MEDICAL LASER UPDATE -- December 1995

11/27 -- The Gray Sheet reports that the U.S. District Court in California ruled on November 8th that SLT's contact laser products do not infringe Trimedyne's patent, U.S. 4,646,737, that covers devices that use laser energy to cause localized vaporization of tissue. Trimedyne also sued SLT over its patent covering a wide range of reflective type lateral lasing devices, such as its Urolase side firing fiber. The judgement only applied to the '737 patent. The judge found in favor of SLT because although the '737 patent describes a device in which all laser energy is absorbed and converted into thermal energy (Trimedyne's metal hot tip), SLT's contact tips, while also heating up, allow laser energy to pass into the patient's tissue

12/1 -- Washington Hospital Center, Washington, DC, has been added to the Heart Laser Revascularization Clinical Trials by PLC Systems, becoming the twelfth U.S. clinical site in evaluating the effectiveness of the Heart Laser in treating coronary artery disease.

12/6 -- Laser Industries and Surgical Laser Technologies have settled their outstanding litigation. Part of the settlement is an agreement by Sharplan, Laser Industries U.S. subsidiary, to pay SLT $8.125 million. Laser Industries and Sharplan will attempt to recover a portion of the settlement from Dornier Medizintechnik of Germany, the successor to MBB Medizintechnik, who supplied Sharplan a portion of the products covered in the litigation. In addition to the cash settlement, Laser Industries and Sharplan continue to be bound by the Court Order of April 1993, "to be permanently enjoined and restrained from the unauthorized making or using or selling...any products in the United States found to be infringed".

Laser Industries noted in its news release that the settlement removes the need to go through a trial before a jury, with the possibility of treble damages and attorney fees, and will allow the company to devote all its resources to growing its business. The company noted that it had had record revenues for the first nine months of the year, reaching $36.5 million, and expected to record sales of close to $50 million for the full year. (We forecast sales of $52 million for the company for the year -- see our attached year-end market forecast.)

12/7 -- PLC Systems announced that the FDA and HCFA had classified the Heart Laser as investigational/non-experimental, allowing for the procedure to qualify for Medicare reimbursement. Since the majority of patients being treated are over 65 and insured by Medicare, they will now be eligible for Medicare reimbursement, which should expedite enrollment in the ongoing clinical trials.

12/11 -- Palomar Medical Technologies announced that its subsidiary, Spectrum Medical Technologies, had filed its 510 (k) application with the FDA for its laser-based hair

removal system, licensed from Mass General Hospital. According to the company, the clinical data obtained from MGH is the basis of the submission and demonstrates that the laser treatment delays hair regrowth, and in some cases, may permanently remove hair.

12/11 -- According to the Gray Sheet, Thermolase will submit a 510 (k) for its skin rejuvenation laser in late 1996 or early 1997. The device is currently in clinical trials for rejuvenating sun-damaged skin in a process involving application of an Nd:YAG laser to skin treated with a special lotion (a modified version of its hair removal carbon-filled potion). The skin treatment potion allegedly penetrates more deeply into the skin than does the hair potion. During the skin rejuvenation process, the laser "interacts preferentially" with the lotion-soaked skin, leaving a "rejuvenated" surface, according to the firm. The company estimates the annual "skin rejuvenation" market, including the sale of facial creams, to be $1.5 billion, and is anticipated to grow 20% over the next five years, and 36% over the next 10 years! (Why isn't anybody looking at the New Star Laser holmium thermal collagen shrinking approach?)

12/14 -- Trimedyne reported results for its fourth quarter and fiscal year ending September 30th, posting sales for the quarter of $3.2 million and fiscal year sales of $13.0 million, compared to sales of $13.3 million for the previous year. (We are estimating calendar year sales of $15 million for the company, especially if BPH fiber sales increase with the new FDA ruling (see last month's MLR)). The major drain on the company, including a $1.2 million write-down of inventories and receivables and legal fees. The latter are for the Bard litigation over urological laser and fiber sales, and for the suit against SLT over contact tipped fibers.

MEDICAL LASER UPDATE -- JANUARY 1996

12/29 -- **QLT Therapeutics** announced that it had exercised it existing option to reacquire certain marketing and distribution rights from **American Cyanamid** to Photofrin, for use in photodynamic therapy treatment for cancers, in countries where regulatory and pricing approvals have not yet been received. QLT will reacquire rights in all jurisdictions except for Japan, where Cyanamid will retain exclusive marketing and distribution rights, and in Italy, for which the option to reacquire rights is retained until further notice. QLT previously had reacquired rights to Photofrin in Canada and the U.S. on September 7, 1994. The company had begun negotiations to reacquire rights in the Netherlands, where regulatory and pricing approvals have been received.

12/29 -- **Biolase Technology** announced that it anticipates a loss per share of $0.04 to $0.06 for the three months ending December 31, compared to a loss of $0.19 per share for the same period last year. Fourth quarter sales are expected to be less than third quarter results, but somewhat higher than last year's fourth quarter. The company

continues to expand its European and Asian distribution networks for its Elmer, erbium dental laser system, and Laserspray, an accessory for attachment to anyone's YAG laser for cooling teeth being worked on.

1/1 --According to the Gray Sheet, **ArthroCare** is going public, offering 2 million shares, expected to be priced at $11 to $13. The company filed a registration statement on December 15th, with Robertson, Stephen & Co., and Volpe, Welty & Co. as underwriters. The company has developed an electrosurgery system intended to replace tools currently used in arthroscopic surgery. The system "ablates" soft tissue while simultaneously achieving hemostasis, according to the company, enabling the physician to remove damaged tissue while reducing the need for the frequent change of instruments that is common to arthroscopic procedures. ArthroCare's system gained FDA 510 (k) clearance in March for use in arthroscopic knee, shoulder, elbow and ankle procedures.

Also in the same issue of the Gray Sheet, it was announced that **Xillix** (Vancouver, BC) had submitted its PMA application for its LifeLung, a laser-based device designed to detect early-stage lung cancer. Multi-center studies of the device, completed in early 1995, had demonstrated a "171%" improvement in the physician's ability to detect tissue suspicious for moderate/severe dysplasia or worse (cancer), compared to white-light bronchoscopy alone. The company is seeking expedited review of the PMA.

1/3 -- **Premier Laser Systems** received FDA clearance for it Aurora diode-based dental laser. It is the first diode laser developed for dental applications such as gingival (gum) surgery and re-contouring, diseased soft tissue removal, and dental implant recovery. The laser has a list price of $19,500. Premier is also cleared to market five other dental laser systems; two argon lasers for curing composite materials, the Alta CO_2, Pegasus YAG, and Centuri erbium lasers for soft tissue work. The company, in May 1995, submitted clinical data from 1200 patients in support of its application for hard tissue clearance for cavity preparation, caries removal, and etching teeth surfaces with its Centauri Er:YAG laser system.

1/4 --**Candela Laser Corp.**, has changed its name to **Candela Corp.**, to better reflect the major diversification strategy underway. The company intends to continue to develop its core laser business, but is also developing two other major areas of emphasis; the distribution of cryogenic surgical devices for ablation of prostate tissue and liver metastases, and its laser cosmetic services, Candela Skin Care Centers. The company claims to be in the process of establishing an international chain of cosmetic clinics that will provide a full line of skin care services. The first Skin Care Clinic opened in Framingham, MA in October, and the company plans to open "multiple" centers throughout the United States. (No timeline was given, nor any mention of "international" expansion.)

1/9 -- The "other shoe" finally dropped with the announcement by **QLT Therapeutics** of their agreement with **Sanofi Winthrop** to become the U.S. marketing partner for Photofrin. (See the 12/27 announcement in last month's Briefing, page 7.) Under the agreement, Sanofi Winthrop gains exclusive U.S. marketing rights to Photofrin, benzoporphyrin (BPD), and other light-activated compounds for treatment of cancers and pre-cancerous conditions. Sanofi Winthrop includes a $10 million access fee, comprised of a preferred stock purchase by Sanofi, and a cash payment. A further $16.5 million in milestone payments are possible for specified development of indications related to cancers of the lung, head and neck, as well as Barrett's esophagus, a pre-cancerous condition. In addition, the agreement calls for QLT to receive reimbursement of manufacturing costs and royalty payments based on product sales. Sanofi Winthrop plans to use its existing marketing and distribution network to provide the drugs available. In addition to the Sanofi agreement, QLT has agreements in place with **Laserscope** and **Coherent, Inc.**, to supply the lasers used to activate Photofrin. Laserscope has developed an add-on dye laser device that can be adapted to the more than 1000 installed KTP:YAG lasers, while Coherent manufactures two argon-pumped dye lasers that have been approved for the PDT esophageal cancer procedure with Photofrin.

1/10 -- **PLC Medical** announced that it had shipped six Heart Lasers and the accompanying TMR (transmyocardial revascularization) kits to **Imatron Japan**, in the fourth quarter of 1995. In August, the company announced the signing of a contract with Imatron, which called for the shipment of five lasers, but Imatron increased the contract to include a sixth laser. Clinical trials for TMR in Japan are set to begin in the first quarter of 1996. PLC had stated it expected to ship 20 Heart Lasers in 1995, however, with the shipment of six lasers to Imatron, as well as Heart Laser shipments to other areas of the world in the fourth quarter, "the company has exceeded this expectation", according to president M. Lee Hibbs. The company has been granted expedited review of its PMA application by the FDA, for the treatment of cardiac patients with medically refractive angina, who are not candidates for angioplasty or bypass surgery.

1/11 -- **Laserscope** puts out its own press release about the 12/27 QLT approval for Photofrin. The company will supply its Model 630 or 630XP PDT dye modules, which can be powered by either the 700 or 800 series KTP/532 or KTP/YAG Surgical Laser systems. Sanofi Winthrop will supply the drug (see the 1/9 announcement above), while Laserscope (and Coherent) will supply and service the lasers and QLT's Optiguide fiberoptic delivery devices. According to Robert McCormick, Laserscope president, the 630 and 630XP dye modules can be easily linked to 70% of the company's worldwide installed base of more than 1500 KTP/532 and KTP/YAG surgical lasers. McCormick estimates that the market for PDT laser/devices (including fiber delivery systems, but excluding pharmaceuticals) could reach $125 million by 2001.

1/15 -- **Palomar Medical** announced that its **Dynamem, Inc.** subsidiary had introduced a family of new flexible circuit memory modules that offer dramatic memory increases for high-end computer work stations and servers. The new 64 megabyte and 128 megabyte memory modules utilize Dynamem's patented Foldable Rigid Assembly Memory Module (FRAMM) technology to double and quadruple memory in the same physical space as standard SIMMs.

1/16 -- **Endocare, Inc.** announced that its Registration Statement as filed with the SEC became effective on January 12th, with the shares of the company now trading on the OTC/Bulletin Board under the symbol ENDO. Endocare was previously a wholly owned subsidiary of **Medstone International**. Endocare manufactures and markets devices to treat urological diseases, including Prolase side firing laser fibers, VaporBar, and UroLoop electrosurgical electrodes, all used for treating BPH. CryoCare, a cryogenic system for treating prostatic cancer is in clinical trials. The company also announced an international distribution agreement with **AMCO, Inc.** of Tokyo, who will have exclusive marketing rights in Japan for Endocare's VaporBar and UroLoop products.

1/17 -- **Candela Corp.** has been granted TUV approval to sell its newest vascular lesion laser, the Candela-1B, in Germany. According to the company, to date, more than 600 vascular lesion lasers have been installed around the world, for the removal of lesions such as port-wine stains, birthmarks, warts, and facial spider veins.

1/17 -- **Florida Heart Institute** joins **PLC Systems** as the thirteenth clinical site to participate in clinical trials of the Heart Laser for TMR, in the protocol evaluating the effectiveness of the laser in treating coronary artery disease. According to Dr. Robert Rudko, Chairman, through December 31st, 350 patients have been treated with the Heart Laser in the United States, and more than 900 patients outside of the U.S.

1/17 -- **Mattan Corp.** appointed Mark Miller, formerly President of **Nutri/System, Inc.**, to the position of President of the companies subsidiary, **The Medical Laser Institute of America**. MLIA provides non-invasive laser procedures to the U.S. $15 billion cosmetic surgery market.

1/17 -- **Coherent, Inc.**, finally joined the fray, with its announcement about QLT's FDA clearance for Photofrin. The company will supply its Lambda Plus PDL 1 and Lambda Plus PDL 2 argon-pumped dye laser systems for use with the photoactivated drug, along with the QLT Optiguide fiberoptic delivery system. Coherent has a worldwide agreement with QLT for the development, manufacture, and distribution of medical devices for the emerging photodynamic therapy (PDT) market.

1/18 -- **Tissue Technologies** announced that it would be shipping the first ten production units of the Tru-Pulse CO_2 laser for skin resurfacing this month. The company has

expanded its production facility to meet the demand for the laser. (Reportedly, the company had orders for more than 350 systems!) The laser sells for under $50,000 (actually $49,500), and the company claims to have an order backlog in excess of $15 million, and is quoting new customers 90 day delivery.

1/22 -- **Thermolase** has entered into a joint venture to market its SoftLight hair removal and skin rejuvenation technologies in Japan. The JV partner is the Illinois-based **Fox River Investment Group**, who have contributed $20 million to the venture to open spas in Japan, beginning in 1997. Thermolase will initially hold a 50% stake in the venture, with an option to increase its holdings to 51 percent. Thermolase will receive minimum guaranteed payments of $2 million in fiscal 1996, and $1 million in fiscal 1997. According to John Hansen, president of Thermolase, salons offering aesthetic services have become increasingly popular in Japan over the past 40 years. "Since the late '70s, when these salons started offering hair removal, both waxing and electrolysis have gained wide acceptance with clients...We believe that Japan could represent one of the largest markets in the world."

1/23 -- **Coherent, Inc.** reported record first quarter results, with sales up 43% and income up 85%! Sales for the medical business sector for the quarter ended December 31st were up 55% compared to the same quarter a year ago. A portion of the medical sales growth was attributed to achieving full production of the company's UltraPulse CO_2 laser system for skin resurfacing, reducing the extensive backlog on this product. The company's sales for the quarter were $83.7 million, with a net income of $6.5 million. (We estimated that calendar year 4th quarter medical laser sales in 1994 were $35 million, so with a 55% increase, this year's 4th quarter sales should have been approximately $54 million! If that is so, our estimate for calendar year 1995 sales of $140 million is somewhat underestimated, with yearly sales closer to $152 million!)

1/24 -- **Thermolase** has signed a lease for a 6500 square foot retail space in Dallas, TX, for its second Spa Thira, to offer its SoftLight hair removal process. The first spa was opened in La Jolla, CA in late October, and is apparently doing quite well. According to the company, the average client is spending more than $3000, thus calling for a much larger spa in Dallas, with additional treatment rooms.

1/25 -- **QLT Therapeutics** announced that **Sanofi Winthrop** had completed a $5 million equity investment as agreed to under its recently announced (January 9) U.S. marketing agreement. Sanofi has purchased 368,069 non-transferable convertible Series D First Preference Shares, issued at $13.58 per share.

MEDICAL/SURGICAL LASER UPDATE -- FEBRUARY 1996

1/26 **Candela Corp.** (the new name) announced revenues and profits for the three months ending Dec. 30th. For the quarter, the company had revenues of $7.3 million, with net

income of $381,000 or $0.07 per share. Company president Gerard Puorro stated he was pleased with the results and remains confident about the future. Two new products were launched; the ScleroLASER for leg veins, and the AlexLAZR for pigmented lesions and tattoos, along with opening of the first Candela Skin Care Center.

1/29 **BioLase Technology** announced its appointment by the Korean Dental Assoc. and the Korean Laser Dental Soc. as one of only two laser manufacturers whose systems were approved for marketing in South Korea.

1/29 **Reliant Technologies** has filed an antitrust lawsuit in the U.S. District Court of CA against **Laser Industries** and its subsidiary, **Sharplan Lasers**, charging attempts to monopolize the market for medical laser scanning systems, through their U.S. Patent 5,411,502, which Reliant claims was obtained by fraud. (This is in retaliation to the lawsuit filed by Laser Industries and Sharplan against Reliant last September, alleging infringement of the '502 patent.)

In response to the Reliant press release, **Laser Industries** released a statement of its own. Benjamin Givli, Laser Industries chairman and CEO said that the company had amended its complaint against Reliant to include additional counts based on facts learned during discovery proceedings. Laser Industries views the new suit as "meritless".

1/29 **Palomar Medical Technologies** announced that its **Star Technologies** subsidiary had accepted an order for laser diode arrays from **Mitsubishi Electric** of Japan, the first major order for the Star laser diode arrays. Star Technologies, which develops and manufacturers custom laser diode arrays for research and OEM supply, is a business unit of **Star Medical Technologies**.

1/29 According to the *Gray Sheet*, **VidaMed**, expects to submit 510(k)s for TUNA (transurethral needle ablation) BPH in March or April. One of the submissions will be for the TUNA 3 system, intended solely for BPH; the other will be for the Trans *Universal* Needle Ablation System, which already has general-use clearance for soft tissue applications. Both products treat BPH by applying radiofrequency energy to the prostate via a catheter with two needle electrodes. Once the company obtains clearance for the Trans Universal system, it will change the product's name to TUNA 5. Both systems currently sell for about $29,000, with a per procedure disposable adding an additional $795 to the cost.

1/30 **Indigo Medical** announced that it had received 510(k) clearance for the use of its portable 830 Diode Laser for general surgery, urology, and gastroenterology applications. The clearance also covers the use of the laser interstitially, where a fiberoptic probe is inserted to selectively heat and coagulate tissue in the areas cited,

but not for the treatment of BPH. The company is pursuing a separate 510(k) application for this indication, and has treated approximately 100 patients, with six-month follow up in process. The 830 Diode Laser is being marketed in most overseas markets through its German and Hong Kong subsidiaries.

1/30 **Laserscope** announced its fourth quarter and year results, with revenues of $7.0 million for the quarter and $30.1 million for the year. Both results were substantially below comparative figures for the same time last year. A net loss of $1.7 million (24 cents per share) was recorded for the quarter, and a net loss of $3.5 million (51 cents per share) for the year.

According to president Robert McCormick, product shipment delays, related to software modifications in its laser systems, delays in receipt of certain letters of credit for purchases, and restructuring charges negatively impacted the fourth quarter results. The company said the issues are being resolved and that the accumulated backlog of products will ship in the first quarter of 1996. Also, the clearance of PDT in December will allow the company to begin shipping laser systems and delivery systems for use with PDT.

1/30 **Thermolase** signed up for a Beverly Hills Spa Thira, its third announced hair removal spa; the first in La Jolla has been open since October, and a second was announced for Dallas on January 24th (see last month's briefing). The Beverly Hills spa, to serve Los Angeles, should be open by mid-summer.

1/31 **BioLase Technology** announced it had filed a patent application for its fluid conditioning technology for clinical applications. The application describes a unique process of altering the flavor or scent of fluids (including air), typically administered during medical and dental procedures. The BioLase Fluid Conditioning System also allows for the delivery of sterilized water during medical and dental treatments.

2/2 **Trimedyne** reported its quarterly results, showing revenues of $2.964 million and a loss of $886,000 or 9 cents per share for the quarter. (Final sales for the calendar year for Trimedyne were $13 million, against our prediction of $15 million.) According to president Peter Hyde, "In an effort to mitigate damages in our lawsuit with C.R. Bard, (we) have trained our sales force and launched two sidefiring fibers for use in urology. Sales of these products are expected to have a small but increasing impact on revenues, beginning in the quarter ending March 31st."

2/5 **Spectranetics** announced its fourth quarter results with revenues for the quarter of $4.2 million, up 18% from last year, and a net loss of $384,000 or 2 cents per share, compared with $480,000 for the same quarter last year. For the year, revenues were $17.3 million, up 51%, with a net loss of $2.2 million or 12 cents per share. This

compared with a net loss of $10.7 million for 1994. (Our estimate for 1995 sales had been $18 million.)

2/5 I received the December 20th prospectus for **ESC Medical Systems Ltd.**, which develops, manufactures, and markets medical devices utilizing proprietary intense pulsed light source technology for non-invasive treatment of varicose veins and other benign vascular lesions. The non-laser based PhotoDerm VL, for leg veins, spider veins, port wine stains and other vascular lesions, has received 510(k) clearance and is used in over 90 offices and clinics throughout the world. Another company product, the PhotoDerm PL, uses the proprietary pulsed light source for the treatment of benign pigmented lesions, such as age spots, sun spots and tattoos. The PhotoDerm PL can be sold as a stand alone product or as an add on to the PhotoDerm VL, but has not yet been cleared for sale in the U.S., with distribution limited to clinical test sites. The company also holds worldwide right to a patented technology for use in PDT, with the first product in this field showing effective results in the treatment of basal cell carcinoma, a highly prevalent skin cancer. The company, which was incorporated in Israel in 1992, and has executive offices there, also operates a U.S. sales office in Needham, MA. The company is offering 2.3 million shares at an assumed offering price of $13.00, with the $27 million to be raised to be used for marketing and sales, for additional R&D (including clinical trials), and for working capital.

2/5 According to the *Grey Sheet*, **Venisect's** Laser Lancet 510(k), submitted in early December should clear the FDA shortly. This would allow the use of the hand-held Lancet for taking blood samples. The battery-powered laser weighs about six pounds and is designed to painlessly perforate the skin using a flashlamp laser. (I believe it is an erbium:YAG?) The user then collects a blood sample in a vial. A one-inch disposable tip attaches to the proximal end of the device. The Laser Lancet will be priced in the $6000 to $8000 range. The cost of the additional disposable tips will be determined following FDA approval to market. The company received FDA approval of an IDE for a study of a modified version of the Laser Lancet as a transdermal drug delivery device for lidocaine, insulin, interferon, and hydrocortisone. The company expects the trial to be completed over the next 60 days, hoping to submit a 510(k) upon completion of the study. Preliminary studies of the Lancet to deliver lidocaine show that the skin is completely anesthetized for the purpose of blood sampling or IV insertions within 3 minutes. After 6 minutes of topical application, the anesthesia has reached a depth of over one inch, which allows a complete pain block for bone marrow transplants aspirations, epidural insertions, and many forms of minor surgery. Using a Laser Lancet with a longer tip enables the device to alter the surface of the skin, improving the ability to absorb drugs. Venisect is developing the Laser Lancet in cooperation with St. Louis-based **LaBarge, Inc.**, which holds exclusive manufacturing rights.

Also in the Feb 5 issue of the *Grey Sheet*, is a complimentary story about **Candela**, and its broadened business focus, which continues to impress investors. Helped by several positive announcements, the newly renamed company's stock gained 2 5/8ths points during January, for a 50.9% increase.

2/6 **Schwartz Electro-Optics** announced that it had received FDA clearance to market its TriLase 2940 erbium laser for use in a variety of applications, including plastic surgery and dermatology. The laser has been designed specifically for precise tissue ablation and vaporization, including for the skin. This is the second medical laser the company has brought to the market in the last four months, the other being its TriLase 2100 holmium laser. The company also markets it TriLase Dermatology laser, containing three wavelengths -- 1064 nm (YAG), 532 nm (doubled YAG), and 752 nm (alexandrite).

2/7 **Thermolase** announced its quarterly results, reporting revenues of $7.4 million for the quarter, compared to $5.8 million for the same quarter last year. The company had a loss of only $82,000 in spite of the enormous investment in the quarter in signing leases for two additional spas and finalizing a joint venture to market its SoftLight hair removal process in Japan.

2/7 **Eclipse Surgical** named Richard Mueller as president and COO. The company is in investigational studies for the use of its holmium:YAG laser for transmycardial revascularization (TMR). (This is the procedure being done worldwide by **PLC Systems**, and its Heart Laser. Others in the hunt include Cardiogenesis also evaluating a holmium:YAG laser, and Acculase, using an excimer laser for the TMR procedure.)

2/7 As noted above, I finally got caught up with the January back issues of the *Grey Sheet*. In addition to those items above, there is a note in the January 8 issue that **Medstone** and **Ciba-Geigy** will share the costs of a new analysis for a combined PMA/NDA covering the use of Actigall in lithotripsy. This project resurrects Medstone's pursuit of FDA approval for biliary lithotripsy, abandoned in 1990, for its STS Lithotriptor, a shock wave generating device approved for treating kidney stones. Currently, no lithotriptor device is approved for biliary applications. Seeking to refocus its business, Medstone is planning to spin off its **Endocare** and **UroGen** subsidiaries in mid-January. Endocare manufactures a line of urological laser catheters, including the Pro-Lase II side-firing catheter. (See last month's January 16 briefing note.) UroGen is a small molecular pharmaceutical business, with no approved products as yet.

In the January 15th issue, **Premier Laser Systems** notes that it is lowering the price of its Aurora diode laser to $19,500, considerably below competing lasers, primarily Nd:YAGs selling for $25,000 to $40,000. The Aurora is designed to act on soft dental tissue applications such as gingival (gum) surgery and recontouring, diseased soft

tissue removal, and dental implant recovery. The laser was cleared by the FDA on December 15th and is slated for shipping later in January. (See last month's January 3 briefing note.)

In the same issue was more on **ArthroCare**, also taken from its IPO filing. (See our January 1st briefing note last month.) Also, reporting on comments made at a January 17th session of the American Stock Exchange Health Care Conference, Yacha Sutton, president and COO of **Laser Industries** noted that clinical trials conducted over the past six months on its newly acquired laser hair removal system had shown very good results. The company expects to submit a 510(k) application shortly, for what could be "one of its `hottest' laser products in 1997". (See the December 27th briefing note for more on Laser Industries entry into the hair removal market.)

2/8 **Spectranetics** announced at the Piper Jaffray Medical Device Conference that it had begun three new clinical studies related to the use of the excimer laser in cardiology. The three procedures are: 1) for removing pacemaker leads, 2) for clearing totally blocked arteries, and 3) for treating restenotic stents.

The company noted that between 5 and 10 percent of the approximately 300,000 worldwide pacemaker leads implanted annually may require removal during their term of use. By using a minimally invasive technique employing their laser sheath technique, both the time necessary and the risk to patients is reduced. Seven medical centers are engaged in a 318 patient randomized trial. Also, more than 100,000 patients annually cannot be treated by conventional interventions because of totally occluded arteries. The current alternative treatments for these patients are limited to the use of drugs or coronary bypass surgery. With the company's newly designed Prima Laser guidewire, designed to cross blockages, an FDA approved laser catheter can then be used to further open the occlusion. Tests are underway at 11 U.S. sites, and European randomized trials are continuing at 15 medical centers. To date, the Prima guidewire has been used on more than 500 patients with a success rate of approximately 60%. In addition, more than 250,000 stents were deployed in 1995, and use of the device is growing at a 20% rate. Between 10 to 20 percent of the stents may develop blockages due to restenosis, or plaque buildup, which can lead to partial or total occlusions. Spectranetics believes that its excimer laser can remove the plaque rather than extruding it as is done with percutaneous catheter atherectomy (PTCA). The company expects to commence an investigational trial during the second quarter of 1996.

2/9-
2/12 In a series of announcements, **Palomar Medical Technologies** first announced that it would have its Epilaser hair removal system on display at the American Academy of Dermatology meeting in Washington, DC, which started on Saturday, February 10th. On Saturday, the company announced that it had acquired **Tissue Technologies** in a

stock swap, giving Palomar an entry into the lucrative skin resurfacing market. Finally on Monday the 12th. the company's subsidiary **Spectrum Medical** released a news statement describing all the lasers it had on display at the AAD, the prototype Epilaser, a copper vapor laser for treating spider veins, and its ruby laser for tattoo removal and for treatment of benign pigmented lesions. **Tissue Technologies**, posted a large sign in its booth at the AAD, announcing its acquisition by Palomar. Further, the company notes that it has a backlog of more than $20 million for its skin resurfacing laser. (There is an excellant writeup about the Tissue Technologies acquisition in the Feb. 19th issue of *The Gray Sheet*. And the March 4th issue of *Business Week*, in the Inside Wall Street column, features the meteoric rise of Palomar's stock based on the potential for Epilaser in hair removal. As noted in the article, the company received more than 500 "legitimate" inquiries about the Epilaser, following its unveiling at the AAD, as noted above.)

The same Feb. 19th issue also describes the launch of **Coherent's** Versapulse solid-state aesthetic laser system at the AAD. A 510(k) was submitted in December and approval is expected in March. The device offers three different Q-switched wavelengths for the treatment of pigmented lesions and tattoo removal, and also offers a "variable pulse width green wavelength for vascular lesions".

2/12 **Reliant Technologies** announced that it had received FDA 510(k) clearance to market its AccuScan CO_2 laser scanner. The device, designed for a variety of aesthetic surgical applications, will scan a laser beam in an Archimedes spiral pattern that can ablate target tissue to a controlled depth. The suggested selling price for the device is $12,500. First deliveries of the scanner are slated for the second quarter of 1996.

2/12 The Feb. 12th issue of *The Gray Sheet* describes the **CardioGenesis** transmycardial revascularization system, that is currently in Phase 1 clinical trials. This is a holmium:YAG laser whose energy is delivered via a fiberoptic catheter, rather than direct delivery like the **PLC Systems'** Heart Laser. The company expects the 12 patients in the Phase 1 trial will undergo TMR by the end of March, and after 3-month data is collected, the firm will seek permission to expand to a Phase 2 randomized trial in support of the firm's PMA application. The laser can be used either outside in (similar to the Heart Laser), or inside/out via percutaneous catheter delivery into the left ventricle. The company also expects that its laser system will be priced considerably below the Heart Laser, since it is only 150 pounds vs. 2000 pounds for the PLC system.

The same issue of *The Gray Sheet* also includes a story about the **Eclipse Surgical Technologies** anticipation of clinical trials starting in the second quarter of this year for its holmium:YAG TMR laser. (The only other company working on TMR is **Acculase**, a subsidiary of **Helionetics**. Acculase is expected to begin its clinical trials shortly, with an excimer laser system.)

2/14 **Trimedyne** announced that it had entered the laser lithotripsy market with its pulsed holmium laser and an "extremely" small, flexible optical fiber, both of which are FDA cleared and available for sale. The laser will sell for between $105,000 and $110,000, while the fiber costs $265.

2/15 **Palomar Medical Technologies** announced that it had received an equity investment of $6 million from **Travelers Corporation**, the parent of **Smith Barney**. (It should be noted that the **Spectrum Medical Technologies** booth at the recent American Academy of Dermatology was the "star" of the show, exhibiting both its new hair removal Epilaser and a copper vapor laser for spider veins -- see the 2/9-2/12 briefs. It was also learned that after the announcement of its acquisition by Palomar, **Tissue Technologies** had a sign to that effect put up in its booth.)

2/15 **Premier Laser Systems** reported its quarterly results, with net sales of $712,000, giving the company calendar year sales of $1.5 million. The increase in sales over last years same quarter was attributed to the introduction of two new dental lasers (argon and diode) and renewed sales of the company's erbium:YAG lasers with a fiber optic delivery system from its new supplier. Company president Colette Cozean commented that she was pleased to the market reaction to its new products, with first four weeks of the quarter ending March 31st showing booked orders totalling more than $1 million, and current bookings running at the rate of one new laser per day. She went on to say that due to inventory lead times, the company will probably not be able to ship all these orders during the quarter, but will leave the quarter with a record backlog.

2/19 **Barron's** had a fairly negative report on **Thermolase** and its market capitalization of $1 billion, claiming the company would have to gain control of the total hair removal market to achieve that valuation! The article also mentioned the three new competitors entering the hair removal market, **Palomar Medical Technologies**, **DUSA Pharmaceuticals**, and **Laser Industries**.

2/20 **Laser Industries** announced a record fourth quarter and year, with fourth quarter sales reaching $13.5 million, and 1995 sales reaching $50.1 million. For the quarter, the company had a net loss of $6.4 million (96 cents per share) and $2.3 million loss for the year (37 cents per share). The net losses for the quarter and the year were attributed to the litigation settlement with **Surgical Laser Technologies**. The company has formed a new joint venture subsidiary, **Sharplan 2000 Inc.**, for the new hair removal venture. Because of the surger in aesthetic lasers, the company ended the year with a backlog of $6.5 million, and with a cash position of $4.5 million.

2/22 **PLC Systems** announced that the first combined procedure using its Heart Laser for revascularization in conjuction with a minimally invasive coronary artery bypass graft (CABG), the so-called "trap-door procedure", which does not require an extensive

opening in the patient's chest, and without the use of a heart lung machine. The surgery was performed at the Feiring Heart Clinic in Norway, on a 59-year old male patient.

2/22 **Surgical Laser Technology** announced its fourth quarter and year ending results. The company had quarterly sales of $3.8 million and net income of $3.9 million (which included settlement of the **Laser Industries** suit, which added $5.9 million -- settlement of $8.1 million less litigation expenses of $2.2 million. For the year, the company had revenues of $14.8 million and a net loss of $58,000.

Surgical Update--March 1996

2/26 **Premier Laser Systems** begins shipments of its Aurora diode laser-based dental laser system, the first diode lasers available for use in gingival and other soft tissue applications, such as gum reconturing and diseased tissue removal. The laser can also be used for dental implant recovery.

2/26 **Candela** has begun a program of substantial discounts to users of current **ESC** Photoderm-VL light systems, to trade up to the newest longpulse ScleroLaser technology for treating leg veins.

2/26 According to the February 26th *Gray Sheet*, **Angion**, developers of an RF ablation catheter, has established clinical sites under an approved IDE for a Phase 1 trial that will include up to 20 radiofrequency ablation procedures in four centers. Because of a patented porous metal tip electrode, while the RF energy is being delivered, irrigation fluid flows through the catheter body and is forced through a multiplicity of pores in the tip. This provides about a 300% increase in ablation of the lesions, than is attainable with conventional radiofrequency catheters. Angion also has a laser catheter currently in trial for ventricular applications, and it has been used to treat approximately 70 patients in the U.S. with good results to date.

2/27 **PLC Systems** reported its fourth quarter and year-end financial results, with 4th quarter revenues of $7.4 million and net income of $3.2 million (19 cents/share). For the year, revenues were $13.3 million, and net income was $2.0 million (12 cents/share). The company reported it had shipped 9 Heart Lasers in the fourth quarter, seven of which were sold (6 in Japan and 1 in Asia) and 2 were placements (Florida Heart Institute and Washington Hospital Center). For the year, the company shipped 23 Heart Lasers, 14 of which were sales and the remainder placements, which compared to 12 shipments (10 sales) in 1994. Under the placement strategy, the company receives recurring revenues based on usage, rather than a one-time revenue for the sale, plus an installation fee of $25,000. In 1995, product sales (including disposables) were $11.9 million, while placement/service revenues were $1.4 million. The goal for 1996 is to ship more than 30 Heart Lasers, and to expand the ongoing

clinical trials, including instead of or in conjunction with repeat bypass surgery. The company is now authorized to conduct trials at 20 U.S. clinical sites.

2/29 **Sunrise Technologies** commented on the FDA's Advisory Panel's vote on the use of the company's dental laser for treating hard tissue, following a Feb. 28th advisory panel vote (11-0) recommending against approval of the firm's PMA application. The advisory panel raised concerns over potential risks of the device, especially the possibility of pulpal damage due to thermal penetration. According to the March 4th *Grey Sheet*, the meeting marked the second review of the SunLase by the dental panel. In the first review, in 1990, the advisory panel also recommended against approval, noting inappropriate study design and a lack of long-term followup and histological data. Sunrise president David Light said, "We will continue to evaluate the best use of our resources for FDA clinical trials...in the meantime we will focus on selling the dental products for which we do have approval, including the MicroPrep air abrasion system for cavity preparation, and the SunLaser for soft tissue management". Richard Norman, DDS, School of Dental Medicine, Southern IL Univ., said, "I would think that considerably more data would have to be generated to prove the benefits (of the SunLase) outweigh the risks posed by use in hard tissue applications." Sunrise had presented data from a randomized 130-patient clinical trial in support of its PMA, submitted in October 1994, for the pulsed YAG laser for the removal of incipient pit and fissure first degree carious lesions in enamel. Of the 130 patients, 115 had first-degree caries (386 lesions), and 15 had second-degree lesions (41 lesions). Thirty percent of the teeth undergoing laser treatment required subsequent dental handpiece treatment. There was no statistical difference in the outcome regardless of whether the laser, drill, or laser/drill treatments were used. Sunrise went on to say that the primary loser in the decision was the consumer, since the use of the laser minimizes discomfort by eliminating vibration and water spray, and reducing noise, without the need for anesthesia.

The company also announced its fourth quarter and year end results. Revenues for the 4th quarter were $1.6 million, with a net loss of $1.3 million (-5 cents/share). For the year, revenues were $5.3 million and a net loss of $4.1 million (-28 cents/share). David Light, president, called 1995 a transition year, with a change in its dental business to a direct sales approach, rather than selling through distributors. In ophthalmology, its Laser BioTech subsidiary concentrated on implementation of FDA clinical strategies for the Sunrise Corneal Shaping System for treating hyperopia, using laser thermal keratoplasty (LTK), which is currently in Phase 2a trials.

2/29 **Laserscope** reported it had received ISO 9001 certification and CE mark registration from the British Standard Institution. According to president Robert McCormick, "The certification will allow us to compete more effectively in Europe and other international markets by greatly simplifying the regulatory approval processes. In

1995, international revenues represented 23% of total revenues, compared to 17% and 13% for 1994 and 1993.

3/4 Today I received a copy of Sean Chaitman's (HJ Meyers) report on the laser industry, entitled, "Lasers: Overview of an Emerging Technology". The report covers both the medical laser industry, as well as the use of lasers in optical scanning and telecommunications. (In addition, in the package, were his reports of Jan. 30 and Feb. 26 on **Laser Industries**, discussing in detail, Laser Industries entry into the hair removal market. More on this later.) The Laser report describes the status of the medical laser industry, using my estimates (taken with permission from the January Medical Laser Report). It describes the various lasers used and the applications both in ophthalmology and surgery, emphasizing the aesthetic market potential of wrinkle and hair removal, and including laser hair transplantation and laser tooth whitening. There is also a lengthy discussion of the cardiology market, with an emphasis on transmycardial revascularization, using the PLC Systems Heart Laser. In all, a fairly comprehensive overview of the medical market.

The Laser Industries reports profile the company and its products, describing laser wrinkle removal as having "explosive growth". In fiscal 1995, CO_2 lasers for wrinkle removal accounted for approximately 40% of sales, with 525 systems sold. Sean expects that an additional 650 units will be sold in fiscal 1996. (And Sharplan/Laser Industries has only about a 25% share of the total market! In the Laser Industry Report above, Sean states that Coherent generated about $60 million in CO_2 system sales, while Sharplan had sales of about $20 million, with anticipation of sales of an additional 4000 systems to be sold over the next two years.) Some new products to be introduced in 1996 include a 15 watt CO_2 laser for oral/dental applications; a 20 watt diode laser for general surgery, ENT, urology (a little low in power for BPH), and gastroenterology; and a 40 watt holmium laser for orthopedics and urology. In addition, Laser Industries is introducing a minimally invasive system which incorporates a video camera and ultrasound imaging system to be used in laparoscopic surgery. It enables the surgeon to view either the ultrasound image on a video monitor, the operation directly, or both simultaneously. It will be marketed for its ability to assist surgeons in detecting pathologies in the liver or colon and to help eliminate many cancer operations. The ultrasound system is unique (according to Sean) in that it enables the surgeon to view the interior of organs targeted. (It seems to me that other ultrasound systems that I have seen do the same thing.)

The report goes on to detail how Laser Industries entered into an agreement with **Classy Lady** to enter the hair removal market, and how Sean sees a potential market for Laser Industries of 3000 systems at $120,000 or a market of $360 million. (I think that **Thermolase** and **Palomar Medical** might have something to say about that!) The Feb. 26 report updates the January report, stating that the hair removal laser is in clinical testing in Europe, and that FDA marketing approval is expected by summer of

this year. The report goes on to state that management is evaluating opening laser cosmetic centers (ala Candela) that could potentially offer skin resurfacing, hair transplants, hair removal, treatment of vascular lesions and several other cosmetic procedures related to products manufactured by the company.

3/4 Robertson, Stephens & Co. announced that it had initiated coverage of **ArthroCare**, developers of an innovative technology based on the use of RF energy that combines the advantages of lasers with monopolar electrodes at an attractive price point. According to the March 18th *Gray Sheet*, the company obtained 510 (k) clearance for its bipolar urological device for use in endoscopic urological procedures, including resection of prostate tissue, and non-malignant bladder wall tumors.

3/4 Another analyst at HJ Meyers, Amy Bell, issued a "strong buy" recommendation accompanying her report on **Palomar Medical Technologies**. She is seeking an intermediate target price of $25 per share, up from the $13 per share when she wrote the report (and the $10-11 per share as this is being written). Her analysis is based on Palomar's "aggressive and continuing investment in product development, product acquisition, and marketing, positioning the company to be a major participant in rapidly growing multimillion dollar markets". She discussed the company's pending acquisition of **Tissue Technologies** (just awaiting final closure), giving the company a full-range of FDA approved cosmetic laser products, and the recent filing by its **Spectrum Medical Technologies** subsidiary for 510 (k) FDA approval of its hair removal process. The report also describes the electronics businesses of Palomar: Dynaco, the flexible circuit manufacturer; Dynamem, producers of compact memory modules; and Dynasys, developers of a new proprietary personal computer, that permits the user to replace components easily without professional assistance.

3/6 **Energy Life Systems** announces that it has obtained a patent and an SBIR grant from NIH to develop a fiberoptic laser catheter for simultaneous diagnosis and treatment of cardiac arrhythmias, especially ventricular tachycardia, an irregular, rapid heart beat, one of the leading causes of death in the U.S. According to the company, the laser ablation technology under development promises to provide a cost-effective and minimally invasive cure for this disease.

3/7 **Palomar Medical** announced that it has participated in a $4 million private placement for **Laser Master International**, a producer of industrial and commercial products based on computer-driven laser energy. Palomar's investment was $1 million, through the purchase of a million shares of Laser Master.

3/11 According to the March 11th issue of *The Gray Sheet*, **Spectranetics** will begin a randomized trial for its PRIMA laser guidewire in April. PRIMA is an .018 inch diameter catheter that crosses total occlusions by vaporizing the plaque, and acts as a guidewire for subsequent treatment with conventional laser angioplasty catheters,

balloons, and/or stents. PRIMA is intended to be an alternative to drug or bypass surgery for total occlusions that cannot be crossed with conventional guidewires. The 15-center study will included 200 patients, randomized either to the PRIMA or a conventional guidewire for crossing total occlusions in native coronary arteries. (The laser guidewire will be coupled to the company's CVX-300 excimer laser, which sells for $200,000, and was approved in February 1993 for use with conventional laser catheters to perform coronary angioplasty.)

3/13 **LCA-Vision** has signed a major three-year agreement with the St. Vincent Hospital and Health Care Center, an 882-bed, two hospital complex in Indianapolis. The agreement calls for LCA-Vision to provide a variety of services to assist St. Vincent in implementing and managing an advanced and minimally invasive "Surgical Center of Excellence" at both of its operating units, Indianapolis Hospital, and St. Vincent Carmel Hospital, in Carmel, Indiana, an Indianapolis suburb. St. Vincent, affiliated with the 37-hospital Daughters of Charity National Healthcare System, is the second member of the system to contract with LCA-Vision for these types of services.

3/15 **Palomar Medical** reports its fourth quarter and year-end results. Palomar had revenues of $6.1 million for the quarter, with a net loss of $5.1 million (-34 cents/share), while revenues for the year were $21.8 million, and a net loss for the year of $9.95 million (-82 cents/share). According to Chairman and CEO Steve Georgiev, the company had an outstanding year with dramatically increased revenues through the strategy of acquisitions, joint ventures, and product development. Georgiev believes that the company is positioned to become the "dominant cosmetic laser company offering the broadest selection of proprietary products in the market".

3/18 According to the March 18 *Gray Sheet*, **Vidamed** has submitted a 510 (k) application ti the FDA for its TUNA (transurethral needle ablation) system for the treatment of BPH. The submission includes clinical data from over 100 patients comparing TUNA to TURP (transurethral resection of the prostate). Results of the study will be presented at the American Urological Association meeting in Orlando in May.

3/19 **Trimedyne** announced that its side-firing laser fibers and its YAG laser were the first products to obtain FDA approval for the treatment of BPH. (I don't believe that this is truly accurate, because SLT's laser and contact tips were actually the first approved for treating BPH.) Marvin Loeb, Chairman and CEO, said, "Now that the FDA has cleared our lasers and side-firing laser fibers...reimbursement by Medicare, Blue Cross and other insurance companies, which has been denied in about half of the states, should soon be universally available".

3/20-
3/22 **Palomar** announces another equity investment, this time in **Skysat Communications Network Corporation**. Skysat is engaged in the research and development for

marketing unmanned aircraft systems for commercial applications in the rapidly evolving and expanding telecommunications industry. The Skysat System will consist of a network of remotely powered sub-spaced platforms, circling at an altitude of approximately 60,000 to 80,000 feet for up to six months of continuous operation. This will provide regional telecommunications and broadcast services, and will be able to interface with, compliment, and support, current satellite and ground-based telecommunications systems for use with cellular or personal communication services, long distance communications, and TV and radio broadcasting. Palomar's investment was $1 million, for 500,000 shares of common stock and a warrant to purchase an additional 2 million shares at $1 per share. According to Chairman and CEO Steve Georgiev, "We believe that the laser diode technology being developed at our **Star** subsidiary has enormous commercial potential in the burgeoning telecommunications industry...Skysat and Palomar have committed to working together to commercialize our proprietary technologies".

3/21 **Trimedyne** responds to "misleading" newswire story. (Apparently, a Dow Jones Newswire story circulated during the late afternoon of 3/20, which must have carried negative news about the laser approach, and positive news about the various rollerblade electrode approaches for treating BPH.) Marvin Loeb, Chairman and CEO said, "Our phone lines have been flooded with callers asking about the story that appeared on the DJNW in the late afternoon yesterday, causing us to respond". He went on to say that, "We are not familiar with the physician quoted in the story or his credentials, but in a published article in *Urology Times* in March 1996, Anthony Middleton Chairman of the Health Policy Council of the AUA's Western Section said, `That in his experience, the type of electrosurgery vaporization devices mentioned in the Dow Jones story didn't offer very significant advantages over traditional electrosurgery procedures in the treatment of BPH...a clinical trial of several hundred patients versus traditional surgery (or Trimedyne's new laser procedure) would be needed to compare blood loss, operating time, hospital stay, and post-operative bleeding following the procedures'".

3/22 **DUSA Pharmacueticals** and **Mass General Hospital**, have announced two new agreements for the hospital to undertake independent investigation of the use of ALA PDT for the permanent removal of hair, and for the use of ALA Photodiagnosis (PD) to detect bladder cancer. (The hospital's Wellman Laboratory of Photomedicine already was doing some research into hair removal using ALA, as well as its use in treating psoriasis.)

3/22 **Rockford Industries** and **Trimedyne** have announced an agreement for Rockford to provide financing for customers of Trimedyne's laser systems.

3/20 I forgot to include the analyst's report on **ArthroCare** from Robertson, Stephens & Co., that I received late last month. (See the March 4th brief last month. I have also requested a copy of the Volpe, Welty & Co report on the same company announced in a recent Barrons, and will report on it when received.) ArthroCare, as previously reported is developing an rf device that reportedly combines the advantages of a laser (to ablate or vaporize tissue) and a monopolar electrode (to coagulate and cause hemostasis), at a very low price point, in arthroscopic procedures as well as in urological and gynelogical procedures. According to the RS report, the company will first target arthroscopy and the 1.8 million arthroscopic procedures performed annually. RS believes that ArthroCare will enter urology (the treatment of BPH) and gynecology (intra-uterine soft tissue resection) in 1997; while investigating dermatology (wrinkle removal) and periodontal (gingivitis) markets for entry in 1998. All in all, a very bullish report on ArthroCare by RS & Co.

3/27 **Candela Corp.** has amended its stockholders rights plan to prevent an acquirer from gaining control. Under the new plan, the threshold for becoming an acquiring person was raised from 18.5% to 25% of the company's outstanding common stock.

3/28-
4/1 **Trimedyne** announced that the FDA had granted additional clearances for its pulsed holmium laser and related disposable fiber optic devices, for all soft tissue applications in ear, nose, and throat surgery. The expanded applications include tonsillectomy and uvula soft palate surgery (the procedure to reduce snoring or for treating obstructive sleep apnea), as well as a variety of other ENT procedures. According to company officials, the holmium laser is now cleared for sale for minimally invasive procedures in arthroscopy, spinal disc decompression, lithotripsy, gynecology, peripheral artery angioplasty, and general surgery.

Then in the April 1st *Barrons*, Cheryl Einhorn wrote a negative piece about Trimedyne, commenting on the recent BPH approval (see the March 19th brief) and wondering if it was too little and too late, quoting a Dr. Harcharan Gill, a professor of urology at Stanford University Medical School, who said, "Lasers have seen their best days (in treating BPH). We've tried them and put them on the back burner. I don't think the stock deserves all this attention." The article goes on to state that even Trimedyne president Peter Hyde concedes that the prospects for growth in laser sales (for BPH) are virtually nonexistent. The author then goes on to put the blame on the lengthy FDA approval process.

3/28-
4/1 **QLT PhotoTherapeutics** released its 1995 financial results, followed closely by the announcement that the company had filed a registration statement for the issuance of 3 million common shares, to raise the funds necessary to continue funding R&D programs, including preclinical testing and further clinical trials for PHOTOFRIN®,

BPD, and third-generation photosensitizers, and to enhance the manufacturing and commercialization of the company's products. The financial results showed that the company had revenues of $2.5 million in 1995, and a net loss of $14.7 million. According to the company, it ended the year with available cash reserves of approximately $16.1 million and no long-term debt. As previously noted (January 25 brief), the company has signed a U.S. marketing agreement with **Sanofi Winthrop**, in exchange for issuance of preferred stock for total cash proceeds of $5 million, and common stock for an additional $7.5 million. The prospectus (received on 4/6) lists all the company's products, their approval status, and the companies having the marketing rights for each world area. It is interesting to note that in addition to the several cancer indications, both the BPD and third generation photosensitizers (unidentified, but one of which may be Zinc Phthalocyanine [ZnPc], obtained under an agreement with Ciba Vision Ophthalmics AG) are being investigated for treating psoriasis, arthritis, restenosis (after angioplasty), and for several indications in the eye (in collaboration with **Ciba Vision**) including glaucoma, age-related macular degeneration, and secondary cataracts. In addition to the several approvals in the U.S., Japan, Canada, and the Netherlands, cancer treatment approvals are anticipated shortly in other European countries, and the company is negotiating with European drug companies for marketing rights for PHOTOFRIN® in those countries.

3/27-4/1 The treatment of cancer by PDT seems to be a hot item. On 4/1 I received a copy of the **PDT, Inc.** prospectus offering 1.5 million shares, to raise additional funds to carry on its R&D and clinical testing programs. Unlike QLT PhotoTherapeutics, PDT is engaged in the integrated development of a drug and the appropriate delivery systems for treating cancers and other disease indications in dermatology, urology, gynecology, ophthalmology, and cardiology. Its lead drug is tin ethyl etiopurpurin ($SnET_2$), which it is developing in collaboration with corporate partners **Pharmacia & Upjohn**, **Boston Scientific**, and **Cordis Corporation**, a **Johnson & Johnson Company**. In addition to the several cancer indications listed in the prospectus, the company is in clinical trials for treating age-related macular degeneration and glaucoma in ophthalmology, BPH in urology, psoriasis in dermatology, dysfunctional uterine bleeding in gynecology, and restenosis in cardiology.

In a second cancer-related announcement, the **Cancer Research Campaign** (Britain), and the **Paterson Institute** (Manchester, England) have developed a new laser-like lamp treatment for skin cancer patients. To date more than 150 patients with non-melanoma types of skin cancer have benefitted from the 45 minute photodynamic lamp therapy that kills cancer cells. The lamp is being tested in hospitals in Scotland and northern England. CRC is patenting the cancer lamp, which is called photodynamic therapy, and is apparently negotiating with British and American companies for rights to develop the lamp for the international market.

4/2 **Laser Industries** reported that it was confident of its legal position re: **Reliant Technologies**, even though a California court had denied its efforts to have an antitrust complaint by Reliant dismissed on the basis of procedural defects. However, one of Reliant's claims, related to Laser Industries/Sharplan attempting to monopolize the market for medical laser scanning systems, was dismissed as being premature under California law. The antitrust complaint followed a September 1995 patent infringement suit brought against Reliant by Sharplan Lasers, a Laser Industries U.S. subsidiary. The California court consolidated the two legal actions and both cases will now proceed with discovery.

4/2 **Coherent Inc.** announced that it had reached agreement with **Matsumoto Medical Instruments**, its former distributor of medical products in Japan, to acquire exclusive distribution rights for Coherent's products in Japan. Under the prior arrangement, both parties would have distributed the Coherent products for an additional six months. The agreement also provides for Coherent to repurchase its inventory from Matsumoto, and allows for Coherent to assume full service and warranty support immediately for its customers on an exclusive basis.

4/2 **Palomar Medical Technologies** subsidiary **Palomar Electronics Corp.** announced that it had signed an exclusive five-year agreement with **New Media Corp.**, to provide turn-key electronic assembly for all of New Media's products. New Media, of Irvine, CA, is a leader in PCMCIA products for laptop and portable computers, including "plug and play" cards for Fax/modems, SCSI Adapters, LAN adapters and stereo sound cards.

4/2 **Ion Laser Technology** announced that it had closed on its private placement for $5 million, to be used in setting up 17 tooth whitening centers. (The FDA recently granted the company approval for the use of two of its laser systems for tooth whitening.) The private placement was with **CAP Advisors** of Geneva, Switzerland. ILT will issue 300,000 restricted shares of its common stock at $15 per share. In addition, CAP will receive an option on 1 million shares at $20/share, and will have the right to appoint two persons to the ILT board of directors. (CAP Advisors is managed by Tony Pilaro, co-founder of **Taunton Technologies**, the predecessor of **VISX**.

4/3 **Sunrise Technologies** announced a new U.S. dental distribution agreement with **Sullivan Dental Products**, the country's second full-service distributor for dental equipment and supplies. The agreement calls for the distribution of Sunrise's cavity preparation air abrasion systems, the MicroPrep Associate and Director models.

4/4 **PLC Systems** said that it shipped seven Heart Lasers in the first quarter. All were sent to customers in Europe, including the first lasers to France, Spain and Italy. Three laser were also shipped to Germany, giving a total of 12 lasers in that country.

Approximately 1150 TMR procedures using the Heart Laser have been performed outside of the U.S., and the results continue to support the potential effectiveness of the laser treatment. Most recently, surgeons in Italy and Norway have performed a minimally invasive procedure known as the "trap-door procedure". The company expects to ship at least 30 Heart Lasers in 1996, and hopes to receive FDA approval in the U.S. sometime in 1997.

4/4 **Endocare** reported its 1996 results. The company was spun out of Medstone in January 1996, and now operates as a totally independent company marketing surgical devices for the treatment of prostate diseases. Revenues were $1.3 million, a 50% reduction from the previous year, and a loss of $577,000, as the shift from laser-based therapy to electrosurgical vaporization continues. During the fourth quarter, the company introduced two new electro-vaporization devices, but the products came too late to offset the decline in its traditional side-firing laser fibers.

4/7 **Possis Medical** announced that it had received conditional approval from the FDA to expand into Phase 2 clinical trials for its AngioJet Rapid Thrombectomy System to remove blood clots in coronary arteries and bypass grafts. The go-ahead was after the successful completion of VeGAS Phase 1 study, initially a 60 patient trial at 4 U.S. interventional cardiology centers, begun in June 1995 that was later expanded by the FDA. To date, in excess of 80 patients have been successfully treated with the system in coronary applications.

4/8 **Laser Industries** announced that as part of its strategy to become a service provider, it will open several aesthetic laser centers to be located in key metropolitan cities around the world. The first three centers are scheduled to be open by the end of 1996 in New York, Barcelona, and Tel Aviv, offering patients a variety of surgical services including laser skin resurfacing, hair transplantation, removal of tattoos and pigmented lesions, and eventually, hair removal. The centers will be operated by prestigious physicians who are expert in cosmetic surgery and who are experienced in laser aesthetic procedures. The company will provide specialized state-of-the-art lasers including its SilkTouch and new EpiTouch, soon to be introduced for hair removal. The company also announced record first quarter revenues of more than $14 million, with full results to be released toward the end of the month.

4/8 Analyst Christina Kohihaas of **CSK Research** released a strong buy report on **Palomar Medical Technologies**. According to Christina, Palomar is well positioned with a full range of FDA approved cosmetic laser products, including lasers for wrinkle removal, tattoo removal, and treatment of benign skin lesions such as birthmarks, age spots, and spider veins. Palomar's hair removal laser, with expected FDA clearance in the second quarter of 1996, will give the company a complete suite of laser-based cosmetic procedure products. Revenues are expected to expand from $22 million in 1995, to $80 million in 1996 and $250 million in 1997!

4/9 **Coherent Inc.** announced that it had received FDA clearance for its new multi-wavelength VersaPulse Aesthetic laser. The solid-state device features four wavelengths for the removal of tattoos and treatment of both vascular and pigmented lesions, such as birthmarks, port wine stains, and telangiectasias -- the unsightly veins in the legs and face. The laser is composed of a Q-switched YAG, a Q-switched alexandrite, a Q-switched doubled YAG, and a varipulse doubled YAG. In essence, it has three wavelengths, and two pulse width delivery systems for the doubled YAG wavelength for treatment of both pigmented and vascular lesions. In partnership with the UltraPulse CO_2 laser, the two laser offer most of what a cosmetic laser center requires.

4/9 **Palomar Medical Technologies** announced that its subsidiary **Spectrum Medical Technologies** had received clearance in Canada for its new laser-based hair removal system, the Epilaser. Palomar plans to market the system through Toronto-based **Sigmacon**, the largest distributor of medical lasers in Canada. The company believes that the hair removal market in Canada could be $300 million per year in services. (The laser is a long-pulsed Q-switched ruby laser.)

4/9 **Candela Corp.** said that the FDA had approved it HCS 2000 urethral warming catheter system that is used in conjunction with a cryogenic surgical procedure for removal of prostate tissue. The device is ancillary to the company's LCS 3000 cryosurgical device used to treat prostate disease. The HCS 2000 acts as a warming device during the procedure and provides the surgeon with an additional margin of safety. In the procedure, the surgeon uses five probes to surround the lesion with an ice ball that destroys the lesion in a minimally invasive process, and the warming device controls the expansion of the ice ball so as not to destroy healthy tissue. The new device will be on display at the upcoming AUA meeting in Orlando on May 5th.

4/9 **Lasermedics** has submitted a PMMA supplement to the FDA for the Microlight 830 laser system in response to the FDA's request for additional information and clarification of the initial PMMA submitted in March 1995. The Microlight 830 is for the treatment of carpal tunnel syndrome using low level laser energy, and is supported by double blind studies conducted by General Motors and the Mayo Clinic, and progressive non-blinded studies. According to the company, it is expected that future clinical uses for low level laser technology will include wound healing, sports medicine, and dental applications such as stomatitis. The company expects to obtain FDA approval for treating carpal tunnel syndrome by the fall of 1996.

4/10 The April issue of *Advanced Technology in Surgical Care* has a lead story about how some of the leading practitioners in skin resurfacing are getting together to draw up guidelines for training those entering the field. With laser skin resurfacing one of the fastest growing specialty fields, and doctors outside of dermatology and plastic surgery getting involved, a group of 15 specialists in a variety of fields have organized

into the Laser Education Foundation to offer recommendations on safe settings for the use of high energy, quick pulsed laser for skin resurfacing. (Anyone wishing a copy of the article give me a call.)

4/10 Sean Chaitman of **H.J. Meyers & Co.** released his newest report on the cosmetic laser industry, on laser hair removal, and initiating coverage of **Thermolase**. The report is a good overview of laser hair removal, including his estimates for the market size and reporting on the activities of six competitors in the field, **DUSA Pharmaceutical**, **ESC Medical Systems**, **Laser Industries** and **Selvac**, **Palomar Medical Technologies**, and **Thermolase**. Sean builds his case for continuing revenues for the laser producers by charging a 10% royalty (per procedure fee) on each hair removal procedure, which could lead to a $160 million annual market for the laser manufacturers, in addition to annual equipment sales of $180 million, and $180 million in physician/spa charges. All in all, a very lucrative market! (Call if you would like a copy of this interesting report.)

4/12 **Mattan** has agreed with a group of physicians, to form an alliance via a joint venture agreement, to develop 50 **Medical Laser Institute of America** clinics in the U.S. over a three-year period. (I believe this is for establishing cosmetic laser clinics.) The agreement endeavors to open 12 clinics in the first year. The investment group will provide $20 million in capital to open the clinics in return for a 40% ownership, payable following repayment of the initial investment. MLIA will hold the remaining 60% with options to increase that holding to 100%. MLIA will receive a $100,000 per year management fee per clinic.

4/12 **Milkhaus Laboratory** has received FDA IDE approval to begin a clinical trial for its investigational drug product HP-4 for the treatment of benign prostate hyperplasia (BPH). The 12-week double blind trial will be conducted at Yale University Hospital, and at a family practice in Meadville, PA.

4/15 **Laser Industries** announced the FDA marketing clearance for its new FeatherTouch SilkLaser skin resurfacing system. According to the company, the patent-pending FeatherTouch system vaporizes extremely shallow layers of tissue and is especially appropriate for patients concerned with erythema, for treating delicate areas of the face (such as eyelids); for removing very fine wrinkle lines, or for simply "freshening" the skin. The FeatherTouch system operates at 10 times the scanning speed of the SilkTouch system, thereby providing a shallower effect. By combining FeatherTouch with SilkTouch, the physician can adjust the depth of penetration from shallow to full thickness of the epidermal layer of skin. The price of the package (with a 20 watt or higher CO_2 laser) varies from $49,000 to $98,900. The product was launched at the recent ASLMS meeting in Orlando. (See my accompanying ASLMS report for details on this and other skin resurfacing lasers.)

4/15 **Computer Motion** (Goleta, GA) demonstrated the AESOP TS prototype telesurgical robotic positioning system at the Endo-Laparoscopic Center at Yale University School of Medicine. AESOP (automated endoscopic system for optimal positioning) is the first and only FDA approved surgical robot that assists surgeon teams in minimally invasive surgery procedures, by providing steady and controlled video images. The technology has also been used successfully in global telesurgical experiments.

4/15 **Lasermedics** announced that it had entered into a letter of intent to acquire certain assets of **Henley Healthcare**, a division of **Maxxim Medical**. Henley specializes in the manufacture and marketing of a line of physical therapy products, with gross sales in 1995 of $18.8 million. Lasermedics will acquire the assets of Henley for about $13 million cash and convertible debt. Henley will become an operating division of Lasermedics, headquartered in Sugar Land, TX.

4/15 Analyst Jeffrey Berg of M.H. Meyerson released his report on **DUSA Pharmaceuticals**, with a strong buy recommendation. His reasons include the fact that DUSA has pioneered the use of aminolevelulinic acid (ALA) for PDT therapy and photodiagnosis using a non-laser light; it is the only company testing PDT for actinic keratoses, a common precancerous skin condition; is evaluating ALA as a diagnostic for bladder cancer, that according to Berg, could become a "standard of care"; and has a pipeline of applications in its portfolio that include treatment of acne and psoriasis, removal of unwanted body hair, treatment of basal cell carcinoma, and as a minimally invasive treatment for endometrial ablation. One of the unique characteristics of ALA is that it can be applied topically, not injected like all other PDT drugs. Also, unlike other PDT photosensitizers, ALA is a naturally occurring precursor of a photosensitizer, that becomes converted into a photosensitive agent by a cellular process within the body. This may allow greater selectivity of activity of the agent. Jeffrey is projecting revenues from sales of ALA to hit $26 million by 1999, with total revenues to be $35 million.

4/16 **Thermolase** has expanded it marketing strategy by inviting dermatologists and plastic surgeons to license its laser-based hair removal process, as a complement to its Spa Thira salons. The company plans to establish a network of physicians who will offer the SoftLight process as part of their practices. Unlike laser manufacturers, Thermolase does not intend to sell its lasers, but will, under the proposed licensing plan, provide doctors with use of the lasers for a per-procedure fee, which will vary depending on the location treated. (I did not attend the presentation offered during the ASLMS meeting, but am trying to get a copy of the licensing proposal.)

4/16 **QLT PhotoTherapeutics** announced that it had received clearance from health authorities in France to begin marketing PHOTOFRIN® as a treatment for certain lung and esophageal cancers at both early and advanced stages. The company may now apply to the authorities for a pricing decision and reimbursement under the

national health care plan in France. The company also noted that it is in negotiations with a new alliance partner to market PHOTOFRIN® in France and other European jurisdictions.

4/16 **Palomar Medical Technologies** announced that its subsidiary, **Spectrum Medical Technologies** had signed an agreement with **The Laser and Skin Surgery Center** of New York, one of the world's most comprehensive laser facilities with more than 12 different lasers in daily clinical use, as a test site for the compnay's new laser-based hair removal system, EpiLaser.

4/17 **Angion** said that its Sentinel implantable cardioverter defibrillator had received the CE mark, allowing marketing in all countries of the European Union. The device is used for treating cardiac arrhythmias (irregular heartbeats). The company is also developing RF and laser catheter ablation systems for this application.

4/18 *The Wall Street Journal* featured an article on cosmetic lasers, quoting yours truly as predicting that the laser treatment market will grow to between $4 billion to $5 billion a year within five years. The article went on to quote the prices being charged at both **Spa Thira** and at the **Candela Laser Center** for various treatments, from $2900 for a full facial wrinkle removal treatment, to $5000 for full body hair removal!

4/18 **Thermolase** said that it had signed a 10-year lease for a building in Denver to open another Spar Thira hair-removal salon. This will be the fourth spa to be opened, the others being in La Jolla, Dallas, and in Beverly Hills.

4/19 **Biolase Technology** released its year-ending results, showing a net loss for the year of $2.0 million (21 cents/share) on sales of $1.2 million. This compared to sales in 1994 of $1.1 million and a net loss of $3.1 million (40 cents/share).

4/19 **Ion Laser Technology** began trading on the American Stock Exchange primary list, under the symbol ILT. The stock had been listed on the Emerging Company Marketplace. (The company recently received marketing clearance for laser tooth whitening, using two of its laser systems.)

4/19 **QLT PhotoTherapeutics** announced that it had concluded an agreement with an underwriting group led by Nesbitt Burns to sell 3 million shares in the U.S. and Canada, at an offering price of CDN $21.25, to raise CDN $63.75 million ($46.9 million). The company said it plans to use the proceeds to fund R&D, including pre-clinical testing and clinical trials for PHOTOFRIN®, BPD, and third-generation photosensitizers, and to enhance the manufacturing and commercialization of its products.

4/19 The March/April issue of *Biophotonics International* contained an interesting article entitled, "Taking the guesswork out of tissue welding with lasers". The article describes some of the approaches being taken to improve tissue welding, including the approach underway at **Lawrence Livermore National Labs** to determine the right combination of laser pulse duration and number of pulses to obtain optimum welding temperatures. In a CRADA with LLNL, Barbara Soltz of **Conversion Energy Enterprises**, will develop an optical feedback system to control the amount of energy delivered to the weld site.

Another article in the same issue discussed the work underway at **PDT Inc.** to use its lead drug $SnET_2$ to treat a variety of diseases, including AIDS-related Kaposi's sarcoma. The drug has successfully completed a Phase I/II PDT study for this application.

4/22 The April 22nd *Gray Sheet* notes that both **Eclipse Surgical Technologies** and **CardioGenesis Corp.** have filed registration statements with the SEC for IPOs. Eclipse will be issuing 4 million shares, expected to be priced at $13-15 per share, while CardioGenesis will issue 2.7 million shares at between $14-16 each. Both companies are involved in clinical trials using holmium laser systems for transmycardial revascularization. (I have ordered copies of both prospecti.)

4/22 **Coherent, Inc.** announced record second quarter (three months ending March 30) results, with net sales of $90.6 million and a net income of $7.4 million (64 cents/share). The company said that the current quarter and six month results in its medical segment were up 43% and 31% respectively.

4/23 **QLT PhotoTherapuetics** said that preliminary research results released at the ARVO meeting in Ft. Lauderdale, showed that the joint study co-sponsored by QLT and **Ciba Vision Ophthalmics** of the use of BPD to treat age-related macular degeneration appears promising. Researchers taking part in the study from University Eye Hospital of Lubeck, Germany, and the Mass. Eye and Ear Infirmary of Boston, are optimistic that BPD may provide selective treatment of the severe wet form of AMD, according to Julia Levy, president and CEO of the firm.

4/23 **Palomar Medical Technologies** announced that its subsidiary, **Spectrum Medical Technologies**, had signed an exclusive agreement with **Medical Alliance Inc.** for supplying mobile hair removal services to physicians. MAI is the largest provider of mobile surgical services to over 4000 physicians in the U.S. and Canada. The Spectrum EpiLaser will be added to the existing Mobile Aesthetic Laser Units that are offered by MAI.

4/24 **PLC Systems** reported its first quarter results, with revenues of $4.8 million and net income of $1.3 million (7 cents/share). As previously noted (see 4/9 brief), the

company shipped 7 Heart Lasers in the first quarter, and expects to ship 30 systems in 1996.

4/24 **Laserscope** announced today that it had signed a definitive agreement for **Heraeus Surgical** to be integrated into Laserscope. According to president Robert McCormick of Laserscope, the combined annual sales of the two companies will approximate $60 million. (My estimated sales figures for 1995 for the two companies were $30 million for Laserscope and $33 million for Heraeus Surgical.) The partnership will give Laserscope an entry into the cosmetic market, with the acquisition of the Heraeus LaserSonics Paragon line of CO_2 lasers and scanners. Heraeus MED GmbH will receive approximately 4.6 million shares of newly issued Laserscope common stock and a $2 million payment in exchange for the stock of Heraeus Surgical and certain assets of its German distributor affiliate. (See my attached writeup of a brief history of LaserSonics -- from Cooper Labs, to independence, to its affiliation with Heraeus.)

4/25 **PDT, Inc.** offering of 1.5 million shares was priced at $48 per share. The offering is expected to close on April 30.

4/25 **QLT PhotoTherapeutics** announced that it had completed its offering of 3 million shares, with a total of 3,450,000 shares sold for gross proceeds of CDN $73.3 million. The company also announced that PDT with PHOTOFRIN® will be covered under Japanese National Health Insurance, according to the Japanese Ministry of Health and Welfare. **Lederle**, QLT's partner in Japan, can now begin its full marketing program. PHOTOFRIN® will be reimbursed up to approximately $2000 for the use of each vial of the drug. Typically, two vials are used in each treatment. PHOTOFRIN® is approved in Japan for treatment of early-stage lung cancer, superficial esophageal cancer, superficial and early-stage gastric cancers, early-stage cervical cancer, as well as cervical dysplasia, a pre-cancerous condition.

4/26 **ArthroCare** announced that it had revenues in the first quarter of $1.2 million, with net losses of $1.7 million (25 cents/share). I also received the March 4th Volpe, Welty report on the company that I had requested, and the analysts Phil Nalbone and Sarah Althoff have written a strong recommendation for the company and its products. In comparison to laser systems costing $80,000 to $125,000, and the $4000 to $9500 monoelectrode electrosurgical unit with a $40-50 disposable tip, the ArthroCare $12,500 multielectrode unit is much more practical and gives the surgeon greater versatility in tissue sculpting. The ArthroCare unit was designed to achieve precise ablation and simultaneous hemostasis of soft tissue while minimizing damage to underlying tissue. The system can be applied to a wide range of arthroscopic procedures in the knee, shoulder, elbow and ankle.

4/29 **Palomar Medical Technologies** announced that it has received a $4.8 million order for 40 EpiLaser systems from its Canadian distributor, **Sigmacon Laser Services**.

Spectrum Medical Technologies expects to fill the order and begin delivering the systems during the third quarter of this year. It was also announced that Spectrum Medical will be moving to a larger facility to accommodate laser system production rates approaching 100 systems per month by the end of the year.

MEDICAL/SURGICAL LASER UPDATE -- MAY 1996

4/29 *The Gray Sheet* contained a story about the consolidation of **Heraeus Surgical** and **Laserscope**, saying that the transaction should be completed by the end of the year. (See the 4/24 brief in last month's issue.) The deal is valued at about $18.4 million, with Laserscope paying 4.6 million newly issued shares of stock and $2 million in cash to Heraeus MED, Surgical's parent company. After completion of the acquisition later this summer, Heraeus' Milpitas headquarters and manufacturing facilities will be shut down and functions transferred to Laserscope's San Jose facility, about two miles away. Both companies sustained operating losses in 1995, but Laserscope hopes that the consolidated operations will enable the combined firm to achieve profitability. There is little overlap in product lines, except in side-firing fibers for treating BPH.

4/29 **JMAR Industries** said it has reached an agreement with a major U.S. supplier of medical equipment to develop and deliver a prototype, pocket-sized laser device designed as a bladeless alternative to the sharp-edged instruments currently used to withdraw blood for diagnostic analysis. The device is a rechargeable, battery-powered instrument that operates a diode-pumped laser (?), for sampling the blood, and a tiny, blunt, disposable tip to isolate the skin from the device. The device is an outgrowth of the company's ongoing x-ray lithography program, which is covered by 8 issued or applied for patents.

4/30 *The Wall Street Journal* reports that **Palomar Medical Technologies** is close to completing its acquisition of **Tissue Technologies**, which should occur within the week, for $34.5 million.

4/30 **PDT, Inc.** raised over $65 million in its completed common stock offering. The company plans to use the proceeds for clinical and pre-clinical testing, research and development, and general corporate purposes.

4/30 **PLC Systems** announced that the results of a multi-center study of TMR using the Heart Laser, presented at the American Association of Thoracic Surgeons in San Diego, demonstrated that TMR relieves angina in patients with severe coronary artery disease. The average preoperative angina score was 3.8 (on a scale of 0-4), while postoperatively, the score was 1.4 at twelve months.

4/30 **Laserscope** reported its first quarter results, with net income of $137,000 (2 cents/share) on revenues of $7.7 million. President Robert McCormick called the results encouraging, representing the positive effect of the restructuring actions taken in the latter half of 1995, with revenues up 10% over the fourth quarter of 1995.

4/30 **Cell Robotics** announced that it had received international notice of allowance for patent claims covering its multifaceted crystal resonator (MCR) technology. Previously granted in the U.S., the allowance will allow the company to obtain patent coverage in major international markets. The MCR technology is a key feature of the finger perforator "Lasette" that is used to obtain blood samples. The MCR patent should also allow the introduction of a low-cost skin resurfacing laser for use in dermatology.

5/1 **Laser Industries/Sharplan** got the first specific FDA approval (April 25th) for the treatment of wrinkles with its SilkTouch Flash Scanner and its FeatherTouch SilkLaser system. Although Laser Industries, along with several other companies, have had general approval for skin resurfacing -- but not specifically for wrinkle removal -- it will be interesting to see if the other companies now go ahead and obtain similar approvals to allow them to mention wrinkle removal in their advertising!

5/1 **Lasermedics** completed the acquisition of **Henley Healthcare** (see last month's 4/15 brief), a division of **Maxxim Medical**. (Henley specializes in the manufacturing and marketing of a line of physical therapy products, with gross sales in 1995 of $18.8 million.)

5/1 **Helionetics** announced that pre-clinical studies of the **Acculase** excimer laser system for TMR have been completed, and the company intends to file an FDA application to begin human clinical trials this summer. Acculase is a subsidiary of **Laser Photonics**, a Helionetics subsidiary.

5/2 **Trimedyne** announced that the Japanese Ministry of Health has approved the reimbursement for the use of lasers to treat enlarged prostates in men, at a rate of approximately $2400 per treatment. This covers the hospital charges and the cost of the laser fiber.

5/2 **Biolase Technology** announced the completion of development of its LaserBrush, a mass market product that will illuminate, target, clean, and whiten teeth. The LaserBrush is a hand-held, portable tooth brushing instrument, which the company hopes to have available within the next six to nine months. The device will require the use of the company's specially formulated toothpaste. (As far as I can determine, this is based on the use of a diode laser that delivers energy through the brush's fibers.)

5/3 **DUSA Pharmaceuticals** raised $5.4 million in a primary offering of 750,000 shares. The company also reported its first quarter results, showing a net loss of $1.1 million (13 cents/share), with interest income of $269,000. The company is engaged in the development of ALA PDT and PD (photodiagnosis) for multiple medical indications.

5/3 The May issue of *Advanced Technology in Surgical Care* spotlighted an article on laser therapy advances in the treatment of leg veins, highlighting the ScleroLaser from **Candela Corp.**, and the Cool Laser Optic cooling device developed by Dr. Cyrus Chess.

5/3 I received the April 24th prospectus for **Cardiogenesis**. The company is evaluating the use of a holmium laser to perform TMR, both from the outside; thoroscopically (TTMR), intraoperatively (ITMR), and inside, percutaneously (PMR). The company will offer 2.7 million shares in its offering for an expected price of between $14-16. The company also announced that it had treated 9 "no option" heart disease patients in the U.S. and Europe with its intraoperative TMR device, under an IDE granted in August 1995. Neither its thoroscopic or percutaneous device clinical trials have yet started.

5/6 **ThermoLase** announced its second quarter (March 30) results, reporting revenues of $7.0 million and a net loss of $77,000. The company said that it now intends to offer its SoftLight hair removal system to physicians, as well as through its own spas. The company claims that it had "a strong response" from the physicians attending its announcement meeting at the ASLMS in Orlando. (My understanding is that this may be far from the truth, because of the onerous terms that the company was asking for. I am still trying to obtain a copy of the actual contract.)

In addition, according to the May 6th *Gray Sheet*, ThermoLase's sister company, **Lorad Corporation**, which produces ThermoLase's YAG laser, had a recall action taken by FDA because the 9 distributed lasers failed to comply with regs having to do with calibration procedures and schedules. It appears that field correction of the operating manuals was approved by the FDA.

5/6 **Laser Industries** announced record revenues and earnings for the first quarter, with sales reaching $14.0 million and net income for the quarter at $1.9 million, a 72% increase over income for the comparable quarter last year. Earnings per share were 29 cents. The company's backlog of orders remains at a similar level as at the close of 1995.

5/6 **Palomar Medical Technologies** announced that it had completed its acquisition of **Tissue Technologies**.

5/6 **Candela Corporation** announced its fiscal third quarter results (March 30), with revenues of $7.0 million and a net income of $254,000, compared to $11,000 for the same period last year. The company also announced that initial shipments of the ScleroLaser, for treating leg veins, occurred in the quarter.

5/7 **Spectranetics** declared a dividend distribution of preferred stock to its shareholders, with one share of preferred for each share of common stock.

5/7 The FDA approved **EDAP Technomed's** microwave Positron device for transurethral thermotherapy in the treatment of BPH. The system is composed of a small treatment catheter with an antenna tip that emits energy, while a cooling system circulates water within the catheter to protect nearby tissue.

5/7 **American Dental Technologies** announced first quarter sales of $5.3 million and a net income of $448,000 or 3 cents/share. The company expects to complete its merger with **Texas Airsonics** shortly.

5/8 **Trimedyne** reported its second fiscal quarter results (March 30) with revenues of $3.0 million and a net loss of $980,000 or 10 cents/share. According to president Peter Hyde, the continued tightening of hospital budgets for capital equipment, especially overseas, is the overriding reason for the lowered results. However, interest in sidefiring fibers for treating BPH began to pick up late in the quarter as a result of the FDA clearance to market their lasers and fibers for this indication. The company completed a private placement in April that resulted in proceeds of $2.6 million.

5/8 **Premier Laser Systems** announced that it had filed a 510 (k) notice of intent to market the use of the company's argon-based laser systems to activate, more quickly and effectively, bleaching substances employed in a cosmetic teeth whitening dentistry procedure. (Other teeth whitening procedures are currently being marketed by **ILT** and proposed by **BioLase** -- see above.)

5/8 **Spectranetics** said it has implemented a "poison-pill" shareholders rights plan to thwart possible takeover attempts. The plan allows existing shareholders to purchase additional shares at a discount if an outside party acquires a 15% stake in the company without permission of the board of directors.

5/8 **PDT, Inc.** announced that it had begun Phase 1/2 clinical trials in ophthalmology with its leading PDT drug, SnET2, to treat complications of advanced age-related macular degeneration, a leading cause of blindness. With recent advances into Phase 3 studies for SnET2 in oncology, the progress into another clinical area is an important step in PDTI's strategy to develop photodynamic therapy in a number of potential disease applications.

5/8-
5/9 **Palomar Medical Technologies** was ranked as the eighth fastest-growing company in the U.S. by *Inc. Magazine*. The company also announced that world-renowned laser expert Dr. Gregory Altschuler had joined the company as director of R&D. Dr. Altschuler formerly had been Department Head at the Institute of Fine Mechanics in St. Petersburg, Russia, a world-recognized center for laser development.

5/9 **ThermoLase** announced that it had signed a 10-year lease for retail space in the River Oaks section of Houston, for another Spa Thira hair removal salon. This is the fifth location announced by the firm.

5/9 Not to be outdone by ThermoLase, **Candela Corporation** announced that it has entered into a long-term lease in Scottsdale, AZ where it will open the world's first integrated spa and cosmetic laser center. The company said that the Scottsdale spa will be the prototype for future centers that are being planned throughout the U.S. The 7555 sq. ft. free-standing building will house five of the most advanced lasers to treat wrinkles, facial spider veins, scars, pigmented lesions, leg veins, and other cosmetic problems. The spa and health club will offer the highest quality salon services, massage, skincare, personal training, and exercise facilities.

5/10 **Palomar Medical Technologies** reported its first quarter results, showing revenues of $5.3 million and a net loss for the quarter of $5.5 million (29 cents/share). These revenues do not include the revenue for the recently acquired **Tissue Technologies**, which will be included in the next quarterly statement. The first quarter results include substantial expenditures associated with pre-production expenses in preparation for large-scale laser production, marketing, and sales expenses related to the initial market introduction of several new electronic products, and acquisition expenses associated with the TT acquisition.

5/11 The April issue of *The Journal of Clinical Laser Medicine & Surgery* contains an excellent overview article about the status of **DUSA's** PDT and PD (photodiagnosis) programs using ALA. It describes the various programs underway and the mechanism of action of conversion of the precursor ALA into protoporphyrin IX.

5/13 **Surgical Laser Technologies** claims that it won its second judgement over **Trimedyne** in association with Trimedyne's claims that SLT's contact tips infringed its hot tip patents. The U.S. District Court for the Central District of California granted SLT's motion for summary judgement that its tips did not infringe a second patent held by Trimedyne. In the first case, settled last November, the Court ruled that SLT's tips did not infringe the so called `hot tip' patents. Another action, on the sidefiring urological probes, is expected to be ruled on in the next two months.

In a separate announcement, SLT announced its first quarter results and strategic business development plans. Sales for the first quarter were $2.8 million, compared to $4.2 million for the same quarter in 1995, but a significantly reduced net loss from $1.3 million to only $820,000 (8 cents/share) for this year. The company has initiated a broad range of external and internal business development programs with the goal of positioning the company by years end for profitability and sustained revenue growth. Along with its investment banking firm, the company is actively seeking to identify and pursue synergistic product line expansions and strategic business opportunities.

5/13 **Coherent Inc.** announced today that its president and COO (and old friend) Henry (Hank) Gauthier would retire on July 1st. He will be replaced by Dr. Bernard Couillaud, currently Vice President and General Manager of Coherent's Laser Group.

5/13-
5/14 **Sunrise Technologies** announced its first quarter results, with revenues of $1.5 million and a net loss of $1.4 million (6 cents/share). The company's MicroPrep air abrasion cavity preparation system continues to show strong customer acceptance, accounting for approximately 64% of the company's quarterly revenues. Its dental laser sales into the international market experienced a decrease compared to the first quarter of last year.

The company also announced that it had signed a distribution agreement with **SPCTEK**, a front runner in the emerging dental and medical equipment market in China, which could generate several million dollars in revenues over the next several years.

5/13 West Coast-based Cruttendon Roth will hold its first annual HealthCare conference in New York City on June 6th, introducing the heads of 35 mostly western companies to Wall Street investors. Top management of some of California's fastest growing biomed, medical device and healthcare companies will converge on the Big Apple hoping to catch the eye of the nation's institutional investors. Some of the medical laser companies on the list include: **BioLase Technology**, **DUSA Pharmaceuticals**, **Palomar Medical Technologies**, and **PLC Medical Systems**.

5/14 **PDT, Inc.** released its first quarter results showing a net loss of $1.6 million (18 cents/share) on revenues of $629,000. R&D expenses increased to $4.7 million from $1.2 million for the same period last year. The company recently completed a secondary offering (April 30th), raising approximately $65.4 million.

5/14 **PLC Systems** announced that doctors at the Max Planck Institut in Germany had presented papers at the Annual Meeting of the German Society of Cardiologists which provide the first proof of blood flow through an open TMR channel. The paper,

"Transmural Laser Revascularization: First Proof of perfusion through open laser channels", demonstrated that the channels created by the Heart Laser remain patent in beating human hearts. (As a result of the news hitting the newswires/TV broadcasts, PLC's stock jumped in trading.)

5/14 **DUSA Pharmaceuticals** reported 90-100% efficacy in the Phase 2 clinical trials of its topical ALA PDT for the treatment of pre-cancerous actinic keratoses of the face and scalp. This study represents the first use of the DUSA non-laser blue light source, which is capable of treating an entire face or scalp at once. With data available for 36 patients at the optimal light dose, approximately 90% of the treated AKs cleared completely after just one treatment. The few remaining lesions cleared after a second treatment, leading to an overall response rate of 100%. The overall placebo response rate was 26%.

5/15 **Laserscope** reported early success in treating leg veins with its patented StarPulse technology, with the new Aura KTP laser system. Spider-like veins on the legs, face, neck and back were treated, with immediate dramatic results. In almost every situation, the veins were virtually erased or very significantly improved. Histological data suggested that small veins treated with StarPulse were selectively fibrosed without affecting adjacent tissue or collagen. The StarPulse (long pulses) operates at pulse widths between 1 and 30 ms range, between the pulse width obtainable with argon lasers and pulsed dye lasers.

5/15 **Xytronix** (San Diego) has received an exclusive worldwide license for the Laser/Sensitizer Assisted Immunotherapy (LSAI) technology, developed by **Wound Healing of Oklahoma** to destruct tumor tissue in a specific target site. The WHO technology involves injecting a tumor with an infrared absorbing dye and an immunoadjuvant, followed by treatment with an infrared laser. The treatment attempts to "trigger an immune reaction in the patient to complete the destruction of the primary tumor and to destroy metastatic tumors", according to the company. Patents for the technique are pending. The treatment is anticipated for use in treating lung and prostate cancers, with first target for breast cancer. Human clinical trials are expected to begin before the end of 1996. Xytronix also has an involvement with **Binary Therapeutics** in the PDT area.

5/16 **DUSA Pharmaceuticals** and **MeL-Co** reported that its Lipomelanin-LQ synthetic melanin specifically designed for use as a black hair coloring agent, was launched at an industry trade show in New Jersey on May 15th. MeL-Co produces the Lipomelanin-LQ and markets it to cosmetic and hair care companies for use in semi-permanent hair dyes, coloring shampoos, and coloring creme rinses. Lipomelanin-LQ is the first product of a collaboration between DUSA and MeL-Co to develop a series of Lipomelanin compounds for use in over-the-counter and/or cosmetic products, with potential applications such as skin or hair coloring ingredients, anti-oxidants, and

UVA sunscreen agents. The rights to these compounds were licensed by DUSA from inventors at the University of Toronto, and are being developed for DUSA by MeL-Co, a leading melanin specialty company.

5/16 **Endocare** reported its first quarter results with revenues of $371,000 and a net loss of $578,000 (9 cents/share). The company develops, manufactures, and markets devices to treat diseases of the prostate.

5/16 **QLT PhotoTherapeutics** reported its first quarter results, with a net loss of $2.9 million (14 cents/share) on revenues of $345,000. With the recent approval of Photofrin in France and the decision of the Japanese Ministry of Health to grant reimbursement coverage, the company can now commence full marketing efforts in both areas.

5/16-
5/21 **Helionetics/Laser Photonics**, in a letter to shareholders on May 16 and in a news release dated May 21st, reported on the two recent studies conducted with its **Acculase** excimer laser system at the New York Hospital/Cornell Medical Center and at the Heart Institute of Good Samaritan Hospital, Los Angeles, that showed good results with its TMR procedure to treat ischemic heart disease. Because the excimer laser tends to induce less thermal damage than either the holmium or CO_2 lasers also being evaluated for TMR, physicians working with the excimer believe that it will increase patency in the channels created. (The press release goes on to compare the characteristics and features of the excimer laser with the two holmium (**Cardiogenesis** and **Eclipse Surgical**) and the CO_2 (**PLC Systems**) lasers under investigation for TMR.) Laser Photonics expects to file for IDE approval within the next 30 days to commence Phase 1 trials sometime this summer.

5/20 **ThermoLase** announced that it had signed another lease for a Spa Thira, this time in Boca Raton, Florida. (The second Spa Thira, in Dallas, is scheduled to open this month.)

5/20 **BioLase Technology** reported its quarterly results, with a net loss of $497,000 on revenues of $144,000.

5/21 **Spectranetics** announced that the FDA had approved expansion of its pacemaker lead removal trial from 9 to 14 sites in the PLEXES (Pacing Lead Extraction with Excimer Sheath) randomized trial, with patient enrollment increased from 318 to 368.

5/21-
5/22 **Premier Laser Systems** released its fourth fiscal quarter results (March 31) with sales increasing to $638,000, compared to $97,000 for the same period last year, and a net loss of $2.2 million (46 cents/share). The increase in sales was primarily a result of

the introduction last fall of new argon and diode lasers for use in composite hardening and for soft tissue use in dentistry.

The company also announced on May 22nd that it had filed a registration statement related to a 2.5 million common stock offering, to be underwritten by Rodman & Renshaw as the manager. The company will use the proceeds to expand its marketing and distribution, including into international markets, and for new product introduction, through acquisitions, strategic alliances or internal development.

5/21 **Endocare** announced that it had received approval for marketing in Japan for its PROlase urological fibers, used by urologists to perform laser prostatectomy. Laser prostatectomy was recently granted reimbursement approval by the Japanese Ministry of Health, an act expected to spur the demand for side-firing laser fibers in Japan.

5/22 **Coherent, Inc.** said it had received approval to market and sell its UltraPulse laser system for resurfacing aged and sun damaged skin or skin blemishes, in Japan. In addition to the cosmetic and dermatological areas, the company also obtained sales approval for general surgery, ENT, and gynecology.

5/22 **Cell Robotics** reported its first quarter results, reducing its net loss to $351,000 for the quarter compared to $380,000 for the same period last year. The company also announce it had finalized the agreement with **GEM Edwards** for the manufacture, distribution, and sales of its laser skin perforator for diabetic patients. GEM Edwards has guaranteed the production of 2500 units and estimates the U.S. sales of this product will top $20 million in three years.

5/22 **Palomar Medical Technologies** announced that Dr. Ronald Wheeland, one of the world's foremost laser dermatologists had been named vice president and medical director. In addition, Dr. Wheeland will establish and operate a clinical laser center in Sacramento, CA.

5/23 The use of lasers in dentistry appears to be a hot topic this month, with several announcements about the use of lasers to brighten/whiten teeth, and the laser toothbrush above (see the May 2 brief). My endodontist provide me with his current copy of *Dentistry Today* (May issue), which happened to contain two articles about laser dentistry. The first, "Whitening Lasers May be Wave of the Future", describes the **Ion Laser Technology** "Brite Smiles" technique, the combination of using an argon laser to activate a bleach, followed by the use of a CO_2 laser to activate a heat catalyst that mixes with the hydrogen peroxide and two bleaches used in the process.

The second article, "Cyberknife: Dental Lasers Enter the 21st Century" provides an overview of where (and where not) dental lasers are today, and where they may be going. (As has been pointed out to me on several occasions, until, and if, a truly low-

cost system is developed (under $25,000) that can be used for both soft (dentin) and hard (enamel) tissues, as well as for removal of both amalgam and composite fillings, and be used to prepare the vital tooth surfaces for receipt of the new filling material, dental lasers will remain a dream and not a reality.)

MEDICAL/SURGICAL UPDATE -- JUNE 1996

5/21 **PDT Inc.** announced that David Mai had assumed the position of president, with Gary Kledzik continuing as chairman and CEO. Mr. Mai will also continue as president of PDTI's subsidiary, **PDT Cardiovascular**.

5/28 **ESC Medical** has signed a letter of intent to acquire **LBT Ltd.**, an Israeli company specializing in the development and manufacturing of laser systems for the cosmetic/medical markets. The agreement is for $5.2 million, and will include employment of LBT's two founders for a period of three years. LBT's products include the Topaz 30, a surgical CO_2 laser system, and the Derma 20, an erbium:YAG laser system, used for general dermatological applications. ESC intends to introduce the two laser products into the U.S. market after obtaining 510 (k) clearances from the FDA.

ESC also announced that it had filed a registration statement with the SEC for a public offering of 3.8 million shares of common stock. Smith Barney, Goldman Sacs and Montgomery Securities will underwrite the offering.

5/31 **QLT PhotoTherapeutics** announced that it had notified American Home Products of its intention to call for redemption of the 500,000 Series C First Preference Shares held by AHP.

5/31 *The Boston Business Journal* featured an article about **Palomar Medical Technologies** in its Stock Watch column. It notes the meteoric rise of the company's stock from $4 last September to the mid teens recently stating, "The rise is all the more amazing considering that the company...has never reported a profit...and doesn't even expect to until 1997." The article goes on to relate the developments in cosmetic laser surgery, with the potential for hair removal and wrinkle removal and skin resurfacing driving the optimism.

6/1 *Healthcare Technology Management*, in their June issue, has a column by Wayne Hibbs about "A Light at the End of the Tunnel for Photodynamic Therapy". Mr. Hibbs discusses the unique FDA approval for a drug-device combined protocol for the treatment of obstructing esophageal tumors. He believes that PDT could become a routine clinical procedure in time, with inoperable tumors being pre-treated with PDT before surgeons access the tumor using minimally invasive techniques, as PDT

combines with MIS to treat tumors with a whole new generation of local light-activated pharmaceuticals.

6/3 **Classy Lady by Mehl** said it had filed a 510 (k) notice seeking approval for its hair removal process, and that it intends to merge with **Selvac**. Upon approval of the merger, Selvac intends to be renamed **Mehl/Biophile International**. (This company has signed a marketing agreement (December 27, 1995) with **Laser Industries/ Sharplan**, for the latter to be a non-exclusive marketer of the laser-based process.)

6/3 According to **ThermoLase**, it has completed licensing agreements with three laser dermatologists who will become the first physicians to offer the patented SoftLight hair removal process in their practices. The three are Dr. David Goldberg of the Skin Laser Center in Westwood, NJ (who did the clinical workup on the system for ThermoLase); Dr. Curt Littler affiliated with the Scripps Clinic in La Jolla, CA; and Dr. Roy Geronemus of the Laser and Skin Surgery Center of New York. Under terms of the agreement, ThermoLase will provide the doctors with use of the laser and charge them a per-procedure fee, that will depend on the location of the treatment, on the body, along with minimum monthly payments after six months.

6/4 **Eclipse Surgical Technologies** announced the initial public offering of 4 million common shares, at a price of $16 per share. (See the April 22nd brief.) The offering is managed by PaineWebber, Deutsche Morgan Grenfell, and Jefferies & Company. The net proceeds will be used for R&D, including clinical trials; expansion of sales and marketing resources; capital expenditures; repayment of outstanding debt and overdue obligations; and corporate purposes. Eclipse is one of four companies pursuing the TMR market. (The others are **PLC**, **CardioGenesis**, and **Acculase**.) (A copy of the final prospectus was received on June 21st.)

In other news, Eclipse announced that it had received orders for eight Eclipse TMR 2000 lasers from **Sorin Biomedics Cardio, S.p.A** for distribution in Europe. Two of the lasers have been shipped for installation in hospitals in Italy and Spain. Eclipse is currently negotiating an international distribution agreement with Sorin, one of the world's largest cardiovascular surgery companies, and a subsidiary of **Fiat S.p.A**.

6/4 **ThermoLase** announced that it had opened its second Spa Thira in Dallas, TX. Located in a retail plaza, the 6500 sq. ft. facility has 11 treatment rooms, and is significantly larger than the company's first spa which opened in La Jolla, CA last fall.

6/4 *Investor's Business Daily* had a nice writeup about **Palomar Medical Technology** and its growing businesses, from cosmetic lasers to computers.

6/6 **Candela Corporation** announced that they have initiated a joint development agreement with the **Beckman Laser Institute and Medical Clinic of the University of**

California, to develop a new proprietary dynamic cooling device that will enhance the effectiveness of laser skin treatments. The device was conceived at Beckman and will be perfected and clinically tested there. Candela said that it had applied for FDA clearance of the unique device and anticipates receiving it this summer. The device is different from other skin cooling devices in that it selectively cools the top two layers of skin during laser treatments, reducing thermal injury without effecting treatment efficacy. It should significantly reduce the pain of laser skin treatments.

6/6 As noted in the May 13th brief, Cruttendon Roth held its first HealthCare conference in New York today. Among the laser companies putting out news releases about their presentations at the conference were **Palomar Medical Technologies**, **PLC Systems**, **Endocare**, and **DUSA Pharmaceuticals**.

6/6 **Ion Laser Technology** announced that it had reached its objective of opening 20 laser tooth whitening locations within 90 days of receiving FDA marketing clearance for its laser-based system. The company has now installed, trained, and certified dentists and hygienists at 21 locations throughout the U.S., and is currently expanding its training capacity at the Birmingham Training Facility, and establishing a new facility in Salt Lake City to increase the rate at which whitening locations can be opened.

6/10 The June 10th issue of *Business Week* contains an article on photodynamic therapy, entitled, "A Ray of Hope for Cancer Patients". The story discusses the development of PDT and the recent FDA approval for treating end-stage esophageal cancers, and the approvals for PHOTOFRIN in other world areas. In addition to mentioning the work being done by **QLT PhotoTherapeutics**, **DUSA Pharmaceutical**, **PDT Inc.**, and **Pharmacyclics**, a new entrant that recently appeared on the scene, are also mentioned. (I have made contact with this new company and will publish more when I receive the information promised. See the June 17th brief about this company.) The article focuses on the potential "multibillion dollar" market for PDT drugs to treat cancers and other afflictions, such as age-related macular degeneration and psoriasis.

6/10 **CardioGenesis** announced that it had received clearance to expand its muliticenter Phase 2 clinical trial for its intraoperative transmyocardial revascularization system in patient with coronary artery disease that cannot be treated by other methods.

6/10 **Laser Industries** announced that it had filed with the SEC to offer 2.4 million shares of common stock, 2 million shares from Laser Industries, and 400,000 shares from **Trans-Resources Inc**. and its indirect subsidiary, **Haifa Chemical Holdings**. The net proceeds to Laser Industries will be applied to repayment of bank debt, the development of new products, expansion of worldwide marketing activities, and the formation or acquisition of new businesses and technologies, including the establishment and operation of laser treatment centers. The offering will be led by Salomon Bros., with Furman Selz and Oppenheimer & Co. as co-managers. (I

requested a copy of the prospectus which was received on June 21st. Of interest in the prospectus was the fact that the company offers 23 laser systems, which in addition to the CO_2 and YAG surgical systems, includes holmium, diode, pulsed dye, and ruby laser types. CO_2 lasers currently account for approximately 80% of company sales.)

6/11 *The Boston Globe* ran a feature article on its Living/Arts pages on "Zapping Away the Years", discussing the pros and cons of cosmetic laser surgery. The article featured the types of surgery that are currently being performed at the local **Candela Skin Care Center**. Typical prices quoted for facial wrinkle removal laser surgery are eyes, mouth, and forehead - $950 each; cheeks and chin - $1900; and the full package - $3000.

6/11 The June issue of *Photonics Spectra* includes an article on medical lasers written by Brenda Ropoulos, marketing manager for **Coherent Medical**. The article, entitled, "Medical Lasers: New Wavelengths, New Designs Enhance Cost Effectiveness", discusses the multi-tissue capabilities and multi-wavelength tunability of some of today's new lasers. Applications include the use of holmium lasers in arthroscopy and urology, as well as in gynecology, ENT, and general surgery; and the use of multi-wavelength devices (such as the new Coherent aesthetic system) that includes three wavelengths -- q-switched YAG, doubled YAG, and alexandrite, for tattoos and pigmented lesions; and a variable pulsed doubled YAG, for the treatment of vascular lesions, all in one device. The article also discusses the relatively new short-pulsed CO_2 lasers used for skin resurfacing, and the erbium:YAG laser that shows potential for precision microsurgery, such as vitreo-retinal surgery. (Although slanted towards Coherent products, the article is balanced by mentioning competitive products as well.)

6/14 **PLC Systems** announced at its annual meeting that the **Columbia Regional Medical Center at Bayonet Point, FL** had joined the TMR clinical trials of the Heart Laser, with the first two TMR procedures scheduled. Columbia is the fourteenth clinical site to participate in the protocols evaluating the effectiveness of the Heart Laser in treating coronary artery disease. Dr. Rudko, chairman of PLC, stated that to date 500 patients had been treated with the Heart Laser in the U.S., and an additional 1350 patients treated outside the U.S.

6/17 In a related TMR story, **Eclipse Surgical Technologies** announced that it had reached an agreement with **Sorin Biomedica Cardio S.p.A** for the marketing and distribution of Eclipse's TMR laser products outside the United States. (See the June 4th brief for the initial announcement of this agreement.) According to the news release, since September 1995 through April 1996, Eclipse had installed TMR lasers in 20 hospitals in the U.S., more than any other provider (note in the above brief that PLC has 14 hospital locations in the U.S., but more locations outside the U.S.), and in two hospitals in Europe.

6/14 **Medical Alliance, Inc.** announced the acquisition of the assets and accounts of Chicago-based **Mobile Surgical Services**. The acquisition will consolidate and increase Medical Alliance's capabilities in providing mobile laser services in the Chicago area. MAI plans to add **Spectrum Medical Technology's** EpiLaser laser-based hair removal system upon it receiving FDA marketing approval. MAI has an agreement with Spectrum to be the exclusive mobile provider of the EpiLaser in the U.S. Since 1989, MAI has enabled approximately 4000 physicians to perform over 100,000 laser procedures in their offices.

6/15 According to *Health Technology Trends*, published by ECRI, TURP remains the "gold standard" for treating BPH. Although electrovaporization (EVP) of the prostate won the popularity poll at the recent AUA annual meeting, a study presented at the meeting suggested that complications of the use of EVP could require additional surgery. The study was the first to compare TURP, EVP, and visually assisted laser prostatectomy (VLAP) for treating an enlarged prostate. According to Dr. Erik Enquist, chief of urology at George Washington University Hospital, "EVP looks promising for improving a patient's symptoms and other objective measures, but because of the complications associated with the procedure, we need to learn more about the technique and its thermal effects". The complications were caused by tissue left behind after EVP, which required surgery with a resectoscope to excise the tissue. The laser, according to Dr. Enquist, appears to have fallen from the urologist's favor. In the comparative study, symptom relief after laser surgery took several weeks, with TURP and EVP providing more immediate symptom relief. The laser also caused irritative symptoms such as burning during urination, which could last for up to three months. The laser procedure does, however, cause less bleeding complications than TURP, while EVP also offers some benefit of reduced bleeding. In Enquist's opinion, EVP has replaced the laser. He feels that more prospective, randomized studies are needed before a conclusion about any technique can be reached.

6/17 In a related item, **Prosurg's** electrovaporization products have received Japanese Ministry of Health approval, as well as a certificate for export from the FDA. The products are distributed by **Getz Brothers** in Japan, Asia, and the Pacific Far East region. In Europe, Latin America, Mexico, the Caribbean, and Canada, the Prosurg devices are distributed by **Bard International**, while Prosurg distributes its products domestically.

6/17 **Pharmacyclics** of Sunnyvale, CA announced the results of the first study of its water-soluble photosensitizer lutetium texaphyrin (Lu-Tex) at the annual meeting of the American Society for Photobiology in Atlanta this past weekend. (See the related story mentioning Pharmacyclics that appeared in the June 10 issue of Business Week.) The firm said that 19 patients with either malignant melanoma, breast cancer, Kaposi's sarcoma, or invasive basal cell carcinoma, accessible to illumination by an externally applied light source (720 to 760 nm for activating the drug), were treated with a single

injection of Lu-Tex in a dose-escalation study, followed three to eight hours later by illumination of the tumors. The drug was well tolerated in the Phase 1 clinical trials. According to the principal trial investigator, Dr. Jeffrey Wieman of the **Dept. of Surgery/Surgical Oncology at the Univ. of Louisville**, "These early findings are very encouraging. They indicate that the drug has the potential for use in treating a variety of cancers, including large, deeply situated or pigmented tumors". Other participating clinical centers include **Stanford Medical Center** and the **University of Tennessee Thompson Cancer Center**. The proprietary drug product is derived from Pharmacyclics core technology in biometallic chemistry. (I have made contact with the company, as note above, and will report more when the information is received. Apparently, a stock offering is underway and a prospectus will be sent to me when it becomes available.)

6/17 **Lasermedics** announced that it had filed to become listed on the NASDAQ SmallCap Market.

6/18 **Montgomery Securities** analyst Kurt Kruger has initiated coverage of **CardioGenesis Corporation**. He expects the company's stock to rise to the $17-21 range over the long-term. Kruger believes that the smaller, significantly less costly laser being used by CardioGenesis, compared to the laser used by **PLC Systems**, plus the ability to use the system percutaneously, will enable the company to become the leader in the TMR field.

6/18 **Sunrise Technologies** has entered into a private label agreement with **New Image Industries**, the market leader in the intra-oral camera industry. The agreement calls for Sunrise's air abrasion systems, the MicroPrep and Director models, to be manufactured and labeled as New Image products. The OEM arrangement will enable Sunrise to expand its reach in the dental field.

6/19 **PLC Systems** announced that the first Heart Laser had been shipped to China (Zibo), with patient cases scheduled for the end of the month.

6/19 **ThermoLase** said that it had signed an agreement to invest $4.4 million in **AntiCancer Inc.**, a San Diego-based biotechnology firm, in exchange for a 10% stake in the company. The company believes that the technology under development at AntiCancer has the potential to enhance the effectiveness of the Thira cream used in the SoftLight hair removal process. AntiCancer's technologies also have potential for permanent hair coloring and for enhanced hair growth. ThermoLase has entered into an agreement to license AntiCancer's technology as it pertains to these and other potential hair-related products. The base technology was developed as a means to prevent or inhibit hair loss caused by chemotherapy, using liposomes as delivery agents to specifically target hair follicles.

6/19 **MEHL/Biophile International** and its **SLS** unit said that it was in negotiations to explore the development of a string of joint venture laser centers in a host of countries across the globe. The company has targeted 32 centers by year's end, to be located in New Zealand, Australia, South Africa, Switzerland, Denmark, Germany, France, Spain, United Kingdom, Austria, Bulgaria, Sweden, Holland, Italy, Israel, Egypt, the United Arab Emirates, Thailand, Taiwan, Korea, Japan, and Hong Kong. The company said it expects to initiate 300 additional joint venture collaborations in five continents over the next two years. The SLS unit develops and evaluates laser hair removal technology and markets its Chromos 694 ruby laser depilation system outside the U.S. It has 10 systems operating in various sites and has treated hundreds. MEHL is currently seeking FDA approval for its Chromos 694 system for use in the United States.

6/22 I had requested and finally received an info package from **Mattan Corporation** and its **Medical Laser Institute of America**. Mattan is a holding company whose sole operating subsidiary is MLIA. MLIA operates a full service medical laser outpatient clinic in Des Plaines, IL (a suburb of Chicago), providing cosmetic laser treatments for a wide range of skin conditions. The company also plans to offer laser refractive surgery. According to the May 1996 report to shareholders, the company was planning to establish a model clinic in the Oak Brook Medical and Surgical Centre, in an affluent suburb of Chicago, which was to operational in July. It was to be the first of a series of 12 new model clinics to be opened by MLIA over the next year. Lease negotiations were in the final stages for two clinics in California for opening in late summer/early fall, with MLIA expecting to open a minimum of 50 clinics over the next three years. (See the April 12 surgical and May 28 ophthalmic briefs for more on this agreement and some of the above news.)

MEDICAL/SURGICAL UPDATE -- JULY 1996

6/23 The *New York Sunday Times* presented an unflattering look at **ESC Medical Systems** and its non-laser light sources for use in dermatology, especially the treatment of spider veins. This review preceded the announced secondary offering by the company. Although the system seems to work in the hands of those trained to use it and willing to experiment to find the right settings, it is not easy to use and can result in problems. As stated by the author, "Many doctors have questions about the effectiveness of ESC's machine, the Photoderm VL, in part because the science of treating veins is complex...investors may want to examine these ideas more closely... like lasers, its machine can cause discoloration or blistering on dark-skinned patients, or patients with tans or freckles. These problems may cut down on its usefulness...If doctors -- who are crucial in marketing any medical device -- have problems with the Photoderm, they are more likely to use rival machines or alternative treatments...ESC's market potential may not be as large as Wall Street believes."

6/24 **Laser Industries** received FDA marketing clearance for its EpiTouch ruby laser for the treatment of tattoos and other pigmented lesions. The laser was unveiled last month at the Clinical Dermatology 2000 conference in Vancouver, Canada, and is currently being sold in Europe and the Pacific Rim countries. It will be introduced to the U.S. market at the AAD meeting scheduled for Orlando July 25-27. Laser Industries has filed a 510 (k) application for the EpiTouch laser for hair removal, with ongoing clinical tests showing that it is fast, relatively painless, and causes fewer side effects than certain other methods of long-term hair removal.

6/24 **Ion Laser Technology** reported results for its fourth quarter, ending March 31st, with revenues of $1.4 million and net income of $75,704 or 2 cents per share. For the fiscal year, the company had revenues of $4.2 million and a net income of $17,424, 1 cent/share. Updating its laser teeth whitening locations, the company said that the process was now available in over 25 dental offices throughout the U.S., with an additional 33 offices under contract to open, and deposits from another 31 dentists. Negotiations have begun to establish centers in several foreign countries.

6/25 **PLC Systems** announced that the results of a two-year clinical study of TMR on twenty patients at Brigham and Women's Hospital were recently published in *The Journal of Thoracic and Cardiovascular Surgery*. The results showed a dramatic reduction in angina class and significant increases in reperfusion, concluding that the TMR procedure is "a simple operative technique that may improve myocardial perfusion and provide angina relief". To date approximately 2000 patients have been treated with the Heart Laser in 19 countries around the world.

6/25 The July issue of *Advanced Technology in Surgical Care* has a lead article on the use of holmium lasers in surgery. The article states that recent advances make this laser the choice for many procedures. "Described by physicians as the `Swiss army knife' or the `workhorse' of laser surgery, the holmium laser's combination of high power/low energy delivery in a short time frame allows for simultaneous cutting, coagulation, lithotripsy, and vaporization with one tool." It is being used in ambulatory and surgical centers for head and neck surgery, including sinonasal and sinus surgery; surgery of the eardrum and dermis to shrink and tighten tympanic membrane in hearing impaired patients; in endoscopic procedures in arthroscopy, both for removing tissue and for tissue-shrinking; and in soft tissue urological applications. In addition, the holmium laser is used experimentally in the eye for treating hyperopia; tear-duct creation; cataract removal; and enhancement in the nose. It is also being investigated for drilling holes into damaged heart tissue, among other applications. (Anyone wanting a copy of the five-page article give me a call.)

6/26 The FDA has cleared the first voice-controlled surgical robot, the AESOP 2000 from **Computer Motion** of Goleta, CA. AESOP can be used to manipulate and position a laparoscope at the vocal direction of the surgeon, enabling the surgeon to keep a

watch on the video monitor as he positions the laparoscope. According to the July 8th issue of *The Gray Sheet*, the company plans to begin shipping the units in the third quarter of this year. The AESOP 2000 unit is under evaluation at 20 clinical sites across the U.S. It is a successor to the AESOP 1000, a hand or foot operated model, that has had sales of 160 units and been used in over 14,000 MIS procedures. The model 1000 is upgradeable to the model 2000.

6/26 **Paine Webber** analyst Charles Olsziewski has begun coverage of **Eclipse Surgical Technologies** with a "buy" recommendation. He writes that Eclipse hold the biggest domestic installed base of holmium lasers employed in transmyocardial revascularization and that Eclipse's laser system holds several advantages over **PLC Systems'** competing laser including ease of use, size, therapeutic performance and general system design. (However, he doesn't mention any advantages over Cardiogenesis' competing system.)

6/26 Analyst Frank Lyles of **Preferred Technology** begins coverage of one of our companies, **DUSA Pharmaceuticals**, with a "buy" recommendation. (DUSA is in clinical evaluation of its PDT drug ALA for several indications including bladder cancer diagnosis and the treatment of precancerous skin lesions.)

6/26 **Pharmacyclics** announced that its drug gadolinium-texaphyrin (Gd-Tex) is showing promising signs as a tumor-selective radiation sensitizer in Phase Ib/II multicenter clinical trials. Gd-Tex was found to capture free radicals during radiation treatment to create longer-lived and more potent radicals for action on the cancer cells at the tumor site, thus increasing tumor response without increasing damage to normal tissue. Also, Gd-Tex is detectable by MRI, making it possible to evaluate the localization of the drug in the body. The company said it is developing Gd-Tex as a radiation sensitizer for use in patients with metastases of the brain, who are receiving radiation therapy. (For more information about this drug company and its PDT drugs under development, see last month's 6/10 and 6/17 briefs.)

6/27 The *Dow Jones Newswire* reported that **Ion Laser Technology** had received an FDA warning letter, dated June 18th, concerning its CO_2 and argon lasers' operating manuals lacking procedures and a schedule for recalibration. The letter also recommended that the company include information about the lasers' wavelengths so that users could easily select the correct protective eyewear. The company responded by saying that the warning letter would not delay laser placements, as the deficiencies were minor, and that the FDA had indicated that the firm could continue to ship products while the corrections were made. On July 2nd the company said it had completed documentation to bring all laser systems into compliance with the issues raised by the warning letter, with a written plan for correction sent to the FDA on June 28th.

According to the July 1st issue of *The Gray Sheet*, the tooth whitening package, consisting of the argon and CO_2 lasers, 20 whitening kits, certification, training, advertising, and an initial supply of marketing materials is priced at $39,500. Each procedure, which takes about an one and half to two hours, costs about $500.

6/27-
6/28 **ESC Medical** announced that it had completed its purchase of the outstanding shares of **LBT** (Israel), a developer of cosmetic and surgical laser systems (see the 5/28 brief in last month's issue). The agreement calls for a payment of $5.2 million in cash to current LBT stockholders, and will include employment of LBT's two founders for a period of three years. LBT's products include the Topaz 30, a surgical CO_2 laser and scanner system, and the Derma 20, an erbium:YAG laser system, used for general dermatological applications, including skin resurfacing. ESC intends to introduce the two laser products into the U.S. market after obtaining 510 (k) clearances from the FDA.

The company also responded to the June 23rd NY Times article (see first surgical laser item above), by stating that at least five practicing physicians who own the Photoderm VL system, with whom the reporter spoke, all cited very positive results in the hundreds of patients they have treated. None of these doctors were quoted nor were their positive experiences with a wide range of patients exhibiting various skin colors, types, and vessel sizes noted. (The news release goes on to name the prominent doctors, including David Goldberg, Roy Geronemus, and Arielle Kauver.)

6/27 **PLC Systems** said that one-year follow-up in 34 patients in a Saudi Arabia study supports the use of TMR as an alternative to first bypass surgery. The study, presented at the "Techniques in Cardiology and Cardiovascular Surgery Conference" in Nice, France, showed that 90% of the patients either stopped antianginal therapy or received minimal therapy. In a German study, patency and blood flow through channels created with The Heart Laser were demonstrated after three months. In another study, another set of German doctors were able to demonstrate that mortality rates in a group which received medical treatment only, were three times greater than those with TMR treatment in an end-stage coronary artery disease population. PLC Systems is near completion of tabulating the data on a controlled, randomized trial conducted in the U.S. which compares outcomes of patients receiving TMR using the Heart Laser to patients who receive only medical therapy. To date, the mortality rate is nearly double in the medical therapy group.

6/28 **QLT PhotoTherapeutics** announced that it had issued 1.18 million common shares to **American Home Products** for the conversion of 500,000 shares of Series "C" 8% First Preference Shares and the $996,703 in accrued cumulative unpaid dividends held by AHP. After the conversion, AHP holds 8.6% of the common shares outstanding in the company.

6/28 **Spectranetics** has filed a shelf registration statement with the SEC, which, when effective, would allow the company to issue up to $50 million of its securities.

6/28 According to *The Dow Jones Newswire* (and further amplified in the June 24th issue of *The Gray Sheet*), the FDA announced that it has decided to approve medical devices for orphan diseases, in a move to stimulate manufacturers to make products for rare conditions that have a limited market potential. Orphan diseases include those that inflict less than 4000 people annually. Under the new Humanitarian Use Device (HUD) program, marketing approval requires that device makers demonstrate safety and that their devices will have a likely benefit to patients, under a humanitarian device exemption (HDE) but will not have to run lengthy studies to prove efficacy. The program is similar to an existing process for approving drugs for orphan disorders, called the Orphan Drug program.

7/1-
7/2 **Candela** announced that it had acquired **Spa Management**, doing business as **Le Pli at the Heritage**, one of New England's premier day spa, salon, and health club, which is located at the Heritage On The Garden building in Boston's Back Bay. The spa's former owner is joining **Candela Skin Care Centers** as chief operating officer. A January 1997 re-opening, under the new name Candela Laser Cosmetic Center and Spa, will add laser treatments to the menu of service already offered by the spa and health club, such as massage, skin care, personal training and health club benefits.

According to the July 2nd *Boston Globe*, the acquisition was for under $1 million, for the enterprise which generates about $2 million in revenues annually.

7/1 **Boston Scientific** has acquired distribution rights, except for the U.S. and Japan, to the transurethral thermo-ablation therapy system developed by **Urologix**. The system is for the treatment of BPH. Urologix also extended exclusive distribution rights in Japan to **Nihon Kohden**, a leading manufacturer and distributor of medical devices in that country, where an application for regulatory approval is pending. (Urologix retained distribution rights for the U.S. market and intends to file a PMA for marketing later this year.)

7/2 **Premier Laser Systems** announced that its Dental Products Group had entered into a one-year joint marketing agreement with Salt Lake City-based **Stardent International Labs**, in which the two companies will combine Stardent's teeth bleaching and whitening products with Premier's argon laser systems, used to accelerate the whitening process. Under the agreement, both companies will continue to manufacture and market their respective products and systems independently, but will actively promote whitener/laser packages to dentists, subject to FDA clearance of the laser for this application, as well as work together to develop new products to enhance laser bleaching procedures. Premier sells the Arago portable argon laser priced at

$8950, and a Multi-Operatory Dentalaser, for use in as many as five operatories, that sells for up to $19,000. According to **Clinical Research Associates**, whitening procedures are routinely conducted by 7 of every 10 dentists, and a growing number are using lasers for the procedure. During clinical trials for the FDA clearance (under review for about two months), Premier officials claim that their laser demonstrated a three-shade change following a one-hour treatment with the laser.

7/3 **Candela Corporation** has re-offered its ESC-to-ScleroLaser trade up program in the wake of the negative publicity generated by the *NY Times* article about **ESC's** Photoderm device. One week after the Times article citing the medical community's questions about the efficacy and safety of the Photoderm VL non-laser system for treating leg veins (see first surgical item above), Candela has extended its offer to current ESC physicians/users to trade up to its advanced ScleroLaser technology for a substantial discount from the list price. The program was originally offered in February, following the publication of another critical report in *Medical Laser Insight*, citing "significant and irreversible tissue damage" as a potential adverse effect associated with the non-selective light source devices such as the Photoderm VL.

7/3 **ESC Medical Systems** reported the pricing of an offering of 3.8 million shares at $24.75/share. The company anticipated receiving about $17.6 million from the offering, underwritten by Smith Barney, Goldman Sachs, and Montgomery Securities.

7/3 **Microwave Medical**, a subsidiary of **Dynamic Associates** (Scottsdale, AZ) said it has completed the first stage of development of its device known as the Therm-T to eradicate spider veins or telangiectasia, and superficial varicose veins. The device heats tissue by microwave energy much as a microwave oven heats food. By using variable frequencies and a specific applicator design, heat can be applied to different tissue at varied depths in the body. The blood below the skin surface can be heated to the point of coagulation while not affecting the surrounding area, according to the company. Once it necroses, the body closes off that blood supply and cleans out the tissue. Initial computer simulations verified with tissue studies have been completed, and Microwave said that the studies yielded an ability to select proper dosing, power, and frequency. Physical body simulations have been done with bovine, porcine, and chicken tissues, and animal protocol testing will begin this month.

7/5 I received a report written by Sean Chaitman of H.J. Meyers on **Coherent, Inc.**, dated June 25th. (Sean has also written on the laser hair removal market back in April and on **Laser Industries** in March.) Sean breaks down Coherent's sales into those for electro-optics, and those for medical related products. For the fiscal year ending September 30th, Sean shows 1995 sales for the medical group at $126 million or 44% of total sales. This grows to an estimated $157 million for fiscal 1996, and $190 million in fiscal 1997. It is interesting to note that he mentions that the recently cleared VersaPulse multiwavelength laser, priced at $225,000, can be used for both

tattoo, pigmented and vascular lesion applications, and may be cleared for use on leg veins as well. The report also mentions that although Coherent is not aggressively marketing its excimer laser for refractive surgery internationally, it is working on a second generation prototype, which is at the exploratory/developmental stage.

7/8 **Surgical Laser Technologies** announced that it had completed the sublease of its corporate headquarters building in Oaks, PA, to Suburban Cable TV Co. SLT will immediately move its corporate administrative and sales and marketing operations to a 42,000 square foot leased facility in Montgomeryville. The company's engineering and manufacturing operations will move to the new facility by January. The move eliminates excess space and significantly reduces SLT's operating expenses. The Montgomeryville location is within 12 miles of the current facilities.

7/8 **Candela Corporation** said it had received FDA clearance for its Alexlazr for use in treating pigmented lesions or brown spots of the skin, commonly attributed to sun exposure and sun damage. The company estimates the potential projected market size is $2 billion, with over 28 million patients in the U.S. alone. The patient population consists of individuals from 30 to 80 years old with lighter-skin types. With typical treatment charges of $100 to $400 per session, for one to four sessions, this procedure is an attractive alternative for individuals currently using bleaching or anti-ageing creams, which must be used daily for several months before results are seen. In contrast, the laser treatment can be effective in as few as two treatments. The Alexlazr can now be used for several multi-billion dollar applications, the removal of unwanted tattoos, dermal pigmented lesions, and for sun spots.

7/9 **Star Medical Technologies**, a subsidiary of **Palomar Medical Technologies**, announced that it had received U.S. Patent 5,527,350, issued on June 18, 1996, for the use of the company's high-powered pulsed diode laser for the treatment of psoriasis. (I believe that this laser is in clinical trials for the application at the Wellman Laboratories of Photomedicine at MGH in Boston.)

7/9 **CardioGenesis** announced that it had received the CE mark for the use of its ITMR products in patients with severe coronary artery disease, who are not candidates for conventional therapies including CABG and angioplasty, in the European Community.

7/9 **Eclipse Surgical Technologies** announced that it had delivered 11 TMR lasers during the second quarter, giving it a total of 22 lasers in hospitals in the United States, more than any other supplier. The company is in Phase II investigational TMR studies with its holmium laser system in treating patients with severe angina who are not candidates for balloon angioplasty or bypass procedures.

7/10 **Ion Laser Technology** has petitioned the Patent Office for an expedited review of its proprietary laser-based tooth whitening procedure, as a result of activities by competitors believed to employ ILT's technology. (See the July 2nd brief above, on the agreement by Premier and Stardent to cross-market their products in this arena.)

7/10 **Lasermedics** announced that the FDA had completed its initial review of the MicroLight 830 application for treating carpel tunnel syndrome and found the application sufficiently complete to permit a substantive review. The PMA was submitted on April 2, 1996.

7/10 **PDT Inc.** and personnel from UC/San Francisco presented the results from a Phase I/II clinical trial for AIDS-associated Kaposi's sarcoma, using PDTI's investigational drug SnET2, at the World AIDS Conference in Vancouver. Twenty-nine patients with 172 skin lesions were treated using various drug and light combinations. Therapeutic doses of SnET2 and light showed a positive clinical effect on KS skin lesions, particularly with papular-stage KS. Tumor responses were consistent with results announced earlier by the company, demonstrating the potential clinical utility of SnET2 in the management of local KS.

7/11 **Physicians Laser Services** (Boca Raton, FL), acquired **United Laser Systems, Inc.** of Portland, CT, in a stock swap. Both companies are mobile medical laser providers.

7/15 **CardioGenesis** reported its second quarter results with revenues of $1.2 million, primarily from sales of its ITMR lasers into European and U.S. clinical sites. The net loss for the quarter was $1.9 million (18 cents/share).

In other news the company announced that it had received IDE approval to begin a Phase II ITMR study in "no option" patients in the U.S., and would begin enrolling patients immediately. The company also expects to seek approval from both U.S. and European regulatory officials to begin human clinical trials for its percutaneous myocardial revascularization (PMR) system by the end of the year.

7/15 **Palomar Medical Technologies** announced that it had received FDA marketing approval for its long-pulsed ruby Epilaser for a wide range of dermatological applications (but **not** for hair removal!) on July 12th. The company added that it had recently received orders for the Epilaser from Europe and the Far East totaling $12 million, in addition to the $4.8 million in orders from Canada announced last April (see the 4/29 brief in the April issue of Executive Laser Briefing.) A company official also said that they were comfortable with analyst's range for second quarter revenues of between $15-17 million, representing a three-fold increase over the first quarter. The increase is principally due to the sales of lasers by recent acquisition **Tissue Technologies**, and the rapid increase in specialty electronic sales. According to the

company, **Travelers Corporation** has made an additional $6 million investment, bringing its total investment to $12 million since February 1996.

According to *The Boston Globe*, and *The Dow Jones Newswire*, the Traveler's investment makes it the largest corporate owner, with a stake of about 3%. The Globe story went on to state that the FDA had turned down the Epilaser for hair removal, but that the company plans to submit additional data to support its FDA filing. In a research report issued by Jonathan Cohen of *Smith Barney*, the analyst stated that he believed that the laser would be widely used "off label" for hair removal.

Separately, the July 22nd issue of *The Gray Sheet* reported on a July 15th investor conference held in New York City by Steve Georgiev, Chairman and CEO of Palomar. At the meeting Georgiev stated that the Epilaser would generate between $10 to $15 million in revenues by the end of the year. He said that the company planned to begin shipping the laser during the third quarter at a list price of $100,000. The unveiling of the laser at the AAD meeting in February had generated over 500 sales inquiries. The company estimates that 2/3rds of 1996 Epilaser sales will be sent to U.S. customers, with the remainder being sold overseas, including Europe, where the device is still awaiting CE mark and TUV clearance. Georgiev said Palomar/Spectrum Medical will be production-limited for the rest of the year, until 1997. Georgiev reiterated at the investor meeting that "Doctors who in fact are now capable of buying the laser can...if they choose, use it for hair removal, because they (physicians) are not regulated by the FDA." Palomar will not formally market or encourage the use of the device for hair removal until FDA clearance is received.

The Gray Sheet also noted that **Thermolase** held a July 16th teleconference in response to the Palomar announcements. John Hansen, Thermolase president and CEO maintained that "there is nothing new with respect to what Palomar is offering these physicians...it is a little bit unrealistic to presume that physicians are going to want to entertain somewhat novel off-label practices with lasers that have not been approved by FDA...it has serious implications for their malpractice insurance." He further noted that Thermolase has licensed several physicians to use its Softlight hair removal procedure, has opened two spas, one in Texas and one in La Jolla, California, and hopes to have 85 licensed physicians and 10 spas by the end of 1996.

7/15 **Rare Earth Medical** (West Yarmouth, MA) announced that it had received two separate NIH research grants totaling $200,000. The first grant is to finance the construction and testing of a device to better control the laser treatment of cancerous tumors. REM will use the National Cancer Institute grant to develop a device for optically monitoring the extent of tissue being heated, to ensure that the entire tumor has been destroyed. The **University of Texas/M.D. Anderson Cancer Center** will perform the clinical evaluation, under the direction of Pathologist Dr. Sharon Thomsen. The second grant, funded by NCHD, will finance the development of a

novel technology to replace tubal ligation surgery, sought by 700,000 women annually to prevent pregnancies. The company will use the grant to develop a special laser fiber that will be placed in a woman's fallopian tube without the normal risks of surgery. The laser fiber is activated, heating the fallopian tube tissue, and the tube will heal closed in the weeks following the procedure. Dr. Massoud Motamedi at the **University of Texas Medical Branch at Galveston** will direct the clinical evaluation. Recent experiments in Europe have verified that the REM laser fibers can be easily placed in a fallopian tube under endoscopic visualization. Rare Earth Medical develops medical laser fibers which have been used in Europe in the esophagus, prostate, heart, liver, and other body parts.

7/15 **Candela Corporation** announced that its Vascular Lesion Laser has evolved into an all purpose laser, with new applications and expanded capabilities. The newest capabilities, along with their annual market potential as estimated by the company, include: warts ($80 million); scars, including acne, burn, and surgical ($80 million); stretch marks ($100 million); rosacea -- red facial lesions usually concentrated on the nose and cheeks ($40 million); and vulvodynia (?)($1 million). These conditions are in addition to port wine stains, hemangiomas, facial spider veins, and other vascular abnormalities, which the laser was originally designed to treat, and which represent a combined estimated annual market of $250 million.

7/16 **PDT Inc.** announced that its board of directors had authorized the repurchase of up to 600,000 share of stock of the 12.3 million shares outstanding.

7/16 **Laserscope** reported its second quarter results with a 23% increase in revenues over last year's quarter, to $8.5 million. Net income was $250,000 (3 cents/share), compared to a loss of $840,000 for last year's second quarter. President Robert McCormick attributed the increase to the success of the Aura laser system and the restructuring actions taken in the latter half of 1995. The company indicated that the financial performance of Heraeus Surgical, which Laserscope is in the process of acquiring, was also improving, due to the success of its Paragon skin resurfacing laser. The acquisition, pending shareholder and regulatory approval, is expected to close in September.

7/17 Ron Rosenberg of *The Boston Globe* interviewed John Hansen, president of **Thermolase**. He reported that Thermolase was taking a different approach than selling lasers, by opening spas and giving the lasers to interested doctors under a sort of leasing program that allows both Thermolase and the doctor to share the revenues. "Our objective is to create a brand-new business for the plastic surgeon and dermatologist who is not involved in hair-removal today...an income opportunity." Under the program, physicians can charge patients any amount, but must pay Thermolase anywhere from $200 for removal of an upper lip "mustache" to $1000 for removal of back hair. After six months, the doctor must pay a minimum of $17,500

per month to keep the laser. (Physicians generally charge the patient double or triple the wholesale price, quoted above.)

7/18 **Surgical Laser Technologies** won a third summary judgement over **Trimedyne** in their ongoing suit over patent infringement on, in this case, side-firing probes. The court ruled that SLT's contact laser products do not infringe Trimedyne's patent 5,380,317, which covers a wide-range of reflective type lateral lasing devices, and its patent 4,646,737, covering devices that use laser energy to cause localized vaporization of tissue. Last November the court ruled that SLT's products did not infringe the '737 patent. Following the latest ruling, the court also granted SLT's motion for final judgement in the case; however, Trimedyne believes that the ruling was inappropriate and has filed a motion for reconsideration. They may file an appeal.

7/18 Frank Lyles of Preferred Technology Inc., has written a research report on **DUSA Pharmaceuticals**, initiating coverage of the firm with a "buy" recommendation. (I also reviewed analyst Jeffrey Berg's report on DUSA back in April. See my April 15th brief.) Lyle's report details the various clinical trials under way for the topical application of DUSA's lead PDT drug ALA, including hair removal, bladder cancer diagnosis, and actinic keratoses. Initial studies are also underway for endometrial ablation, acne treatment, and other cancers of epithelial origin, including breast cancer, pancreatic cancer, and other skin cancers. The report contains a chart comparing the PDT applications for DUSA, **QLT**, **PDT**, and **Pharmacyclics**.

7/18 **Laser Photonics** announced that it had signed a three-year contract with **American Lasers**, making that firm the exclusive distributor of the Laser Photonics ruby laser systems, which are used for dermatological purposes. Under the agreement terms, Photonics will deliver laser systems worth $1.2 million in the first year, with the three-year deal expected to exceed $5.4 million. This contract marks Laser Photonics entry into the dermatology market. According to the company, America Lasers has strong ties in the U.S. and Pacific Rim markets. The ruby laser is a preferred treatment method for tattoo and pigmented lesion removal, and is under consideration for hair removal. According to the company, the market for tattoo removal is estimated at between $80 to $100 million, the pigmented lesion market is another $100 million market, while hair removal is currently estimated to be $1 billion, and expected by some analysts (including me) to exceed $5 billion within 4-5 years. The Laser Photonics ruby laser has been modified to operate in both the short pulse mode for tattoo removal, and the long pulse mode for hair removal, giving the laser advantages over other laser manufacturers who market two different products for these applications. (Such as **Spectrum Medical/Palomar**!) The Laser Photonics ruby laser has received 510 (k) approval for tattoo removal, and expects to receive approval for hair removal during the fourth quarter of 1996.

The company also noted that it expects to file for IDE approval for its **Acculase** excimer laser for use in transmyocardial revascularization within a few days (see the 7/23 brief), and to commence Phase I trials late this summer.

7/19 Both **EquiMed** and **Palomar Medical Technologies** announced an exclusive revenue-sharing agreement to form cosmetic laser centers on a national basis. Under the master agreement signed with **Cosmetic Technologies International**, a Palomar subsidiary, Palomar will supply a suite of cosmetic lasers, including lasers for skin resurfacing, pigmented lesions, tattoos, age spots, spider veins, and the Epilaser, which was just approved for dermatology applications, and awaits approval for hair removal. In addition to lasers from Palomar subsidiaries **Spectrum Medical** and **Tissue Technologies**, Palomar has agreed to provide lasers of other manufacturers to EquiMed if they will enhance the revenues of the centers to be established. A pilot program will be instituted in six target EquiMed centers throughout the country during the third quarter of this year, with the remainder of 50 laser centers to be rolled out during 1997. Palomar will provide a site manager to assist the EquiMed doctors to prepare patients for the laser procedures, and to provide technical support and training at each center. Revenues produced by the laser procedures will be split evenly between the two companies. According to *Business Week*, EquiMed, a national physician practice management company, with over 80 facilities in the U.S., operates 30 radiation/oncology therapy centers and 18 ophthalmology clinics in 16 states. These include 7 ambulatory surgical suites. The agreement calls for installation of cosmetic laser suites at all of EquiMed's wholly owned ophthalmological and surgery centers.

Three days later, on July 22nd, a second Palomar/Cosmetic Technologies International cosmetic laser agreement was announced, this time with **Medical Alliance Inc.**, a mobile laser provider. Under this agreement, CTI will provide MAI with its Spectrum Medical Epilaser ruby lasers on an exclusive basis for mobile use, again, with both companies sharing the revenues produced by its use. MAI will receive priority shipment of a portion of Spectrum's initial production, enabling nationwide access to MAI's customer base of more than 1500 dermatologists and plastic surgeons over a six month period. MAI currently operates in 40 states and in Canada. The company plans to organize dozens of training workshops in major cities across the U.S., utilizing world renowned physician faculty to train cosmetic surgeons and their staff to effectively treat patient with the Epilaser. (Over the years, MAI, North America's largest provider of mobile surgical services on a per use basis, has enabled about 4000 physicians to perform more than 10,000 procedures in their offices since 1989.) The company also maintains contracts with more than 100 of the nation's leading managed care organizations. Epilaser will represent the fourth cosmetic laser modality that MAI has offered to the dermatology and plastic surgery market. Other lasers in their armamentarium include the **Coherent** UltraPulse,

Cynosure's flashlamp-pulsed dye laser, and the q-switched, frequency-doubled YAG laser from **Continuum Biomedical**.

7/22 In a related manner, the July 22nd issue of *The Gray Sheet* notes that both **Palomar** and **Thermolase** are developing next-generation hair removal lasers. Thermolase plans to submit a supplement for a higher-powered laser, capable of treating a larger surface area for use in its hair removal spas. Palomar is developing an easier to use and less expensive ruby laser, expected to be introduced in late 1997, while also working on the development of diode lasers for several different dermatological applications including burn diagnosis, hair removal, and also non-surgical tonsillectomy.

7/22 The August issue of *Health Technology Management* contains an article on the cosmetic laser market, entitled, "Beaming Up". It discusses "niche" applications being targeted by laser producers, including both skin treatment and refractive surgery, noting the latest developments in both.

7/22 A supplement to the July issue of *Dermatology Times* previews the upcoming (July 24-28) AAD '96 meeting in Orlando, noting several of the laser-related offerings. These include the many new kinds of lasers coming to the market for management of cutaneous disorders in the kick-off session; with subsequent sessions covering an overview of lasers in dermatology (Changing Wavelengths in Laser Therapy), an introduction (Laser Symposium), and sessions on more specialized techniques (Laser Resurfacing, Laser Treatment of Scars, and Laser Treatment of Pigmented Lesions).

7/22 **Spectranetics** reported its second quarter results with revenues of $5.4 million and a net loss of $238,000 (1 cent/share). Revenues for the six month period were $10.1 million, and a net loss of $967,000 (5 cents/share). Both revenue amounts were increases over the same time period last year by 20% for the quarter, and 16% for the half year. According to management, the increases were primarily a result of increased catheter sales from the introduction of the Vitesse E-II and catheters sold in support of ongoing clinical trials in Europe and the U.S.

7/23 **Eclipse Surgical** reported its second quarter results with revenues totalling $2.2 million and a net loss of $730,000 (5 cents/share) for the quarter, and $4.0 million revenues and a net loss of $654,000 (5 cents/share) for the half. Highlights of the second quarter as reported by management included its successful initial public offering on May 31st; customer interest for its lasers and accessories for treatment of heart disease by TMR, with 22 lasers in hospitals as of June 30th; the distribution agreement signed with **Sorin Biomedica Cardio** in June providing for minimum purchases of 30 lasers in 1997; continuation of Phase II clinicals for patients with severe angina, and initiation of Phase I clinicals for TMR as an adjunct to bypass

surgery; and the filing of additional patents for laser technology, fiberoptic handpieces, and methods related to heart revascularization.

7/23 **Laser Photonics**, as noted previously, filed an IDE application on behalf of its subsidiary, **AccuLase**, seeking permission to begin human clinical trials using the AccuLase excimer laser for TMR procedures. **Helionetics**, Laser Photonics parent company, also noted that it had continued funding nonclinical research into TMR with the Good Samaritan Hospital of Los Angeles. The hospital will focus on using the AccuLase excimer laser to find direct proof of reperfusion in ischemic tissue using PET scanning technology.

7/23 **ESC Medical Systems** announced record second quarter and six month financial results, showing revenues for the quarter of $6.8 million and net income (exclusive of non-recurring expenses associated with the acquisition of LBT Ltd) of $2.7 million (16 cents/share). Including a one-time charge of $3.5 million in connection with the purchase of LBT, the company had a loss of $0.8 million or 5 cents/share. For the half, revenues were $12.1 million and net income (again excluding the charge noted above) was $4.7 million. With the charge, net income was $1.2 million or 7 cents/share. The company noted that with the acquisition of LBT, the company was now selling six commercial products. These include the PhotoDerm VL, the PhotoDerm PL (in international markets only pending U.S. marketing approval), the first few units of its EpiLight Hair Removal System (in the final stages of clinical trials and documentation for approval filing in the U.S.); and the first commercial units outside the U.S. of their first PDT product, the VersaLight for non-invasive treatment of skin cancers. The LBT products include the Topaz 30 surgical CO_2 laser and the Derma 20 erbium:YAG laser for dermatology, both of which are currently sold outside the U.S. until marketing clearance is obtained.

7/23 **Iridex Corporation** released its second quarter financials, with revenues of $2.5 million and net income of $182,000 (3 cents/share). For the six months, revenues were $4.9 million and net income was $407,000 (7 cents/share).

7/24 Ron Rosenberg wrote in today's *Boston Globe* about the trend to revenue sharing among laser producers, picking up on the Palomar/EquiMed and Palomar/MAI deals. Rather than a physician purchasing a $100,000 to $250,000 laser, the companies are making the lasers available on a revenue-sharing basis. Ron noted that the EquiMed deal stood out from competitive deals because Palomar was providing more in the way of equipment and services than its rivals (like Thermolase). Quoting Steve Georgiev, chairman of Palomar, "When fully implemented, each (EquiMed)laser center has the potential to generate several million dollars in revenues (annually).

7/24 **Coherent Inc.** announces record earnings for its third fiscal quarter, ending June 29th. The company had sales of $89 million and a net income of $7.9 million (68

cents/share) for the quarter. Medical laser sales were $38.1 million and $119.6 million for the nine month period, up 14% and 35% respectively.

7/24 **Candela Corporation** announced the addition of the ScleroPlus laser to its family of laser systems designed to treat a variety of cosmetic conditions. The new laser allows physicians to treat leg veins, facial spider veins, warts, scars, stretch marks, port wine stains, and other vascular lesions. This is one in the line of innovative vascular lesion lasers introduced by the company since 1988. The ScleroPlus combines the features of both the original vascular lesion laser and the ScleroLaser, introduce last February, into one system.

7/25 **PLC Systems** reported its second quarter results showing revenues of $1.4 million and a net loss of $903,000 (5 cents/share). For the six month period, the company had revenues of $6.3 million and a net income of $374,000 (2 cents/share). The company said it had shipped 4 Heart Lasers in the quarter (3 placements -- which involves recurring revenues based on an installation fee of $25,000 and fees for ongoing patient useage -- and one sale), and received a purchase order for a fifth system, which was shipped the first week in July. The company now has Heart Lasers installed at 15 U.S. sites, and has an additional 40 systems in 21 countries around the world, entering into new markets in Europe and Asia during the second quarter. (Fifteen of the 55 lasers installed have been shipped under the "placement" model.) PLC expects to ship 30 systems in 1996.

7/26 **Laser Industries** reported its second quarter results with record sales and earnings. Sales for the second quarter were $14.5 million, up 18% from the same quarter last year, with net income of $2.1 million (31 cents/share), up 56%. For the six month period, slaes were $28.6 million and income was $4.1 million (59 cents/share). According to Benjamin Givli, chairman, the revenue growth was driven by sales of laser products for aesthetic applications.

MEDICAL/SURGICAL UPDATE -- AUGUST 1996

7/26 Amy Bell of H.J. Meyers wrote another report on **Palomar Medical Technologies**, indicating a strong buy recommendation. She commented on the recent FDA approval of the EpiLaser for cosmetic applications and the $17 million in orders for the device for sale outside of the U.S. She believes the recent joint agreement with **Equimed** to open 50 cosmetic laser centers on a shared revenue basis, will add $500,000 to the company's top line in 1996, and up to $12 million in 1997. She also noted the announced strong preliminary second quarter revenue stream. Her conclusions were that the company may be on the brink of substantial revenue and earnings growth, which to this point have been generated by Dynaco, but which may be changing with

the sales of wrinkle removal and hair removal lasers. Her outlook is for revenues reaching $80 million and a net loss per share of 51 cents, up from fiscal 1995 revenues of $21.8 million and a loss of 87 cents/share.

7/29 The July 29th *Gray Sheet* notes an FDA enforcement report for a company called **DioLase** of Berkeley, CA regarding their Model 100 biostimulation laser. The firm acknowledged a field correction was initiated following the July 15th warning letter about the problems with the 34 units of the laser that had been distributed. (Since no biostimulation has been approved for sale, I believe that these units must be for veterinary use for treating animals ?)

7/30 **Laser Industries** announced that it had commenced its public offering of 1 million shares at $12.50. The offering was handled by Salomon Brothers, Furman Selz, and Oppenheimer. The proceed will be used for repayment of bank debt, development of new products, expansion of worldwide marketing activities, the formation or acquisition of new business and technologies, and for working capital. The company, as previously noted, began trading on the NASDAQ national market under the symbol LASRF.

7/30 **Coherent, Inc.** announced that it had signed a technology transfer and license agreement with **Blue Sky Research**, related to BSR's patented CircuLaser diodes. Under the terms, Coherent is exclusively licensed to manufacture CircuLasers for incorporation into diode laser modules. The two companies also agreed to jointly develop improvements to the technology, which incorporates BSR's low-loss microlens, hermetically sealed within a diode laser package. This compact solid-state laser delivers a bright beam using very low power. They will compete directly with HeNe gas lasers, used for alignment, positioning and inspection, supermarket scanning, and medical laser systems.

7/31 **Sunrise Technologies** and **American Dental Technologies** announced that they had settled all the lawsuits between them. An appeal relating to disputes arising from a February 1994 settlement agreement will be dismissed and Sunrise will release the $940,178 judgement against ADT last August. In addition, all three patent cases still pending will be dismissed. ADT will license Sunrise under its dental air abrasive method and systems patent in return for a royalty on air abrasive products manufactured, sold or leased by Sunrise, with Sunrise acknowledging the validity of ADT's method and systems patents. ADT will acknowledge that Sunrise's current products are not infringing ADT's apparatus patents or any other non-dental air abrasive patents owned by ADT. Sunrise's patent license will be non-exclusive.

7/31 **JMAR** said that it had received the final $475,000 payment from **Laser Industries** on its sale of **Surgilase** to that company in December 1994. (The approximate payment

was $6.7 million, of which $3.75 million was paid in cash installments and $2.95 million was payable by assumption of liabilities.)

7/31 **PLC Systems, Inc.** announced that the company's key patent for TMR has been issued in Japan and Europe. The patent covers the synchronization of the firing of the laser to a patient's EKG signal, which was initially issued in the U.S. in 1992. The synchronization assures that the laser is fired during the brief period when the heart is electrically insensitive to stimuli, therefore protecting the heart against harmful arrhythmias.

7/31 According to an item in the August 5th *Gray Sheet*, **Vidamed** has halted its transurethral needle ablation (TUNA) BPH training program and withdrawn its home page on the internet, in response to a July 16th warning letter from the FDA citing the firm for pre-approval promotion of the system. The company began physician training in May and continued the program until receipt of the warning letter. (The company had submitted a 510 (k) premarket notification in March, and is awaiting final notification of approval.

8/1 **Sharplan Lasers** announced that it had received FDA approval to market its EpiTouch ruby laser for the treatment of tattoos and pigmented lesions. The company currently has a 510 (k) application pending for use of this laser for hair removal (as does **Palomar**). The EpiTouch laser is priced at $119,000. The laser, introduced at last week's AAD meeting in Orlando, is sold outside the U.S., with demand straining production capabilities. According to the company, deliveries are taking 90 days or longer. The system provides both a Q-switched and free-running mode for enhanced utility in dermatologic/plastic surgery clinics. The company has also developed proprietary energy delivery technology and patent-pending epidermal cooling methodologies for hair removal that will set the EpiTouch laser apart from other lasers. The system is used without the need to wax beforehand or the use of messy black lotions or creams (such as used with the **Thermolase** system).

8/2 I received a letter from **Applied Optronics Corporation** introducing its complete line of photodynamic diode laser systems. The AOC PDT series, meant for the PDT researcher, are offered from 2 to 8 watts to tissue at discrete wavelengths from 650 nm to 690 nm, with a full line of fiberoptic diffusers. The lasers are priced starting at $25,900 for a 2 watt 690 nm system.

8/2 **Premier Laser Systems** reported that it had received FDA clearance under an IDE to treat 120 patients for the final clinical testing of its Centauri erbium:YAG laser for cavity preparation, decay removal, and other dental hard tissue procedures in support of its pending marketing approval. The company said that with 100 of the 120 patients treatments completed, it expects to finish the testing within two weeks. The total number of people treated to date exceeds 1300. After the latest patient group have

been reexamined after 90 days to determine efficacy of the laser treatment and the company's new reusable delivery fibers, the company will file the data and await FDA marketing clearance.

8/2 **Surgical Laser Technologies** and **Health Services Corporation of America (HSCA)** have entered into a two-year comprehensive vendor agreement. Under the agreement, SLT will work closely with HSCA in providing HSCA member organizations with special surgical laser programs and pricing discounts to meet their surgical laser needs. The contract will provide both lasers and laser delivery systems (laser probes, scalpels, and fibers) for use with both SLT lasers and lasers manufactured by other laser vendors. The new agreement is in addition to the existing HSCA contract with the **Mediq PRN/SLT** joint venture, which provides members with laser support services on an as needed basis. (HSCA is one of the oldest and largest group purchasing organizations in the country, representing over 2300 members and a purchasing volume of over $2.1 billion.)

8/2 **Luxar** claims that its new NovaScan system for cosmetic skin resurfacing enables a physician to resurface an entire face in less than 30 minutes. The new scanning system was designed and is manufactured by Luxar.

8/5 **ThermoLase Corporation** announced its quarterly results for the quarter ending June 29th. The company reported revenues of $6.3 million and a net loss of $22,000. According to president John Hansen, "We are happy to report substantial and continued progress in our efforts to commercialize our SoftLight hair removal technology. Spa Thira Dallas opened in June and locations in Houston, Denver, Beverly Hills, and Boca Raton are under construction." (Most importantly, no clinical data has yet been released to show how effective this technology is. According to knowledgeable people in the field, the ThermoLase approach may not be as effective in removing unwanted hair as the approaches being taken by Palomar and Sharplan, using the ruby laser and selective photothermolysis. I am preparing a "white paper" on this subject and will report more after I complete my research.)

8/5 **Ion Laser Technology** reported its quarterly results showing net income of $134,070 (3 cents/share) on revenues of $1.4 million. The company expects to have 38 BriteSmile tooth whitening centers in operation by mid-August.

8/6 **ArthroCare** has received 510 (k) clearance to market a periodontal device, which is under development by the company. This raises to six, the major joints of the body that its products can be used for, as well as for urological and periodontal indications, although the company's focus remains arthroscopic orthopedics. The company's proprietary surgical equipment ablates soft tissue, with hemostasis acieved, and is used in urology, gynecology, dermatology and plastic, oral, and general surgery.

8/6 **Laser Photonics** announced at a meeting of the NY Society of Security Analysts that it expects to report an operational profit of approximately $275,000 on revenues of approximately $3.7 million in calendar/fiscal 1996. The company also expects to achieve revenues of approximately $6 million in 1997. The company's analytical division should increase from the current run rate of about $2 million to about $10 million within five years.

In the August 9th *Wall Street Journal* there was a notice of settlement of the class action shareholder's suit for $575,000 plus interest.

8/6 **DUSA Pharmaceuticals** reported its second quarter results with a loss of $1.9 million (21 cents/share), compared to a loss of $731,468 for the same period last year. R&D expenditures related to the company's ALA PDT development program totaled $1.8 million for the quarter. Dr. Geoffrey Shulman, CEO said that R&D expenditures increased significantly during the quarter, in line with expanded ALA PDT and photodiagnosis (PD) clinical trial programs. The Phase 2b precancerous actinic keratoses trials had up to 100% clearing and Phase 3 studies are scheduled to begin in the 4th quarter. A multicenter trial for PD for the early detection of bladder cancer is scheduled to begin soon. Developmental work continues on the use of ALA for hair removal, treatment of acne, and endometrial ablation.

8/6 **Salomon Brothers** released its first research report on **Laser Industries** (they were one of the underwriters of the recent stock offering -- **Oppenheimer**, the other co-sponsor, released its research report on August 16th). Analyst Eli Kammerman wrote a good, if biased, report, recommending a strong buy. (The major problem I had with the report was that there was **no** balance, hardly any mention of competition, with the implication that Laser Industries was the leader in the several fields of interest like skin resurfacing -- which they're not!) The author expects the sales of lasers for skin resurfacing, hair transplantation, and hair removal to "propel revenue growth of 20% for the next three years". The report contains some interesting statistics such as "approximately 1500 lasers for skin resurfacing have been sold by all manufacturers since late 1994, and these devices have been used to perform over 40,000 procedures to date, with most patients highly satisfied with the outcome". If chemical peels, dermabrasions, and retin A treatments are added, the primary market for skin resurfacing is greater than 1.1 million, leaving much room for growth. And if only about 1500 units have been installed, then the U.S. penetration of dermatologist, and plastic surgeons is only about 12%. If general surgeons and ophthalmologists are included, only 3% penetration has been achieved to date. Eli also believes that hair transplantation with the CO_2 laser constitutes a major market for Sharplan/Laser Industries. I don't agree, as this is only a small niche market, and nowhere as big as the hair removal market. As previously noted, Laser Industries received clearance for its double usage EpiTouch ruby laser for removal of tattoos and treatment of pigmented lesions, but is still awaiting approval of labeling for hair removal. One

interesting note, according to Eli, the company intends to open three laser treatment centers by 1997 as a pilot program to evaluate the feasibility of being a service provider. The centers are scheduled to open in New York, Tel Aviv, and Barcelona.

8/7 **PDT Inc.** reported its second quarter and six month results, with total revenues for the quarter of $756,000 and a net loss of $1.7 million (14 cents/share). For the six month period, revenues were $1.4 million and the net loss of $8.5 million (76 cents/share). There were no comments on the figures by management.

8/8 **Candela Corporation** reported that revenues and profits had increased for its fiscal year (ended June 29th) on record unit shipments. Revenues for the quarter were $9.1 million, a 15% increase over the same quarter last year, and net income was $658,000, an 82% increase. For its fiscal year, the company had revenues of $30.4 million with net income of $1.2 million. (Financial results include the results of recent acquisition Spa Management.) According to president and CEO Gerard Puorro, "The fourth quarter and full year each set a record in terms of unit shipments. Our two new aesthetic devices, the ScleroLaser and AlexLazr, have kicked into gear and are selling quite well. Our newest ScleroPlus laser, introduced last month...should further accelerate our penetration into these aesthetic markets."

8/8 **Cell Robotics** received an FDA IDE on July 25th for its laser skin perforator. This allows the company to begin clinical testing of its new miniature laser device to support evaluation of safety and efficacy before market release. The company expects to complete the testing in 4-6 weeks and submit the clinical data in support of its 510 (k) in the fall. (**Gem Edwards** has licensed the perforator for distribution in the U.S.) The company also announced that the first prototype erbium:YAG skin resurfacing laser had been completed. Discussions are being held with two large potential marketing partners (not identified) for this market.

8/12 **Palomar Medical Technologies** said that it was a featured presenter at this week's annual meeting of the Society of Clinical and Medical Electrologists, held in Hawaii. At the conference, Palomar personnel demonstrated the Epilaser, under investigation for hair removal. Palomar presented a panel discussion on the various ways in which electrologists might incorporate the Epilaser into their practices when FDA marketing clearance is obtained.

8/12 **Cell Robotics** and **Big Sky Laser Technologies** announced the formation of a strategic alliance to jointly develop, manufacture, and market laser medical devices. As part of the alliance, Cell Robotics will determine market applications, feasibility, develop "breadboard prototypes", and prepare FDA submittals. Big Sky will complete the development of commercial products and provide the manufacturing capability. Both companies will maintain the ability to independently develop and manufacture certain product lines. Initially, the alliance will enable Cell Robotics to rapidly introduce to

international markets the Lasette laser finger perforator. The sales launch for the first production units is expected in 1997. The er:YAG crystals for the laser will be produced by Cell Robotics partner **The New Technology Engineering Center** in Russia. The crystals will be available for Big Sky to use in other laser products.

8/12 **CardioGenesis** has received approval to begin a major new clinical study of its intraoperative transmyocardial revascularization system (ITMRR). In this study, it will be evaluated as an adjunctive therapy to CABG in patients with angina, who are only partially treatable by bypass graft. The company plans to enroll up to 500 patients in the study to be conducted at major U.S. hospitals that specialize in cardiovascular surgery.

8/12 In a similar vein, the August 12th *Barrons* contains an August 6th release from **Helionetics** reporting on a meeting with security analysts, in which the company states that it "is holding discussions with major companies operating in the international cardiovascular area with a view toward strategic alliances for both research and marketing" (of its AccuLase TMR laser, which is expected to begin human clinical trials later this year). At the analyst meeting, Peter Whittaker, a leading TMR researcher, and director of the laser laboratory at the Heart Institute of Good Samaritan Hospital in Los Angeles, said that his latest experiments with the AccuLase laser showed that channels remained patent (open) for as long as four months.

8/12 **Surgical Laser Technologies** announced that Keith Stoneback has assumed the positions of president and CEO, replacing James Appleby, who had stepped down to pursue other business interests. Stoneback was most recently in management positions at AMSCO International and American Hospital Supply before that.

8/13 **BioLase** announced that it had shipped the first production level Millennium unit to one of the largest dental product distributors in Germany. The Millennium utilizes the company's hydro-kinetic tissue cutting technology that uses water cooling and an erbium laser to swiftly cut through both soft and hard dental tissues in a non-thermal mode.

8/13 **Surgical Laser Technologies** released its second quarter results showing net sales of $2.8 million and a net loss of $1.7 million (17 cents/share). Revenues for first quarter were also $2.8 million, while last year's second quarter had revenues of $3.8 million. For the six month period, sales were $5.5 million compared to $8.0 million last year, with a net loss of $1.8 million (18 cents/share). The company CFO optimistically expects growth in the second half of the year, especially in light of the expanding service programs with **Tenet Healthcare** and **Health Services Corporation of America**.

8/14 **Palomar Medical Technologies** reported its second quarter results with revenues increasing 182% to $17.5 million and an expected loss of $8.0 million (32 cents/share). For the six month period, revenues increased to $24.5 million, compared to $9.8 million for last year, with a loss of $15.3 million (66 cents/share). Steve Georgiev, chairman and CEO said that revenues tripled from the first quarter as a result of investments made this year. The quarter included approximately $3 million in product development, research, and pre-production expenses associated with launching of Epilaser, and initial rollout of cosmetic laser centers as part of the **EquiMed** revenue sharing agreement, and start-up costs for two new specialty electronic products. An additional $2 million was invested in marketing and sales to introduce new products in the quarter, which will begin to contribute to dramatic revenue growth, expected to continue in the future. There were also non-recurring costs associated with the acquisition of **Tissue Technologies** in the quarter.

8/14 **Trimedyne Inc.** reported its third fiscal quarter results with revenues of $3.4 million, a 4% decline for the same quarter a year ago, but 14% higher than for the preceeding quarter. The net loss for the quarter was $1.2 million (11 cents/share), compared with a net loss of $852,000 for the preceeding quarter. One major expense item was legal fees of $360,000 due to the suits against **C.R. Bard** and **Surgical Laser Technologies**. According to president Peter Hyde, revenues for the quarter did not meet expectations, particularly in the urology market, which has not produced sales of a meaningful amount, and prospects in this field remain uncertain. However, orthopedic laser and disposables sales were up 4% compared to a year ago, and up 23% from the prior quarter. Commenting on the outcome of the lawsuits against SLT, chairman Marvin Loeb said, "The courts found that SLT did not infringe our patents, but we believe the court's decisions are in error and the company is considering if it will appeal any of the decisions."

8/14 **Candela Corporation** said that it had received notification from the American Urological Association that the AUA no longer viewed cryosurgery as experimental or investigational, paving the way for reimbursement for the procedure by health insurance carriers in the treatment of prostate disease. (On August 20th, the company received notification through the Society of Urological Cryosurgeons that Medicare of Transamerica Life, the administrators for Southern California, would begin reimbursement for the use of cryosurgery in the treatment of prostate disease, retroactive to July 1st.)

8/14 **Sunrise Technologies International** reported its second quarter results with revenues of $1.0 million and a net loss for the quarter of $1.5 million (6 cents/share). For the half year, revenues were $2.6 million, compared to 43.3 million a year ago, and the net loss was $3.0 million (12 cents/share) compared to $1.4 million last year. Microprep, the air abrasion cavity preparation system accounted for approximately 64% of sales in the second quarter. "Now that all litigation between Sunrise and

American Dental Technologies is settled, the company can now focus on development of its dental business and markets", said David Light, president and CEO. As for its ophthalmic subsidiary, **Laser Biotech**, five sites are conducting expanded Phase 2 trials of its Corneal Shaping System for the treatment of hyperopia, with the 100 patients in the trial expected to be treated by September.

8/15 **PLC Systems** announced the results of a six month controlled randomized clinical trial comparing TMR with the Heart Laser to medical therapy. Average angina levels with TMR were reduced to 1.7 scores from 3.7 and in the TMR group, mortality rates were 63% lower than the medical therapy group in the 100 patient study, conducted at 12 clinical sites across the U.S. The data from this study, as well as the one-year follow-up from a 201 patient TMR study using the Heart Laser were part of a recent follow-up submission to the FDA as part of the company's PMA submission.

8/15 **Premier Laser Systems** reported first fiscal quarter results showing revenues of $1.3 million, substantially up from the same quarter last year, and up 86% from the previous quarter. The increase in sales was primarily due to the continued ramp-up in sales of the company's dental laser systems. The quarter's loss was $697,000 (15 cents/share), compared with a loss of $1.2 million for the same quarter last year. During the quarter, the company filed a notice of intent to market its argon-based laser system to activate bleaching systems employed in "teeth whitening" procedures. The company also introduced the first fully integrated erbium:YAG laser system for performing ophthalmic procedures (see my ASCRS writeup sent with the June briefing). Also, under its strategic alliance with **The Medical Laser Institute of America**, MLIA has started ordering laser systems for installation into its Chicago cosmetic surgery center. A second center is under construction in Southern California.

8/15 With the acquisition of **Henley Healthcare** in April, **Lasermedics** reported record quarterly sales of $2.7 million, compared to sales of $56,700 for the same quarter last year. The company reported a net loss of $519,000 (33 cents/share). The acquisition of Henley provides a worldwide marketing outlet for the company's Microlight 830 carpel tunnel treatment laser, which is still undergoing review by the FDA.

8/15 **Laser Industries** announced the authorization for redemption of the entire outstanding amount of its 8% Convertible Subordinated Debentures due September 15, 2006, that were issued in September 1986, of which an aggregate of $2.6 million remain outstanding.

8/15 **Ion Laser Technology** has signed an exclusive distribution agreement with **Laser Estetica S.L.** of Madrid, Spain, to establish BriteSmile laser teeth whitening centers throughout Spain. Government approvals are expected by January 1997.

8/15 According to two new studies published in the *New England Journal of Medicine*, as reported in today's *Wall Street Journal*, laparoscopic surgery for hysterectomy is 21% to 61% more expensive than either traditional abdominal surgical techniques or vaginal procedures due to longer procedure time and more expensive disposable equipment required. However, according to laparoscopic instrument makers **U.S. Surgical** and **Johnson & Johnson's Ethicon Endosurgery** unit, although the "surgery costs" might be higher for laparoscopic surgery, the overall costs are lower, and if quality of life, with significantly less pain, shorter recovery times, and back to work times, is figured in, the minimally invasive approach would still be favored. Also, if reusable instruments are used, the cost differences narrow considerably. (Of the approximately 600,000 hysterectomies performed annually, only about 7% are being performed laparoscopically, while 63% are done through abdominal incision and about 30% are done vaginally.)

8/16 The July/August issue of *Biophotonics International* contains a very well written article entitled, "Aesthetic laser surgery: an emerging marketplace". Author Iain Miller covers the field of aesthetic surgery from skin resurfacing to some of the newer applications such as hair removal and leg-vein treatment which, together, promise sustainable growth for the medical laser industry. (Call for a copy of the article.)

8/16 The August issue of *Laser Focus World* contains Kathy Kincade's piece on "Erbium lasers vie for spot in medical mainstream". The article describes some of the new applications for erbium lasers in dermatology, dentistry, and ophthalmology. In dermatology, erbium laser are being investigated for skin resurfacing, supposedly offering less thermal damage and shorter recovery times. In dentistry, erbium systems are approved for soft tissue effects and are investigational for hard tissue use. Ophthalmic applications include precise vitreoretinal surgery for removal of dense membranes close to the retina that are difficult to cut, anterior capsulotomy, glaucoma treatment, and potentially for cataract removal.

8/16 **LaBarge** and **Venisect** jointly announced that the FDA had requested additional information in order to complete its review of Venisect's Laser Lancet application for blood sampling. The companies said that due to the anticipated time required to gather and provide the additional information, its marketing clearance could be delayed for several months. In the meantime, international sales efforts are proceeding with the regulatory process underway in a number of foreign countries.

8/16 **Trimedyne** said that the U.S. Patent Office had upheld the validity of all of the claims in its key patent covering higher powered, more versatile pulsed laser systems than those of competitors. In 1995, **Laser Industries** had filed a petition for re-examining of Trimedynes' U.S. Patent 5,387,211. After review, the PTO affirmed the validity of the patent. Laser Industries has the right to appeal the decision, but Trimedyne does

not believe that an appeal would be successful. (The patent applies to Trimedyne's high powered holmium laser systems, but can be applied to other lasers as well.)

8/21 **Laserscope** said that it received its 100th order for its Aura KTP laser system, used for office-based procedures in dermatology, aesthetic surgery, ENT, urology, and gynecology. The Aura is used with the company's Starpulse technology, allowing the system's continuous wave operation to be converted by a simple dial setting to a fully variable pulsing mode. In the pulse mode, from 1 to 50 milliseconds, the system is able to treat a variety of vascular lesions, including leg veins, by matching the pulse width to the thermal relaxation times of the various tissues being treated.

8/21 **ESC Medical Systems** announced that it had completed clinical trials and filed with the FDA for 510 (k) clearance for its Epilight hair removal system. The Epilight device is based on the company's proprietary intense pulsed light technology to selectively eliminate hair follicles without damaging the skin. The computerized system is programmed to permit the physician to utilize it for a variety of hair and skin color combinations.

8/21 **Premier Laser Systems** said that it had received FDA clearance to market a teeth whitening system featuring the company's multi-operatory Dentalaser argon laser in combination with teeth bleaching and whitening products from six manufacturers. Premier has a joint marketing agreement with **Stardent International Labs** for this system. According to president Colette Cozean, "One of the advantages of the Premier system is that it takes an investment of only $9000 by the dentist to purchase a laser, compared with a $40,000 investment to set up competing whitening centers. The cost of the whitening reagents that can be used with the system is only about $25 per procedure, about one-fifth of that charged by the competition."

8/24 An article by Milt Freudenheim in today's *New York Times* discusses the shift by doctors to elective surgeries and their more attractive fees, caused by the cutting of reimbursed fees on Medicare and other covered non-elective surgeries. Examples cited include the shift from breast reconstruction of cancer patients to breast enlargements by some plastic and reconstructive surgeons, as the fees for the former were cut by 60% or more to under $2000, while the elective breast enlargement surgeries can earn fees of close to $4000 and take considerably less time to perform. Other examples include the shift to cosmetic surgeries, including laser cosmetic applications; the growth in refractive procedures as cataract fees are reduced; laser surgery to reduce snoring by ENT specialists; and urologists performing penis-enlargement surgery for $4800 to $7000, compared to getting only $600 for treating BPH.

8/26 **Laser Photonics** and **Acculase** announced that it had received FDA approval to begin human clinical trials of its Acculase laser for TMR, on patients suffering from angina

who are no longer candidates for CABG or angioplasty. During Phase 1, Laser Photonics plans to enroll 30 patients to undergo the procedure, which will be conducted at the New York Hospital-Cornell Medical Center and at The Heart Institute of Good Samaritan Hospital in Los Angeles. (The Acculase laser is the only excimer laser being evaluated for this procedure.)

8/27 **Premier Laser Systems** said that its Dental Products Group had entered into agreements with three long-established dental laser systems distributors to serve the company's customers in Canada, Korea, and Australia. The agreements are with **Canadian Dental Corporation** (for Canada), **Design for Vision Pty Ltd** (for Australia), and with Seoul-based **Korea Medical Industry** (for Korea). To initiate the agreements, the distributors have purchased a total of 10 dental lasers systems.

8/27 **Infinite Machines** announced that it had acquired a majority interest in **Spectra Acquisition Corporation**, which recently acquired the operating assets of **Spectra Science Corporation**, the inventor of LaserPaint. (LaserPaint is a technology that can convert materials such as plastics, liquids, and powders into lasers for commercial and medical applications. One of the leading medical uses is as an in-situ light delivery system for photodynamic therapy applications.)

MEDICAL/SURGICAL UPDATE -- SEPTEMBER 1996

8/26 The August 26th *Gray Sheet* reports that the launch of **QLT PhotoTherapeutic's** Photofrin laser-light activated cancer drug for advanced esophageal cancer by U.S. marketing partner **Sanofi Winthrop**, is scheduled for September, pending FDA's sign off on promotional materials. **Laserscope's** and **Coherent's** laser systems, approved for marketing for photodynamic therapy in December 1995, along with the drug, will be marketed separately by the two firms. According to Julia Levy, president and CEO, pivotal clinical trials with Photofrin will begin before year's end for treating Barrett's esophagus, a pre-cancerous condition. A supplementary new drug application for the treatment of lung cancer, will be filed with the FDA, also before the end of the year.

8/28 **ThermoLase** has announced a program, through August 27, 1997, authorizing the repurchase of up to $10 million of the company's stock.

8/29 **BioLase Technology** announced its second quarter results, with a net loss of $611,000 (5 cents/share) on revenues of $161,000. This compares to a net loss of $375,000 (4 cents/share) on revenues of $413,000 for the same period last year.

9/1 The September 1st issue of *Ophthalmology Times* contains an excellent article describing the differences between laser skin resurfacing and chemical peels, and the advantages of the laser treatment. Written by Dr. Kenneth Steinsapir, of the Jules Stein Eye Institute, UCLA School of Medicine, it covers the techniques required to

perform both chemical peels and the use of the laser and concludes that chemical peels, although having lower costs, requires a higher degree of skill to apply the reagents to obtain a beautiful result and avoid scarring. Obtaining consistently excellent results with lasers, requires a level of mastery that is more easily reached that that required for chemical treatment. Also, remember that many patients think a chemical peel is an outdated procedure and specifically pursue laser resurfacing. With proper training, laser resurfacing can be safely practiced after a relatively short learning period. These factors probably more than compensate for the increased expense of providing this service.

9/2 An innovative new dental laser was launched at the Vienna University Dental School by the Austrian company **Dentek**. The Dentek LD 15 was designed and developed by Dentek and incorporates the diode laser technology developed by **Diomed** of the UK. The device, which operates at 810 nm, contains a user specific interface for dental use and a unique delivery system. It will sell for about half the price of conventional dental lasers, between $30,000 to $35,000 in Europe. The laser can be used for root canal treatment, caries prevention, and soft tissue surgery. By incorporating a proprietary dye specific to the laser wavelength, the system can be used to remove dental caries. The dye is only absorbed within the caries, ensuring that surrounding dental tissue is not damaged.

9/3 **Cool Laser Optics** announced that it had signed a licensing agreement with **Coherent, Inc.** regarding its cooling technology useful for aesthetic laser surgery. The license paves the way for the cooling devices to be sold and used with Coherent's lasers in a variety of clinical and cosmetic applications. The license relates to the patents issued to Dr. Cyrus Chess of Norwalk, CT and assigned to Cool Laser Optics. The devices allow the simultaneous cooling of skin while laser energy is applied. The announcement was made by Michael Barretti, recently appointed president of Cool Laser, and formerly associated with **Cynosure, Inc.** Cool Laser will continue to market the device on its own as an accessory for existing laser systems. Other licenses, with major laser companies, are in the works.

9/3 **Laserscope** announced that it had completed the acquisition of **Heraeus Surgical**. The combined company will have annual sales of more than $60 million, putting it into the upper tier of fewer than six medical laser companies with sales of greater than $50 million. The company also announced that it had received more than 100 orders for its Aura laser system, making substantial inroads into the growing market to treat vascular lesions, which includes the treatment of leg veins. With the Heraeus Surgical deal complete, the company will begin aggressively marketing the newly acquired Paragon CO_2 laser system for skin resurfacing, using similar strategies as with the successful rollout of the Aura system.

9/3 **Energy Life Systems** of Costa Mesa, CA, announced that it had received a grant from the National Heart, Lung, and Blood Institute to develop a proprietary fiberoptic device and method for monitoring the viability of heart tissue. The grant was made under the auspices of the SBIR program of NIH. According to company president Hany Hussein (formerly of **Trimedyne)**, recent developments have led to the recognition of the previously unknown conditions of "stunning" and "hibernation" of the myocardium that can be mistaken for total infarction (death) of the muscle. Because viable myocardium can be salvaged, it is important to distinguish between viable and infarcted heart muscle tissue. The product concept is a patented fiberoptic catheter and minimally invasive method for direct measurement of the viability of the non-contracting segments of the heart during the time of cardiac catherization. The estimated worldwide market for the product could exceed $650 million annually, and the savings to the healthcare system could exceed $800 million per year.

9/5 **ESC Medical Systems** named Dr. Shimon Eckhouse, president and CEO and a founder of the company, to chairman of the board.

9/5 **Bear Stearn** analysts Frederick Wise and Emil Westergaard released their followup report on **CardioGenesis**, with a "buy" rating. The report provides a good background on both the company and TMR, discussing both **PLC Systems** and **Eclipse Surgical** as competitors to the CardioGenesis system. The report also provides information on the potential market for TMR, giving a potential patient universe of 695,000 patients; including those having inoperable coronary artery disease, those requiring a redo bypass, those who could get TMR either with or as a replacement for bypass, and those who might get TMR as an adjunct to angioplasty. It also projects the analyst's estimates for CardioGenesis worldwide laser system installations for TMR, showing 30 systems in 1996, 153 in 1997, and 378 in 1998 -- what about the competition? (The report does not discuss either **Acculase** or, the newest entry, **U.S. Surgical** -- see our 9/9 brief below.)

9/9 **Trimedyne Inc.** announced it will commence worldwide marketing of its proprietary OmniView Spinal Endoscope for the outpatient treatment of herniated discs, a condition requiring surgery for an estimated 400,000 people annually in the U.S. The new endoscope is only 4.2 mm in diameter, providing a minimally invasive alternative to the costly open surgical procedure known as laminectomy. The scope also contains a channel for the company's Sidefire Laser Needle, through which its OmniPulse-Max holmium laser energy can be delivered to vaporize the protruding disc material. The endoscope contains 30,000 pixels for maximum clarity and is lightweight, less than 1/4 the weight of conventional spinal endoscopes. MIS spinal surgery for herniated discs can reduce current 1-5 days hospital stays for spinal surgery to an outpatient procedure.

9/9 Today, I received one of the best analyst's reports that I have ever read. This one was by Mary Ann Gray and Susan Burnett of **Dillon Read**, published on August 12th on **QLT PhotoTherapeutics**. The analyst's initial report on the company is accompanied with a "buy recommendation". It covers QLT's participation in photodynamic therapy thoroughly, from "soup to nuts", including writeups on all the company's products, and the applications for which they are indicated, and their status; some information about the various laser light sources that will be used for drug activation; on the company's marketing partners in various parts of the world; and details about the competition. This includes some of the smaller and newer participants such as **Pharmacyclics** and **Scotia Pharmaceuticals**, and their product status. As expected, there is a breakdown of anticipated revenues from both its corporate partners and from royalties, out to 1999. All in all, one of the best reports I have ever read and, certainly, the best one on the emerging field of photodynamic therapy.

9/9 An analyst's report from Barrow Street Research of NYC, on **Physicians Laser Services, Inc.**, written by Scott Baily and John Attalienti, presents a compelling story about this provider of mobile laser services. PLS provides three different cosmetic lasers to doctor's offices, a Coherent Ultrapulse CO_2, a Cynosure Vascular Lesion laser, and a Con Bio Q-switched nd:YAG. The company basically operates in southern Florida and in Connecticut, with the recent acquisition of **United Laser Systems** of Portland, CT. The company has announced expansion plans. It has signed letters of intent to acquire an additional three unnamed mobile laser companies within the next 90 days. This will extend its reach to the New York metropolitan area; Baltimore; Washington, DC; Virginia; the Carolinas; and certain parts of the Mid-west. The "new" territories encompass 14 states plus the District of Columbia. (An ambitious plan, especially for a company with revenues in 1995 of only $197,400, and a net loss of $167,900!) The only problem with this report is the absence of any coverage of competing firms, such as **Medical Alliance** (see the July 19th brief in the July issue).

9/9 In a surprise (at least to me) announcement, **U.S. Surgical** announced that it was beginning Phase 1 clinical trials for transmyocardial revascularization using an excimer laser. The first trials, under an IDE was performed on September 2nd by Dr. Steven Gundy at the Loma Linda (CA) University Medical Center. It turns out that USS had acquired a controlling interest in Munich, Germany-based excimer laser manufacturer, **Medolas** in July. (That announcement escaped all of the medical laser press, as far as I can tell.) I contacted the company and asked for a copy of that news release, dated July 23rd, which was the announcement of USS's second quarter results. However, it contained the statement that the company had acquired an 80% interest in Medolas, a leading European developer of excimer lasers for cardiovascular conditions, including worldwide sales and distributions rights to all its products. Apparently, Medolas' laser has been used in more than 200 TMR clinical procedures during the past 12 months, the second largest clinical series, according to

the company. (Of course, **PLC Systems** has done the most clinical trials, and **Acculase**, the subsidiary of **Laser Photonics**, is also conducting TMR trials with its excimer laser.)

9/10 **CSK Research** released the latest in its reports on **Palomar Medical Technologies**. Analysts Christine and Neal Kohlhass still call the company a "strong buy". They state that Palomar is the only company with a full suite of FDA-cleared laser products addressing the $15 billion cosmetic laser procedures market, and that the company's goal is to become the largest cosmetic laser company in the world. The report notes that the recently approved EpiLaser, although not specifically cleared for hair removal, will likely be used for this purpose by physicians using if "off label". The company has the capacity to produce about 150 EpiLaser systems in 1996, and is in the process of ramping up production capability to produce 100 lasers per month, beginning in the first quarter of 1997. CSK also discusses the agreement with mobile laser provider **Medical Alliance** and the agreement with **EquiMed** to open 50 cosmetic laser centers under a profit sharing arrangement.

9/10 **PLC Systems** got some very good news from the FDA, saying that the company could stop randomizing patients from receiving medical management instead of TMR in their clinical study of the two techniques in end-stage coronary artery disease. Due to the dramatically better results with TMR, using The Heart Laser, the FDA said that all referred patients can now be treated with TMR. In the trial of 121 randomly split patients, 71% of the 56 patients receiving TMR recorded a decrease of at least two classes of angina, whereas all the patients receiving medical therapy remained in the same class or got worse. The overall mortality rate in the TMR group was 6% versus 16% for the medical management group. The September 11th *Wall Street Journal* noted that the company's stock rose 20% on the announcement. Two additional clinical trials are also underway; TMR vs. repeat cardiac bypass surgery, and TMR as an adjunct to cardiac bypass surgery.

9/11 In an allied announcement to the above, **CardioGenesis** announced that it was suing **PLC Systems** seeking a judgement that PLC's U.S. Patent 5,125,926 pertaining to a heart-synchronized pulsed laser system was invalid and unenforceable. The company is also seeking to enter judgement that CardioGenesis' TMR systems do not infringe the PLC patent. According to CardioGenesis president and CEO Allen Hill, they brought the suit because PLC had contacted their clinical research partners and potential customers making claims about its patent rights with which CardioGenesis disagrees.

9/12 **Pharmacyclics** and **Hoechst Celanese Fine Chemicals** business unit have forged a manufacturing pact for the production of the bulk-drug substance contained in Pharmacyclics' texaphyrin PDT and radiation sensitizer products. Initially, the agreement will include Lu-Tex, in clinical trials for the photodynamic therapy

treatment of cancer and atherosclerosis, and Gd-Tex, for radiation sensitization in cancer treatment. Gd-Tex is currently in multi-center Phase Ib/II testing in patients receiving radiation therapy for brain metastases arising from various cancers, while Lu-Tex is in Phase I multi-center study for tumors accessible to externally applied light, including breast cancer, malignant melanoma, and Kaposi's Sarcoma. Pharmacyclics plans to contract with one or more manufacturers to produce the finished Gd-Tex and Lu-Tex products for marketing.

9/13 The September issue of *MedPro Month* contains a short article about **Dynamic Associates** of Scottsdale, AZ, having devised a microwave system to "erase varicose and spider veins". As stated, varicose and spider veins arise when the valve systems malfunction and blood stops moving. The key to preventing a recurrence is elimination of the flawed feeder veins. As noted, laser treatment is available for varicose veins, but doesn't work well on leg vessels. According to a spokesperson for Dynamic Associates, "The beauty of microwaves is by changing frequency we get depth control and we know how far we're going". The Dynamics Associates system combines ultrasound and a wand-like microwave probe. The device is scheduled to enter human clinical trials in late 1996.

9/15 In a followup to our August 27th brief on the acquisition of **Spectra Science** by **Infinite Machines**, the September 15th issue of *Laser Report* states that the acquisition was for a cash transaction of $2.7 million, and about $1.5 million was invested in Spectra by a group that included a French bank and a venture capital firm. The article also notes that Spectra is currently funding *in vivo* PDT testing with Foscan, a PDT drug developed by **Scotia Pharmaceuticals** of England.

The same issue of *Laser Report* also notes that **Diomed**, the surgical diode laser pioneer, intends to expand into the material processing area. The company has created an industrial division which will capitalize on the company's expertise in producing high-powered diode lasers, up to 60 watts output (from a patented coupling system), for cutting and welding of plastics and metals, and soldering, brazing, and microwelding. A new system is being built with funds provided by the UK government that will produce 120 watt outputs, doubling the power densities available. (Also see our 9/2 brief, above, detailing Diomed's collaboration with **Dentek** in producing a new diode-based dental laser.)

9/16 **ESC Medical Systems** announced that it had received FDA clearance for its PhotoDerm PL device for the non-laser, pulsed light treatment of benign pigmented lesions and multicolored tattoos. The PhotoDerm PL can be sold as an upgrade to the already approved PhotoDerm VL device, or as a stand-alone product.

9/16 **Mehl/Biophile International** said in a release that it expects men to comprise up to 25% of the worldwide market for its hair removal laser system. The company expects

that men will want to forgo shaving on a daily basis, increasing its estimates to include $100 million over the next five years for the men's market. Mehl expects to have over 300 worldwide laser installations by the end of 1997. The basis for the new projections was a study conducted by the **Mehl/SLS Group** in Europe that found, surprisingly, of the 400 clients treated, 25% were men. This higher than expected percentage of men seeking hair depilation demonstrates the demand for treatment by men. The company also noted that recent biopsy results after multiple treatments with its Chromos 694 ruby laser showed that the need for shaving may become obsolete, representing a possible "paradigm shift in personal hair removal since the safety razor". The company said that reliable estimates for current annual expenditures by men for hair care and shaving are approximately $1 billion.

9/17 Today's *Wall Street Journal* notes that a group including **Bulldog Capital Management L.P.** reported a 6.2% investment stake in **DUSA Pharmaceuticals** in a filing with the SEC. The group said it owns 581,500 common share of the company, 126,000 of which it purchased between June 7 and August 1st.

9/17 **Reliant Technologies** said it had been granted two new U.S. Patents, 5,546,214 and 5,531,740, relating to the control of lasers via its mirror-based technology. The delivery devices based on the patents are used for the advanced treatment of tissue surfaces and for venular malformations. The '214 patent is directed to a method and apparatus for treatment of a surface with a scanning laser beam having an improved intensity cross section, and is incorporated in the company's AccuScan Laser Scanner. The '740 patent is directed to a method and apparatus for automated color-activated scanning treatment of venular malformations such as port wine stains and spider veins. The device uses color-discriminating detectors to activate the laser only when and if the skin is of a pre-determined color. Reliant plans to start production and marketing of this device in the beginning of 1997.

9/18 **Ion Laser Technology** announced the successful development of a prototype device to allow the faster photo-chemical reaction in the tooth whitening process when used in conjunction with the company's laser systems. The device was developed as part of a research project with **United Technologies Research Center**. ILT is applying for patent protection on the new device, which will be introduced during the first half of 1997. ILT is also working with the UT Research Center on the enhancement of the company's proprietary laser whitening chemical formulation. The objective of the research is to continually improve the whitening process and reduce the patient chair time for the procedure. The company markets the tooth whitening technique (lasers and chemicals) under the BriteSmile tradename.

9/24 **American Dental Technologies** has introduced a new stand-alone version of its Plasma Arc Curing system, intended to rapidly cure composite filling materials, but whose xenon light can be used to dramatically enhance the speed of bleaching teeth at

a reduced cost compared to some laser systems. Dentists using the PAC and the popular Shofu Hi Lite bleaching material have reported whitening one arch as much as two shades in just one 30-40 minute session, according to the company. The PAC light sells for under $7000, or about one-fifth the cost of some laser bleaching systems.

9/24 **Candela Corporation** announced that it had received clearance from the FDA to market a new device to significantly reduce pain during laser surgery. The instrument, known as the Dynamic Cooling Device, was designed in conjunction with the **Beckman Laser Institute**. The DCD is different from other skin cooling devices in that it selectively cools the top layers of the skin during laser treatment by introducing short bursts of a cooling agent, similar to freon, that is sprayed onto the skin milliseconds before delivery of the laser pulse. This microburst of coolant reduces the pain felt, allowing a patient to receive more laser therapy during each session, reducing the number of visits required by as much as 30 percent. The device, priced at under $20,000, is scheduled for general availability by mid-1997. Candela plans to introduce the device for initial use with its line of vascular and sclerolasers, eventually extending it to its entire line of six different cosmetic lasers, over 500 of which are installed worldwide. However, according to *The Boston Globe*, the initial model of the device is limited to working on birthmarks. The company is developing a similar cooling system device for its lasers that are used to remove tattoos and pigmented lesions.

9/24 **Eclipse Surgical Technologies** said that it had successfully completed its Phase I clinical trial for TMR and had received clearance to proceed into Phase II as an adjunct to CABG. This is the second Phase II trial for the company's TMR holmium laser, the first being to evaluate TMR as sole therapy for patients who are not candidates for balloon angioplasty or bypass surgery. The new Phase II trial will be a randomized comparative study of the Eclipse TMR procedure combined with bypass surgery, versus bypass surgery alone. The study, scheduled to begin this month, is expected to target a minimum of 300 patients at 20 sites.

9/25 **Clinicon Corporation** of Carlsbad, CA announced that its SureScan laser pattern generator had received FDA marketing clearance and had generated considerable interest at a recent European aesthetic surgery meeting. SureScan converts any CO_2 laser, pulsed or CW, into an aesthetic surgical laser to perform a wide range of cosmetic procedures. The device can produce a variety of scan patterns and scan sizes, selectable up to about 22 mm. The SureScan will be available both for direct sale to physicians for under $20,000, and as an OEM add-on from selected laser suppliers.

9/26 **Mehl/Biophile International** announced that it had formed a strategic alliance with **Applied Genetics** of Freeport, NY, to develop liposome-based products for

dermatologic application and use with the Mehl hair removal laser system. The joint effort involves the short-term development of personal care products, as well as the long-term research and development of future proprietary dermatologic pharmaceuticals. These products will be marketed throughout the Mehl/SLS world-wide network of laser hair removal installations, which are projected to reach 300 by the end of 1997. The agreement includes an infusion of capital to fund R&D, as well as an equity investment by Mehl in the privately held Applied Genetics. Applied Genetics manufactures cosmetic ingredients, including the new drug, T4N5 liposome lotion, which is in Phase III clinical trials for the prevention of sun damage to skin.

MEDICAL/SURGICAL UPDATE -- OCTOBER 1996

9/26 **Cell Robotics International** announced that all of its Class A warrants had been exercised generating approximately $2 million in proceeds. The company also announced that it had retained the investor relations firm **Coffin-KCSA** to handle its account.

9/26 **Premier Laser Systems** announced that it had filed a registration statement with the SEC relating to an $11 million secondary offering to be handled by DH Blair. The proceeds for the offering will be used to expand marketing and distribution, including international markets, and new product introductions through acquisitions, strategic alliances or internal development. The company also plans to invest in inventory and demonstration or loaner equipment and to fund additional R&D, including clinical trials and regulatory activities.

The "red herring", received on October 3rd, describes the company's proprietary laser products including argon, diode, CO_2, YAG, erbium, and holmium, and some of the application areas for which these lasers are being used. These include dentistry, both soft and hard tissue removal, as well as composite curing and tooth whitening; eye disorders including cataract removal, glaucoma treatment, and corneal sculpting; and tissue "melding" (their term in replacement of tissue welding), to replace sutures and staples. The latter application was obtained through the acquisition of **Proclosure, Inc.** in December 1993. The prospectus notes that Premier has a strategic partner in this area who is conducting animal tests in support of IDEs for use in the areas of arteries, veins, blood vessels and ducts. The company is conducting Phase I clinical trials for skin and hypospadias (lengthening the urethra to the end of the penis in infant boys), and has completed trials for vasovasotomy, the reversal of vasectomies, which demonstrated a success rate of 89%. The partner, **Nippon Shoji Kaisha, Ltd**, has a marketing agreement signed in 1994 to distribute the company's YAG laser for tissue melding applications in Japan, China, and Taiwan, subject to regulatory approval.

The company's strategic emphasis is on applications for its erbium laser technology, specifically its use in dentistry for hard tissue applications (caries removal) and in ophthalmology both for cataract emulsification and corneal reshaping. The erbium laser has been approved for certain cosmetic ophthalmic applications (see our brief of June 4) and is currently in clinical investigation for cataract removal, glaucoma filtration procedures, corneal reshaping, and removal of vitreous bands. In addition, clinical data in support of its 510 (k) application for dental hard tissue uses has been submitted to the FDA. (It is likely that FDA will require a PMA submission, rather than 510 (k) for caries removal, the "homerun" of laser dental applications.)

The company also has a purchasing agreement, signed in December 1995 that runs until December 31, 2005, with **Mattan Corporation**, the parent of **Medical Laser Institute of America**, to supply the latter's requirements for cosmetic lasers, accessories, and disposables, to be used in MLIA's cosmetic laser centers being established across the United States.

The prospectus also describes the company's problems (and lawsuit) with its former erbium laser fiber supplier, **Infrared Fiber Systems** (now exclusively supplying that fiber to **Coherent Medical**), and states that the company had recently procured two new (unnamed) sources for these fibers. Two of the company's lasers are manufactured by others; the MOD argon laser, used for tooth whitening and composite curing, from **International Biolaser Corporation**, and its portable Arago argon lasers from **Lasermed, Inc.**, also used for composite curing.

9/27 The newest laser cosmetic procedure, according to *The Wall Street Journal*, is reduction/tightening of the ear lobes. After smoothing out wrinkles, some doctors are lifting the lobes made droopy by years of wearing dangling earrings! (Do your ears hang low, do they wobble to and fro?) Dr. Roy Geronemous of New York says he is doing about 10 patients a month, while Dr. Bruce Katz (also of New York) does four or five ear treatments a week, at $750 per set! About 15% of his cases are men, who have stretched their lobes from wearing earrings. Using the CO_2 laser, three or four passes makes a layer of tissue disappear and the collagen shrinkage contracts up to 40% of the lobes, which take about a week to heal.

10/1 **QLT PhotoTherapeutics** announced that its U.S. marketing partner, **Sanofi Winthrop**, had officially launched Photofrin for treating cancer. The first application, approved last December, is for the palliative treatment of end-stage esophageal cancer, for those patients with totally obstructing tumors and certain partially obstructing tumors. According to the American Cancer Society, there are more than 12,000 new cases of esophageal cancer and 11,000 deaths annually.

In an allied announcement, researchers at Columbia-Presbyterian Medical Center in New York announced that they were offering the PDT treatment for esophageal

cancer patients. According to the doctors cited, some patients whose cancers are caught early can be cured with photodynamic therapy. A precursor to esophageal cancer, Barrett's esophagus, caused by chronic reflux disease, is a pre-malignant condition. Regular biopsies of Barrett's patients can detect esophageal cancer at the early, treatable stage, and PDT treatment can remove all of the abnormal Barrett's tissue.

10/2 **Surgical Laser Technologies** announced that it had reached an agreement in principle with **Mediq PRN** to acquire from Mediq its 50% interest in **Mediq PRN/SLT**, the joint venture formed by the two companies to offer laser rental services. SLT will now own, control, and continue to operate the laser rental business, providing both short-term and per procedure rental services to hospitals, doctors and other health care providers. With the change, SLT will become responsible for the management, sales, and operations of the business, while Mediq PRN will continue to contract its logistics services to SLT, ensuring that the quality of the service formerly provided by the joint venture will not be compromised.

10/2 **Coherent Inc.** announced that its Medical Group had begun shipment of its new VersaPulse VPW (variable pulse width) Aesthetic laser. With this system, physicians can selectively treat blood vessel abnormalities of the skin in both adults and children. These include vessel malformations, port wine stains, and telangiectasia, the unsightly veins of the legs and face. The VersaPulse VPW effectively treats lesions containing larger vessels that are resistant to treatment with conventional vascular lesion lasers. The adjustable pulses can be tailored to coagulate larger vessels without rupture, bleeding, and bruising. The VersaPulse VPW is the first of a family of aesthetic lasers that will have multiple wavelengths, containing both Q-switched YAG, doubled YAG, alexandrite, and the variable pulsewidth doubled YAG for vascular lesions. (See our April 9th brief on approval of this laser system.)

10/3 **CardioGenesis** announced that it had received expedited review status for its multi-center, prospective, randomized study of its intraoperative transmyocardial revascularization (ITMR) system in 150 "no option" patients at up to 20 clinical sites. Preliminary results from 15 of the 29 patients enrolled showed a two point drop in angina pain class, from an average of 3.5 prior to the treatment, to 1.7 three months after therapy. Ninety three percent demonstrated significant improvement in angina class, with 67% reporting the two point drop. The results will be presented at a CardioGenesis sponsored symposium during the European Association of Cardio Thoracic Surgery in Prague, Czechoslovakia on October 7th, at which time the company will initiate commercial launch of the ITMR system in Europe.

The company is also conducting a second Phase II study of ITMR as an adjunct to first CABG in 500 patients at 25 clinical sites, and is also completing its pre-clinical

review of its percutaneous system (PMR), and expects to initiate human clinical trials internationally by the end of the year.

10/3 **DUSA Pharmaceuticals** sent out its mid-year report, detailing the status of its several ALA PDT and PD programs. The most advanced program is for treating actinic keratoses, with the Phase IIb multi-center clinical trial completed with good results. An additional Phase II test to insure that the drug dose being used is as low as possible, while still giving excellent results, is well underway at 8 sites. Phase III trials are expected to get underway in the fourth quarter, with an NDA planned for late 1997.

Development work continues on the use of ALA as a diagnostic for bladder cancer. The first U.S. clinical trial is now underway at MGH in Boston, and the company is preparing an additional multi-center trial beginning in the fourth quarter, using a new formulation of Levulan (DUSA's new name for ALA) and a specially modified light source. Market research shows that bladder cancer visualization represents a major opportunity for DUSA, with approximately 800,000-900,000 surveillance procedures carried out in the U.S. each year.

DUSA is supporting independent research at MGH to optimize the selectivity of Levulan in PDT for human hair removal. This work was completed during the second quarter and the data is being utilized in the preparation of protocols for a Phase I/IIa human hair removal trial planned to start later in 1996. The company has developed a proprietary non-laser light source for use in these trials.

The company's first acne clinical trial was also completed during the second quarter with encouraging results. Following completion of data analysis, a Phase II study is planned. DUSA is also developing its ALA PDT system for use in endometrial ablation as an alternative for hysterectomy for patients with excessive uterine bleeding. A protocol for an investigator sponsored pilot clinical trial supported by DUSA was submitted to the FDA earlier this year, in which patients who responded well to ALA PDT would not require a hysterectomy. However, the FDA has decided that the first trial of any new method for endometrial ablation should be carried out on patients scheduled for hysterectomy, in order to better assess the extent of EA, and the safety of the procedure. A new protocol has been submitted, and approval to begin the trial is expected shortly.

The company continues to monitor and support independent ALA PDT research around the world, focusing on potential future indications for DUSA. Some promising research projects include the diagnosis and treatment of early lung, brain, and GI cancers and pre-cancers; and various auto-immune and inflammatory conditions, and even infectious diseases. The company continues to support work on psoriasis, skin cancer, and alopecia areata, an immune-mediated form of hair loss.

Other corporate developments have been covered in previous briefs -- see the briefs of 4/15, 5/5, 5/14, 5/16, and 6/26.

10/3 The CBS program *48 Hours* included a segment on laser skin resurfacing, showing the downside of the procedure. Three problem cases were featured (of the thousands of successful cases done): one women who's face seemed never to heal, as well as having a drooping eyelid that did not recover; a second woman had several perforations of her cornea, which required corneal surgery to correct (how in the world did that ever occur?); while a man lost sight in one eye due to a hemorrhage behind the eye -- possibly caused by sneezing or excessive exercise, I couldn't figure out the cause of this one, but it was not directly related to the skin resurfacing procedure.

Both **Palomar Medical** and **Laser Industries** put out news releases about the program. Palomar welcomed a public airing of the safety-related issues, because, it "believes that that is a major advantage of its Tru-Pulse system, with an excellent record of safety and clinical performance". Laser Industries said that it expected the program would spur the sales of the company's SilkLaser system, "as this system with its Flashscanner technology is the only product with marketing clearance from the FDA specifically for the treatment of wrinkles".

10/4 Cornell University Medical College in New York has received FDA approval to initiate a research program for the evaluation of the **Helionetics/Acculase** excimer laser system for TMR. (See the 8/26 brief. At the time I was under the impression that the Acculase excimer was the only excimer laser being used for this procedure. With the announcement of **U.S. Surgical** that it had entered the TMR arena -- see the 9/9 brief, and the 10/4 brief immediately below -- with its acquisition of **Medolas** of Germany, there are now at least two excimer lasers being investigated for TMR.)

10/4 The October issue of *Medical Laser Report* has a lead story about **U.S. Surgical's** entry into the TMR field. Editor Kathy Kincade unearthed an interesting item; apparently, the company is using another excimer laser system -- not the **Medolas** system -- for its Phase I clinical trials! According to company officials, the Phase II trials will be done with the Medolas system. (So whose system is being used for the Phase I trials?) Also of note, the proprietary laser energy delivery system was developed by U.S. Surgical.

10/5 The October issue of *OE Reports* contains an interesting invention/product from **New Vision Systems, Ltd.** of Israel. It is a "thimble camera". The patented device is a configuration of a miniature video camera and a light source, along with an accessory (laser ?) channel, in a sterilizable housing, which is all mounted on a disposable protective sheath that fits on the end of a finger. This allows normal accessibility by the hand or finger in difficult to reach places. "If you can touch it with your finger, the device can be placed there!" A whole family of integral accessories, such as

insufflation, suction, electrocautery, biopsy forceps, surgical laser, etc. can be added to the device, to allow the user to optimize performing the operations with a single finger. (Call me if your interested in seeing the writeup and diagrams of the device.)

10/7 **DUSA Pharmaceuticals** reported encouraging results from its Phase I/II dose-ranging studies of ALA PDT for the treatment of acne vulgaris. The study on inflammatory acne was conducted by Dr. Luciann Hruza of Washington University School of Medicine in St. Louis. The treatment protocol was carried out on 80 acne lesions on 10 patients, with a single light treatment administered at six different dose levels and two drug concentrations. After 7 days, 80%-100% improvement was seen in up to 75% of the ALA treated areas, compared to none of the "light alone" control sites, and 29% of the "ALA alone" control sites. After 21 days, significant clearing had occurred in up to 80% of the ALA PDT sites compared to 40% of the "light alone", and 25% of the ALA alone sites. The company is now working on a new protocol incorporating multiple treatments in preparation for a Phase IIa clinical trial to start next year.

10/7 **ThermoLase** announced the opening of three more Spa Thira salons. The new salons are located in Beverly Hills, CA; Houston, TX; and Denver, CO, bringing the number of currently open spas up to five. Two additional spas are under construction in Boca Raton, FL and in Troy, MI.

10/7 **Johnson & Johnson** announced the acquisition of **Indigo Medical**, a Palo Alto, California-based portable diode laser system manufacturer. Indigo is a pioneer in the use of diode lasers for interstitial thermotherapy, and has received FDA approval for use in treating general urological conditions. Indigo also markets diode lasers in Europe for treating benign prostate hyperplasia (BPH), a condition, according to the company, that affects 20 million men worldwide. The company is seeking clearance from the FDA for treating this condition in the U.S. (Indigo was formed in 1990 with the help of the **Johnson & Johnson Development Corporation**, **Lovelace Scientific Resources**, and the **Kirkland Air Force Base Phillips Labs**.)

According to the October 14th *Gray Sheet*, J&J may make Indigo the first piece of a new urology products unit within its **Ethicon Endosurgery** minimally invasive surgery division. The Indigo 830 laser system received a 510 (k) clearance for general indications in January, and was launched in May.

10/8 **Cell Robotics International** announced that *Red Chip Review*, a leading newsletter for emerging growth companies, had initiated coverage of the company.

10/8 **QLT PhotoTherapeutics** announced that it had re-acquired the Italian rights for Photofrin from **American Cyanamid**. The purpose is to pursue a centralized marketing strategy in Europe with a new (unnamed) marketing partner. The company has held discussions with several pharmaceutical companies that have operations

throughout Europe, including Italy. The latter is one of five European countries where medical regulators are reviewing marketing applications for Photofrin, which was approved in Holland in 1994, and in France in January, 1996. QLT had exercised its option to re-acquire North American rights in 1994, and all other global rights except for Japan and Italy in 1995.

As previously noted (see October 1st brief above), the company's U.S. marketing partner, **Sanofi Winthrop**, launched Photofrin in the U.S. on October 1st. The company also announced that it was on schedule to file a comprehensive supplementary NDA (sNDA) with the FDA before the end of 1996 for the use of Photofrin as a treatment for early and advanced stages of non-small cell lung cancer. The filing will include results from 10 studies conducted in North America and Europe involving about 700 patients. QLT will also begin a registration clinical trial for the use of Photofrin to treat Barrett's Esophagus in late 1996 or early 1997.

10/8 An announcement from **Vidamed** states that it had received FDA approval for the application of its transurethral needle ablation system (TUNA) for the treatment of symptomatic BPH. The TUNA system uses localized heat to treat the enlarged prostate tissue. The company claims that a typical TUNA procedure, performed in the physician's office, will cost less than $3600, compared with current payments of $4800-$8000 for TURP and $3700 to $7000 for the various laser treatments.

10/9 **Ion Laser Technology** announced that it now had fifty Britesmile Laser Tooth Whitening locations, with over 100 dentists and hygienists trained in the procedure. The fifty centers are located in 22 states nationwide.

10/11 **Prosurg** announced that it had obtained a U.S. patent, 5,562,703, for its RF needle ablation device used for interstitial ablation treatment of urological and gynecological disorders. The RF needle device consists of retractable needle electrodes which can be used in conjunction with commercially available diagnostic endoscopes to facilitate its placement in body tissue under endoscopic vision.

10/11 **Eclipse Surgical Technologies** announced that it had completed enrollment of 100 patients in its Phase II study of TMR as compared to drug therapy. The FDA has granted expedited review status for this study.

The news release contains a statement attributed to Dr. Allan Lansing of Louisville, KY, "The Eclipse TMR laser system is the safest, simplest, and most reliable TMR laser system that I have ever used. It has given me the best results to date."

In a later statement, released over the *Dow Jones News Wire* on October 21st, the doctor denied making the comments attributed to him in the Eclipse press release. He further told Dow Jones that the Eclipse device posed a greater risk to heart patients

than a competing laser system, that produced by **PLC Systems**. He said that the Eclipse holmium laser system tended to have a greater tendency to induce irregular heartbeat than the PLC system that is synchronized to blast the heart between beats. "While the Eclipse system may be a little simpler to use, it poses a greater risk to heart patients than the PLC system because it lacks synchronization".

Eclipse officials retorted by saying that Lansing's comments were read back to him three times before they were included in the press release. Lansing later apologized for "all the uproar" regarding his comments. "In retrospect, I believe I was misquoted, but my thoughts may have been misinterpreted and misunderstood. I am a strong believer in TMR and in both the PLC and Eclipse Systems, and feel privileged to have the opportunity to work with each of them."

10/14 According to *The Gray Sheet*, **Vidamed's** TUNA (transurethral needle ablation) system shipments are under way following FDA clearance on October 8th, for localized heating to treat BPH. The TUNA system uses a disposable catheter with two needle electrodes and an RF generator, priced at $29,500, and a fiber optic system for positioning and viewing the device. The catheter sells for $795, and the procedure, when performed in a urologist's office, costs about $3600.

In another article, *The Gray Sheet* reports that the FDA issued a guidance in the October 8th *Federal Register* stating that peer-reviewed journal articles detailing efficacy studies used for product approval may be reprinted and distributed by manufacturers.

10/14 In the current issue of *Lasers in Surgery and Medicine*, (Volume 19, No. 2), a letter to the editor asks the question, "Laser Hair Transplantation: Is it Really State of the Art? The three page letter from Drs. Robert Bernstein and William Rassman questions the validity of using a laser to create the holes for transplanted hair, and calling the procedure "laser hair transplantation". The laser is used solely to create the holes or slits for the grafts to be inserted into. Until lasers are used in other major components of the transplant, such as harvesting, graft dissection, or placing, "laser hair transplantation" should be replaced with a term such as "laser site creation".

Dr. Walter Unger, one of the first to use lasers in this procedure responded with his own two-page letter. He agreed, in general, with the vast majority of what the doctors had to say, but he said he had chosen the name "laser hair transplanting" simply because it was easy to say, rather than "laser site creation hair transplantation". His letter answers the specific points made by the writers. (Anyone who would like a copy of the total correspondence on this subject, give me a call.)

10/15 **Mehl/Biophile International** announced that its majority-owned subsidiary, **SLS/Biophile, Ltd** had commenced shipment of the company's proprietary Chromos

694 ruby long-pulsed laser hair removal systems. The company said that five systems would be delivered this week, and 10 additional system by the end of the month. The systems are being placed with physicians, hospitals, and medical clinics outside the U.S. under license agreements. Mehl plans to produce and deliver an additional 15-20 systems by the end of 1996. The company notes that the laser is produced under the Zais patent, and the Clement patent pending, and has been granted full CE approval for marketing in Europe.

10/15 **CardioGenesis** reported its third quarter results with sales of $1.1 million of its intraoperative transmyocardial revascularization (ITMR) system to customers in Europe and for clinical trial sites in the U.S. A net loss of $1.9 million (16 cents/share) was recorded. The company is conducting two multi-center, prospective, randomized studies of its ITMR system, one in "no option" patients with ITMR as the stand alone procedure, and the other study as an adjunct to first CABG. A total of 695 patients and 45 clinical sites are approved to be included in these two protocols. The company is also completing pre-clinical studies on its percutaneous myocardial revascularization (PMR) system and expects to initiate human clinical trials internationally by the end of the year, and to seek FDA approval to start U.S. trials during the first quarter of 1997.

10/15 **Laser Industries** reported record preliminary revenues of $14.6 million, up 16% over the same quarter last year. Final results for the third quarter will be announced later this month. The company noted that it still had a backlog of orders totalling approximately $6 million. They also said that they had displayed their EpiTouch ruby laser for hair removal at a meeting of the European Academy of Dermatology and Virology held in Lisbon, Portugal that started last week, with presentations of their latest clinical results on hair removal from two doctors, Dr. Peter Noren of Sweden, and Dr. Monica Elman of Israel.

10/16 **Trimedyne** said that it would appeal decisions made by the Federal Court in Orange County, CA on its patent infringement lawsuit against **Surgical Laser Technologies**. Based on advice from counsel, the company will appeal the court's decision on two U.S. patents, one on contact laser surgery, and the other covering sidefiring laser devices to treat BPH.

10/16 **Coherent Inc.** announced the introduction of two new additions to its family of UltraPulse aesthetic lasers. The UltraPulse 5000C with CPG (computerized pattern generator) introduced two years ago, is the premier laser for aesthetic procedures. The new models, the UltraPulse 2500C and the 2500C with CPG, operate at reduced rates, while maintaining the control and uniformity that has made UltraPulse the acknowledged performance standard. The new systems are priced from $75,000 to $90,000, compared to the $120,000 for the model 5000C. Both of the new lasers can be upgraded to meet the performance of the 5000C.

10/17 Following up the announcement made on October 15th, of the first shipments of the Chromos 694 ruby lasers, **Mehl/Biophile** announced that its subsidiary, **SLS/Biophile** will begin producing 30 Chromos 694 hair removal laser systems per month, beginning in January 1997. Each system will be put under a license agreement, which will bring Mehl/Biophile a continuing percentage of revenues, or $15,000 per system per month, whichever is greater. The company plans to place a minimum of 300 systems in the field by the end of 1997. They claim to have letters of intent for more than 200 laser systems, signed by potential customers from around the world, and license agreements have been executed.

10/17 **Sorin Biomedica Cardio SpA**, the distributor for **Eclipse's** TMR laser system outside the U.S., announced that Professor Uberto Bortolotti of Cisnello Hospital, Pisa, Italy, performed the first minimally invasive TMR procedure ever on October 10th, using the Eclipse holmium laser. A 53 year-old man with intractable angina who had no surgical option was treated without complications and was discharged from the hospital 5 days later, with 34 new channels for blood flow in his heart. The technique used was to place 3 small holes through the patient's chest without the need for the traditional 12 inch incision used for CABG.

10/17 **Spectronetics** announced its third quarter results with a 29% increase in revenues to $5.6 million, and a loss for the quarter of $69,000 (0 cents/share). For the nine month period, revenues exceeded $15.7 million, a 20% increase over the same time period last year.

10/17 **Helionetics** announced that the first human trial with its short-pulse AccuLase excimer laser for TMR was performed last Monday at the New York Hospital-Cornell Medical Center in New York. The procedure was performed on a 42 year old woman suffering from coronary heart disease, for which no other procedure was available based on her medical history. The laser was used to drill twenty four holes through the heart wall into the left ventricle chamber to allow blood to flow directly into the myocardium, restoring oxygen-rich blood to the heart muscle. An additional 29 procedures will be performed as part of the Phase I human clinical trials.

10/18 **CardioGenesis** announced that **PLC Systems** had responded to the complaint filed by CardioGenesis against PLC Systems' U.S. Patent 5,125,926, asking the court to declare that its TMR products do not infringe the PLC patent, and asking for a declaration that the patent was invalid and unenforceable. In its response, PLC has taken the position that its patent had been infringed by CardioGenesis, but makes no further claims. Now the matter will go forward in the courts.

10/20 The September/October issue of *Biophotonics International* contains an interesting article about a study done to determine whether pulsed holmium lasers used in arthroscopic surgery for treating knee joints may cause more damage to tissue than

previously thought. The study, done by researchers in the **Department of Orthopedic Surgery at Johns Hopkins University**, was funded in part by the **Hospital for Special Surgery** in New York, and by **Coherent Inc.** The researchers at Johns Hopkins used autoradiography and electron microscopy techniques to examine cartilage at the cellular level. Their findings suggest "that even when there is no visible evidence of damage, significant cell death in the articular (joint) cartilage may occur following exposure to the laser's energy". The surgeons concluded that the holmium laser may cause "semiablative" zones where no injury is immediately visible, but chondrocyte death may occur, which does not occur with conventional cartilage repair surgery. Further studies examining the holmium laser's effects on cartilage are tentatively scheduled to begin at the Hospital for Special Surgery in late 1996. Coherent intends to continue its presence -- most likely in the form of financial support. A spokesperson for Coherent said, "We are trying to gather more information so we can have a better knowledge of the laser's effect at the cellular level."

10/21 **Palomar Medical** reported that its estimated revenues for the third quarter will be approximately $25 million, a 320% increase compared to the same quarter last year.

10/21 The Federal Court in Newark, NJ had denied motions by **CR Bard** to dismiss **Trimedyne's** multimillion lawsuit against Bard for breach of their exclusive worldwide distribution agreement, and other claims. The suit will now proceed to the discovery and deposition phase.

10/21 Doctors from University Hospital Hamburg, Germany, at **PLC Systems'** European TMR Symposium, provided additional proof of blood flow through open TMR channels created by the company's Heart Laser. Fourteen patients were evaluated post-TMR, and 11 had sufficient image quality to show blood flowing between the left ventricular cavity and the myocardium in 9 of the 11 patients, all of whom showed a reduction of at least two angina classes.

10/21 **Ion Laser Technology** has exercised its option to acquire 100,000 shares of common stock, at a price of $1.50 per share, from **United Technologies Corporation**, pursuant to the ILT/UT development agreement.

10/21 **Biolase Inc.** announced the completion of a private placement of equity financing, worth $5 million to the company.

10/22 **Laserscope** announced its third quarter results, with revenues of $10.6 million, up 50% from the same quarter last year. Net income, excluding non-recurring charges associated with the company's acquisition of **Heraeus Surgical**, increased 74% from the immediately preceding quarter to $44,000 (5 cents/share). With the charges of $3.2 million in association with the acquisition, the company reported a net loss for the quarter of $2.81 million (32 cents/share). The third quarter results include

approximately $1.5 million of revenue attributable to the first month of Heraeus Surgical's operations.

10/22 **ESC Medical Systems Ltd.** announced its record third quarter results, with net sales increasing to $9.2 million, compared to $2.5 million for the same quarter last year. Net income was $3.6 million (20 cents/share). Dr. Shimon Eckhouse, president and CEO, noted that the worldwide response to its PhotoDerm VL product for removal of leg veins and other benign vascular lesions remained strong, while the introduction of the PhotoDerm PL for the non-invasive treatment of benign lesions and tattoos has been positive, both as a standalone, and as an upgrade for the PhotoDerm VL. He stated that the company had completed clinical trials and filed with FDA for clearance of its Epilight Hair Removal System in August, and International demand was strong, with the company beginning to place systems in key locations in Europe. ESC has also completed the integration of **LBT Ltd.**, which enables it to add two additional key products to its line, the Topaz-30 and Derma 20 lasers, which address the rapidly growing skin resurfacing marketplace.

10/22 **Palomar Medical** said that it had received a letter from the FDA notifying the company not to promote its Epilaser for hair removal. The Epilaser had previously been approved for a range of dermatological applications, but not specifically for hair removal. The company says that it has submitted additional data in its 510 (k) application to the FDA, which is now being reviewed by the agency. The company believes that the letter received today will not have any effect on that process, as it has reviewed its promotional literature and believes it is in compliance with all FDA regulations.

10/23 **PLC Systems** reported its third quarter results with revenues increasing to $2.5 million. The net loss for the quarter was $562,000 (3 cents/share). Nine month revenues were $8.8 million, an increase of 47%, with a net loss of $1.2 million. The company said it shipped eight Heart Lasers in the quarter, of which two were for research and clinical testing in Europe, and two were for U.S. clinical sites.

10/23 **Spectranetics** received clearance from the FDA to end randomization of a clinical trial using the company's CVX-300 laser to remove pacemaker leads. This clears the way for physicians involved in the trial to now recommend using the laser over other extraction techniques. The FDA also approved expansion of the trial from 14 to 20 clinical sites, increasing the number of patients who can be treated from 282 to 600.

10/24 **ThermoLase** announced that it had signed three more leases, bringing the number of Spa Thira sites opened or planned to 10. Five spas are currently treating patients and two more are scheduled to open by early November. The new leases are for retail space in Greenwich, CT; Manhasset, NY; and suburban Minneapolis. Each of the spas

will have 10 treatment rooms featuring the ThermoLase SoftLight hair removal process. (In addition to its wholly owned spas, the company has signed leasing agreements with a number of practitioners to place its laser-based system into their offices for a minimum monthly fee of $16,000.)

10/24 **Helionetics** and **Laser Photonics** have decided to reposition their subsidiary, **AccuLase** as an independent stand-alone company, subject to public financing now under negotiation. Acculase is conducting clinical trials of its excimer laser system for performing transmyocardial revascularization, with the first patient treated the previous week -- see the October 17th brief above.

10/24 **ESC Medical Systems** announced that the FDA had cleared its pulsed-light PhotoDerm PL for use in treating pigmented lesions such as sun spots, age spots and birthmarks, as well as multicolored tattoos. The clinical success of the PhotoDerm PL is largely attributed to its flexible treatment parameters, which can be adjusted to optimally fit the color and depth of the lesion with the natural skin pigmentation of the patient. At present, there are more than 250 PhotoDerm systems installed in clinics worldwide.

10/28 **ThermoLase** reported that cash receipts at its first Spa Thira, opened last October in La Jolla, CA exceeded $2.7 million for the year. Most customers pay in advance for a series of treatments, so these cash receipts are deferred and recorded as revenues over the course of the treatment. Operating margins for the La Jolla spa are running between 40 and 50 percent. President John Hansen stated, "We believe that the success we've had at La Jolla demonstrates the real commercial value of our SoftLight technology, and represents an important new milestone for ThermoLase. The results at La Jolla don't necessarily reflect the results that we will achieve at other spas, but we believe that ThermoLase is moving rapidly from technological leadership to business leadership in the hair-removal industry, as we set the standard for this new service."

10/28 **Cell Robotics International** said it received final approval from the FDA for its IDE to begin human clinical trials for its Lasette laser finger perforator. Clinical trials had been initiated under a conditional IDE granted on August 26th. Final IDE approval came after the company made some agreed-to changes in the testing protocol. A 510 (k) submission is planned for November 1996. The company and its development partner, **Big Sky Laser Technologies** have finalized the basic pre-production design and 20 to 50 pre-production prototypes will be built by the end of the year. The current engineering prototype is 7"x3½"x1½", and easily fits into a small notebook, similar to a daily planner.

10/28 **Premier Laser Systems** announced it had completed its public offering handled by D.H. Blair, raising $9.2 million. The proceeds will be used to expand marketing and

distribution efforts, to fund new product introductions, and for other general corporate purposes.

10/28 **Candela Corporation** reported a 27% increase in revenues and improved profitability for its first fiscal quarter of 1997. With several new products being introduced, including the ScleroPlus and the AlexLazr, revenues for the quarter were $7.6 million, and net income was $510,000 (9 cents/share). (Revenues include the results for Spa Management, which was acquired in June, 1996.) Company officials believe that the recent FDA clearance for the Dynamic Cooling Device should carry revenue momentum into the company's second quarter and beyond. Gerard Puorro, president and CEO also commented on the development of Candela Skin Care Centers, which posted a 31% increase in revenues, "As we open other locations during the fiscal year, we will continue to move forward with precise steps as a leader in this emerging field, one of great importance to aging baby boomers."

10/30 For the second time in a week, **Spectranetics** received clearance to expand its clinical trial using its excimer laser to remove pacemaker leads. By authorizing the use of larger size sheaths, the latest FDA action clears the way for implantable cardioverter defibrillator (ICD) leads, and larger diameter pacing leads to now be included in the ongoing study.

10/30 **ThermoLase** announced two distribution/marketing agreements for its SoftLight system to be marketed in France and in Saudi Arabia. For the French market, ThermoLase has entered into a 50/50 joint venture with **Groupe Jacques Dessange** to market the hair removal and its skin rejuvenation technology. Through its salons, Groupe Jacques is the leading provider of premium hair and skin care services in France, and with more than 500 salons in 34 countries, it is recognized around the world for innovation and customer service in beauty. The joint venture plans to open Spa Thira salons as well as offer the service within existing Jacques Dessange salons in France.

The second announced agreement was entered into with **Medic**, a medical supply and service company operated by Shiek Ibrahim El Khereiji. Medic will market the SoftLight process in Saudi Arabia. Under the terms of the agreement, ThermoLase will receive a fee of $1 million over two years, subject to certain conditions, plus a percentage of gross revenues derived from the venture. The agreement requires Medic to meet certain minimum operating and expansion goals. After obtaining the necessary regulatory approvals, Medic plans to open three spas in major cities over the next two years.

10/30 **Coherent, Inc.** reported its fourth fiscal quarter results, with record revenues of $100.8 million, of which $43.3 million represented medical laser sales. Net income for the quarter was $8.6 million. Medical sales for the fiscal year were $162.8 million,

29% higher than the previous year. (According to an analyst following the company, sales of Coherent's UltraPulse laser had leveled off, probably because of resistance to its high price, and this was the reason for the introduction of the two new lower priced models -- see the October 16th brief above.)

10/30 **ESC Medical Systems** filed a 510 (k) application with the FDA for clearance to market its Derma 20 erbium:YAG laser system in the United States. The company said that the Derma 20, an advanced pulsed erbium laser system, will be used for general dermatological applications, including the fast growing skin resurfacing market. (This laser is one of the several laser systems the company obtained with its acquisition of **LBT Ltd.** of Israel, earlier this year.)

MEDICAL/SURGICAL LASER UPDATE -- NOVEMBER 1996

10/28 **Laser Industries** reported its third quarter results, with a 16.5% increase in revenues to $14.6 million, and a net income gain of 41% to $2.2 million (25 cents/share). For the nine month period, revenues were $43.3 million, up 18%, and net income was $6.3 million (88 cents/share), up 55%. According to chairman and CEO Benjamin Givli, "Our results reflect the fast growing market for aesthetic applications...we offer the broadest range of systems ranging from low-end to high-end for the treatment of wrinkles."

10/31 **PDT Inc.** announced its third quarter results with revenues of $1.7 million and a net loss of $4.2 million (33 cents/share). For the nine months, revenues were $3.8 million and the net loss was $12.6 million ($1.10/share). During the quarter, PDT announced the agreement with **Pharmacia & Upjohn** for the co-development of a PDT therapy for eye diseases, similar to agreements for the fields of oncology, dermatology and urology. P&U will pay PDTI royalties, milestone payments, and reimburse the company for certain development and clinical expenses. The company has submitted an IND to start clinical trials with SnET2 for the treatment of BPH, and is in Phase II/III trials for cutaneous cancers, and Phase I/II trials in ophthalmology.

11/1 **ThermoLase** announced that it had signed a lease for a Spa Thira salon in Palm Beach, FL. The 4000 sq. ft. spa is expected to open in 1997. The company has 5 spas open; 2 more scheduled to open in November; and three additional leases signed.

11/5 **Laser Industries** announced that it had received marketing clearance from the FDA for the used of its Sharplan SilkTouch flashscan technology for hair transplantation. The company submitted data on 69 patients on whom hair transplantation was performed using the Sharplan SilkLaser, along with six-month followup results. The laser was used to create recipient holes in the patient's scalp so that hair grafts could be transplanted. The hair growth began, on average, at around nine weeks.

The company also noted that it had received notice of allowance from the U.S. Patent Office for its patent application covering the use of a scanner such as SilkTouch for hair transplantation. As noted by the company, according to the American Academy of Cosmetic Surgery, 197,276 people underwent the procedure in 1994, spending $789 million. It is estimated that 40 million men in the U.S. are bald, and about one-quarter spend roughly $550 million a year on drugs to grow hair or on the purchase of wigs or toupees.

11/5 **Ion Laser Technology** released its quarterly results showing revenues of $2.0 million and earnings of $74,700 (2 cents/share). Lynn Barney, president and CEO commented that revenues were up 40% over the previous quarter as the company continues to build its distribution of BriteSmile Laser Whitening systems, with over 50 centers nationwide, and an additional 40 sites under contract.

11/5 **DUSA Pharmaceuticals** reported its third quarter results with a loss of $1.7 million (18 cents/share) and only interest income of $225,000. The company is conducting multi-center Phase II trials for actinic keratoses and preparing for upcoming Phase III trials for AK and bladder cancer photodiagnosis. The company is also supporting ongoing development programs in hair removal, acne and endometrial ablation.

11/5 **ThermoLase** announced its fiscal year-end results with revenues of $27.8 million and a net loss of $1.4 million. Revenues for the quarter were $7.1 million and a net loss of $1.2 million (3 cents/share).

11/6 **Surgical Laser Technologies** reported its third quarter results with net sales of $2.4 million and a net loss of $2.5 million (25 cents/share). The third quarter loss included restructuring charges of $1.5 million (15 cents/share), which included severance charges as well as a writeoff of certain leasehold improvements made at its former manufacturing facility. New company president and CEO Keith Stoneback commented that the company has reorganized its domestic salesforce to focus on working with its customers to enhance utilization of our lasers and thereby create demand for our disposable products. The company is also evaluating opportunities to expand its international presence in certain important markets.

11/7 **Eclipse Surgical Technologies** announced its quarterly results with revenues of $2.9 million and a net loss of $674,000 (4 cents/share). For the nine month period, revenues were $6.8 million and the net loss was $1.3 million (9 cents/share). During the quarter the company shipped 15 TMR lasers, bringing the total number to 44; with 33 in the U.S.

11/11 In a study presented at the American Society of Plastic and Reconstructive Surgeons, being held in Dallas, Dr. Jay Burns reported that aggressive treatment of skin resurfacing with a CO_2 laser gave better longer lasting results than less aggressive

treatment. In a prospective study of 70 patients who received full face treatment, the first group receiving less aggressive treatment showed that wrinkles returning as early as three to six months, while the remainder of the study group who received aggressive treatment had longer-lasting results. (The press release did not state whose laser system was used.)

11/11 **Cardiogenesis**, reporting from the American Heart Association meeting in New Orleans, said that it had completed the first procedures in humans with its percutaneous myocardial revascularization (PMR) system. Two patients with angina resulting from severe coronary artery disease were treated last week at the Herzzentrum (Heart Center) in Frankfort, Germany. Cardiogenesis is the first company to initiate human clinical trials using this minimally invasive approach to the treatment of angina. According to the company, the treatments went as planned, with the first patient released from the hospital, and the second expected to be released this week. The PMR system is designed to be used by an interventional cardiologist in a cardiac catheterization laboratory in contrast to intraoperative TMR, performed by surgeons in an operating room. In PMR, a steering catheter is positioned within the left ventricle and the laser fired from the inside out.

11/11 **Trimedyne** became the latest entrant into the TMR field with the announcement that it had invested $2 million in **Cardiodyne**, a wholly owned subsidiary. Cardiodyne is developing a proprietary laser system for use in TMR. The newly formed company will use the Trimedyne Superpulse Holmium laser, as well as a proprietary Autofire automated firing system, and a proprietary disposable Channel Maker optical fiber device. Trimedyne said that it had sold more than 240 holmium lasers to hospitals throughout the world for other approved uses, many of which could be converted with the Autofire system to perform TMR. The Autofire system is designed to create holes through the heart wall in 1/5 second between heartbeats. Cardiodyne holds the basic U.S. patent on triggering the firing of a laser in the heart from the movement of the heart, reacting to a signal from the patient's electrocardiogram. This enables the channels to be made during diastole, when the heart is fully expanded and the wall is thinnest and there is less risk of an arrhythmia. The company plans to apply to the FDA for approval to commence clinical trials in early 1997. The initial trials will be performed as an adjunct to CABG, to provide an alternative source of blood to the heart muscle if one or more of the grafted vessels, or an unbypassed artery, fails. At about the same time, the company plans to request approval to commence clinical trials on humans in a minimally invasive procedure, through a needle puncture between the ribs. In this procedure, the placement of the Channel Maker optical fiber will be observed through an endoscope inserted into the chest cavity through a separate puncture beneath the rib cage. Eventually, the company foresees using its patented Spectraprobe optical fiber through a directable electrophysiology catheter, which would be moved into the left ventricle and fired from the inside out. The Spectraprobe fiber consists of a metal tip attached to the end of a tiny, very flexible

fiber. The metal tip contains a lens that diverges or spreads the laser beam enabling the device to create a channel larger than the optical fiber. It is approved for use in clearing plaque deposits in peripheral arteries.

Phillip Palmer, formerly vice president of corporate development at **St, Jude Medical**, has joined Cardiodyne as its president and COO.

Cardiodyne also holds exclusive licenses to two patents covering the Xpand expandable coronary laser catheter, which after insertion into a coronary artery, can be expanded to vaporize plaque blocking that artery. The catheter can also be used to vaporize clots or tissue which has grown into a stent used to prop open an artery after balloon angioplasty. This device has been successfully tested in a limited number of humans in studies conducted outside of the United States.

11/12 **PLC Systems** announced that clinical studies approved by the Japanese Ministry of Health would begin immediately. The company will ship an additional two Heart Lasers to **Imatron Japan** in the fourth quarter for these trials. The company had shipped six lasers to Imatron in December 1995 for the research and pre-clinical studies of TMR. Imatron has informed the company that Japanese MHW approval of the Heart Laser is expected in late 1997. With two lasers being transported between four hospitals, there will be a total of 10 clinical sites conducting the studies in Japan, and a total of 60 patients enrolled.

11/12 **Vidamed** has opened a web site to make information available to the public about BPH. It will feature the company's TUNA system, recently cleared to treat this condition, as well as patient information, a schedule of scientific meetings, recent news releases, and a bibliography of relevant medical articles.

11/13 **Palomar Medical Technologies** released its third quarter results with revenues increasing 321% over last years third quarter to $24.7 million and 41% over the previous quarter. The company had a net loss of $3.9 million (15 cents/share). For the nine month period, revenues were $49.2 million and the loss was $19.2 million (80 cents/share). The losses were attributed to the buildup of sales, marketing, and manufacturing capacity associated with new product introductions. In a teleconference held with analysts, Steve Georgiev revealed that medical systems sales contributed between $5 to $6 million of the revenues. Total company revenues are expected to reach $80 million in 1996 and $250 million in 1997, at which time the company will become profitable! The company expects to ship 40 to 60 Epilasers before the end of the year and 70 systems per month beginning next year. It is also shipping about 40 Tissue Technologies CO_2 lasers per month. In commenting about the ongoing clinical trials for hair removal, Georgiev noted that data on an additional 50 patients was submitted to the FDA on October 1st and that the company expects to get a favorable response from the FDA to market its Epilaser for this application within the next two

to three months. Commenting on the Zaias patent on hair removal (held by rival **Mehl/Biophile** and licensed to **Laser Industries/Sharplan**), Georgiev said that the company had received legal opinions that its procedure did not interfere, and the company, with MGH, had filed a series of patents that are expected to issue shortly. (Its international filings are now in the public domain and open to scrutiny.)

In a separate announcement on November 12th, the company announced that it had signed its third agreement to open cosmetic laser centers under a revenue sharing agreement. **Cosmetic Technology International**, a division of Palomar, had signed with **Healthcare 2000 International**, to provide a full line of cosmetic lasers and services to Healthcare's subsidiary, **CosmeticCare 2000**. According to Palomar, the deal is worth, at a minimum, $15 million. Along with the previously announced deals with **Equimed** and **Medical Alliance**, CTI has now signed deals valued at approximately $73 million after the opening of the 85-90 cosmetic laser centers planned, but which could go higher if demand for the laser services is as great as anticipated.

Commenting on the cosmetic laser center deals, Steve Georgiev noted that the company's goal was to participate in at least 200 laser centers operating in the U.S., and an equal number operating in Europe and in Pacific Rim countries. Negotiations are underway with companies that could become partners for the European and Far East expansions.

11/13 **Luxar Corporation** announced the availability of a new scanning system for skin resurfacing. The new scanning handpiece, called the SureScan system, is easily attached to the company's NovaPulse CO_2 laser system and offers the physician a choice of four computer-generated scanning patterns. In addition, the laser beam density is adjustable and the scan area can be optimized to fit the treatment zone. The SureScan offers pre-programmed laser patterns and settings for maximum beam manipulation. This advanced scanner will be offered in addition to the company's own NovaScan unit. According to company officials, the NovaScan is a $10,000 add-on, while the more versatile SureScan unit will sell for about $22,000. (This is in addition to the base price of the NovaPulse laser of $44,500.) The company claims it is currently the leading seller of CO_2 lasers, with an installed base of over 3500 units.

11/14 **Candela Corporation** announced that the Japanese government had cleared two of its lasers for treating skin conditions. Both the Alexlazr and PLTL Pigmented Lesion/Tatulazr lasers received approval from the Japanese Ministry of Health and obtained reimbursement approval from the National Health Insurance of Japan. The approvals are expected to expand the potential market for Candela in Japan, by adding 2000 public hospital sites.

11/14 **Premier Laser Systems** reported results for its fiscal second quarter, showing revenues of $1.2 million, up nearly five-fold from the same quarter a year ago, and a loss of $973,000 (20 cents/share). The strong second quarter sales were primarily due to sale of laser systems into the dental market, including its Auroa diode laser for soft tissue procedures and the Arago and MOD argon lasers for composite curing and, after FDA clearance in mid-August, for teeth whitening. Sales of lasers to ophthalmologists continued at a rate similar to the company's first quarter.

11/14 **Pharmacyclics**, the developer of lutetium texaphyrin (Lu-Tex), a photosenstizer for photodynamic therapy, released its third quarter results, showing no revenues and R&D expenses of $2.5 million, compared to $1.8 million for the same quarter last year. The higher R&D costs were incurred in clinical trials and patent costs. Lu-Tex is in Phase I clinical trials for treatment of cancer and atherosclerosis.

11/18-
11/19 **QLT PhotoTherapeutics** released its third quarter results showing a net loss of $2.7 million (12 cents/share) and with available cash reserves of approximately $92.3 million and no long-term debt. For the nine month period, the net loss was $10.5 million or 53 cents/share. The company's financials showed royalties on product sales of $175,000 for the quarter and $283,000 for the nine months, reflecting the early sales efforts by partner **Sanofi Winthrop**, who launched Photofrin sales in the U.S. on October 1st, and modest sales by **Lederle (Japan)** in Japan. The company hopes to meet three milestones in the fourth quarter: the initiation of registration studies for the use of BPD-MA in age-related macular degeneration; the filing of a comprehensive supplementary NDA in the U.S. for Photofrin for the treatment of non-small cell lung cancer; and the completion of negotiations for a European oncology partnership. *Dow Jones* reported that the company also planned to start Phase II/III trials of Photofrin to treat Barret's Esophagus early next year, with the FDA accepting the company's plans for the Barret's trials.

11/19 **Sunrise Technologies** announced that it had signed a letter of intent to sell its dental division to privately held **Lares Research** for $7 million, with payment in a combination of cash, notes, and stock warrants. Lares will pay Sunrise $5 million upon closing. The dental division is comprised of the MicroPrep air abrasion system for cavity preparation as well as a line of dental lasers. Lares is a leader in the manufacturing and distribution of quality dental handpieces. Sunrise intends to concentrate on the refractive surgery market.

11/19 **Cell Robotics** announced its quarterly results with sales of $130,000 and a net loss of $424,000 (10 cents/share). Year to date sales were $524,000 and a net loss of $1.1 million (80 cents/share). Company president Ronald Lohrding commented that with no long-term debt and cash of $2.1 million, the company is positioned to introduce its

new medical laser products, which have been favorably received by its target audiences.

11/19 **Pharmacyclics** announced that it had completed a private placement to an institutional buyor of 580,000 shares of unregistered common stock, raising $8.1 million. The company has agreed to register the stock six months after the date of closing. According to president Richard Miller, the additional capital, together with its cash balance, should take the company through late 1998 without the need for additional funds.

11/20 **Laser Industries** announced that it had received marketing clearance from the FDA for its patented SurgiTouch Flashscan CO_2 laser technology specifically for myringotomy, a procedure used to treat Secretory Otitis Media, commonly known as chronic ear infection. The laser myringotomy keeps the tympanic membrane open for several weeks without insertion of ventilation tubes, but with complete and spontaneous healing of the membrane. Lase myringotomy also allows endoscopic inspection of the middle ear cavity and its related structure. According to the company, over 1 million myringotomies with the insertion of ventilation tubes are performed annually in the United States alone. The procedure is usually performed in a hospital operating room under general anesthesia, making this an expensive and prolonged surgical procedure. Utilizing the SurgiTouch technique, the procedure can be done in a physician's office and only local anesthesia is needed for patients six years or older. The Sharplan SurgiTouch is part of a new line of laser accessories presented by Sharplan Lasers (the company's U.S. marketer) during the annual meeting of the American Academy of Otolaryngology in Washington, DC last month. Additional new equipment introduced by the company for ENT specialists included an advanced micromanipulator for larynx surgery and an endoscopic CO_2 laser fiber delivery system which allows surgical procedures to be performed in outpatient or private clinics rather than in the hospital.

11/21 **Luxar Corporation** said it is now marketing a medical laser system specifically designed for use by veterinarians on animal patients. The new CO_2 model, the AccuVet system, assists veterinarians in performing laser assisted dermatology, dermatologic ophthalmology, oral, and general surgery procedures. The new laser system is small and portable, enabling veterinarians to easily transport the unit between multiple hospitals.

11/21 **Premier Laser Systems** reported that a total of 160 argon laser systems for tooth whitening acceleration and composite curing procedures have been sold to dental practices throughout the U.S. during the last twelve month period. The value of these systems is approximately $2 million. According to the American Academy of Cosmetic Dentists, the overall market potential in the U.S. for billable tooth whitening

procedures, a significant percentage of which will be done with lasers, at more than $3 billion.

11/21 **Palomar Medical Technologies** announced that its **Spectrum Medical Technologies** subsidiary had signed an agreement valued at approximately $5 million to sell its Epilaser system to **Mutoh Novatek** for distribution in Japan. Mutoh Novatek is the exclusive export and marketing liaison in Japan for all Palomar lasers. According to the company, Japan represents a market estimated in the hundreds of millions for dermatological treatments with lasers.

11/25 **BioLase Technology** announced the conversion of 99 of 100 of its 6% Series A Redeemable Convertible Preferred Stock, issued in conjunction with a private placement, resulting in the issuance of 1.8 million shares of common stock. The effective conversion price was $2.75.

11/25 **Premier Laser Systems** promoted Daniel Caruso to senior VP, sales and marketing. Reporting to Caruso are the directors of International Sales and Marketing, the Dental Products Group, as well as the Surgery, Ophthalmology, and Dermatology Products operations.

MEDICAL/SURGICAL LASER UPDATE -- DECEMBER 1996

11/26 **Spectranetics** announced that it had filed a PMA for its excimer laser sheath, a device to remove pacemaker and implantable cardioverter defibrillator (ICD) leads. If the FDA approves the submission, use of the Laser Sheath will go from investigational status to full market release. The PMA was filed based on the results of clinical trials performed on more than 300 patients at 14 U.S. sites. The trial, begun in November 1995, and expanded to 20 sites earlier this month, will continue while the FDA reviews the submission. Pacing leads eventually become ineffective, requiring new leads to be implanted. Historically, the old leads had been left in place, because they were often imbedded in scar tissue making extraction traumatic and dangerous. The Laser Sheath works by using laser energy to ablate through the scar tissue around the lead, allowing removal.

11/28 **QLT PhotoTherapeutics** expects to post a profit in its fourth quarter, and in the first quarter of next year, according to company officials. The company doesn't expect to sustain quarterly profits for the remainder of 1997, but revenues from sales of its recently approved cancer therapy products could make the company profitable the following year. According to John Galbraith, CFO, "We need about $75 million in revenues to be profitable...most investment analysts think we can do this by 1998...based on the market research we've done with our partners, we should be able to achieve this." In an interview with Dow Jones, Galbraith said that Photofrin won't

be a blockbuster drug, with sales between $300 to $500 million a year because cancer therapy is too segmented, instead he is pinning his financial hopes on QLT's followup drug benzoporphyrin derivative (BPD), which is currently being tested to treat age-related macular degeneration, a disease widely recognized as a leading cause of blindness in older people. Galbraith expects QLT to be in position to start marketing BPD in 1999, with a faster ramp-up than with Photofrin. Julia Levy, QLT president went on to say that the company has had "extremely good results" from ongoing clinical tests involving 140 patients. The company recently applied to expand its test program to 500 patients at 18 centers, and is also planning to begin trials in Japan.

11/30 I received Steve Handley's Smith Barney November 25th report on **Coherent**, in which he upgraded his rating on the company from a high risk buy to a medium risk buy. He believes the company's stock price will reach $55 within 12 months from its present level of $40. In the report he discusses the company's medical laser business in some detail; breaking out surgical sales as 54% of fiscal year 96 total medical laser sales of $162.8 million, and ophthalmic sales of 34%. Service accounts for the remainder. Within the surgical sales of $88.4 million, UltraPulse CO_2 laser represented some $60 million (about 500 lasers at $120K), while the holmium and holmium/YAG VersaPulse orthopedic lasers accounted for $17 million. Disposables accounted for $11.4 million. Steve believes that UltraPulse sales will level off due to greater competition at lower prices, accounting for Coherent's introduction of lower priced UltraPulse models. He is also looking for the slack to be taken up by sales of the company's new VersaPulse Aesthetic line of lasers, which he believes will contribute $18 million in sales in fiscal 1997. Overall, he is anticipating a 28% increase in medical laser sales for fiscal 1997. According to his analysis, about 15% of UltraPulse sales are into Europe, and this will increase over the next several years. The new Aesthetic Laser line has started with the newly introduced VersaPulse VPW (variable pulse width). This is doubled YAG for treating vascular lesions, including facial veins and leg veins, portwine stains and vessel malformations. It lists at $125,000, compared to the 4 in 1 VersaPulse C announced earlier this year that will sell for $225,000. It is intended for the flexible treatment of pigmented lesions and tattoos (with three different wavelengths -- YAG, alexandrite, and doubled YAG), while the VPW version can be used for vascular lesions. The VersaPulse C is under consideration for use in hair removal, but additional clinical research is needed to ascertain its effectiveness for this application.

In the ophthalmic arena, Coherent markets the Schwind excimer laser internationally, except in Germany and Korea. (The company has decided not to enter the U.S. market because of the long FDA process.) Coherent's Lambda Physik subsidiary sells the excimer laser engines used in the Schwind Keratom to Schwind for about $80,000, and then Coherent sells the finished system internationally for about $350,000. Handley estimates that Coherent sold about 20 excimer systems in FY96, primarily in Latin America and China, and sold more than twice that number of excimer engines

to Schwind. According to Handley, Coherent is committed to becoming an increasingly strong participant in the PRK market and is developing a new non-excimer system (erbium ?), including a variety of accessories, which it hope to offer outside of the U.S. in about two years, at which time it would also begin U.S. clinical trials. Other ophthalmic lasers include the Ultima and Novus photocoagulators, and the Novus Omni, an argon-pumped dye laser that offers multiple color wavelengths, which is popular in Japan, and commands a premium price. The company also just introduced a new erbium laser for retinal and vitreal surgery, which sells for $150,000, and began shipping its $50,000 Selecta 7000 (a doubled YAG) for selective laser trabeculoplasty, for treating open angle glaucoma.

11/30 I also received both the 10-K and 1996 Annual Report from **Pharmacyclics, Inc.** The reports contain some interesting information about its photodynamic therapy programs. The 10-K reveals that the company is collaborating with **Coherent** for the development of a laser to produce 732 nm output (probably a diode laser), which is being used in the multicenter Phase 1 clinical studies. It has also purchased LED devices from **Quantum Devices** that are capable of producing the required wavelength for activating Lu-Tex (lutetium texaphyrin). The LEDs are in pre-clinical animal studies. According to the annual report, Lu-Tex has shown activity in breast cancer, melanoma, renal cell cancer, Kaposi's sarcoma, basal cell cancer and others, including some tumors that are resistant to radiation or chemotherapy treatments. Lu-Tex may have potential for treating large tumors because it is activated by longer wavelengths (720-760 nm) that can penetrate deeply into tissue. Lu-Tex is also being evaluated for the PDT treatment of age-related macular degeneration, and a topical form of Lu-Tex may be used for treating various applications in dermatology. Both of the latter are currently being studied in animal models.

12/3 **Premier Laser Systems** has named Bradley Bockhorst, DMD, as director of its Dental Products Group. Dr. Bockhorst will head the marketing and sales of Premier's dental laser products worldwide.

12/4 **PLC Systems** received FDA approval to expand the number of clinical sites for its Heart Laser trials. The company will now be able to use the Heart Laser as sole therapy for end-stage coronary artery disease on 300 patients at 20 sites. The company has two other IDEs for TMR using the Heart Laser, as an adjunct to cardiac bypass surgery and as an alternative to repeat bypass surgery.

12/4 **DUSA Pharmaceuticals** reported that it had started Phase 3 clinical trials using its ALA PDT for the treatment of multiple actinic keratoses. Two multicenter trials are being conducted at 13 leading U.S. dermatology research centers. Each blinded trial includes 100 patients, with each patient having 4-15 AKs of the face or scalp. Patients will be treated with 20% ALA topical solution which will be activated by a fixed dose of a non-laser blue light, using DUSA's proprietary light source. In the company's

Phase 2 trials, this combination resulted in 90% complete clearing of the lesions with one treatment, and 100% with two treatments. Active development programs continue in bladder cancer diagnosis, hair removal, treatment of acne, and endometrial ablation.

12/5-
12/6 Two announcements from **Mehl/Biophile International**. First, the company announced that it had placed a total of 20 of its Chromos 694 ruby long-pulse hair removal lasers with various professionals around the world. Each system is expected to generate a minimum of $15,000 per month revenue to the company. Systems have been placed in Denmark, Tasmania, New Zealand, Australia, England, Republic of South Africa, North Wales, Norway, Ireland, and Canada, with the latter the first system in North America. The company expects to have a total of 30-35 systems in place by year's end, and will produce 30 systems per month commencing in January 1997, in order to meet its goal of a minimum of 300 systems in operation by the end of 1997.

The following day, they announced that the company had commenced an action to terminate the joint venture agreement between it and **Laser Industries**. The joint venture was originally formed in December 1995 when Laser Industries and Classy Lady by Mehl of Puerto Rico, now owned by Mehl/Biophile, entered into a 50/50 venture, Sharplan 2000, to exploit the patented laser hair removal technology exclusively licensed to Classy Lady. The joint venture was to have been managed exclusively by Laser Industries. However, based on information discovered by Mehl, Classy Lady has brought an action to terminate the license granted to Sharplan 2000, and unwind the joint venture. The action is based on a dispute concerning the nature of technological and financial contributions made to the joint venture by Laser Industries and, an additional disagreement about whether Laser utilized technology within the joint venture, which was, in fact, developed by a third party, **SLS Wales Ltd.**, the laser company acquired by Mehl in June 1996 (an 81% interest) -- which has been renamed **SLS(Biophile) Limited** -- and from whom Mehl obtains its ruby lasers. In a separate action filed in England, SLS has commenced action against Laser Industries and SLS's manufacturer (**Spectron UK ?**), for orders preventing Laser Industries from using SLS's technology and stopping SLS's manufacturer from supplying SLS's technology to Laser Industries.

12/9 **Laser Industries** responded to the above suits. The company claims that it learned of both actions on December 6th. Laser Industries believes that the demand for arbitration on the joint venture, and the London lawsuit, are part of a "cynical campaign" orchestrated by Mehl/Biophile to interfere with Laser Industries' business interests and to destroy the joint venture so that Mehl's newly acquired subsidiary SLS(Biophile) can seek to monopolize the laser hair removal field. According to Ben Givli, chairman and CEO, "Laser Industries and Sharplan 2000 believe there is no

basis for Mehl/Biophile's attempt to terminate the joint venture, and that SLS(Biophile) Ltd. will not be able to compete lawfully with the joint venture...Laser and Sharplan 2000 intend to seek appropriate relief against Mehl/Biophile and its affiliates for the tortuous conduct and multiple breaches of contract and fiduciary duty, including filing claims for monetary damages."

12/10 **Laserscope** announced that it had signed an agreement with **Exim International Trading Company**, whereby Exim will market Laserscope products in China, Hong Kong, and Vietnam. Based in Orlando, FL, Exim is an export firm focused on sales and marketing of client' medical technology product lines to major purchasers and distributors in China and Vietnam. According to Exim's vice chairman Myron Freedman, "The total external investment in China's health industry is about $11 billion, with the medical device investment about $2 billion per year...with the rapid development of China's economy, coupled with the recent decree that China will provide universal health care coverage by the year 2000, the outlook for advanced medical technology manufacturers like Laserscope is very encouraging."

12/10 **Cell Robotics** announced the appointment of Travis Lee as vice president of sales and marketing. Mr. Lee, formerly with Laserscope/Heraeus Surgical, will be responsible for the 1997 launch of three new laser-based medical products, and ongoing corporate sales and marketing. The three new products are the Lasette, a laser finger perforator for painless blood sampling; an in vitro fertilization workstation, and an erbium laser for skin resurfacing.

12/11 **Ion Laser Technology** has signed an agreement with **Teeth White Laser Centers, LP**, a Dallas-based business group, to establish up to 36 BriteSmile Laser Tooth Whitening Systems in dental offices within the Dallas/Ft. Worth Metroplex area. The agreement requires that 15 systems be installed within the next 12 months. Five dental locations have already been determined, and systems will be shipped in December for early 1997 installation and training. Five additional systems are to be shipped in January. The agreement is similar to the one signed this summer with a Las Vegas firm, representing up to 12 BriteSmile systems for that area. Four of the 12 systems will have been purchased by the end of this month.

12/12 **Candela Corporation** plans to enter the skin resurfacing market with an agreement reached with **Fotona d.d.**, a laser company located in Slovenia, to market internationally that company's erbium:YAG laser, known as Skinlight. The advanced Skinlight system includes scanning technology and higher average power than any erbium device now in use, to provide minimal thermal damage to the skin, which will provide faster recovery times than many of the devices on the market today. Application for approval in the U.S. has been filed by Fotona. Meanwhile, Candela will begin overseas marketing and training to serve the global markets including the

Far East, South America, South Africa, and some European countries. The agreement with Fotona does not include the United Kingdom, France, or Germany.

12/15 Two recent publications had major articles covering the growing applications for erbium lasers. Volume 19 of *Lasers in Surgery and Medicine* had an article by Kaufman and Hibst on "Pulsed Erbium:YAG Laser Ablation in Cutaneous Surgery", which discussed the use of a pulsed erbium laser for skin resurfacing. The authors concluded that the laser was good for precise etching of delicate superficial skin lesions and had the potential for skin resurfacing. The second article, in the November/December issue of *BioPhotonics International*, written by Klaus Vogler of **Lambda Physik** and Max Reindl of **Wavelight Laser** of Germany, discussed all of the new applications under evaluation with erbium lasers, including dentistry (soft and hard tooth applications), dermatology (skin resurfacing), otolaryngology (?), and three applications in ophthalmology -- phacoemulsification of the nucleus (cataract removal), sclerostomy (glaucoma treatment) and PRK (reshaping of the cornea). One application not mentioned was Coherent's use of erbium for vitreoretinal treatment. (This is an excellent article. Anyone wishing a copy should call me.)

12/15 According to a new publication from the publishers of *The Gray Sheet*, called *The Silver Sheet*, covering regulatory matters only, are two notices about FDA warning letters to laser manufacturers. In the first, **Dynamic Light Ltd.** received a warning letter on October 31st for its VisErase dermatologic laser for lacking recalibration procedures. The second letter went to **Premier Laser Systems** on November 6th, stating that the instruction manual for its Aurora diode surgical laser system lacked calibration procedures. The firm was also cited for failing to submit annual reports to the FDA for its laser products.

12/15 I received the 10Q for the quarter ending September 30, 1996 for **Physicians Laser Service**. The company, which rents lasers to doctors in Florida, Connecticut, and New York, had third quarter revenues of $117,000, and a net income of $4730. For the nine months, the company had revenues of $299,300, and net income of $48,400. According to the 10Q, the company acquired **PLSVA** and **PLSNY** on October 30th, and November 4th, respectively, and intends to make one additional acquisition (**Tri-State Laser Corp**., before the end of the year, pursuant to an executed letter of intent, and four acquisitions in 1997. Through August 1996, the company had identified 10 acquisition candidates. Sales for the year ending Dec. 31, 1996 are projected to $1 million, compared to the nine month sales recorded of $497,000. With the four additional acquisitions, the company expects to generate revenues of $4.7 million in 1997, with a pre-tax profit of approximately $716,000. The company also expects to have a private offering in 1997 to raise approximately $3 million in capital.

12/16 **Coherent Inc.** announced that it had expanded its semiconductor laser capabilities through the acquisition of 80% of the shares of **Tutcore OY Ltd.**, of Tampere,

Finland, with an option to acquire the remaining shares in the future. Tutcore specializes in the growth and processing of aluminum-free epitaxial wafers for the production of semiconductor lasers, of which, Coherent is the world's largest manufacturer for scientific, medical, and commercial applications. According to Coherent, the demand for laser diodes in these markets is currently about $200 million annually, and growing rapidly.

12/16 **Fahnstock & Co.** analysts Juan Noble and Ed White have initiated coverage of **PLC Systems**, with a buy rating. (I have requested a copy of this report, but am still awaiting its arrival.)

12/18 **Laserscope** announced that it had filed three 510(k)s for 1) its new Laserscope erbium:YAG laser system, 2) the Parascan scanning device to perform skin resurfacing using the Paragon CO_2 laser system, and 3) a new Q-switched YAG configuration of its Orion laser system, for tattoo removal. The erbium laser system' approval will pave the way for U.S. sales of this laser presently manufactured by Laserscope's newest subsidiary, **NWL Laser Technologie**, of Germany. Laserscope currently holds a 32% equity interest, which it expects to increase to a majority position later this year. According to the company, the three submissions will further enhance its position in the aesthetic laser treatment market, which has been estimated, by analysts, to grow between $4 billion to $5 billion a year within 5 years, from its less than $1 billion today.

12/18 **Ion Laser Technology** announced that it had received notification from the Patent Office of the allowance of claims for a patent for a dental device delivering substantially collimated (laser) light for curing composites, used by dentists in place of metal fillings to fill cavities and match the color of the tooth. The delivery device will couple with the company's high powered argon laser to ensure the proper amount of energy delivery to optimally activate the photo-thermal reaction, while minimizing under-activation. According to Lynn Barney, company president and CEO, it appears that at least one company may be in violation of the patent when it issues. The company is also pursuing a similar patent/claim for use with its tooth whitening process.

12/18 **Eclipse Surgical Technologies** announced that it had received approval to market its TMR laser into the European Community countries, with receipt of the CE Mark. Receipt of the Mark allows the company to formally launch its TMR laser into Europe through its international distributor, **Sorin Biomedica Cardio SpA**, according to the company, one of the leading open-heart surgery supply companies in Europe. Eclipse believes that the market outside of the U.S. is comparable in size to that within the United States. Eclipse has shipped more than 50 TMR lasers in 1996, with recent installations in China, Australia, Italy, Spain and the Netherlands.

12/18 **QLT PhotoTherapeutics** and **Speywood Pharmaceuticals Ltd.**, part of **Beaufour Ipsen**, a leading European pharmaceutical group, announced the signing of a licensing, co-development, and marketing agreement, for the exclusive European marketing and distribution rights to Photofrin and one of QLT's second generation compounds (BPD ?), the PDT drugs for treating cancers. Specifically, the drugs will be used for treating cancerous and pre-cancerous disease conditions including Barrett's esophagus and benign prostate hyperplasia. For the rights, Beaufour Ipsen will provide up to $28 million in access fees, milestone payments, and minimum R&D funding commitments. The R&D funding for Europe will complement the work by QLT and its other strategic partners outside of Europe. Additional R&D costs in excess of the minimum commitment of Beaufour Ipsen will be shared equally by BP and QLT. QLT will be responsible for manufacturing and BP will pay QLT a royalty on product sales plus a manufacturing transfer price. BP will assume primary responsibility for European clinical and regulatory work related to oncology submissions for Photofrin and the second generation product. According to Dr. Julia Levy, president and CEO of QLT, "This new alliance will ensure we are able to move quickly to complete drug registration for Photofrin in Europe, expand our label claims for Photofrin, and successfully develop a second-generation oncology compound for Europe." In Europe, Photofrin has been approved for the treatment of early and advanced cancers of the lung and esophagus in France and the Netherlands. Product license applications seeking marketing approval for Photofrin are also under review in five other European countries, including Italy and Germany. According to a company executive of Beaufour Ipsen, nearly 40% of the world market for oncology drugs is located in Europe, making it an important world area for oncology drug marketing.

12/19 **PDT, Inc.** announced that its device manufacturing subsidiary had been recommended for registration to ISO 9001 and EN 46001 quality standards, prerequisites for obtaining the CE Mark, allowing marketing of medical devices into the European Community.

12/19 **ESC Medical Systems** announced that it had filed a 510(k) application for clearance to market the Topaz 30 surgical CO_2 laser system in the U.S., for general surgical and dermatological applications, including skin resurfacing. According to the company, the Topaz has received strong international acceptance, with the sale of over 50 systems. The laser is manufactured by **LBT Ltd.** of Israel, recently acquired by ESC Medical. LBT specializes in the development and manufacture of minimally invasive laser systems for the cosmetic/medical markets. The Topaz 30 will compliment ESC's Derma 20 erbium:YAG laser system (also from LBT), which is also awaiting FDA marketing clearance for cosmetic applications, including skin resurfacing/wrinkle removal, and the Epilight hair removal system, also awaiting FDA clearance.

12/19 **ThermoLase Corporation** said that it intends to offer shareholders the opportunity to exchange one share of existing common stock and $3.00, for a new ThermoLase unit,

consisting of one share of common stock and one redemption right. The redemption right would entitle the holder to sell the related share of common stock to the company for $20.25 during the first 20 business days after the fourth anniversary of the closing of the exchange offer. The redemption right would expire and become worthless if the closing price of the common stock had been at least $26.00 for 20 of 30 consecutive trading days. The company's obligations under the redemption rights would be guaranteed on a subordinated basis by **Thermo Electron Corporation**, the company's ultimate parent.

12/19 **Palomar Medical Technologies** announced that its **Cosmetic Technology International** subsidiary had signed its first international revenue sharing agreements in the United Kingdom and in Australia, to provide cosmetic lasers and services. In the UK, CTI will provide a full line of dermatological lasers and services to **Independent British Healthcare (IBH)**, a private chain of 17 hospitals, in an exclusive five-year revenue sharing agreement. In Australia, CTI will provide lasers to 10 centers in cities located throughout the continent. The two agreements have a combined total minimum worth of $43 million, according to Palomar. Under terms of both agreements, CTI will provide marketing, operational support, service and training. Additionally, Palomar will establish CTI United Kingdom in London, and CTI Australia in Sydney, in conjunction with **Dynamic Light** companies in the UK and Australia, as CTI's country managers to oversee operations and to identify potential new partners. With $73 million in previous U.S. agreements, the new agreements puts Palomar's licensing deals over the $110 million mark.

12/20 **BioLase Technology** announced the signing of a three-year distribution agreement for its Millennium Hydro-Kinetic Tissue Cutting system with **Orbis High Tech Dental GmbH**, the largest high-tech dental equipment distributor in Germany. Under the contract, Orbis has made a purchase commitment in excess of $12 million, for the non-laser tissue cutting device. (The hydro-kinetic technology utilizes electro-magnetic energy pulses to rapidly energize and transform atomized water droplets into microscopic high-speed water particles that cut tissue. The company is seeking FDA clearance for the device for use in dentistry, and dermatology, including cosmetic surgery.) BioLase intends to move forward with its marketing efforts for the device throughout Europe and the Pacific Rim countries in 1997.

12/23 **Cell Robotics International** announced that it had provided clinical data in a 510(k) notification to the FDA regarding its new Lasette laser finger perforator, that will be used to produce a small hole in a patient's finger for the collection of a few small drops of blood, in a nearly painless manner. The Lasette is intended for use by diabetic patients to keep better track of their glucose levels, by reducing the discomfort of finger pricking, and encouraging more frequent monitoring. The Lasette is compact, approximately 1½"x3½"x7" in size, similar to a small zipper notebook used to carry a daily planner, and battery operated. (I believe that it is an erbium:YAG

laser.) According to the company, the diabetic market consists of about 20 million patients worldwide, who should test their glucose level four times a day, although many do not test that frequently, primarily because of the pain associated with using a steel lancet.

12/23 **Medical Laser Technologies**, a developer of medical-imaging equipment, announced that it has terminated its negotiations with **R.F. Management Corporation**, a provider of financial and management services to the medical imaging industry, concerning the merger of the two companies, because the two were unable to agree upon a plan of action.

12/26 **The Gargiulo Group**, a division of **Oscar Gruss & Son**, has issued an investment summary on **Laserscope**, upgrading its rating from a hold, to a buy rating. This preliminary report states that with the acquisition of **Heraeus Surgical**, Laserscope has become the largest non-ophthalmic laser company in the world. (I think that Coherent might dispute this!) Although Laserscope experienced a decline in revenues and an operating loss in 1995, due to the further slowdown in the U.S. capital equipment market, the reconfigured company should see a strong revenue and earnings rebound, especially with sales directed toward the strongly growing cosmetic surgery market. The report points out two laser products with growth potential: the Aura doubled YAG laser for spider and leg veins; and the Paragon CO_2 laser for the skin resurfacing market. According to the report, since its launch in December 1995, Laserscope has received orders for over 150 Aura systems, while the Paragon laser should compete very well against the established Coherent and Sharplan systems in the $110 million market that is growing at 10% annually. At present, Laserscope is shipping the Paragon laser for $60,000 ($80,000 with a scanner) in the U.S. versus Coherent's price of $125,000. (But Coherent just introduced two lower priced models, starting at $75,000 (without a scanner) and $90,000 with. And Sharplan and others sell their CO_2 lasers for appreciably less! Also, the report does not mention Laserscope's recent acquisition of a 32% interest in NWL of Germany, and its erbium laser technology for wrinkle removal (see the 12/18 brief)! In speaking to the analyst who wrote the report, Justin Tang, I was told that a more comprehensive report on the company, which would include the latter information, is in the works, and will be published shortly. I was promised a copy.)