting on the results, chairman Marvin Loeb said that the quarter's results were disappointing, but that the company was looking forward to the introduction of its new cosmetic laser at cosmetic and dermatology meetings in May in New York and Boston.

2/12 **Coherent Inc.** announced that beginning April 1st, the company's laser group will sell and service its scientific and commercial products directly in Japan. Under an agreement reached with its current distributor **Marubun Corporation**, both parties agreed to facilitate a smooth transition of the business to Coherent's Japanese subsidiary, **Coherent Japan Co., Ltd.** The agreement obligates Coherent Japan to repurchase its inventory from Marubun and assume full service and warranty support to its customers on an exclusive basis. (This transaction includes the medical products business.) Marubun will continue to distribute scientific and some commercial products for Coherent's 80% owned subsidiary, **Lambda Physik**.

2/12 **Surgical Laser Technologies** announced that it had been granted its motion for partial summary judgement in the suit brought by Norio Daikuzono, the owner of three SLT patents in contact laser technology. The court ruled that SLT does not owe Daikuzono any salary under an earlier employment arrangement and that the statute of limitations bars any claim by Daikuzono for allegedly unpaid royalties accruing before February 1991, nor are any royalties owed from the settlement proceeds received by SLT from Sharplan in December 1995. The trial of the remaining issues in the suit filed in February 1995 is expected to take place in 1997.

2/13 **PLC Systems** has established three new international subsidiaries in France, Switzerland and Singapore, in anticipation of FDA approval of its Heart Laser. The subsidiary established in Switzerland will serve as the hub of the company's international operations. Lee Hibbs, president and CEO noted that, "Due to the company's direct sales efforts, TMR using the Heart Laser is a treatment alternative for patients in 29 countries on almost every continent. The market potential for TMR...in Europe and Asia is about equal in size to the U.S. market and is continuing to grow." He also commented that, "Based on discussions with the FDA, PLC Systems' management believes its PMA application for the Heart Laser is on track for approval this year."

2/13 **ThermoLase** announced that it had opened its Spa Thiras in Manhasset, NY and Greenwich, CT, bringing the number of spas currently open to ten. According to president John Hansen, the national rollout continues as well as publicizing the product (laser hair removal) in ads running in major women's magazines such as Vogue, Cosmopolitan, and Self, as well as in 30-second TV spots.

2/13 **Trimedyne** announced that **Getz Brothers**, a leading distributor of cardiovascular devices in Japan and the Pacific Rim had purchased a 5% equity investment in

Cardiodyne, the company's cardiovascular subsidiary, for $1 million. Getz also agreed to purchase the company's TMR laser and disposable ChanneLite laser fibers from Cardiodyne for clinical trials in Japan, which are expected to begin in mid-1997. Getz is owned by the **Marmon Group** of Chicago, and had sales of approximately $700 million in 1996.

2/17 **QLT PhotoTherapeutics** reported its fourth quarter and year end results. For the quarter, the company had net income of $4.0 million (17 cents/share) on revenues of $10.9 million, $9.5 million of which was from collabrative arrangements, and only $386,000 from royalties on product sales. For the year, the company reported revenues of $18.2 million ($669,000 from royalties on product sales) and a net loss of $4.7 million (19 cents/share). Kenneth Galbraith, senior VP and CFO, said that the financial results for the fourth quarter reflected revenues from collabrative arrangements in the U.S. and Europe, and the early sales efforts of **Sanofi Pharmaceuticals**, (who launched Photofrin in the U.S. late in the year). "Photofrin sales efforts for 1997 should continue to grow as additional laser placements are made in the United States and Japan. In addition, our European partner, **Beaufour Ipsen**, should be conducting an initial launch in Europe by mid-1997."

2/18 **Palomar Medical Technologies** announced that its **Tissue Technologies** subsidiary had received additional clearance from the FDA to sell and market its TruPulse CO_2 laser for the treatment of wrinkles, scar revision, and burn debridement. Palomar is the third company to receive such approval for wrinkles, the others being **Sharplan** and **Coherent**.

2/18 **BlueStone Capital** announced that it had initiated coverage of **Premier Laser Systems** with a buy recommendation. (I received the report late in the month, and it looks quite complete in its coverage of Premier's activities. A lot of hope for success for the company depends on its obtaining FDA approval for hard dental tissue use for its erbium laser, and for cataract removal approval with the ophthalmic version of the same. Anyone wishing a copy of the report should call me.)

2/19 **ESC Medical Systems** announced the acquisition of **Luxar Corporation**. This move gives ESC a stronger hand in product offerings for the rapidly growing cosmetic surgery market, as Luxar has a worldwide installed base of over 3000 CO_2 lasers, and a 65 person domestic field force and a network of international distributors, to market and service its products. For the fiscal year ended September 30th, Luxar recorded net sales of $28.1 million and net income of $4.5 million. For the year ended December 31st, ESC reported net income, excluding acquisition related expenses, of $12.7 million (74 cent/share) on sales of $32.9 million. The acquisition is expected to accounted for as a pooling of interests and ESC will issue approximately 2.5 million shares, subject to adjustment in certain events. The transaction is expected to be completed within 30 days, subject to approval by the shareholders of Luxar and other

conditions. Following the acquisition, Luxar will operate as subsidiary of ESC Medical, and will be headed by its current CEO Roseanne Hirsch, who will be nominated to ESC's board of directors.

2/19 **Laser Industries** announced record sales and earnings for the fourth quarter and year. Sales in the quarter were $15.5 million, a 14% gain over the same quarter last year, and net income was $2.5 million (29 cents/share), compared with net income before litigation expenses of $1.7 million in 1995. For the year, sales rose 17% to $58.7 million, with net income of $8.8 million ($1.17/share). (1995's results included an $8.1 million settlement with **Surgical Laser Technologies**.)

2/19 **Palomar Medical Technologies** announced that it had entered into an exclusive relationship with **Copelco Capital**, one of the world's largest leasing companies, to become the private label leasing company for Palomar's line of cosmetic lasers. Under the terms of the agreement, Palomar's sales and distribution team can offer physicians who want to acquire lasers, the full range of Copelco's leasing and purchasing programs. Copelco will administer Palomar's entire proprietary leasing program, including sales training, marketing support, billing, collections, and reporting. Copelco will also establish a staff dedicated solely to expediting Palomar leasing transactions. Copelco is owned by **Itochu, Inc.** of Japan, a multi-billion trading company.

2/24 **Mehl/Biophile International** announced that it had entered into a strategic alliance with **Biophile, Inc.**, Thailand, for the placement of its hair removal laser system. The new venture will create a network of hair removal clinics throughout the Asian region, and will link the 90 cosmetic clinics already established in Thailand by Biophile Thailand. Mehl estimates that approximately 150 of its hair removal laser systems will be delivered under the terms of the alliance by the end of 1998, beginning during the second quarter of this year. These systems are in addition to the current backlog of 247 systems to be placed in other parts of the world. Under this alliance, systems will be placed in Thailand, Malaysia, Indonesia, and Hong Kong. Plans also include additional placements in other Asian countries, and negotiations are underway for placement in China.

Mehl had already established clinic networks in, and delivered lasers to Europe, Australia, South Africa, and New Zealand. The laser systems are produced at the Mehl manufacturing facility, **SLS Biophile**, in Wales, UK. (There is no word yet about the battle between Mehl/Biophile and **Laser Industries**, over their joint venture agreement signed in December 1995, which apparently has fallen apart. See our brief of 12/6 in the December issue of **Executive Laser Briefing**.)

2/3 *The Gray Sheet* noted that a number of **Xanar** Surgical CO_2 lasers, produced by **Coherent Medical**, had been recalled by Coherent in May 1996 because the 12 units failed to comply with regulations in that they might deliver twice the power requested by the user and displayed on the terminal. A field correction was completed by the manufacturer.

2/13 **Pharmacyclics** reported financial results for its fiscal second quarter (ending December 31st) with a net loss of $2.6 million (29 cents/share), on revenues of $25,000. R&D expenses increased to $2.5 million for the three months, compared to $1.5 million for the same period last year.

2/20 **Sharplan Lasers** announced the marketing clearance for its XJ Dual Mode Scanner for attachment to the SilkLaser aesthetic CO_2 laser line. The product is unique in that it incorporates two distinct scanning technologies within one system. It can be used to automatically generate high energy pulsed patterns for skin resurfacing in a variety of shapes and sizes, as well as in Sharplan's patented flashscan mode, for a faster healing technique to treat wrinkles and scars.

2/20 **Pharmacyclics** announced that it had completed a private placement of approximately 860,000 shares to four investors at $19.05/share, raising $16.4 million. The placement was done to accelerate development of its two cancer treatment products and to intensify efforts in treating atherosclerosis using photodynamic angioplasty. The additional capital brings the company's cash balance to $40 million.

2/21 The Board of Directors of **Mattan Corporation** decided to request a halt in trading of its shares on the Alberta Stock Exchange. This was prompted by the company's inability to secure financing within the required time frame set up by the board, to enable it to initiate a national program for its operating subsidiary, **Medical Laser Institute of America**. As a result, the Board, subject to regulatory and shareholder approval, has decided to sell MLIA, following the surrender of shares by certain members of management and associated parties. The terms of these arrangements are expected to be announced by March 31st, and brought before shareholders in late May 1997. In addition, the Board accepted the resignation of Mark Miller as president and CEO of MLIA, with Dan Anbar agreeing to temporarily assume those roles.

2/24 *Investor's Business Daily* carried a story about **QLT PhotoTherapeutics** and its PDT cancer therapy for treating lung cancer. According to analysts approval for this indication could come by year's end. Clinicals are being conducted at prominent cancer centers such as Grant Hospital and the Mayo Clinic. The story also mentions the work being done with QLT's second generation photosensitizer BPD, in treating age-related macular degeneration.

2/25 **ESC Medical Systems** announced that it had received ISO 9001 and EN 46001 registration for its intense light medical devices for skin treatments. In addition, the devices, including the PhotoDerm VL, PhotoDerm PL, PhotoDerm VL/PL, EpiLight, and the VersaLight, had received CE Mark for marketing into Europe.

2/26 **PLC Systems** announced that the FDA had filed the company's expedited PMA for treating diseased heart tissue. The filing indicates that the FDA has accepted and is prepared to review the application. The company hopes to receive marketing approval for its Heart Laser, which will then allow it to be used as adjunct therapy for the approximately 675,000 cardiac bypass surgeries performed worldwide.

2/26 **Cell Robotics International** announced that it had received confirmation that it can begin marketing its In Vitro Fertilization Workstation into the European Community. According to the notifying body, the workstation will not be classified as a medical device but will fall under general requirements as an electronic and laser device. This classification will allow the company to begin marketing the product more quickly than anticipated. The workstation is currently under review by the FDA for an IDE, to allow the company to begin human clinical testing. Upon approval of the IDE, the company will begin a clinical trial of the device at five in-vitro fertilization clinics -- one in Europe, one in Israel, and three in the United States. (See the February 7th brief in last month's newsletter for more information.)

2/27 **PLC Systems** announced its fourth quarter and year-end results, with quarter revenues of $3.1 million, compared to revenues of $7.3 million last year, and a net loss of $1.4 million (8 cents/share). For the year, revenues were $11.9 million, compared to $13.3 in 1995. The net loss was $1.5 million (9 cents/share), compared to net income of $2 million last year. The company shipped 13 Heart Lasers in the fourth quarter, 9 of which were placements, and 4 were sales. For the year, the company shipped 31 laser systems, 17 placements and 13 sales (with one laser shipped for R&D purposes). This compares to the shipment of 23 Heart Lasers in 1995, of which 9 were placements and 14 were sales. Placement/service fees in 1996 doubled the fees collected in 1995.

Management estimates the initial U.S. market for TMR using the Heart Laser to be 150,000 patients and growing, with the greatest market potential to be as an adjunct to CABG. To date, 3000 patients in 29 countries have received treatment, with the number in 1996 doubling the number treated, as well as the number of countries in which the laser is available. The company expects to exceed the number of lasers shipped in 1996, in 1997.

2/27 **EquiMed**, a trans-national medical practice management and services company, announced that it expects 1997 to be a pivotal year for the company. Recent developments and 1997 prospects include:

Restructuring -- major decisions made in the second half of 1996 and the first quarter of 1997, particularly the sale of EquiMed's ophthalmic division to **Physicians Resource Group**, and consolidation of related party transactions have cleared the way for EquiMed to capitalize on its core competencies, which are its profitable oncology practice management; the acquisition of other practice management opportunities such as **Anesthesia Solutions**; its expertise in managing the business and administrative aspects of medical practices via off-shore labor resources of its Management Services Organizations; and the development of new, medically related but consumer driven businesses such as laser cosmetic treatment facilities called **Rejuve Image Enhancement Centers**, which will open in three U.S. cities in the first quarter of 1997.

Estimated 1997 Results -- the company expects 1997 revenues to be $137 million with net income of $14 million (46 cents/share). The company expects that its existing Oncology Group will produce revenues of $58 million, with an additional $15 million from new acquisitions; Anesthesia Solutions should produce $36 million in revenues; and with 5 Rejuve centers in operation by end of year, revenues are projected at $8 million, with EquiMed's partner **Palomar Laser Technologies** sharing equally in these revenues. Current plans call for as many as 24 centers to be opened by the end of 1998, with estimated revenues for EquiMed/Palomar to be $32 million by then.

3/1 The February issue of *MedPro Month* contained a nice writeup about the potential for laser hair removal, taken from my "white paper".

3/3 **DUSA Pharmaceuticals** reported the results of its Phase 3 trials, highlights for the year, and its financial results. The company achieved a key corporate objective by initiating a pivotal Phase 3 clinical trial of Levulan PDT for pre-cancerous actinic keratoses (AK) of the skin, following Phase 2 data which showed complete clinical clearance of up to 100% of lesions after 1-2 treatments. The two Phase 3 studies of 100 patients each are being carried out at 13 sites across the U.S., and are now actively soliciting patients, with completion targeted for late summer 1997. During 1996, the company also completed a Phase 1/2 Levulan PDT acne study and advanced development of bladder cancer photodiagnosis, and hair removal programs. The latter were carried out by independent investigators at Massachusetts General Hospital. Other achievements in 1996 included the unveiling of DUSA's low cost non-laser blue light source for AK treatment; the disentanglement of remaining ownership and administrative ties with DUSA's former controlling shareholder; and a follow-on public offering of 750,000 common shares.

In 1997, the company expects to complete Phase 3 AK trials in preparation for its first planned NDA application to the FDA; commence Phase 1/2 multicenter bladder cancer and hair removal trials; and support further studies on acne and endometrial

ablation. In addition, the company **has begun to seek strategic partnership(s) in the field of dermatology.**

For the year, the net loss was $6.8 million (75 cent/share), with R&D costs at $5.7 million, or 72% of total 1996 expenses.

3/3 As written in the March 3rd issue of *EyeWorld News*, **HGM Medical Laser Systems** has announced a new erbium:YAG laser for cosmetic skin resurfacing, the Spectrum Renaissance laser. Attempts to reach HGM for more information have, to date, been unsuccessful.

3/3 **American Dental Technologies** announced its year-end results. Revenues for the year were $20.5 million, up 54% from the $13.3 million reported for 1995. The company had a net profit of $5.6 million (22 cents/share), which included a one-time benefit of $2.7 million of related party royalty income. Income from operations was $3.0 million.

3/4 Steve Handley of Smith Barney sent along his research note on **ESC Medical**. The note discusses the recent acquisition of **Luxar** by ESC, and how the company will fully capitalize on the acquisition in 1998 by utilization of Luxar's worldwide sales force and installed base of over 3000 lasers. The note also speculates on the potential of ESC's EpiLight hair removal system which is awaiting FDA marketing clearance. According to the note, Luxar had sales exceeding 900 lasers in its fiscal year ending September 20th, with FY96 revenues of $28.1 million, compared to $13 million in FY95. For the quarter ending December 31st, the company had revenues of $9.7 million, more than double the year earlier period. One of the new products in the pipeline includes a non-invasive roller/pressure system that seeks, during about 14 treatments, to move fat out of the body and thereby reduce cellulite in patient's legs and hips. It is scheduled to be introduced to the market during the June quarter. Another new product is a teeth whitening system utilizing a CO_2 laser, and a material applied by dentists to the teeth. Luxar hopes for 510(k) marketing approval in the December quarter. Luxar's domestic sales force consists of 51 people that are either direct employees or independent reps who focus on Luxar's products, as well as 14 distributors. This will represent a significant addition to ESC's direct sales force of 15 persons, plus two distributing organizations. In addition, the large base of existing Luxar product users should represent numerous good candidates to purchase additional ESC products, such as the EpiLight hair removal system.

The February 24th issue of *The Gray Sheet* also contains an extensive writeup of the ESC/Luxar February 19th deal. The only additional news is that ESC has placed 250 PhotoDerm systems worldwide, and more than 50 Topaz and Derma systems (from the acquisition of **LBT** in Israel) in non-U.S. markets. Luxar has 150 employees, while ESC had 138, 35 of whom are based in the U.S.

3/5 **Laserscope** announced that it had received FDA clearance to market its ParaScan scanning device and CBH-1 Collimated Beam Handpiece with the Pulsar CO_2 laser system for skin resurfacing, laser abrasion, the treatment of wrinkles and warts, and scar revision. Pulsar is the new name for the Paragon CO_2 laser system obtained in the acquisition of **Heraeus Surgical** last August. In addition, the company has approval for its Aura doubled YAG laser for the treatment of surface leg veins.

3/5 **ThermoLase** announced that it expects to commence its previously announced exchange offer to shareholders on March 6th. The offer will allow shareholders to exchange one share of common stock and $3.00 in cash for one new ThermoLase Unit consisting of one share of common stock and one redemption right. The redemption right entitles the holder to sell the related share of stock to the company for $20.25 during the first 20 business days after the fourth anniversary of the expiration date of the offering.

3/5 **Candela Corporation** announced that the German government had cleared a wide range of its cosmetic medical laser products, including granting of the CE Mark for sale of the devices throughout the European Community. Among the cleared products were the ScleroLaser, the ScleroLaser Plus, and the elongated spot handpiece for use with the SPTL-1b vascular lesion laser.

3/6 **QLT PhotoTherapeutics** said that long-term data on the use of Photofrin for treating various cancers was released at the International Photodynamic Therapy Symposium held in Tokyo. Dr. H. Kato of the Tokyo Medical College reported that PDT with Photofrin was shown to provide long-term tumor response in over 50% of patients with early-stage superficial lung cancer, who would otherwise have required surgery. In another presentation, Dr. M. Leroy of the Centre Medico-Chirurgical Foch, Paris, showed that 88% of patients with inoperable early-stage lung cancer achieved a complete tumor response with PDT in clinical trials conducted between 1990 and 1993. Also, Dr. Charles Lightdale of Columbia University College of Physicians and Surgeons, New York, told delegates that PDT with Photofrin may be a curative in selected patients with superficial esophageal cancer, and was an effective treatment in the relief of dysphagia (difficulty in swallowing) in patients with advanced esophageal cancer. QLT is planning to initiate Phase 3 trials in patients with early-stage esophageal cancers later this year.

3/6 **ICON Centers for Cosmetic Surgery** announced the formation of the company and the appointment of Robert Qualls as president and CEO. (Qualls was most recently president and CEO of **LaserSight Technologies**, a subsidiary of **LaserSight Inc.**) ICON is the nation's first physician practice management company committed to developing a national and, ultimately, international, network of cosmetic surgery centers. ICON plans to acquire 200 plastic surgery and cosmetic dermatology practices within the next five years. Mr. Qualls explained that the cosmetic surgery

market, currently a $3.4 billion market and growing at 20% per year, coupled with the 76 million baby boomers beginning to turn 50, creates a tremendous opportunity in the development of highly successful cosmetic surgery practices. "To achieve their potential, these practices will require cost-effective, high quality marketing, professional management, and extensive capital for new technology. ICON has the resources to contribute marketing expertise as well as skilled and professional management to the practices we acquire to enhance their position in a growing market." ICON is headquartered in Johns Island, SC. (I have just completed a market opportunity study for ICON that can be obtained by contacting Mr. Qualls at 1-800-951-ICON.)

3/7 **Premier Laser Systems** has announced that it will begin in-house manufacturing of its Arago II, an enhanced version of its Arago Portable argon laser used in the curing of dental composites for filling cavities. The company said it had a small inventory of the Arago laser, but that its manufacturer had ceased shipping the product, and so it decided to manufacture the laser in-house to prevent a prolonged interruption in providing the laser. The company said that customers with pending Arago orders could convert them to an Arago II, or buy the company's Multiple-Operatory Dentalaser, which is used both in composite curing and for tooth whitening procedures. The company expects shipments of the Arago II to commence this summer.

3/7 *Investor's Business Daily* ran a story entitled, "Watch Out When `Story' Stocks Skip Ahead", which discussed whether to jump on the bandwagon when you hear about a breakthrough product, such as a toothpaste that reverses dental decay. The story also talked about the problems that a promising company, such as **Ion Laser Technology** can run into. As you know, ILT sells a tooth whitening laser system. Its stock shot up from late 1995 through mid-1996 on the excitement of the $40,000 system that could replace current tooth whitening/brightening treatments. The company's stock jumped almost sixfold to a high of 31. Then the bubble burst. The company had trouble adjusting from an industrial laser company to a consumer-oriented company, according to analyst Eric Peterson of Pennsylvania Merchant Group. At first the company had trouble producing enough systems, but the real problem was that ILT has been unable to convert heavy interest into strong sales. Although there were many inquiries, most doctors were hesitant to shell out $40,000 for the laser. As setbacks hit, the stock slid lower, and now is about 8. ILT still has a lot of promise, its technology works and it has overcome some setbacks and just got a new chief executive. But so far, said analyst David Settle of ComVest Partners, the only help ILT has been to many investors is an example of what to be aware of. (It should also be noted that several companies, including **Premier Laser Systems** sell much less expensive tooth whitening laser systems.)

3/10-

3/11 **Palomar Medical Technologies** announced that the FDA had granted marketing clearance for its EpiLaser system for hair removal. Palomar is the second company to gain clearance, following the approval in 1995 for **ThermoLase**. The Palomar system uses a ruby laser to effectively heat the melanin in the hair follicles and destroy the growing hairs. With the clearance, Palomar now has approved systems for both of the fastest growing cosmetic markets -- hair removal and wrinkle removal, both multi-billion dollar markets.

Following the Palomar announcement, **Mehl/Biophile** announced that its wholly owned subsidiary, **Selvac Acquisition Corporation**, had filed suit on March 7th against Palomar and its subsidiaries, **Spectrum Medical Technologies**, **Spectrum Financial Services**, and a New Jersey dermatologist (presumably using the EpiLaser for hair removal), for patent infringement and unfair competition. The suit filed in the U.S. District Court for New Jersey, alleges that the defendants have improperly marketed their laser hair removal products before receiving FDA clearance, and that the laser infringes on the "Zaias" patent exclusively licensed to Selvac. (No mention was made of the "right" granted to **Laser Industries/Sharplan 2000** under the December 1995 agreement between the two companies, which is now in dispute.)

Both the approval and the law suit were prominently mentioned in stories appearing on March 11th in both *The Boston Globe* and *The Wall Street Journal*.

3/11-
3/12 In follow-ups to the above announced lawsuit for patent infringement against Palomar by Mehl/Biophile, **Palomar** announced that the Rox Anderson patent assigned to Massachusetts General Hospital (U.S Patent 5,595,568), licensed to Palomar and under which its laser operates, had issued on January 21, 1997. Palomar then announced that it had filed a declaratory judgement several months ago against Mehl/Biophile seeking a declaration that Palomar's EpiLaser laser-hair removal system did not infringe on Mehl's method, and furthermore, that Mehl's patent was both invalid and unenforceable. That suit had been filed in the U.S. District Court in Boston. According to Steven Georgiev, Palomar's chairman and CEO, the suit was filed upon learning that Mehl/Biophile was misrepresenting to Palomar's customers that its product might infringe on their patent. With the issuance of the MGH patent, all of the information is now in the public domain allowing for resolution of the issues.

3/11-
3/13 The day after Palomar's announcement of clearance for its laser hair removal system, **Laser Industries** said that it had also received notification of approval for marketing of its EpiTouch ruby laser system on March 7th. The EpiTouch, unlike the Palomar system, is a dual mode system, which can be used in the Q-switched mode for tattoo removal, and in the normal running mode for hair removal. Laser Industries said that

the EpiTouch laser would be sold in the U.S. through Sharplan 2000, a joint venture of Laser Industries and **Mehl/Biophile International**. (Again, no mention of the lawsuit recently filed by Mehl/Biophile to dissolve the partnership.)

Not to be outdone, again, **Mehl/Biophile** announced two days later that it too had received FDA clearance for marketing its SLS Chromos 694 long pulse ruby laser for hair removal. The company also noted that its subsidiary **SLS Biophile** had already received full CE Mark approval for marketing the system in Europe and other parts of the world, and that 45 systems had been placed with professionals outside the U.S. under licensing agreements. (Mehl/Biophile places the lasers under a fee for service agreement, whereby it collects a monthly minimum fee or percentage of revenue for use of the laser.) Mr. Mehl also noted that the company had agreements for placement of approximately 400 systems outside the United States, and expected the same impressive reception for its system in the U.S. now that it had FDA marketing clearance.

3/11 **PDT Inc.** announced fourth quarter and year-end results with revenues and net interest income increasing to $2.2 million for the quarter, up from $316,000 for the fourth quarter in 1995. The net loss for the quarter was $3.5 million (28 cents/share). Revenues and net interest income for the year was $6.0 million with a net loss of $16.1 million ($1.37/share). Some milestones for the year include achieving ISO 9001 and EN 46001 registration for its device manufacturing business and expanding clinical trials worldwide by beginning Phase 2/3 trials for metastatic breast cancer in France and Phase 2/3 clinical trials for basal cell carcinoma in Australia. The company also announced a co-development agreement with **Ramus Medical Technologies** to expand its cardiovascular program to target the coronary artery bypass market.

3/11 **Eclipse Surgical Technologies** commented on a recent HCFA ruling regarding transmyocardial revascularization. The ruling institutes a national non-coverage policy for all TMR procedures performed on Medicare patients in the United States, effective on May 19, 1997. The company expects this ruling to result in a significant increase in expenses associated with conducting the required clinical trials and a significant reduction in U.S. revenues, at least over the short term. Chairman Douglas Murphy-Chutorian, MD, indicated that he was very disappointed with the HCFA ruling, but that he was hopeful that once the FDA grants marketing clearance for TMR, to any TMR company, that HCFA will reconsider coverage of the procedure.

The company said that it had completed its Phase 2 clinical trial comparing TMR to drug therapy and would have six-month followup data in April, which would be submitted to the FDA by mid-summer. The company said that it would provide the FDA with all the necessary data to expedite a PMA approval.

3/11 **Pharmacyclics** announced that the Decision Network Committee of the NCI had voted unanimously in favor of supporting additional clinical trials for two products developed by Pharmacyclics based on the company's texaphyrin technology, gadolinium texaphyrin (Gd-Tex), and lutetium texaphyrin (Lu-Tex). The company and NCI were now in the process of structuring a CRADA to sponsor multiple clinical trials evaluating both compounds in several types of cancers. The company has completed Phase 1 trials of the photosensitizer Lu-Tex for the photodynamic treatment of metastatic cancers involving the skin or subcutaneous tissue and plans to initiate Phase 2 testing in the second quarter of this year. Gd-Tex, a radiation/chemo-sensitizer is currently in a multicenter Phase 1b/2 trial for the treatment of brain metastases.

3/11 **Laserscope** and **QLT PhotoTherapeutics** jointly announced the extension of their strategic alliance for the development, manufacturing, and distribution of medical devices for the PDT market. Under the extended agreement, QLT will co-fund two Laserscope R&D projects, in which, to date, QLT has funded for a total of $475,000. Under the agreement, Laserscope will receive additional payments for future milestones reached, and QLT will receive royalties from future Laserscope sales of specific disposable and light source products. One of the programs to be co-funded is the development and commercialization of a low-cost 630 nm diode laser system to activate QLT's photosensitizer drug, Photofrin. At present, Photofrin is activated by a Laserscope 630 or 630XP PDT dye module, powered by either a Laserscope 700 or 800 series KTP/532 or KTP/YAG surgical laser systems. (The drug is also activated, under a separate agreement, by the **Coherent Medical** argon pumped dye laser, see the following brief.) QLT will provide Laserscope with appropriate regulatory support in obtaining PMA approvals for various Laserscope PDT delivery devices, as well as provide Laserscope with non-exclusive access to QLT technology relating to PDT devices, including optical biopsy, a cancer diagnostic process employing fluorescence imaging. As part of the agreement, Laserscope will make its new TheraStat product line and certain other disposable devices available on an OEM basis to QLT's other device partners. The TheraStat product line is a family of cylindrical and spherical PDT fiber optic light diffusing devices licensed to Laserscope by **Rare Earth Medical**, under a separate strategic alliance.

Laserscope and QLT entered into an initial cooperative distribution, development, and marketing agreement in February 1994, which was expanded in September 1995, when Laserscope received packaging and distribution rights to QLT's Optiguide fiber optic diffusing devices for PDT applications. In November 1996, Laserscope began making the Optiguide product line available to QLT's other device partners.

3/12 **Coherent Inc.** announced that it had filed a supplemental PMA with the FDA for the PDT therapy utilizing Photofrin, in the treatment of specific types of lung cancer. The supplemental PMA will be evaluated alongside the supplemental NDA for Photofrin

that has been filed by Coherent's technology partner, **QLT PhotoTherapeutics**. The S/NDA is for the PDT treatment of reduction of obstruction, and palliation of symptoms in patients with obstructing endobronchial non-small cell lung cancer (NSCLC), and also for the treatment of endobronchial carcinoma in situ, or microinvasive NSCLC in patients for whom surgery and radiotherapy are not indicated. (For additional details, see last months February 11th brief for QLT.) Coherent currently markets it Lambda Plus PDL 1 laser system, which has a fixed wavelength of 630 nm, and the Lambda Plus PDT 2, which is tunable between 630 and 690 nm, both of which are argon-pumped dye lasers, and a variety of delivery systems and accessories.

3/12 **Sunrise Technologies** announced the completion of a private placement of two-year convertible notes and warrants, resulting in gross proceeds to Sunrise of $4.1 million. The proceeds will be used to fund its ophthalmic subsidiary's FDA clinical trials, new product development, and sales and marketing activities outside the United States. The private placement was facilitated by Pennsylvania Merchant Group. (According to my notes, this is the second private placement done for Sunrise by Pennsylvania Merchant Group, with the raising of $2.25 million back in August of last year.)

3/12 **ESC Medical Systems** announced that it had completed its acquisition of **Luxar Corporation**. The transaction would be accounted for as a pooling of interests, with ESC issuing up to 2.5 million shares of common stock. Smith Barney and Needham & Co. served as financial advisors to ESC and Luxar respectively. Luxar will operate as a subsidiary of ESC, and will continue to be headed by its current CEO Roseanne Hirsch, who will be nominated to ESC's Board of Directors.

3/13 **PLC Systems** commented today on the recent HCFA ruling on TMR (also see the 3/11 brief and comments by **Eclipse Surgical**). PLC said that the non-coverage policy for TMR on Medicare patients will not impact private payors, a number of which do provide reimbursement for patients receiving TMR treatment with its Heart Laser. The company believes that by issuing the non-coverage instruction, HCFA is following its past policy to withhold reimbursement before an investigational device receives FDA approval. HCFA has agreed to look at the safety and efficacy data of PLC's clinical trials at the time of FDA panel review. PLC submitted its PMA application to the FDA in April 1995. The application was granted expedited review due to its potential use in patients with medically refractory angina, for whom no legally marketed therapeutic device is available. In February 1997, the FDA filed the application, meaning it was acceptable for review. The company believes that FDA approval may be granted this summer, and that the data submitted to support FDA approval will warrant a withdrawal of the non-coverage instruction made by HCFA. The company is not sure if any reversal in the coverage instruction will be product specific, or industry wide for TMR.

3/13 **C.R. Bard** announced that they had entered into an exclusive worldwide distribution agreement with **CorMedica Corporation**, a privately held Natick, MA company, to market that company's proprietary, patented, integrated system for catheter-based percutaneous transluminal endomyocardial revascularization (PTER). Under the agreement, CorMedica will design, develop, and manufacture PTER products for Bard's worldwide sale and distribution. These products will be used to treat patients with severe coronary artery disease by delivering laser energy through the catheter to create channels in areas of the heart muscle which have been deprived of oxygenated blood. (I have talked with the principal at CorMedica, and learned that they will OEM the laser for use with their catheters, but do not wish to disclose which laser type they will use at this time.) The products will bear the Bard name in the marketplace.

As you are aware, there are currently seven other company's vying for this marketplace, with **PLC Systems** (CO_2) clearly in the lead, with approval for their TMR system possible within the next 60 to 90 days. The others with TMR and percutaneous systems include **Circulase** (also CO_2); **Eclipse Surgical**, **CardioGenesis**, and **Trimedyne/Cardiodyne** (all with holmium:YAG systems); and **Acculase** and **US Surgical/Medolas** (with excimer laser systems).

3/14 **Spectranetics** announced that it had received the CE mark for its complete range of laser sheath products, used in the removal of pacemaker and implantable cardioverter defibrillator leads, allowing the marketing of these products into Europe. The company estimates that over 300,000 people undergo lead implantation each year, and removal of these leads may be required at some point in time due to infection, loss of venous flow through thrombosis, product recall, or failure. Results from the company's clinical trials show that explant success rate is 50% greater with the laser sheath. Since November 1995, over 400 patients worldwide have been treated with the laser sheath.

3/14 **Cell Robotics** announced that it had received approval of its IDE to conduct a clinical trial of its In Vitro Fertilization Workstation, designed to improve pregnancy success rates in the treatment of infertility. The clinical trials will be conducted at five in vitro fertilization clinics, as noted in the February 26th brief, above.

3/17 **Trimedyne** announced that its subsidiary, **Cardiodyne** had completed the initial pre-clinical testing of its proprietary laser system for TMR. The testing was done at the Harbor UCLA Medical Center. Cardiodyne hopes to begin human clinical trials later this summer. The Cardiodyne TMR laser is an 80 watt superpulsed holmium:YAG laser, which uses the company's proprietary Autofire system to synchronize the laser firing with the patient's ECG between heartbeats, when the heart is momentarily at rest. The system also uses the company's proprietary Channelmaker fibers. Trimedyne/Cardiodyne holds the rights to the Shturman patent (U.S. 4,788,975), which describes firing on the leading edge of the R-wave, and which pre-dates the

Rudko patent (U.S. 5,125,926) used by **PLC Systems**, which describes firing at the peak of the R-wave. According to a principal of Trimedyne, the company has put both PLC and **CardioGenisis** on notice about their laser triggering patent position.

3/17 **ESC Medical Systems** announced that it had received FDA clearance for its Topaz 30 surgical CO_2 laser system, from **LBT** in Israel, for general surgical and dermatological applications, including skin resurfacing. The company said that over 60 systems had been sold and placed outside of the U.S. The company is still awaiting clearance for its more advanced Derma 20 (erbium) laser, as well as its EpiLight hair removal system.

3/17 **American Dental Technologies** announced that shareholders had approved a previously announced one-for-four reverse stock split.

3/18 **Palomar Medical Technologies** reported its fourth quarter results and announced a letter of intent to develop "Centers of Excellence" cosmetic laser centers with **Columbia Healthcare Corporation**. For the quarter, the company had revenues of $20.9 million and a loss of $18.7 million (69 cents/share), of which $11.5 million (40 cents/share) was attributable to non-recurring write-offs. For the year, revenues were $70.1 million, and a loss of $37.9 million ($1.49/share), again including the $11.5 million writeoff. As far as I could determine, medical sales for the quarter were in the $2 million range, giving the total for the year at about $18 million, considerably down from my $24 million estimate. Apparently, the long time to hair removal approval slowed down ruby laser sales, and may also have effected CO_2 laser (**Tissue Technology**) sales as well. In any event, I am forecasting that medical sales will reach $50 million in 1997!

Palomar intends to spin out **Nexar**, its computer company, by mid-April, and also expects to spin out the remainder of its electronics group later this year, which will enable the company to concentrate all of its efforts on its core cosmetic laser business. The company also noted that it had established a subsidiary in the United Kingdom (Palomar UK?), both to manufacture lasers and to distribute them throughout Europe.

Under the terms of the revenue sharing agreement with Columbia/HCA's Ambulatory Surgery Division, Palomar's subsidiary, **Cosmetic Technology International (CTI)**, will provide services to HCA consisting of equipment (including lasers), non-recourse patient financing, operational support, education, and training. Columbia will provide facility space, clinical personnel, and administrative services at those ambulatory surgery centers best suited for the addition of a cosmetic laser center. Columbia, a $20 billion company, owns and operates approximately 343 hospitals, 147 patient surgery centers, and more than 550 home health care locations in 37 states, the United Kingdom, and in Switzerland.

In a teleconference following the two announcements, Palomar officials discussed their implications. Steve Georgiev, chairman, said that it was the company's goal to have revenue sharing agreements covering 200 cosmetic laser centers in the U.S. over the next several years, and a comparable number outside the U.S., 100 in Europe and 100 in the Far East. These could be with different partners. It was his expectation that each would generate between $1 million to $1.5 million in revenues on average, and with a 40-50% gross margin, provide generous returns to each of the partners. With 400 centers in full operation, Palomar might expect to gain $150 million annually in revenues. Palomar's cost for equiping each center will run between $200,000 to $300,000 each, with additional costs for the personnel for education, training, marketing, and service.

3/18 **Coherent, Inc.** announced that it had completed a sub-license agreement with **Uniphase** for a series of patents for the manufacturing of solid-state blue lasers. One of the key patents covers intra-cavity frequency doubling YAG wavelengths between 870-960 nm, that produces blue and a blue-green emission between 435-480 nm. These blue/blue-green wavelengths are important for many commercial and scientific applications, ranging from semiconductor inspection and remote sensing, to printing and biotechnology (DNA analysis). When applied to the revolutionary diode-pumped YAG microchip laser technology gained from the recently announced acquisition of **Micracor**, it could lead to low-cost, ultra-compact, solid-state lasers in the near future.

3/19 A new clinical study supports **PLC Systems'** Heart Laser as an adjunct to minimally invasive (beating heart) bypass surgery. The results were reported at the recent American College of Cardiology (ACC) meeting held in Anaheim. In a study of 56 patients, fifty percent suffered from either Class III of IV angina. At twelve months followup, 92% of the patients were angina free and had doubled their exercise tolerance time to 9.4 minutes post-op, from 5.2 minutes pre-op. More importantly, the 12-month followup on myocardial perfusion data indicated a similar increase between areas receiving a bypass graft and areas receiving TMR with the heart laser.

3/19 **Mehl/Biophile International** stated that it believes its laser hair removal technology, and the patents and patents pending, are dominant in the field. According to Thomas Mehl, chairman, the Zaias patent is the dominant patent in the field, and is the first patent issued to apply laser technology directly to the skin surface to remove unwanted hair and significantly diminish hair regrowth. He went on to say that he believes that the company's Chromos 694 long pulse ruby laser hair removal system is superior to all other hair removal systems on the market, including the **ESC** non-laser system which has not yet received FDA approval. The company has placed approximately 45 Marc I units outside of the U.S. The Marc II system, scheduled for delivery after June 1997 to replace the Marc I systems and be available for new installations, will incorporate advanced software controls including a Smartcard for treatment tracking, a skin and hair color sensor to automatically set laser operating

parameters, and a scanning laser delivery system to maximize treatment efficiency and speed. Planned enhancements to the Marc series include the introduction of the Marc III and Marc IV in 1998 and 1999 respectively, which will incorporate advanced control and tracking systems and enhanced laser cycle times. Additionally, an advanced liposome delivery system will further improve the Chromos 694 permanency rates. In total, a Mehl/Biophile partner will receive over one million dollars in continually updated equipment, service, training, maintenance, and advertising over the course of five years, according to the news release. The company claimed that it had agreements for the delivery of 400 Marc systems from professionals outside of the U.S., with each system to be licensed to selected treatment providers who will pay Mehl monthly, the greater of a percentage of revenue, or a fixed predetermined minimum. A second manufacturing facility, besides its plant in Wales, is scheduled for Puerto Rico in the latter half of this year.

The Chromos 694 Marc II was to be exhibited at the AAD meeting, held in San Francisco at the end of the month.

3/20 **American Dental Technologies** announced that the FDA had granted 510(k) clearance for its PulseMaster lasers for laser curettage, the removal of diseased or inflamed soft tissue in the periodontal pocket. This allows the use of the laser by dentists for treating clinical situations including gingival disease, gingival bleeding, probe depth, and attachment loss and tooth mobility. With an estimated 80 percent of Americans suffering from some form of periodontal disease, the use of the laser to treat some of the causes in their earliest stages, will help to reduce this problem.

3/21 **Palomar Medical Technologies** said that it would be featuring its recently approved EpiLaser at the AAD meeting in San Francisco. The company also announced that it would be debuting its TruScan pattern generating/scanning system for its TruPulse CO_2 laser used in the treatment of wrinkles.

3/24 A brief story about **Laser Industries** appears in this week's issue of *Forbes*. According to analysts quoted in the story, they believe that Laser's stock will rebound from its current price of about $12/share, and could reach $18 within a year. Analysts are also quoted as saying that they believe that Laser Industries will win their patent licensing dispute with **Mehl/Biophile** over rights for laser hair removal.

3/25 **Circulase**, a new startup company in the burgeoning TMR market, announced that it was about to begin animal studies with its "second generation" short-pulse CO_2 laser for transmyocardial revascularization (TMR). The company said it would use the animal studies to scientifically establish the optimum treatment parameters for its laser to perform TMR. The company estimates that the global market for this procedure is nearly $1 billion annually. Circulase uses a proprietary CO_2 laser design to generate extremely short pulses of high energy with which to drill TMR channels

through the heart muscle in less than 1 millisecond, resulting in considerably less thermal damage to adjacent heart tissue. All the laser technology currently under development by other companies require from 50 milliseconds, up to several seconds to drill channels, resulting in thermal damage which can lead to closure of the channels. Circulase believes that its studies may prove the clear-cut advantages of using short pulses to ablate clean TMR holes. The company hopes to begin human clinical trials worldwide shortly.

MEDICAL/SURGICAL LASER UPDATE -- APRIL 1997

3/27 **DUSA Pharmaceuticals** reported the first results from a DUSA-supported study of the selectivity of Levulan (ALA) for photodynamic therapy of cervical intraepithelial neoplasia (CIN). The study, conducted at the **Beckman Laser Institute** showed that after 1.5 hours of topical application, ALA demonstrated excellent selectivity for CIN tissue, which was confirmed by pathology. Based on the excellent results, the Beckman researchers are entering into the second phase of the study in which CIN patients will be treated with Levulan PDT. (CIN is identified in approximately 2%-3% of all Pap smears. Treatment generally involves the surgical removal of some parts of the uterine cervix with possible complications such as bleeding, pain and infertility.) "The results of this preliminary study suggest that Levulan may be useful in the selective diagnosis and/or treatment of this common pre-malignant disorder", according to Dr. Geoffrey Shulman, DUSA president and CEO.

3/26 **Sunrise Technologies** announced it has signed an agreement to sell its dental division to **Lares Research**, a privately-held company headquartered in Chico, California. Under the purchase agreement, Lares will pay $5.5 million -- $4 million in cash and $1.5 million in notes payable over four years. The Sunrise dental division manufactures Microprep air abrasion systems for cavity preparation and a line of SunLase dental lasers. The proceeds from this transaction, along with the recent $4.2 million private placement will help fund the company's ophthalmic strategy -- see the 3/31 brief in the ophthalmic laser update section.

3/31 **Lasermedics** announced that it had acquired the sole and exclusive worldwide right to manufacture, market, and distribute the MicroLight 830 laser, a low-level laser currently utilized in the therapeutic treatment of carpal tunnel syndrome under an IDE program. The license was acquired from **CB Svendsen a/s** of Denmark, the developer and original manufacturer of the product, who had been producing the laser under a license agreement for Lasermedics. Under a separate agreement, CB Svendsen will continue to manufacture the product for Lasermedics for international distribution. The marketing and distribution rights were obtained for a one-time payment, made when the agreement was executed, and a quarterly royalty payment based on revenue from sales of the product over the next seven years. Additionally, the manufacturing rights were acquired for a one-time payment due by June 15, 1988. At the end of the

seven-year period, Lasermedics will own the technology outright. (No word in the press release of the status of the FDA filing for clearance of the MicroLight for use in treating carpal tunnel syndrome in the U.S., which has been ongoing for well over two years.)

3/31 **EquiMed** announced its fourth quarter results, with revenues of $20.5 million and net income from operations of $2.8 million (10 cents/share). For the year, net revenues were $99.7 million with a net loss of $15.8 million (57 cents/share). The results include the effect of an extraordinary first quarter charge relating to the early extinguishment of debt, a non-recurring item related to the change from S Corp. to C Corp. tax status, and the writedown of goodwill associated with the sale of the ophthalmology division effective November 1, 1996. The total of these items was $25.4 million. Without these items, net income would have been $9.8 million. Currently, EquiMed owns or operates 41 oncology or oncology-related centers, along with exclusive contracts with 28 hospitals to provide anesthesiology staffing. (The deal with **Palomar Medical Technologies** to jointly own and operate **Rejuve Image Enhancement Centers** has collapsed -- see our brief of February 27th in the March newsletter. This is, in part, why Palomar signed on with **Columbia/HCA** -- see the March 18th brief last month.)

4/1 **Laser Industries** announced that it had acquired **Spectron Laser Systems Ltd.**, a producer of ruby laser technology (and supplier of ruby rods to several laser manufacturers). Spectron will supply ruby lasers for Laser Industries and increase its capacity for these lasers, enabling the company to meet the growing demand for its recently FDA-cleared EpiTouch ruby laser system for hair removal. (It is my understanding that Spectron was the ruby rod supplier for **Surgical Laser Systems of Wales**, now **SLS Biophile**, a subsidiary of **Mehl/Biophile**, who produces Mehl's Chromos 694 ruby laser. The acquisition may have been in retaliation for the lawsuit filed by Mehl against Laser Industries and Sharplan 2000, the joint venture between Mehl and Laser Industries -- see the December 6th brief in the December newsletter.)

4/1 **StockNet-USA.com**, is a new web site that provides free corporate reports on small- and mid-cap publicly-held companies. Data includes stock prices, business developments, financial information, company addresses, names of key executives, and company news releases. I happened to pick up this web site because **Biolase Technology** is one of the companies listed.

A recent conversation with a correspondent for another electronic news service that was preparing a profile on **VISX**, informed me that it will be providing health care news for **CH Cast**, **ConnectedHealth.Net's** interactive news distribution service. The yet unnamed publication will provide news briefs as well as in-depth analyses, allowing end-users to access as little or as much information as they need. The publications' staff of reporters will report from around the country on breaking news

from the industry, Congress, the courts, the stock markets, and major medical meetings and conventions. Initially, the electronic publication will be available to a limited number of users as a complimentary subscription. For more information, contact Don Johnson, **The Business Word, Inc.** at 303-290-8500.

4/2 **ThermoLase** has entered into an agreement with **Global Enterprise Technologies Corp.** to market its SoftLight hair removal process, and when available, its laser skin resurfacing technology, in the United Arab Emirates and Oman. Global, a privately-held company in Waltham, MA, specializes in high-technology applications in a variety of fields, including medical lasers. After obtaining any necessary regulatory approvals, Global plans to open two Spa Thira salons this year, with more to follow in 1998.

4/2 **DUSA Pharmaceuticals** reported that it had initiated its Phase 1/2 multicenter clinical study of Levulan PDT for permanent hair removal. The new protocol will test topical Levulan 20% solution and various light doses produced by the company's proprietary non-laser light source. The study will be conducted at three test sites across the United States, at the Wellman Labs, where the original studies had been held showing up to a 40%-50% hair loss with six month followup; with Dr. Melanie Grossman at the Laser Skin Care Center of NYC; and at Cal/Irvine.

4/2 **Biolase Technology** announced its fourth quarter and year-end results, with sales for the quarter of $255,000 and a net loss of $787,300 (6 cents/share), while for the year sales were $691,800, resulting in a net loss of $2.5 million (21 cents/share). According to president and CEO Donald La Point, results were in line with expectations. The company expects to launch its LaserBrush during 1997, along with continued sales of its Millennium Hydrokinetic Tissue Cutting system, that utilizes electromagnetic energy laser pulses to rapidly energize and transform small atomized water droplets into smaller high-speed cutting particles. A version of this latter erbium-laser based device was shown at the recent American Academy of Dermatology meeting in San Francisco for skin resurfacing. The LaserBrush uses light transmitted around the toothbrush bristles to interact with its proprietary toothpaste to whiten teeth and neutralize bacteria in the mouth.

4/3 In two announcements, **ThermoLase** said that the preliminary results of its previously announced exchange offer showed that 5 million shares of common stock and an additional $1.5 million in cash had been tendered, for an aggregate of 4.5 million exchange units. Since ThermoLase will issue only 2 million units, a pro rata distribution will take place.

The second announcement was the filing of a 510 (k) application for clearance to market its laser skin resurfacing technology. The technology utilizes the same carbon-based solution activated by its SoftLight laser, to improve the skin's texture and

elasticity, and to smooth wrinkles. Clinical trials were conducted with dermatologists in New Jersey and New Mexico.

4/3 **Lasermedics** announced its year-end results. Since this company is now essentially in the physical medicine and rehabilitation business, I have decided to drop coverage from my reports until, and if, it ever obtains FDA approval for its MicroLight 830 biostimulation laser, at which time I will begin coverage again. I will continue to report on any activities concerning its laser products that come across my desk, i.e., the notice in the 3/31 brief above.

4/4 **Ion Laser Technology** announced the findings of a multi-center laser bleaching study conducted by Drs. George Freedman and Robert Reyto. The preliminary results of over 500 arches studied indicated that significant tooth whitening is obtained with the BriteSmile dual laser tooth whitening method. On average, the maxillary teeth (uppers) were bleached 8.0 shades on the Vita scale, while lower teeth whitened 8.5 shades. Depending on initial tooth color before treatment, the darkest teeth whitened as much as 12 shades. One dentist participating in the trials noted that with home bleaching products two to three shades lightening were usually found, while with the two-hour laser treatment, his patients were averaging seven or more shade lightening. His three-dentist practice has treated over 200 patients and is now averaging two treatments per day.

4/4 **Eclipse Surgical Technologies** reported promising follow-up results in its randomized Phase 2 clinical trials of TMR. The data will form the basis of the company's PMA application later this summer, after six-month follow-up is completed. The trial was conducted at 20 U.S. hospitals under an IDE, comparing Eclipse TMR for patients with angina and severe heart disease for whom no other treatment option is available, to the results from a similar group of patients treated with drug therapy only. At three months post TMR, 86% of the TMR treated patients had improved to class II angina or better, while only 12% of the drug-treated patients showed similar improvements.

4/7 **Cool Laser Optics** announced that it had signed a licensing agreement with **Cynosure**, paving the way for the sale of cooling devices to be used with the Cynosure laser systems in a variety of clinical and cosmetic applications. Cynosure plans to finalize a design which will integrate the cooling device into the handpiece of its vascular and alexandrite lasers, allowing the physicians to increase fluences and thus providing them with a broader range of treatment operating parameters. (The only other licensee that I am aware of, is **Coherent Medical**.)

4/7 **Iridex Corporation** announced that it had received 510(k) clearance for the use of its DioLite 532 diode-pumped YAG laser for the treatment of vascular and pigmented skin lesions. Shipments of the DioLite 532 are expected to begin during the third quarter of 1997. The 15 lb. laser is priced at $44,500.

4/8 **Biolase Technology** announced that its common stock had been listed on the Berlin Stock Exchange, effective April 2nd.

4/8 **ThermoLase** announced the final results of its exchange offer -- see the 4/3 brief above. In the exchange, 5.0 million shares of common stock and an additional $1.5 million were validly tendered, for an aggregate of 4.4 million units. Since only 2 million units will be issued, these will be pro rated to those tendering.

4/9 **Ion Laser Technology** announced that it had received notice of a U.S. patent covering its tooth whitening process. The 37 allowed claims include coverage of a wide range of activating chemicals in varying strengths to be used with either its argon or CO_2 lasers to whiten teeth. The patent is expected to issue shortly. The new patent will be the third in the series for cosmetic dentistry, with the others having to do with composite curing and protecting the mucous membranes while treating teeth with home bleaching methods (the original BriteSmile patent).

4/9 **ThermoLase** announced that it had signed a lease agreement for retail space in the South Beach area of Miami Beach. ThermoLase intends to open a Spa Thira salon this summer on Miami Beach's Collins Avenue. Ten Spa Thiras are currently open, featuring ThermoLase's patented SoftLight hair removal process.

4/10 **Laserscope** announced that it had requested approval from the FDA to market a new higher-powered version of its 800 Series Dual Wavelength KTP/YAG surgical laser system. The new configuration boosts KTP energy levels from 36 to 50 watts, as well as delivering 100 watts of YAG energy, enabling shorter procedure times in a variety of applications, including urology, gynecology, ENT, aesthetic surgery, and thoracic surgery. Upon approval, the higher power configuration will be available as a field upgrade for the approximately 600 installed Laserscope 800 series systems throughout the world.

4/10 **QLT PhotoTherapeutics** said that its Board of Directors had approved certain amendments to the company's Shareholder Protection Rights plan, effective March 31st. The rights plan, as amended, is subject to re-confirmation by shareholders at the company's annual meeting scheduled for May 12th in Vancouver. The amendments have to do with ownership positions and other terms necessary for takeover bids.

4/10 **PLC Systems** announced that clinical studies with its Heart Laser are underway in Japan, the 2nd largest cardiovascular medical market in the world, with close to 400 open-heart centers. The clinical protocol was developed by PLC's Japanese partner, **Imatron Japan**. In March, the Heart Institute of Japan, located at Tokyo Women's Medical Center performed the country's first TMR procedure as part of the Ministry of Health Welfare approval process. Several additional patients have since undergone TMR with the Heart Laser. A total of 60 patients will be enrolled in the Japanese

study. Currently, PLC has 8 lasers in leading hospitals, and another 10 hospitals will be involved in the study, which should be accomplished over the next three to four months. Including Japan, the company has 20 Heart Lasers installed at leading centers in Asia and the Pacific Rim countries.

4/10 **Eclipse Surgical Technologies** announced its first quarter results with net revenues of $1.2 million and a net loss of $3.9 million (24 cents/share). The company states that it remains on track to submit its PMA application by mid-summer.

4/10 **Cowan & Joseph** announced that it had added a trio of new healthcare accounts to its portfolio. Among the new accounts was **Rejuve Image Enhancement Centers**, which I thought had died a natural death along with the collapse of the **Palomar Medical**/**Equimed** deal -- see the March 31st Equimed brief above. I reached Rejuve CEO David Challonen, who told me that Rejuve remains alive and well, with one center open in New Orleans and another being built in Beaverton, OR. The company has plans to open an additional six centers by year's end -- if all goes according to plan. And Rejuve remains a wholly-owned subsidiary of Equimed.

Some of Cowan & Joseph's other clients include **Marco Technologies**, a supplier of ophthalmic equipment, including lasers; **VISX**; **Alcon Laboratories**; **Equimed**; and **Beacon Eye Institute**.

4/14 **ThermoLase** announced that it had signed a lease for retail space in downtown Chicago for its next Spa Thira salon. The two-story salon is scheduled to open this summer.

4/14 **Eclipse Surgical** announced that it had expanded its TMR patent portfolio by licensing a series of patents for fundamental catheter technology to be used with its TMR system. The patents cover technology for a coronary steering system with an articulating distal catheter tip. This technology will be coupled with Eclipse's highly flexible multi-optical fiber laser delivery systems to precisely control the placement of laser channels during percutaneous myocardial revascularization. After extensive pre-clinical testing, the company has completed design and construction of clinical devices in preparation for beginning clinical trials, once an IDE is obtained.

4/15 **ESC Medical Systems** received FDA clearance to market its Derma 20 erbium laser system for general dermatology applications, including the fast growing skin resurfacing procedure. (The fifth erbium laser system to receive FDA marketing approval.) The Derma 20 has received acceptance overseas, with over 50 system placed. According to the company, the system delivers the highest energy per pulse/repetition rate combination currently available in the market. In addition, clinical trials conducted internationally indicate that the Derma 20 is effective for hair

transplantation procedures. The company intends to continue to study this expanded use of the device.

4/15 **CardioGenesis** and **Chiron Corporation** have entered into a research collaboration to focus on the development of methods to enhance TMR for the treatment of myocardial ischemia. The pre-clinical research program will take place at a major university medical research center, with Chiron providing its proprietary cardiovascular compounds. Both CardioGenesis' epicardial and endocardial approaches to TMR will be used in the studies, including the company's intraoperative transmyocardial revascularization system. Chiron is interested in elucidating the mechanisms underlying myocardial ischemia, and is exploring a number of therapeutic options for treating this and other types of coronary artery disease. They intend to work with CardioGenesis to explore potential synergy between TMR and novel biological agents for the treatment of cardiovascular disease.

4/15 **Spectranetics** reported its first quarter results with revenues of $4.6 million, down 2% from last year's first quarter. Total laser placements in the quarter were comparable with last year, but a higher percentage of 1997 placements were rentals rather than sales, which contributed to the decreased laser revenues. The net loss for the quarter was $1.5 million (8 cents/share).

4/15 Another quick note from a 10K, **Sunrise Technologies'** accountants have included a paragraph in the firm's 10K doubting the company's ability to continue as an ongoing concern in their most recent audit of March 10th. Sunrise reported a net loss of $6.0 million in 1996 and $4.1 million in 1995. As of 12/31/06 the company had cash and equivalents of $647,000, down from $3.5 million at the end of 1995. In March, the company completed a private placement of notes and warrants netting $4.1 million, and announced its intention to sell its dental laser division for $4 million in cash and $1.5 million in notes payable over four years.

4/16 According to an article in *The Los Angeles Times*, the FDA has warned **Trimedyne** to correct alleged deficiencies in the manufacture of its surgical lasers. On April 7th, a warning letter was issued to the company alleging that it had failed to report information involving injuries to individuals treated with its laser systems and that it hadn't established procedures to make sure its products conformed to specifications. The letter also indicated that the company's plans to remedy the situation were adequate, but that changes involving certain technical issues are still being evaluated. Apparently, the problem involved damaged mirrors inside the company's holmium lasers that changed the laser beam's outputs. According to a representative of the company, a couple of the injuries occurred when the physician was using the laser in an experimental setting.

4/16 **Candela Corporation** announced the opening of a new laser cosmetic center in Cairo, Egypt, within the Al-Salam International Hospital, a joint-venture with local Egyptian investors. The company owns 51% of the venture. Several other centers are in the planning stages. In addition to the Cairo LaserSpa, Candela has two other spas, one in Scottsdale, AZ, which opened last month, and another located in Boston which will open later this month. The status of the company's Candela Skin Care Center in Framingham, MA, the first such opened, is not mentioned in the news release.

4/17 **Premier Laser Systems** announced that it will lead a consortium of investors who have signed a letter of intent to purchase Illinois-based **Medical Laser Institute of America (MLIA)** from its Canadian parent **Mattan Corporation**, in an exchange of shares. Premier had made an investment in Mattan stock in 1996, entirely because of Premier's interest in MLIA, which operates one cosmetic laser surgery center in the Chicago area, and has plans to develop additional centers in Illinois and California. Under an agreement signed with Mattan earlier this week, the Premier-led consortium will surrender its Mattan shares in exchange for ownership of MLIA, which will remain a privately-held Illinois corporation. MLIA and Premier will retain their agreement which appoints Premier the exclusive provider of lasers and laser-related disposables for all MLIA centers. Back in February -- see the 2/21 brief in the March newsletter -- the Board of directors of Mattan stopped trading in its stock because it was unable to raise funds necessary to continue with the MLIA program, and decided to sell this subsidiary.

Premier's investment in MLIA is a minority position and the company will have no day-to-day role in MLIA management. There is no present plan of taking MLIA public.

4/17 **CardioGenesis** announced its first quarter results with revenues of $1.6 million, from sales of its intraoperative TMR (ITMR) system into Europe and into clinical trials sites in the U.S. This compared to sales of its ITMR system of $0.6 million in the same quarter in 1996. Net losses for the quarter were $3.6 million (30 cents/share). The company closed the quarter with $55.2 million in cash. The company expects to file a PMA for its ITMR system by the end of the year.

4/17 **Palomar Medical Technologies** announced that its **Cosmetic Technology International** subsidiary has signed an exclusive five-year, $30 million revenue sharing agreement with **Dynamic Light Ltd.** of Australia, to develop cosmetic "Centers of Excellence" offering a full line of lasers, medical devices and services. Dynamic will be CTI's in-country manager in placing a full line of cosmetic lasers into a minimum of 15 dermatology and plastic surgery locations throughout Australia. Under terms of the agreement, CTI will provide services to Dynamic Light consisting of equipment, operational support, service, education, and training. Dynamic Light, in

partnership with participating Australian physicians, will provide facilities, clinical personnel, and administrative services at the centers.

4/17 **Cell Robotics** announced its year end results, with a net loss for the year of $1.5 million (37 cents/share), on revenues of $663,300. This compares with a net loss of $1.4 million (66 cents/share) on revenues of $942,700 for the previous year. Based on the company's acquisition of multifaceted crystal resonator technology last year, that permits the design and manufacture of compact, robust, solid-state or crystal lasers at what the company believes the lowest costs in the industry, the company plans to launch three innovative laser medical devices this year. These include the Lasette, laser finger perforator for taking blood samples; an erbium skin resurfacing laser for cosmetic applications; and an in-vitro fertilization workstation aimed at improving human fertility success rates.

4/17 **PDT, Inc.** announced that it is expanding the Phase 2/3 clinical trial of SnET2 (Purlytin) photodynamic therapy for cutaneous metastatic breast cancer to include a broader patient population. The study protocol has been expanded to allow patients on certain chemotherapies to participate in the trials, and also to enable individuals on hormonal therapy to enter the study earlier in their treatment regimens.

4/21 **Spectranetics** announced that it had received conditional approval of its IDE to modify the clinical study protocol for its total occlusive device, the Prima laser guidewire. The Prima is designed to pass through totally occluded coronary arteries using excimer laser ablation. The modification in the study, recommended by physicians participating in the protocol, calls for patients to be treated with the Prima laser guidewire if they have previously failed treatment with a mechanical guidewire. The study is expected to commence by June 1997 and will enroll 120 patients. Originally, 200 patients were to have been randomimally treated with either the laser or mechanical guidewires, even if they had previously failed a mechanical guidewire treatment.

4/21 **Coherent Inc.** reported its fiscal second quarter results for the quarter ended March 29th. Sales for the quarter were $91.0 million, slightly higher than for the corressponding period last year, with a negative impact of $3.0 million for the strong U.S. dollar against foreign currency, and sales and manufacturing delays within the Medical Group's VersaPulse C and VPW product lines. While sales of these products were $3.4 million for the quarter, more than twice that amount was ordered by customers. The delays were eliminated subsequent to the quarter's end. Net income for the quarter was $8.9 million (76 cents/share). For the quarter, medical laser sales were $39.0 million, according to a company spokesperson, down from $41.3 million for the previous quarter.

4/22 **Laserscope** released its first quarter results, with the highest quarterly revenues in company history. Revenues for the quarter were $15.8 million (the combined sales of Laserscope and its acquisition last August of Heraeus Surgical), with net income of $0.9 million (7 cents/share). The increased sales were both from current and new distribution, and the combined product lines, including a significant non-laser business component, Heraeus' operating room equipment. Aura laser sales remain strong, improvements in international markets, and the continued strength of the aesthetic surgery business all contributed to the increased sales. Several new products, including higher power KTP lasers for possible use by ENT surgeons in removing tonsils, treating snoring, sinuses, etc., are on the drawing board for release this summer. At the recent American Urological Association meeting, the company introduced a new treatment for trigonitis, an irritation of the female bladder neck. According to company officials, physicians that took part in discussions about the new treatment were excited about the opportunity to be able to treat the problem with the company's sidefiring laser system and obtain 80%-90% cure rates, in what could be another office-based procedure. During a Q&A session as part of a teleconference report of the quarter's results, President Robert McCormick commented on the upside potential for sale of PDT lasers and disposables, especially if the treatment of lung cancers comes through later this year. The potential number of patients to be treated would be some sixteen times larger than the present population with late stage esophageal cancers, resulting in a magnitude of order increase in sales of laser systems to activate the PDT drugs. (The company now claims to be selling 1 or 2 PDT laser systems per month.)

4/22 The Board of Directors of **PLC Systems** announced that it had retained the services of Goldman Sachs & Co. as the company's financial advisor in seeking a strategic alliance partner. The board also accepted the resignation of president and CEO Lee Hibbs, effective July 31st. The retention of Goldman Sachs is in anticipation of approval of the company's PMA for its Heart Laser, which has been accepted for filing by the FDA. Final approval could come as early as this summer, or by year's end.

4/23 **Eclipse Surgical Technologies** announced that it had received an IDE to begin the first clinical study in the U.S. of a new minimally-invasive surgical approach to TMR. The company hopes to achieve the same 86% improvement in angina symptoms seen with its intraoperative approach with the new minimally invasive approach. The new approach uses a high-tech steering mechanism and an additional fiber-optic channel to deliver camera images of the heart and to deliver laser pulses with smaller incisions for the patient. The new Eclipse tool allows a 1/2 inch incision with the potential for reductions in post-surgery recovery times.

4/23 **Laser Industries** announced that it had acquired a majority interest in **Sahar Technologies**, one of the largest developers and OEM suppliers of CO_2, erbium, and

other laser scanners used for aesthetic and medical applications. (Sahar is the exclusive supplier of the SureScan scanner sold both by **Luxar** and **Clinicon**.) Since Sahar will be operated as an independent subsidiary of Laser Industries, it will compete directly with **Sharplan** (FeatherTouch) for sale of scanners for CO_2 laser systems. According to the news release, Laser Industries will own an 80% interest in the company, which reported sales of $2 million and net income of $300,000 in 1996.

4/24 **Candela Corporation** reported continued strong sales of its core medical and cosmetic laser systems, with revenues for its fiscal third quarter of $8.8 million, up 17% from the same quarter a year ago. Net income was $303,000 (5 cents/share), compared with $231,000 for last year's third quarter. For the nine month period, revenues are up 21% from the similar period last year, and net income was 27 cents/share compared with 11 cents in fiscal 1996's first nine months. More than $1 million in expenses for the startup of two U.S. LaserSpas impacted profits in the quarter. During the quarter the company opened its Scottsdale LaserSpa, a combination spa, salon, and cosmetic laser treatment center, and during April, opened a laser treatment center in Cairo and its second LaserSpa in an expanded location in Boston. (No mention of the first skin treatment center in Framingham, MA, which now may be closed.)

4/24 **ESC Medical Systems** announced its first quarter results with record sales more than doubling to $23.0 million, compared to sales of $10.1 million for the same quarter a year ago. Net income, excluding nonrecurring merger expenses of $4.6 million, associated with the acquisition of **Luxar Corporation**, increased to $5.7 million (28 cents/share), compared to $2.4 million in 1996. (The results and comparisons include the operations of Luxar.) During the past several months the company has received FDA clearance for its Topaz 30 and Derma 20 lasers for dermatological applications and is rapidly proceeding with the integration of Luxar into ESC.

4/24 **Surgical Laser Technologies** announced its first quarter results with revenues of $3.1 million, an increase of 11% over last year's first quarter (and a slight increase over the fourth quarter's results), and a net loss of $197,000 (2 cents/share), a reduction of 76% from last year's quarter. Operating expenses were down 20% due to cost reduction measures taken in the second half of 1996. In addition, the cash position remains strong at $6.3 million, after a positive cash flow in the first quarter of $203,000. The plan for ongoing success is to position the company to provide a broader array of products to a more select market segment, and to expand and improve international relationships, consistent with the new focus of products to selected markets.

4/24 **Mattan Corporation** announced that it had signed a letter of intent with **Premier Laser Systems** and certain other existing shareholders of Mattan, under which these shareholders will exchange their shares of Mattan for all of the issued and outstanding shares of Mattan's operating subsidiary, **The Medical Laser Institute of America (MLIA)**. A final agreement should be ready within two weeks. In addition, the Board

of Directors is actively seeking other parties to vend into Mattan a suitable operating business. The Board anticipates being in a position to file a plan for reactivation of Mattan by May 1st.

MEDICAL/SURGICAL LASER UPDATE -- MAY 1997

4/16 **LaBarge, Inc.** and **Venisect Inc.** jointly announced that the FDA had granted marketing clearance for their Laser Lancet, a portable, battery-powered laser device to draw capillary blood for clinical testing without the use of sharp instruments. The device works by sending a pulse of erbium laser energy, through a proprietary disposable plastic tube, which perforates the skin, making a small slit in the fingertip, just deep enough to break through the skin's outer layers and into the capillary bed. Clinical tests with the lancet show it is fast and effective for routine blood chemistry tests requiring a small amount of blood. Venisect will market the Laser Lancet, which will be manufactured by LaBarge. Venisect also announced that certain patent claims related to the Laser Lancet have been allowed, in addition to the one patent issued and several others pending on the laser technology.

According to our conversations with personnel associated with the company, the device is expected to sell for under $10,000. Others working on similar devices include **Cell Robotics** and **Becton Dickinson** in association with **JMAR**. All are erbium-based laser systems.

4/29 **ThermoLase** announced that more than 20,000 SoftLight hair removal treatments have been performed since the opening of the first Spa Thira in November 1995. The process is now available at 10 Spa Thiras and through doctors across the country who have recently become SoftLight licensees. With the exception of men's beards, the SoftLight process has been used to safely remove hair from almost anywhere it grows.

4/29 Both **Palomar Medical** and **Mehl/Biophile** issued releases stating that they had agreed to drop the Massachusetts-based lawsuit, clearing the way to go forward with the New Jersey-based suit. In its release, Mehl stated that it was confident that the New Jersey court will find that Palomar's hair removal system infringes the Zaias patent, award damages, and enjoin any further infringement by Palomar. Palomar said that it conceded nothing on the merits of the litigation and that the company is convinced the Zaias patent is invalid, and that a judge and jury will so hold, and that Palomar has committed no infringement whatsoever.

4/30 **American Dental** reported a net income of $886,300 in its first quarter (12 cents/share), on net sales of $5.3 million. The increase was attributed primarily to an increase in KCP sales volumes (the company's sandblaster device) in the United States. International KCP and dental laser sales volumes were down from last year's

first quarter due to dealer inventory adjustments. The company's president, Ben Gallant, anticipates that 1997 sales will be higher than in 1996.

4/30 **ThermoLase** reported its fiscal second quarter results of revenues of $11.7 million, compared to only $7.0 million a year ago. The net loss for the quarter was $3.7 million (9 cents/share), compared with $77,000 last year. According to president John Hansen, the highlight of the quarter was the submission of a 510(k) for laser skin resurfacing using its patented technology. The company looks forward to introducing this new product both in its spas and through its physician network, as well as overseas.

4/30 **PLC Systems** said that it had submitted long-term results of its clinical studies evaluating TMR with the company's Heart Laser, as a post-filing PMA in preparation for an expected FDA Advisory Panel Meeting. According to chairman Dr. Robert Rudko, the clinical findings continue to be very impressive, and he expects they will support FDA approval of the device sometime this summer. At the last available followup, approximately 70% of the 300 patients treated with TMR experienced a clinically significant decrease in angina post-op. This is in contrast with only 6% in the control group.

4/30 **PDT Inc.** announced that officers and directors holding an aggregate of more than 3.5 million shares have once again agreed with the company to extend their stock lock-up agreement to October 1997 (originally entered into with the company's public offering in April 1995). According to Gary Kedzik, chairman and CEO, this is meant to show the market that the company's stock is not for sale, and that management is committed to the success of the company.

5/1 **PLC Systems** announced first quarter results with revenues of $1.6 million and a net loss of $3.0 million (18 cents/share). The company shipped six Heart Lasers in the first quarter, of which five were placements and one was a sale. Through the first quarter, PLC has shipped 80 Heart Lasers. Under the placement model, the company receives a $25,000 installation fee and ongoing revenues each time the laser is used. PLC believes that this strategy will provide up to three times the revenues over a three to five year period than a straight sale. Placement revenues were up approximately 30% over the same quarter a year ago. To date, 3000 patients have been treated with the Heart Laser.

5/2 **DUSA Pharmaceuticals** announced that patient enrollment had passed the two-thirds point for its Phase 3 clinical trials of Levulan PDT for pre-cancerous actinic keratoses of the skin, with full enrollment expected during the second quarter. The study will finish three months after full enrollment, when the company plans to submit its first planned NDA to the FDA by late '97/early '98. In addition, the company continued preparations for the start of its multi-centered clinical trial on Levulan photodiagnosis

of bladder cancer -- expected to begin in Q3 '97, initiated its Phase 2/3 Levulan PD trial for permanent hair removal, and announced results from a promising independent study showing Levulan is highly selective for pre-cancers of the cervix, a major women's health issue. DUSA continues strategic alliance/marketing discussions with a number of potential partners in the field of dermatology.

The company also announced corporate highlights and financial results for the first quarter, with a net loss of $1.4 million (15 cents/share). R&D costs were $1.3 million, up from $950,000 in the prior year. As of March 31st, DUSA had cash and U.S. Government securities totaling $18.0 million.

5/2 **Mehl/Biophile** announced its fiscal third quarter results with revenues of $582,800 and a net loss of $4.1 million (10 cents/share). Company chairman Thomas Mehl noted that the company was transitioning from R&D into producing revenues, having gone from producing 1 laser system per month to over 30 systems, with the capability of producing 60 lasers per month. Since receiving EC approval for marketing outside of the U.S., Mehl had placed 30 systems in the field, and has 40 systems ready to be shipped to the U.S., and 40 worldwide as soon as contracts and training are finalized. The company has received private financing to support its increased production and continue research. Mehl is now completing plans for training its professional partners in the U.S. and expects to start delivery of the Chromos 694 laser in the near future.

Revenues generated by the Chromos 694 laser deployed outside the U.S. under revenue sharing agreements have averaged $4000 to $14,000 per system per month in the first calendar quarter of 1997. These results were achieved by systems operating from one to three months and are supportive of the anticipated rapid market acceptance of the Chromos system. The company's business plan projects a total of 300 systems to be in the field worldwide by the end of the year.

5/5 **Laser Industries** reported its record first quarter results with sales rising to $16.4 million and net income of $2.6 million (31 cents/share). During the quarter the company completed negotiations for the acquisition of **Sahar Technologies**; completed the acquisition **Spectron Laser Systems**; and received FDA marketing clearance for its EpiTouch laser hair removal system. Laser Industries opened its initial patient care center in Tel Aviv in February, with additional center openings planned for this year.

5/5 **Trimedyne** announced that its 90% owned subsidiary, **Cardiodyne**, had successfully completed its animal studies for TMR to create lasered channels within dog heart muscle, with six week followup showing the creation of new connecting vessels. During the TMR procedures 20 to 50 channels were made through the heart wall into the left ventricle. Cardiodyne will now submit an application to the FDA to begin clinical trials of its CArdiodyne MR system, which consist of its Superpulse holmium

laser, Autofire interface system, and Channelmaker optical fibers. Cardiodyne holds a basic patent on firing a laser into the heart synchronized with the patient's ECG.

5/5 **Premier Laser Systems** announced its fiscal fourth quarter results with revenues of $1.6 million, an increase of 144% over the same quarter last year, and a net loss of $2.9 million (41 cents/share). For its fiscal year, sales of $5.5 million were a gain of more than 225% from fiscal 1996, and a net loss of $5.6 million (96 cents/share). The increases were primarily from brisk sales of the company's dental lasers and related products, including the Multi-Operatory Dentalaser (argon) used for teeth whitening and composite curing, and its Aurora (diode) laser used for soft-tissue procedures and periodontics. Premier also showed increased sales of its erbium:YAG and neodymium:YAG lasers for applications in surgery and ophthalmology. The fourth quarter loss included a writeoff of $881,000 relating to the company's investment in **Mattan Corporation**, and $250,000 of acquired in-process R&D at **Data.Site** and, in it fiscal year losses, a $332,000 settlement reported last summer involving a discontinued joint venture relating to argon laser outsource manufacturing. The company has announced the pending acquisition of **EyeSys Technologies**, a leading corneal topographer company.

Security analyst Scott Baily of **BlueStone Capital** issued a strong buy rating for Premier in his April 29th update, stating that he was confident that Premier would receive FDA approval for hard tissue dental procedures, giving it a unique position in the dentistry market. (This approval came through on May 7th! -- see our brief below.) His report also followed the announcements about EyeSys and the distribution agreement between EyeSys and **Marco Technologies** and **Nidek** -- see the April 28th ophthalmology briefs in this issue.

5/6 Continuing on its warpath against **Palomar Medical Technologies**, **Mehl/Biophile** announced that it expected Palomar to include a counterclaim to invalidate the patent owned by Dr. Nardo Zaias and exclusively licensed to Mehl, in its answer in the patent infringement and unfair competition suit filed by Mehl against Palomar in the Federal District Court in New Jersey. Mehl/Biophile reiterated its optimism that the Palomar Epilaser would be found to infringe the Zaias patent and that Mehl would vigorously enforce the protection of the patent against any and all infringements on their patent rights. According to a spokesperson for Mehl, despite the likely counterclaim, no credible defense has been raised by Palomar. The company's general counsel remarked that, "Based upon the documents and information found in the recently dismissed Massachusetts case, Palomar has yet to tender anything that might support its request to invalidate the Zaias patent." The company further stated that it does not expect the legal proceedings involving Palomar to in anyway affect or negatively impact Mehl's achieving its strategic objective of placing 120 Chromos 694 hair removal lasers within the U.S. market over the next 180 days. The company also expects that its worldwide installations to reach 300 by January 1998.

5/6 **Ion Laser Technology** announced that a definitive agreement for a $3 million private placement with **LCO Investments** and chairman of ILT, Richard Braddock. The placement is an accretion to a $5 million investment made in March 1996, which brings the total shares placed with LCD and Mr. Braddock to 708,572, at an average share price of $10.16, increasing LCD's stake in the company to 13.35%. LCD Investments is managed by Anthony M. Pilaro, founding director and former chief executive of Duty Free Shoppers, and also the founder of the predecessor of **VISX** (**Taunton Technology**). The investment will be used to expand marketing of the company's BriteSmile tooth whitening process.

A recent initial clinical survey of the company's BriteSmile process showed that the dual-laser process achieved an average of 8 to 8.5 shades whiter teeth from an average two-hour chair time visit.

5/6 **PDT Inc.** announced its first quarter results and a clinical trial update. For the quarter, revenues and net interest increased to $925,000 and the net loss for the quarter was $5.4 million (44 cents/share). This compared to revenues of $704,000 and a net loss of $6.8 million (65 cents/share) for the same quarter last year.

Noteworthy developments during the quarter included the regulatory go-ahead to expand its Phase 2/3 clinical trial for cutaneous metastatic breast cancer to broader patent populations, including opening new CMBC sites in Europe. The company also expects to complete enrollment this month for the first phase of its Phase 1/2 ophthalmology clinical trials of Purlytin for the treatment of advanced age-related macular degeneration. In addition, PDT and **Pharmacia & Upjohn** were issued a patent covering the current formulation of Purlytin, further strengthening the proprietary position of the drug. Relatedly, the companies are working to establish additional formulations for Purlytin which will be used to segment different disease markets. PDT also received notice of allowance for a patent related to PDT diagnostics, bringing the company's total to 42 patents in the field of PDT.

5/6 *The Boston Globe* had an article about the opening of **Candela's** Boston health club, beauty salon, and laser clinic. The Candela LaserSpa opened last week and offers customers a workout, massage, and laser treatment, all under the same roof. The other recently opened LaserSpa is in Scottsdale, Arizona. Combining a clinic with a health club/salon puts the lasers near a target audience of affluent women in their 40s and 50s. The hope is that the spa and salon customers will become more interested in laser surgery as they talk to other spa customers who have undergone the procedures and see the results. According to Candela, adding lasers to the spa's menu of services could double the LaserSpas annual revenues of $2 million. If that happens, Candela intends to buy more spas and combine them with laser centers.

5/7-

5/8 **Premier Laser Systems** announced that the FDA had granted the first ever clearance to market a laser system for hard tissue procedures, including caries (decayed tissue) removal, cavity preparation, and related applications. The clearance was granted for Premier's Centauri erbium laser, which delivers the laser energy through a specially designed handpiece and fiber optics, which also allows the delivery of air and/or water to the treatment spot. With an estimated 170 million hard tissue procedures performed annually, the company believes it may sell as many as 10,000 to 15,000 erbium lasers for those applications over the next decade. The laser will sell for approximately $39,000, while the additional cost per procedure should average about $10 to $15. Shipments will begin later this quarter, after a training program is initiated. The clearance was based on data developed on more than 1300 procedures done by clinicians in five states. According to president Colette Cozean, "Extensive pre-clinical and clinical studies, with a three-year follow-up, have shown that Centauri's overall performance and safety offer patient comfort and other significant advantages when compared with the traditional high-speed drill."

In a conversation with Colette and Dr. Jim Pelagalli, Premier's chief clinical investigator for the dental laser, I learned that the FDA clearance was via the 510(k) route, with the company showing equivalence of the action of the laser to a mechanical device. The clearance is for all classes of dental decay, cavity preparation for restoratives, and for modification or etching of enamel and dentin. As for speed of use, because anesthesia is not required, the overall time for access, removal of decay, preparation for restoration, and the application of the restoration is about the same or shorter for most fillings, and only somewhat longer for occlusions of molar surfaces. Most interesting is that both air and water can be applied along with the laser energy and, in fact, it is preferred that water be used for the effect it causes, and because it then doesn't dry out the tissue being treated. In the 1400 cases involved in the FDA filing, only 3 patients requested anesthesia! I was assured that the patient would be aware and have some pain long before damage to the pulp or other vital tissue occurs.

Some of the benefits claimed in using the laser include: 1) ability for a 3-D preparation; 2) 50% greater bond strength than with an acid etch; 3) reduction of bacteria at the cavity site; and 4) preservation of tooth structure.

As noted above, the cost for the reusable handpiece and for amortization of the laser should only add about $10 to $15 to the cost of the procedure -- and in survey work I am familiar with, this added cost will easily be absorbed by the patient to avoid the use of the drill and anesthesia needles. As for competition, **Biolase** is apparently just beginning to the process for seeking clearance for its erbium laser/water droplet system, and **American Dental Technologies** does not appear to have a similar laser, relying instead on its KCP sandblaster device to compete. Outside of the U.S., at least three companies have erbium laser dental systems, **KaVo** of Germany; **Fotona** of Slovenia; and **Morita** of Japan. To the best of my knowledge, none of these plan to

enter the U.S. market anytime soon but, with Premier's approval, that could rapidly change.

As expected, the announcement got wide press coverage, with stories appearing in *The Wall Street Journal*, *Chicago Tribune*, *USA Today*, *New York Times*, and *the Los Angeles Times*, to mention a few.

Both Biolase and American Dental Technologies issued defensive news releases: Biolase contending that its Millennium laser-based hydrokinetic system was superior to conventional lasers, cutting tissue as precisely as a laser but without the thermal damage typically related to lasers, and it was "virtually" pain free. American Dental Technologies was even more defensive pointing out that its KCP system was cleared for use with children, while the Premier laser was not. I was told that it was just a matter of time until the information collected on the 80 children that had been treated could be assessed as to whether primary or secondary teeth had been treated, but that there hadn't been any problems with the children treated. ADT also noted that the KCP system performs caries removal and cavity preparation faster than the erbium laser, the cost of the laser was more than double the cost of the top of the line KCP device, and that there were costs associated with maintenance of the laser and fiber optic delivery system. All in all, this was still a coup for Premier!

Following all this news, Scott Baily of Bluestone Capital reiterated a strong buy for Premier, even though the stock price had skyrocketed to nearly triple the value before the announcement.

5/13 **Ion Laser Technology** announced that it had closed the previously announced $3 million private placement with **LCO Investments**. (See the 5/6 brief above.)

5/13 **Biolase Technology** announced first quarter results with sales of $134,400 and a net loss of $767,700 (6 cents/share). According to company officials, the first quarter was a period of stepped-up activity in preparation for the launch of two major products, the Millennium Hydrokinetic Tissue Cutting System, for both hard and soft tissue applications, and the LaserBrush, a consumer home dental maintenance system. The Millennium began shipping to the company's German distributor, **Orbis High Tech Dental**, while the LaserBrush will begin shipping by the end of the third quarter.

5/14 **QLT PhotoTherapeutics** reported a net loss of $1.7 million (7 cents/share) on royalty income of $297,000 for the quarter, a decline from the royalties collected in the company's fourth quarter. Interest and other income for the quarter was $1.8 million. According to the company's CFO, Kenneth Galbraith, "The level of Photfrin sales for the quarter reflected market build-up, continued expansion of laser sites, and the initial impact of new marketing programs by the company's partners. In 1997, we expect the FDA to review our recent supplemental filing for the treatment of non-

small cell lung cancer...we also anticipate additional approvals and filings for Photofrin this year in a number of European countries." Total expenses increased to $4.5 million due to expenses relating to the ongoing Phase 3 trials for the use of BPD-MA in treating age-related macular degeneration.

5/14 **Laser Industries** announced the opening of two aesthetic laser treatment centers in the New York metropolitan area. The International Laser and Aesthetic Surgery Centers will provide comprehensive medical cosmetic services, such as hair removal and skin resurfacing, to patients in the U.S. The two centers will operate through the company's subsidiary, **International Medical Laser Centers**. Initially, the two centers will be located on the premises of Dr. Kenneth Rothaus' Manhattan and Larchmont offices. In addition to laser surgery, the offices will offer all plastic surgery services, for which Dr. Rothaus is widely recognized. It is anticipated that additional sites will be opened internationally before the end of the year.

5/14 **Laserscope** announced a new surgical procedure and a new medical device using its KTP/532 based laser systems, to treat chronic bladder syndrome, a urological condition that affects more than 5 million women in the U.S. annually. The new procedure, Visual Laser Ablation of the Trigone (VLAT) and the new device, the UltraStat 10 (a single use, disposable sidefiring delivery system), were previewed at last month's American Urological Association convention. (Also see our 4/22 brief last month.) Lasers that can be used with the delivery system include the company's Aura, Orion, and the 800-Series surgical laser systems. VLAT can be performed in an office setting for less than $1000, compared to the more than $3000 that would be charged in a hospital setting. The VLAT procedure essentially desurfaces and partially denerves the lining of the trigone, the triangular region of the bladder located between the two openings of the ureter, carrying urine from the kidney into the bladder.

5/15 **Spectranetics** announced that it had received approval from the FDA to expand its clinical trial for the Laser Sheath, from 20 to 35 domestic sites, and from 760 to 1360 patients. The expansion will allow the company to introduce the laser sheath to sites which previously could remove pacemaker leads only through non-laser techniques. The trial is designed to evaluate the safety and efficacy of the laser sheath to remove pacing/ICD (implantable cardioverter defibrillator) leads, used to regulate the heartbeat with electrical pulses, implanted in patients. Some leads may require removal due to infection, loss of venous flow, product recall, or failure. Historically, the old leads have been left in place because they were often heavily embedded in fibrotic tissue, making extraction traumatic and potentially dangerous. Annually, approximately 300,000 pacemaker and ICD leads are implanted worldwide, and the company estimates that approximately 10% of these leads may require removal for various medical reasons. An excellent article describing the technique for lead removal with the laser sheath was published in the May 12th issue of *The Boston*

Globe, entitled, "Getting the lead out". Anyone wishing to see a copy of the story should call me.

5/15 **Palomar Medical Technologies** announced that it had named a new CEO and president, Louis (Dan) Valente -- see the "people in the news" section of this newsletter for more details -- and also released its first quarter results. For the quarter, revenues increased 191% to $20.1 million compared to the same quarter last year, while the company's net loss increased to $15.4 million (50 cents/share), up from $7.3 million in last year's first quarter. The increased net loss was attributed to three factors: the minimal revenues from sales of its EpiLaser hair removal system, cleared for marketing with just three weeks left in the quarter; lower sales volumes from its electronic businesses; and start up costs associated with its revenue sharing businesses. In addition, the company has reserved an additional $2.5 million (11 cents/share) for possible costs associated with litigation matters (with **Mehl/Biophile**). The company also announced that its Board of Directors had authorized the repurchase of up to 1 million shares of common stock over a one-year period, as they felt that the common stock price did not reflect the value of the business, or the substantial growth prospects of its cosmetic laser products and services. In addition, the company also announced that its **Cosmetic Technology International** subsidiary had negotiated a termination of the **EquiMed** revenue sharing agreement, and that CTI was engaged in litigation regarding its revenue sharing agreement with **Medical Alliance**, which had agreed to face-to-face settlement discussions. (See the 3/31 and 4/10 briefs in the last issue for more background information on this subject.)

5/15 This issue of *Laser Report* has an article about the development of a compact, battery-powered, diode-pumped, doubled YAG laser that emits up to 4 W CW, produced by **Light Solutions Corporation**. Originally designed for the U.S. Army, the device is intended to be weapon-mounted and is enclosed in a 3 x 1 x 5 inch package, and powered by a torpedo batter, which is about the size of a standard D cell, but with higher current capacity. With a low duty cycle, the battery power lasts about 20 minutes. A non-battery-operated version of the laser was recently introduced at the AAD meeting by **Iriderm**, a subsidiary of **Iridex Corporation**. The Diolite 532 received a 510(k) clearance from the FDA for the treatment of vascular and pigmented skin lesions. It is claimed by the company to be the smallest and most portable laser ever introduced for treating pigmented lesions.

5/16 **American Dental Technologies** put out a news release in response to a stock price decline after the clearance of **Premier Medical Laser's** erbium laser for hard tissue dental applications. ADT announced that it owned the basic patents for the use of erbium lasers in the dental field, U.S. patents 5,257,935 and 5,342,198, which cover the use of erbium lasers on teeth. The company also commented that experience in Europe and in the Pacific Rim has shown serious limitations and insignificant penetration of erbium lasers into the dental market, and negligible effect on the sales

of its KCP air abrasive system. Due to the superior performance and cost advantage of the KCP system, ADT had chosen not to exploit its patents at this time.

5/19 **Eclipse Surgical** announced that it had received ISO 9001 certification for its laser products, allowing their marketing into Europe and markets worldwide. The company received the CE Mark for its Eclipse 2000 TMR laser system in 1996. The ISO 9001 certification will expedite the marketing of its disposable fiberoptic devices into Europe.

5/19 **ThermoLase** announced its first European Spa Thira, which has opened in Paris. The spa was established through a joint venture between ThermoLase and **Groupe Jacques Dessange**, and bears both the Jacques Dessange and Spar Thira names. Groupe Jacques Dessange is a leading provider of premium hair and skin care services in France, and has more than 500 locations in 34 countries. The joint venture plans to open additional Spa Thiras in France.

5/19 **Trimedyne** announced that it would be a participant at the **Cruttenden Roth** Healthcare conference held in New York. The company planned to discuss both its orthopedics and cardiology laser systems and its new dermatology laser, expected to be introduced in late 1997. (This "unique" laser system was scheduled for introduction this spring but, apparently, problems have held up its introduction.) The company claims its dermatology laser can do everything today's CO_2 and erbium lasers can do in wrinkle removal and face resurfacing, as well as procedures no other cosmetic laser is capable of doing. Trimedyne plans to capitalize on the unique capabilities of this new laser by establishing laser cosmetic surgery centers in conjunction with hospital chains, outpatient surgery centers and surgeons.

5/19 **PLC Systems** announced that it had been informed by the FDA that the advisory panel meeting, which will discuss its Heart Laser PMA, will be held on July 28th and 29th.

5/20 **Premier Laser Systems** said that the response from the dental community and the public had been stronger than anticipated, clogging phone lines with hundreds of calls daily and swamping the company's Web site with up to 12,000 hits per day. It appears that the opportunity for virtually painless hard-tissue dentistry has very widespread appeal. Colette Cozean, president and CEO said, "We originally estimated that of the 120,000 dentists currently in practice in the U.S., we would hear from 1% to 2% as `early adopters' in the first 12 to 18 months. It is now apparent that the level of enthusiasm among dentists and patients may be much higher than that. As of last week, we had logged more than 1200 expressions of interest...with about 10% of calls ordering a Centauri by phone; about 20% signing up for training courses; about 50% have requested specifications and/or other literature...and the remaining 20% have asked specific questions that were answered with no further follow-up needed." Premier plans to ship the first 8 lasers this month, with one to two dozen more in June,

with the larger ramp up in shipments likely to begin over the summer. At this point the company believes it can produce up to 400 systems before the end of its fiscal year on March 31, 1998, and is examining ways in which to increase the build schedule to accommodate demand.

An article in the *Los Angeles Times* commented on **American Dental Technologies'** claims that it held basic patents on erbium laser technology of the type being used by Premier, and its experience with erbium lasers "had serious limitations" compared with other dental systems (see the 5/16 brief above). Premier countered that it was confident that it did not infringe any valid patents held by "disgruntled competitor" American Dental, and would defend its position in court if necessary. An ADT spokesperson declined to say if the company would file a patent infringement lawsuit against Premier, noting that infringement can only occur when a product is delivered to a customer. In a *Dow Jones* release, Premier described its patent position as "solid". Premier said it holds patents on the use of erbium with water on hard tissue and on higher frequency erbium laser systems, both of which are designed to accelerate cavity preparation. Other patents held include fiber delivery of high energies with erbium fiber delivery systems and tip designs, and the use of a laser and aiming beam focused on target tissue.

5/20 **BioLase Technology** provided shareholders with a clarification of its technology versus that of Premier at is annual meeting. Citing many inquiries from the investment community, Donald LaPoint, president and CEO, advised attendees about the differences between his Millennium system and that used by Premier. "While both systems use an erbium-based laser and both have the potential to replace the standard dental drill, the similarities stop there...as noted by Dr. Richard Hansen of UCLA's Dental School, the Premier laser system removes hard tissue primarily through absorption of laser energy and subsequent vaporization. The laser energy seems to interact directly with the tissue and it is the beam which primarily affects tissue cutting. The water stream...provides cooling and helps direct the laser energy thereby increasing cutting efficiency." In contrast, the Millennium system is not a laser-cutting system, but rather is a hydro-kinetic tissue cutting system. The laser is used to energize and transform atomized water droplets into microscopic, high speed water particles capable of cutting both hard and soft tissue. (No mention was made of the FDA status of the Millennium system.)

5/20 **DUSA Pharmaceuticals** announced the signing of an agreement with **Richard Wolf Medical Instruments**, to collaborate on the development of DUSA's Levulan (ALA) Photodiagnosis (PD) for enhanced detection of bladder cancer. Under the agreement, Wolf will provide, at no cost to DUSA, proprietary non-laser light sources and cystoscopes, along with technical and regulatory support, for the upcoming Phase 1/2 clinical trials. The trials will examine the use of Levulan PD to enhance the visual detection of bladder cancer. In return, DUSA plans to seek regulatory approval for the

Wolflight sources to be used in this indication. Upon approval, both companies plan to co-operate in the marketing of the system, with the intention that DUSA will retain revenues from Levulan sales, while Wold will retain revenue from device sales. Under the agreement, DUSA has the right to qualify other manufacturers' light sources/cystoscopes for use in Levulan PD of bladder cancer.

On May 22nd, the company announced the completion of patient enrollment for its pivotal Phase 3 trial of Levulan PDT for pre-cancerous actinic keratoses (AK) of the skin. Investigators at 16 sites have now enrolled more than 200 patients, each with 4 to 15 AKs, for a total of between 800 and 3000 AKs. Each patient is followed after treatment for 3 months to determine safety and efficacy, including a re-treatment if necessary after 8 weeks. Once all the patients have completed follow-up, the data will be collected and analyzed for submission of an NDA, expected to occur by late 1997 or early 1998.

5/20 **Cell Robotics** announced first quarter results with revenues of $256,500, double those of last year's same quarter. For the quarter, the company had a net loss of $487,400 (10 cents/share). Revenues resulted entirely from product sales of laser instruments into research lab markets.

5/20 *The Boston Herald* interviewed new **Palomar Medical** president Dan Valente and in going through some SEC filings, uncovered some loans and financial arrangements with current officers and others that that Valente apparently was unaware of. He claimed that he was not aware of the details of these financial arragnements, but that in the future, all transactions would be related to the core business.

5/22 **Trimedyne** announced its fiscal second quarter results with revenues from continuing operations of $1.8 million, a 17% decrease from comparable results for the same quarter a year ago. The net loss for the quarter was $1.9 million (18 cents/share), about double from a year ago. The company's loss for the quarter and six-month period included a non-recurring loss of $276,000 from the sale of **Poly-Optical Products**, sold at the end of January, and $320,000 of startup and R&D costs of **Cardiodyne**, the company's 90% owned cardiovascular laser subsidiary. Trimedyne also said that it was delaying the introduction of its new cosmetic laser until September, in order to add additional features to the laser, which are expected to increase its versatility and enhance its appeal to cosmetic surgeons and dermatologists. (I had heard that there had been some difficulty with the laser system, and it was pulled back from introduction this spring for re-tooling.)

5/22 **Candela Corporation** announced that it had received FDA clearance for a microprocessor-driven skin scanning device for use in aesthetic surgery. Developed by **Fotona d.d.**, and known as Skinscan, it is believed to be the first scanner for an erbium laser ever cleared by the FDA. The device can be used with the Skinlight

erbium laser system to ensure consistent, precise treatment for all soft tissue applications, such as on the face. Both Skinscan and Skinlight are made for Candela by Fotona, the Slovenia-based developer of the systems. Skinscan provides precision and uniformity when treating large areas of skin during a single session. It can reduce laser procedure time and is equipped with a variety of patterned shapes and sizes.

5/23 **Cell Robotics** announced that it had launched its in vitro fertilization work station at the 10th World Congress on In Vitro Fertilization and Assisted Reproduction, held in Vancouver, British Columbia. The IVF Workstation is the first to offer in vitro fertilization clinics laser assisted hatching of the embryo, sperm injection, and computer assisted measurements in an integrated computer controlled instrument. This promising new technology is now available to IVF clinics in Europe and other countries where regulation permits. In the U.S., a clinical trial of the workstation is being conducted under an IDE.

5/27 **ThermoLase** announced that it had entered into a franchise agreement with **LaserSoft SA**, a privately-held Swiss company based in Lugano, to market its SoftLight hair removal process and its skin resurfacing technology in Switzerland. Pending the attainment of any necessary regulatory approvals, LaserSoft plans to open Spa Thira salons in various Swiss cities, including Lugano and Zurich, and to license the technology to physicians.

5/27 **PLC Systems** announced that the FDA had granted the company's request to expand the number of clinical sites available to treat patients with the Heart Laser TMR system. Thirty five clinical sites may now enroll end-stage coronary artery disease patients, up from the 20 sites previously approved.

MEDICAL/SURGICAL LASER UPDATE -- JUNE 1997

5/19 **Pharmacyclics** presented the results from its Phase 1 clinical trial of Lu-Tex, the company's photodynamic therapy drug, for the treatment of advanced local or metastatic cancer at the American Society of Clinical Oncology meeting held in Denver. Of the 35 patients enrolled in the dose evaluation study, 16 had breast cancer, 7 melanoma, and 12 other types of tumors. The patients received an intravenous injection of Lu-Tex, followed three to eight hours later by illumination of the tumors with light. Within the treated group, 73 breast cancer lesions were evaluated with a total response rate of 64%, with 46% having complete disappearance of the tumor, and 18% having a 50% reduction in tumor size. Among the melanoma patients, 45 lesions were studied with a complete response seen in 29% and a partial response in 20%.

5/28 **Laserscope** announced the availability of an advanced operating table, the AlphaStar, one of the products obtained from the acquisition by Laserscope of **Heraeus Surgical**.

5/28 **Candela Corporation's** ScleroPlus advanced cosmetic laser was recognized as a recipient of *Photonics Spectra* Circle of Excellence Award, as one of the 25 most technically innovative products of the year. The ScleroPlus offers a wide array of wavelengths for treating vascular lesions including leg and facial veins, port wine stains, hemangiomas, stretch marks, scars, warts, and other vascular abnormalities.

6/2 **Laser Industries** was granted three recent patents covering key laser products and applications in the cosmetic laser field. U.S. Patent 5,611,795 covers a broad range of proprietary methods for performing laser skin resurfacing. U.S. Patent 5,624,434 covers the use of laser technology for the treatment of scars, involving the preparation of recipient holes, obtaining a plug of skin from other body areas and the grafting thereof into the recipient holes around the scarred tissue. U.S. Patent 5,619,285 covers laser scanning technology embodied in the company's Silktouch and Feathertouch products for aesthetic laser dermatology and other procedures. In addition, Laser Industries has been notified that its patent for a proprietary method of laser hair transplantation has been allowed. (Anyone wishing to download the patent abstracts and claims, can access IBM's website and obtain the information on the internet. The website is **www.ibm.com/patents**. Go to the search section and write in the patent number to obtain the abstract and first claim. Go to the claim and you will see a link to obtain the rest of the claims. If this seems like too much work, call me and I'll send you a copy of my downloaded copies. I also downloaded copies of the **American Dental Technologies'** patents on dental lasers covering the erbium wavelengths, mentioned in last month's newsletter.)

6/2 **Premier Laser** said that over $20 million in proceeds had been generated from the voluntary exercise of publicly traded Class A and B Warrants. The money generated from the exercise of the warrants will be used to expand efforts on several fronts, including both ophthalmology and dentistry, according to president Colette Cozean. The first Centauri dental lasers were shipped last month, and Premier expects to ship up to 24 this month. The company believes that approximately 400 systems could be manufactured by the end of its fiscal year, next March 31st, with the possibility of potentially increasing that number to accommodate demand. Introduction of the company's ophthalmic laser is planned for this summer as well, and Premier has scheduled shipments of several erbium lasers for ophthalmic procedures for the current quarter.

A story in *Investor's Business Daily* said that the company's phone lines have been swamped with up to 200 calls a day since the announcement of hard dental tissue approval on May 7th, with the web site logging over 52,000 visits in the first week. So far, according to the story, roughly 12% of callers have ordered a laser over the phone, 20% have signed up for training courses (about 200 are currently enrolled), and about 50% have requested information and other details on the dental laser. Scott Baily of Bluestone Capital expects Premier to hit $30 million in sales in fiscal 1998,

and about $120 million in the year 2000. (Our estimates for calendar year 1997 are for sales in the $20 million range.)

6/3 **Eclipse Surgical** announced that it had received an IDE to begin clinical trials of a new catheter approach to transmyocardial revascularization, using percutaneous techniques. The approach will use Eclipse's patented steerable catheter with an articulating distal catheter tip, used in conjunction with the company's multi-optical fiber, holmium laser delivery system.

6/3 **Infinite Machine's Laser Fare** subsidiary has been awarded a follow-on Small Business Technology Transfer Grant by the Air Force/Phillips Laboratory at Kirkland AFB, NM, to complete the commercialization of a new high power, high brightness diode laser for a variety of applications including materials processing. Using Grating Coupled Surface Emitting Laser (GCSEL) diode technology, jointly developed by Laser Fare and **A.F. Ioffe Physico-Technical Institute** in St. Petersburg, Russia, the program is expected to lead to a variety of commercial applications. Laser Fare's high brightness GCSEL devices will produce a narrow, high-power output beam which can be focused to small spots, enabling a range of new applications in materials processing, medicine, and solid-state laser pumping.

6/5 **Palomar Medical Technologies** said that it would appeal this week's federal magistrate's order awarding damages of $3.17 million to **Commonwealth Associates** in its complaint against Palomar for breach of contract. In January, the U.S. District Court for the Southern District of NY granted Commonwealth's motion for partial summary judgement as to liability. Palomar will file an appeal with the Court of Appeals for the Second Circuit, contesting both rulings, liability and damages. As of the first quarter, Palomar had reserved $2.75 million in anticipation of possible costs associated with litigation matters, including the case with Commonwealth. (For the background of this lawsuit, see the January 1997 issue of the briefing.)

6/5 **Spectranetics** announced that the FDA had notified the company that its Laser Sheath PMA, used for pacemaker lead extractions, is scheduled for a hearing before its Circulatory System Device Advisory Panel on July 29th. The company started the randomized trial in November 1995 and submitted its PMA application in November 1996, with expedited review status granted in December 1996.

6/11 **Laserscope** announced that it had received approval from the FDA for a new, higher-powered, surgical laser system, its 800 Series dual wavelength KTP/YAG laser. The new configuration boosts the KTP energy levels to 50 watts, while still delivering 100 watts of YAG energy. The laser will have applications in gynecology, plastic surgery, thoracic surgery, and especially in urology. A recent study, published in *Urology*, concluded that KTP vaporization may be as effective in living human prostates, as it was in living dog prostates, and may be a useful treatment for BPH. The new higher-

powered configuration is expected to be available in the fall as a field upgrade for the approximately 1000 installed Laserscope Series 800 systems throughout the world.

6/11 **Frost & Sullivan** has launched a new report taking the pulse of the interventional cardiovascular device industry, entitled, "U.S. Interventional Cardiovascular Device Markets". The report focuses on devices such as coronary stents, percutaneous transluminal coronary angioplasty (PTCA) balloon catheters, the atherectomy device market, and laser angioplasty. According to the table of contents, the report also provides a brief overview of the growing markets for transmyocardial revascularization (TMR) and minimally invasive CABG (MIDCAB). The report, #5600-54, is expected to be published this month, and costs $3295. (For more information, call Keith Hammond of Frost & Sullivan at 415-237-4384.)

According to the executive summary, in 1996 the market for interventional cardiovascular devices was valued at $897.7 million, with a forecasted growth rate of 15%, driven primarily by growth in the coronary artery stent market, currently the most dynamic in interventional cardiology. Stents represented $422.2 million in revenues in 1996, and are growing at 28%. Laser angioplasty, on the other hand, had total revenues of only $9.9 million, with a growth rate of 0.3%! The primary reason given for the low growth of laser angioplasty is that reimbursement is difficult for capital equipment, and the procedure is reimbursed separately from diagnosis related group payments. And with Medicare reimbursement levels decreasing each year, the ability to sell (high ticket) laser equipment largely depends on the direction of federal healthcare policy and Medicare reimbursement guidelines. The problem of restenosis with laser angioplasty combined with balloon PTCA, although not mentioned specifically, remains another major obstacle to the use of lasers. (There was no information given in the executive summary about either TMR or MIDCAB. The list of companies shown in the table of contents as working on TMR included **AccuLase**, **Cardiodyne**, **CardioGenesis**, **Eclipse Surgical**, **PLC Medical Systems**, and **U.S. Surgical**, but lacked at least two companies, **Circulase** and **CorMedica**.)

6/12 **Eclipse Surgical Technologies** announced that it completed its first human case using its percutaneous transluminal myocardial revascularization catheter. The procedure was performed using the Eclipse system in Argentina, earlier this week. In total, three patients were successfully treated at Sanatorio Allende in Cordoba, Argentina by Dr. William Knopf of St. Joseph's Hospital of Atlanta, and Dr. Hugo Londero of Sanatorio Allende. All of the patients had a history of coronary artery disease and angina.

6/15 *The Los Angeles Times* Life & Style Section ran two stories profiling Colette Cozean of **Premier Laser Systems**. The first story, which ran June 15th, profiled the CEO, the events surrounding the first approval of a hard tissue dental laser, how she manages her family life, and how she happened to become one of the subjects in her company's

clinical trial on dental lasers. The second story, which ran on June 29th in the same section of the paper, contained much of the same material. (I have no idea why essentially the same story ran twice in the same newspaper!)

6/16 **Laser Corporation**, the parent of **American Laser**, announced that it had received 510(k) approval for its new solid-state laser system for dermatological applications. The Nuvolase 660, a doubled YAG operating at 532 nm, is designed to provide physicians for multiple use in the treatment of benign, cutaneous vascular and pigmented lesions. The company also markets two gas lasers, the Nuvolase 620 (argon) and the model 640 (krypton), which were recently exhibited at the American Society of Plastic and Reconstructive Surgons annual meeting, and at the American Academy of Dermatology meeting. The company has begun scheduling office demonstrations for interested physicians, with anticipated sales beginning in next quarter. A line of Nuvolase products for ophthalmolgy will be introduced soon.

6/17 **ESC Medical Systems** announced that it had received notification of a warning letter from the FDA regarding the promotion of its Derma 20 laser system. In the letter, the FDA indicated that it does not allow the narrowing of the originally cleared clinical application by quoting specific clinical indications. Apparently, the company had made specific claims, such as its use for skin resurfacing, for the laser in a recorded message that could be accessed by the general public. The laser had been cleared for generic "incision, excision, ablation, vaporization, and hemostasis of soft tissue". ESC said it had responded to the FDA's request by modifying its promotional material. (The warning letter may have been the cause of the sudden 20% drop in the company's stock price a week earlier.)

6/17-
6/18 **Cell Robotics** and **GEM Edwards** have agreed to terminate their U.S. distribution and development agreement for the laser Lassette. Cell Robotics is now free to negotiate worldwide distribution with someone else. The reason given for the agreement termination was that GEM is a distributor of diabetic products primarily to the home market, while the FDA is requiring that the Lassette be introduced into the clinical market first. (Cell Robotics has a joint development agreement with **Big Sky Laser Technologies** to finalize the Lassette product design and to manufacture the laser product.) Cell Robotics hopes to receive FDA clearance to sell the device into the clinical market within a few weeks. (The similar product from **LaBarge/Venisect** was approved on April 16th.)

The company also announced that it would introduce its Lassette laser finger perforator at the American Diabetes Association meeting held in Boston June 21-24. A news conference was scheduled for Monday June 23rd. The Lassette uses an erbium laser to open a small hole in the skin to allow the collection of a few drops of capillary blood for diabetics to use in testing their glucose levels. The nearly painless

procedure eliminates the possible cross contamination accidents from using needlesticks. The American Diabetes Association estimates that 16 million Americans are afflicted with diabetes, of which approximately 800,000 are type I who do not produce insulin and require daily insulin shots. Many type II diabetics also require daily shots. The worldwide total of diabetics is estimated at more than 100 million.

6/18 **Infinite Machine's** subsidiary **Spectra Science Corporation** said that it had received positive results from a first round of in vivo tests, performed at the Ontario Cancer Institute by Drs. Brian Wilson and Lothar Lilge. The tests were aimed at comparing the efficacy of Spectra's low cost disposable light source with a costly, high-maintenance dye laser for use in photodynamic therapy to activate Photofrin. The results of the skin sensitivity tests in a rat model showed that the two light sources were completely equivalent, an important step in validating Spectra Science's technology. According to Nabil Lawandy, CEO of Spectra Science, and the inventor of LaserPaint, "This work, along with our previous results with Foscan (the photosensitizer from **Scotia Pharmaceuticals**), will be part of an important arsenal of experimental evidence required to move LaserPaint PDT technology through the FDA approval cycle, possibly through an abridged `substantially equivalent' 510 (k) classification." (The Spectra Science LaserPaint technology is essentially a plastic matrix containing a dye at the end of a catheter, that emits the needed 630 nm light when activated by a laser source, such as a doubled YAG (532 nm) laser.)

6/19 **Laserscope** announced that it had acquired controlling interest in **NWL Laser Technologie, GmbH**, with the acquisition of stock to bring its ownership up to 52%. As a result, Laserscope will consolidate NWL's financial operations with its own as of June 13th. Laserscope had signed a definitive agreement with NWL in March 1995, which included an initial investment, options to make additional investments, and a cross-development and distribution agreement. NWL, a private company had revenues of approximately $6.5 million and a pre-tax operating profit of 5% in 1996. Included in these revenues, was approximately $1.9 million relating to the sale of Laserscope products by NWL under the existing distribution agreement. The company's line of products include erbium, pulsed YAG, ruby, argon, krypton, and CO_2 lasers. NWL's erbium:YAG laser is used in skin resurfacing, while the ruby is used for both hair and tattoo removal. In addition, the company produces a line of industrial lasers.

6/19 **Rare Earth Medical** has been awarded a two-year, $750,000 Phase II SBIR grant by the Heart, Lung and Blood Institute of NIH, to fund further development of a novel 8 French heart catheter that may eventually allow physicians to use laser energy to treat ventricular tachycardia (VT). VT is characterized by a rapidly beating heart, normally more than 100 beats per minute, responsible for nearly 400,000 cases of sudden cardiac death annually. Working in collaboration with Massoud Motamedi and David Ware of the University of Texas Medical Branch at Galvaston, Rare Earth had

developed a catheter system that allowed the passage of a laser diffusing device to the heart, and the subsequent insertion of the diffuser into the ventricle for the laser exposure. The goal of the new research effort is for the simultaneous mapping and laser ablation, by developing a novel diode laser-based approach for deep coagulation of ventricular tissue, needed to treat VT. The eventual aim of the study is to establish that interstitial catheter ablation using a diffusing tip and a diode laser is safe, efficacious, and cost effective for treating VT. According to Rare Earth CEO Edward Sinofsky, the company anticipates partnering with an existing electrophysiology company within the next 18 months to begin the process of moving this technology to the market.

6/20 **Premier Laser Systems** announced that it had received orders valued at approximately $2.3 million for 64 of its newly approved erbium dental laser. The company also reported that it had processed more than 2500 inquiries from dentists across the U.S. and a number of foreign countries, with an average of 150 calls taken per day. The Centauri laser is currently priced at $35,595. The company has also expanded its mandatory training program to 43 sessions through August, with nearly all of the sessions completely filled. Premier currently believes that it will be able to manufacture 100 laser systems per month until the end of the year to meet the demand, shipping on a first come first served basis.

6/20 The **American Academy of Cosmetic Surgery** has released its latest statistics for 1996. According to the Academy's news release, more and more American men are seeking out new procedures that will improve their appearance, and are, in fact, becoming more the target of cosmetic surgeons wielding the latest chemical peels and laser resurfacing devices. Cosmetic surgery is still gaining popularity in the U.S., and men remain the fastest growing segment, according to statistics collected two years ago in a similar effort. Some of the fastest growing procedures include chemical peels, sclerotherapy (vein surgery), liposuction, and hair transplantation. Laser resurfacing, an emerging technology in 1994 gained ground quickly, jumping to 138,000 procedures in 1996.

Some 690,000 men underwent cosmetic surgery in 1996, compared to 568,000 in 1994. Among men, the top five surgical procedures were hair transplantation (31%), chemical peels (10%), liposuction (8%), sclerotherapy and blepharoplasty (4% each). The top five procedures for women were chemical peels (18%), sclerotherapy (also 18%), liposuction (9%), laser resurfacing (4.5%), and blepharoplasty (3%). For more information about the latest report, call Maureen Smyth of the American Academy of Cosmetic Surgery at 312-527-6713.

(As I mentioned in the March newsletter, I prepared an extensive report on the potential growth of the cosmetic laser industry, including all the new laser procedures,

for **ICON Centers for Cosmetic Surgery**. Copies may be obtainable from ICON's parent company, **Atlantic Central Enterprises**, in Toronto, at 416-364-0012.)

6/24 According to a report released by **ThermoLase**, Americans report that body hair, both wanted and unwanted, continues to play an important role in their lives; as a source of pride and self-esteem, and an outlet for self expression. Among the survey's key findings was that for a majority of American women, unwanted body hair carries a serious social stigma, with 63% saying that not removing it would make people think that they don't care about their appearance. The study also reflected American's concern for cleanliness and hygiene, with 35% citing "feeling cleaner" as a key motivation for removing body hair, followed by "feeling sexier" (32%), and "more spontaneous" (31%). Men persist in maintaining a double standard, of preferring women without visible body hair, while seeing it (their own body hair) as a sign of masculinity that makes them more attractive to women, ignoring a change in women's attitude in which 67% say that hairy men "turn them off". The study was conducted by **The Brain Waves Group** in March 1997 for ThermoLase.

6/25 **Premier Laser Systems** announced that its Centauri erbium laser system had met the electrical performance standards for European countries of the Geneva-based IEC. While the IEC approval is not required for marketing into Europe, the clearance assures dentists (and ophthalmologists) that the products are safe for use. According to a report in *The Los Angeles Times*, the approval opens the way to a market of approximately 125,000 dentists, roughly the same size as in the U.S.

Analyst Scott Baily at BlueStone Capital reiterated his strong buy rating on Premier. His new 12 month target for the stock is $17-$20, up from his original target of $12-$15. He now estimates that fiscal revenue will approach $30 million, up from $20 million, and that 1999 estimated fiscal revenue could reach $60 million.

6/25 **American Dental Technologies** announced that it had an agreement with **Denics Co. Ltd.** to cancel its Pacific Rim venture agreement, and for ADT to purchase, for $1 million, Denic's rights in the joint venture to manufacture, market, distribute, and sell dental air abrasive and laser products in the Pacific Rim. Under the new agreement, Denics will continue to distribute ADT's products in Japan, and has given ADT a firm contract/purchase order for lasers totalling $3.3 million, beginning in September 1997 through March 1999, for distribution in Japan.

6/26 Not to be outdone by the competition, **Biolase Technology** announced that it had shipped 10 Millennium HydroKinetic tissue cutting systems to its distribution partner, **Orbis High Tech Dental**, in Germany. The shipments were the first commercial production runs of the innovative dental system, and were part of a $12 million minimum purchase agreement with the distributor. The company estimates that with more than 400,000 dentists practicing overseas, compared to about 150,000

domestically, the international market would appear to be substantially larger than that in the United States.

6/27 **Lasermedics** was approved for trading on the NASDAQ, and will change its name to **Henley Healthcare**. Until I hear more about their therapeutic laser product still in clinical testing for treating carpel tunnel syndrome, I intend to drop this company from my screening list.

6/26 **Sunrise Technologies** announced the successful completion of the divestiture of its dental operations to **Lares Research**, a privately-held California Corporation. Sunrise received $4 million in cash plus a note for $1.5 million payable over 4 years. Sunrise will now concentrate its activities on its ophthalmic business, completing the clinical evaluation of its LTK Corneal Shaping system for correction of hyperopia. With the closing of the sale, David Light, chairman and CEO announced his resignation. The Board of Directors has appointed Russell Trenary, the head of its ophthalmic operation, as president and CEO. Joseph Koenig was appointed chairman.

In a related announcement, **American Dental Technologies** said that it had agreed to transfer its license for the sale of dental lasers and air abrasive systems from Sunrise to Lares, as a result of the sale of Sunrises' dental business. ADT will receive a cash payment of $275,000 from Sunrise and will receive an additional $100,000 on payment in full of a note between Sunrise and Lares in connection with the transaction. The company will also continue to receive a royalty on air abrasive instruments and a royalty on the sale of dental lasers.

6/27 **EquiMed**, which is in a legal battle with **Physicians Resource Group** over the sale of its ophthalmic division to PRG (see the June 23rd brief in the ophthalmic section), announced a 1 for 6 reverse stock split, which will effectively reduce the number of outstanding shares of stock. EquiMed provides medical practice management services to its affiliated oncology and medical practices, and is in the process of developing **Rejuve Image Enhancement Centers** for cosmetic surgery (see the April 10th brief in the April 1997 issue).

6/30 **Surgical Laser Technologies** and **Diomed Ltd.**, a UK-based manufacturer of diode surgical lasers, announced that they have entered into a private label supply agreement. Under the agreement, Diomed will purchase all of their requirements for contact probes and disposable fiber delivery systems, made to Diomed's specifications and trademark, for use with its diode laser systems. Diomed distributes its laser products worldwide, with its major marketing activities focused on the European and Asia Pacific markets. According to Keith Stoneback, CEO of SLT, the relationship with Diomed will enhance Diomed's products while providing SLT an effective way to increase sales of contact technology in Europe and the Far East.

MEDICAL/SURGICAL LASER UPDATE -- JULY 1997

7/1 **Ion Laser Technology** announced an alliance with **Dental/Medical Diagnostic Systems**. The two-part agreement includes non-exclusive domestic and selective international sales by Dental/Medical of ILT's BriteSmile laser tooth whitening dual laser system (including sales of laser tooth whitening reagent kits) and, conditional upon performance, grants Dental/Medical exclusive worldwide distribution of ILT's new Argo HP subsecond dental composite curing and whitening device. The latter utilizes a proprietary argon light-energy source and activates dental materials in under a second. The BriteSmile portion of the agreement is estimated to result in $4.5 million in equipment sales for the first twelve months plus additional whitening chemical sales. The Argo portion of the agreement is anticipated to produce five-year revenues to ILT of at least $36 million over the term, provided Dental/Medical purchases sufficient Argo devices to maintain exclusivity. The company expects that there will be additional revenues from the sales of related consumables. Dental/Medical will be responsible for marketing development and funding, international approvals, product launch, and distribution. The product launch of the Argo device is anticipated during the fiscal second quarter, with revenues beginning in the following quarter. Dental/Medical is a leading supplier of intra-oral cameras.

The company also announced its fourth fiscal quarter and year end results for the year ended March 31st. ILT had revenues during the quarter of $1.6 million and $7.1 million for the year. The company had a net loss of $1.1 million (21 cents/share) for the quarter, and $779,250 (15 cents/share) for the year. Dental product sales grew from $2.1 million in fiscal '96, to $5.1 million in fiscal '97, primarily based on the spring 1996 introduction of the BriteSmile process.

7/2 **Laser Industries** recently introduced its computerized erbium laser system for extremely superficial skin resurfacing at the World Congress of Dermatology in Sydney, Australia. The company has applied for FDA clearance of this laser and expects to begin shipping the product to non-USA customers this September, and to U.S. customers following FDA marketing clearance. Clinical trials on the erbium laser were conducted by Dr. Cynthia Weinstein, based in Melbourne, Australia. Her results showed that the unique integration of the scanner with the high repetition rate laser enabled extremely homogeneous and superficial laser peeling with rapid healing and an absence of prolonged skin redness (erythema). The erbium laser complements its Sharplan SilkLaser product line, which includes the FeatherTouch CO_2 skin resurfacing system for deeper lines, wrinkles, scars, and hair transplantation, and its EpiTouch laser for hair removal and the treatment of tattoos and pigmented lesions.

Separately, the FDA has granted clearance for the Softscan laser scanner, developed and manufactured by **Sahar Technologies**, Laser Industries' recently acquired subsidiary. The clearance covers three additional wavelengths; green (532 nm), YAG

(1064 nm), and the erbium (2940 nm) laser. Previously, the scanner had been approved for use with CO_2 systems. The clearance covers the manipulation of a pulsed or continuous wave laser beam for use in dermatology for the treatment of soft tissue, including ablation, vaporization, and coagulation.

7/3 More on **American Laser** (last month's brief of June 16th). I received a package of information from **Laser Corporation**, the parent of American Laser, an OEM laser systems manufacturer, and **American Laser Medical**, founded in 1993 to design and market both laser- and non-laser-based systems into the medical marketplace. Current products include the Nuvolase 600 series of medical laser systems for use in dermatology (doubled YAG, argon and krypton lasers), the Patient Archiving & Imaging System, a computerized office management and patient case file system, and SimulEyes, an ophthalmic educational device which simulates retinal laser treatments. Another subsidiary, **American Laser Software**, develops software for medical devices. Current customers of Laser Corporation include **Xerox Corporation**, **Carl Zeiss**, **Alcon**, and **Bio-Rad**. The medical lasers were developed in conjunction with the company's long established European partner (Carl Zeiss ?) to fill the need for a simplified, flexible design, high performance lasers for the office environment. (More information about this interesting company can be obtained by contacting Joyce Wickham, president and CEO at 801-972-1311.)

7/7 **QLT PhotoTherapuetics** announced that it had filed a supplemental new drug submission with the Canadian Health Protection Branch seeking approval of Photofrin as a treatment for specific types of lung cancer. Dr. Julia Levy, president and CEO, said that the submission was based on data from clinical trials involving 650 patients in Canada, the U.S., and Europe, showing Photofrin to be promising in treating certain early and late-stage lung cancers. "Although the commercial significance of the Canadian market is much smaller than other markets where we have received or are seeking approval, it is important to us to be able to offer this potential treatment to Canadians." A similar application was filed with the FDA in February. The Canadian filing was for Photofrin to be used for reduction of obstruction and palliation of symptoms in patients with obstructing endobronchial nonsmall cell lung cancer (NSCLC), and also for treatment of superficial endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated. Three-quarters of all lung cancers are identified as NSCLC.

In two multicenter randomized controlled studies comparing PDT using Photofrin with YAG laser therapy for the palliation of patients with advanced disease, Photofrin was reported to be equal to or better than the YAG laser therapy for objective tumor response, palliation of symptoms, and time to local progression. In patients with early-stage superficial lung cancer, results from three single-arm studies showed PDT with Photofrin provided complete tumor responses while preserving normal lung tissue. Photofrin is currently marketed in Canada for the treatment of certain types of bladder

and esophageal cancers by **Ligand Pharmaceuticals**, QLT's marketing partner in that country. Photofrin has also been approved for lung cancer and esophageal cancer treatment in France and the Netherlands; for esophageal cancer in the U.S.; and for early-stage lung cancer, superficial esophageal cancer, superficial and early-stage gastric cancers, early-stage cervical cancer, and cervical dysplasia, a pre-cancerous condition, in Japan. Additional European approvals are expected in 1997.

7/8 **Eclipse Surgical** said that it had submitted its PMA application for the use of the Eclipse laser system to treat patients with Class IV angina (chest pain) caused by coronary artery disease using transmyocardial revascularization. Eclipse presented six-month Phase II data from its randomized study of the safety and efficacy of TMR compared to drug therapy in Class IV angina patients who are considered otherwise inoperable. The data demonstrated improvement in angina symptoms for 92% of the TMR-treated patients after six months, while only 18% of the drug-treated patients experienced the same results. Twelve month Phase I data was also presented to the FDA. Eclipse is also conducting clinical trials of TMR in conjunction with bypass surgery and percutaneous TMR (PTMR) studies, inserting the laser catheter from the inside out. Eclipse began its PTMR studies outside of the U.S. last month, and recently received FDA approval to begin studies in the U.S.

7/8 The brokerage firm **Meyers-Pollock-Robins** released a bullish report on **Mehl/Biophile International**, written by senior research analyst Dennis Roth. According to the 24-page report, MPR believes that Mehl may become the dominant company in the $1 billion U.S./$3 billion annual worldwide professional hair removal services market now served by electrolysis. "Since laser hair removal is capable of removing multiple hairs with minimal discomfort, making it practical to treat much larger body areas...therefore, we expect the laser hair removal services market to double to $6 billion, worldwide, in the next 5-7 years." With four domestic competitors and only three in Europe, the large and expanding worldwide market is "wide open", and presents substantial growth opportunities for these first companies.

The report goes on to explain that Mehl provides its laser free of charge, including installation and maintenance and laser upgrades as they are developed, in exchange for 50% of the gross revenues generated by its licensed service providers. (Other companies such as **Laser Industries** and **Palomar Medical Technologies** sell their laser systems -- although Laser Industries has begun opening high-scale hair removal spas, and Palomar is partnering with companies such as **Columbia/HCA** to develop and open cosmetic surgery centers, including laser hair removal, on a 50/50 profit split. **ThermoLase** also has opened hair removal spas, and is providing its laser-based system to physicians on a revenue sharing basis.)

Roth projects Mehl's sales to jump from $3.1 million in fiscal '97 (year ending 5/31), to $50.5 million in fiscal '98, and $212.2 in fiscal '99. He also contends that Mehl may

have a dominant laser patent position and that its Chromos 694 Marc II long pulse ruby laser is the most efficient, effective, and operator friendly hair removal laser now available. (Some of the factors leading to that conclusion are the use of an automatic scanner attached to a fiber optic delivery system, and an auto fluence test built into the system, which automatically adjusts the fluence level -- based on reflectance data -- depending upon the skin type. In addition, the Marc II laser incorporates a "smart card" which records all laser parameters, as well as patient data, and can be used to "shut off" the laser if the licensee has not paid his share of the gross revenues!)

The report compares the Mehl system with its competitor's systems, both in clinical results and in operating parameters. In addition, the report discusses the marketing strategies of the various companies, and estimates the near term and longer term production capacities of all the competitors. It also relates the background and status of the legal battles ensuing between Mehl and Palomar, and Mehl and Laser Industries.

All in all, the most comprehensive report, to date, covering the burgeoning laser hair removal industry. (For more information about this report, contact Meyers-Pollock-Robbins at 703-893-8080.)

7/8 **ESC Medical Systems** announced that it had received FDA approval for marketing its EpiLight hair removal system in the U.S. The EpiLight depilation product is based on ESC's proprietary intense pulsed light technology. The approval was based on an extensive clinical study performed by several investigators in the U.S. that demonstrated the safety and efficacy of the system to treat a wide range of skin and hair colors. By utilizing a large footprint with each pulse of light, large body surfaces can be treated rapidly. The device can be adjusted and customized according to the patient's hair color, skin type, and particular body area to be treated, by selecting a wide range of treatment parameters such as spectral output, pulse structure, and pulse duration. For the patient, this means a higher clearance rate, faster treatment time, and improved skin resilience with less pain, according to the company.

7/9 **ThermoLase** announced it had entered into an exclusive franchise agreement with **Spa Brasil Ltda.**, a privately-held company based in Rio de Janeiro, to market it SoftLight hair removal process and its skin resurfacing technology in Brazil. After obtaining any necessary government approvals, Spa Brasil plans to open a Spa Thira salon in Sao Paulo or Rio de Janeiro within six months. Additional spas are expected to be established in other urban centers throughout the country, with a commitment to open 10 Spa Thiras within five years after obtaining appropriate approvals. Under the agreement, Spa Brasil may also license Brazilian physicians to offer the SoftLight treatments.

7/9 **Collagen Corporation** has formed a new company, **Aesthetic Technologies Corporation**, to further separate its **Aesthetics Technologies Group**, previously announced. (For more on this see the January 1997 issue of the Briefing, People in the News section.) Gary Petersmyer has been named president and CEO. ATC will focus on accelerating growth of its profitable aesthetic and reconstructive surgery business, with expanded new product offerings such as Hylaform viscoelastic gel, SoftForm facial implant, and ReGenesis Medical Skin Solutions, according to Petersmyer. (At one time, Collagen and Aesthetic Technologies were contemplating the acquisition of a complimentary laser skin tightening process. To my knowledge, that opportunity was not consummated.)

7/9 **Ion Laser Technology** announced the FDA approval of its new high powered argon light dental composite curing and tooth whitening device, the Argo HP. With a revolutionary laser-like design, the beam allows for up to ten times the power output as compared to conventional lamps or laser systems presently used in dental curing. This concentrated power enables tooth-colored composites to be safely activated or cured, literally in a flash, or less than a second, with no patient discomfort, according to the company. The Argon HP also can be used for tooth whitening, but will not directly compete with the company's laser tooth whitening system, composed of a dual laser BriteSmile process -- including both a high powered argon and a low powered CO_2 laser. It will be used to compete against xenon-lamp and single laser systems which are used to activate tooth whitening chemicals. ILT is developing special whitening reagents and composite materials to be used with the Argon HP.

The company also announced that it had received a U.S. Patent, 5,645,428, for its proprietary laser tooth whitening process. The patent includes 37 claims pertaining to the use of lasers with chemical agents in tooth whitening procedures. According to the company's patent counsel, the patent covers the use of argon and carbon dioxide lasers, used independently or together, in conjunction with chemical whitening agents to effect the whitening of teeth, as well as the chemical agents themselves. Included among the agents used in the patented process are hydrogen peroxide and carbamide peroxide, the two most common tooth whitening agents. (I attempted to obtain a copy of the patent off of the IBM patent website, but it had not yet been posted. I expect that I will have a copy before the end of the month.)

7/10 **PLC Systems** announced that its Japanese partner and distributor, **Imatron Japan**, had purchased four additional Heart Laser TMR systems from the company. All four were shipped during the second quarter. Imatron is managing and funding the regulatory approval process in Japan. With the new systems, there are now 12 Heart Lasers operational in Japan, to serve the approximately 400 open-heart centers, the second largest market for TMR outside of the U.S.

7/10 **Mehl/Biophile International** announced that it had scheduled installation of its Chromos 694 long pulse ruby laser hair removal system in the United States, commencing later this month. The company has established a training center in New York City, with the first course scheduled for the week of July 14th. Mehl expects between 75 to 100 physicians, who have agreed to become licensees, will be trained at the center over an initial two-week training period. Installation of the laser will be made shortly after each licensee is certified on the system. Initially, Mehl plans to concentrate its U.S. installations on the East and West Coasts. According to Thomas Mehl, chairman, the company intends to complete the installation of as many as 70 systems in the U.S. by the end of September, and remains confident that they will have a minimum of 300 systems installed worldwide by the end of 1997. Mehl intends to open a second U.S. training center in California shortly, to accommodate professionals on the West Coast. (For more on Mehl and the other laser hair removal laser companies, see the 7/8 brief above, based on the report written by Dennis Roth of **Meyers-Pollock-Robbins**.)

7/10 **Eclipse Surgical Technologies** announced its second quarter results with revenues of $1.3 million and a net loss of $4.6 million (28 cents/share). (For the latest update on Eclipse, see the July 8th brief above.)

7/10 I received an interesting phone call and package of information from Tom Cekoric, president and CEO of **Applied Optronics**. AO has developed a diode laser version of a hair removal laser which, in my opinion, holds great promise for this competitive market. The new system, called the Episcan hair removal system is based on a 690 nm diode laser, with a high power output (10 watts cw), capable of achieving 1-80 J/cm^2 to tissue, using a 1.2 mm spot that is fiber delivered to a specially designed, microprocessor controlled scanner that can deliver a 4x4 to 10x10 mm square, line, rectangle, trapezoid, hexagon, or triangular shaped spot, with the dwell time on tissue adjustable from 1 to 100 ms. The repetition rate is 1 scan per 3 seconds. The Episcan is a compact, self-contained device, including a calibration function, an adjustable power output, timer, and visible aiming beam. The high electrical efficiency of the diode lasers and the use of thermoelectric (Peltier) coolers eliminates the need for water cooling and assures low maintenance and reliable laser operation. The unit operates on normal wall outlet electricity. The scanner is footswitch operated and automatically scans the 1.2 mm spot through the selected pattern in about 3 seconds, with the dwell time (exposure per spot) set for between 1 to 100 milliseconds, approximating the thermal relaxation time of hair follicles. When the scan is completed, each spot has received the same energy dose as if the whole area had received a single high energy ruby laser pulse. The device weighs about 50 pounds and will sell for under $60,000! A prototype unit has been built and the company is about to begin clinical testing. (The company is seeking a marketing partner for the laser. For more information about this innovative device, call Tom Cekoric or Doug Mead at Applied Optronics at 908-753-6300.)

7/11 I received two additional analyst reports on **ThermoLase** in the hair removal market, from analysts at **Salomon Brothers** and **Lehman Brothers**. The first report, by analyst Marie Conway (who wrote the first report on this market and on the company back in October 1994, when she was with **NatWest Securities**). It should also be noted that NatWest and Lehman Brothers took ThermoLase public. Ms. Conway's report, dated May 14, 1997, is generally quite good with lots of information about where ThermoLase is and where they are going but, apparently, she has bought into the ThermoLase story, even as she uses lots of "hedge" clauses. For example, "We believe that ThermoLase could earn close to $1.00 per share in fiscal 1999 **if** the company is successful in improving the efficacy of the hair removal process and can execute an effective commercialization plan." She goes on to note, "ThermoLase shares have been under intense selling pressure over the past year. We believe that two events occurred that caused the share price to swoon: (1) The growing understanding that the ThermoLase hair removal process was **not** permanent and, in fact was not "long term" for most customers caused many investors to reevaluate ThermoLase's profit prospects. (2) A bevy of companies (including Palomar, Laser Industries, and ESC Medical received marketing clearance from the FDA for their hair removal systems." She also notes, "These announcements raised the specter of intense competition and reduced pricing...all of these systems seem to work about the same in terms of duration. ThermoLase is spending $7.5 million on R&D this year...to increase the time between treatments...will ThermoLase be able to improve the hair removal process by enhancing initial results and by extending the duration between laser treatments?"

The report states that ThermoLase has 10 spas currently in operation, and that another ten to fifteen are expected to open by year's end -- each spa has about ten YAG lasers -- and assumes that 200 doctors will be signed up for the licensing program by the end of 1997, and that revenues from this source are projected to be about $50,000 per doctor per year. This includes an upfront $10,000 license fee and a base per procedure fee that typically is about 30-40% of what the doctor charges the patient. Her model for revenues shows laser-based revenues of about $30 million for fiscal 1997, increasing to $84 million in fiscal 1998, and $150 million in fiscal 1999, with the company becoming profitable in fiscal 1998! All in all, a very comprehensive report -- if you believe in the ThermoLase technology.

On the other hand, the Lehman Brothers' report, written by analyst Angus Macdonald, and dated May 22, 1997, is one of the worst analyst reports I have read. It says practically nothing except for giving the Spa Thira pricing for different hair removal categories, again noting that multiple treatments are necessary -- and with five treatments costing between $1500 to $2100 for single areas, and multiple areas up as much as $6000!

7/15 **American Dental Technologies** released its quarterly results, with revenues of $5.4 million and record net income of $1.4 million (18 cents/share) for the quarter and six month period. President Ben Gallant noted that the company had received approval for use of its laser in the treatment of periodontal disease, the second largest reason for tooth loss. (I believe that most of the revenues reported were for the sale of the company's line of sandblaster products, rather than its lasers -- although no breakdown between the two product lines was noted, although a $3.3 million purchase order for its dental lasers was received from its Japanese distributor.)

7/15-
7/16 **CardioGenesis** announced that it had received approval from the FDA to begin multi-center clinical trials of its percutaneous TMR approach to treat Class III or Class IV angina in no-option patients at up to ten clinical sites. Since last November, when the first humans were treated with PMR in Europe, over 20 no-option patients have received treatment with promising results. Total procedure time has averaged 50 minutes for experienced cardiologists, with the time to create ten or more channels averaging less than fifteen minutes. The majority of patients have been discharged from the hospital in two or three days.

The next day the company reported its second quarter results with revenues of $2.7 million and a net loss of $3.7 million (31 cents/share). The revenues were primarily from the sales of its intraoperative TMR system into Europe and into its clinical sites in the U.S., and for the first time, into Japan, according to Allen Hill, president and CEO.

7/16 **Spectranetics** also announced its second quarter results. The company reported revenues of $4.6 million and a net loss of $1.4 million (8 cents/share). Revenue decreases during the three and six months compared to the same periods in 1996, were primarily a result of decreased laser revenues combined with unfavorable fluctuations of the Dutch guilder foreign currency exchange rate in relation to the U.S. dollar. Actual placements of new lasers with customers in 1997 were close to 1996 levels, however, revenues for the period ending June 30th 1996 also included sales of six lasers which had previously been rented. There were no comparable sales in 1997.

7/16 **Cell Robotics** announced that it had received clearance from the FDA to market its erbium laser for dermatology and other applications. The FDA indications for use included small and large joint arthroscopy, including microdiscectomies, endoscopic procedures, and general surgical procedures for cutting (incision/excision), vaporizing, and coagulation of soft tissue, including skin, subcutaneous tissue, muscle, meniscus, mucous membrane, lymph vessels and nodes, organs, and glands. The company expects that the erbium laser will be ready for delivery this fall to physician's offices. The system is said to be portable, lightweight, and affordable. The

press release notes that the April issue of *Medical Laser Insight* reports that an estimated 100 erbium lasers have been sold since the AAD meeting in March.

7/17 **Ion Laser Technology** and **Laser Industries** jointly announced that they had signed an exclusive distributor agreement whereby **Sharplan Lasers Europe** will market ILT's BriteSmile laser tooth whitening products through its worldwide distribution channels in selected countries in Europe, Latin America, and the Middle East. The two companies will combine products to complete the dual-laser process. ILT will provide the argon laser and laser whitening reagent kits, and Sharplan will provide its own 15 watt CO_2 laser, retrofitted for the dental market to ILT's specifications. In addition, Sharplan will also distribute the BriteSmile home use tooth bleaching product on a non-exclusive basis. ILT has received the initial order for the LTW products from Sharplan.

7/18 **American Dental Technologies** announced that it had signed a letter of intent with **Continuum Electro-Optics**, a manufacturer of medical and dental lasers, with the intention of entering a non-exclusive license of ADT's U.S. Patents 5,257,935 and 5,342,198, which cover the use of erbium lasers in dental procedures on hard tissue. Additionally, the companies intend to enter into a distribution agreement under which ADT would distribute a Continuum produced erbium laser for use in hard tissue dental applications such as cavity preparations. Continuum is a subsidiary of **Hoya Corporation**, which is wholly owned by **Hoya, Ltd.** of Japan.

7/18 **ThermoLase Corporation** reported that its physician licensing program, which has established a network of doctors across the country offering the SoftLight hair removal process, is working quite well. To date, ThermoLase has placed 126 lasers in practices in 33 states and Canada. In addition, approximately 500 doctors have been trained to offer the SoftLight process through an agreement with **Medical Alliance**, the nation's leading provider of medical equipment on a temporary basis. Several of the licensees have more than one SoftLight laser in their practice, and pay a per-procedure fee to ThermoLase, which runs ads in major magazines supporting this program, and claims that as many as 3500 people call their toll-free number each week. Since the number went on line in January, more than 55,000 people have inquired about SoftLight.

In addition to the physician licensing program, the company now has 12 domestic Spa Thira salons open and just recently opened its first European spa in Paris. In excess of 50,000 commercial treatments have been performed since the opening of the first spa in November 1995 and, through April, ThermoLase had earned cumulative revenues of more than $15 million from its hair removal services, including the physician licensing program and international licensing agreements. (The real question is, how many of the 50,000 treatments were repeat treatments because of the lack of permanency of the initial or second treatment?)

7/19 There were several interesting items in the June/July issue of *MedPro Month*. A cover story on coronary stents includes a graphic of worldwide coronary artery disease procedures by type for 1996 and projected for 2001. It is interesting to note that conventional CABG will decrease from 603,000 procedures to 591,000, while laser TMR alone, will go from 2000 procedures to 121,000 in that time frame, and laser angioplasty is not listed at all. (Adjunctive TMR was incorporated into the CABG and angioplasty numbers, so that the total of TMR procedures will be much greater than the 121,000 shown.) The other two fast growing areas of treatment are radiation therapy to prevent restenosis, and minimally invasive cardiac surgery (MICS); with the former going from zero to 113,000 procedures, while the latter will reach 567,000 procedures in 2001. (The graphic data was attributed to Kurt Kruger of Montgomery Securities.)

Another feature story covers urology and prostate disease. A graphic accompanying the story shows that in the U.S., conventional TURP will go from 185,000 procedures in 1996 to about 75,000 in 2001 for the treatment of BPH, while laser surgery will only double, from about 23,000 procedures in 1996 to 50,000 in 2001. New procedures, including transurethral needle ablation (TUNA), focused ultrasound, and transurethral thermal ablation, among others, are projected to increase from 2000 procedures to 425,000 over the period. (Another of the "new" procedures noted was the use of photodynamic therapy to control BPH.)

A brief on the increase of in-office surgeries -- which could account for up to 20% of all U.S. surgical procedures by the year 2000 -- features **Medical Alliance**, the largest supplier of mobile medical technology for office use. (Also see the ThermoLase brief above.) The company provides surgical equipment and support services allowing doctors to perform 25 different office-based procedures across several medical specialties, including gynecology/urology, gastroenterology, podiatry, dermatology, and otolaryngology -- with many of the procedures laser-based. In addition, the company provides lasers for a wide range of cosmetic/aesthetic elective procedures. According to the brief, last year, MA facilitated 26,800 medical/surgical and 41,800 aesthetic elective procedures, resulting in net revenues of $17.3 million.

Another article of interest pointed out Eastern Europe's growing medical market. "As free market economics take hold, the region encompassing Eastern Europe and the former Soviet Union is emerging as one of the world's fastest growing medical markets...with per capita drug and device spending... at only 10%-20% of Western Europe's rate, there is room for dramatic and sustainable growth." The population of the 27 countries is 425 million, and exceeds that of the European Union (EU), but their GNP is less than 10% of the EU (or U.S.). All in all, a significant medical market opportunity.

7/21 **Surgical Laser Technologies** and **C.R. Bard** announced that they had settled their litigation in the U.S. District Court for the Eastern District of Pennsylvania. The terms of the settlement were not disclosed. (I have no record of the litigation between the two companies, but if more is learned, I will pass it along.)

7/22 **Coherent Inc.** reported record orders, sales, and net income for its fiscal third quarter, ending June 28th. For the quarter, the company had incoming orders of $108.7 million, sales of $102.3 million and net income of $11.4 million (97 cents/share), which included a one-time pretax gain of $3.5 million ($2.2 million after tax) on the sale of the company's former headquarters. Net income exclusive of the facility gain was $9.2 million (78 cents/share). Higher sales and improved gross margins were the primary factors contributing to the 16% growth in income. The company's backlog has grown $26.4 million fiscal year to date, and stands at $86.4 million at quarter's end.

According to a company official, the medical group's sales for the quarter were $45.3 million, up from $39 million in the previous quarter, and up from $38.1 million in the same quarter a year ago. This puts the company ahead of last year's calendar years total of $163 million, but leaves them a long way to go to hit my projection of $180 million for this calendar year.

7/22 **PLC Systems** announced that it had secured a $20 million financing commitment through **Smith Barney**, from funds advised by **Brown Simpson Asset Management LLC** and **Southbrook International Investments, Ltd**. Under the terms, PLC has received $10 million from the issuance of convertible debentures due July 17, 2002, with a commitment to receive an additional $10 million at the option of the company subject to certain conditions. In connection with the transaction, PLC has issued to the funds, a warrant to purchase 65,000 share of common stock at $27.97 per share upon filing the appropriate registration statement. According to chairman Robert Rudko, the financing will support the launch of the Heart Laser TMR system to the nearly 1000 open-heart centers in the U.S. upon a potential FDA approval. The FDA's advisory panel meets to discuss the company's PMA on July 28th.

7/22 **ESC Medical Systems** announced record second quarter results with sales of $25.5 million and net income of $6.5 million (32 cents/share). For the six month period, sales more than doubled to $48.5 million from the same period last year, and net income grew to $12.2 million (60 cents/share), excluding the cost of the merger with **Luxar** in 1997, and non-recurring expenses for the **LBT** acquisition in 1996. Actual net income for the six month period was $7.5 million (37 cents/share). (The second quarter results include the full integration of Luxar's sales into those of ESC. In 1996, Luxar had sales of $28 million for the year, or a run rate of approximately $7 million per quarter. If the combined sales continue on the same trendline, ESC's sales for

1997 will far exceed my projection of $65 million and be closer to $90 million for the year.)

7/23 **Laserscope** announced its second quarter results with revenues of $15.2 million and net income of $756,000 (6 cents/share). For the half year, revenues were $31 million, up 91% over the same period last year, with net income at $1.6 million (13 cents/share). Fiscal second quarter and six-month results included contributions from **Heraeus Surgical**, acquired in August 1996, and six month results included $933,000 in revenues from the operations of **NWL Laser Technologie** from June 13-30, based on the majority ownership of NWL announced on that date. Robert McCormick, president and CEO said that the six-month results were the highest revenues in the company's history and reflected the benefits of several steps taken over the last few quarters to accelerate growth and improve bottom line performance. Among these were the acquisition of Heraeus, the paring of operating expenses, and the strengthening of distribution channels. In addition, continuing strong sales of Aura and Orion laser systems, and strong international operations continued to meet expectations. He said that the company would introduce its erbium laser for skin resurfacing later this year or early next year, to address the softening sales of the CO_2 laser market. Laserscope's desktop Aura laser with StarPulse continues to gain acceptance for the treatment of leg veins and other vascular disorders, and the company intends to offer a new, higher powered Aura laser system later this year.

Lasers represent only about 46% of total sales, with disposables and service accounting for 36%, and it line of operating room products, obtained from Heraeus, the remainder. International sales account for 31% of revenues.

In a teleconference following the issuance of the second quarter results, Mr. McCormick noted that he believes that the CO_2 skin resurfacing market is off about 30% in units and with the drop in average realized price, could be off as much as 40-50% in dollars, to about $150 million worldwide, with most of the sales continuing to be in the U.S. The market for erbium lasers continues to grow and could be as much as $100 to $120 million this year. McCormick also noted that Laserscope's sales were across many disciplines, with only 23% attributed to dermatology/aesthetics, while about 70% is still involved with various surgical specialties. He also mentioned that PDT was on the horizon, with approval in Germany and Italy and others coming along shortly. Laserscope has been in discussions with **Beaufour Ipsen**, **QLT PhotoTherapeutic's** European marketing partner, about selling PDT dye laser units to its installed base of KTP lasers for use in activating Photofrin. In addition, Laserscope is working on a new diode laser for use with Photofrin, and expects to have it ready for introduction into Europe in the first quarter of next year.

I inquired if the company was considering entering the hair removal market, and was told that the ruby laser from NWL was in clinical trials and Laserscope would

probably file a 510(k) in either this year's fourth quarter or early in the first quarter of next year. Also, the company is considering entering the industrial laser market, building on the NWL product line already sold into industry in Europe.

7/24 I received a note and photograph from Dr. Frank O'Donnell regarding a new startup company he has formed, called **Laser SkinToner, Inc.**. The company has been founded around an invention of Dr. O'Donnell's, the use of a solid-state IR laser at certain operating parameters to tighten the skin and remove facial wrinkles without damaging the skin's surface. In a news release dated June 16th, the company noted that it was commencing clinical trials of the Laser SkinToner under an IDE, and described the technology as "the Laser SkinToner is a patent-pending device and method for increasing skin tone and reducing wrinkles and striae without damage to the skin surface. The treatments are done with a local anesthetic in an office setting. Each pass of the laser induces a 5-10% tightening of the skin without surface damage. Patients resume normal activity the same day." Dr. Joseph Muccini, the company's medical director noted that the device allows the doctor to tone up or tighten lax skin without attendant morbidity caused by CO_2 or erbium resurfacing lasers. He believes that the Laser SkinToner could be used alone or in conjunction with superficial chemical peels to provide the cosmetic "tone" that women (and some men) seek. He also noted that this laser can be used to treat abdominal striae, a common problem post-pregnancy. (It should be noted that the pulsed dye laser from **Cynosure** is also being used to treat this condition.)

In use, the laser energy is passed down an optical fiber to a handheld contact delivery device. The probe is held against the skin surface for less than a second for each pass of the laser energy. Typically, two to three shots of the laser are used.

The photograph I received shows the three-month followup to the treatment of a women with wrinkles around her eye. The "after" photograph shows dramatic proof of the effectiveness of the laser in removing superficial wrinkles.

7/24 **Biolase Technology** announced that it had received FDA clearance for its DermaLase erbium (Er,Cr:YSGG) laser for a broad range of dermatological and general surgical applications, for incision, excision, ablation, vaporization, and coagulation of soft tissues. The laser, combined with the company's proprietary air/water spray, results in improved histological effects on tissue, including reduced trauma and faster healing. As a result, the DermaLase is effective for scar revision, removing tumors and cysts, performing diagnostic biopsies, and skin resurfacing, to name just a few applications. In preparation for what is expected to be significant interest in the product, the company is currently interviewing various distributors in appropriate markets and taking measures to increase production volume. According to CEO Donald LaPoint, as quoted in the *Los Angeles Times*, "Sales from the new product could put the San Clemente medical device company in the black next year for the first time."

7/24 **Current Technology Corporation** (Vancouver) and **Unimedix** (East Hanover, NJ) have announced the signing of a national marketing and distribution agreement for Canada. Under the terms of the agreement, Unimedix acquired exclusive Canadian marketing and distribution rights to Current's proprietary ETG (electrotrichogenesis) hair treatment device. The agreement has a potential value of $3.75 million over a five year period, according to the companies. Unimedix is a distributor of high technology medical equipment used in the fields of laser and cosmetic surgery, with a network of physicians and medical center contacts. Current Technology holds exclusive, worldwide marketing right to ETG, an electrotherapeutic device used for the treatment of certain types of common baldness (androgenetic alopecia). In a double blind study conducted at the University of British Columbia, treatment with the ETG device was shown to reduce hair loss and/or generate regrowth in the majority of participants (96%) enrolled in the study. Exclusive national distribution agreements have been signed for 24 countries worldwide. Letter of intent have also been signed with potential national distributors in an additional 8 countries. ETG treatment clinics have opened and are operating in New Zealand, Australia, Mexico, Panama, Indonesia, Argentina, and Canada.

7/24 **Surgical Laser Technologies** released its second quarter results, with revenues of $2.9 million and a net loss of $282,000 (3 cents/share). For the six months, sales increased 8% from the same period last year, to $6 million, and the net loss was reduced 73% to $479,000. Operating expenses were reduced by over $1 million, to $3.9 million, from $5.1 million in the same period in 1996. Keith Stoneback, president and CEO attributed the slow sales performance to sales of consumables that fell below expectations. His three main objectives for the remainder of 1997 are to expand the product line beyond laser-only offerings, and be focused on a specific surgical segment; distribution avenues for its proprietary fiber delivery systems must continue to be added through OEM and private label agreements; and the company must continue to manage and strengthen its balance sheet through effective cash and asset management.

MEDICAL/SURGICAL LASER UPDATE -- AUGUST 1997

7/10 **Schwartz Electro-Optics** announced that the FDA had cleared its higher powered version of the CLR 2940 erbium CrystaLase, which operates at 2 joules. (It is becoming apparent that several companies with erbium lasers for skin resurfacing/wrinkle removal have upgraded their systems to operate at between 1.5 to 2 joules, requiring only 1 pass to remove wrinkles, rather than two or more passes with the 1 to 1.2 joule systems previously announced. I collected information about most of the erbium lasers that were exhibited at the recent AAD meeting in New York, and hope to publish an updated table on these systems shortly.)

7/25 **Abiomed** announced that the National Heart, Lung, and Blood Institute had awarded it a $100,000 SBIR research grant to develop novel tissue solders to be used with the company's laser-assisted microvascular surgery system. In another notice, **Genzyme Corporation** acquired a 14% stake in Abiomed, involving the purchase of 1.15 million common shares at $13/share, or about $15 million. Genzyme and Abiomed will jointly develop and market biosurgical products based on the combined innovations of biotechnology and biomedical engineering from each, in the hopes of creating alternative approaches to surgical problems.

7/28 *The Gray Sheet* reports that **ESC Medical** had begun shipping its Epilight hair removal device the week of July 21st, following its 510(k) clearance on July 8th. The company plans to sell the device in the U.S. through its 80-person direct sales force. According to the report, ESC estimates it had sold approximately 100 Epilight systems internationally, generating about $10 million in sales. In the U.S., the device will sell for $155,000, higher than competitive laser devices. (The **Palomar** Epitouch sells for about $130,000, while the **Laser Industries** EpiTouch system sells for $129,000.)

The same issue of the *Gray Sheet* notes that the dispute between **Surgical Laser Technologies** and **C.R. Bard** (see the July 21 brief last month) was over claims by SLT that Bard reneged on its agreement to purchase and co-promote SLT's urological lasers. SLT had filed a $62 million suit. Settlement terms were not disclosed.

7/28 **Surgical Laser Technologies** announced that it had entered into a marketing rights agreement with **MedTREK Corporation**, and its president Don Gatto. The agreement provides SLT with exclusive worldwide rights to certain new products and devices used within minimally invasive otolaryngology and head and neck surgery (ENT). Financial terms were not disclosed. Gatto, formerly an executive with **Merocel/Xomed Corporation**, has developed a unique array of products designed to meet the special need of ENT surgeons. In conjunction with the agreement, Gatto has joined forces with SLT and will be integral to the development and marketing of the SLT product line into the ENT market.

7/28 **ESC Medical Systems** announced that it had obtained FDA clearance to market its Derma 20 high powered erbium laser in the U.S., for ablation and vaporization of the skin. The laser has a high repetition rate and delivers 1.7 joules per pulse, giving it a high average power for speedy treatment with maximum beam uniformity for high precision and gentle rejuvenation with reduced tissue thermal damage for speedy recovery. (See my comments following the 7/10 brief above. This is one of the new lasers introduced at the recent AAD meeting in New York. It was shown at both the ESC and **Luxar** booths at the show.)

7/28 **American Dental Technologies** announced it had filed a patent infringement suit against **Kreativ Inc.** of Albany, OR, based on ADT's air abrasive patents. The company believes that Kreativ is currently violating at least two of ADT's patents.

7/28 **ThermoLase** announced that its third fiscal quarter revenues more than doubled to a record $12.9 million, compared to $6.3 million for the same quarter a year ago. The net loss for the quarter was $3.7 million (9 cents/share), compared with $22,000 last year. The company also said that it would introduce its SoftLight 2.0 shortly, which is expected to increase the efficacy of its hair removal process.

7/28-
7/29 **PLC Systems** was turned down by the FDA's Circulatory Systems Devices Panel by a 9-2 vote, for its TMR Heart Laser to treat angina. The panel cited large gaps in the company's application that made it impossible to judge the safety and efficacy of the device. The panel said it believes that the Heart Laser holds "great promise", but more data was needed before approval. According to Dr. Susan Alpert, director of the FDA's office of device evaluation, a significant proportion of the data was missing, including followup on some 40% of the patients treated. As noted in the *Wall Street Journal's* writeup, "The panel's tough review of PLC may come as a wakeup call to other companies seeking approval for similar devices...including **CardioGenesis** and **Eclipse Surgical Technologies**. As note in *The Boston Globe*, the vote was a set back for PLC which had been ahead of its competitors on the road to becoming the first company with an approved heart laser for TMR.

The following day, when trading was re-started in the company's stock, it plummeted 48% to close at $13.375 a share, down $12.125. The company issued a statement saying it intended to resubmit its application with more complete data by no later than November. Company chairman Robert Rudko said that he had no doubt that its application will be approved, it is just a matter of how soon the reformatted data can be represented to the FDA. Dr. Rudko blamed the FDA staff for the rejections, saying that it had led the company to believe its clinical data would be sufficient for the panel. The Heart Laser remains on the expedited review path and will continue to be used by its clinical investigators.

Melissa Wilmoth, an analyst with **Smith Barney** said that the large gap in information was caused by the panel's rejection of data from a non-randomized trial in which all patients were treated with laser revascularization. The panel decided to accept only data from a randomized trial in which some patients were treated with TMR and others were treated with drugs. According to a spokesperson for the company, PLC had received clearance from the FDA to file its PMA with 12-month data from the non-randomized trial and six-month data from the randomized trial. The company would have waited until the fall if it had known ahead of time that the panel wanted to see 12-month followup data from the randomized trial. Those results will be available

in September. Wilmoth said that the panel's rejection is likely to delay full FDA approval of the heart device by as much as a year. She downgraded the stock following the vote by the FDA's panel. (Ms. Wilmoth has written a comprehensive report on PLC -- **ESC Medical**, which I have just received and will review later this month.)

Eclipse Surgical is expected to be the next TMR company to get a panel review of its laser system, as the company filed its PMA earlier this month. CardioGenesis is expected to submit its PMA by the end of the year, according to analyst Kurt Kruger of **Montgomery Securities**, the underwriter of CardioGenesis' IPO in May of 1996. Mr. Kruger said that although the company is behind its competitors in the FDA approval process, it is compiling a rigorous set of data to submit to the FDA.

7/29 **Spectranetics Corporation** said that its application for laser sheath removal was unanimously recommended by the FDA's Circulatory System Devices Panel Advisory Committee. The recommendation included certain labeling changes which will be reviewed by the FDA prior to market approval. The panel's vote represents the first formal recommendation of a device specifically designed to assist in the removal of pacemaker and ICD leads, approximately 300,000 of which are implanted worldwide annually, and as many as 10% of which may require removal for various medical reasons. The data presented to the advisory panel showed that the success rate with the laser sheath was 94% compared to approximately 65% for non-laser removals.

7/29 **Rodman & Renshaw** have initiated coverage of **Premier Laser Systems** with a buy rating. In a research note, R&R estimated that Premier would post a loss of 82 cents/share in fiscal 1998 (ending in March) and would earn 57 cents/share in fiscal 1999. (I have requested a copy of the report for review.)

7/29 **Candela Corporation** announced that higher than anticipated start-up costs incurred with its new skin care treatment centers will result in the company reporting a net loss for the fiscal fourth quarter ended on June 28th. The company said its core cosmetic laser and medical device business had strong revenues and, as a result, Candela will report a profit for the full fiscal year when it releases its earnings in early August. Through the first nine months of fiscal 1997, the company had revenues of $25.8 million and net income of $1.5 million (27 cents/share). For the year, revenues are expected to grow 15% from the $30.4 million reported for fiscal 1996, but profits will be lower than the $1.2 million (22 cents/share) reported last year. Commenting on the fiscal fourth quarter, CEO Gerard Puorro said that, "Once we saw that business at our LaserSpa skin care centers was developing more slowly than had been forecast, we began to address these disappointments much more aggressively. We have moved quickly to implement the necessary changes while bolstering our marketing programs. These steps should enable our Boston and Cairo skin care centers to be operating

profitably by calendar year-end, with our Scottsdale facility moving into the black by the end of our current fiscal year."

7/30 According to *Medical Industry Today,* **Somnus Medical Technologies** has received FDA approval for it Somnoplasty RF device to treat snoring and sleep apnea. According to the company, the device uses radio frequency waves to reduce and tighten tissue in the back of the mouth and throat, causing the uvula to retract. Clinical trials in the U.S. showed that the procedure caused less trauma and quicker recovery than conventional laser or knife-based surgeries, minimizing bleeding and pain and preserving the mucosa or surface layers of tissue. During the procedure, a tiny electrode is positioned beneath the surface layers of the soft palate and the Somnoplasty device delivers low levels of RF energy to create molecular friction within the tissue, generating much less heat than lasers, and coagulating the tissue in a confined area. **Medtronic** distributes the Somnoplasty device in Europe and selected Pacific Rim countries.

7/30 **Palomar Medical Technologies** announced record second quarter revenues of $24.8 million, up 41.3% over the same period last year. The company also reported a net loss of $14.8 million (49 cents/share) for the quarter, up from $7.9 million a year ago. For the six-month period, revenues were $44.9 million with a net loss of $30.2 million (66 cents/share). Medical revenues of $7.4 million, were approximately one third of the company's sales, and up significantly from the first quarter's $2.7 million. The increase was attributed to robust sales of the company's Epilaser hair removal system.

7/30 **Laser Photonics** announced that its majority owned subsidiary, **AccuLase Inc.** had entered into a series of agreements with **Baxter Healthcare Corporation**, which provide for a worldwide license grant to Baxter for AccuLase's excimer laser and laser delivery system for cardiovascular and vascular applications. AccuLase will receive $1.55 million from Baxter and will supply it with lasers and receive a royalty on sales of disposable devices. Baxter will assume responsibility for funding and managing the regulatory approvals process as well as managing marketing and sales efforts for the AccuLase excimer laser system, including current efforts in TMR. The agreements grant a security interest in AccuLase's assets to secure its performance, and are conditional upon subordination of an existing lien on AccuLase assets by **Helionetics**, Laser Photonic's principal shareholder.

7/30 **PLC Systems** announced its second quarter and six month results with quarterly revenues of $3.4 million and a net loss of $2.7 million (16 cents/share). For the six month period, revenues were $5.0 million with a net loss of $5.7 million (36 cents/share). The company said it had shipped 8 Heart Lasers in the second quarter, three placements and five sales. PLC chairman noted that the company had expected to ship approximately 50 laser systems this year, which will be impacted by the FDA

panel decision, delaying a number of shipments into future quarters. The fifty shipments were contingent on receiving FDA marketing approval this year.

In a related item, beginning on August 1st, a series of shareholder suits have been filed against the company, basically claiming that shareholders were misled by statements made by management about FDA approval, and alleging that the clinical trial data submitted by the company to the FDA was flawed and produced unreliable results. At last count -- as of August 11th, there were approximately 9 such lawsuits, which, in all likelihood, will be combined into a single class action suit.

7/31 **Laser Industries** announced that the FDA had granted marketing clearance for its computerized 2040 erbium SilkLaser for use in excisions, incisions, ablation, vaporization, or coagulation of soft tissue in plastic and dermatologic surgery. The new computerized laser system is expected to begin shipping in September and is for use in superficial skin resurfacing applications. (The laser and scanning system was on display at the AAD in New York.)

8/1 **Venisect**, the distributor of the Laser Lancet, the first laser finger perforator for obtaining blood samples to win FDA approval (in April) has changed its name to **TransMedica International**.

8/1 **CardioGenesis** announced that it had treated its first patient in its U.S. clinical trials of percutaneous TMR. Allen Hill said that the start of the U.S. clinical trials for its PMR system represents the launch of a major clinical program for the company, and furthers its leadership in the field of TMR.

8/4 **Spectranetics** announced that it had received conditional approval from the FDA to commence testing its minimally invasive peripheral excimer laser angioplasty (PELA) technology at ten medical institutions. The PELA system is designed to treat total occlusions, or blockages, in leg arteries, a condition suffered by more than 3 million people in the U.S. The PELA trial is aimed at treating patients with blockages longer than 10 centimeters for whom medical therapy is inadequate, and bypass surgery inappropriate. As previously noted, Spectranetics received a favorable recommendation from the FDA's advisory panel for its laser sheath system for pacemaker and ICD leads. Training is ongoing to complete expansion to 15 additional sites in the U.S., pending the FDA approval for market release.

8/5 **Laser Industries** reported its second quarter results with sales up 32%. For the six-month period, sales increased by 25%. Second quarter sales reached $19.2 million with net income of $2.7 million (32 cents/share). For the six months, sales were $35.6 million and net income was $5.4 million (62 cents/share). Benjamin Givli, chairman and CEO attributed the increases in the quarter to the company's aggressive acquisition and marketing strategy. The acquisition of **Spectron Laser Systems** in

April allowed the company to ramp up ruby laser production capabilities, which had a direct impact on sales of the company's Epitouch laser hair removal system. The acquisition also created a new revenue stream for commercial laser systems sales for scientific and industrial applications.

8/5 **ThermoLase** announced that it had entered into an agreement to sell $115 million of 4 3/8 percent subordinated debentures due in 2004. The debentures will be convertible into share of common stock at a price of $17.385, and are guaranteed on a subordinated basis by **Thermo Electron Corporation**, ThermoLase's parent (through ownership by **Thermotrex**).

8/6 **Candela Corporation** announced that revenues for its fiscal fourth quarter rose to $9.7 million, resulting from increased sales of its primary cosmetic and medical laser equipment business -- see the July 29th brief above. For the quarter, the company reported a net loss of $1.3 million (23 cents/share), compared to a profit of $651,000 for the same quarter a year ago. For the fiscal year, the company had revenues of $35.5 million and net income of $238,000 (4 cents/share), compared to $1.2 million a year ago. CEO Gerard Puorro noted that the company began shipping its new SkinLight erbium laser and its Dynamic Cooling Device, which selectively cools the top layer of skin during laser treatments. (No mention was made in the release of the pending suit between Candela and the **Regents of the University of California**, filed in June, over Candela's loss of exclusivity for marketing the device based on breach of contract. For more on this law suit see the August 8th brief below.)

As noted in the July 29th brief, Puorro blames the poor performance of Candela's laser skin centers for the quarterly loss and reduced income for the fiscal year.

8/6 **PDT Inc.** reported its second quarter results with revenues and net interest income decreasing to $874,000 from the $1.4 million a year ago. The net loss for the quarter was $5.7 million (46 cents/share), up from a net loss of $1.7 million in last year's second quarter. For the six-month period, revenues and net interest income was $1.8 million and the net loss was $11.2 million (90 cents/share). During the quarter, the company received notification of allowance of three additional patents for its drugs and devices. The first patent is for a light diffusing cardiovascular balloon catheter that allows blood flow while inflated, permitting a longer photodynamic therapy treatment without blocking circulation. The second patent covers a more efficient light emitting diode technology, operated with a 110V AC power source. The third patent covers the linking of monoclonal antibodies to certain photoreactive compounds.

8/6-
8/7 **PLC Systems** reacted to the first three class action shareholder suits that had been filed in Boston against the company (there are at least 9 suits now). Chairman Dr.

Robert Rudko stated, "We believe that the allegations in the complaints are completely without merit and we intend to vigorously defend these actions."

The next day the company released an announcement about the two studies presented to the FDA's Circulatory Systems Devices Panel, the non-randomized study of 201 patients and a 198 patient controlled randomized study. At the panel meeting, the only data reviewed was the data from the randomized study, with the panel requesting that the company submit the additional 12 month followup data as soon as it was available. To comply with the request, the company has stepped up its data collection, with the last patient enrolled eligible for final followup in September. PLC intends to meet with the FDA shortly to finalize a plan for the resubmission, and expects to submit the data from the completed study later in the fall.

8/7 **Ion Laser Technology** released its fiscal first quarter results showing revenues of $2.0 million, up from $1.4 million for the same quarter a year ago. Reflecting the company's efforts in dental product sales, first quarter dental revenues grew from $942,000 in fiscal 1996 to $1.3 million in 1997. The company had a net loss for the quarter of $76,500 (1 cent/share), as compared to net earnings of $134,000 last year. This represents a marked reduction from the $1.1 million net loss for the fiscal fourth quarter. Increased marketing expenses, enhanced personnel, customer support and warranty costs, and engineering costs for the new argon 6800 laser introduced in May accounted for the net loss in the quarter. Tooth whitening reagent sales and revenues for laser tooth whitening kits sold to existing BriteSmile locations (necessary for each patient treatment) accounted for a 36% increase in dental product sales.

8/7 **QLT PhotoTherapeutics** announced that it had received clearance from health authorities in Germany to begin marketing Photofrin as a treatment for early-stage lung cancers. Specifically, Photofrin was approved for the curative treatment of patients with early-stage endobronchial non-small cell lung cancer (NSCLC) who are not indicated for surgery or radiotherapy. According to QLT market research, approximately three-quarters of the 36,800 new cases of lung cancer diagnosed in Germany each year are NSCLC. Photofrin will be marketed throughout Europe by QLT's marketing partner, **Beaufor Ipsen Group**, who signed a licensing, co-development, and marketing agreement in December of 1996, for exclusive European rights to Photofrin and a second generation compound for use in the treatment of cancer, pre-cancerous conditions, and benign prostatic hyperplasia. As part of the German approval, Beaufor Ipsen will pay a $1 million milestone payment to QLT.

In Europe, Photofrin has already received approvals for the treatment of lung and esophageal cancers in France and the Netherlands, while an approval is pending in Italy. BI and QLT plan to file for marketing approval for Photofrin in an additional 11 countries in Europe later this year, and BI will launch Photofrin in all cleared European countries this fall.

Photofrin is currently being marketed in the United States for the treatment of esophageal cancer by **Sanofi Pharmaceuticals**, in Canada for bladder and esophageal cancer by **Ligand Pharmaceuticals**, and in Japan for early-stage lung cancer, superficial esophageal cancer, superficial and early-stage gastric cancer, early-stage cervical cancer and cervical dysplasia by **Lederle (Japan) Ltd.**.

8/8 I received a copy of the complaint and first response and counterclaim in the suit between **Candela Corporation** and the **Regents of the University of California**. The complaint was originally filed in Massachusetts by Candela on June 13th, with the response and counterclaim filed on July 21st. As noted above, the complaint involves an attempt by the Regents to terminate the technology license given to Candela for the exclusive use of the dynamic cooling device (DCD), assigned to the Regents by the inventors. Candela claims that the termination is improper, as it has complied with all the terms of the license entered into on December 19, 1994. That license grants Candela exclusive rights "to use the device in conjunction with a laser that Candela has the legal right to manufacture, sell, or upgrade for use in dermatology and plastic surgery procedures which do not involve the shrinking or removal of collagen and not in conjunction with any other type of laser".

The complaint states that in a letter dated June 10, 1997, the Regents provided Candela with a Notice of Partial Termination, listing certain obligations in the Exclusive License with which Candela allegedly failed to comply, specifically, a) not providing certain information relating to Candela's due diligence obligations; b) not filling the market demand for the Patent Products following commencing of marketing; and c) not paying (patent) prosecution expenses purportedly more than 90 days overdue. Among other things, the termination notice purports to terminate unilaterally the agreement's field of use and substitutes a more restrictive field of use than originally agreed to. Candela asserts that it has fully complied with all of its obligations, spending hundreds of thousands of dollars on the manufacture and development of the DCD, and has worked diligently over the past year to get the device ready for shipment to customers by the end of June 1997. (Planning to ship 25 lasers and DCDs by that time.) Candela states that it had received more than 20 orders for the DCD and over 135 inquiries. Also, the company claims that it has paid the invoice for patent prosecution expenses.

For these reasons, Candela claims that the Regents have materially breached its contractual obligations to Candela by "improperly and without cause purporting to partially terminate the Agreement by issuing the Termination Notice", and asks for a declaration that the original Exclusive License Agreement remains in full force and effect, and asks for an award of damages in an amount to be determined at trial.

The Regents responded on July 21st with its answer and counterclaim, agreeing that there was a controversy between the parties. The Regents denied all of the allegations

by Candela, and allege that they have not breached or terminated the Exclusive License Agreement. They state that Candela had an obligation to fund clinical trials at the Beckman Laser Institute that were required for commercialization of the DCD. Candela failed to do so. Candela also had an obligation to diligently proceed with the development, manufacture, and sale of the DCD and displayed a prototype at the AAD meeting in San Francisco on March 23/24th, representative of the final version. Operation of the prototype was observed by University employees who note that the prototype was non-operative and did not practice the invention licensed to Candela. The Regents also claim that Candela has offered the DCD for sale with lasers whose use falls outside of the field of use granted to it, and had agreed to market the licensed products within six months of receiving approval to do so by the FDA and has failed to do so. The Regents ask the Court for a declaratory judgement that Candela has in fact breached the Exclusive Licensing Agreement and that the Regents notified Candela of the breach and that Candela remains in breach. It asks the Court further to deny any request by Candela for damages, including attorney fees and costs, while awarding the Regents with the right to terminate the Exclusive Agreement and to reduce Candela's exclusivity license to a non-exclusive basis.

(As I have said many times before, only the attorneys get rich!)

8/13 **Premier Laser Systems** reported its fiscal first quarter results with revenues increasing by 68% to $2.1 million from $1.3 million for last year's fiscal first quarter. The company had a net loss of $713,000 (8 cents/share). President and CEO Colette Cozean noted that the increased sales revenue was attributable to increased sales of argon and diode dental lasers for tooth whitening, composite curing, and soft tissue applications, not for sales of the recently cleared Centauri erbium laser for hard dental tissue uses. Because of the timing of FDA clearance for the latter in mid-May, and the need to train dentists prior to shipping of the units, the actual number of erbium dental lasers shipped was nine during the quarter, with seven others allocated to demonstrations in various locations. The order backlog for all laser systems stood at $3.4 million of which $2.6 million was for the erbium dental laser. Since starting dentist training sessions in June, more than 100 dentists have been trained and Premier plans to train up to 500 additional dentists per month across the U.S. and Europe beginning this fall. The company plans to build 25 dental erbium lasers in August, 40 in September, ramping up to a planned 100 systems per month by the end of 1997. The company has continued to have discussions with the FDA in regard to additional submittals for both dental hard tissue uses on children under 18 and for root canal/pulpotomy procedures. A submission for cataract emulsification clinical trials is expected to be made shortly.

Premier's acquisition of Houston-based **EyeSys Technologies** is still pending regulatory approvals, with the anticipated closing in mid-September.

8/13 A new medical laser company, **United Laser Industries** sent along an announcement offering green and yellow light copper vapor lasers, and red light gold vapor lasers manufactured in Russia and other European countries. The lasers are being offered at extremely low prices, ranging from $14,000 for a 1.5 watt red gold vapor laser for PDT applications, to $13,000 to $27,000 for the copper vapor systems, ranging in power from 1 to 10 watts. The gold and copper vapor lasers are produced in Russia by a company called **Mechatron Laser Technics & Optics**. For further information call Dr. Michael Diglov at United Laser Industries at 713-961-7276.

8/13 **Smith Barney** began coverage of **PLC Medical Systems** just prior to its appearance before the FDA's Circulatory Devices Panel, July 28th, and had its PMA for TMR turned down. In this report, analysts Melissa Wilmoth and Stephen Pignalosa were bullish on PLC's prospects and anticipated their receiving approval, giving them a six to nine-month's head start over competitor, **Eclipse Surgical**, whose PMA should be the next reviewed by the FDA's advisory panel.

The report positions PLC as the leader in the development of lasers for TMR, the market for which is estimated to exceed $1 billion worldwide. The initial target population for TMR is end-stage coronary artery disease patients who have no other option, suffering from intractable angina. An interesting aspect of the FDA regulatory process noted, is that PLC and Eclipse are on expedited tracks for approval -- until one achieves it, at which time the other's track is dropped back to normal.

The analysts note that HCFA has suspended Medicare reimbursement for the procedure, effective last May 19th. However, it is expected that reimbursement will be reinstalled concurrent or shortly after FDA approval for the procedure.

Also, several of PLC's competitors are clinically testing percutaneous TMR (PTR), with PLC roughly 18 months behind both **CardioGenesis** and Eclipse. PTR is not expected to reach the U.S. market until late 1999. And, long term efficacy of TMR remains a question, as does the mechanism of how TMR works -- it is only known that reperfusion takes place following TMR and there is a reduction in angina.

The report provides an excellent overview of heart disease and the market potential, traditional treatment methods, and where TMR fits in. It also compares the Heart Laser (CO_2) with the other major competitors lasers (holmium), but doesn't do more than mention the excimer developers. (Leaving out a couple of competitors -- **Cardiodyne**, a subsidiary of **Trimedyne**, and **CorMedica**, who recently struck a development deal with **C.R. Bard**. It doesn't discuss the implications of **Baxter Healthcare** entering the fray via its very recent agreement with **AccuLase/Helionetics** -- which occurred after the report was written.) Some of the other competitors like **Circulase** and **U.S. Surgical/Medolas**, that are farther behind in the regulatory race, are barely mentioned.

There is a little about the patent positions and battles but, again, no mention of the potential fight between Cardiodyne and CardioGenesis or PLC over Trimedyne's patent covering firing the laser at the peak of the R wave (vs. PLC's patent that fires the laser at the beginning of the R wave).

Analysts Melissa Wilmoth and Stephen Pignalosa applaud PLC's marketing strategy, that of placing lasers and charging a per use fee, as well as selling them directly in other instances. The report looks for revenue growth for PLC from $14 million in 1997 to $98 million in 2000, with income reaching $36.7 million by that time (all based on a 1997 marketing approval). To reach those levels, PLC would have to sell 190 lasers and place an additional 345. Hard to do without an approval!

All in all, a good analysis of the TMR market and strongly supportive of PLC's position and strategy.

I also received the same analyst's July 11th report on **ESC Medical Systems**. Apparently, they have picked up coverage of this company from Stephen Handley, who previously covered the company -- see our coverage of his report last March -- who has left Smith Barney. The analysts wrote a positive report on ESC, noting that it appeared attractive and they expected a "near-term pop" in the stock if the company received FDA approval for its EpiLight hair removal device -- which came through on July 7th, but apparently after their report had gone to press. The report is thorough in coverage of the company and its products, containing an interesting comparison chart showing the ESC product line in comparison to its competitors in the various applications in which they all compete. Unfortunately, the chart is not as up-to-date or complete as it could be. The analysts note that the ESC is the clear winner in the laser hair removal patent war since its pulsed light technology is not subject to any of the litigation.

8/13 **QLT PhotoTherapuetics** released its financial results for the second quarter with a net loss of $5.7 million (22 cents/share) on net revenues from investment and royalties of $1.4 million. For the six month period the company had revenues of $3.4 million and a net loss of $8.2 million (32 cents/share). The company ended the quarter with available cash of approximately $96.2 million and no long term debt. Kenneth Galbraith, senior vp and CFO noted that quarter to quarter unit sales of Photofrin increased by 10%, as growth in the U.S. market was offset by lower than expected sales in Japan and Canada. U.S. sales for the second quarter reflect the initial impact of new marketing programs implemented by **Sanofi Pharmaceuticals** in the first half of 1997. The company is currently scheduled to appear before an FDA advisory committee hearing on September 18th for a supplemental filing for the use of Photofrin in the treatment of certain types of non-small cell lung cancer. An expanded approval for Photofrin in the U.S. and the expected European launch by **Beaufor**

Ipsen should significantly increase the market potential for Photofrin, according to Galbraith.

8/13-
8/14 **DUSA Pharmaceuticals** announced that all patients entered in its Phase III Levulan (ALA) PDT trial for the treatment of actinic keratoses have completed their 12 week followup as scheduled. The two parallel Phase III trials at 16 sites across the U.S. involved over 240 patients, each with between 5 and 15 AKs. Now that the clinical portion of the study is completed, DUSA will begin collecting and analyzing the data as the basis for its planned NDA submission, expected to occur in late 1997 or early 1998. The company remains optimistic about the outcome of the current trials.

The company also released its second quarter results with a net loss of $1.7 million (18 cents/share). As of June 30th, the company had cash and U.S. securities totaling $16.3 million and shareholders' equity of $15.9 million.

The following day, DUSA announced that it had filed an IND to begin a Phase I/II multicenter clinical trial using Levulan (ALA) PhotoDetection (PD) for bladder cancer. The seven center study involving 60 patients is designed to assess the ability of Levulan PD to detect bladder cancer in high-risk patients compared to current methods of detection. The study will use light sources and cystoscopes provided by **Richard Wolf Medical Instruments Corporation**, following the recent signing of a strategic co-operation agreement with the company, a world leader in the field of endoscopy. The trial is scheduled to begin in the third quarter, following FDA review of the IND.

8/14 **Laser Corporation** announced its second quarter results with revenues of $1.4 million resulting in net income of $84,900 (12 cents/share). For the six month period, revenues were $2.4 million with a net loss of $74,900 (11 cents/share). The net income in the second quarter resulted from increased OEM sales, according to president and CEO Joyce Wickham. Sales of the company's new medical products are anticipated to begin later this year.

8/14 Dr. John Cooke, of the **Stanford University' Lymphedema Center**, said that patients hobbled by clogged leg arteries may be eligible to receive a new treatment using laser light to activate a drug, that causes plaque in blood vessels to dissolve. The experimental treatment, called photoangioplasty uses lutetium texaphyrin, from **Pharmacyclics**. The drug is injected into the bloodstream and accumulates in the plaque causing the clogged vessel. A laser light, threaded to the site via a catheter is switched on, activating the drug and creating free radicals which cause mild damage to the plaque while not affecting normal tissue.

8/15 **PLC Medical System** announced that it had secured the second $10 million investment, completing a $20 million convertible debenture financing from **Southbrook International Investments, Ltd**; **HBK Investments, LP**; and the **Brown Simpson Strategic Growth Fund LP**. The funds will be kept in escrow and received upon filing a registration statement later this month.

In a related development, another class action law suit was filed by a New York law firm against the company, bringing the total of such lawsuits to about 10, I believe.

8/15 **BioLase** announced its second quarter results with sales of $433,000 and a quarterly loss of $677,900 (5 cents/share). For the six month period, sales were $567,000 and the net loss was $1.4 million (11 cents/share). Donald LaPoint, president and CEO said that the turning point for the company occurred during the second quarter with the shipment of the first production units of its laser-based Millennium products, which incorporate its HydroKinetic technology. The company expects continued growth in sales in the third quarter and beyond. Also, following the close of the quarter, the company received the news that its er,cr:YSSG laser system, the DermaLase, had been FDA approved for broad use in a variety of dermatological soft tissue applications. BioLase intends to commence marketing the system domestically and internationally in September.

8/15 **Trimedyne** reported results for its fiscal third quarter with revenues of $2.5 million, up from the preceding quarter, but down from the same quarter last year. The net loss for the quarter was $1.7 million (15 cents/share), about the same as the preceding quarter. For the nine month period, the net loss was $4.2 million (39 cents/share). The loss included $880,000 of startup and R&D costs of its 90% owned subsidiary, **Cardiodyne**, and a reserve of $200,000 for excess and obsolete inventory. Animal studies for Cardiodyne's TMR system have been completed and it plans to file an IDE to commence human clinical trials shortly, with clinicals expected to begin in late 1997. The company also notes that its "new type" of cosmetic laser, announced earlier this year, is expected to be available for sale in early 1998. Among the procedures that allegedly can be performed with the laser are wrinkle and scar removal without erythema (skin burning) and hair removal which may prove to be permanent. (The laser was expected to be shown at several cosmetic surgery meetings earlier this year, but was not. I understand that technical problems have plagued its development.)

8/17 The August 17th issue of *The New York Times* contains an interesting story about a new method of liposuction, using ultrasonic technology to liquify the fat for safer and easier removal. The story notes, however, that not all doctors are enthusiastic about the technique, observing that inexperienced surgeons have burned patients with the hot ultrasonic equipment.

8/18 **Mehl/Biophile** announced that its wholly owned subsidiary, **Mehl Group Marketing** had installed 31 Chromos 694 long pulse laser hair removal systems with doctors and others in the U.S. during the past 30 days, and that the NY City training center continues to function as both a training and certification center for professional licenses of the system. Further, the company has also completed a training program in Orlando, FL and that an additional 20 laser systems will shortly be installed in the Florida area. A third training center is scheduled to open shortly on the West Coast. Mehl Group intends to have approximately 100 laser systems installed in the U.S. by the end of September, with a total of 300 installed worldwide by the end of 1997.

8/18 **Palomar Medical Technologies** announced that it had reached a settlement with **Commonwealth Associates** in its legal battle over services that were to be provided by Commonwealth. In January, the U.S. District Court for the Southern District of New York had granted Commonwealth's motion for partial summary judgement as to liability. In June, a federal magistrate awarded damages of $3.17 million in Commonwealth's breach of contract case against Palomar. Palomar appealed the award and settled for $1.875 million, being reimbursed $1.6 million of its $3.5 million bond that had been posted for the appeal.

8/19 **Cell Robotics** announced that it had received FDA clearance to market its Lasette laser finger perforator. The hand-held, battery-operated device produces a small hole in the finger with a single pulse of laser light. The initial clearance is for glucose and hematocrit testing in adult patients by professional health care providers. Additional clearances for juveniles in clinical settings and home use for diabetics will be applied for as supplemental approvals at a later date. The device will replace the use of painful lancets for drawing blood samples. Plans call for a fall introduction in clinical markets in the U.S. and the Far East, with subsequent introductions into Europe.

8/20 **Laserscope** announced that it had received an "approvable" letter from the FDA on its supplemental PMA application for use of its laser systems with Photofrin in the treatment of certain early and late-stage lung cancers. According to the letter, final FDA approval for marketing will come after the FDA approves the related application from **QLT PhotoTherapeutics** on its drug, and the related "bundled" laser delivery systems. A hearing before an FDA advisory committee is scheduled for September 8th.

8/21 Both **Mehl/Biophile** and **Palomar Medical Technologies** released statements about a court ruling in their litigation on patent infringement. It is interesting to note the different "spin" put on the ruling by both sides. According to Mehl, the Federal District Court in New Jersey has rejected Palomar's attempt to prevent Mehl from pursuing "unfair competition claims relating to allegations of improper promotion of Palomar's Epilaser for hair removal" in its suit for patent infringement. Mehl claims it

is now free to pursue allegations that Palomar illegally marketed the Epilaser prior to FDA clearance.

On the other hand, Palomar, in its news statement, said that the judge had granted Palomar's motion to dismiss a "portion of the unfair competition claims", which was a result of a June motion filed by Palomar to dismiss the unfair competition claim, to the extent it was premised upon supposed violations of the FDA regulations. The Court granted the motion "to dismiss the plaintiffs' unfair competition claims to the extent that it requires application or interpretation of the FDA regulations". The Court permitted Mehl "to proceed on grounds that support a New Jersey common law unfair competition claim and do not require the court to interpret or apply the FDA regulations". (What did they say?)

8/21 **Cell Robotics** released its second quarter results showing revenues of $278,000 and a net loss of $619,000 (12 cents/share). According to the company, all of the revenues resulted from sales of laser instruments into research lab markets, and did not reflect any sales of medical products, which were just recently approved for marketing by the FDA. The company expects a significant contribution to revenues in the near future from its recently cleared erbium dermatology laser and its Lassette laser finger perforator.

8/21 **Ion Laser Technology** sent out a "Dear Shareholder" letter, with highlights of its annual meeting held August 18th. President and CEO Wyatt Cannady reviewed the following points: the company had stopped the cash flow hemorrhaging, reducing cash burn from $2.9 million to 4432,000 in the latest quarter from the previous six months; had raised new funds to accomplish its goals, including a $3 million private placement and a $1.2 million line of credit, which was not currently being utilized; reduced the rate of capital expenditures for FY '98; reduced the rate of procurement and inventories; recruited a new vp of marketing and sales who should be joining the company in September; continued to invest in R&D projects and new products/systems for future growth, including the Argo 500 (HP) and the next generation of Laser Tooth Whitening Chemical and composite products to be used with the new device; revamped the marketing program; and negotiated a strategic alliance with DMD (**Dental/Medical Diagnostic Systems** -- see the July 1 brief last month) to increase revenues 2-3 fold in the year following the signing of the agreement. Also discussed were the patents for the LTW BriteSmile system, a license for which was granted to dentists using the system. The company is investigating whether the two other companies selling tooth whitening systems (**Premier** and **LaserMed**) were in violation of its patents.

8/21 **ESC Medical Systems** said it was responding to a letter received by its subsidiary, **Luxar Corporation**, from the FDA regarding Luxar's Silhouette Therapeutic Massage System, a non-invasive, therapeutic device which Luxar recently began marketing to

physicians. In the letter, the FDA indicated that it does not allow the use of certain terms in the company's promotional materials which imply the product improves the appearance of cellulite. The Silhouette System will continue to be promoted for its cleared clinical indications, which include local blood circulation and muscle relaxation. The marketing of the Silhouette in international markets is not affected by the warning letter.

8/22 **Physical Science Inc.** (PSI), has been awarded $1.6 million in funding from the U.S. Army Missile Command to design, fabricate, and characterize compact, wavelength diverse, high efficiency dye lasers employing various solid hosts. The research initiative focuses on understanding the photophysics of the dye/host interaction, as well as determining the optimum laser configuration for different applications. The emerging solid-state dye laser technology has the potential of addressing a number of applications that require lasers in the visible portion of the spectrum. Commercial applications include medical procedures and remote sensing of environmental conditions. The work is being headed by Henry Aldag, formerly with **Palomar Medical Technologies**, a pioneer in the use of polymer solid hosts for dye impregnation.

8/25 This week's issue of *Barrons* contains an article showcasing **Laser Industries**, entitled, "Shine a Light on Me". Author Harlan Byrne discusses Laser Industries emergence as a leader in the "fast-developing" medical laser industry, especially "the vanity market for such things as wrinkle and hair removal, and for throat surgery to reduce snoring...another market expected to grow fast is one for the use of lasers for no-noise, no-vibration and practically painless dental drilling." (Although, I wasn't aware that Laser Industries was developing a dental laser!) Byrne comments that aided by "a stream of new products and aggressive marketing" the company has produced sales growth over the past five years of more than 23% compounded annually, well ahead of the industry average of about 16%, according to Laser Industries. And profits have soared at a rate of 58% a year in the same period. Quoting president and COO Yacha Sutton, "We believe we can sustain annual sales growth in excess of 20%, and even higher earnings gains."

According to Sutton, Laser Industries is the leader in the aesthetics market which, according to an outside survey (?) last February noted that Laser had sold 1500 of the 4200 laser systems in use worldwide, compared to **Coherent**, with only 1200 systems sold. (I would guess that Coherent might dispute those numbers.) Beginning next year, Sutton sees a major market opening for dental lasers for drilling hard tissue. With more than 700,000 dentists worldwide, the market appears huge. Laser Industries is still conducting clinical trials on its product, and doesn't anticipate FDA approval for marketing before next year. Acknowledging that **Premier Laser** had beaten them to the punch, Sutton expects his company's product to be faster, less expensive, and thus more competitive.

Sutton also discussed Laser Industries move into the service side of the business by opening its own laser centers. The first one was opened earlier this year in Tel Aviv followed recently by centers in the New York City area -- Manhattan and suburban Larchmont, with centers planned for later this year in Rishon Lezion, Israel, and in Madrid. In a sidebar to the story, Sutton doesn't rule out the possibility that his company could be an acquisition target for much bigger companies, such as **Johnson & Johnson** and **U.S. Surgical** (both of which have recently made inroads into the medical laser industry!).

The company's stock price increased on Monday, following the positive story.

MEDICAL/SURGICAL UPDATE -- SEPTEMBER 1997

8/13 **EquiMed** reported its second quarter results with net revenues of $18.3 million and net income of $3 million (66 cents/share) for the quarter. For the six-month period, net revenues were $37.3 million and net income $5.8 million ($1.26/share).

EquiMed is now a transitional holding company focused primarily on providing physician practice management services, information technology, and outsourcing services primarily to the health care industry. It provides medical practice management services to its affiliated oncology centers and medical practices. The company also operates a cosmetic laser treatment center and is involved, through a captive insurance company, in the reinsurance of professional liability and worker's compensation insurance.

8/18 **Cynosure** announced that it had received 510(k) clearance to market its PhotoGenica LPIR (long-pulsed infrared) laser for the removal of unwanted hair. This flash-lamp excited, solid-state alexandrite laser, operating at 755 nm, has been sold domestically since December 1996 for the treatment of larger leg veins, and internationally, for both hair removal and the large leg vein applications. The laser utilizes the theory of Thermokinetic Selectivity, by delivering a combination of high fluences (40 J/cm^2) and long pulses (up to 20 msec) to damage large targets in the dermis -- like hair and large leg veins -- while leaving smaller surrounding structures unharmed (according to the manufacturer). (Cynosure joins a host of others offering lasers and non-laser energy sources for the removal of unwanted body hair. For additional information about hair removal, see my article in the April and May issues of *Medical Laser Report*.)

8/26 **Urologix** announced that it had obtained marketing approval for a new microwave system for treating enlarged prostates. The system, known as the T3 System during development, will be introduced to the market as the Targis system. With U.S. marketing approval, the company now has clearance to market Targis in the 18 European Union countries, the U.S., Japan, and Canada.

Targis employs a flexible catheter that does not require puncturing of the urethra to destroy the diseased cells, enabling the administration without general or regional anesthesia or intravenous sedation. The system targets heat therapy delivery into the confines of the prostate while maintaining patient comfort during the procedure. The company expects to begin marketing the system during the fourth quarter of this year. (It will compete with conventional TURPS, interstitial laser therapy, and drug therapy now used.)

8/26 **Mehl/Biophile International** announced the completion of a bridge loan of $7 million to be used in connection with the manufacturing and delivery of the Company's Chromos 694 long pulse ruby laser hair removal system, and for general working capital purposes. Thomas Mehl, chairman, personally guaranteed the loan and pledged 8 million shares of his personal stock holdings as collateral.
According to Mehl, since mid-July, the company has installed nearly 40 laser systems in the U.S. and plans to install approximately 60 additional units by the end of September.

8/26 **Laser Photonics** and its subsidiary, **AccuLase** announced that they had finalized their agreement with **Baxter International Corporation's Baxter Healthcare**, for the licensing of AccuLase's excimer lasers. The deal is valued at $1.55 million. Baxter will acquire license, marketing, and manufacturing rights to the AccuLase laser and delivery system for cardiovascular and vascular applications. Laser Photonics is 70% owned by **Helionetics**.

8/28 **Pharmacyclics** released its fourth quarter and fiscal year results, reporting a net loss of $2.3 million (23 cents/share) for the quarter, and a net loss of $10.3 million ($1.11/share) for the year. For the fiscal year, revenues were $25,000, compared to $301,000 for the previous year. Pharmacyclics is developing energy-potentiating drugs designed to improve radiation and chemotherapy of cancer and enable or improve the photodynamic therapy of certain cancers and atherosclerotic cardiovascular disease.

8/28 **Laserscope** announced that its Aura KTP/532 nm laser system had been approved for marketing in Japan by its Ministry of Health and Welfare. The company expects to begin marketing Aura in the fourth quarter, focusing on the ENT market. Aura is a portable, desktop-sized medical laser, ideally suited for a broad range of hospital or in-office ENT procedures, with additional applications in dermatology, gynecology, and urology. The system will be sold in Japan by Laserscope's distributor, **Hoya Continuum Corporation**. Hoya recently sold its 100th Laserscope laser system, an Orion laser, to Tokyo Medical College. According to the company, Japan is the world's second largest medical laser market, behind the U.S., and is a key element in the company's strategic plan to become an industry leader in the international medical

laser business. Since 1994, when only 17% of sales came from international markets, today, overseas business accounts for more than 30% of total revenues.

8/28 **DUSA Pharmaceuticals** released its mid-year report to shareholders. Some of the highlights noted included the substantial completion of its Phase III clinical trial of Levulan (ALA) PDT in the treatment of precancerous actinic keratoses (AK), and signfificant progress on other fronts. The AK trial is expected to be completed by late October/early November, with submission of the NDA expected in early 1998.

The IND for Levulan photodetection of bladder cancer was filed in August, with the clinical trials scheduled to begin in the third quarter. The company initiated a multi-center Phase I/IIa clinical trial for hair removal, using Levulan and a proprietary non-laser red light source. Preliminary results are expected in late 1997/early 1998. A PDT treatment trial for endometrial ablation is expected to get underway during the fourth quarter, and a first acne clinical trial was completed in 1996 using red light activation. A second trial, using a blue light activation source is scheduled to begin in 1998.

8/29 **Premier Laser Systems** held its annual meeting on August 28th, with all proposals submitted to shareholders approved.

9/1 According to this issue of *Laser Report*, **JMAR Industries** has signed a letter of intent to acquire diode-pumped solid-state laser manufacturer **Sante Fe Laser Company**. (No purchase price was given.) For fiscal year 1996, SFL reported sales in excess of $1 million, and JMAR expects sales to exceed $2 million for fiscal 1997. SFL will operate as a separate business unit, reporting to the **Pacific Precision Laboratories** equipment manufacturing division of JMAR. (JMAR might use the newly acquired SFL technology in the manufacture of its Laser Knife laser blood sampler, now in the final stages of development.)

9/2 **Spectranetics** announced that the results of a randomized clinical trial to treat total coronary occlusions, was presented at the European Society of Cardiology meeting recently held in Stockholm, Sweden. The study demonstrated that the company's Prima laser guidewire increased the success rate of treating chronic coronary total occlusions, or completely blocked arteries, by 35% compared with non-laser mechanical guidewires. The study involved 305 patients at 18 leading institutions in Europe, and showed a 63.9% success rate in crossing total occlusions compared with a 47.5% success rate with guidewires.

9/2 Three more class action suits were filed against **PLC Systems**, on behalf of shareholders. This brings the number up to at least 12 or possibly 13.

9/2 **Cell Robotics International** announced that it had signed a distribution deal with **Dae Kwang Meditech Co., Ltd.** a Korean company, and its American counterpart, **Kimex**

Corporation. As part of the agreement, Dae Kwang has committed to purchase approximately $350,000 worth of the Lasette, laser finger perforator, for sale in Korea. Dae Kwang will submit the Lasette to the Korean Government for review before beginning sales. Because the device has been approved by the FDA, it is believed that the review will be brief. Korea is the first international market for the Lasette in CRI's worldwide distribution plan. Similar agreements in Singapore and Thailand are underway, and the company will introduce the Lasette into clinical markets in the U.S., Europe, and the Far East this fall. Discussions continue with major companies for worldwide distribution.

9/3 Laserscope announced it had received marketing clearance from the FDA for its erbium laser system for skin resurfacing. This follows a prior marketing approval for the system in January for surgical incision/excision, vaporization, and coagulation uses in soft tissue. The laser, to be called Vela, allows Laserscope to market both an erbium and CO_2 laser for this end application. It reinforces Laserscope's strategy of product and market diversification, making the company less dependent on any one or two given market segments. Twenty-two percent of revenues come from the aesthetics market, 27% from ENT, 21% from urology, 14% from gynecology, and 15% from all other markets -- including neurosurgery, general surgery, and orthopedics. The company is also investing in and is firmly committed to the development of photodynamic therapy, an emerging, non-surgical, minimally invasive therapy for treating cancer, according to CEO Robert McCormick. The company is moving ahead with plans to introduce a smaller, portable, next-generation erbium laser by early next year.

9/3 **Premier Laser Systems** said that it had signed an exclusive three-year distribution agreement with Korean-based **Trisys**, Peoples Republic of China-based **U.S. Summit Co.**, and Taiwan-based **Great Eurasia Corporation**, relating to its lines of dental lasers, including a combination of its Centauri erbium lasers for hard tissue applications, Arago and MOD argon lasers for tooth whitening and composite curing, and Aurora diode lasers for soft tissue dental procedures. The company said it is also in negotiation with distributors in several other countries.

According to CEO Colette Cozean, the three agreements call for minimum purchases each year of the agreement in order for the distributor to maintain exclusivity. Although there is no guaranteed purchase levels, the combined purchases of lasers call for the three distributors to obtain approximately 350 lasers over the initial three years, and generate revenues of up to $9 million or more.

The company said that it built 16 Centauri lasers in the May-June period, none during July (due to a shortage of certain components), 23 in August, and is on target to manufacture up to 40 systems in September and for the following two months. Premier expects to be able to manufacture up to 100 systems by December. The

company expects to install about 25 to 30 Centauri system during the quarter ending September 30th. During July and August, Premier trained over 100 dentists and their assistants.

Premier claims to have a total dental laser backlog of about $3.4 million, the same as was reported for June 30th. During earlier training sessions, poor fiber performance was noted, but the problem has been largely corrected by relatively minor changes in diameter, polish, and shapes of delivery systems. Training sessions in the last month have seen consistently reliable fiber performance. The company still expects to sell laser systems to the 1 to 2 percent of the U.S.' 120,000 practicing dentists in the first year or two of marketing. (That amounts to 1200 to 2400 systems!) According to the *Los Angeles Times*, the company has only installed "a handful" of Centauri lasers in the U.S., primarily because of the need to train its installers as well as dentist users.

In a related story, senior analyst Scott Baily at **BlueStone Capital** reiterated his strong buy investment rating on the company. He is targeting the company's stock price to reach $17-$20 over the next 12-18 months. He noted that of the June 30th $3.4 million backlog reported by Premier, $2.6 million (65 systems) were for Centauri, nearly $1 million ahead of his estimate.

9/4 **CardioGensis Corporation** announced the preliminary results of a 21-patient feasibility study, conducted in Europe, of its Percutaneous Myocardial Revascularization (PMR) system. Results from six of the patients demonstrated a drop in angina pain class, from an average of 3.0 prior to therapy, to an average of 1.5 at the most recent visit. The results were reported at last week's Congress of the European Society of Cardiology meeting in Stockholm.

With PMR, the beating heart is accessed via a small puncture in the upper thigh, through which a CardioGenesis guiding and steering catheter system places the tip of the catheter within the left ventricle. Laser energy, synchronized to the patient's ECG to minimize the risk of damage resulting from irregular heart beats, is delivered through the fiber optic equipped catheter to create channels from the inside portion of the heart, part way through the diseased area of the left ventricle, for the reperfusion of blood into the ischemic area.

9/4 **ESC Medical Systems** commenced an offering of $100 million of convertible subordinated notes due in 2002. The notes will have a coupon rate of 6% and will be convertible into the company's stock at $46.55/share. The net proceeds will be used for working capital and general corporate purposes, which may include acquisitions.

9/4 **ThermoLase** announced a marketing agreement with **Continuum Biomedical**, a leading manufacturer of YAG lasers with an installed base of 600 lasers worldwide. Under the agreement, Continuum will be able to offer doctors who buy Continuum's

new MedLite IV laser, the option of using it to perform ThermoLase's SoftLight hair removal process. Continuum can make the offer immediately to physicians outside the U.S., where no additional regulatory approval is needed. In this country, Continuum will have to seek marketing clearance from the FDA before it can market its laser for hair removal. The MedLite laser is currently used for removal of tattoos and pigmented lesions.

The agreement will compliment the physician licensing program initiated by ThermoLase over a year ago. Physicians who purchase a MedLite IV laser from Continuum and want the SoftLight option, will execute a license with ThermoLase on substantially the same terms as that granted under ThermoLase's physician licensing program. MedLite users who opt for the ThermoLase program will have to pay ThermoLase the same up-front fee and per procedure fees. Continuum will receive a commission from ThermoLase for each SoftLight license agreement it places with MedLite IV laser users.

In a separate announcement, ThermoLase said that its Board of Directors had authorized the repurchase, through September 4, 1998, of up to 1 million shares of its common stock in the open market, or in negotiated transactions. Since January 1, 1997, ThermoLase and it parent company, **Thermo Electron Corporation** have purchased a total of 2.2 million ThermoLase shares.

9/8 According to a release from **Palomar Medical Technologies**, **Dean Witter Reynolds** had filed an incorrect Form 144 with the SEC on August 25th, stating that Palomar chairman Steven Gergiev had filed to sell 20,000 shares of Palomar stock. Gergiev actually sold stock in an unrelated company, and Dean Witter will file a corrected Form 144 with the SEC.

9/9 **Coherent Inc.** announced that its wholly owned subsidiary, **Coherent Japan**, had received clearance from the Japanese Ministry of Health and Welfare to introduce the first 80 watt holmium laser for medical use in Japan. The VersaPulse Select 80 watt system will be sold in Japan by **MC Medical Co.**, a subsidiary of **Mitsubishi Corporation**. Coherent Japan will provide marketing and technical support directly to customers in Japan under terms of the distribution agreement. One application in which the laser will be used is for prostate resection. Twenty-two thousand men undergo conventional prostate resection surgery each year. The Japanese national medical insurance scheme has recognized laser resection for insurance reimbursement, with a set fee more than double the non-laser electro-surgical resection procedure, encouraging investment by hospitals to equip their operating rooms for the safer laser procedure which also reduces hospital stay and surgery-related complications. According to Coherent, the Japanese market for operating room based multi-specialty surgical lasers is projected to grow to $44 million by 1999. During this period, holmium laser sales are forecast to increase 80% per year.

9/9 **Laser Industries** announced that it had been granted marketing clearance for a new version of its EpiTouch long-pulsed ruby laser hair removal system. The new system possesses a fiberoptic delivery system, rather than an articulated arm. While the articulated arm version possesses a dual mode for both hair and tattoo removal, the new fiber delivery system is dedicated just for hair removal. The company expects to begin shipment of the new product to U.S. customers later this month. (No further information about the specifications for the fiber delivery system was given.)

9/9 **American Dental Technologies** announced that it was moving its common stock listing from the NASDAQ Small Cap Market to the NASDAQ National Market, beginning on September 10th. The company will continue to trade under the symbol ADLI.

9/10 **PDT Inc.** announced that it intends to change its name to **Miravant Medical Technologies**. After shareholder approval, the company will begin trading on the NASDAQ under the MRVT symbol. The company will also brand the name PhotoPoint for its light activated medical procedures and products. PhotoPoint will be positioned as a more advanced version of photodynamic therapy.

9/10 **Robert M. Cohen & Co.** has initiated coverage of **PLC Systems** with a speculative buy rating and a twelve-month price target of $26/share. Analyst Keith Bossey noted that the stock had fallen 52% from its high and was trading well below comparative company valuations at similar stages, due to the FDA panel's non-approval of its Heart Laser system, based on insufficient data. He anticipates the company will receive FDA marketing approval by first quarter 1998. In a best case scenario, with first quarter approval, Bossey estimates 1999 revenues surpassing $77 million, with earnings of 79 cents/share. If approval does not come sometime in 1998, the estimates will be a moot point, as Bossey does not expect the company's cash position to last beyond the first quarter of 1999.

9/11 **PLC Systems** announced that a study of the Heart Laser conducted by Duke University Medical Center had been published in the September issue of the *Journal of the American College of Cardiology*. Eleven patients were evaluated both before and after undergoing TMR, using a technique known as dobutamine stress echocardiography, in which the drug dobutamine places a temporary stress on the heart similar to that caused by exercise. The study found that after undergoing TMR, the patient's hearts were much better able to respond to stress.

9/12 **Premier Laser Systems** announced that it had signed a distribution agreement with Los Angeles-based **Interdent, Inc.**, manufacturer of QuasarBrite, an in-office tooth whitening system specifically designed for use with dental lasers. The agreement enables Premier to "bundle" its argon Arago and Multi-Operatory Dentalaser systems with QuasarBrite and two other Interdent whitening kits, StarBrite for in-office

bleaching, and the Contrast PM take home system. Interdent representatives will co-market Premier lasers to their professional customers. According to the release, The American Academy of Cosmetic Dentists estimates that the annual overall tooth whitening market is more than $3 billion, and that a significant portion of that could be done with lasers.

9/12 The *Associated Press* reported erroneously on September 7th, that a Michigan woman had, on August 14th, become the first person in the U.S. to undergo percutaneous TMR. The AP now says that a similar procedure had been performed at least once before in the U.S. by a physician working with the **Eclipse Surgical Technologies** system, one of at least two companies (the other being **CardioGenesis**) working on percutaneous TMR.

9/15 **PDT Inc.** announced that it had officially changed its name to **Miravant Medical Technologies**, and its NASDAQ symbol to **MRVT**. (See the 9/12 brief above.) In addition, the company is launching a massive corporate communications program to announce the name change and distinguish itself from its competition. Full page ads will be appearing in *The Wall Street Journal, New York Times, Barrons, The Economist,* and other publications. The Wall Street Journal ad appeared on September 16th, and is quite impressive. For more information about the renamed company, see its web page at www.miravant.com, or call the investor relations department at 888-685-6788.

9/16 **Abiomed** said that it had won an SBIR research grant of approximately $750,000 from the National Institute of Diabetes and Digestive and Kidney Diseases, to develop instrumentation and techniques to facilitate tissue approximation and repair in minimally invasive surgical procedures, where current methods of wound closure (suturing, stapling, or clipping) are either contraindicated or extremely difficult to accomplish. The primary emphasis of the research will be to develop a laparoscopic device for laser-assisted reconstruction in urological surgery, where a leak-tight closure is extremely important. An Abiomed spokesperson said that it is expected the program will build on its patented technologies for laser-assisted tissue repair.

9/16 **ESC Medical Systems** announced it plans to introduce its new Derma K laser system for skin rejuvenation at the ASPRS (American Society for Plastic and Reconstructive Surgery) annual meeting in San Francisco, which begins on September 22nd. Initially, the Derma K will be used in the U.S. for investigational purposes only. The system uses a combination of pulsed erbium and CO_2 irradiation to achieve full control of the temperature profile created in living tissue during laser skin ablation, thus obtaining optimal skin rejuvenation with the shortest post-treatment healing period.

9/16 I received a mailing from the *World Future Society*, which included some social and technological forecasts for the next 25 years. Two of the predictions caught my eye, and I would like to share them with you.

- "Nanotechnology, the micromanipulation of materials at the molecular level, will soon bring forth fantastic new breakthroughs such as teeth as hard as diamonds, a baldness cure, and wrinkled skin made smooth again."

- "Computer-aided customization will become routine for many manufactured products. Computers will help you custom-tailor your car, your appliances, as well as your wardrobe." (One of the refractive laser manufacturers, **Autonomous Technologies** is working on developing "custom corneas". The concept involves diagnosing what correction is needed, including astigmatism, and using computer algorithms built into the laser, to shape the corneal surface to match the correction needed.)

9/16 **Pharmacyclics** announced that the NCI will sponsor 9 different human clinical trials in various cancers, using the company's radiation sensitizer Gadolinium-Texaphyrin (Gd-Tex). The Phase I clinical studies will evaluate Gd-Tex as a radiation sensitizer in patients with brain tumors (3 studies), lung cancer (2 studies), head and neck cancer (2 studies), and pancreatic cancer (2 studies). The studies are expected to begin in early 1998, at leading institutions throughout the U.S. (Gd-Tex is one of a group of patented synthetic molecules, called texaphyrins, which capture and focus medically useful forms of energy, such as X-rays, which are used in the radiation therapy of cancer.)

9/17 **CardioGenesis** has filed an amended complaint asking the Federal District Court to consider evidence of inequitable conduct in the U.S. Patent Office, while the U.S. Patent 5,125,926 (the Rudko patent) was being obtained by **PLC Medical Systems**. On September 10, 1996, CardioGenesis filed the original complaint against PLC, which sought a determination that the Rudko patent was invalid and not infringed by CardioGenesis. The amended complaint asserts that the Rudko patent is invalid and unenforceable because of material prior work of another party (prior art) was withheld from the Patent Office by Rudko, based on papers filed with the FDA by Dr. Rudko prior to filing for the patent.

In a related but separate action, CardioGenesis was served with a complaint on September 12th, filed by PLC in Munich, alleging that both CardioGenesis and its former German sales agent had infringed EP 0553576, the European counterpart of the Rudko patent.

PLC issued its comments on the above saying that CardioGenesis was attempting to defend itself in the ongoing patent infringement litigation, and was seeking to raise questions regarding the enforceability of the patent. PLC believes the charges made by CardioGenesis were completely without merit.

9/17 **Cell Robotics** announced that it had received the CE Mark for its Robotics Workstation, LaserTweezers, LaserScissors, and other related components of its research product line. Obtaining the CE Mark allows the sale of products into the European Community of countries, as well as into Brazil and Australia.

9/17 **Laserscope** announced that it had launched a web site designed for its customers, physicians, medical consumers and the general public. The site can be accessed at www.laserscope.com.

9/18 In a surprise announcement, **Palomar Medical Technologies** said it had signed a letter of intent with **Coherent, Inc.** for Coherent to become its exclusive distributor of the EpiLaser hair removal system. The agreement covers the United States, Far East, and most countries in Europe. Under the terms, Coherent would pay an up-front fee for the distribution rights to both the current product and future hair removal products. (Palomar is known to be working on the development of a diode laser for hair removal.) Coherent would also obtain rights for a warrant to purchase a predetermined amount of Palomar common stock.

After the agreement is finalized, Coherent will become responsible for sales, marketing, service, training, and education of physicians in association with use of the EpiLaser. Palomar will continue to design, develop, and manufacture the laser at its Lexington, MA facility.

Palomar will continue its efforts in the service side of the aesthetic market with its **Cosmetic Technologies International** (CTI) subsidiary continuing to develop cosmetic surgery centers in conjunction with **Columbia/HCA** and other partners.

The agreement essentially validates Palomar's approach to the hair removal market, which, as I have stated in the past, is probably superior to other laser and non-laser products available on the market. It also apparently validates Palomar's patents for laser hair removal. This "grand exit strategy" from the hair removal market, will allow the company to focus on developing new products for other applications and, with exercise of the warrant, will gain Coherent an East Coast presence!

9/18 **QLT PhotoTherapeutics** said that the FDA's Oncologic Drugs Advisory Committee had recommended the expansion of approval of QLT's Photofrin for the treatment of early stage lung cancers. Specifically, the committee voted in favor of approving Photofrin for the treatment of endobronchial microinvasive nonsmall cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated. The committee turned down QLT's request for the palliation of advanced lung cancer, as it did not feel the data presented was adequate nor represented well controlled trials, and therefore could not vote on whether it should recommend approval. QLT expects to

discuss with FDA officials what can be done to revive the palliation application, based on the data submitted and on approvals for this indication in other jurisdictions.

Final marketing approval for the treatment of NSCLC is expected by the end of this year, or early next. The supplemental NDA was part of a four-part application for a drug-device combination, consisting of Photofrin and Optiguide cylindrical diffusers, as well as laser systems from both **Coherent Medical** and **Laserscope**.

Analyst Christine Charette of **Nesbitt Burns** of Toronto said that QLT currently has a 10% penetration of the esophageal cancer market, with an estimated 11,000 patients in the U.S. (about half eligible for treatment), giving the company about $1 million in royalties per quarter. She added that the recommendation for NCSLS covered about 20% of the 180,000 patient population, translating to about 36,000 patients, who will use at least one application of Photofrin at a cost of about $4200. Other applications in the pipeline include a treatment for Barrett's Esophagus, a pre-cancerous condition affecting about 1 million people in the U.S. annually, and a therapy to treat age-related macular degeneration, a leading cause of blindness in the elderly, for which there is no effective treatment to date.

In a followup interview with *Dow Jones*, Ms. Charette said that the market size for both early- and late-stage lung cancer should end up being about the same, so that investors shouldn't be concerned about the financial impact that the FDA's panel decision would have on QLT. Charette called the approval of Photofrin for early-stage or curative lung cancer a "huge event", with the only other treatments available to early-stage patients are surgery and radiation, so that the market penetration for treating this condition should be larger than for late-stage disease. For late-stage disease, patients can use chemotherapy, as well as surgery and radiation, because they are only looking for a palliative treatment, not a cure.

By Friday, the 19th, according to the September 22nd *Wall Street Journal*, QLT's stock had dropped by about 15%, as investors apparently did not heed Ms. Charette's advice.

Laserscope said it was pleased with the outcome of the committee review and expects to begin marketing its PDT laser module and disposable fiber optic delivery systems -- priced in the $300 to $600 range -- with Photofrin upon final marketing approval.

9/18 **Mehl/Biophile** reported its fiscal May 31st year-end results, with revenues of $3.6 million and a loss for the year of $13.3 million (35 cents/share). Thomas Mehl, chairman, stated that fiscal 1997 was a transitional year with the company moving from the R&D stage to production and marketing. Since receiving marketing approval for its Chromos 694 laser hair removal system in March, the company has moved to penetrate the U.S. market, requiring expenditures for increased production and

marketing. Also, with the approach of revenue sharing with its customers, the time gap between placement and the receipt of meaningful revenues is several months. Mehl stated that it had installed a total of 48 laser systems in the U.S., and expected to begin receiving meaningful revenues from these systems in early October. An additional 7 lasers have been installed throughout the U.S. for both training and R&D. To date, 161 personnel have been trained on these machines, and Mehl expects to have a total of 300 systems installed worldwide by the end of 1997.

9/18 **Spectranetics** announced that it had received clearance from the FDA to expand the clinical trial of its Laser Sheath, designed to assist in the removal of pacemaker and implantable cardioverter defibrillator leads. The action allows expansion of clinical sites to 50, from 35, and allows an additional 500 patients to be treated. The expansion allows the company to introduce the Laser Sheath to sites which could previously only remove leads through non-laser techniques.

9/22 **Coherent Medical** announced the introduction of the UltraFine erbium laser for superficial skin resurfacing. This new aesthetic laser will compliment the company's UltraPulse system, which has been used in over 200,000 skin resurfacing procedures throughout the world.

9/22 **Cell Robotics** announced that it had signed two new distributors in Korea and Brazil for its In Vitro Fertilization Workstation product line. These are the first in a series of distribution agreements that will be signed over the coming months in the Far East, Europe, and other countries outside of the U.S. **Shin Han Systek** of Seoul will represent Cell Robotics in Korea, while **Opto Electronica S.A.** in Sao Carlos, will distribute the workstation in Brazil. The IVF Workstation will be introduced to the European market at the Medica convention in Dusseldorf in November, and will be exhibited at the American Society of Reproductive Medicine meeting in Cincinnati in October.

9/22 **ThermoLase** announced the opening of a Spa Thira in Chicago, bringing the number of spas currently open to 14, twelve of which are in the U.S. A Palm Beach, FL location is scheduled to open later this fall. To date, ThermoLase has placed 153 lasers in private practices in 33 states and several international markets.

9/22 **Mehl/Biophile** announced that its subsidiary, **SLS/Biophile**, had received ISO 9001 certification for the manufacture and production of the Chromo 694 long pulse ruby laser hair removal system. SLS/Biophile had already received CE Mark certification, putting it in full compliance with the European Medical Device Directive.

9/23-

9/25 **US Surgical** announced that it had acquired **Progressive Angioplasty Systems**, a company with balloon catheters and coronary stent products, and has established **Vascular Therapies**, a new division to develop and market the company's interventional cardiology, vascular, and cardiovascular products. The new products will join with US Surgical's Mini-CABG instruments and its research and development efforts in myocardial revascularization, to offer a complete range of products for revascularization and restenosis management. (I have queried officials at US Surgical if **LaserSight's** announcement of receiving $4 million from an unnamed company for license of the **IBM** UV laser patents for vascular and cardiovascular applications, had any connection with the formation of the new division. I am awaiting a response. LaserSight would not name the healthcare company that took the license.)

Two days later, **Spectranetics Corporation** announced that it had signed a supply and license agreement with US Surgical, that will allow US Surgical to purchase Spectranetics' excimer lasers and fiber optic probes for use in TMR. USS said that it will fold the laser program into its newly formed Vascular Therapies division, which apparently will be responsible for seeking FDA approval to use the Spectranetics laser for TMR. USS will pay Spectranetics $6.1 million for the purchase of modified CVX-300 lasers and fiber optic devices and for licensing Spectranetics' coupler patents (?) for use in TMR. Spectranetics noted that the approximately 200 currently installed lasers could be modified for TMR.

As part of the alliance between the two companies, they have agreed to investigate and develop products for percutaneous TMR (the inside/out approach). (The major unanswered question is, what is USS planning to do with its 80% owned **Medolas** laser technology, acquired in July 1996?)

9/25 **Robertson, Stephens & Company** has initiated coverage of **Miravant Medical** with a buy rating, and a twelve month target price of $80-$90. Analyst Donald Ellis believes that Miravant is developing breakthrough therapies for diseases that cause significant morbidity and mortality in a broad range of disease categories, including cardiology, oncology, gynecology, ophthalmology, urology, and dermatology. (The only problem is that Miravant is still in Phase III trials for breast cancer, AIDS-related Kaposi's Sarcoma, and basal cell carcinoma; Phase II/III for age-related macular degeneration; and Phase I/II for the treatment of psoriasis. According to the anaylyst, the first marketing approvals are not expected until sometime in 1999! Thus, it could be years before the company shows meaningful revenues.)

The Robertson, Stephens report is thorough in its coverage of Miravant and its technologies, and in competing therapies such as radiotherapy, chemotherapy, and surgery. But the report only briefly mentions **QLT PhotoTherapeutics** first generation approved photosensitizer, Photofrin (and its side effects), without discussing QLT's

second generation photosensitizer, BPD, or other competitors PDT products -- **Dusa'a** Levulan (ALA) and **Scotias'** THPC, among others. It also limits QLT's potential success based on its use of "high priced lasers", without acknowledging that QLT is working to develop lower cost activation light sources, including diode lasers, as well as is Miravant.

9/26 **Spectranetics** announced that it had received FDA marketing clearance for a new coronary angioplasty catheter, the Vitesse E, a 2.0 mm catheter for use with its approved excimer laser, the CVX-300. The Vitesse E increases the ablation area resulting in a larger lumen created during laser angioplasty. The company plans full product introduction at the American Heart Association meeting in November.

9/26-
9/29 *The Los Angeles Times* reported that **Miravant Medical Technologies** shares rose 20% following the release of the Roberstson, Stephenson report earlier in the week. The companies shares rose $9.75 to $58.25 in trading of 895,000 shares, 11 times the three-month daily average. (This rise could also be in response to the advertising blitz put on by the company, placing full-page ads in major business publications, as noted in the 9/15 brief above.)

The company also announced that it had completed a private equity offering, totalling $45 million, with two unnamed institutional investors.

MEDICAL/SURGICAL LASER UPDATE -- OCTOBER 1997

9/15 According to *Reuters Newswire*, investors in **Palomar Medical Technologies** have filed a class action suit against **H.J. Meyers**, and some of its supervisory personnel, alleging that the brokerage manipulated Palomar's stock price in the period April 29, 1996 to March 26, 1997. The plantiff's attorneys say that the stock price was artificially inflated as a result of "manipulative efforts" by the defendant, among others. The case was filed on September 11, 1997 in the U.S. District Court for the Southern district of New York. Damages will be sought, although no amount was specified in the filing.

9/29 **ESC Medical Systems** said that it had completed the previously announced offering of Convertible Subordinated Notes -- see the September 4 brief in last month's newsletter, and had added an additional $15 million, to make the total $115 million. The proceeds will be used for working capital and general corporate purposes, which may include further acquisitions.

9/30 **Palomar Medical Technologies** announced a restructuring of operations, which included a $23 million charge for the third quarter. The restructuring charge is in addition to an estimated $14 million operating loss for the quarter. The restructuring

consists of approximately $21 million in non-cash charges, comprised of $11 million in write-offs of outside investments in non-core businesses; $7 million in reserves against assets in non-core subsidiaries; a $3 million reserve against divesting a start-up overseas subsidiary (the Hull, England CO_2 laser development effort ?), and restructuring core business operations; and a $2 million reserve for severance costs associated with consolidation of the selling, general, and administrative functions (closing down of selling and marketing operations of medical lasers, associated with the **Coherent** deal), and the closing of certain facilities. (No answer was given to the question of what facilities would be shut down, but it is expected that Palomar management will move from its present Beverly, MA space, into its Lexington, MA manufacturing facility. The question about what would be done with **Tissue Technologies** was also not answered, although there is speculation that TT will be sold to its current management.)

Dan Valente, president and CEO, stated, "After examining the company from top to bottom...I believe the best opportunity to increase shareholder value is to focus operations in the cosmetic laser core business...another key consideration in restructuring now was our recently announced agreement in principle with **Coherent**, which combined with our revenue-sharing agreement with **Columbia/HCA** gives Palomar genuine stability and predictability for the future."

According to the news release, Palomar has installed more than 160 EpiLaser hair removal lasers worldwide, and over 25,000 EpiLaser treatments have been performed. Palomar's Cosmetic Technology International subsidiary has now established more than a dozen revenue-sharing laser centers in the U.S. and internationally. (More on CTI's activities in my recent interview with its chairman, Tom O'Brien, in the enclosed writeup, an edited version of which was published in the October issue of *Medical Laser Report*.)

9/30 **Premier Laser Systems** announced that its common stock would begin trading on the Frankfurt and Berlin stock exchanges.

9/30 **DUSA Pharmaceuticals** said that its board of directors had adopted a shareholder rights plan. The plan provides for the distribution on one right as a dividend for each outstanding share of common stock, and the right to purchase one unit at a price of $50. Each unit consists of one-tenth of a share of common stock and a note equal to nine-tenths of a share based on the price of the company's common stock on the exercise date. The rights may be exercised only if a person or group either acquires or announces a tender offer to acquire 15% or more of the company's outstanding common stock.

9/30 **Eclipse Surgical Technologies** said that it had received nine notices of allowance for new patents from the U.S. Patent Office, in the fields of TMR and percutaneous

TMR. The company said that it had an additional 39 patent applications on file with the patent office.

10/1 A new report from **Decision Resources** assesses the market for therapies to treat non-small cell lung cancer (NSCLC), which represents 75%-85% of all lung cancers. Most cases of NSCLC can be traced to active tobacco consumption, according to Decision Resources. The report covers epidemiology, etiology and pathophysiology, diagnosis and staging, medical practice, current and emerging therapies, and unmet needs in the seven major pharmaceutical markets (France, Germany, Italy, Japan, Spain, the UK, and the U.S.). For more information contact Frank Sama, Marketing Manager of DR at 781-487-3753.

10/1 **PLC Systems** noted that a live TMR procedure was performed before approximately 4000 physicians at the 9th Annual Transcather Cardiovascular Therapeutics Symposium, held in Washington, DC. The TCT meeting is designed for doctors with a special interest in interventional cardiology, such as angioplasty and CABG. Since TMR is an alternative for CABG, it was highlighted at the meeting.

10/6 **ThermoLase** announced that it had entered into two international agreements, the first with ThermoLase UK Ltd., to introduce the Softlight process into England, while the second agreement will provide the hair removal process elsewhere in the UK and Ireland, primarily by licensing to physicians and other qualified licensees. Operations of each separate venture will be managed by Michael Dodd, who successfully ran a chain of 30 hair styling salons in the UK, and operated Michael's of London and Hair Now, two high-end hair salons in Boca Raton, Florida.

10/6 **LaserLite LLC**, the company formed by former **Summit Technology** founder David Muller, through his **Mile Creek Capital LLC** venture capital company, announced that it would join other aesthetic laser companies in addressing the treatment of leg veins and hair removal with its high-powered diode laser. (The company is a joint venture between Mile Creek and **Diomed, Ltd.** of the UK, who will be providing the diode laser technology. LaserLite's diode laser system is expected to launch in the U.S. by year's end. (For more on this and other diode lasers addressing the cosmetic market, see my writeup of the summer AAD meeting, sent to you with the August issue of this newsletter.)

10/6 **Collagen Corporation** announced that it had decided to proceed to separate its **Aesthetics Technologies** business and its **Collagen Technologies** businesses into two publicly traded companies.

10/6-
10/7 **Ion Laser Technology**, through its wholly owned subsidiary, **BriteSmile, Inc.**, has filed patent infringement against **Premier Laser Systems**, **Interdent**, and **LaserMed**,

based on an analysis of ILT's U.S. Patent, 5,645,428. The company has concluded that the three companies are in violation of the patent's claims.

The following day, ILT announced that it had entered into discussions with LaserMed, and had postponed its patent infringement suit against that company, with LaserMed stating it had not infringed the ILT patent.

Premier issued its own statement, saying that it had been served with a complaint, but also denying infringement, saying that the suit was without merit and that it would defend its position. (Premier recently announced a distribution agreement with Interdent -- see the September 9th brief in last month's newsletter.)

10/7 **Laser Industries** announced that it was entering the myocardial revascularization field via a joint development program with **Biosense**, a pioneer in catheter-based cardiovascular navigation systems. The program to be developed will be direct MR, using Biosense's guidance system, catheters and optical fibers, and Laser Industries' Sharplan holmium laser, specifically developed for this application. The system will allow for the direct delivery of laser energy to selected sites on the inner side of the heart wall, a form of percutaneous TMR. According to the release, an IDE has been submitted following a year of successful preclinical studies of patients. The DMR system was demonstrated at the Transcatheter Cardiovascular Therapeutics meeting in Washington, DC, mentioned above.

According to the agreement, Laser Industries and Biosense will jointly develop the laser-based equipment, and Laser Industries will serve as the preferred laser system vendor for the DMR systems sold by Biosense. (Biosense is based in Haifa, Israel, with corporate headquarters in Orangeburg, NY.)

In an interesting development, the agreement between Laser Industries and Biosense will allow **Johnson & Johnson** to enter the laser TMR market, joining other large healthcare companies, **US Surgical**, and **Baxter Healthcare**. On September 25th, **Cordis Corporation**, a wholly-owned subsidiary of **Johnson & Johnson** announced the signing of a definitive merger agreement with Biosense. The closing of the deal is expected to occur by the end of October.

10/7 Another class action suit was filed against **PLC Systems**, this time by the law firm of **Weiss & Yourman** of New York. (I have lost count of the number of suits now filed, but would guess it is more than a dozen.)

10/9 **Robert M. Cohen & Co.** has initiated coverage of **Columbia/HCA**. Analyst Keith Bossey has set a speculative buy rating and a $40 target share price, noting that the recent Government investigation into the company has cut the stock price by 48%, creating an interesting undervaluation situation. I asked Keith if there was any

mention of the Columbia/HCA agreement with **Cosmetic Technologies Incorporated**, and he told me that he had not covered that aspect of Columbia.

10/13 **Eclipse Surgical Technologies** announced that the company has incorporated a new subsidiary, **MicroHeart, Inc.**, to develop biosurgical cardiovascular products, with Michael Wright as CEO. Mr. Wright formerly was with **Johnson & Johnson**, managing various divisions, including developing leading edge cardiology products. MicroHeart will be working on non-laser product opportunities to diversify Eclipse in the cardiovascular arena.

10/13 This week's issue of *Business Week* contains a lengthy profile of Colette Cozean, CEO of **Premier Laser Systems**.

10/14 **Surgical Laser Technologies** reported its quarterly results, with sales of $3 million and net income for the quarter of $47,000, which included a special credit of $177,000 resulting from the beneficial settlement of litigation of $1 million, offset by special charges associated with the sublease of the company's former manufacturing facility in Kentucky, and a write-down of the carrying value of the company's former headquarters facility. The two facility related charges amounted to $823,000. For the nine month period, sales were $9 million, with a net loss of $432,000 (4 cents/share).

10/14 **Coherent, Inc.** announced that it expects net income for its fiscal fourth quarter, ended September 27th, to be between $0.54 and $0.58 per share. Street estimates were for $0.80 per share. Sales are expected to be between $103 and $104 million, a record high for the company, but less than anticipated. According to CFO Robert Quillinan, "With more than half of our business outside of the United States, sales and orders were negatively impacted due to the continued strengthening of the dollar against other major currencies. If exchange rates had remained at last year's levels, sales and orders would have grown 8% and 11% respectively...instead of the 3% and 6% increases actually recorded. At current exchange rates, we anticipate quarter to quarter comparisons to be negatively affected by currency adjustments through the first two quarters of fiscal 1998." Commenting on the preliminary results, Bernard Couillaud, president and CEO noted that the company was also experiencing pricing pressures on its aesthetic laser products for skin resurfacing, and a shift in customer demand to its lower priced, lower margin versions. It also appeared that the sale of aesthetic laser for such applications may be seasonal, as fewer cosmetic procedures are performed during the summer months.

10/14 **Eclipse Surgical Technologies** released its third quarter results with net revenues of $1.4 million and a net loss for the quarter of $4.5 million (27 cents/share).

10/15 **Transmedica/Venisect** announced that it had filed suit against **Cell Robotics International**, claiming willful infringement of its patent on laser perforation of the

skin for capillary blood draws. The action was filed in the U.S. District Court for the Eastern District of Arkansas. Transmedica has asked the court to order Cell Robotics to immediately cease violating its patents, which has been occurring since the latter began marketing its Lasette device in August 1997.

The following day, Cell Robotics responded that it and its advisors had analyzed the Transmedica/Venisect patent and believed that its Lasette laser finger perforator did not infringe it.

10/15 **Dorland's Directories** which has taken over publication of the *Medical & Healthcare Marketplace Guide*, announced the publication of the 13th edition. One of the high-growth markets included in the Marketplace Guide is medical lasers, with the overview written by yours truly. Information about obtaining the Guide can be obtained by calling the publisher at 800-722-7670.

10/16 **Ion Laser Technology** announced that it had signed a five-year distribution agreement with **Dental/Medical Diagnostic Systems, Inc.**, a producer of intra-oral cameras. The agreement calls for Dental/Medical to be exclusive distributor in the U.S. and Canada of ILT's Argo HP subsecond argon dental composite curing and whitening device. Dental/Medical will market the product as its Apollo 9500, priced under $6000. The agreement requires Dental/Medical to purchase a total of $36 million of the Apollo 9500 units (selling a minimum of 3000 units per year) over the next five years to maintain its exclusive distributorship. DMD is also required to distribute exclusively ILT's proprietary, application specific products that are being developed for use in treating patients with the new device, including composite fillings and whitening reagents. Revenues from these additional support products are not included in the $36 million estimate. Introduction of the Apollo 9500 to the dental market will begin at the American Dental Association trade show to be held in Washington, DC on October 18-21. Order taken at the show will be for shipment to begin in early 1998.

DMD will be responsible for the necessary Canadian approvals and marketing. A $250,000 licensing fee has been paid to ILT by DMD. Additionally, DMD will sell ILT's BriteSmile laser tooth whitening system to domestic and selected international dental customers on a non-exclusive, commissioned basis.

According to officials at DMD, the interest in the new technology is substantial, with an estimated market of over $1 billion in the U.S. and Canada.

10/16 **CardioGenesis Corporation** reported its third quarter results, with sales of $1.2 million and a net loss of $5.1 million (42 cents/share). Third quarter sales represented sales of the company's ITMR system into Europe and into its clinical sites in the U.S. For the nine months, sales were $5.5 million with a net loss of $12.4 million ($1.03/share).

10/16 The chief executive of **Tower Hill Holdings**, Sean Daly, expressed his concerns about **Coherent, Inc.'s** fourth quarter earnings estimates -- see the 10/14 brief above -- and its ability to convey its operating strategy to holders and analysts. As a shareholder in Coherent, Daly urged Coherent to either sell the company to a management team that would be more responsive to shareholders, or take swift action to maximize shareholder value. Coherent shares plunged by 12 points on Wednesday, following the announcement on Tuesday that it expected to report earnings of between 54 cents to 58 cents for the quarter. In the year ago fiscal fourth quarter, earnings were 74 cents/share. Three analysts surveyed by **First Call** expected the company to report fourth quarter earnings of 79 cents/share.

10/17 **American Dental Technologies** announced that it had received notification of certification of its Corpus Christi, TX manufacturing plant under ISO 9001.

10/20 **Pharmacyclics** announced that it had signed a licensing agreement with **Nycomed ASA** of Norway, for the development and commercialization of Lu-Tex for the PDT treatment of cancer. Under the terms of the agreement, Nycomed will receive exclusive development and marketing rights to Lu-Tex in Europe, Asia, South America, and Central America. In return, Pharmacyclics will receive a royalty on Nycomed's sales and approximately $14 million in license fee, milestone and development cost subsidies related to the initial cancer indication to be developed by the parties. Approximately $14 million in additional milestone and cost subsidies may be paid by Nycomed during the course of successful development for various subsequent cancer indications. Pharmacyclics retains the development and marketing rights to the product in the U.S., Canada, and Japan. The two companies will share device and clinical development costs required for product approval in the U.S., which will be used as a basis for approval in Europe. Each company will make regulatory submissions in their respective territories. In addition, Pharmacyclics will supply bulk drug substances through its collaboration with **Celenese Corporation**, a subsidiary of **Hoechst AG**. Nycomed will produce finished products for Pharmacyclics and its own use from its Puerto Rico plant.

Lu-Tex is currently in multicenter Phase II clinical trials for breast cancer, and is the subject of a CRADA with NCI to develop the product for additional cancers.

Nycomed has proposed to merge with **Amersham International Plc** of the United Kingdom, to form **Nycomed-Amersham Plc**. The merger is expected to become effective later this month.

10/20 **Spectranetics** released its third quarter results showing revenues of $6.2 million, the highest in any quarter in the company's history. The net loss for the quarter was $609,000 (3 cents/share). For the nine month period, revenues decreased 2% to $15.4 million and the net loss for period was $3.5 million. The quarter's sales were driven by

sales of laser systems and catheters to investigational sites for a new application of the excimer laser for removal of pacemaker and implantable cardioverter defibrillator leads. As of September 30th, 31 U.S. treatment sites were using the Spectranetics laser and disposable laser sheath devices in investigational lead removal procedures. The company has since received approval to expand procedures to a total of 50 U.S. sites. Full marketing approval is pending, following a July panel recommendation for approval. Spectranetics estimates that approximately 30,000 leads each year may require removal because of infection or recall and, in the case of ICD leads, mandatory removal of failed leads.

A $6.1 million agreement announced in September with **US Surgical**, will require USS to make advance payments against future purchases of Spectranetics' laser system and fiber optic probes for use in transmyocardial revascularization. Approximately $2.5 million was paid to the company during the third quarter and is included within current liabilities on the balance sheet. Spectranetics has more than 250 laser angioplasty systems installed worldwide. (The question remains, how many of these systems are in current use?)

10/21 **PLC Systems** announced that the last TMR patients in its controlled-randomized study of the Heart Laser underwent their 12 month followup visit in September. The data has been collected and the analysis, in preparation for a submission to the FDA in November, is on track and going well.

10/21 **ESC Medical Systems** released its third quarter results with net sales climbing to $30 million and net income increasing to $8.1 million (39 cents/share). For the nine month period, net sales reached $78.5 million and net income was $15.6 million (98 cents/share). The restated number for the nine month period include **Luxar** results. According to president and CEO Shimon Eckhouse, "Sales continued to climb as we successfully launched new products in the domestic and international markets. Within the past year, the EpiLight hair removal system, the Derma 20, and the Silhouette Therapeutic Massage system became commercially available in the U.S., and our financial results are just beginning to reflect the high demand for these products."

10/22 **Mehl/Biophile International** announced that it had signed a letter of intent with **KE Medical** of Zurich, Switzerland, for the exclusive marketing, installation, training and servicing of its Chromos 694 hair removal laser in ten European countries. The agreement calls for KE Medical to place a minimum of 300 systems in the licensed territories during the next 36 months. **Mehl Group Marketing**, a wholly owned subsidiary of Mehl, will also receive a portion of the ongoing gross revenues generated by each system. Additionally, KE Medical will syndicate a group of investors to invest between $15 to $20 million in Mehl, through a long-term debenture. The company intends to utilize the financing proceeds to repay its current

bridge loan with **Clearwater Fund**, and for working capital. The agreement is expected to be finalized within the next 30 days.

10/22 **VF Capital Ltd.** of Calgary, announced that it has signed a letter of intent to acquire all of the issued and outstanding shares of **Calgary Centre for Laser Dentistry**. The acquisition price will be $700,000, $200,000 in cash and the remainder in stock. The transaction is part of the corporation's plan to become a professional practice management company, deriving its revenues from the design, building, managing, and marketing state-of-the-art cosmetic dental clinics. The new Laser Dentistry business incorporates a clinic operating in Calgary with a clinic already in place with the **Laser Rejuvenation Clinics Ltd.**, located in Toronto. Both clinics are currently equipped to offer and perform laser tooth whitening using the BriteSmile system. The transaction also includes an exclusive expansion agreement with Laser Rejuvenation Clinics, allowing VF first rights of refusal to locate technologically advanced dental facilities in all future Laser Rejuvenation Clinics across Canada.

10/22 **DUSA Pharmaceuticals** announced positive results from two pivotal Phase III clinical trials of Levulan PDT for the treatment of pre-cancerous actinic keratoses (AK) of the face and scalp. The two parallel studies at a total of 16 sites across the U.S. involved over 240 patients, each with between 4 to 15 AKs. All patients received either 20% Levulan topical solution, or a placebo vehicle, plus blue light. In one study, 86% of the AK lesions on 117 patients responded completely, with a 94% clearing after two treatments. In contrast, only 32% of the lesions cleared with the placebo and blue light. In the second study, 81% of the 126 patients responded completely and 90% after two treatments. This compared with only 20% in the placebo group.

With the Phase III studies now complete, DUSA is in the process of preparing its first NDA and expects to submit it to the FDA in the first quarter of 1998.

10/23 **QLT PhotoTherapeutics** announced that its European partner, **Beaufour Ipsen**, has launched Photofrin in France and Germany. The drug has been approved and is now being marketed in France as a treatment for both early- and late-stage lung and esophageal cancer, and in Germany for early-stage lung cancer. An executive vice president of Beaufours, Stephane Francois stated, "We are firmly committed to the success of Photofrin throughout Europe...a team of 15 dedicated representatives will facilitate the establishment of photodynamic therapy centers at institutions throughout Europe...their efforts will be enhanced by an additional 150 salespeople responsible for generating referrals into these centers." Beaufours expects to launch Photofrin in the Netherlands within the next few months, while approval is still pending in Italy. Beaufour, along with QLT, expect to file for approval of Photofrin in an additional 11 European countries including the UK, with widespread availability anticipated by the end of next year.

10/23 **Candela Corporation** said that total revenues for the first fiscal quarter increased slightly, and that the company reduced its quarterly net loss by sharply cutting startup and certain operating expenses for its new skin care centers. For the quarter, revenues were $7.8 million with a net loss of $851,000 (15 cents/share). In the previous quarter, the company had reported a net loss of $1.3 million (23 cents/share), as it bolstered marketing programs and cut startup expenses for its new laser treatment spas. The company opened three such facilities earlier in the year; LaserSpa health and beauty centers in Boston and Scottsdale, AZ, along with a laser surgery center in Cairo, Egypt. Gerard Puorro, president and CEO said that he believed that Candela had now stabilized their cost structures and that the revitalized marketing programs should help to improve traffic. He expected that both the Boston and Cairo centers to break even by the end of the calendar year, and that the Scottsdale center should be operating in the black by the end of fiscal 1998. Puorro also noted that the company's device business continued to be profitable for the quarter. The company began shipping its new erbium laser along with the dynamic cooling device at the end of fiscal 1997.

10/23 **Laserscope** released its third quarter results with continued strong revenues and earnings. For the quarter, revenues were $15.7 million and net income rose to $901,000 (7 cents/share). For the nine month period, revenues were $46.7 million and net income was $2.5 million (20 cents/share). The third quarter and nine-month results included full consolidation of the operations of **Heraeus Surgical**, while the third quarter results included operations of **NWL**, and nine months' results included three and a half months of NWL's operations.

The company said it was moving ahead with plans to introduce a new generation erbium:YAG laser early next year. Market diversification continues with 26% of revenues during the quarter coming from the ENT market; 23% from aesthetics; 21% from urology; 14% from OB/GYN; and 15% from all other markets, principally neurosurgery, gastroenterology, general surgery, and orthopedics.

10/27 **American Dental Technologies** announced that it had agreed to grant a non-exclusive license to its air abrasive patents to **Danville Engineering** of San Ramon, CA. As part of the agreement, ADT will receive royalties from the sale of Danville's dental air abrasive cavity preparation systems. Danville becomes the third company to obtain a license for the air abrasive system from ADT.

10/27 **Mehl/Biophile International** announced that its **Consumer Products Division**, **Mehl Group Marketing Consumer**, had received FDA clearance to market it consumer hair removal system, Finally Free Ultra, in the U.S. The product will make its national debut at Bloomingdales on Thanksgiving, and will be featured at the International Chicago Housewares Show in January. It will be marketed through high-end retailers and upscale catalogues retailing at $100. Finally Free Ultra features the new Mehl patented method of hair removal, using a dry radio frequency energy that is painlessly

directed through the hair shaft. Like electrolysis, it uses electrical energy but differs in that no needle is used. A coated tweezer grasps the unwanted hair above the skin line. (Apparently, the method treats one hair at a time, a slow, tedious process, similar to electrolysis.)

10/28 **Miravant** and **Medicis Pharmaceutical Corporation** announced that they have signed a letter of intent to develop and commercialize certain PhotoPoint procedures for dermatology applications. The two companies will collaborate on the clinical development and, subject to a definitive agreement, Medicis will distribute and sell certain PhotoPoint products in the U.S. Among the co-development product areas is the treatment of psoriasis and certain (unnamed) skin cancers.

10/28 **Laser Industries** reported record sales and earnings for its third quarter and nine month period. Third quarter sales were $21.1 million with net income of $2.9 million (33 cents/share). For the nine months, sales were $56.8 million with net income of $8.3 million (95 cents/share). According to the company, the improved results were largely due to increased sales of the company's EpiTouch hair removal system, which rose 63% over the prior quarter. Sales in Europe were particularly strong, increasing by 86% over last year's third quarter, partly driven by sales of commercial laser systems manufactured by **Spectron Laser Systems, Ltd.**, acquired by Laser Industries in April. North American sales grew 38% over the same period.

10/29 As expected, **Palomar Medical Technologies** announced that it was moving its corporate headquarters on November 3 to its existing EpiLaser manufacturing facility in Lexington, MA. This move will consolidate its corporate personnel with its R&D personnel, streamlining decision making and maximizing teamwork, while reducing costs. The company noted that to date it had installed over 160 EpiLasers worldwide, and that over 25,000 hair removal treatments had been performed. Also, Palomar's **Cosmetic Technology International** subsidiary had now established more than a dozen revenue-sharing laser centers in the U.S. and internationally. (For more on CTI, see my cover story in the October issue of *Medical Laser Report*.)

10/29 **ESC Medical Systems** announced that it had received FDA clearance to market its DermaScan system, a computerized pattern generator used in conjunction with ESC's skin rejuvenation devices; including the Derma 20 erbium:YAG laser, and the Derma K, combination CO_2/erbium:YAG laser, and the NovaPulse and Topaz 30 CO_2 lasers.

MEDICAL/SURGICAL LASER UPDATE -- NOVEMBER 1997

10/17 *JW Charles/CSG* issued an investment report on **Laser Industries**, written by analysts Allan Ronesss and William Trent, with a "buy" recommendation. (This turned out to be a timely recommendation, with the notice of acquisition of Laser Industries by **ESC Medical** -- see the November 10th brief below.) The key points in the research

report: the market for hair removal alone is vast; Laser Industries has consistently increased operating income for several years; acquisitions could fuel growth; ISO 9001 certification shows high quality assurance; long operating history (since 1973 -- actually 1972) with a solid reputation among doctors and hospitals. The report details Laser Industries participation in several medical specialties, with emphasis on the cosmetic market.

10/20 This issue of *The Gray Sheet* notes that **Laser Industries** has submitted IDEs to conduct clinical trials of its holmium laser to perform direct myocardial revascularization (DMR), in conjunction with a **Biosense** catheter-based cardiovascular navigation system. (See last month's 10/7 brief for more about this collaboration, and the acquisition of Biosense by **Cordis Corporation**, a wholly-owned subsidiary of **Johnson & Johnson**.)

10/29 **Coherent, Inc.** released its fiscal fourth quarter and year-end results with sales totaling $104 million for the quarter and net income of $6.6 million (56 cents/share). For the fiscal year, sales were $391 million and net income came in at $35.3 million. According to company officials, medical laser sales for the quarter were $44.1 million, providing nine month sales of $128.4 million, and in line for $172 - $173 million for the calendar year.

10/29 A new report issued by *Market Pulse* analyzes the minimally invasive cardiac surgery market. The report states that 60% of PTCA and 45% of CABG procedures will convert to MICS by the year 2002. Although not specifically stated in the news release about the report, I was led to believe that there was some information about the use of lasers in cardiology in the report. For further information, contact Market Pulse at 415-398-7144.

10/29 **PLC Systems** reported its third quarter financial results with revenues of $1.9 million and a net loss for the quarter of $3.6 million (21 cents/share). For the nine month period, revenues were $6.9 million and the net loss was $9.3 million (56 cents/share). Dow Smith, president and CEO stated that the company continued to ship Heart Laser systems under its placement program, which provides a limited up front payment and a continuous revenue stream with usage. However, he noted that in the near term, placement revenues may decline due primarily to reimbursement issues. The company is completing the analysis of the 12 month controlled randomized study and expects to submit the information to the FDA in November.

10/30 **Palomar Medical Technologies** announced its third quarter results with revenues of $18.3 million, down from $24.7 million for the same period a year ago. In line with the recently announced restructuring plan, the company reported a net loss of $37.0 million for the quarter ($1.11/share). For the nine month period, revenues were $63.2 million and the net loss was $67.2 million ($2.15/share). President Dan Valente said

that the third quarter was significantly affected by an expected delay in its medical group's sales of EpiLaser, resulting from the September announcement of an agreement with **Coherent, Inc.**, to distribute Palomar's hair removal products. He anticipates that the EpiLaser sales shortfall will be recovered, and possibly surpassed, during the fourth quarter and the first quarter of 1998, once the definitive agreement is in place. The medical group's sales for the quarter were given as $5.8 million, or $17.7 million for the nine month period, therefore lowering our estimate for the year to about $24 - $25 million.

10/30 **Cell Robotics International** announced that the FDA had extended its clearance for the Lasette laser finger perforator to include adults in a clinical setting, including diabetic patients. The previous clearance had been for healthy patients only. The company plans to apply for additional clearances including juveniles in clinical settings and home-use for diabetics.

11/3 *The Gray Sheet* notes that **PLC Systems'** data being re-submitted to the FDA will probably need to undergo a second review by the FDA's Circulatory System Devices Panel. This was stated by the company's chairman, Robert Rudko at an October 27th **Oppenheimer & Co.** conference in New York city.

11/3 *The American Society for Dermatologic Surgery* notes that the erbium laser is the new "wunderkind" in skin rejuvenation. The news release cites a recent article in *Dermatologic Surgery Journal* by co-author David Goldberg, MD, who concluded "that the new pulsed erbium:YAG laser may optimally fulfill the basic requirements for skin rejuvenation as it safely and effectively obtains the desired cosmetic results...for both fine, superficial resurfacing...as well as controlled large superficial tissue removal...especially for body areas like the neck and hands which are difficult to treat with other laser systems".

11/3 **ESC Medical Systems** announced that it had received FDA clearance for its Derma K laser system. The Derma K is a dual laser system with both an erbium:YAG and CO_2 laser, which can operate either simultaneously or separately. Simultaneous operation gives the physician full control of the temperature profile created in tissue during skin rejuvenation. The Derma K has been in clinical use in Europe, Asia, and South America for the past year and, with the FDA clearance, delivery will start immediately in the U.S.

11/3 **Mehl/Biophile International** announced that it had initiated a program to maximize its revenue sharing program with professionals who have chosen to use the company's Chromos 694 long pulse ruby laser hair removal system. Mehl is collaborating with Dennis Jones to provide seminars on interactive marketing on a national basis. The programs are designed by Mr. Jones to assist Mehl's licensees in building successful

laser hair removal businesses. An initial seminar for 50 professionals was held in Miami and a second seminar is scheduled for New York city this week.

11/4 **ThermoLase** reported revenues of $12.1 million for its fiscal fourth quarter and $45.2 million for the fiscal year. The company had a net loss of $3.6 million for the quarter (9 cents/share) and $12.4 million for the year (31 cents/share). ThermoLase reported that it now has 16 Spa Thira locations open around the world and nearly 150 lasers in use through its physician licensing program. The company continues to commit significant resources to R&D to both enhance its SoftLight laser system and to develop its SoftLight laser skin rejuvenation treatment that still awaits FDA marketing clearance.

11/5 **Laserscope** announced that it has added new distributors in Brazil, Argentina, Taiwan, and the United Arab Emirates, expanding its international distribution network to 28 distributors serving 54 countries. The company has direct sales operations in the U.S., the UK, France, and Germany. Robert McCormick, president and CEO, said, "The addition of the new distributors is a key element of the company's long-term strategic plan for creating new opportunities for growth by introducing innovative medical laser products in new and emerging markets. Revenues from international markets today represent 34% of total corporate sales, up from 17% just three years ago, on a higher overall sales base."

11/5 **Mehl/Biophile** said that its majority owned subsidiary, **SLS Biophile, Ltd.** of Wales, had received Canadian approval for the company's Chromos 694 hair removal laser, under CSA, IEC, and UL standards. The laser may now carry the NRTL/C mark that signifies full approval under Canadian Standards and Underwriter's Laboratories. Mehl/Biophile has already received ISO 9001 approval, as well as approval to carry the CE mark.

11/5 **JMAR Industries** announced that it had reassessed and reordered its strategic priorities to more efficiently focus its resources on a broad range of timely market opportunities. The top priority was assigned to its "core" manufacturing equipment product lines aimed at the computer disk drive and semiconductor markets. Second priority was for the continued development of advanced lithography light sources, followed by the ultra-precision manufacturing programs which utilize its short-pulse laser technologies for advanced manufacturing applications. The fourth area of emphasis is the emerging Light Knife series of hand-held lasers designed primarily for medical applications such as needle-less blood sampling, but which the company believes can be utilized in the dental and ophthalmic markets as well.

11/5 *Josenthal Lyon & Ross* has initiated coverage of **Premier Laser Systems** with a buy rating. In a research note, the firm estimated that Premier would post a loss of $1.12 a

share in the fiscal year ending in March and earn 45 cents/share in fiscal 1999. The company set a share target price of $18; shares were recently trading at $10.

11/6 **Mehl/Biophile** announced that it has commenced a pilot TV commercial program in three large U.S. markets. The company began airing its "Nu-Trolysis" laser hair removal commercial over several network and cable stations in New York City, Miami, and West Palm Beach, FL. The 30-second commercial airs through November 14 at various times on about 14 stations in the three areas. The commercial briefly describes the operation of the company's Chromos 694 hair removal laser and its advantages and gives an 800 number for viewers to call to obtain the name and telephone number of the nearest treatment center, or is connected to the nearest center.

11/6 **Candela Corporation** announced that new manufacturing efficiencies and proprietary technology are enabling the company to dramatically lower prices for its Skinlight erbium:YAG product line. The basic Skinlight system now carries a list price of $49,500, down more than 15% from its original price, and from 10% to 20% lower than any competing system. In addition to the new price for the laser system, the company has also reduced the price for its SkinScan computerized pattern scanner, which when purchased with the Skinlight laser, is coupled at $62,500, an additional 10% discount from the SkinScan list price of $14,500. The company claims to have over 1500 lasers installed worldwide, and more than 500,000 aesthetic laser procedures are performed annually with its systems.

11/6 *UBS Securities* has resumed coverage of **QLT PhotoTherapeutics** with a hold rating. In a recent research note, UBS sees QLT posting losses of $0.47 in 1997, $0.45 in 1998, and $0.37 in 1999. The company expects QLT to swing into "marginal profitability" in 2000, at $0.20 a share.

11/10 One surprise follows another in this fast moving industry. Over the weekend, it was announced in Israel that two of its premier laser companies had agreed to merge. It appears that **ESC Medical** will acquire one of the oldest medical laser companies, **Laser Industries** -- founded in 1972! The transaction will make ESC the leading medical laser company in terms of revenues and product offerings, surpassing Coherent Medical. Today's press release states that the combined company expects to generate revenues of approximately $185 million in 1997. According to my estimates for the calendar year, which added up to $181 million, this will surpass Coherent Medical's expected revenues of approximately $172 million. And looking ahead, I have forecast 1998 revenues for Coherent at $180 million, and for the combined ESC Medical/Laser Industries of $210 million!

The transaction between the two companies is valued at $270 million, based on ESC's closing share price of $42. Under terms of the agreement, which has been approved

by the boards of both companies, outstanding shares of Laser Industries will be exchanged at a fixed ratio of .75 share of ESC Medical for each Laser Industries' share, subject to adjustments. The transaction is expected to be treated as a tax-free reorganization for Federal income tax purposes.

Dr. Shimon Eckhouse, ESC chairman, president, and CEO, will continue to hold those titles of the combined company, while Benjamin Givli, Laser Industries' chairman and CEO, along with Thomas Hardy, a director of Laser Industries and president and CEO of **Trans Resources**, its largest single shareholder, will be nominated to ESC's board. No mention was made of the role in the new company for Yacha Sutton, Laser Industries' president and COO. The transaction is expected to close at the end of the first quarter of 1998, subject to approval by the shareholders of both companies, and Israeli and U.S. regulatory authorities. ESC expects to incur a one-time charge related to the transaction in 1998.

Dr. Eckhouse commented, "The combination of ESC and Laser Industries significantly enhances and strengthens our position as a leader in the cosmetic and medical market places. With Laser Industries installed base of approximately 12,000 laser systems and its significant worldwide presence in sales, marketing, distribution, and manufacturing, the combined company will have one of the largest sales forces and a stronger global presence...This transaction will enable us to take full advantage of the growth potential in our marketplace using the combined marketing capabilities and technologies of both companies."

In a research call note issued the same day, *Smith Barney* analyst Melissa Wilmoth said that the transaction would probably add 3 cents/share to ESC's 1998 earnings before synergies and cost cutting. She believes that the transaction is positive because "while the EpiLight has enjoyed a `robust market reception', it nevertheless takes time and effort to learn how to use the products software package...the ruby and alexandrite lasers employ a point and shoot method, with no parameters to learn...now ESC will have hair removal lasers to address all the market preferences. ESC will receive 30 more direct U.S. sales reps, giving the company the largest cosmetic sales force in the world...and an enhanced international distribution network.
The following day, Melissa issued a followup call note on the merger, in which she revised her estimate of earnings gain for ESC upward to 6 cents in 1998 and 20 cents for 1999. She noted "that Laser Industries has an installed base of over 12,000 lasers worldwide and produces over 22 laser systems utilizing 7 different laser types...Products are mostly complimentary; however, the company anticipates eliminating some overlap of products over the next 6 to 12 months. Approximately 405 of Laser Industries' sales are into the medical and hospital markets, a segment where ESC lacks a significant presence. The other 60% of sales are in cosmetic applications, with the biggest portion of sales going to hair removal. Growth in the medical market has been flat, but with a recurring revenue stream from consumables.

Two new products, currently in clinical trials, are aimed at the dental and gynecological markets. Laser Industries is also jointly developing a laser system for TMR with **Biosense**, which was recently acquired by **Johnson & Johnson**." Melissa estimates that Laser Industries' revenues for 1997 will be $78.8 million and $96.0 million for 1998, with net earnings for both years; $10.9 million in '97 and $15.2 million in '98. She expects that ESC will have to take a one-time writeoff in connection with the merger of between $17 to $20 million, but that cost savings of the combination will amount to $5 million in 1998 and $10 million in 1999.

11/10 **Trimedyne Inc.** announced that its 90% owned subsidiary, **Cardiodyne, Inc.** had filed an IDE to begin human clinical trials of its myocardial laser revascularization system for the treatment of angina pectoris and myocardial ischemia. Cardiodyne's MLR system is composed of an 80 watt superpulsed holmium laser, the AutoFire Automated Interface, and the ChannelMaker fiber optic delivery device. Cardiodyne holds an exclusive license to what it claims is the basic U.S. Patent on synchronizing the firing of a laser in the heart with the patient's ECG.

11/10 **Spectranetics** introduced a new directable Vitesse E 2.0 mm eccentric laser catheter at the American Heart Association meeting in Orlando. The Vitesse E 2.0 device is the largest eccentric laser catheter available to interventional cardiologists to photo-ablate, or dissolve, coronary obstructions during coronary angioplasty procedures. The catheter was FDA approved in September, and has been available in Europe since August. The eccentric design allows a channel to be ablated larger than the catheter itself, by combining multiple pass ablation techniques with saline infusion. The company believes that creating a larger opening to improve blood flow can be essential in treating difficult cardiovascular obstructions such as restenotic lesions. (Each year, over 500,000 patients undergo angioplasty in the U.S., and this design could improve the chances that more of those procedures will be done with a laser rather than just a balloon. I believe that the number of laser angioplasties is only about 10% or less of the total angioplasties performed.)

11/11 **Andros Laser and Medical Centers** announced that they have retained the Investment Banking Firm of **American Capital Investors Corp.**, of Newport Beach, CA, to complete its privat placement of $1 million to support its growth. American specializes in raising capital for emerging growth companies through a combination of private placements and public offerings. American said it had sucessfully raised $17 million for a similar medical company and was excited about the potential that Andros represents as a publically traded company. Andros provides advanced laser surgeries in its La Jolla Surgery Center and plans to open three more centers in Southern California.

11/11 According to the *Wall Street Journal*, **Columbia/HCA** is weighing a plan to spin off about a third of its 340 hospitals into a separate publicly owned company. The article

notes that Columbia is also expected to sell or spin off at least some of its lucrative surgery centers, rehabilitation facilities, and diagnostic units. **HealthSouth Corporation** is said to be interested in buying Columbia's rehab and surgery centers. The question is, what effect, if any, will a proposed sell off of the surgery centers have on **Palomar Medical Technologies' CTI** subsidiary, in its plans to co-develop cosmetic laser centers along with Columbia/HCA?

11/11 **Infinite Machine Corporation** has retained **Guidera Communications** to inform Wall Street about "LaserPaint", the technology being commercialized by **Spectra Science Corporation**, a subsidiary of Infinite Machines. In addition to several commercial applications under development for LaserPaint, it has potential use as a monochromatic, omnidirectional laser activation source for photodynamic therapy in the cancer treatment field.

11/12 Talking about photodynamic therapy, today's *Wall Street Journal* features a story about **Miravant's** advertising campaign, with the title, "Miravant Advertises Big, Sans a Product". As I noted in my brief about the advertising plans for this company, it seems a bit premature to put together what has been claimed to be a $2 million advertising campaign before the company has a product to sell. It is likely to be 1999 or 2000 before it obtains FDA marketing approval to sell "PhotoPoint", its PDT drug. A company spokesperson defended the ad campaign by saying that it "raises awareness of the treatment among a number of audiences, including doctors, patients, and potential corporate partners.

11/12 **Premier Laser Systems** reports that it has been selected as a winner of *Popular Science Magazine's* tenth anniversary "Best of What's New" awards for 1997, and its Centauri erbium:YAG laser system has earned American Dental Association recognition as a "hot" topic, one of the developments generating the most calls to the association's headquarters. According to Premier president and CEO Colette Cozean, the number of dentists visiting the company's exhibit at the recent ADA Conference in Washington,DC "exceeded anything experienced in response to a new product in past years. We actually had dentists waiting in line to `test drive' Centauri, using extracted teeth." The company said that more than 150 dentists paid a fee to use Centarui as part of the ADA Conference High Technology symposium.

11/12 **Miravant** announced financial results for the third quarter with revenues and net interest income of $1.3 million and a net loss of $7.8 million (63 cents/share). For the nine month period, revenues and net interest income was $3.1 million and the net loss was $19.0 million ($1.53/share). Highlights of the quarter included the collaboration with **Medicis Pharmaceutical** for dermatology applications with PhotoPoint, and a meeting with the FDA to begin the NDA submission and review process for Purlytin to treat cutaneous metastatic breast cancer. Other strategic alliances developed over the past several years include those with **Boston Scientific**, **Cordis**, a **Johnson &**

Johnson company, **Iris Medical Instruments**, **Pharmacia & Upjohn**, and **Ramus Medical Technologies**.

11/12 Not to be left out, **DUSA Pharmaceuticals** announced the initiation of Phase I/II multicenter clinical trial using Levulan photodetection for bladder cancer. The seven-center U.S. study, involving 60 patients, is designed to assess the ability of Levulan PD to detect bladder cancer in high-risk patients, compared to current methods of detection. Under a previously announced strategic collaboration agreement, the study will use light sources and cystoscopes provide by **Richard Wolf Medical Instruments Corporation**, a leader in the field of endoscopy. The U.S. study follows publication by independent European researchers which reported that ALA PD improved the detection of bladder cancers by up to 20% during cystoscopy by expert urologists, compared to standard white light examination. When precancerous lesions were included, the reported increase was 33%. There are an estimated 800,000 to 900,000 cystoscopies performed annually in the U.S. for the detection of bladder cancer. The company noted that it continued to hold discussions regarding a strategic alliance for dermatology indications.

The company also released its third quarter financials, showing interest income of $213,000 and a net loss of $1.9 million (18 cents/share). For the nine month period, interest income was $707,000 and the net loss was $5.1 million (54 cents/share).

11/13 **Premier Laser Systems** reported its fiscal second quarter results with sales of $3.1 million for the quarter, up from $1.2 million for last year's second quarter. Almost 90% of the quarter's sales were attributable to the sale of dental lasers, with the largest revenues, $1.4 million, coming from sales of the company's Centauri erbium:YAG laser for hard tissue dentistry. The company's Arago and MOD argon lasers for teeth whitening and composite curing, along with its Aurora diode laser for soft tissue procedures, accounted for approximately $1.2 million in sales. The remainder of sales were primarily from the ophthalmics products group, including Data.Site and EyeSys.Premier subsidiaries. Colette Cozean, president and CEO noted that 35 Centauri lasers were shipped during the quarter, with substantially all of the shipments occurring during September as components became available for manufacturing. Manufacturing capacity for the Centauri and other erbium lasers is on track at approximately 40 systems per month, which should reach approximately 100 laser per month by the end of December.

Excluding one time EyeSys transaction charges, the net operating loss fell to $610,000 from the $973,000 reported for the second quarter last fiscal year. The overall net loss for the quarter was $12.0 million ($1.11/share).

Dr. Cozean also noted that "the company believes on good authority that, although certain medical laser companies have recently announced their intention to bring hard-

tissue dental lasers to market in the near future to compete with Centauri in the United States, the federal regulators will require multi-phase, multi-site clinical trials with one-year followups for each and every laser intended for hard-tissue dental use. Consequently, the company believes it is highly unlikely that certain potential competitors will receive clearance to market their hard-tissue lasers within the timeframes they have recently indicated." Dr. Cozean also said that the company's submittal on laser cataract emulsification has been completed according to agreed upon protocols, and that the submittal will be made once certain communications from the FDA have been received, which she expects to be later this month.

11/13 **American Dental Technologies** reported third quarter revenues of $4.0 million and a net income of $157,000 (2 cents/share). For the nine month period, revenues were $15.0 million and net income was $2.4 million (32 cents/share). Revenues in North America were up 80% through the third quarter and now account for 76% of total revenues. The company's air abrasive products are in their fifth year of sales, with only 4% of the market penetrated. ADT reported the sales of more lasers in October than for all of 1996, but the number was not revealed.

11/13 **CardioGenesis Corporation** announced that the results of a clinical trial on "no option" patients using the percutaneous myocardial system were presented at the American Heart Association meeting in Orlando, by Dr. Stephen Oesterle, of the Stanford University Medical Center. He reported, "While still anecdotal, the data indicates that `no option' patients treated with the PMR system achieve angina pain class reduction and improvement in exercise capacity generally consistent with the results achieved in `no option' patients treated with the company's intraoperative transmyocardial revascularization (ITMR) system." Alan Hill, president and CEO noted that the encouraging preliminary data confirm the company's leadership in the field of TMR, and that the less invasive nature of the PMR system may represent a sizeable market opportunity for CardioGenesis.

To date, the company has trained over 20 physicians and treated approximately 60 patients with the technique in 8 clinical sites in the U.S. and Europe. Currently, PMR procedure time is averaging one hour or less and patients are often discharged the day after treatment.

11/13 **Mehl/Biophile** announced that its licensor, Christina Turngren, has been granted U.S. Patent 5,685,833, for the first of what the company expects to be several interlocking patents on its innovative bandage product, Strip-EZE. The worldwide bandage market is estimated to exceed $100 million annually and is dominated by companies such as **Johnson & Johnson**, **Curad**, and **3M**. The new invention, unlike the others, allows an individual to remove the bandage and administer it with a single hand while maintaining sterility. The company has begun the licensing process and expects to generate revenues from this product commencing in 1998.

11/13 **Pharmacyclics** reported financial results for its first fiscal quarter with a net loss of $2.7 million (26 cents/share), and investment income, net of interest expense, was $498,000. As of September 30th, the company had cash, cash equivalents, and investments totaling $33.8 million, compared to $36.9 million at the end of the previous quarter.

11/14 **PLC Systems** released a summary of several TMR studies conducted at the company's Heart Laser clinical sites which were presented at the AHA meeting in Orlando. Approximately 20 TMR related abstracts and presentations were made at the meeting. Two studies suggested that the peak power of the CO_2 Heart Laser may provide clinical benefit without significant detriment to the heart muscle and that the attributes of this laser may allow for the creation of open TMR channels. For the latter conclusion, scientists from Germany were able to support the theory of open TMR channels through the use of myocardial contrast echocardiography. In a 15 patient study, 10 patients showed open TMR channels approximately two weeks following surgery. Further work is being conducted to support the belief that open TMR channels are a factor in the reperfusion of what once was an ischemic heart muscle.

11/14 **Laser Corporation** announced results for the third quarter with revenues of $1.3 million and net income of $16,200 (2 cents/share). For the nine month period, revenues were $3.7 million which resulted in a net loss for the period of $58,700 (9 cents/share). According to president Joyce Wickham, the third quarter's net income was primarily the result of increased OEM sales. She further stated that the company had commenced the sale of cutaneous medical products for dermatology in the fourth quarter. (They also were present at the Academy of Ophthalmology meeting in San Francisco.)

11/14 **Ion Laser Technology** reported its second fiscal quarter and six month results, with revenues for the quarter of $1.1 million and a net loss of $928,000 (17 cents/share), down from revenues of $2.0 million and net income of $75,000. For the six month period, sales were $3.1 million and a net loss of $1.0 million (18 cents/share), down from revenues of $3.4 million and net income of $209,000. Commenting on the operating results, president Wayne Cannady said that the results were affected by the company's strategic refocusing to utilize marketing partners with established distribution channels for more rapid and broader market penetration. Sales cycles were lengthened for the BriteSmile dental laser product lines due to the time to train and build up distributor capabilities. Revenues for the new sub-second cure product line were not yet reflected in this quarter, and are expected to commence in the fourth quarter when product shipments begin.

The remodeling of ILT's headquarters in Salt Lake City, including a state-of-the-art training and education facility, have been completed. The Birmingham, AL training facility has been closed. In addition, ILT has launched a test consumer marketing

campaign for BriteSmile, with media expenses of approximately $250,000. This plus the closing costs of the Alabama facility contributed to the loss in the second quarter.

With marketing partners in place, the company is better focused on future growth. Subject to certain conditions, ILT should receive $5 million in Apollo 9500 purchases from **Dental/Medical Diagnostics Systems**, who is planning to launch the Apollo in the U.S. and Canada. Strategic growth initiatives negotiated during the quarter include an exclusive international distribution agreement with **Laser Industries** for BriteSmile laser whitening products, and the exclusive distribution agreement with DMD for ILT's new sub-second product sales in the U.S. and Canada. DMD's sales organization will also be selling the BriteSmile laser tooth whitening dual-laser system on a non-exclusive commissioned basis.

11/14 **EquiMed** reported its third quarter results with net revenues of $23.8 million and net income of $2.8 million (64 cents/share). For the nine month period, net revenues were $59.8 million and net income was $8.6 million ($1.89/share). EquiMed currently is affiliated with 112 physicians, owning or operating 35 oncology centers and providing anesthesia services to 21 hospitals, and manages 6 complimentary subspecialty practices in medical oncology, urology and internal medicine. It also operates a cosmetic laser treatment center. (Although, I was under the impression that the laser center had been closed, I was reassured by an officer of the company that the center, located in New Orleans, was still in operation.)

11/14 **QLT PhotoTherapeutics** released its financial results for the third quarter incurring a net loss of $3.7 million (14 cents/share) with gross unit sales of Photofrin remaining the same as in the second quarter. However, returns of short-dated product by wholesalers in the U.S. decreased the company's net royalties by approximately $40,000 during the quarter, resulting in net revenues of $2.6 million, which included a milestone $1 million relating to approval of Photofrin in Germany. For the nine month period, net revenues were $6.0 million and the net loss was $11.9 million (46 cents/share). The mid-October launch of Photofrin in France and Germany by **Beaufour Ipsen** and the September recommendation of the FDA advisory committee to approve Photofrin for early-stage non-small cell lung cancer is expected to have a positive effect on product sales throughout 1998.

11/14 According to *Medical Industry Today*, the exhibitors at the recent American Heart Association meeting in Washington revived interest in TMR, with positive news coming from such companies as **CardioGenesis**, **Eclipse Surgical Technologies**, **PLC Systems**, and **U.S. Surgical**. Several multicenter studies from the above showed improvement in angina following treatment. Meanwhile, a study from the University of Pennsylvania Health System proposed that blood vessels formed after TMR could simply be a reaction to tissue injury, and may be unrelated to the laser's properties. Howver, the device firms were not swayed by the argument. PLC Systems and

Eclipse have filed PMAs and CardioGenesis is expected to do so after the first of the year.

11/17 Both **Palomar Medical Technologies** and **Coherent, Inc.** announced that they had signed a definitive partnering agreement for Coherent to act as the exclusive distributor for Palomar's laser-based hair removal system in the U.S., Far East, and most countries in Europe. Key provisions of the final contract include a $3.5 million up-front fee for the distribution rights to Palomar's current and future hair removal products, a license to key patents relating to hair removal, and a three-year warrant to allow Coherent to purchase share of Palomar's common stock with an exercise price of $5.25 per share. Under the terms of the agreement, Coherent, with a sales force of over 200 direct sales representatives, is responsible for sales, marketing, service, training and education, while Palomar will continue to design, develop, and manufacture its laser-based hair removal systems. Bernard Couillard, president and CEO of Coherent noted that its sales force has been trained and is already actively selling the product. Palomar claims that to date, more than 160 EpiLaser systems have been installed worldwide, and that over 25,000 treatments have been performed with the systems. In addition, Palomar's **Cosmetic Technology International** subsidiary has established more than a dozen revenue-sharing cosmetic laser centers in the U.S. and internationally.

11/17 **Surgical Laser Technologies** announced that a settlement had been reached in the suit brought against the company in February 1995 by Norio Daikuzono, the inventor of three of its patents in contact laser technology. Under terms of the settlement, SLT will continue to calculate royalties due Daikuzono under the contact laser patents as it has from the beginning. SLT has agreed to release to Daikuzono certain royalties which it had set aside since 1993, pending receipt from Daikuzono of proper tax documentation. Furthermore, the settlement with Daikuzono and his affiliated company, **SLT Japan Co. Ltd.**, confirms the continuing validity of the prior assignment by Daikuzono to SLT of all rights in the contact laser patents and any other related European and Japanese patent applications and patents issued pursuant to the agreement between them. Under the terms of the agreement, SLT can continue to sell its products worldwide, including Japan, but will not use its own name in Japan to reduce confusion with SLT Japan Co. Ltd. Daikuzono was granted a non-exclusive, royalty-free license to practice in Japan all rights under any patent that may be issued from SLT's Japanese patent applications related to contact laser technology.

11/18 **Biolase Technology** announced its third quarter results with revenues of $605,000, up 40% from its second quarter, and a net loss of $513,000 (4 cents/share). For the nine month period, revenues were $1.2 million and losses were $2.0 million. The company installed a direct sales force in the quarter and reported taking orders for its HydroKinetic Tissue Cutting Systems, both Milennium and Dermalase, for the domestic market, while continuing to negotiate additional distribution agreements.

The company expects a significant increase in revenues for the fourth quarter. (The Dermalase erbium laser system employs water-assisted cutting, cooling and hydration, useful for multiple applications, such as for scar revision, removing of cysts and tumors, performing diagnostic biopsies, and skin resurfacing.

11/18 **Miravant** and **Chiron Diagnostics**, a business unit of **Chiron Corporation**, jointly announced that they have signed a binding letter of intent to collaborate on studies directed toward the early detection and treatment of lung cancer. Chiron is developing an assay that is being evaluated in clinical trials, which may enable Miravant to identify patients in early stages of cancer who are eligible for participation in PhotoPoint clinical trials. Data suggests that the Chiron assay may provide a screening method that is potentially more sensitive, less invasive, and less costly than traditional methods, including sputum cytology, x-ray, and bronchoscopy. Gary Kedzik, chairman and CEO of Miravant said that by linking Chiron's in vitro diagnostic expertise with PhotoPoint technology, we may be able to identify and treat patients in the early stages of cancer when prognosis is best. Under terms of the agreement, the companies will collaborate to design and undertake a series of clinical trials to identify and treat early-stage lung cancer. Specifically, Miravant will conduct the clinical trials with the assistance of Chiron, which will perform diagnostic assays on the subjects defined as being "at risk" for cancer. The results will be provided to Miravant which will use the data to identify patients who are eligible for further evaluation and treatment with PhotoPoint. In addition, Chiron would agree to work exclusively with Miravant in the field of photodynamic therapy for certain oncology indications.

11/19 According to *Federal Filings*, **Palomar Medical Technologies** said that it had sued its 4.5% subordinated convertible debentureholders seeking a declaratory judgement that the company is not in default of any protective covenants contained in the indenture. The suit was filed in the U.S. District Court of Massachusetts on October 16th because some of the holders contend that the company is in breach of certain protective covenants under the indenture. Palomar notified the holders that it is converting the debentures into 914,024 shares of the company's stock. At current exchange rates, the principal amount of the debentures, which are due in 2003, and denominated in Swiss francs, is approximately $6.75 million. In response to the lawsuit, some of the holders sued Palomar on October 22nd in the same court, claiming the company breached the covenants and that they are entitled to immediate payment of their indebtedness. The holders sought a temporary restraining order attaching Palomar's bank accounts and barring it from transferring any interest in securities of its subsidiaries. The Court denied the holder's request at a November 6th hearing, and scheduled a preliminary injunction hearing on essentially the same for November 21.

11/20 **Laserscope** announced that it had entered into a strategic alliance with **Celebration Health**, a new, innovative health care facility in the Walt Disney-inspired community of Celebration, FL, near Orlando. The Celebration Company, a wholly-owned subsidiary of the **Walt Disney Company**, selected Florida Hospital to lead the development of Celebration Health. The new facility features state-of-the-art surgery and diagnostic centers, rehabilitation and sports medicine clinics, health activities and fitness centers, primary care services, specialty physicians, a dental clinic, and a pharmacy. Robert McCormick, president and CEO of Laserscope said that leading physicians and hospital administrators from around the world will visit the facility to examine advanced medical technology and the latest in patient care. Celebration Health will be a national showcase for Laserscope's innovative medical products. Among other strategic corporate partners are **Johnson & Johnson**, **General Electric Medical Systems**, **GlaxoWellcome**, **Sprint**, **Wyeth-Ayerst Laboratories**, **Delta Dental**, and **Astra Merck**.

At Celebration, Laserscope has supplied products from its Ascent Medical Systems line, the latest in surgical suite design, including ceiling mounted equipment organizers, which move operating equipment and patient monitoring devices off the floor to optimal positions overhead, as well as CVAC centralized smoke evacuation systems. An important feature of the Celebration surgical suite will be Laserscope's Hanavision Interactive Surgical Video System, which allows viewing of live or recorded procedures and provides uplinks for remote diagnostics and teaching purposes. Celebration also selected Laserscope's new Pulsar Laser System, an effective skin resurfacing and wrinkle removal laser, as well as a versatile surgical laser, with applications in gynecology, and ENT surgery.

11/21 **Eclipse Surgical Technologies** announced that the FDA had approved commencement of its Phase II pivotal study of percutaneous transluminal myocardial revascularization (PTMR). The study is currently limited to the company's Phase I clinical sites. The company also noted that it had completed Phase II of its surgical TMR study, for which a PMA had been submitted in July 1997.

11/25 **Cell Robotics International** reported its third quarter results with revenues of $294,000 and a net loss for the quarter of $713,000 (14 cents/share). For the nine month period, revenues were $829,000 and the loss was $1.8 million (36 cents/share). The company expects significant revenues in 1998 from the recently launched Lasette erbiuim laser finger perforator that received FDA clearance in October for professional use with adult diabetic patients. The RevitaLase, another erbium:YAG laser, for use in dermatoloy, also received FDA approval and should contribute to 1998 revenues.

11/25 **Medical Resources Management**, a leading provider of mobile laser/surgical services, announced that it had acquired **Texas Oxygen and Medical Equipment Company**, a

provider of biomedical services and medical equipment rentals in the state of Texas. TOMEC reported annual revenues of approximately $450,000, and will operate as a wholly-owned subsidiary of Medical Resources Management.

MEDICAL/SURGICAL LASER UPDATE -- DECEMBER 1997

11/5 I received (belatedly) another analyst report on **Premier Laser Systems**, this one by William Relyea of **Josephthal Lyon & Ross**. For a number of reasons, the analyst thinks Premier is an attractive investment: the company has created large potential earnings opportunities in medical laser systems and fiberoptic delivery systems; it is a technology leader in three markets -- dental, ophthalmic, and surgical (?); it has a large patent portfolio; and it has managed a large number of FDA approvals, with several key clinical milestones coming over the next several years. The report focuses on the dental and cataract removal markets and opportunities without, as is usual with analyst reports, going into specifics about the downside or risks involved in entering these markets. On the surgical side, the report discusses Premier's role in developing tissue "melding/welding" techniques (which I believe are a long way from the market) and its sales of cosmetic lasers (which badly lag the market leaders). In all a well written, bullish, report.

11/9 I received a copy of an article from an unnamed Alabamian newspaper, that describes the outlook for a startup company that intends to consolidate the high-end U.S. dental industry, by providing services like general, cosmetic, and restorative dentistry, endodontics and aesthetic orthodontics. The company, called **Genus**, was founded by William Dexheimer, the former COO of Birmingham-based **MedPartners**, is also planning to add aesthetic medical services, such as plastic surgery, cosmetic dermatology, and hair restoration and removal. Investors have funded the startup to the tune of $19.5 million and Genus is off and running. The company will manage high-end aesthetic medical and aesthetic/specialty dental practices across the nation, with the dental component, called **DenCor**, operating as a separate division because of some state laws that prohibit doctors and dentists from practicing in the same company. Six deals are in the works in the Birmingham area, and Dexheimer expects Genus to generate revenues at a rate of more than $15 million a year by the end of this month (November). Across the nation, Dexheimer is negotiating a pipeline of deals with revenue potentials of $139 million. The company is being backed by venture capital investors including **Sprout** of California, **Richland Ventures** of Nashville, and **Chancellor LGT** and **Oak Investment** of New York. Genus will acquire the assets of dental and aesthetic medical practices and then manage the businesses. Eventually, Dexheimer wants to build Signature Centers, freestanding facilities near retail areas, but not malls, that are visited by his targeted markets. Each center would be 20,000 to 30,000 sq. ft., with 10 to 15 providers and the latest technology. They would be designed and finished to a higher standard than that usually associated with dentists and medicine, to give high income consumers a surrogate measure of quality.

11/17 *The Gray Sheet* contains an in-depth look at the proposed acquisition of **Laser Industries** by **ESC Medical**. The article notes that of the $78 million in revenues generated by Laser Industries over the past 12 months, 39% came from the cosmetic laser market, 45% from the medical laser market, 12% from the industrial market, and 4% from "other" revenue generating activities; while nearly all of ESC's revenues are derived from cosmetic surgery products. Following the merger, nearly three-quarters of the firm's combined revenues would result from the cosmetic market, leaving 19% in medical, and 5% in industrial. While ESC's products focus on non-invasive procedures done primarily in the physician's office, Laser Industries products are sold to both physician and hospital markets, with more than 20 of Laser Industries' Sharplan line of lasers used in gynecological, neurological, dental, and orthopedic applications.

Integration plans have not yet been finalized, but ESC said that it had no plans to reduce the size of Laser Industries sales force. Following the merger, the two companies will have approximately 100 sales representatives, who will be trained to cross-sell each other's products. (No mention was made of the dispensation of the only major potential cross over product lines, the CO_2 lasers sold by both Laser Industries and Luxor.)

11/25 As all of you must be aware, the Congress passed and the President signed a sweeping new FDA reform act, that will reform the authority given the FDA to oversee and govern medical devices. The reform basically loosens the regulatory requirements, attempting to make the FDA more reasonable and flexible. Time will tell if this really occurs. Since I have no expertise in matters pertaining to the FDA, I will not attempt to interpret the new law. However, I have obtained two writeups that attempt to explain what may happen, one an overview from an FDA consultant to one of the medical device companies, and the other, the significant PMA provisions passed by the Senate and the House, and from the Conference Report passed by both (as reproduced by *The Gray Sheet)*. I will be happy to make copies of either or both available to anyone who requests them.

11/25 **Medical Resource Management**, a leading provider of mobile laser/surgical services in the Western U.S., announced that it had acquired **Texas Oxygen and Medical Equipment Company**, a provider of biomedical services and medical equipment rentals in the state of Texas.

11/25 Here is a strange news release that I found on the *PRNewswire*. **Lasertec International, Inc.**, a U.S.-based newly traded company that develops advanced laser systems and technologies for use in medical and environmental applications, announced that in vitro tests utilizing its proprietary Photo Therapic Resonancy (PTR) (?) system have resulted in a 100% success rate when used in the analysis and treatment of superficial tumors of the bladder and vocal cords. The study was done by

the laboratories of the Public Hospital of Paris and Lasertec. The study evaluated 150 cases in the specialties of urology, vocal cords, hepatology, and dermatology. Based on these encouraging results, the company plans to immediately begin studying its PTR systems in animals and humans.

The PTR was developed by Professor Guy Cherbit, who has over 25 years experience in the field of biomolecular spectroscopy. Based on proprietary and complex algorithms, the PTR system is designed to selectively target and destroy only cancerous cells while leaving healthy, surrounding tissue unaffected. Lasertec believes their use of laser resonancy (?) in the treatment of cancers is revolutionary, and could potentially save lives, simplify treatments, and reduce medical costs.

Lasertec International claims to have developed and successfully launched several first-in-its-field advanced laser systems, ranging from medical laser positioning systems sold worldwide to companies such as Siemens, Philips, and Cisbio; to advanced laser instrument systems used for biological/chemical analysis and monitoring of matter, including municipal water supplies. (This is a company that I will have to follow up on!)

11/26 **American Dental Technologies** announced that it had signed an agreement to acquire **The Dental Probe, Inc.**(TDP). TDP is a privately held company which manufactures and markets the Interprobe, which was originally developed by **Bausch & Lomb**, and a second generation unit, the Probe One, a diagnostic tool used by dentists in soft tissue management. There are currently over 1400 units in the field, which can be used along with ADT's soft tissue dental lasers for laser curettage. After the merger, ADT will own 100% of TDP's outstanding stock in exchange for $250,000 and 61,500 shares of ADT's common stock. It is anticipated that the deal will close by December 31st.

12/1 **Mehl/Biophile** and **Medcap Financial** jointly announced that they have entered into a financing program under which Medcap will finance Mehl's Chromos 694 long pulse hair removal laser in the U.S. Under terms of the agreement, Medcap will provide a financing payment of approximately $100,000 to Mehl, for each laser placed with a qualified physician. The practitioner will receive a three-year license to utilize the laser and will be responsible for 36 monthly payments of approximately $3500. Mehl will also continue to share with the practitioners revenues generated by the laser system. Medcap will provide the billing and collection for each account, and will also introduce Mehl's hair removal technology to selected physicians among its substantial physician client base. Medcap has secured funding commitments for at least $50 million of Mehl lasers in 1998, and has agreed to finance, under the same terms and conditions, lasers already placed by Mehl in the U.S., with those practitioners who sign a new service contract. Mehl estimates that at least half of the 70 U.S.-based practitioners will convert to the new service contract and become financed by

Medcap. The two companies have also agreed to explore a similar financing arrangement for Mehl lasers installed outside of the U.S.

12/1 *The Gray Sheet* reports that according to the Commerce Department's 1998 *U.S. Industry and Trade Outlook*, the U.S. dental equipment and supplies sector is anticipated to grow 10-11% annually through the first part of the next century, out pacing the 7% growth foreseen in other segments of the U.S. medical device industry over the next five years. Commerce anticipates the dental equipment sector, which grew 12% to $2.4 billion in 1996, will increase 11% in 1997 to $2.7 billion, and 10% to $3 billion in 1998. U.S. dental products manufacturers hold an estimated 50% share of the $5.2 billion global market for dental equipment and supplies.

12/1 **Miravant** announced at the **BancAmerica Robertson Stephens 1997 Medical Conference**, that it had obtained statistically significant results from an interim analysis of its Phase III data for its PhotoPoint procedure in treating advanced breast cancer patients with metastatic tumors involving the skin (CMBC), and who have failed radiation therapy. The technology has been tested in 17 clinical studies at 44 sites worldwide for a variety of cancers involving the skin, including metastatic tumors, basal cell carcinoma, and AIDS-related Kaposi's sarcoma. In two open-label, multi-center Phase III studies, 65 CMBC patients were treated with PhotoPoint. A total of 415 tumors were randomized to light treatment or no light treatment (controls), and tumor responses were evaluated from one week to 6 months after treatment. In the interim analysis, 67% of the tumors treated with light responded to treatment, of which 95% were recorded as complete responses. (No mention of the response of control tumors was given.)

12/1 As posted on the ISRS *In Focus* website, the **American Society of Plastic and Reconstructive Surgery** said that its members did 5000 facelifts on males last year, an 80% increase from 1992. The society's members also performed 11,200 lid procedures and 1900 brow lifts, increases of 25% and 42% respectively. Although men continue to be only a small percentage of plastic surgery volume, it is interesting to note that they do represent an increasing patient population, who are becoming more concerned with appearance than previous generations.

In an allied story, from the October issue of *The BBI Newsletter*, the **American Academy of Cosmetic Surgery** reported that plastic surgery of all kinds is on the rise. According to their statistics, there has been a 21% increase in all cosmetic surgeries over the past two years, including a double-digit percentage rise in four of the top five cosmetic applications; with laser resurfacing up 16% to 138,000 procedures, hair transplantation/restoration up 16% to 244,000 procedures, liposuction up 29% to 292,000 procedures, and sclerotherapy up 52% to 516,000 procedures. And the most popular procedure of all -- chemical peel -- produced a triple digit increase, up 119% to 556,000 procedures. According to the AACS, laser resurfacing (as I have

predicted) is displacing, but also augmenting chemical peels. This organization also reported that an increasing number of men are undergoing cosmetic surgery, from 568,000 procedures in 1994, to 690,000 in 1996. The top five procedures for men were hair restoration/transplantation (31%); chemical peel (10%); liposuction (8%); sclerotherapy (4%); and blepharoplasty (4%). For women, the top five procedures were chemical peel (18%); sclerotherapy (18%); liposuction (9%); laser resurfacing (4.5%); and blepharoplasty (3%).

12/2 **PLC Systems** announced that it had submitted to the FDA, 12 month data from a controlled, randomized study of TMR using its Heart Laser. The additional submission was in response to a list of requests for additional information made by the FDA following last July's review of the Heart Laser's PMA application. The new data submitted represents the substantial portion of information requested by the FDA; the company will submit the remaining data later this month.

12/4 **Laser Photonics** announced that it had completed the private placement of 1.5 million shares at $4.00/share, raising $5.5 million in equity. In addition to the share of common stock, the investors received warrants to purchase an additional 750,000 shares at an exercise price of $4.00. The net proceeds of the offering will be applied to corporate working capital and **to the purchase of a worldwide exclusive license for the application of excimer laser technology to cardiovascular and vascular applications**, for its majority owned subsidiary **Acculase**. Earlier this year, Acculase entered into a series of agreements with **Baxter Healthcare** to perform, among other things, clinical trials on TMR with its excimer technology. Baxter has committed to fund TMR clinical trials through all FDA and other international regulatory approval processes. (This announcement, reinforces my belief that the **LaserSight** agreement to license cardiovascular and vascular rights to the **IBM** UV patents were to Baxter -- see the September newsletter -- who will pass these rights along to Laser Photonics and Acculase, as part of their agreements.)

12/5 **Premier Laser Systems** said that it had set January 6th as the redemption date for its Class A warrants, excersizable at $6.50 for one share of common stock and one Class B warrant.

12/5 **ThermoLase** announced that it had signed a lease for an additional Spa Thira, which it plans to open sometime during fiscal 1998. Expenditures for leasehold improvements and laser systems for the new spa should amount to between $1.5 to $2.5 million. The company presently operates 16 Spa Thiras. In addition, ThermoLase expects to utilize approximately $8 to $9 million in 1998 for equipment related to its licensing program for physicians. In fiscal 1997, revenues for international licensing fees totaled about $4.2 million, while overall revenues were $45.2 million. The company's net loss for the year widened to $12.4 million (31 cents/share), up from a loss of $1.4 million in 1996.

12/9 **Miravant** announced that its board of directors had authorized management to repurchase up to 750,000 shares of common stock, in addition to the approximately 400,000 shares already acquired pursuant to a July 1996 repurchase program. The company currently has 14 million shares outstanding. In addition, all directors and all executive officers have signed an agreement to lock-up all their shares and vested options until at least June 1998, representing in aggregate, approximately 3.5 million shares.

12/9 **Dynamic Associates, Inc.** announced that its **Microwave Medical Corporation** subsidiary, had received regulatory approval to begin its Phase II clinical trials of a proprietary microwave-based hair removal system. The company also announced that clinical trials of the system would commence in Germany and at several U.S. sites by years end. The company recently completed a Phase I safety study, and the Phase II study will be designed to prove efficacy. According to Rainer Marquart, PhD, and president of MMC, "Our preclinical studies have shown permanent hair removal...by permanent we mean we have witnessed complete destruction down to the base of nearly all hair follicles in treated areas...except for a small number of follicles that were significantly altered, the hair follicles in the treated areas have been completely eradicated, which means it is unlikely that hair will grow back."

The company chose Germany for its Phase II studies, which will be conducted according to U.S. FDA guidelines, as there is no formal regulatory process for hair removal systems in Europe. This means that if the data from the studies show efficacy, the company will be in a position to commence a roll-out of the product to the European marketplace towards the end of the summer. European sales will be handled through Microwave Medical GmbH, a company subsidiary located in Bensheim, Germany. The German trial is scheduled to last approximately four months. The company also anticipates holding a separate clinical trial to prove efficacy for its microwave technology for the removal of spider veins.

12/9 **ESC Medical Systems** made news again, with the announcement of three separate agreements, designed to strengthen the company's product offerings, enhance its future product pipeline in the cosmetic and medical markets, and reinforce its intellectual property position. First, the company announced that it had agreed to acquire **Applied Optronics Corporation**, a leading developer and manufacturer of high power solid-state diode lasers. This acquisition is expected to strengthen ESC's capabilities in the development of next generation products designed for the cosmetic market. AOC has diode lasers in clinical trials for hair removal and the treatment of vascular lesions. In addition, AOC is a leading supplier of diode lasers for use in activating photodynamic therapy photosensitizers, including Foscan, the **Scotia Quanta Nova** drug being used in the treatment of cancers of the head and neck and laryngeal cancer.

Separately, ESC announced that it had obtained exclusive worldwide rights to a series of patents and patent filings of Dr. Iain Miller (now head of Massachusetts General Hospital's intellectual property office), in the areas of laser hair removal and treatment of vascular lesions using diode lasers.

The company also announced an agreement with **FineTech Chemicals, Ltd.** the supplier of ALAFine, a medical grade of ALA (delta aminolevulinic acid) a photodynamic therapy photosensitizer, used in the treatment of skin cancers as well as other cancers. ESC will have worldwide rights to distribute ALAFine for all types of PDT applications. (Interestingly enough, I was under the impression that **DUSA Pharmaceuticals** held the worldwide patents to the use of ALA in photodynamic therapy. I raised this point with Dr. Stuart Marcus, DUSA's R&D director, and was told that this was true. He didn't understand how ESC would be able to market ALA for PDT without licensing DUSA's patents. A spokesperson for ESC said that we would have to just wait and see.)

12/10 **BioLase Technology** announced that it had obtained a $2.5 million line of credit to be utilized to acquire and manufacture inventory. The credit line was obtained from the New York branch of **Banca della Svizzer Italiana**, a subsidiary of **Swiss Bank Corporation**, and is for one year, with two six-month renewal options.

12/10 A new report from **Decision Resources, Inc.** examines the epidemiology of eight types of cancer -- gastric, non-Hodgkin's lymphomas, bladder cancer, pancreatic and liver cancers, malignant melanoma, acute myeloid leukemia, and acute lymphocytic leukemia. These eight might be considered relatively minor neoplasms because of their low incidence relative to other cancers, but these indications have a disproportionately large impact on cancer mortality in the world's major pharmaceutical markets of France, Germany, Italy, Japan, Spain, the UK, and the U.S. The new report, entitled Cancer Epidemiology, examines population trends in these eight cancer groups through 2006. For more detailed information contact Frank Sama, Marketing Manager, Decision Resources, at 781-487-3753.

12/10 **Candela Corporation** announced that it had received FDA clearance for its new long-pulse alexandrite laser, called GentleLase. The new laser will initially be used by dermatologists and other physicians to treat vascular lesions. It is being introduced in North America at $59,500, which Candela claims is 50% to 60% lower than competitive systems. The introductory price is in effect until the end of the American Academy of Dermatology annual meeting, which runs from February 27 through March 4th. The laser is available with Candela's proprietary Dynamic Cooling Device, which selectively cools the upper layers of skin prior to the laser pulse, minimizing pain and reducing thermal exposure to the epidermis and upper layers of the skin, allowing for treatment of darker skin types. Candela intends to begin shipping production models of the new laser in the U.S. during the first quarter of

1998. (Since this laser is similar to **Cynosure's** alexandrite system, it will also be used for hair removal upon receiving FDA approval for that indication.)

A Candela spokesperson added that the GentleLase represents the culmination of a nine year commitment to the design, development, and delivery of the most advanced solid-state alexandrite laser system available. During this period, Candela has placed over 400 systems in North America and abroad, earning recognition as the world's premier developer of alexandrite laser systems. Candela claims to have an installed base of more than 1500 lasers worldwide, which perform over 500,000 aesthetic laser procedures annually.

12/10 On the same day as Candela's announcement, **Laser Industries** announced it had received FDA approval for its alexandrite laser system for laser hair removal. The company claims the alexandrite laser is faster than the ruby in removing unwanted hair. (No product name for the new laser was announced.)

12/11 **Eclipse Surgical Technologies** announced that it had received notices of allowance for seven new patents, bringing Eclipse's patent portfolio to 21 allowed or issued patents and 36 additional patents pending. The new patents allowed cover both TMR and PTMR. One of the patents covers a non-synchronized method of performing both TMR and PTMR, describing the optimal laser parameters for holmium and excimer TMR. Other allowed patents cover a catheter for PTMR, a proprietary surgical handpiece, minimally invasive surgery tools, and a mechanical/optical system for TMR.

12/11 **Spectranetics** announced that it had received FDA clearance to market its 12 Fr. Laser Sheath, a new device for removing pacemaker and implantable cardioverter defibrillator leads. Each year, approximately 480,000 pacemaker and ICD leads are implanted, and about 10% may require removal for medical reasons. The Laser Sheath method of removal is less time consuming and is less risky than surgical removal.

12/11 **C.R. Bard** announced that it had increased its investment in **CorMedica**, a privately-held company engaged in the development of proprietary, integrated systems for catheter-based PTER (percutaneous transluminal endomyocardial revascularization) procedures. William Longfield, chairman and CEO of Bard said that the investment demonstrates the company's ongoing commitment to technological innovation in treating cardiovascular disease. The minimally invasive PTER technique can be performed by delivering laser energy through a tiny catheter placed inside a patient's heart. CoreMedica recently received notice of allowance for a patent covering its tracking and navigation system, which offers the interventional cardiologist a highly efficient means to create the beneficial laser channels.

12/11 According to *Dow Jones News Service*, **Miravant Medical Technologies'** stock fell more than 11%, as "a tug of war between supporters and its detractors lurched in favor of those pulling downhill...Miravant hasn't yet developed any products, nor has it received FDA approval for its [PhotoPoint] treatment...its aggressive self-marketing...helped propel the stock to a 52 week high of 72 on October 10, also attracted short sellers who thought the stock's rise was overdone...lately, the short sellers have Miravant on the defensive...the stock closed Thursday at 35 3/8, down 4 1/2, is now just half of its peak...Market sources said that rumors are swirling that Miravant has missed some of its milestones...analyst Don Ellis of Robertson Stephens said that none of the rumors making the rounds now contain any information that hasn't been out there for a month."

12/12 Not to be outdone, *Dow Jones News Service*, also commented on **QLT PhotoTherapeutic's** stock price the following day. DJNS said that QLT's stock is trading near its 52 week low and has fallen about 57% from its high of 39 reached in February. Analysts said that the stock drop reflects weakness in the biotechnology sector, overall market weakness, and end of the year tax loss selling, and not a fundamental weakness in the company. However, QLT did report disappointing sales of Photofrin in Canada and Japan in its third quarter results in mid-November. In Toronto, the stock is currently trading at 16.90. However, several analysts are still bullish on the company, with Mary Ann Gray of SBC Warburg Dillon Read still recommending a "buy" on the stock, and Ann Dulhanty of Eagle & Partners calling the stock a "long term buy".

12/15 **Palomar Medical Technologies** announced that it had reached an agreement to sell its electronic subsidiaries to a group led by its **Dynaco** management. The transaction will be completed in two phases; the first phase with the immediate sale of three units, Comtel Electronics, Dynamem, and Indra Technologies Division. In the second phase, Palomar will sell Dynaco to the same management group no late than June 30, 1998. The overall price for both phases is approximately $10 million in notes, common stock, and warrants payable over a pre-designated time period. Dan Valente, chairman and CEO commented that the sale of the subsidiaries was part of the company's divestiture of non-core businesses, so that it could focus primarily on its laser-based hair removal business.

12/15 **PLC Systems** said that it had submitted all of the requested data on TMR using the Heart Laser to the FDA. The company said that it had been informed that the data would receive expedited review, and that the review was underway. (The question remains whether the company's data will go before the FDA's Cardiovascular advisory panel for re-review.)

12/15 An article on laser-based hair removal appears in this month's issue of *Forbes*. The article plays up the role that **ThermoLase** had in interesting Wall Street in this

phenomenon, discussing that ThermoLase, the operator of 16 Spa Thira salons and who licenses its lasers to physicians, has a market valuation of $570 million on revenues of just $45 million. The story goes on to mention that in the last year, five other technologies have been approved by the FDA for hair removal, with the most serious challenger being **ESC Medical Systems**, especially with its recent acquisition of **Laser Industries**. The article asks if all this hairy hubbub is worth it? And responds with a line from a satisfied customer, who had spent $3400 on electrolysis and waxing over the years to get smooth legs, and just spent $2600 at Spa Thira for a laser job, and claims that "now I can wear sexy lingerie to bed, whereas before I had to wear pajamas so as not to scratch my husband" -- which reminds me of the famous tagline used by **CooperVision** in its TV commercials for extended wear contact lenses during the early 1980s -- "Now, I can see past my bedcovers!"

12/15 Sean Chaitman, medical device analyst with **H.J. Meyers & Co.** issued his latest research report on **Coherent, Inc.** Mr. Chaitman recently raised his investment opinion to "Buy" from "Neutral", believing that the company's shares had undergone severe selling pressures since the negative pre-announcement of fiscal fourth quarter results, and losing 43% of value, and was now in an oversold condition. Two of the reasons for his enthusiasm for the stock is its entry into the laser hair removal market through its distribution deal with **Palomar Medical Technologies**, and its advanced R&D stages for a new high margin leg vein removal laser, scheduled for introduction in the first quarter of 1998. (No mention of the type of laser was made.)

12/16 **Premier Laser Systems** announced that it had received notice of allowance of three new patents, two U.S., and one European, covering aspects of its dental, ophthalmic, and surgical product lines. The European patent protect the company's high-frequency erbium laser for hard tissue dental procedures and for a range of ophthalmic applications; the U.S. patents concern its angle tips and touch tips integral to its laser delivery systems, used with Premier's erbium, YAG, and diode lasers. With these awards, the company now holds 42 patents, of which 17 are international.

12/16 **Ion Laser Technology** announced the receipt of the first purchase order from **Dental/Medical Diagnostic Systems** for $2.87 million of ILT's Argo HP dental curing and whitening devices, which DMD will market as its Apollo 9500. As previously announced, DMD has exclusive distribution rights for ILT Argo HP product line in the U.S. and Canada, and non-exclusive rights outside of those areas.

The purchase order provides a shipping schedule to begin in February 1998, and continue through June 1998. DMD will begin filling its backlog of orders to dentists in February, upon receipt of the product from ILT.

12/18 **Eclipse Surgical Technologies** announced that the FDA had given permission to begin what the company believes is the first clinical trial for the use of PTMR in

conjunction with percutaneous coronary interventions, such as balloon angioplasty and stents. The Phase I trial has commenced at three sites in the U.S.

12/18 **Surgical Laser Technologies** announced that it had entered into an agreement with **CorMedica**, which calls for SLT to develop and supply lasers and fiberoptic delivery systems for CorMedica to incorporate into their proprietary catheter tracking and navigation system. (The type of laser that SLT will supply to CorMedica is not identified but, based on what technologies SLT is known to posses, I would anticipate that it would be a holmium:YAG system. I have placed calls to both SLT and CorMedica for confirmation.)

12/18 The FDA issued a warning about the eye damage danger of misuse of hand-held laser pointers, especially by children. According to *HHS News*, the products are generally safe when used as intended, but with recent price reductions and wider marketing practices, the FDA is concerned about their promotion and use as children's toys. The news release notes that the light energy produced by laser pointers can be more damaging than staring directly into the sun.

12/19 *MassHighTech* carried a front-page article on laser-based hair removal, discussing some of the local companies involved, including **Cynosure** (alexandrite), **Candela** (awaiting hair removal approval for its alexandrite laser), and **Palomar** (ruby laser sold through **Coherent Medical**). Left out of the story was local company **ESC Medical**. ESC has both a pulsed light system and, soon, lasers for hair removal, once the acquisition of **Laser Industries**, with both a ruby and alexandrite laser goes through.

12/19 **Cell Robotics** announced that it would amend its current registration statement, filed on November 24th, to cover the sale of approximately 400,000 units at $20/share, in addition to the sale of common stock as noted in the registration. The proceeds will be used for manufacturing, marketing, selling and distribution of the company's new medical laser products.

12/19 **Candela Corporation** said that it had applied to the FDA for marketing clearance for its new long-pulse alexandrite laser for hair removal. (It is believed that a 510(k) application was filed.) The laser system, GentleLase, received clearance for use in vascular lesions last week (see the December 10th brief above).

12/21 *The Boston Sunday Globe* carried a story written by Diane Hamilton of *Bloomberg News*, about the status of photodynamic therapy for the treatment of cancers. Entitled, "Light-sensitive drugs excite cancer doctors, companies", Ms. Hamilton, noted that some analysts believe that PDT drugs could be worth hundreds of millions of dollars in aggregate sales, taking a major role in cancer treatment next to chemotherapy, surgery, hormone therapy, and other widely used treatments.

The article discusses most of the known companies involved -- **Scotia Holdings, PLC**, **Miravant**, **DUSA Pharmaceuticals**, **QLT PhotoTherapeutics**, and **Pharmacyclics** -- but also discussed two companies that I hadn't heard about before, **Pacific Pharmaceuticals**, a San Diego-based biotechnology firm developing a boronated porphyrin compound (BOPP), and **Light Sciences LP**, a Seattle-based company developing PDT drug delivery technology. According to David Horrobin, CEO of Scotia, "New diagnostic methods, combined with PDT will be a boon for treating cancer in its early stages -- when treatment can be most effective, particularly with PDT."

As reported by Ms. Hamilton, "With big money pouring into photodynamic therapy development, investors started to notice, pushing up share prices for a handful of companies in the sector, including Miravant, QLT PhotoTherapeutics Inc., Dusa Pharmaceuticals Inc., Pharmacyclics Inc., Scotia, and others in the last two years. While some gains have eased, industry watchers say it won't be long before more ventures are signed, pushing shares back up. And at least five major drugmakers are rushing their PDT drugs through development, which could further boost the sector."

"It's still the early days, however, and only one drug, QLT's Photofrin, has made it on the market. Sales have been slower than some analysts expected, although they anticipate more approvals soon. Skeptics say early optimism might be misguided, however. `I think it will be a very valuable area, but I don't think the current generation of drugs has solved all the problems,' said Andrew Clark, a fund manager at Finsbury Asset Management, which invests in biotechnology. `There is nearly always a gap between promise and delivery.' PDT drugs have one key benefit over other widely used cancer treatments such as chemotherapy: They are largely nontoxic when ingested into the body. Beams of light, usually from a laser, are focused on the site of the cancer, which activate the drugs. This spreads oxygen `free radicals', which kill cancer cells locally."

12/22 I received a research report, published on December 3rd by Sarah Althoff of *Principal Financial Securities*, on **Henley Healthcare**. In discussing the company's MicroLight 830, the hand-held, low-energy laser device for treating carpel tunnel syndrome (CTS), Ms. Althoff says that the company expects to complete the required clinical testing in early 1998, after which it will file a PMA for U.S. marketing approval. (Apparently, the company decided that a 510(k) application, as it intended to file, so they told me several years ago, didn't satisfy the FDA, and that a full-blown PMA would be required.) The report notes that more than half of the CTS patients treated in the clinical trials experienced a reduction in tissue swelling and an alleviation of the CTS symptoms. The MicroLight device is currently slated for a European launch in mid-'98 in part through the **Cybex International** network, and Ms. Althoff believes that the device could reach the U.S. market in late 4Q '98, or early 1Q '99. She

estimates a quick 1% penetration of an estimated 100,000-unit core market for the $8000 device.

12/23 **Palomar Medical Technologies** announced that the management of its **Tissue Technologies** subsidiary had bought out the division, which would be renamed **Tissue Medical Lasers, Inc.** Under terms of the agreement, Palomar received a note receivable, a 15% equity stake, and warrants to buy an additional 10% share. Palomar will also receive a royalty on all Tru-Pulse CO_2 resurfacing lasers sold by TMI, in addition to royalties on successor products and any other cosmetic laser products sold by TMI over the next 10 years. Palomar will also receive discounted pricing for the purchase of TMI laser systems by its **Cosmetic Technology International** subsidiary. (The company has now increased its count of EpiLasers installed to 180, and the number of hair removal procedures performed to 30,000.)