**MEDICAL/SURGICAL LASER UPDATE -- JANUARY 1998**

12/15 *The Gray Sheet* contains additional information about the **Spectranetics'** 12 Fr. laser sheath for pacemaker/ICD lead removals, recently approved for marketing -- see the December 11th brief last month. Seminars for new users will start in January, with shipments beginning immediately to the 39 U.S. clinical sites that have already been trained in use of the device. The fiberoptic system sells for $1850, and is used in conjunction with the company's CVX-300 excimer laser, which sells for $185,000. The FDA is requiring Spectranetics to perform a two-year post market surveillance study to asses long term safety and efficacy of the laser sheath system.

In the PMA, one-year data on 244 laser sheath-assisted removals showed 94% were completed with no major complications, compared to 64% of 221 leads removed in a cohort study using conventional extraction tools. The company estimates that about 480,000 pacemaker and ICD leads are implanted worldwide annually, of which about 10% may require removal for medical reasons. The company is developing larger sizes of the laser sheath, with clinical trials for sizes 14 and 16 Fr. ongoing. The company hopes to submit PMA supplements for the larger size sheaths in the second quarter of 1998.

12/29 I received the **Cell Robotics International'** preliminary "red herring" for its common stock offering. The company seeks to offer 2 million shares at between $4 and $5 per share. This will raise the number of outstanding shares to 7.2 million. The products highlighted in the offering statement are the Lasette finger perforator; its in vitro fertilization workstation; its LaserTweezers and LaserScissors workstation; and the RevitaLase, an erbium:YAG dermatology laser. The latter product has received FDA clearance but is undergoing continuing testing to finalize protocols for clinical use. The company expects to begin shipping the RevitaLase during the first quarter of 1998. The prospectus notes that the erbium crystals used in the Lasette and RevitaLase are produced in Russia, through a strategic relationship, which gives the company a significant cost advantage over competing systems. However, the continuation of this relationship with its Russian source is in doubt due to current unresolved disputes, including questions related to crystal quality. If this source of supply is cut off, the company could lose it strategically important competitive advantage.

12/29 Although not strictly a laser device, **Computer Motion's** surgeon-controlled robotic arm, AESOP, now with Voice Control (AESOP 3000), was granted 510(k) clearance for assisting in new, advanced minimally invasive heart surgery procedures. The surgeon-controlled robotic arm is capable of maneuvering and positioning an endoscope containing a light source and video pickup, in thoracic procedures, with the surgeon able to control the arm's movements using a proprietary speech recognition

technoloy, allowing direct voice control over the robotic arm. Obviously, this technique could include laser TMR at some point in its development.

12/31 **Pharmacyclics** announced that it had filed a registration statement with the SEC for a public offering of 1.75 million primary shares of common stock. Following the offering, the company will have approximately 11.9 million shares outstanding. The offering is being underwritten by **Hambrecht & Quist**, **Cowen and Company**, and **Pacific Growth Equities**.

12/31 **Trimedyne** reported its financial results for the fourth quarter and fiscal year ended September 30th, which included results for its 90% owned subsidiary, **Cardiodyne**, on a consolidated basis. Revenues for the quarter were $2.8 million, an increase of 14% over the preceding quarter, but 11% less than for the same quarter a year ago. The net loss was $1.3 million (12 cents/share), which included $596,000 of startup and R&D costs for Cardiodyne. For the fiscal year, revenues were $9.3 million, a decrease of 2% from the prior year. The net loss for the fiscal year was $5.8 million (51 cents/share), including $1.5 million for Cardiodyne.

As reported earlier -- see the November Briefing -- Cardiodyne has filed an application with the FDA to commence human clinical testing. The company now expects to begin testing its myocardial laser revascularization system in April 1998, at which time the company also expects to begin marketing the system outside of the United States. Trimedyne is also developing a "new type" of laser for use in cosmetic surgery -- see last year's August 15th brief -- but no news of when it might be shown to the public was forthcoming other than its name, the Monarch Cosmetic Laser.

1/1 The December issue of *The Journal of Clinical Laser Medicine & Surgery* is devoted to clinical papers and historical overviews of the field of transmyocardial revascularization. Papers by Timothy Sanborn, MD, a pioneer in the use of lasers in cardiology, trace the history of laser use in cardiology, and Mahmood Mirhoseini, MD, the inventor of TMR, traces its history. Other papers provide clinical data on the use of the $CO_2$ laser, the holmium laser, and the excimer laser in TMR; the use of both outside in and inside out techniques; and a final paper by Robert March looks at current experiences and future directions for TMR.

1/6 **Premier Laser Systems** announced redemption of its Class A Warrants, pursuant to the December 5th announcement. A preliminary count indicated that more than 95% of the approximately 2 million warrants outstanding were converted at $6.50.

The company also said that it had finalized a letter of intent with **Henry Schein Inc.** to become a distributor of Premier's dental laser products. The non-exclusive agreement involves the domestic sales of four models of lasers for the dental market, including the Centauri erbium:YAG for use in decay removal and related hard tissue

applications; the Arago and MOD argon lasers for composite curing and teeth whitening procedures; and the Aurora diode laser for soft tissue surgery.

1/6 **QLT PhotoTherapuetics** announced that in conjunction with its European marketing partner, **Beaufour Ipsen Group**, it was submitting applications in nine European Union countries, including the UK, for approval of Photofrin as a treatment for certain lung and esophageal cancers. The applications were filed in the UK, Ireland, Spain, Portugal, Belgium, Denmark, Sweden, Finland, and Greece. As a result of the filings, QLT expects to increase the availability of Photofrin over the next 12 to 18 months so that an even greater number of lung and esophageal cancer patients can access the technology. A spokesperson for Beaufour Ipsen said that he expected the drug to have widespread commercial availability throughout Europe by mid-1998. Photofrin has already been approved in the Netherlands for certain lung and esophageal cancers and is being marketed for these indications in France, and in Germany for early lung cancer. Approval in Italy is pending.

1/6 **Spectranetics** said that it had obtained a $5 million credit facility from Silicon Valley Bank of Boulder, CO, to support working capital and finance new and existing fixed assets. The credit facility, along with a $6.1 million supply and license agreement recently reached with **U.S. Surgical**, to use its excimer laser in conjunction with that company's TMR studies, strengthens the company's financial resources, according to president Joseph Largey.

1/6 **American Dental Technologies** announced that it had granted a non-exclusive license to **Continuum Electro-Optics** for its U.S. Patents 5,257,935 and 5,342,198, and foreign counterparts, for the use of erbium:YAG lasers for cavity preparation, in exchange for the agreement of Continuum to pay royalties. Additionally, the companies agreed to jointly defend the patents and continue discussions for joint marketing of erbium lasers in hard tissue dental applications. Continuum is a subsidiary of **Hoya Corporation USA**, which is wholly owned by **Hoya Ltd.** of Japan. Hoya has been manufacturing and selling erbium dental lasers in Japan for over 3 years.

1/6 As reported in the "Heard on the Street" column in *The Wall Street Journal*, **Paine Webber** strategist Edward Kerschner included **Eclipse Surgical** among his 31 favorite drug and medical companies likely to be acquired.

1/7 **QLT PhotoTherapuetics** announced the initiation of a Phase III pivotal clinical trial to investigate the use of Photofrin as a treatment for Barrett's esophagus, a pre-cancerous condition that afflicts up to two million Americans. The randomized trial will be conducted at approximately 30 sites in North America and Europe and will involve 200 patients with high-grade dysplasia, which is the final stage of abnormal tissue transformation associated with Barrett's esophagus before the onset of esophageal

cancer. According to the company, an estimated 20 million Americans suffer from chronic heartburn, and 10% to 13% will develop Barrett's esophagus. Of these, approximately 90% have metaplasia, and 10% have dysplasia. Patients with dysplasia can further be broken down into 60% with low-grade dysplasia and 40% with high-grade. Patients with Barrett's esophagus have a 30 to 40 times greater chance of developing esophageal cancer than people without Barrett's. There is no currently approved treatment to reverse the condition and decrease the risk of developing cancer. PDT, as a minimally invasive out-patient procedure appears to fill the bill. In earlier clinical trials of Photofrin, based on a group of 55 patients with dysplasia or superficial esophageal cancer, preliminary results showed that the dysplasia was eliminated in 76% of patients, and the superficial cancer successfully eliminated in all the seven patients who had this diagnosis.

1/7 As reported in *Medical Industry Today*, a Montreal, Quebec company called **Theratechnologies** yesterday filed a request with Canadian health regulators to begin human clinical trials of its PDT ex vivo purging process to treat chronic myeloid leukemia (CML). The company said that it plans to form strategic alliances to push other products into the clinical development stage. The CML purging process involves withdrawing bone marrow or peripheral blood samples from patients, saturating the cancerous cells with the company's patented photosensitive molecule TH 9402, and purging them by exposure to an activated light source. Preclinical trials have shown that the purging process not only destroys cancerous cells, but allows healthy stem cells to survive. The cells are then re-infused into the patient through an autologous graft, to restore the bone marrow function. The request in Canada is equivalent to an IND request that the company filed in the U.S.

1/9-
1/12 **QLT PhotoTherapeutics** announced that it had received marketing approval for Photofrin as a potentially curative treatment for certain types of early-stage microinvasive lung cancer. Specifically, the FDA approved Photofrin for the treatment of microinvasive endobronchial non-small cell lung cancer in patients who are not indicated for surgery or radiotherapy. This new option, which can be performed on an outpatient basis, is now available for people whose lung cancer is diagnosed at an early stage, but for a variety of reasons, are not eligible for surgery or radiotherapy. Dr. Julia Levy, QLT president and CEO noted, "This is a landmark decision for Photofrin, PDT, and for QLT. It marks the first North American approval of the technology as a potentially curative treatment, which is where PDT can provide the greatest benefit to patients."

According to the American Cancer Society, the 5-year survival rate for the 178,000 Americans diagnosed with lung cancer each year is only 14%. The poor survival rate is attributable to the fact that only 15% of lung cancer is detected at an early stage.

Improved techniques for early detection make the outlook for the disease more promising.

The FDA approval includes marketing clearances for laser systems from **Coherent** and **Laserscope**, along with a fiber optic delivery system, the Optiguide Cylindrical Fiber Optic Diffuser, produced for QLT by Laserscope. Photofrin is marketed exclusively in the U.S. by **Sanofi Pharmaceuticals**, the U.S. pharmaceutical unit of **Sanofi, Inc.** The lasers approved include two Coherent Lambda Plus models, the PDL1 and PDL2, and two Laserscope dye modules, the Series 600 and 630, that attach to its KTP lasers, the Series 800 Laserscope Surgical Laser Systems.

According to Sanofi Pharmaceuticals, there are currently 50 medical centers in the U.S. with the resources available to provide PDT with Photofrin. Laserscope reported that coordinated marketing activities with Sanofi could commence as early as the second quarter of 1998.

1/11 *The Chicago Tribune* carried a story about cold laser therapy, the use of the **Henley Healthcare** Microlight 830 diode laser, being used by chiropractor Lloyd Fielder, to augment natural healing in soft tissues, such as tendinitis and carpel tunnel syndrome. The laser is being used in a clinical study to determine the effectiveness of low-level infrared laser energy in the treatment of pain, muscle/joint injuries, and soft tissue injuries. According to Fielder, each medical professional taking part in the study is limited to treating 250 patients with the laser. Joyce Heinrich, director of regulatory affairs for Henley (formerly **Lasermedics**), said that the study began during the third quarter of 1995 and is expected to be finished within a year. The actual end, however, is dependent on when investigators finish treating their allotted number of patients. Once this information is collected, Henley/Lasermedics will turn it over to an independent review board for analysis, with the results going to the FDA for clearance to market the laser system. Fielder, who is also using the laser for treating carpel tunnel syndrome, noted that patients he has treated usually start seeing results after about five treatments and appears to be more effective than surgery, which carries a less than 50% success rate.

1/11 **Laserscope** released preliminary financial results for the fourth quarter and year. The company expects revenues for the quarter to be between $14.2 and $14.4 million, and for the year to be between $61 and $62 million. (The latter is $1 million short of our estimated results.) For the quarter, the company will realize a net loss between $1.2 and $1.7 million (9 to 13 cents/share), while for the year, net income is expected to be between $0.8 and $1.3 million (7 to 11 cents/share).

The company indicated that lower than expected fourth quarter orders for laser systems in the U.S., and shipment delays in operating room products to U.S. hospitals affected its quarterly revenues adversely. These somewhat lower revenues resulted in

approximately break-even profitability for the quarter, with a non-cash inventory charge of between $1.2 and $1.7 million, relating to excess laser and hospital equipment in order to more closely balance inventory with anticipated future requirements.

1/12 **Medical Industries of America** announced the cancellation of its formal letter of intent to acquire Florida-based **Physician Laser Services**, as previously announced last October. Following an extensive due diligence and negotiation process, MIA has elected not to proceed with the acquisition.

1/12 **Indigo Medical**, a **Johnson & Johnson** company, announced that the Indigo LaserOptic Treatment System had received FDA marketing clearance for the treatment of enlarged prostates or benign prostate hyperplasia (BPH). The Indigo system combines fiber optics with a diode laser, which, using indirect visualization, can be used to quickly and safely destroy a precise area of the prostate in a procedure known as interstitial laser coagulation. In a comparison study against TURP (transurethral resection of the prostate), the laser treatment required 52% less hospitalization time than the TURP treatment, and resulted in a statistically significant improvement in AUA score, peak uroflow rate, and quality of life assessments over a six-month evaluation period. The Indigo system is currently in use at approximately 55 sites across the country, including some of the leading centers of prostate treatment, and will become more widely available in the coming months. The system, also known as the Indigo 830e, is an advance on the Indigo 830, which was marketed only in Europe.

1/13 **Laser Photonics** announced that it had initiated a series of agreements with **Massachusetts General Hospital (MGH)**, relating to the use of the company's proprietary excimer laser developed by its subsidiary, **Acculase, Inc.**, for among other things, the diagnosis and treatment of psoriasis. The agreement includes an exclusive worldwide royalty-bearing license for an invention pertaining to Phototherapy Methods and Systems, developed through research conducted by Rox Anderson, MD, of MGH, for which the hospital has filed a provisional patent application. Additionally, the company has agreed to fund research, to be conducted by Dr. Anderson at the **Wellman Laboratories of Photomedicine**, using the Acculase excimer laser system, which is expected to lead to a 510(k) application for the use of the combined proprietary technologies developed by the company and MGH. Laser Photonics and Dr. Anderson believe that the use of the company's excimer laser as a source of UV light, and its delivery system, combined with MGH's phototherapy methods and systems technology, will significantly improve the number of treatments needed to obtain clearance of remission of psoriatic plaques, by targeting only the skin lesions and not healthy skin.

The Acculase excimer laser is currently being used for the treatment of coronary heart disease through TMR, in clinical trials at New York Hospital, Cornell Medical Center, and The Hospital of the Good Samaritan, Los Angeles. The rights to the cardiovascular and vascular markets have been licensed to **Baxter Healthcare**, a subsidiary of **Baxter International**.

1/13 Two seemingly unrelated articles appeared on the same page of the January issue of *Medical Laser Report.* The first article related to the issuance of a patent, U.S. 5,620,439 to **Spire Corporation** and Dr. George Abela. The patent is for a catheter and technique for endovascular myocardial revascularization using a diode-pumped endolaser, i.e., pumping a solid-state crystal laser located at the end of an optical fiber. The distal laser could be made of a crystal such as erbium:YAG, giving the ability of delivering erbium energy within the body, without the need of transmitting it through a zirconium fluoride-type fiber. The second article discussed the increase in investment of **C.R. Bard** in **CorMedica Corporation**, and the development and supply agreement reached between CorMedica and **Surgical Laser Technologies**.

But the two articles are related. George Abela is one of the founders of CorMedica, and the patent could be the nucleus of future delivery systems for that company. In a discussion with president Frank Martin, I learned that both Spire and Dr. Abela will share the use of the patent, which would be developed by Spire. Frank also confirmed what I had guessed in the brief about the agreement with SLT, that the laser supplied to CorMedica by SLT is a holmium:YAG, that is being used in CorMedica's clinical trials for percutaneous TMR, called PTER (percutaneous transluminal endocardial revascularization) by CorMedica. Frank also mentioned that CorMedica has been notified about the allowance of a key patent covering their tracking and navigation catheter which is an important part of their PTER approach. He expects the patent to issue shortly.

1/13 Another article in the same issue of *Medical Laser Report* discusses a new approach to the treatment of brain hemorrhages following a ruptured aneurysm or head injury, using a pulsed laser. Recent animal research done by Dr. Rox Anderson of the **Wellman Laboratories of Photomedicine**, part of **Massachusetts General Hospital**, using a laser catheter is showing promise in reversing vasospasm caused by subarachnoid (middle of the brain) hemorrhage. The new treatment utilizes an ultrapulsed laser to generate cavitation inside a catheter, launching a fluid wave. Autologous blood or saline is driven at a high velocity out of the end of the catheter, causing a sudden increase of pressure directly at the end of the catheter which dilates the artery in a fashion similar to balloon angioplasty. As Dr. Anderson calls it, "Its a laser-driven squirt cannon!" According to Dr. Anderson, the technique works quite well in reversing spasm, opening the relaxed vessel, without apparent side effects. The laser technique is being developed by the Wellman Labs in conjunction with

**Schwartz Electro-Optics**. Dr. Anderson expects the treatment to enter human clinical trials within the next year.

1/14 **Palomar Medical Technologies** announced that it had received approximately $6 million in orders for 50 EpiLasers since the partnership with **Coherent, Inc.** began in November. To date, 40 of the 50 orders have been shipped, with the remaining units scheduled for imminent shipment. Bernard Couillaud, president and CEO of Coherent said, "Our entry into the hair removal market with Palomar's EpiLaser has yielded exceptional success so far, and is serving as a perfect compliment to our complete line of cosmetic lasers that we currently offer to physicians worldwide." According to Palomar, more than 200 EpiLasers have been installed worldwide, and more than 30,000 hair removal treatments have been performed. In addition, Palomar's **Cosmetic Technology International Inc.** subsidiary, has now established more than a dozen revenue sharing laser centers in the U.S. and abroad.

1/15 **Premier Laser Systems** said that it had completed the Class A Warrant redemption, first reported in our January 6 brief. During the warrant call period, 2.2 million, or approximately 99% of the outstanding warrants were exercised, resulting in gross proceeds to the company of more than $14.3 million.

1/15 **Candela Corporation** announced that lower than expected sales of medical laser devices, and a decision to close it Scottsdale, AZ skin care spa, resulted in the company posting a fiscal second quarter net loss of $4.4 million (78 cents/share), compared to a net income of $736,000 for the same period a year ago. The company said that medical devices sales accounted for approximately $232,000 (4 cents) of the loss, with the skin care center accounting for $1.053 and a restructuring charge of $2.6 million, primarily for the closing of the Scottsdale facility, accounting for the bulk of the remainder. A charge against earnings of $550,000 to recover receivables from one of the company's outside distributors, was also included in the quarterly loss.

Sales for the quarter were $8.5 million, compared with $9.4 million a year ago. The current year's sales were below expectations for both medical and aesthetic lasers, including a significant decline in orders from South Korea and else\where in the Far East. For the first half of fiscal 1998, Candela reported sales of $16.4 million and a net loss of $5.3 million (94 cents/share). (The company hit our target of $35 million for calendar 1997 revenues.)

Gerard Puorro, president and CEO said, "We have been monitoring developments at our two U.S. spa locations very closely. And while we remain convinced that they have the potential to become winners someday, what we encountered became a much too large drain on our capital and became more of a distraction than an opportunity...We have been quite successful at developing and marketing and producing leading-edge medical and cosmetic laser devices, and we stand to regain

our sales and earnings momentum quickest by focusing on what we do best as we work to rebuild shareholder value. Accordingly, we closed our location in Scottsdale effective today, but our Boston facility will conduct business as usual as we work to continue to improve its financial performance and evaluate alternative strategies to maximize its value."

Candela's shares dropped 38% in value the following day, according to *Dow Jones News Service*, reaching a 52 week low of 2 7/8, before recovering somewhat to 3 1/8, down 1 1/2. More than 82,300 shares traded, compared to an average daily trading volume of 16,580 shares. The previous 52-week low was 4, set on October 28th.

1/15 **Rare Earth Medical** announced that it had received notification of allowance from the U.S. Patent Office for its "platform technology" Lightstic fiber optic laser diffusing devices. The patent is entitled "Phototherapy Methods and Apparatus" and protects the FDA-cleared Lightstic 360 and Lightstic 180 configurations. The company's intellectual property portfolio is now approaching 30 U.S. and foreign patents. The Lightstic delivery systems are being used by several pharmaceutical companies with PDT drug development programs. Rare Earth has partnered with **Laserscope** to supply this rapidly emerging market with the Rare Earth devices.

1/15 I learned from the December issue of the *ASLMS Newsletter* about the passing of laser pioneer, Dr. Leon Goldman on December 2nd. Dr. Goldman was 91. He was one of the first to use lasers in dermatology, shortly after the laser was developed in 1960. Among his accomplishments were the founding of the ASLMS, the founding of a laser technology laboratory and pioneering studies of lasers as a medical tool at the dermatology department at the University of Cincinnati, and the many books and articles he wrote on the use of lasers in medicine. Donations in his memory are suggested to the Department of Dermatology, College of Medicine, University of Cincinnati Foundation, 425 Oak Street, Cincinnati, OH 45219.

1/19 Today's *Boston Globe* carried an interesting article about dental lasers. Author Judy Foreman discussed the new hard tissue laser recently introduced by **Premier Laser Systems**, interviewing a patient who had had the laser procedure performed by a local dentist. The patient exclaimed, "I didn't feel a thing. There was no Novocaine...it's amazing." Foreman also noted that another option was available in Sweden. A new gel called Carisolv is being used to dissolve tooth decay in a matter of minutes. Carisolv apparently is a mixture of three amino acids and sodium hyperchlorite that dissolves decay with minimum pain, developed by a company called **MediTeam** in Gothenburg, Sweden. (It sounds very much like a product I investigated in the early 1970s called GK 101, and commercialized as Caridex by **National Patent Development Corporation**. It also was an amino acid solution that claimed to "do away with drilling" and "be painless dentistry". These claims were not borne out, as

the drill was still needed to gain access to the decay and to re-shape the cavity for retention of the amalgam filling.)

The dental laser article mentions that **BioLase Technology** is also developing a hard tissue laser, but doesn't mention the work being done by the **American Dental Technologies/Continuum Biomedical** consortium. The story says that many dentists and the ADA aren't yet convinced of the merits of the Premier dental laser, with the ADA's associate director for science, Dr. Dan Meyer stating, "We still have concerns, among them the possibility that the laser might cause heat damage to the delicate inner tooth pulp, despite a built-in water spray designed to keep things cool. The laser also doesn't provide dentists the tactile feedback of high-speed drills, which allows them to "feel" how the procedure is going." Dr. Harvey Wigdor, a laser research dentist at Ravenswood Hospital Medical Center in Chicago, is also skeptical. He says that the laser will not take the place of the drill because it is underpowered, doesn't remove enamel well, and works satisfactorily only on very small cavities. Based on his research, however, he doesn't think the laser's heat damages the tooth pulp. He also agrees that the energy of the laser helps kill bacteria.

A sidebar covers do-it-yourself tooth whitening, discouraging it except under a dentist's supervision. The ADA is also against do-it-yourself tooth bleaching because the bleaching agents can be corrosive to the gums. The sidebar also mentions the new laser tooth whitening techniques, especially BriteSmile, developed by **Ion Laser Technology**. This technique uses an argon laser to activate a 50% solution of hydrogen peroxide, followed by the use of a $CO_2$ laser to seal the surface, in what can be a several hour procedure costing $900. It also mentions that one should read the labels carefully. One home kit, developed by BioLase, is called a LaserBrush for use with whitening tooth pastes. Despite its name, there is no laser involved!

1/20 **PLC Systems** announced that it had received an additional patent related to its Heart Laser System for TMR. The newly issued patent, U.S. 5,700,259 is for a thoroscopic TMR handpiece assembly, which will fit between a patient's ribs, for a minimally invasive approach to TMR. The thoroscopic approach allows the surgeon to perform TMR through one inch incisions in the chest cavity, without spreading the patient's ribs, compared to the four to six inch incision utilized in a conventional TMR procedure.

1/20 **Mehl/Biophile International** announced that it had negotiated a 90 day extension on the maturity of its $7 million Senior Secured Debt with the **Clearwater Fund**, along with provisions for further extensions of the maturity date subject to certain conditions. Additionally, chairman Thomas Mehl and Dr. Nardo Zaias had each agreed to contribute 4 million shares of their personal common stock to enhance shareholder value. Prior to the giveback, the company had 43,993,301 shares

outstanding (now reduced to 36 million). Mr. Mehl and Dr. Zaias will each receive five-year options, vestable in two years, to purchase 2 million shares at $5 per share.

1/20 **Medical Industries of America** announced that it had signed a letter of intent with the **Institute of Medicine and Cardiology, P.A.**, a large, independent physician practice in Okeechobee, FL, whereby **Heart Labs of America**, a wholly owned subsidiary of MIA will provide a mobile cardiac catherization lab for the practice's exclusive use.

1/20 **Rofin-Sinar Technologies**, a leading developer of high performance laser beam sources, announced the formation of a new UK-based company, **Rofin-Sinar UK, Ltd.** to develop and manufacture a new range of low-power lasers, to compliment its existing portfolio of products. As part of its investment in the UK company, Rofin-Sinar has entered into a definitive agreement to acquire the business assets of **Palomar Medical Technologies' Kingston on Hull UK**, a wholly owned subsidiary of Palomar. Terms of the acquisition were not disclosed.

The new range of products is based on sealed gas laser expertise and proprietary diffusion-cooled slab laser technology in the range of 25 to 600 watts, brought to Rofin-Sinar by the transfer of experienced personnel from the Palomar unit to the new entity. Rofin-Sinar's products are primarily sold into the industrial market.

1/22 **Laser Corporation's** board of directors announced that a special one-time five-for-four stock dividend to be issued on Feb. 18, 1998 to shareholders of record as of Jan. 30, 1998. The stock dividend was declared in response to newly approved quantitative maintenance requirements for continued listing on the NASDAQ SmallCap Stock Market. One of the new requirements is that there be a minimum of 500,000 shares of public float. The dividend will increase the shares of public float to over 554,000 shares, thus satisfying the requirement.

1/22 **Computer Motion** announced the first human surgical procedures performed with the assistance of its HERMES Operating Room Control Center, the world's first system capable of networking medical equipment in the operating room, allowing surgeons to have direct control over these devices using simple verbal commands. The HERMES system was used by Dr. Carlos Gracia, a leading endoscopic surgeon at San Ramon Regional Medical Center in San Ramon, CA, to successfully perform five minimally invasive surgeries; a right inguinal hernia repair on two male patients, aged 74 and 49; an appendectomy on a 66 year-old male patient; an anterior spinal fusion procedure on a 44 year-old female patient; and a splenectomy on a 21 year-old female patient. The HERMES system provided Dr. Gracia with the ability to voice control four medical devices; a video camera, light source, video printer, and a videocassette recorder. (For information about Computer Motion's AESOP, a surgical robot capable of positioning an endoscope in response to a surgeons verbal command, see the December 29th brief above.)

Computer Motion has pending multiple 510(k) applications for the HERMES OR Control Center and the voice control of a number of devices. These will facilitate the surgeon controlling a number of devices outside of the sterile area within which he is working. In addition to AESOP, the company is also developing the ZEUS robotic surgical system for endoscopic coronary artery bypass grafting (E-CABG).

On January 26th, the company issued a press release about the ZEUS system. At the *Facts and Myths of Minimally Invasive Cardiac Surgery* symposium, held immediately prior to the **Society of Thoracic Surgeons Annual Meeting**, Dr. Ralph Damiano, Chief of Cardiothoracic Surgery at Penn State Geisinger Health System's Milton Hershey Medical Center, presented his team's preclinical work demonstrating the feasibility of performing heart bypass surgery through incisions in the chest wall smaller than the diameter of a pencil, and controlled using the computerized robotic surgical system ZEUS. One of the scientific presentations showed a coronary anastomosis joining of two 1-2 millimeter diameter blood vessels. The ZEUS system is comprised of three interactive robotic arms placed at the OR table, a dedicated computer controller and an ergonomic surgeon console. One robotic arm is used to position the endoscope, while the other two are used to manipulate surgical instruments controlled by the surgeon. Computer Motion plans to initiate the process for obtaining FDA clearance to market the ZEUS system later this year.

1/23 I received a package of information about a new Swiss company that manufactures light delivery systems for PDT. The company, **Medlight SA**, located in Ecublens, Switzerland, is a spin-off of the PDT research group of the **Swiss Federal Institute of Technology**. The delivery systems for esophagus, bronchial tree, uterus, head and neck, skin, and blood vessels, were developed in close collaboration with several university hospitals in Switzerland and Europe, and are being used around the world with several different photosensitizers. For further information, either contact Dr. Roland Bays, executive director, at 41-21-697-0775, e-mail at webmaster@medlight.com, or visit their website at www.medlight.com.

1/26 **ESC Medical** announced the results for the fourth quarter and year with record results. For the quarter, net sales were $34.3 million and net income was $9.2 million (45 cents/share), excluding non-recurring items. Including the non-recurring items, net income was $6.2 million (30 cents/share). For the year, net sales were $112.7 million and net income rose to $29.5 million ($1.43/share). With the non-recurring items, 1997 net income was $21.8 million or $1.06/share.

Dr. Shimon Eckhouse, president, CEO, and chairman commented, "1997 was another record year with sequential revenue growth each quarter while maintaining high and consistent profitability...The integration of **Luxar** in early 1997 reflects our ability to effectively grow our business both internally and through acquisition...In November, we announced a definitive agreement to merge with **Laser Industries**...This

transaction is expected to close soon after the companies' February 15, 1998 shareholders meetings...In December, ESC announced the acquisition of **Applied Optronics Corporation**, as well as an exclusive distribution agreement with **FineTech Chemicals**, and the purchase of various patents and patent applications...These initiatives demonstrate our continued efforts to pursue related strategic opportunities to further broaden our product line and heighten our intellectual property position."

**MEDICAL/SURGICAL LASER UPDATE -- FEBRUARY 1998**

1/26 This week's issue of *Newsweek* has an article on photodynamic therapy. It describes the clinical study of early-stage lung cancer using Photofrin, relating how one man's lung cancer was cleared up by the treatment. The irony of the story is that the man who took part in the clinical study wouldn't be eligible for the treatment today, as the treatment is only cleared for early-stage cancer for those without any other option! PDT is also now cleared for late-stage esophageal cancer treatment.

1/27 **Laserscope** said it had filed for 510(k) clearance for a new portable, high power erbium:YAG laser system, for use in dermatology, cosmetic and plastic surgery, general surgery, gynecology, ENT, and ophthalmology. According to CEO Robert McCormick, the Venus laser system will be the smallest, yet among the most powerful erbium lasers on the market for skin resurfacing and other laser procedures. The Venus is roughly the same size as the company's desktop Aura KTP system, about one-half the size and weight of most other erbium lasers.

1/27 **Spectranetics** announced that it had received CE mark approval in Europe for its excimer laser coronary angioplasty catheters for the treatment of obstructed coronary stents.

1/27 **Computer Motion** announced it had launched its voice-controlled surgical robot, AESOP 3000. The device is a surgeon controlled robotic arm capable of maneuvering and positioning an endoscope in new advanced minimally invasive heart surgery procedures, such as endoscopic coronary heart bypass grafting.

1/27 **Medical Industries of America** released a statement by its president and CEO Paul Pershes, commenting that the new management team has made a commitment to restoring value in MIOA, which many felt was on the brink of collapse just over a year ago, by effecting a dramatic turnaround. Upon final completion of its annual audit, the company expects to show approximately $7 million in revenue with realized profits of approximately $1 million.

1/27 A story put out by *Knight Ridder Tribune Business News*, published in *The Arizona Republic* about **Candela Corporation's** closing of its Scottsdale cosmetic surgery center, stated that the closure was "to slow a flood of red ink at the Boston-based

company." The 7500 square foot spa, which employed 35 people, opened last February and was billed as the "world's first fully integrated spa and cosmetic laser center." Besides a typical spa fare of hair care, body wraps and massages, the $2 million facility offered a variety of laser surgical procedures aimed at obliterating wrinkles, stretch marks, age spots, freckles and tattoos. Cost of the surgical procedures ran from several hundred dollars for removal of a brown spot from the face or hand, to several thousand dollars for a full facial laser treatment. Although the spa had been well received, it was not making any money.

A similar story also appeared in *Mass High Tech*, quoting analyst Bob Davis, author of the *Napeague Letter*, who stated that "Candela has not been looking good for some time now. The skin care centers were absorbing a substantial portion of the company's cash flows and a progressively larger negative impact on its profitability. I look at this [move] as news that they are back on track." I was also quoted saying that, "They are a device maker without any experience in running a consumer service business and they got in over their head, especially with the Arizona one, because it was too far from Boston for them to closely manage." Candela noted that it will keep its Boston spa location open for the time being, saying that it has a more advantageous address than the abandoned spa, and an established clientele, unlike Scottsdale.

1/27 **Baxter Healthcare**, the principal U.S. operating subsidiary of **Baxter International**, announced that its **Cardiovascular Group** has established an agreement with the **Cleveland Clinic Foundation's Lerner Research Institute** to jointly develop new products for treating late-stage cardiovascular disease. Under the terms of the agreement, Baxter has exclusive rights to devices, processes, and intellectual properties that are developed by the Lerner Research Institute and funded by Baxter, primarily related to conventional and minimally invasive cardiac surgery procedures.

1/27 **Laser Power Corporation** reported a net loss of $809,000 (13 cents/share) for its first fiscal quarter, ended December 31st. For the quarter, revenues were $5.7 million. The company designs, manufactures, and markets high-performance lasers and laser optics for industrial, medical, and military applications, with a series of new microlasers to be introduced at the upcoming OE/LASE meeting in San Jose -- see the January 30th brief below.

1/29 **Palomar Medical Technologies** announced that it had become the first company to receive clearance from the FDA to sell and market its new patented diode laser system for hair removal and the treatment of leg veins. Developed by Palomar's subsidiary, **Star Medical Technologies**, the new laser will be added to the **Coherent** arsenal, and introduced at the upcoming American Academy of Dermatology meeting in Orlando at the end of this month. According to the February issue of *Medical Laser Report*, the 810 nm laser device will be called LightSheer. The diode laser has a much longer pulse duration, up to 20 ms, compared to the ruby laser at 3 ms. According to

Steve Duddy, hair removal product development manager for Coherent, both the EpiLaser and LightSheer will sell for about the same price, $125,000 to $130,000. Both systems incorporate Palomar's patented cooling technology.

Also in the February issue of MLR is a story about laser reshaping of cartilage for repair of damaged areas of the body. Work done at the **Beckmann Laser Institute** and at the **Russian Academy of Sciences** has shown that laser-mediated stress relaxation can alter cartilage shape, ushering in a new era in cosmetic rhinoplasty. The technique involves reshaping small sections of donor cartilage into mechanically stable shapes to reconstruct complex anatomic structures, such as the external ear, without significant loss or waste of the harvested tissue. According to one of the researchers at the Beckmann, Brian Wong, MD, the technique may be reversible and could be adapted for use in minimally invasive or endoscopic procedures, without having to carve, suture, or morselize the cartilage.

1/29 **Cardiogenesis** announced it had received approval to market the Axcis PMR system for percutaneous myocardial revascularization in the European Community, receiving the CE mark, in no option patients with severe coronary artery disease, who are not candidates for conventional therapies.

1/29 **Spectranetics** reported fourth quarter and year end results with revenues for the quarter of $6.5 million, the highest in the company's history. Laser systems sales and rentals rose 130% and sales of disposable laser delivery devices increased 32% in the quarter, compared to the same quarter a year ago. The net loss for the quarter was $1.1 million (6 cents/share), primarily due to an increase in operating expenses, as the company continued buildup of marketing and sales expenses, along with increased spending for R&D and clinical studies. For the year, revenues were $21.9 million with a net loss of $4.6 million (25 cents/share). The strong second half reflected the acceptance of new cardiovascular applications for the excimer laser, especially the laser removal of pacemaker and defibrillator leads. Spectranetics has trained 60 medical centers worldwide in lead removal and is focusing substantial clinical, marketing and operational expenditures on the new procedure.

1/29 **Coherent** announced results for its first fiscal quarter with sales of $101.4 million, 2% lower than for the preceding quarter, and net income at $7.5 million (64 cents/share). Of the total sales, medical lasers represented $42.4 million, giving the company a total of $170.8 million for the calendar year, $3 million lower than our forecast of $174 million. President and CEO Bernard Couillaud noted that the company's distribution agreement with **Palomar Medical Technologies** was off to a good start, with bookings of 40 orders for EpiLasers in less than two months (actually in six weeks). He also said that sales of its Ultrapulse and Ultrafine cosmetic lasers were the strongest in two years, with the erbium laser achieving record orders in its first market exposure. In commenting about the new diode laser for hair removal from Palomar, he said that the

company expects to add it to its line of laser products, with discussions currently taking place. He noted that the pricing would be similar to the ruby laser.

1/30 **Premier Laser Systems** and **Interdent** announced that they have filed counterclaims against **BriteSmile**, alleging that its laser bleaching patent was invalid and unenforceable. (BriteSmile is a wholly owned subsidiary of **Ion Laser Technology**.) The BriteSmile patent claims a laser bleaching procedure involving application of a bleaching agent to a patient's teeth, followed by exposure of the bleaching agent to laser energy to accelerate the action of the bleaching agent. The counterclaim states that the same procedure had been practiced commercially by dentists long before BriteSmile filed for its patent, making it invalid. It also claims that the patent's inventors were aware of this fact but did not inform the Patent Office, rendering the patent unenforceable. With this evidence, Premier Laser and Interdent intend to file a motion for summary judgement seeking invalidation of the patent and a determination that BriteSmile committed inequitable conduct.

On February 3rd, BriteSmile responded to the counterclaim suit, stating that Premier Laser's and Interdent's defenses and counterclaim appear to be standard tactics employed by many defendants. Wyatt Cannady, president and CEO, stated that BriteSmile believes its patent is valid and will let the courts decide.

1/30 **Laser Power Corporation** introduced its multiple microlaser products at Photonics West exhibition in San Jose. The three new products included a 5 W 1064 nm infrared microlaser aimed at the desktop materials processing, marking and printing markets; a 0.5 W red microlaser with applications in photodynamic therapy cancer treatments; and three new lower power green and blue microlasers for the biomedical instrumentation and fluorescence spectroscopy markets, generally served by conventional gas and solid-state laser technology. (A profile of Laser Power Corporation appeared in the February 4th issue of *The San Diego Union-Tribune*.)

2/1 There is a new OEM laser manufacturer in the "heart laser" field, according to an article in the *Sunday Republican*, a Springfield, MA newspaper. A small, startup company started by two former engineers from another small company, **Convergent Energy** of Sturbridge, MA, have begun developing high power $CO_2$ lasers, primarily for the industrial field, but also useful for drilling the human heart. Nathan Monty and Paul Jackson have formed **Excitation LLC**, which is now operating at the Springfield Technical Community College Technology Park. In a conversation with Jackson, I learned that Excitation is seeking to supply its high power slab $CO_2$ lasers for use in TMR. Anyone interested can get in touch with Msrs. Jackson or Monty at 413-272-3924.

2/2 **Pharmacyclics** announced that it commenced its public offering of 2.0 million shares of common stock at a price of $21.75 per share, which is expected to net

approximately $41.3 million. The company intends to use the proceeds from R&D activities, including clinical trials, process development, and manufacturing support.

2/3 **Lasertec International** announced that in vivo tests resulted in a 100% success in the definite conclusion that the non-intrusive detection and treatment of cancerous cell did not harm healthy tissues in the animals tested utilizing its proprietary PhotoTherapy Resonance system. The testing was done in a joint study between Lasertec and Paris-based Ecole Nationale Veterinaire de Maison Alfort.

2/3 **Cynosure** released a statement saying that all lasers for hair removal were not the same. Some can burn, blister, or discolor the skin and may even cause permanent scarring. The release goes on to say that the company's Thermokinetic Selectivity process is employed exclusively by its lasers, whereby the long pulse of its alexandrite PhotoGenica LPIR laser destroys the hair follicle while sparing the outer skin.

2/3 **Coherent** announced that its board of directors had declared a 2-for-1 split of its common stock, for shareholders of record on February 17th. The split should increase liquidity in the stock. Technically, the stock split will be effected in the form of a dividend, giving one share of stock to each holder of a share. After the split, the company will have about 23.2 million shares outstanding.

2/4 **ThermoLase** announced revenues of $13.4 million for the quarter ended January 3, 1998. The net loss for the quarter was $2.0 million (5 cents/share).

2/5 **CardioGenesis** reported its fourth quarter and year end results with revenues for the quarter of $2.1 million, from sales of its TMR, ITMR, and PMR systems, including disposable components, to international customers and into its clinical trial sites in the U.S. Net losses for the quarter were $5.6 million (46 cents/share). For the year, sales were $7.6 million, in line with our estimates, up from $4.0 million a year ago. The net loss for the year was $18 million ($1.49/share).

2/5 **Computer Motion** announced a record quarter and year for its robotic systems. Fourth quarter revenues were $2.1 million, up from $1.5 million a year ago, while full year revenues were $6.6 million, up 63% from last year's $4.1 million. Net loss for the quarter was $2.1 million (24 cents/share), while for the year, the loss was $9.2 million ($1.69/share).

2/6 **Cell Robotics International** announced that it had closed a secondary offering of 400,000 units at $8.25 per unit. Each unit consists of one share of convertible preferred stock and two common stock purchase warrants, exercisable to purchase common stock at $2.40. Each share is convertible into 4 shares of common stock under certain circumstances. The proceeds will be used to repay a short-term loan and to support manufacturing, marketing, selling and distribution of the company's new

medical laser products, the finger perforator Lasette; the RevitaLase erbium:YAG laser for dermatology; the In Vitro Fertilization Workstation for improving IVF procedures; and the Cell Robotics Workstation, a research instrument which incorporates the Laser Tweezers and Laser Scissors for manipulating and cutting cells and chromosomes.

2/6 **Medical Industries of America** said that it had signed two letters of intent with **Global Medical Care, BVI, Ltd**, which includes the sale of a mobile cardiac catherization unit to be based in Nigeria, and to jointly own, manage, and operate **Global Air Charter**, a MIOA air ambulance service in Africa, Europe, and the Middle East.

2/6 **Mehl/Biophile** announced it had obtained a $2.5 million secured revolving line of credit with the **Clearwater Fund, LLC**, the company's largest shareholder. The fund will be for general operating purposes.

2/9 **Cell Robotics International** announced it signed a letter of intent to distribute the Lasette laser finger perforator, with **SKK (Sanwa Kagaku Kenyusho Co., Ltd.)** of Japan. As part of the agreement, SKK has committed to purchase a minimum of 500 Lasettes in the first year. SKK will submit the Lasette to the Japanese Ministry of Health, and after approval, begin promotion and sales activities. Cell Robotics believes that Japan represents 15% of the world market for blood-sampling products.

2/10 **BioLase** announced the commencement of shipments of its Millenium HydroKinetic tissue cutting laser system in the U.S. during the fourth quarter, and said it will continue to fill domestic orders during the first quarter of 1998. Since October 1997, the company had received 22 domestic orders for systems, and has begun filling those orders.

2/10 **PLC Systems** stock posted solid gains for the second straight day, up 15% following a rise of 18%. A company official thought that the buying activity was probably caused by rumors about an upcoming FDA hearing for the company's Heart Laser. The CFO, Patricia Murphy, said that the FDA had given the company a date, but PLC had decided against publicly announcing it, because it may be changed due to time conflicts among some of the participants.

2/10 **Preferred Capital Markets** initiated coverage of **Coherent, Inc.** with a buy rating and per share estimates of $3.19 for fiscal year 1998, and a twelve-month target price of $64 per share. I requested and received a copy of the comprehensive report, authored by analyst J.D. Abouchar, a newcomer to the laser industry. Mr. Abouchar is projecting 1998 fiscal year medical laser sales for Coherent of $190 million and $210 million in 1999, up from $167 million in fiscal 1997. The report notes that Coherent is the undisputed leader in laser system sales for ophthalmic procedures, and a leader in

surgical lasers as well, with strong sales of lasers for aesthetic procedures, including hair removal, wrinkle removal, and treatment of tattoos and skin lesions.

2/11 **Medical Alliance** announced results for the fourth quarter and year end, with revenues for the quarter of $4.1 million and a net loss of $827,000 (13 cents/share). For the year, revenues were $18.8 million and the net loss was $2.9 million (48 cents/share). Medical/surgical procedures for the quarter totaled 7058, compared to 6821 a year ago, giving a total for the year of 27,010, compared to 26,769 in 1996. Aesthetic elective procedures were 12,865 for the quarter and 58,809 for the year. This compared to 11,211 and 41,816 respectively, for 1996.

2/11 **Clarus Medical Systems** has introduced a laser-assisted spinal endoscope that is compatible with the **Trimedyne** Omni-Pulse holmium:YAG laser system. The product, called LASE, is used to treat low back pain with associated leg pain caused by contained herniations of the lumbar disc. The company also offers a version of the endoscope compatible with the **Coherent** VersaPulse laser system. According to the company, low back pain affects millions of people, and over 36% of the patients with such pain had a herniated disc. With over 4000 procedures completed, LASE has demonstrated that it is an excellent adjunct to conservative therapy.

2/11 **ArthroCare Corporation** and **Boston Scientific** announced an agreement in which Boston Scientific will develop and market ArthroCare's proprietary Coblation technology for use in myocardial revascularization. Coblation is a promising new treatment for heart disease, in which radio frequency energy is used to remove a small amount of heart tissue to stimulate the formation of new blood vessels. ArthroCare's RF systems are currently used to perform closed joint surgery, including many types of shoulder and knee joint revisions.

2/11 **QLT PhotoTherapeutics** reported financial results for the fourth quarter and year, with a net loss of $16.7 million (64 cents/share)[in Canadian dollars] for the year, compared to a net loss of $4.7 million (19 cents/share) in 1996. For the quarter, the net loss was $4.7 million (18 cents/share), compared to net income of $4.0 million or 17 cents/share for the same quarter a year ago. Total revenues for the quarter were $4.3 million, which included a milestone payment of US $1 million ($1.4 mln Cdn) from **Beaufour Ipsen**, relating to the launch of Photofrin in France. This compared to revenues of $10.9 million a year ago. Royalty revenues from Photofrin in the fourth quarter were $416,000, up 98% from the third quarter, mainly due to increased sales in the United States. Total revenues in the fourth quarter of 1996 included collaborative payments of $9.5 million from new strategic alliances formed by the company.

Total revenue for the year was $10.3 million, including revenue of $2.8 million from the company's collaborative agreement with Beaufour Ipsen. The company earned

royalty revenue for the year of approximately $1.2 million on end-user sales of Photofrin of approximately $4.8 million.

Some of the business objectives over the next several years include:

- the completion of clinical development and commercialization of BPD-MA for the treatment of ARMD in conjunction with **Ciba Vision**;
- the expansion of commercial opportunities for Photofrin and BPD-MA in the treatment of cancer by seeking approvals in new markets and conducting additional clinical studies in new indications, including Barrett's esophagus;
- the advancement of research and early clinical development in the use of photodynamic therapy in the treatment of autoimmune conditions; and
- the development of several new photosensitizers for future clinical development.

2/12 **Pharmacyclics** reported its financial results for its second fiscal quarter ended December 31st, with a net loss of $443,000 (4 cents/share), compared to a net loss of $2.6 million (29 cents/share) for the same quarter a year ago. During the quarter, the company had revenue of $2.9 million, compared to $25,000 during last year's second fiscal quarter. The revenues this year consisted of license payments and contract R&D revenues related to previously announced agreements with **Nycomed Imaging A/S** and **Alcon Pharmaceuticals, Ltd.** During the quarter, the company established two collaborations, with Nycomed for marketing rights to Lutrin for the treatment of cancer outside of the U.S., Canada and Japan; and with Alcon for the worldwide development and marketing rights to Lu-Tex for ophthalmic conditions.

2/12 **Eclipse Surgical Technologies** released its fourth quarter and year-end results. Total revenues for the quarter were $1.6 million with a net loss of $5.2 million (31 cents/share). For the year, revenues were $5.5 million and the net loss was $18.2 million ($1.11/share).

2/12 **Premier Laser Systems** announced its third fiscal quarter results with revenues rising 480% from the previous year to a record $7.2 million, due to the success of the company's dental lasers and the growth of its ophthalmic business. The company reported its first quarterly profit with net income of $500,000 (4 cents/share). Due to increased production volumes and manufacturing efficiency, gross margins for the quarter grew to 46%, up from 36% for last year's third quarter. For the nine month period, revenues were $12.3 million with a net loss of $12.2 million ($1.14/share).

The company hopes that the FDA will clear its erbium dental laser for hard tissue procedures on patients under age 18, and for "laser curettage" in the quarter ending March 31st. A company executive commented that reports from the field indicate that

the dental laser's optical fibers are yielding between 40 to 50 procedures before factory re-polishing is required.

2/13 **Ion Laser Technology** reported its fiscal third quarter and nine month results. For the quarter, the company had a net loss of $1.4 million (24 cents/share) on revenues of $851,500. Revenues for the nine months period were $4.0 million with a net loss of $2.4 million (41 cents/share). Dental equipment sales in the third quarter were $435,000, compared to $1.4 million for the same quarter a year ago. Wyatt Cannady, CEO commented that sales of laser tooth whitening systems were impacted in the quarter due to the design and market evaluation of the next generation of BriteSmile laser tooth whitening products. The new system will offer both the dental professional and patient a faster, easier, and more cost effective procedure, which will be introduced at the Chicago Mid-Winter Dental convention being held next week.

2/13 **Interdent** issued a response to recent public comments by **BriteSmile's** president, Wyatt Cannady -- see the February 3rd comments, contained in the January 30th brief above. Kenneth Rosenblood, president of Interdent said, "Mr. Cannady is wrong on both counts. Interdent is a privately-held company and doesn't have the resources to play litigation games. We are, however, going to prove our right to sell our products and we are going to do so quickly." Interdent is preparing a summary judgement motion which will be filed soon. The company will also seek to have BriteSmile pay its attorney's fees.

2/13 **Columbia/HCA** released its fourth quarter and year-end results, which I will not relate in the newsletter. I mention it only for the interesting report it makes about both outpatient revenues as a percent of patient revenues, and the number of surgery cases performed and revenues per patient day/admission. For the quarter, the hospital chain performed 484,700 surgery cases and 2.0 million for the year. Its revenues per patient day averages about $1200, and per admission about $6000 (with an average length of stay of about 5 days). I have inquired about its relationship with **Cosmetic Technologies International**, the joint venture with **Palomar Medical Technologies'** subsidiary, to establish cosmetic laser centers within Columbia's ambulatory surgical centers, but have yet to receive a response.

2/17 **ESC Medical** and **Laser Industries** said that ESC's previously announced acquisition of Laser Industries had been approved at separate shareholder meetings of both companies, and is expected to close within a few days. Under the terms, each Laser Industries shareholder will receive 0.75 shares of ESC's common stock, resulting in the issuance of approximately 7 million new ESC shares.

2/18 **American Dental Technologies** announced that it had completed the acquisition of **The Dental Probe, Inc.**, a privately-held company which manufactures and markets the Interprobe, originally developed by **Bausch & Lomb**, and a second generation

unit, the Probe One. The acquisition was made in exchange for $250,000 cash and 61,500 shares of ADT's common stock.

2/18 **Diomed**, the UK-based world leader in diode laser technology, announced the shipment of the first batch of CE marked Diomed 630 PDT lasers for photodynamic therapy applications. Portable, compact, and easy to use, the new diode laser brings PDT within easy reach of every European cancer treatment center. The new laser is applicable for the activation of Photofrin, which is being launched into Europe by **QLT PhotoTherapeutic's** marketing partner, **Beaufour Ipsen**. The Diomed laser is claimed to be the lowest cost entry in the PDT laser market, although no price was given in the news release. Diomed, who pioneered the use of surgical diodes, beginning in 1993, has over 500 diode-based surgical lasers in operation in over 25 countries worldwide.

2/19 **Laserscope** reported its fourth quarter and year end results, with revenues for the quarter of $14.7 million, compared to $16.1 million for the same quarter a year ago. The company reported a net loss of $3.4 million (27 cents/share) compared to net income of $730,000 a year ago. Included in the quarter were charges of $3 million to write off inventory consisting primarily of components and service parts for laser and hospital equipment products, that were considered excessive in light of planned new product introductions in 1998, and lower than expected fourth quarter sales and bookings. For the year, revenues were $61.3 million, just short of our $64 million forecast. A net loss of $840,000 (7 cents/share) was incurred, after taking the $3 million inventory charges. Excluding the inventory charges, net income for the year would have been $2.2 million.

2/19 **PLC Medical** announced that its international subsidiary, **PLC Medical Systems, A.G.** had entered into an exclusive distribution agreement with **U.S.-China Industrial Exchange (Chindex)**, the largest independent American distributor of Western health care products in China. The agreement is for the distribution of the Heart Laser to cardiac care centers and hospitals in China. First shipments are expected to begin in the second half of 1998. PLC currently has four Heart Lasers in operation in China and Hong Kong.

2/19 **Ion Laser Technology** announced the introduction of the new BriteSmile Esteem laser tooth whitening system. Prototypes were shown at the Chicago Mid-Winter Dental convention currently running. The new system offers dentists and patients a simpler, faster, and more cost-effective tooth whitening procedure with up to nine-plus shades of whitening improvement in approximately one hour. The multi-function BriteSmile Esteem system has received FDA marketing clearance for tooth whitening, sub-second dental composite curing, and for soft tissue treatment. It is being introduced at $13,995. The systems utilizes ILT's new argon non-laser plasma technology, emitting light in the blue 400-500 nm range, along with a carbon dioxide laser. The argon

plasma device replaces the argon laser used in the original BriteSmile dual laser technique. The dual energy system, housed in a single unit, is expected to be available for shipment in the latter half of the quarter ending June 30th.

ILT also announced that it had signed an R&D contract with a dental chemical research firm to enhance ILT's chemistry for whitening teeth. Specifically, the research firm is developing a high-speed whitening chemistry to be used with the company's original BriteSmile system and for the next generation BriteSmile Esteem treatment kit. The improved system will use a simplified light-activated isolation system for gum tissues, eliminating several time-consuming steps in the original procedure. The new system is also expected to be available in the latter half of the June 30 quarter, and to be priced competitively with other light-activated whitening chemistry in the market.

2/19 The newly restructured **Palomar Medical Technologies** reported its fourth quarter and year-end results for continuing operations. For the quarter, the company had revenues of $5.3 million, compared with revenues of $4.1 million for the same quarter a year ago. Palomar reported a net loss for the quarter of $14.9 million (39 cents/share), or which appoximately $2.5 million (6 cents/share) was non-recurring, non-cash charges related to the company's conversion of its Swiss Franc debenture. For the year, revenues from continuing operations increased 19.1% to $21.0 million and the net loss was $58.4 million ($1.79/share), of which $13.0 million (37 cents/share) was a restructuring charge and asset writeoff from continuing operations.

During a teleconference held in conjuction with the financial statement release, CEO Dan Valente commented on the tumultous year that Palomar had had. Since becoming CEO in May, he assessed all the business that the company was in and decided to concentrate on its core cosmetic laser business, selling off all of the rest. He has consolidated the company from 12 locations to two, aligned the company with **Coherent, Inc.**, accelerated product development at its **Star Medical Technologies** subsidiary, and emerged from this transition period expecting to assume its technology leadership position and become profitable by the fourth quarter of this year.

In discussing the new diode laser, to be introduced at the upcoming AAD meeting (see the January 29th brief above), it will also be part of the Coherent distribution deal, as soon as a few small details are worked out. It will include the patented cooling device and sell for $150,000 (because it is dual purpose -- both for hair removal and for the treatment of leg veins), compared to $130,000 for the EpiLaser. The diode will also have gross margins of 40-50%, compared to very small margins on the ruby laser. As for the **CTI** venture with **Columbia/HCA**, Valente said that Palomar was looking very closely at the cost models for the six centers already in operation, treating them as beta sites, before additional centers are opened. Including

the Columbia sites, the company currently has about 10-12 revenue sharing cosmetic laser sites operating.

2/20 **Trimedyne** reported results for its first fiscal quarter, ended December 31st, with revenues of $2.1 million, a decrease of 3% from the same quarter a year ago. The company had a net loss from continuing operations of $1.1 million (10 cents/share), which included $657,000 of start up R&D for its 90% owned subsidiary, **Cardiodyne**. The latter has filed an application with the FDA to begin human clinical trials of its myocardial laser revascularization system, expected to begin this spring.

2/23 **Palomar Medical Technologies** said that it had moved for summary judgement to terminate the patent case with **Mehl/Biophile International**. Palomar is seeking to invalidate all of the claims in Dr. Nardo Zaias' laser hair removal patent, which is licensed to Mehl's **Selvac** subsidiary. In its motion, Palomar argues that the Zaias patent contains no invention, but simply copies a prior laser treatment used and published years before by researchers at Massachusetts General Hospital (MGH), and that the Zaias patent copies a laser treatment method described in an old brochure/instructional manual produced by **Spectrum Medical Technologies**, now a subsidiary of Palomar. The brochure included pictures showing hair removal accomplished with a Q-switched ruby laser, which was never disclosed in the Zaias patent application. For these and other reasons, Palomar believes that Mehl's lawsuit is an extraordinary abuse of the U.S. patent system. Palomar's motion will be decided by the U.S. District Court in New Jersey.

2/23 **Candela Corporation** announced that it has begun marketing a dual laser system that can be used for both cosmetic resurfacing treatment of the face, and for treating facial veins and other vascular lesions. The new laser, known as the SkinPlus laser, combines an erbium:YAG for resurfacing and a doubled YAG KTP/532 laser for the vascular lesion treatment. The company said that by combining the two lasers into one console, the cost of the system could be reduced to approximately the same as a single purpose aesthetic laser system. The laser will be priced at $79,500, or combined with its SkinScan capability, at $89,500. The SkinScan unit alone sells for $14,000.

2/23 **ESC Medical Systems** announced that it had completed the acquisition of **Laser Industries**. Commenting on the acquisition, Dr. Shimon Eckhouse, president, CEO, and chairman of ESC said, "We are extremely excited about the powerful combination of ESC Medical Systems and Laser Industries, which now positions ESC as a stronger force in the global cosmetic and medical markets. Through Laser's line of sophisticated lasers, we have the ability to reach a broader segment of the market while also enter new markets. Furthermore, through our expanded marketing and distribution channels, we can more aggressively penetrate the global markets and meet the increasing demands of our customers. As we move forward, we are excited about ESC's strengthened competitive position and plan to capitalize and benefit from

the growing opportunities in our industry." Laser Industries markets more than 20 laser systems under the **Sharplan** trade name, while ESC markets both lasers and intense pulsed light non-laser products aimed at the cosmetic laser trade. (There is only a small area of crossover between the two combined companies, primarily in the $CO_2$ laser area. Some of Sharplan's $CO_2$ laser products compete directly with those of ESC subsidiary, **Luxar**.

2/23 **Standard & Poor** revised its outlook for **ESC Medical** to "positive" from "stable", following the completion of its acquisition of **Laser Industries**. The release noted that ESC would be "greatly challenged to control and further grow operations that were only one-fourth its current size just one year ago. Competition is strong, as several other companies have developed similar devices for treating the same conditions. Moreover, ESC's narrow product portfolio and dependence on a few products make the company vulnerable to technological and market changes...Continued new product development, successful integration of acquisitions, and maintenance of moderate financial policies could lead to ratings upgrade."

2/23 **Surgical Laser Technologies** announced its results for the fourth quarter and year's end. Sales for the quarter were $2.7 million, compared to $3.0 million a year ago. Net income was $51,000 (1 cent/share), compared to a net loss of $264,000 a year ago. For the year, sales were $11.7 million, up from $11.0 in 1996, with a net loss of $381,000 (4 cents/share), down from $4.5 million (46 cents/share) a year ago. The 1997 results included a net special credit of $177,000 resulting from the benefit obtained in the settlement of certain litigation of $1 million, offset in part by facility-related charges amounting to $823,000.

**MEDICAL/SURGICAL LASER UPDATE -- MARCH 1998**

1/19 In a followup to the brief announcing the approval of **QLT PhotoTherapeutic's** Photofrin for microinvasive non-small cell lung cancer (see the January 9-12 brief in the January issue), *The Gray Sheet* says that Photofrin is already in use in approximately 60 centers throughout the U.S. according to QLT. In our original brief, **Sanofi Winthrop** had said that there were 50 centers actively using the drug. *The Gray Sheet* says that the FDA Oncologic Drugs Advisory review panel voted 6-4 against recommending that Photofrin be indicated for carcinoma in situ, maintaining that the benefits for this early stage cancer were less compelling than those for microinvasive cancer patients, especially when Photofrin's adverse event prevent profile was taken into consideration.

2/23 Barbara Marsh of the *Los Angeles Times* wrote a piece about cosmetic uses of lasers entitled, "The Cutting Edge: The Light Brigade -- Lasers fix vision, treat cancer, even whiten teeth -- but they have a dark side". The latter reference is to the potential use of lasers by those not fully trained to use them, and the potential problems that that can

cause. "Experts say lasers aren't for the untrained. They suspect far more injuries are caused than official figures indicate -- and the handful that are reported indicate how serious the injuries can be...Rockwell Laser Industries, a consulting firm, reports that in recent years, patients as well as physicians and other professionals have suffered burns, loss of facial hair and eye damage. Hospital curtains have been set afire. Faulty equipment, failure of safety gear, removal of safety goggles or equipment being accidently switched on have been blamed." In December, the California Department of Consumer Affairs determined that only doctors -- or nurses or physician assistants under a doctor's supervision -- can use a laser to remove hair. That left 2000 electrologists throughout the state fearing a loss of their livelihood...[Electrologists] are trying to find a legislator to sponsor a bill that would permit them to use lasers...they are no more dangerous that the electrical probes they have always used said a spokesperson.

2/24 **Spectranetics** outlined the expanded market for its technology in treating cardiovascular disorders at the "Know Your Colorado Companies" symposium. The company's CVX 300 excimer laser has been used to treat severe blockages of coronary arteries since 1993. Under a new management team, Spectranetics has expanded its technology into new cardiovascular markets that provide minimally invasive treatment options for cardiovascular patients. Some of these include:

- excimer laser removal of non-functioning and problem pacemaker and implanted defibrillator leads, with an estimated market potential in excess of $75 million annually;

- excimer laser clearing of stents because of restenosis in up to 30% of stent placements;

- excimer laser clearing of peripheral blockages, such as in obstructed leg or peripheral arteries, as an alternative to femoral bypass surgery or amputation;
- transmyocardial revascularization, the procedure to create small holes in oxygen-starved heart muscle to stimulate growth of new blood vessels in patients with limited treatment options. Through a strategic partnership, **U.S. Surgical** will purchase Spectranetics laser system and disposables for use in the TMR procedures.

2/25 **PLC Systems** announced financial results for the fourth quarter and year end. Revenues for the quarter were $2 million, compared to $3.1 million for the same quarter a year ago. The net loss was $5.1 million (28 cents/share). For the year, total revenues were $8.9 million, down from $11.9 million for 1996. The difference was due to a decrease in Heart Laser sales, the majority of which were completed through distributors which carry a lower selling price. The net loss for the year was $14.4

million (84 cent/share), due in part to higher operating costs in anticipation of launching Heart Laser sales following its review by the FDA during the summer.

At year's end, more than 3500 patients had been treated with the Heart Laser, and 26 systems were shipped in 1997, for a total of 99 systems installed in 30 countries.

2/25 **Mehl/Biophile** reiterated its intention to continue a vigorous patent infringement suit against **Palomar Medical Technologies**, stating it expected that the Federal Court will find Palomar and those customers using its EpiLaser systems to be willful infringers of the Zaias patent, licensed to it. The release was in response to a press release by Palomar saying it had filed a motion for summary judgement in the litigation, challenging the validity of the Zaias patent (see our February 23 brief in last month's issue). According to Jack Forrest, CEO of Mehl, "After careful study of Palomar's filing, it is our considered opinion that the filing of the motion is not only legally ill-conceived, but we also question whether the recent Palomar press release filing was made as public relations gambit in view of next week's American Academy of Dermatology convention in Orlando." Mehl expects that Palomar's motion will be rejected by the Court and that the action will do no more than minimally delay the determination that Palomar's EpiLaser hair removal device infringes the Zaias patent and that Palomar has engaged in a systematic plan of unfair competition and misrepresentation in its marketing efforts for the EpiLaser.

2/25 In a message from Bill Kelley, general manager North America for **Aesculap Meditec**, I was told that Aesculap claims to have sold the largest number of erbium lasers worldwide. With erbium products sold for use in dermatology, dentistry, and ophthalmology, the number approaches 700 systems. Further, the company intends to show its Ruby Star laser for hair removal at the AAD meeting in Orlando. The ruby has a variable spot size up to 10 mm, with a variable fluence up to 80 J/cm$^2$. Kelley claims that the unit is half the size of most other ruby lasers and is designed to fit into a corner of the OR. "As skin cooling is still very controversial in terms of which way is best, our plan is to initially not offer cooling ourselves, but to provide the buyer with information on what many options that are available to him so that he can choose for himself which way he prefers."

Other aesthetic lasers in the Aesculap line include Cutilase, a diode-pumped doubled YAG for vascular and pigmented lesions; two erbium:YAG lasers, the Dermablate at 1.2 J, and the Dermablate 1 at 2.2 J to tissue for skin resurfacing; the DLS 5 argon laser for skin lesions; and the above mentioned Ruby Star for both hair removal and with a Q-switched mode for tattoo removal.

The company is also introducing a new ophthalmic 532 nm green laser that they call EyeLase Green. It will compete against the **Iris Medical** 532 laser. Both are diode-

pumped YAGs, but the difference is that the Aesculap system is CW whereas the Iris system is pulsed. The EyeLase is a 2 W system that guarantees 1.7 W to the cornea, where 1 watt of 532 nm is equivalent to 2 watts of argon photocoagulation. The new laser is FDA approved and sells with a choice of endoprobes, slitlamps, or indirect ophthalmoscopes.

Other ophthalmic lasers include the Argus, an argon laser, along with the EyeLase, for retinal photocoagulation; the MEL 60 and 70 excimer lasers, the former a slit scanner, while the latter is a spot scanner with a tracker; the MQL 12 YAG for posterior capsulotomies; and the Phacolase, an erbium laser for laser phacoemulsification. The excimers and the Phacolase are not cleared for sale in the U.S., while the Ruby Star and the Demablate 1 are in registration and should be cleared by the end of April.

2/26 **Laserscope** said that it would introduce three new laser systems for the aesthetic market at the AAD meeting. The Venus erbium:YAG system, for skin resurfacing and other medical problems, is the smallest, yet among the most powerful, commercially available erbium lasers, with a suggested selling price of $39,995. The new Aura SL doubled YAG green laser system has been configured to meet the growing demand for lasers designed to treat and remove facial veins and pigmented lesions. It is available with an integrated robotic scanner and delivers shorter pulse widths than diode-pumped systems, more closely matching the thermal relaxation times of the targeted blood vessels, minimizing collateral damage. It will also be offered at a suggested price of $39,995. The third laser is the Levante dual-mode ruby laser, developed by **NWL Laser Technologie GmbH**, a Laserscope subsidiary. The 684 nm wavelength ruby laser was designed exclusively for dermatologic and aesthetic applications, specifically for removal of hair, tattoos and pigmented lesions. The dual action system offers both short and longer pulse durations, and includes an optional, adjustable scanner which can treat areas ranging up to 4"x4". It has a suggested selling price of $110,000, and will be available for sale only outside of the U.S.

2/26 **Ion Laser Technology** said that it had been awarded the ISO 9001 quality standards certification for manufacturing, a step toward CE marking for the company's products, required to market to the member states of the European Union. The new argon plasma sub-second curing device is the first ILT product to be submitted for CE marking, expected later this summer.

2/27 **Cynosure** released information about three new laser products debuting at the AAD meeting. The Comfor-Touch Laser Cooling Tip is for use with aesthetic lasers to reduce the need for anesthetics. The Comfor-Touch system consists of a freestanding chiller and a handpiece-mounted cooling tip. The lightweight and transparent cooling tip is mounted to the laser handpiece and allows effortless user control during treatment. It is designed for use with Cynosure's Apogee alexandrite long pulse laser for hair and leg vein removal, and for the PhotoGenica VLS, a dual pulse (450 or

1500 ms) multiple wavelength (585, 590, 595, and 600 nm) and Photogenica V vascular lesion lasers.

The Apogee, a second generation of the company's PhotoGenica LPIR laser, is a flashlamp-excited, solid-state laser with a wavelength of 755 nm, taking advantage of the theory of Thermokinetic Selectivity by combining high fluences (50 J/cm$^2$) and extremely long pulses (up to 20 ms) to damage large targets in the dermis like hair follicles and leg veins, while leaving smaller surrounding structures unharmed. It is claimed to be 56% faster than the LPIR, for faster hair removal. The faster speed is made possible by the addition of a larger spot size of 12.5 mm (in addition to the 7 and 10 mm spot size choices), with more energy which can cover a 1/2 inch area per second. The Apogee will be available in April.

The third new product is the PhotoAppeal erbium:YAG laser for skin resurfacing and rejuvenation. The laser delivers up to 2 J of energy per treatment pulse and has a zoom handpiece which provides an adjustable treatment "spot" of 2, 5, and 7 mm. This allows the physician to adjust the treatment area without changing handpieces. The laser also features unique multiple pulse durations of 200, 350, and 700 ms, which allows for both controlled ablation and thermal ablation. The PhotoAppeal also has a controlled repetition rate of from 3 to 12 Hz, enabling better control in small treatment areas, especially around the lips and eyelids, while allowing larger areas to be treated faster.

3/2 **Coherent Inc.** and its **Medical Group** introduced the LightSheer diode laser for hair removal at the AAD meeting this week in Orlando. The LightSheer was developed by **Palomar Medical Technologies** (actually, Palomar's **Star Medical Technologies** subsidiary -- see the January 29th brief in the February issue) and is the latest product to be introduced with the Coherent/Palomar label and will serve as a compliment to the long pulse ruby EpiLaser system. The diode laser is compact and can be installed in offices with limited space. It comes with the patented ChillTip contact cooling delivery system used with the EpiLaser. Although not mentioned in the release, according to sources at Palomar, the LightSheer will sell for roughly $150,000, because it is a dual use laser, also useful for removal of leg veins, compared to the single use EpiLaser, which sells for about $130,000.

3/3 **Laserscope** said that it had been informed by **Heraeus Med GmbH** that it had commenced selling a limited number of the 4.6 million shares of Laserscope shares it had received in connection with the of **Heraeus Surgical** and certain other assets to Laserscope in August 1996. Laserscope estimates that the maximum number of shares that Heraeus Med could sell in the initial three month period under Rule 144 is approximately 382,000 shares, including approximately 175,000 shares which have been sold since February 26th. Heraeus Med is a subsidiary of **Heraeus Holding GmbH**, a privately-held company based in Hanau, Germany.

3/3 **Lasertec International** announced that the CCPPRB, a European entity established for the protection of patients undergoing experimental medical testing, has provided clearance for human testing of the company's resonant phototherapy laser system in the detection and treatment of bladder cancer. The approval to proceed with ex-vivo testing represents the first time cancer tests utilizing the company's PTR has been authorized. This will be the final clinical stage in the approval process to commercially market the technology in Europe. The PTR tests will be conducted at the Hospital Cochin in Paris, at the urology center of Professor Debre, under the supervision of Professor Marc Zerbib, and Lasertec's Professor Guy Cherbit. The team has selected thirty patients who will receive the bladder cancer treatment utilizing the laser resonance. Following removal of cancer tissue by resonance, the patients will be monitored for a designated period in order to evaluate the tolerance level of the treatment.

The phototherapy resonance system was developed by Lasertec's Professor Guy Cherbit, who has over 25 years experience in the field of biomolecular spectroscopy, the interaction between light and matter. Based on Lasertec's proprietary and complex algorithms, the PTR system is designed to selectively target and destroy only cancerous cells while leaving healthy, surrounding cells unaffected. The company believes that the use of laser resonance is revolutionary and could possibly save lives, simplifying treatments, and reduce medical costs.

3/4 **Eclipse Surgical Technologies** announced that a blinded, independent data and safety monitoring committee had reviewed the results of its clinical trial studying TMR performed in conjunction with bypass graft surgery, and concluded that no additional patients need to be enrolled in the study. The clinical data showed eight times fewer early deaths in the TMR plus bypass group, compared to conventional bypass surgery alone. The company has notified the FDA of these findings and await their opinion of the results. Dr. Douglas Murphy-Chutorian, chairman and CEO of Eclipse said, "To our knowledge, this is the first prospective, randomized study of TMR and bypass surgery to show the reduction in early deaths compared to conventional bypass surgery. We are seeking the FDA's guidance on how to proceed."

3/5 **PLC Systems** announced that an FDA Advisory Panel will review the company's revised PMA data for TMR using the Heart Laser on April 24th. William Dow, president and CEO said that PLC was able to successfully complete the collection and analyses of the 12 month data from the controlled, randomized study of TMR as requested by the July 28th FDA Panel. They believe that the data continues to support the benefits of TMR using the PLC laser and look forward to the panel's review.

3/6 **Photogen Technologies** announced that Dr. Eric Wachter, one of its principle scientists, will be presenting the preliminary results of the company's current animal studies at the Spring Topical Meeting of the Optical Society of America, to be held

March 9th in Orlando. The studies, being conducted under contracts with the University of Tennessee School of Veterinary Medicine and the Thompson Cancer Survival Center, demonstrate controlled simultaneous two-photon activation of Photofrin, using light at 730 nm, in the livers of laboratory mice. The company believes this is the first demonstration of in vivo activation of a photoactive agent using a two-photon activation process.

Results confirm the noninvasive activation of Photofrin by observation of lesions formed on the livers of Photofrin-treated laboratory mice. The lesions were well defined with cell necrosis limited to the focal region of the activation beam. This contrasts to substantial collateral damage observed in animals treated with Photofrin and using single photon activation process with light at 630 nm. Other experiments showed substantially less increase in tissue temperature during laser exposure at 730 nm than with laser activation at 630 nm.

Photogen's two-photon activation process is expected to substantially increase the effective treatment depth of existing photoactive agents, enabling noninvasive therapies. The two-photon process may also enable the use of certain phototoxic agents previously thought to be ineffective for deep tissue treatment. This was due to the need for activation at wavelengths below 600 nm, where deep tissue penetration is not effective. However, additional testing will be necessary to confirm these possibilities.

3/9 In a presentation at the Annual Liberty Dental Conference in Philadelphia, Dr. Benjamin Po of the Dental Department at St. Christopher's Hospital for Children, said that the use of the YAG dental laser holds great promise for future pain-free dental treatment of children. Lasers have been approved by the FDA for use in the dental treatment of adults, but not yet for young children. Research efforts continue to support the positive use of lasers for dental applications in children. In fact, according to Dr. Po, YAG lasers can be used to remove caries and plaque without the use of anesthetics, and he hopes that the YAG laser will soon be approved for use in the dental treatment of children. (In response to a call to Dr. Po, his references to the "YAG" laser were meant to be for the erbium:YAG laser. It is the erbium laser that has been approved for the removal of caries and treatment of plaque in adults, and not the "YAG" laser. The erbium laser is awaiting approval for expanded use with children, according to **Premier Laser Systems**.)

3/10 **American Dental Technologies** reported net income for 1997 of $3.6 million ( 47 cent/share), on revenues of $21.4 million, up from $20.5 million in 1996. Company president and CEO Ben Gallant said that sales in North America had increased 49% in 1997, but that foreign sales had declined due to dealer reductions of inventory. He expects, however, that 1998's foreign sales will likely exceed those in 1997, as firm orders and shipments to foreign distributors year-to-date were approximately 70% of

1997's totals. (According to a company spokesperson, lasers represent only about 15% of total revenues. So, of the $21.4 million in sales for the year, only about $3.2 million is attributable to the sale of dental lasers.)

3/10 **Laser Photonics** reports that its subsidiary, **AccuLase** received a $600,000 milestone payment from **Baxter Healthcare Corporation**, a subsidiary of **Baxter International**, for the delivery of two of the company's new excimer lasers. As previously announced, Baxter has licensed the worldwide rights to market and sell the company's laser and laser delivery system for cardiovascular and vascular applications. Once commercialized, the company will manufacture and sell the devices to Baxter, and will receive royalties based upon unit sales. Laser Photonics will continue to provide technical expertise to Baxter.

In addition to the alliance with Baxter, Laser Photonics has a series of agreements with **Massachusetts General Hospital (MGH)** relating to the use of its proprietary excimer laser for the treatment of psoriasis, under a patent-pending technique developed by Dr. Rox Anderson. (See the January 13th brief in the January issue for more details.) Baxter is currently conducting clinical trials with the laser to perform TMR for advanced coronary disease at New York Hospital's Cornell Medical Center, and The Hospital of the Good Samaritan, Los Angeles.

3/10 **Pharmacyclics** announced that it had completed patient enrollment in its Phase II portion of a Phase Ib/II clinical trial for its radiation sensitizer Gd-Tex, for the treatment of brain metastases. Twenty-one patients were enrolled in the study designed to evaluate the safety and tumor response in a group of patients receiving maximally-tolerated doses of the drug, based on a Phase Ib dose escalation study performed on 39 patients. Interim results of the Phase Ib trial, reported in October showed that Gd-Tex was well tolerated, with reversible liver enzyme elevation as the dose-limiting toxicity. MRIs confirmed that the drug accumulated in tumors but not in adjacent tissue. Although not designed to evaluate efficacy, a favorable effect on survival was reported. The Phase Ib/II trial should provide the data needed to initiate the Phase III trial, expected to begin in mid-1998.

3/10 This month's issue of *Medical Laser Report* contains two articles of interest. The cover story is about how several of the companies attempting to enter the cosmetic laser center market are having problems. Mentioned are **ThermoLase**, **Palomar Medical Technologies**, **Candela** (see the March 17th brief below for the latest information about this company's venture), and **Laser Industries**. From Kathy Kincade's interviews of the principles of each, it appears that none are yet seeing the flow of profits that they expected when they entered into this business, in fact, all have changed their business plans.

The other story of interest is the first reports back from the American Academy of Dermatology meeting, held earlier this month in Orlando. According to the initial reports, there was a plethora of erbium lasers being exhibited, with most physicians unable to distinguish between the offerings. Also, there was a variety of wavelengths available for the other "hot" area, hair removal, ruby, alexandrite, and the first diode laser offerings from at least five suppliers -- **Palomar/Coherent**, **LaserLite**, **ESC Medical** (from its new **Applied Optronics** subsidiary), **Mehl/Biophile**, and **Nidek** -- making the decision of which hair removal laser to purchase/lease also a tough decision. In addition, several companies introduced new doubled YAG lasers, as well as new, compact models of older laser systems.

Over the next several months, I will attempt to sort out the various options available for several specialty applications, in a series of tables listing the lasers available for applications such as skin resurfacing, hair removal, pigmented and vascular lesion treatment, and for tooth whitening and caries removal in dentistry.

3/12 **Miravant** announced its financial results for the fourth quarter and year, with revenues for the quarter decreasing to $1.8 million from $2.2 million for the same period last year, and a net loss for the quarter of $11.2 million (80 cents/share), compared to $3.5 million (28 cent/share) for last year's fourth quarter. For the year, revenues were $4.9 million, compared to $6 million for 1996, and a net loss of $30.2 million ($2.36/share) compared to $16.1 or $1.37/share for 1996.

Company chairman and CEO Gary Kledzik said that Miravant realized very positive results both in its cutaneous metastatic breast cancer (CMBC) and ophthalmology clinical trials last year, along with establishing several advantageous strategic alliances. In the CMBC trials, the company is working diligently toward its first NDA submission, while in age-related macular degeneration (ARMD), the company's clinical trials showed it was able to stabilize and dramatically improve vision in early clinical trials. During the year, the company changed its name from **PDT, Inc.** to Miravant, and branded its proprietary technology, PhotoPoint, in order to illustrate its commitment to creating an advanced form of photoselective medicine. The company announced strategic alliances with **Medicis Pharmaceutical Corporation** to develop and commercialize PhotoPoint procedures for dermatology, and with **Chiron Diagnostics** to detect and treat early-stage lung cancer. Other strategic relationships include **Boston Scientific Corporation**; **Cordis**, a **Johnson & Johnson Company**; **Iridex Corporation**; **Pharmacia & Upjohn**; and **Ramus Medical Technologies**.

3/12 Dr. Michael Berns, professor at the University of California, Irvine, and president of **The Beckman Laser Institute**, in his presentation at the American Physical Society Meeting in Los Angeles on March 17th, will discuss how laser-based technologies are being used to advance reproductive health issues. Using his inventions in laser scissors and laser tweezers, researchers have the ability to cut genes out of

chromosomes and insert them into living cells, or capture an individual motile sperm. (This research to better understand and manipulate the functions of human cells is further described in an article published in the April 1998 edition of *Scientific American*.)

Dr. Berns states, "There are a number of ways these [laser] beams are being used in biology and medicine. Laser scissors, with their short intense pulses of light, are being tested to perform human `assisted hatching'. In this procedure, the laser scissors cut a small trench in the embryo's protective layer, the zona pelucida. The trench helps the embryo hatch in the uterus and become a healthy fetus. The laser-aided technique may be particularly important for women over 30 because the zona pelucida is thought to toughen as women age. Assisted hatching trials have recently begun in Los Angeles and Atlanta."

3/13 **DUSA Pharmaceuticals** updated the status of its strategic alliance discussions and NDA filing progress, along with corporate highlights and audited financial results for the year ended December 31st. In dermatology, the company said it had reached an agreement in principle on a dermatology marketing and development agreement with an unnamed multi-national pharmaceutical company, who intends to market DUSA's Levulan PDT treatment for actinic keratoses (AK), along with other dermatology products to be developed by both parties. The companies are currently negotiating a definitive agreement.

Based on its successful Phase III clinical trials on Levulan for AK, the company is preparing to file its first NDA, which is planned for Q2 1998, rather than the previously announced Q1. This is due to the move by DUSA's subcontractor of Levulan Kerastick applicators to new facilities, causing a minor delay in commercial production runs scheduled for the new site.

Other 1997 highlights include beginning a multi-center Phase I/II clinical trial to study its second lead indication, Levulan photodetection (PD) of bladder cancer, late in 1997. Early tests show that multiple bladder cancers have been detected using Levulan and blue light, that were missed with white light visualization and random biopsies, the current standard of use. During 1997, DUSA also initiated a Phase I/II Levulan hair removal trial and supported independent investigators in Levulan PDT/PD studies in promising indications at leading academic centers in North America and Europe. The company also announced its strategic cooperation agreement with **Richard Wolf Medical Instruments** for light sources and cystoscopes to be used in the bladder cancer PD trials; the negotiation of a modified licensing agreement for Levulan PDT/PD with **PARTEQ**, the technology transfer arm of **Queen's University**; the move of DUSA's R&D administration offices to larger quarters in Valhalla, NY; the adoption of a shareholders rights plan; and financial

analyst reports recommending DUSA from **Hambrecht & Quist** and **CIBC Wood Gundy**.

For the year, the company sustained a net loss of $7.1 million (76 cents/share), compared to $6.8 million (75 cents/share) in 1996. At year's end, the company had cash and cash equivalents totaling $12.7 million, compared to $19.7 million in 1996.

3/13 **Photogen Technologies** announced the completion of a private placement of 875,000 shares of common stock for $8 a share to a number of accredited investors. The company received $7 million from the offering, and expects to use the proceeds over the next 19-24 months for corporate overhead and operating expenses, animal and clinical trials, the purchase of scientific and laboratory equipment, and for other working capital purposes.

3/16 **ThermoTrex Corporation** announced that it expects significantly higher earnings for the second quarter of fiscal 1998, ending April 4th, compared with the same quarter a year ago. Earnings for the current quarter will reflect a net gain of approximately $23.5 million from a secondary offering of ThermoTrex's **Trex Medical** subsidiary, which was completed in February. (ThermoTrex, a subsidiary of **Thermo Electron**, is the parent corporation of **ThermoLase**, which offers personal care products and hair removal lasers and spas.)

3/16 A new treatment that prevents arteries from re-clogging after angioplasty is being evaluated in clinical trials at **Columbia-Presbyterian Medical Center**. In the treatment, radiation is applied to the interior of the arteries immediately after balloon angioplasty has been performed. Columbia-Presbyterian is currently the only center testing the procedure. Since restenosis occurs in approximately 30-40% of the 500,000 or so angioplasties performed annually, something was needed. The use of stents has helped, but restenosis remains a significant problem. The restensosis occurs, it is hypothesized, because of a response to the damage caused by the inflating balloon during angioplasty. The vessels react by proliferation of a scar-like lesion, which allows re-accumulation of the plaque, re-clogging the artery. In animal experiments, Dr. Judah Weinberger, MD and his colleagues, found that using intracoronary irradiation, done by placing a balloon tipped catheter filled with a radioisotope at the angioplasty site, the proliferating cells stopped growing and the vessel walls healed without the formation of occlusive lesions.

The treatment has also shown promise in humans. In a pilot study conducted elsewhere, only 15% of patients restenosed, far below the expected rate. "This is the first therapy that holds significant hope for achieving long-term suppression of restenosis", said Dr. Weinberger, "Up to 90% of patients undergoing interventional procedures could be eligible for intracoronary radiation." The current study involves

60 patients with angina, and is primarily intended to test the safety of intracoronary irradiation.

(I have included this brief because laser angioplasty, which under current protocols calls for balloon angioplasty to follow the laser intervention, also suffers from high restensosis rates. If this technique provides the long-term relief from restenosis claimed, it could provide the impetus to restart studies of the use of lasers, combined with followup irradiation, for clearing clogged arteries. Laser angioplasty is currently only performed on about 10% -- or less -- of angioplasty candidates.)

3/17 **Candela Corporation** announced that it had reached a preliminary agreement to sell its skin care centers in Boston and Scottsdale to **Advanced Medical Alliance**. The terms of the transaction include a cash payment of approximately $3 million. The agreement is expected to be finalized by the end of March. Advanced Medical is a San Diego-based company that provides complete aesthetic/cosmetic services to consumers in facilities operating as "Centers of Excellence".

Candela said that the impact of the divestitures would result in one-time earnings credit in excess of $1 million, or more than 20 cents/share. Commenting on the sale of the skin care centers, president and CEO Gerard Puorro said, "We took a major write-off last quarter, primarily to put the continuing high costs and losses from the skin care venture behind us. With this transaction, we are able to recoup a significant amount of the cash we invested and re-apply those and other resources to foster additional continuing growth in our core laser device business."

The president and CEO of Advanced Medical is Alan Danto, formerly president and COO of **CTI**, the subsidiary of **Palomar Medical Technologies** now devoted to opening cosmetic laser centers primarily within **Columbia/HCA** surgery centers. Advanced Medical has three other cosmetic service centers on the west coast. In addition to the two newly acquired spas, the company has plans to open additional centers across the country and internationally. Danto plans to reopen the Scottsdale center by May 15th. An interview conducted with Danto, just after the announcement of his acquisition of the Candela centers, for publication in next month's issue of *Medical Laser Report*, is included with this issue of **Executive Laser Briefing**.

3/18 **Eclipse Surgical Technologies** announced that it had submitted an amendment to its application for PMA to the FDA, to sell its products for TMR. The amendment includes 12 month followup clinical trial data from its pivotal Phase II study, a randomized, controlled study comparing TMR to drug therapy in patients with Class IV angina, with no other surgical options. The initial PMA was sent to the FDA on July 1, 1997. The next step in the process is for the FDA to decide whether to file the PMA and grant a review by its Circulatory Devices Review Panel.

3/18 According to *Federal Filings*, **Thermo Electron** has upped its stake in **ThermoLase** to 72.1%, purchasing 568,100 shares between February 5th and March 12th, to give it a total of 27,433,504 shares.

3/19 **VidaMed** announced the publication of a peer-reviewed article reporting positive results of its TUNA (transurethral needle ablation) procedure at twelve months, will appear in the March issue of *Urology*. The article is entitled, "Transurethral Needle Ablation of Benign Prostate Hyperplasia: 12-Month Results of a Prospective, Multicenter U.S. Study". The study included 130 patients treated with the TUNA procedure, with no patients requiring followup retreatment at 1 year. Ten thousand TUNA procedures have been performed worldwide, 4000 in the U.S.

3/19 **Integrated Surgical Systems** announced the sale of its ROBODOC surgical assistant system to **Orthopadische Klinik**, in Rothenburg, Germany, increasing the installed base of ROBODOC systems to fourteen. According to ISS, the ROBODOC system has been used to perform precise total hip replacement surgical procedures on more than 2300 patients worldwide. ROBODOC is presently being marketed in Europe and ISS expects to file for FDA approval in the U.S. this year. NeuroMate, ISS' neurosurgery product, the first robotic technology for use in stereotactic brain surgeries has been installed in seven sites in France and Japan, which have supported neurosurgery on more than 1500 patients to date.

3/20 I received a letter from Dr. Bruce Sand, the inventor of the "collagen shrinking" technology assigned to **Sunrise Technologies International**. He has recently taken on the assignment to assist Sunrise in licensing potential applications for the intellectual properties outside of refractive surgery. Some of the potential areas available for licensing, such as for the treatment of glaucoma, strabismus, in orthopedics, aesthetic surgery, otology, urology, GI, and cardiology, are listed on the enclosure included with this month's newsletter.

3/23 **Premier Laser Systems** said that the previously announced agreement with **Henry Schein, Inc.** has been expanded to include direct and/or catalog sales programs in Canada, Germany, Spain, France, the Benelux countries, Mexico, and South America. The broadened agreement was signed by Premier and Schein at the 1998 Chicago Dental Society Mid-Winger meeting, where the companies together booked more than $500,000 in system orders, from U.S. and foreign-based practitioners. Several hundred dentists visited the Premier and Schein exhibits over the two day meeting, and tested the company's laser products. Schein plans to aggressively market Premier's Centauri erbium:YAG laser across the nation and in Europe.

3/23 **Cell Robotics International** announced that the United States District Court for the Eastern District of Arkansas had granted CRI's motion to dismiss the **Venisect (TransMedica)** patent infringement suit involving the Lasette. The lawsuit was

dismissed due to lack of personal jurisdiction and improper venue. The ruling does not prevent Venisect from refiling the suit in a proper jurisdiction at a later date.

3/23 **ConsenSys Software Corporation**, the innovator of configurable, rapid product development management software, announced that **CardioGenesis** had successfully deployed ConsenSys MedDev, used for design change control and document management, in speeding up the development of its cardiovascular TMR laser devices. According to ConsenSys, MedDev is enabling Cardiogenesis to more effectively meet the rigorous controls of the FDA and CE Mark regulatory agencies.

3/23 A writeup in this week's issue of *Mass High Tech* about **Cynosure**, said that the company had recently opened up a new section in its facility in Chelmsford, now using 47,000 square feet, primarily to meet the demand for its recently introduced hair removal lasers. According to senior vice president and chief marketing officer Robert Hubert, "Most of the growth is attributed to sales of our hair removal lasers. The growth in this product has been phenomenal." Hubert said that Cynosure has seen its share of growth driven by this explosive market, causing the company to both expand and hire more people. The company has gone from about 80 employees in January 1997 to nearly 140. He went on to estimate revenues for this privately-held company at $23.6 million in 1997, with expectations to reach $40 million this year. He said that Cynosure achieved revenues of more than $9 million in its most recent quarter, surpassing the revenues of its nearby "nemesis" **Candela**, which reported sales in its most recent quarter of $8.5 million. He went on to say, "The cosmetic laser market is amazing. Even I am amazed at what people will pay for this type of treatment. It's a good market to be in."

3/24 **ThermoTrex** announced that its board of directors authorized the repurchase of up to 2 million shares of its **ThermoLase** subsidiary, as they become available at prices the company believes are attractive.

3/25 A pioneer in percutaneous TMR, Dr. Payaz Shawl, said that the procedure is now being performed at the Washington Adventist Hospital in Takoma Park, MD. Dr. Shawl, who conducted a live demonstration of the technique at the hospital on March 24thm, said "This procedure gives a new hope for those patients [suffering from coronary artery disease] without having to undergo invasive surgery." (Dr. Shawl uses the **Eclipse Surgical** PTMR system.)

3/30 **Palomar Medical** announced that it had received approximately $7 million in orders for its LightSheer diode and EpiLaser hair removal systems, from **Coherent, Inc.**, its exclusive distributor. According to Ken Witte, vice president of Coherent's Aesthetic Business Unit, "The arrival of Palomar's diode system to complement the popular EpiLaser product has elevated activity to a new level. We are maximizing our resources to sustain the early leadership role that we have gained with our physician

customers." Palomar has the only FDA clearance to date to sell a diode laser for hair removal.

**MEDICAL/SURGICAL LASER UPDATE -- APRIL 1998**

3/30 **Cell Robotics** announced that it had submitted clinical trial data to the FDA, requesting clearance to use the Lasette laser finger perforator on children to sample blood for glucose testing under professional supervision. In the study, 63% of the participants felt no pain whatsoever, and none felt as much pain as from using their conventional lancet. The Lasette is the only laser device cleared by the FDA for use in glucose testing by adults, including diabetics, in clinical settings. Clinical trials are also underway to seek home-use glucose testing clearance.

3/31 **Laser Corporation** announced the results for its fiscal year ending December 31st. The company had revenues of $5.1 million, up from $3.5 million for 1996, and recognized a net loss of $254,600 (30 cents/share), down from a net loss of $668,000 in 1996. The increased revenues were due to a strong growth in the company's OEM sales and the commencement of sales of dermatology medical systems during the fourth quarter, which contributed 5% to the total revenues. The company anticipates the introduction of ophthalmic laser products during 1998.

3/31 An article to be published in the *American Journal of Otolaryngology* describes a new bloodless method for removing tonsils in children being used by ENTs at the Temple University Children's Medical Center in Philadelphia. The technique uses bipolar electrosurgical scissors, originally designed for removing adult abdominal tumors, but which can be modified to permit bloodless tonsillectomies, even in very small children. (It is my understanding that work is underway to develop small surgical lasers to do the same thing.)

3/31 **Biolase Technology** reported year-end results and announced the signing of two letters of intent for exclusive international distribution rights. For the year, revenues were $1.8 million, compared to $691,800 for 1996. The company had a net loss for the year of $2.8 million (21 cents/share). During the year, the company transitioned from R&D to manufacturing and distribution. It completed and submitted its clinical data for the Millenium and commenced international sales in Germany. Biolase also said that it had signed letters of intent for exclusive Millenium distribution rights in Italy and Canada; the agreements with **Sweden & Martina SpA** for Italy, and **Ash Temple Limited**, for Canada.

4/1 **CardioGenesis** announced the preliminary results of a pilot clinical study in "no option" patients treated with the company's Axcis PMR system for percutaneous myocardial revascularization. The findings were discussed in a paper presented at the American College of Cardiology conference in Atlanta. The study, conducted at The

Heart Center in Leipzig, was done on patients with severe coronary artery disease and Class III or IV angina, all of whom were untreatable with CABG or PTCA, and were taking maximum levels of anti-anginal drugs. Primary outcome measures were reduction in angina class and improvement in exercise tolerance, with patients returning 3, 6, and 12 weeks after the procedure for evaluation. Of the 28 patients successfully treated, 13 had reached the six month evaluation period and reported a 50% reduction in mean angina class, and a 70% improvement in exercise tolerance. More than 150 patients worldwide have been treated with the Axcis PMR system since beginning trials in Europe in November 1996.

4/2 **Premier Laser Systems** announced that it had adopted a shareholder rights plan by declaring a dividend distribution of one Preferred Share Purchase Right on each outstanding share of common stock, payable on April 14th to stockholders of record.

4/2 **Ramus Medical**, a subsidiary of **Miravant Medical Technologies**, announced initiation of clinical trials for its Rapidgraft, a blood vessel graft intended to replace damaged coronary and peripheral arteries. Rapidgraft is constructed at the time of bypass surgery from the patient's own pericardium (tissue surrounding the heart) or other fibrous tissue and potentially eliminates additional surgery to harvest blood vessels for grafts from other body locations. The technique consists of a disposable kit in which a rectangular pattern of tissue is supported between two concentric mating stents to form a cylindrical conduit that it sutured into place with standard surgical techniques.

4/6-
4/7 **Cell Robotics** said that it had received notice of allowance from the U.S. Patent Office for a new Lasette skin perforator patent. The patent covers the use of a multimode laser beam distribution to provide nearly painless and more effective capillary blood sampling.

The following day, the company reported its financial results for 1997. The company had revenues of $1 million, up from $663,300 in 1996, and a net loss of $2.5 million (48 cents/share), compared to a loss of $1.5 million in the previous year.

4/7 **Medical Alliance** announced that it had signed an agreement with the **Gynecare Division** of **Ethicon**, a **Johnson & Johnson** subsidiary, to make Gynecare's ThermaChoice Uterine Balloon Therapy and VesaPoint bipolar electrosurgical system available to physician's offices affiliated with Medical Alliance. According to the company, the introduction of the two technologies could reduce many of the more than 600,000 hysterectomies performed annually in the U.S. The Uterine Balloon Therapy system treats excessive menstrual bleeding (menorrhagia) due to benign causes in pre-menopausal women who have completed child bearing, and which accounts for more than 30% of the hysterectomies performed in the U.S. The balloon

therapy preserves the uterus but ablates the lining and cells responsible for menorrhagia through the use of heat. The VersaPoint system for hysteroscopic fibroid removal is designed as an innovative, minimally invasive alternative to hysterectomy to treat certain types of uterine fibroids. Approximately an additional 30% of hysterectomies are performed for fibroids.

4/8 **Coherent Inc.** announced that it expected net income for the second fiscal quarter ending March 28th to be slightly lower than the 32 cents/share achieved in the preceding quarter, estimating income to be approximately 29 cents/share versus street estimates of 32-37 cents. Sale will be about $106 million. Dr. Bernard Couillaud, president and CEO attributed the lowered results to manufacturing problems associated with yield issues on key purchased components included in some of the company's higher margin products, which led to lower sales and gross margins than anticipated. The company is committed to a number of long term projects that represent significant opportunities including the development of DUV lasers at **Lambda Physik**, semiconductor products at its Semiconductor Group, and refractive and hair removal products at its Medical Group. "These projects require significant current investment with only a modest corresponding increase in current revenues." For the first six months of this fiscal year, orders were approximately 10% higher than those for the same period last year, at $225 million. Dr. Couillaud remains optimistic that the company's financial performance will improve during the second half of the fiscal year.

The company's shares dropped 2.3% following the announcement, according to *Dow Jones News Service*.

4/8 **PLC Systems** said that it had shipped its 100th Heart Laser during its first quarter. The laser was sent to the Grant/Riverside Methodist Hospital in Columbus, Ohio.

4/10 I received a requested information package from **Pacific Pharmaceuticals**, an R&D company actively engaged in the development of cancer therapies. The company is currently developing a Phase I/II chemosensitizer to overcome cancer drug resistance in brain and other cancers, a photodynamic therapy with a proprietary boronated porphyrin (BOPP) molecule for use in brain cancer, and a proprietary immunotherapy for the treatment of metastatic breast cancer. As noted in the information sent, Pacific is preparing to become a key participant in the photodynamic therapy arena with its BOPP compound scheduled to begin clinical trials in the first half of 1998. In June 1996, Pacific Pharmaceuticals entered into an agreement which granted it the option to acquire **Binary Therapeutics, Inc.**, a privately held company, which owned certain proprietary technologies in PDT and a related area, boron neutron capture therapy. Pacific submitted an IND in 1998 for BOPP and is preparing for a human clinical trial in brain cancer with the drug.

4/10 According to the Winter 1997 issue of *The Ballistic Missile Defense Organization Update*, **Kigre, Inc.** the development of light detection and ranging (LIDAR) transmitters for BMDO, has led to a product line of miniature flashlamp-pumped lasers that can deliver megawatts of peak power for a variety of applications. In the medical arena, doctors could use them in dermatological handpieces for the removal of tattoos and for the treatment of vascular lesions. (I seem to recall seeing these hand-held lasers on display at either an ASLMS or SPIE meeting within the past couple of years.) In a conversation with a company spokesperson, I learned that Kigre can produce the lasers from almost any solid-state crystal. They have produced YAG, doubled YAG, erbium, holmium and even alexandrite devices. Anyone seeking further information about the devices or possibly licensing the technology can contact Michael Meyers of Kigre at 843-681-5800.

4/10 *The BBI Newsletter* contains an article by Michael Moretti on the laser hair removal status, stating that the market is booming. Michael reports that at least 10 laser companies are now involved. (For a complete listing, see the attached table with this issue of the newsletter.) **Coherent Medical** reports that about 200 of its EpiLaser ruby systems have been sold and another 300 will be sold this year. **Thermolase** and **Continuum Biomedical**, both using Q-switched YAG lasers and a topical carbon-based suspension, say that about 150 of their systems are in use. **Cynosure** reports that since December 1996, they have shipped more than 185 of their long-pulsed alexandrite systems, at an average price of $139,000. Candela hopes to shake up the market with its version of an alexandrite laser priced at $60,000. And of course, **ESC Medical** has its pulsed light source, with an output adjustable from 590 nm to 1200 nm, useful on all skin types, selling for $150,000.

4/13 **Computer Motion** announced that it had established European clinical sites and partnerships for minimally invasive heart bypass surgery using its Zeus robotic surgical system. The partnerships were formed with Rikshospitalet, The National Hospital, University of Oslo; and the University Hospital Grosshadern, in Munich. Both will develop minimally invasive cardiac procedures through incisions smaller than the diameter of a pencil in the chest wall. The Zeus robotic surgical system is composed of three interactive robotic arms placed at the operating table, a dedicated computer controller, and an ergonomically enhanced surgeon console. One robotic arm is used to position the endoscope while the other two manipulate surgical instruments under the direct control of the surgeon.

4/13 **Laser Photonics** said it had signed a letter of intent to sell certain company assets, including those of its wholly-owned subsidiary, **Laser Analytics**, for approximately $1.3 million in cash and assumed liabilities, to **American Lasers, Inc.** The agreement excludes business operations conducted in San Diego which relate to the company's excimer laser and delivery systems.

4/9-
4/14 In a series of releases over several days, two competing societies released statistics about aesthetic plastic surgery. First the American Society for Aesthetic Plastic Surgery (ASAPS) said that more than 2 million cosmetic surgeries or non-surgical cosmetic procedures were performed on Americans in 1997, quoting from its survey of doctors certified by several medical boards, including the American Board of Plastic Surgery. The top procedures nationally were chemical peels, collagen injections, liposuction, cosmetic eyelid surgery, and laser skin resurfacing, with men accounting for 14% of all procedures, up 64% since 1994. The top procedures for men are hair transplantation, nose reshaping, and liposuction. Baby-boomers accounted for 46% of the cosmetic procedures. ASAPS members performed an average of 320 cosmetic procedures in 1997, with the most frequently performed procedures being liposuction, cosmetic eyelid surgery, breast augmentation and facelifts. Of interest (and as contrasted with the data from the second source below) of the total 2.1 million procedures done in last year, 154,153 were laser skin resurfacing, or 7.3%. Eighty seven percent of these were done on women.

The competing release was from data collected by the American Society of Plastic and Reconstructive Surgeons (ASPRS), based on data collected from its approximately 5000 member surgeons. The latest total number of cosmetic surgeries that I could find on this organization's web site was 1.9 million for 1996. Of that total, 46,253 were laser skin resurfacings, representing 2.4% of the total. However, in listing the percentage change for the top five procedures for 1997 over 1996, the society showed that 20% fewer laser skin resurfacings were done by their membership in 1997, a total of only 36,860 procedures. (I guess that means that the majority of these procedures are done by other than members of the ASPRS!) The other top procedures and their percentage change were liposuction (+36%), breast augmentation (+39%), eyelid surgery (+45%), and facelifts (+15%).

(I also have very good comparative statistics on cosmetic procedures -- that I have used in preparing market studies on the cosmetic market and the potential for laser techniques replacing surgical techniques -- from the American Academy of Cosmetic Surgery.)

4/14 **Mehl/Biophile** released its financial results for the fiscal third quarter ending February 28th. Revenues for the quarter were $1.1 million, up from $582,800 for the same period a year ago, with a net loss of $5.2 million (19 cents/share). For the nine month period, revenues were $2.9 million, compared to $2.4 million a year ago, and the net loss was $14.2 million (42 cents/share). According to chairman and CEO Jack Forrest, the results were reflective of the failure of the company's previous market strategy. Future periods should begin to reflect the impact of significant changes in its market approach, an increase in marketing and sales efforts, continuing cost-reduction measures, and the introduction of additional consumer products.

The company also announced that it had negotiated a complete restructuring of the outstanding debt with Clearwater Fund IV, LLC. The existing $7 million secured note, due to mature on April 15th, and the $2.5 million revolving credit facility, have been restructured into a $1 million revolving credit maturing on June 1, 1999 and a $9.2 million term loan. "While the company continues to suffer from a lack of liquidity, the prospect of an economic Armageddon has now been removed. With prudent fiscal management, reasonable sales levels and an increased focus on marketing of the company's consumer products, it is our hope and plan that internally generated funds will be sufficient to meet our short and intermediate term needs," according to Forrest.

4/14 **BioLase** announced that it had entered into a letter of intent to acquire all of the assets of **Laser Skin Toner**, a company founded by Frank O'Donnell, chairman of **LaserSight**. Completion of the acquisition in which BioLase would issue shares of its common stock for the assets, is subject to a number of conditions including satisfactory completion of due diligence and the negotiation and execution of a mutually acceptable definitive agreement. Laser Skin Toner is a development stage company working on a proprietary non-invasive, laser-based surgical technology applicable to aesthetic skin rejuvenation. The technology employs a proprietary approach to delivering focused laser energy to the dermis without damage to the epidermis. It is expected to be particularly effective in dealing with striae (stretch marks) and facial skin laxity, among other applications.

Donald La Point, president and CEO of BioLase expects the Laser Skin Toner approach to complement its DermaLase erbium laser skin resurfacing system, as a non-ablative approach for the removal of minor wrinkles. (The Laser Skin Toner system uses a solid-state IR laser (either diode or YAG) to target the collagen in the dermis, causing shrinkage without damage to the surface of the skin, in a manner similar to the 1.3 micron YAG laser used by **Laser Aesthetics** to potentially shrink subsurface collagen.)

4/14 **Spectranetics** announced that the FDA had cleared the expansion of clinical trials for the company's 14 and 16 French Laser Sheaths, designed to assist in the removal of larger pacemaker and implantable cardioverter defibrillator leads. The expansion increases the number of sites that can investigate the lead removal from 50 to 65.

4/14 According to **Unicorn Financial Services**, in March, more than 1300 patients chose to finance their elective surgeries such as plastic surgery and laser vision correction, through a new monthly payment plan. This was twice as many people than in the previous month. Anne Tynion, president and CEO of Unicorn said, "Record numbers of patients are choosing to proceed with elective surgeries not covered by insurance because of the flexibility made possible through financing." The company's four-line faxable application is usually approved in less than five minutes and the average

interest rate is less than 10%. The Unicorn program is available to physicians specializing in plastic surgery, laser vision correction, and cosmetic dental surgery.

4/15 **CardioGenesis** reported results for the first quarter with sales of $850,000 for its ITMR and PMR revascularization products and associated disposables to international customers and U.S. clinical sites. This compared to sales of $1.6 million for the first quarter in 1997. The reduction in sales compared to the same quarter last year was due to the lack of reimbursement in Europe and constraints on capital purchases by various governments outside of the U.S.The net loss for the quarter was $5.6 million (46 cents/share).

4/15 **Transmedica International** said it had filed a notice of appeal in the U.S. District Court of Arkansas in its patent infringement suit against **Cell Robotics**. The original case had been dismissed on technical grounds of improper venue on March 12th. Transmedica's legal counsel disagrees with the judge's ruling and has appealed the decision with the U.S. Court of Appeals.

4/15 **Premier Laser Systems** announced that its relationship with **Henry Schein** had reached an impasse and that its board of directors had authorized management to initiate legal action against Schein if no other resolution could be found. The board made its decision following identification of irreconcilable differences which arose during negotiations with Schein. Schein notified Premier that it would not take a previously announced $4.5 million in dental lasers and associated disposables during Premier's fiscal fourth quarter ended March 31st, and disputed an order shipped during the fiscal third quarter. It also notified Premier that Schein preferred that any future orders be placed on a fully contingent basis, contrary to Premier's understanding of the terms of a letter of intent signed by Schein in December. At the time of this notification, most of the $4.5 million in intended fourth-quarter products had already been manufactured and placed in inventory to meet the expected sales.

Premier now anticipates that it may be required to restate results for the third fiscal quarter which would then show revenues of approximately $4.7 million, after subtracting the $2.5 million in disputed orders. Premier also anticipates that its revenues for the fourth quarter will be approximately $4.5 million lower with a substantial negative effect on net results. Sales of dental lasers are likely to be negatively effected for several months because the company had reduced its own sales force in reliance on the expected Schein sales and had refrained from signing additional distributors and shipping to them due to Schein's expressed desire for exclusivity in the dental laser marketplace until mid-1998. Premier has now begun discussions with certain dental products distributors who had indicated interest during the time Schein had requested exclusivity, and is expanding its direct sales force as well. Collete Cozean, Premier's chairman and CEO commented, "This situation is extremely puzzling and frustrating for us. Schein had indicated no dissatisfaction with

our products, and has in fact been selling Premier lasers to its customers. We have also been shipping products to Schein international sales organizations at Schein's request. As many people around the country already know, Schein featured our Centauri dental laser on the cover of a catalog mailer recently sent to many thousands of dentists."

On the same day, Henry Schein responded to Premier's announcement with its own statement. "Any claims made by Premier Laser Systems against Henry Schein, Inc. would be entirely unwarranted and without merit. The facts confirm that Henry Schein did not issue a purchase order for the products Premier claims were sold during Premier's fiscal third quarter, nor did Premier send an invoice to Henry Schein for these products, each of which are standard business practices in our industry; and accordingly, there cannot be a valid claim against Henry Schein." The statement went on to say, "It is unfortunate given our marketing efforts with respect to these products that Premier felt it had to pursue this avenue. Should a resolution not be reached, Henry Schein will vigorously defend any legal action."

The complete story has yet to be told. As it develops, I will keep you posted.

4/15 **Medical Industries of America** reported its revenues for the year had increased by 259% to $4.7 million, and that net losses had decreased 87% to $1.1 million (21 cents/share).

4/15 **Cell Robotics** announced that the *Red Chip Review* had issued a buy recommendation for its stock, with the statement, "We would recommend the stock to risk-tolerant investors because of the significant growth potential the company offers as a result of its new products, but those same new product launches also carry with them significant risk."

4/15 **Mile Creek Capital, LLC** announced that two of its portfolio companies, **PharmaWave, LLC**, had signed a key technology transfer agreement with **Massachusetts General Hospital**, and **LaserLite LLC** had received FDA marketing approval for its diode laser product for aesthetic procedures.

PharmaWave is engaged in developing a transdermal, non-injectable drug delivery system for a large class of therapeutic compounds. The technology transfer agreement with MGH grants PharmaWave the rights to certain of the hospital's patents, using shock-induced stress waves, created by laser energy, to enhance the outer permeability of the skin and enable the controlled transport of large molecules, such as insulin, across the barrier membrane.

LaserLite received FDA approval for its FeatherLite diode laser for aesthetic applications. The laser can also be used for the removal of unsightly leg veins and

removal of unwanted hair. The laser is currently undergoing clinical trials for these two applications. The company recently introduced a 60-watt diode laser system priced at $79,000.

4/16 **HealthSouth Corporation** announced that it had entered into a definitive agreement with **Columbia/HCA** to acquire 34 ambulatory surgery centers. The centers are located in Alabama, California, Iowa, Illinois, Kentucky, Louisiana, Minnesota, Mississippi, North Carolina, Nevada, Oregon, Rhode Island, and Texas. HealthSouth had agreed to pay Columbia $550 million upon closing, which is expected by early in the third quarter. Upon completion of the acquisition, HealthSouth will operate approximately 212 outpatient surgery centers, along with over 1200 outpatient rehabilitation centers, 112 diagnostic centers, 108 occupational health centers, and over 100 locations providing other patient care services.

4/16 **EDAP TMS S.A.** of France, announced that its wholly-owned subsidiary, **Technomed Medical Systems, S.A.** had filed a patent infringement suit against **Dornier Medical Systems**, involving patents relating to transurethral microwave therapy (TUMT) for the treatment of BPH. EDAP markets TUMT patented devices under the name of Prostatron, and filed against Dornier's device, UroWave.

4/16 **Surgical Laser Technologies** announced first quarter results with revenues of $2.4 million and a net loss of $461,000 (5 cents/share). Comparable sales in last year's first quarter were $3.3 million. Keith Stoneback, president and CEO said that domestic hospital budget constraints and the Asian financial situation combined to negatively impact the company's first quarter sales. He also said that the company's development and supply agreement with **CorMedica** should begin to produce revenues during the next twelve months, with SLT being on schedule to make the first system shipment next quarter.

4/16 **Candela Corporation** announced that it had posted a small net loss for its fiscal third quarter and that its primary cosmetic medical laser equipment business had returned to profitability. For the three months ending March 28th, the company had revenues of $8.6 million, slightly less than a year ago, but up from the $8.5 million posted in the December quarter. The net loss was $194,000 (3 cents/share), which includes losses from its Boston skin care center, which remains in operation. These losses were offset by operating income of $296,000 from its laser business.

Last month Candela had announced it had reached a preliminary agreement to sell both of its skin care centers locations to **Advanced Medical Alliance**. Candela said that negotiations to complete the $3 million transaction are continuing, but on a non-exclusive basis. (Apparently, Advanced Medical Alliance is having difficulty in raising the $3 million necessary to complete the deal. And Candela has decided to re-open the negotiations with other interested parties.)

In a press briefing following the news release, Gerard Puorro, president and CEO said that the company had received orders surpassing expectations for its recently introduced GentleLase alexandrite laser for hair removal and vascular lesion treatment.

4/20 **Optomedic Medical Technologies, Ltd.**, an Israeli company, has filed a registration statement with the SEC for a proposed public offering of shares and warrants worth approximately $11.5 million. **M.H. Myerson & Co.**, is the proposed underwriter. (The company is the producer of the "so-called" Kaplan Pendulaser, a small, portable, office-based $CO_2$ laser that is currently marketed in the U.S. by **KMC Systems**. (I have requested a copy of the prospectus.)

4/21 **Palomar Medical Technologies** announced that a follow-on patent that strengthens its position in laser hair removal technology, had issued to Massachusetts General Hospital. The patent, U.S. 5,735,844, relates to the long-term removal of unwanted hair by use of a laser or other suitable light source, with controlled cooling of the outer skin allowing greater energy to reach the targeted hair follicle without damage to the skin.

4/21 **Dornier Medical Systems** confirmed that it had filed lawsuits against **EDAP Technomed** (see the 4/16 brief above) to invalidate patents allegedly owned by EDAP and its U.S. subsidiary. Dornier's complaints cite its invention of cooled microwave hyperthermia probes prior to 1974, and specify numerous bases for invalidating Technomed's patents.

4/21 **ESC Medical Systems** reported results for its first quarter, showing net sales grew to $59.5 million, up from $39.4 million for the same quarter a year ago (both results being the combined sales for ESC and **Laser Industries**, its recent acquisition). Net income increased to $12.7 million (46 cents/share), compared with $8.3 million (31 cents/share) in last year's first quarter. The 1998 first quarter results exclude a one-time charge of $29 million associated with the Laser Industries acquisition. With the charge, ESC reported a net loss for the quarter of $16.2 million (62 cents/share). As stated by Shimon Eckhouse, president, CEO, and chairman, "ESC's acquisition of Laser Industries...has significantly enhanced our revenues, profits, and position in the market. Sales of the combined company in the first quarter of 1998 almost doubled compared with ESC's fourth quarter sales of $34.5 million...the company is now ideally positioned for future growth and expansion into new markets." He went on to say, "We are strategically progressing with the integration of Laser Industries and are focused on streamlining operations and R&D efforts through extensive evaluations of product offerings, resources, and distributors...We have integrated several key Laser Industries managers, strengthening ESC's senior management team."

4/21 **Eclipse Surgical Technologies** reported its first quarter results with revenues of $1.6 million, up from $1.2 million in last year's first quarter, and a net loss of $5.6 million (33 cents/share).

4/21 **Coherent, Inc.** announced results for its fiscal quarter ending March 28th. The results were in line with the preliminary results released earlier (see the 4/8 brief above). Sales for the quarter were $105.9 million, up 16% compared to the same quarter a year ago, and net income was $6.8 million (29 cents/share), 23% lower than last year's same quarter. The lower net income was primarily attributed to lower gross profit as a percentage of sales due to manufacturing problems associated with yield issues on key purchased components, and higher R&D spending. Incoming orders and sales were $109.2 million, an increase of 3% over last years quarter, with the company's backlog standing at more than $93 million at the end of the quarter.
Coherent reported that its medical group had sales for the quarter of $43.7 million, up from the $42.4 million for the prior quarter, and up from the $39.1 million in last year's second fiscal quarter. According to Dr. Bernard Couillaud, president and CEO, hair lasers contributed to strong sales in the fiscal first quarter, but fell to less half the total in the second quarter. The company has a current backlog of 60 units for the LightSheer diode laser, and will ship in the third fiscal quarter as many as **Palomar's** subsidiary, **Star Medical Technologies** can produce and ship to them.

4/21 The current issue of *Forbes* carries a devastating article on **Miravant Medical Technologies**. The title tells it all -- "Miravant invites investors to ride with it into the land of miracles. Frankly, we'd rather watch from the sidewalk." As quoted by a Merril Lynch veteran drug analyst, "Never have I seen a [drug] company spend money advertising a product it doesn't even have on the market, before the technology has been proven and approval has been gained." (He is referring to the $4 million the company spent on advertising last fall, with splashy ads in almost all of the business journals and newspapers.) And as the Forbes author says, "Yet except for its stock [price], Miravant has nothing much to sell." The author goes on to end the article by saying, "Give this one a wide, very wide, berth."

4/22 **Spectranetics** reported its first quarter results with revenues of $6.6 million, the third straight quarter of record revenues. This helped cut the net loss to $794,000 (4 cents/share), down from double that a year ago. Company president and CEO Joseph Largey said that domestic sales of laser systems and catheters continue to drive revenues, with sales of laser catheters doubled, and the company also shipped $1.2 million in laser systems for TMR to its partner **U.S. Surgical**.

4/22 **Pacific Pharmaceuticals** announced that it will commence a human safety study of its PDT compound BOPP in patients with malignant brain cancer, after receiving FDA acceptance of its IND application. The 25-30 patient clinical study will be conducted at the Royal Melbourne Hospital in Australia.

4/23 **ArthroCare Corporation** said that it was entering the cosmetic surgery market and that it had formed a new division, called **Visage**, to commercialize its technology in that field. The move marks the company's first direct move into markets outside of arthroscopy. Visage will market directly to dermatologists and other specialists in the field of cosmetic surgery in the U.S. directly, and through a subsidiary, **ArthroCare Europe AB**. Visage will begin marketing its Cosmetic Surgery System immediately for skin resurfacing and wrinkle removal, and in the U.S. under its 510(k) approval for general dermatology. The system uses a patented method of tissue removal called Coblation, that uses radiofrequency energy to remove tissue in a method considerably cooler than that of traditional electrosurgery or lasers. The Coblation approach disintegrates tissue layer by layer giving the surgeon control to remove and sculpt tissue with minimum damage to surrounding tissue.

ArthroCare signed an agreement with **Boston Scientific's SciMed** division in February, for that company to develop and market Coblation-based devices for TMR in treating heart disease. ArthroCare intends to apply its technology in a broad range of surgical fields including cardiology, dermatology, urology, gynecology, and plastic, oral, and general surgery.

4/23 **Laserscope** reported its results for the first quarter with revenues of $13.6 million, compared to $15.8 million for the same quarter a year ago. The company had a net loss of $230,000 (22 cents/share). Robert McCormick, president and CEO, said that the company's performance continued to be affected by the sluggishness in the U.S. cosmetic laser market, a decline in sales of operating room products to U.S. hospitals, and by economic disruptions in Asia. Sales of PDT laser systems, however, increased following the FDA's approval of the treatment of certain types of early-stage lung cancers. Laserscope is addressing the cosmetic laser market through the introduction of three new lasers at last month's AAD meeting. Orders were taken for all three and shipments are expected in the third quarter.

4/24 **Premier Laser Systems** said that it was in discussions with several dental products distributors following the problems encountered with **Henry Schein**. The company said it also was continuing to hold discussions with Schein about resolving their differences.

4/24 The FDA's advisory panel reviewing **PLC's** Heart Laser PMA, voted unanimously to recommend that the device be approved for marketing to patients who suffer from severe, unstable angina, and are not amenable to conventional coronary revascularization techniques (bypass or angioplasty). The panel noted that post-marketing surveillance should be considered by the FDA in giving its approval. Ronald Opel, an analyst with Fechtor, Detwiler, said that the overall worldwide market for TMR exceeds $2 billion. He felt that PLC could generate roughly $75 million in revenues 12 months after receiving final approval, and $125 million in

annual revenues after the second year, with greater than 50% growth for several succeeding years. PLC estimates that there are roughly 250,000 end-stage coronary artery disease (CAD) patients in the U.S. and Europe, and approximately 100,000 new patients diagnosed with CAD annually. The Heart Laser sells for about $500,000 but hospitals can rent the system for about $25,000 upfront, and pay an additional $3000 to $3500 each time it is used, according to Mr. Opel.

4/27 **PLC Systems** announced that it had secured a financing commitment up to $10 million from two institutional investors. Under terms of the financing, PLC has received $5 million from the issuance of convertible debentures, with a commitment to receive up to an additional $5 million. PLC will file a registration statement for the share underlying the debentures. The funds will be used to support the market launch of the Heart Laser upon receiving final FDA marketing approval, and to conduct additional research into adjunct TMR areas.

4/27 **Championship Auto Racing Teams (CART)** becomes the first sport industry to make the Theralase biostimulation treatment available for its racing teams. Under terms of a sponsorship agreement, **Laser BioTherapy** of Dallas, will make its biostimulation system available for use at CART's MobileMedical facility, beginning with this weekend's Grand Prix race at Nazareth (PA) Speedway, and at all of the remaining 13 North America event on the Championship Series schedule. Traditionally, CART's athletes have relied on anti-inflammatory medications and cortisone injections to help ease pain and discomfort during races. With CART's participation in a clinical trial to determine the effectiveness of laser therapy in treating pain and inflammation of muscles and joints in sports injuries, the laser therapy will be available for use. CART is joining three other medical institutions performing clinical studies, the Mayo Clinic of Rochester, MN, Texas Woman's University of Dallas, and Northside Hospital of Atlanta. The Theralase laser has been authorized for clinical use under approved protocols.

**MEDICAL/SURGICAL LASER UPDATE -- MAY 1998**

4/27 **LaserLite LLC** announced that it had received FDA approval for marketing its diode laser for the treatment of leg veins. The 450 joule device has a list price of less than $80,000.

4/28 **Miravant** announced that it had sent a letter to the editor of *Forbes*, responding to the negative article published in its May 4th issue (see last month's 4/21 brief). The letter states, "Your article on Miravant Medical Technologies was so full of inaccuracies that it's hard to know where to begin to set the record straight. Your reporter did not seem to grasp the potential of our medical technology or understand the drug approval process. As a result, the conclusions they reached were simply wrong." Regarding the "hyping" of the stock, so that insiders could "make a killing", Miravant said that its

current officers and directors are bound by lock up agreements and have never sold a share. The rest of the letter goes on in the same tone, with management denying that it was promoting its accomplishments before they began.

4/28 **BioLase** said that it had been awarded a patent from the U.S. Patent Office for its pioneering "cool-cutting" technology, which uses water particles, not thermal heat, to cut both hard and soft human tissue. The patent covers the company's Hydrokinetic Laser Cutting technology used in both its Millenium dental and DermaLase cosmetic lasers.

4/29 **Palomar Medical Technologies** released its first quarter results, with revenues increasing to $7.1 million, compared with $2.7 million for the same quarter a year ago and $5.3 million for the fourth quarter. The company also reported a net loss of $6.8 million (15 cents/share), down from $10.3 million a year ago, and $14.9 million for the preceding quarter. During a teleconference following the financial data release, management noted that the company had begun shipping its LightSheer diode hair removal lasers to **Coherent**, with 10% of the $6 million in laser sales representing the LightSheer product. The new ruby laser, the EpiLaser 2, is still under FDA review and should be ready for rollout by the end of the summer. In response to questions about CTI (the laser center subsidiary), Dan Valente, CEO said that they were still re-assessing the opportunity, and were making slow progress in opening new centers in conjunction with **Columbia/HCA**. Currently only five Columbia sites are open (the same number as were open at the end of the last quarter).

4/29 **PLC Systems** reported financial results for the first quarter. Total revenues were $945,000, compared to $1.6 million for last year's first quarter, due to a decrease in Heart Laser sales and in the method of shipment. All of the lasers shipped this year were under the company's placement program, and included a decline in placement revenues due to the lack of medical reimbursement by Medicare and other third party payors. This is expected to continue in the near term until HCFA reinstates medical reimbursement after the system receives FDA approval, sometime later this summer. Of the total revenues received, $365,000 represented product sales, while $580,000 represented procedure revenues. For the quarter, the company had a net loss of $3.9 million (21 cents/share).

4/30 **QLT PhotoTherapeutics** at its annual meeting, reported continued sales growth of Photofrin and steady progress in its clinical trial programs. First quarter royalty revenues were $459,500 on end-user sales of Photofrin of about $2.2 million, up 55% from the first quarter a year ago, and up 10% from the preceding quarter. Unit sales increased by 16% over the fourth quarter and largely reflect continued growth in Photofrin sales into the U.S. by QLT's U.S. partner, **Sanofi Pharmaceuticals**. QLT reported a net loss for the quarter of $4.6 million (19 cents/share), with R&D costs

totaling $5.7 million up 108% from last year's first quarter, but down 14% from fourth quarter costs.

Commenting on the progress in the clinical trial programs, CEO Dr. Julia Levy said that the conclusion and analysis of the macular degeneration trials will be the most significant and most anticipated milestone for QLT this year. "The success of this program will play a key role in our mission of becoming a top-tier biopharmaceutical company." QLT and its partner **Ciba Vision** expect to submit data to various regulatory agencies in North America and Europe for the approval of verteporfin for treatment of AMD in 1999. The company also began a pivotal Phase III trial of Photofrin for the treatment of Barrett's esophagus during the first quarter, and expects to be in position to file for approval in 2000.

QLT also announced a new strategic alliance, with **C.R. Bard**, for the use of photodynamic therapy in the treatment of restenosis, a common vascular condition. Under terms of the partnership, Bard will fund product development and clinical research for a therapeutic system and procedure for reduction of arterial restenosis utilizing localized delivery of PDT with Photofrin, and have exclusive worldwide marketing rights. Pending approval of the process, QLT will receive royalty payments or co-fund R&D at a later date in exchange for an increased share of sales revenues.

5/4 According to *NewsPage*, **Eclipse Surgical Technologies** has been awarded a new patent on a laser device with a piercing tip for TMR procedures. The method patent describes the combined mechanical/laser procedure by inserting a mechanical piercing device and an elongated flexible lasing apparatus into the chest cavity of a patient.

5/4 **Premier Laser** announced that it was introducing its Arago II argon laser, a simpler, less expensive version of its Arago portable laser, for tooth whitening and composite curing. The new laser, which delivers similar power capabilities, will sell for $5500, compared to the Arago at just under $9000.

5/5 **Spectranetics** announced that it had signed a strategic agreement with **Orbus Medical Technologies**, to distribute and market a next-generation coronary stent called R Stent. Spectranetics will assist Orbus, a privately-held Florida company, in the regulatory process, first in Europe, and then in the U.S. and Japan. Once regulatory approval is obtained, Spectranetics plans to market the R Stent to a core customer base of high-volume physicians and medical centers in those countries, focusing on the most complex patient cases. The R Stent is a stainless steel, DNA-ladder-like design which conforms to the natural anatomy of coronary arteries, and provides structural support, radial strength, and flexibility.

5/5 **Eclipse Surgical Technologies** said that the FDA had accepted for filing the company's amended PMA application containing 12 month followup data. The

company expects to present its data to a Circulatory Systems Devices Panel as the next step in obtaining marketing approval of its laser system for TMR. No panel date has yet been set.

5/5 **Physical Sciences Inc. (PSI)** announced that it had been awarded a follow-on three-year, $5 million research contract, with initial funding of $857,000, from the U.S. Army Aviation and Missile Command at Redstone Arsenal, Alabama, to continue development of advanced solid-state dye lasers. PSI is developing a state-of-the-art, energy-efficient, solid-state dye laser which will lead to a major breakthrough in dye laser technology. The use of a solid polymer host for the lasing dye combines the compact convenience of a non-flowing gain medium with the wavelength diversity of conventional liquid dye media. The device will have military application in underwater surveillance, communications, and remote sensing of battlefield contaminants. Commercial applications include medical procedures and remote sensing of environmental constituents, where liquid dye lasers are already being used.

5/5 **PLC Systems** said that physicians presented the results of two studies using its Heart Laser at the American Association of Thoracic Surgeons in Boston. The two studies indicated that 70-90% of patients experienced significant relief from angina in their 1 and 2 year follow up examinations. This compared to only 13% of the patient who continued on medical management.

5/5 *Dow Jones* reported that **Ion Laser Technology** has had a "cash crunch" and its "weakened financial condition" will force it to restructure its operations, research activities, and management and research personnel, moves that will result in a pre-tax restructuring charge of $2.2 million in its fiscal fourth quarter. The company also named a new CEO, announced the resignation of its chairman and CFO (see the People section of this newsletter), and said delays in development of a new product (the Apollo 9500) have sparked a cash shortage that is forcing a halt in development of that and other products. ILT plans to shut down its manufacturing operations in Salt Lake City, sell its plant as soon as practicable and relocate company headquarters to Pennsylvania. The company will terminate and make severance payments for substantially all of its employees, and is considering establishment of new production facilities at the Pennsylvania location, but a final decision has not yet been made. ILT also plans to close down, or if a purchaser can be found, sell its industrial laser division. Production of its Apollo 9500 dental tooth whitening laser is expected to be moved to Illinois on an interim basis. Because of production delays, ILT doesn't expect to meet the June 30th deadline for delivering Apollo 9500 units to its domestic distributor, **Dental/Medical Diagnostic Systems**. If it misses the deadline, DMDS could terminate the agreement and require a refund of $500,000 in advance payments. The company is re-evaluating the Apollo 9500's design and plans to revise the products specifications. Until improvements are made, the company will not deliver any units.

ILT said that it had expected that whitening chemistry and composite materials used with the Apollo 9500 would produce revenue in fiscal 1998, but now that was uncertain. While development continues on the Apollo 9500, ILT will focus on developing tooth-whitening materials and a second-generation laser tooth-whitening system.

Dental/Medical Diagnostic Systems said that it had been informed that ILT could not deliver the Apollo 9500 dental lasers as required in its agreement with ILT. Therefore, DMDS plans to pursue other options and will file for a 510(k) notification with the FDA for its Apollo 95E system within the next two weeks, which would permit it to market that product in the U.S. upon notification from the FDA. DMDS began international marketing of the Apollo 95E tooth whitening and composite curing laser at the end of March. The Apollo 95E has many of the attributes of the 9500; cures composites in 1-3 seconds, and whitens teeth in the dentists' office in under an hour. The company has received orders for 800 units of the 95E and had shipped in excess of 300. The development of the 95E was funded by DMDS and it is produced at its European operation for the international market.

5/5 **Cell Robotics** announced that two pregnancies have occurred as a result of the company's clinical trial of its In Vitro Fertilization Workstation. The pregnancies are significant not only because they occurred in previously infertile women, but also because these women are representative of a growing population of women who turn to and are seeking more successful assisted reproduction technology, such as the company's, to achieve pregnancy. The IVF Workstation is being tested in an FDA-approved clinical trial at sites in Belgium, Australia, Israel, and in the United States.

5/6 The *Los Angeles Times Mirror* reports that a **Premier Laser Systems** shareholder had filed a class action lawsuit, accusing the company of violating securities laws by issuing misleading information about its lasers sales in hopes of inflating its stock. The complaint contends that the company improperly booked shipments to a distributor as sales, hoping to boost financial results and its stock price, so that it could use the inflated stock to pay for the merger with **Ophthalmic Imaging Systems**. (The alleged offense concerns the breakup of the distributorship agreement between Premier and **Henry Shein**, over dental laser sales to Schein which it claims it did not order.) Premier denies any improper conduct.

5/6 **BioLase Technology** announced that it had signed an exclusive agreement with Tokyo-based **Meditec Corporation**, a wholly-owned subsidiary of **Marubeni Corporation**, to distribute BioLase's newly patented non-thermal HydroKinetics laser tissue cutting products throughout Japan. The three-year, $10.7 million minimum purchase agreement, commences upon Japanese regulatory clearance, anticipated within fiscal 1999. Meditec will distribute BioLase's two major laser-based systems

utilizing the HydroKinetics technology, Millenium for dentistry, and DermaLase for the medical industry.

5/6 **ESC Medical Systems** announced that its **Laser Industries Ltd.** subsidiary and certain other related entities, had entered into a settlement with **Mehl/Biophile International** and its related entities which, among other things, resolves all outstanding arbitration and litigation proceedings between the two companies. Under the terms of settlement, Mehl has granted ESC and its associated companies, a sublicense to the Zaias patent and certain other rights relating to intellectual property in the field of hair removal by lasers. In addition, under the settlement terms, **Sharplan 2000**, a joint venture company formed in December 1995 by Mehl' subsidiary **Mehl Technologies** and Laser Industries will now become a wholly owned subsidiary of **Sharplan Lasers Inc.**, an ESC group company. Mehl will receive an immediate cash payment and may receive additional cash payments subject to future events. The specific financial terms were not disclosed.

The settlement also provided for the dismissal of all pending legal actions in the United Kingdom between **SLS (Biophile) Limited**, a Mehl subsidiary, and **Spectron Laser Systems, Ltd.**, an ESC subsidiary.

5/6-
5/7 **ArthroCare** announced that it is entering the otorhinolaryngology (ENT) business and that it had formed a new division, **ENTec**, to commercialize its patented Coblation technology in this field. The ENTec Surgery System will be introduced at the annual spring meeting of the American Academy of Otolaryngology in Palm Beach, FL. "Because many ENT specialists also perform cosmetic and reconstructive surgery, moving into head and neck at this time will enable us to capitalize on marketing and distribution synergies across the two markets," said Michael Baker, president and CEO. "And since the ENTec products are compatible with our arthroscopy operating system, we will be also able to tap into the more than 2000 units already in place worldwide." ENTec estimates that of the 1.4 million head and neck surgeries performed worldwide, approximately 25% will be for the treatment of chronic sinusitis or nasal polyposis, with the ENTec Surgery System currently indicated for use in such procedures, as well as for head and neck surgery in general. Coblation uses radio frequency energy to remove tissue through a significantly cooler process than that of traditional electrosurgery or lasers.

The following day, ArthroCare announced the introduction of two new wands that expand the company's line of instruments for removing or shrinking tissue during arthroscopic joint surgery. The company now markets 20 arthroscopic wands in a range of sizes, power, and function that enable the surgeon to operate on a variety of abnormalities in essentially every major joint in the body.

5/7 **American Dental Technologies** reported financial results for its first quarter, with revenues of $5.6 million and net income of $841,000 (12 cents/share). Ben Gallant, president and CEO said that, "Sales in North America increased approximately 25% in the first quarter compared to 1997, however, as expected, foreign sales declined. We expect continued growth in North America sales for the remainder of 1998, and anticipate foreign sales in 1998 will exceed those in 1997."

5/7 **Cell Robotics** announced that it had signed an exclusive distribution agreement with **C.A. Continental**, to sell its laser Lasette finger perforator in China. CAC forecasts that it will sell 2000, 4000, and 9000 Lasettes respectively, in the first three years of the agreement, and has placed orders for the first 50 laser units and 144,000 disposable tips.

Cell Robotics also announced that the U.S. launch of the product would be at the American Diabetes Association meeting in Chicago June 13-16.

5/8 The second class action lawsuit was filed by another attorney's office against **Premier Laser Systems**. This suit was filed by the offices of **Milberg-Weiss**, while the first suit was filed by **Stull, Stull & Brody**. (See the 5/6 brief above.)

5/11 **American Dental Technologies** announced that long-standing major shareholders recently exercised warrants to purchase 391,000 shares, providing the company with a new $1.6 million investment. The funds will be used for added marketing and sales efforts, additional R&D, and vigorous pursuit of several key lawsuits related to the company's intellectual properties.

5/11 **Eclipse Surgical Technologies** announced that the FDA had approved its IDE for starting Phase II clinicals of its percutaneous transmyocardial revascularization (PTR) study in conjunction with other coronary interventions, such as balloon angioplasty and stents. The randomized, controlled study will compare this combined treatment to both balloon and stent therapy alone.

5/11 **Cell Robotics** reported its first quarter financial results. The company had revenues of $456,000, up 78% compared to revenues for last year's first quarter, and a net loss of $294,700 (6 cents/share). Most of the sales increase was due to demand for the Cell Robotics Workstation (which incorporates the LaserTweezers), with small contributions from both the Lasette and the IVF Workstation. Dr. Ronald Lorhding, president and CEO believes that it will be the third and fourth quarters before these new products make substantial contributions to revenues.

5/11 **LCO Investments Ltd.** increased its holdings in **Ion Laser Technology** to 41.6%, purchasing an additional 1.9 million shares at $2.69/share.

5/11 **ThermoLase** reported revenues of $8.1 million for its latest quarter, compared with $11.7 million for the same quarter a year ago. The net loss for the quarter was $8.5 million (22 cents/share), up from $3.7 million a year ago. Gary Weinstein, chairman, said we are extremely disappointed with the results and are working to refocus the business, including changes in management and a new marketing strategy.

5/12 **Laserscope** announced that **Heraeus Med GmbH**, the company's largest shareholder, entered into a series of agreements whereby it sold all of its 4.3 million shares in an unregistered private sale to a limited number of accredited investors, predominantly institutional purchasers. In connection with the sale, the three directors designated by Heraeus have resigned from the Laserscope board.

5/12 **BlueStone Capital Partners'** senior analyst Scott Baily has initiated coverage of **BioLase Technology** with a "strong buy" recommendation, and a 12-18 month price target of $7-$10 per share. Baily's recommendation is based on the recent patent issued to BioLase for its unique Hydrokinetic laser cutting technology, incorporated into both its Millennium hard tissue dental laser and its DermaLase soft tissue/skin resurfacing device. Further, Baily expects that the Millennium laser-based system will be next to receive hard tissue dental approval during the second or third quarter of this year (it currently has soft tissue approval), and that the company will also obtain approval for its Lazar ToothBrush, a non-laser tooth whitening product (it uses a light source to activate a special toothpaste), and possibly for its recently acquired Laser SkinToner (skin rejuvination) device. He expects revenues to more than double to $4.5 million, with a loss of 15 cents/share in 1998, compared to revenues of $1.8 million and a loss of 21 cents/share in 1997. And revenues to grow to $13 million in 1999 with net profits of 10 cents/share. (We are also forecasting revenues in 1998 for this company at the $4 million level.)

5/12 **Medical Alliance** announced that its board of directors had authorized the repurchase of up to 1 million shares of the company's stock over the next 12 months.

5/13 **DUSA Pharmaceuticals** announced corporate highlights and financial results for the first quarter. The highlights included updates on the status of its dermatology strategic alliance with a still unnamed major multi-national pharmaceutical company for marketing of the company's actinic keratoses (AK) products, and the development of other dermatology products. An agreement in principle was announced on March 13th, and DUSA has been working since then to finalize the contract. DUSA remains confident that the agreement will be successfully completed. The company also noted that its subcontractor for Levulan Kerastick applicators for the treatment of AK is nearing completion of two commercial runs which are required prior to its NDA submission. Filing is planned for late in the second quarter.

The company also reported that at a recent workshop on ALA PDT, promising new studies in humans were presented including ALA PDT/PD for the treatment of Barrett's esophagus, endometrial ablation, and bladder cancer; the first case reports of the use of Levulan for prevention of restenosis after angioplasty; and for the enhanced detection of a variety of cancers, including brain cancer at the time of tumor resection.

In its financial report, the company's net loss for the quarter was $1.4 million (15 cents/share), compared to $1.4 million a year ago. R&D costs were $1.1 million, compared to $1.3 million a year ago.

5/13 Another law firm has announced its intention to file a class action suit against **Premier Laser Systems**. This time its is **Abbey, Gardy & Squitieri** of New York.

5/14 **Pharmacyclics** reported its fiscal third quarter results with a net loss of $2.8 million (25 cents/share) and recognized revenues of $452,000, which consisted of contract research and development revenues related to its collaborative agreement with **Nycomed Imaging A/S**, and its development agreement with **Alcon Pharmaceuticals**.

5/14 **Miravant** announced its financial results for the first quarter with revenues of $1.9 million and a net loss of $7.9 million (56 cents/share). The net loss was consistent with the company's progress in conducting Phase III clinical trials. The company has cash and cash equivalents and securities of $67.3 million.

5/15 According to a Colorado Springs' newspaper, *The World Reporter*, **Spectranetics'** CEO Joseph Largey said at its annual meeting that the company has entered into a period of what it hopes will be "white-hot growth", spurred in part by stepped-up marketing. The company has begun placing ads in professional journals, running TV spots in cities where heart surgery conventions were taking place, and sending direct mail ads to convention-going cardiologists. According to Largey, revenues are growing and the net loss is shrinking. The Laser Sheath is a key source of revenue, with Largey expecting sales to reach $6 million in 1998 and $12 million in 1999. The total market for lead-extraction devices is about $75 million, with the laser device able to remove about 94% of defective leads, compared to only about 65% success with mechanical procedures. He expects total company revenues to hit $30 million soon, from about a $25 million rate (which we have also forecast for 1998) based on first quarter results.

5/15 **Laser Corporation** announced first quarter results with revenues of $865,000 and a net loss of $268,500 (31 cents/share). According to president and CEO Joyce Wickham, the company's first quarter net loss was primarily a result of a downward fluctuation in the demand for its OEM laser products, and the less than expected sales of its medical laser systems. The latter was adversely effected by the inability of a supplier to deliver a useable laser which is a component in the company's medical

products. The company is currently working with the supplier to resolve the existing laser useablilty issues.

5/15 **Dental/Medical Diagnostic Systems** released its first quarter results with net revenues of $2.1 million, down from $3.9 million a year ago. The decrease was primarily a result of reduced TeliCam sales both domestically and internationally. The company did, however, begin shipping the Apollo 95E tooth whitening and curing device into international markets. On May 5th, it was announced that **Ion Laser Technology** had indicated it would be unable to deliver, as agreed, the Apollo 9500 dental laser system, for which DMDS has exclusive marketing rights in the U.S. and Canada. By failing to deliver, ILT is not in compliance and DMDS will seek the immediate return of an approximately $500,000 inventory deposit and license fee. DMDS is accelerating its Apollo 95E program and expects to file shortly for 510(k) approval for marketing this product in the U.S.

5/18 **ThermoLase** announced that it had received FDA clearance to market its SoftLight laser for skin resurfacing. The skin treatment process employs the same low energy dermatological laser used in the company's hair removal process, in combination with an activating lotion. The laser's energy reacts with the lotion, creating heat and mechanical energy that removes the tough outer layer of dead skin. The new skin resurfacing service will be available in all of the company's Spa Thira locations, as well through its physician licensees.

5/19 **BioLase Technology** announced that it had completed a Regulation D private placement, with gross proceeds of $3.9 million, to be used for general operating capital and to fund the refinement and improvement of existing products and products currently under development.

5/19 **Laserscope** announced that its PDT laser systems were being used in a recently initiated Phase I clinical study to evaluate the photoangioplasty treatment of patients with peripheral vascular disease, using the photosensitizer drug ANTRIN, manufactured by **Pharmacyclics**. In the minimally invasive process, patients are injected with ANTRIN which, when subsequently activated by Laserscope's PDT laser systems, dissolves the plaque in blood vessels with little or no damage to healthy surrounding blood vessel walls. According to Laserscope president and CEO Robert McCormick, "The potential of being able to treat atherosclerosis effectively and safely with a drug-laser combination would represent a major breakthrough in the treatment of cardiovascular disease." Unlike current relatively indiscriminate therapies, the new drug-laser treatment has the potential to eradicate plaque over long segments of arteries, avoid damage to artery walls, and preclude restenosis. The Phase I clinical trial using ANTRIN activated by a 732 nm dye laser, is underway at Stanford University. (The laser system used is essentially the same system used to activate Photofrin, but adjusted to run at 732 nm.)

5/20 **ESC Medical Systems** announced that it had received marketing approval from the FDA for its PhotoDerm VL deep vessel accessory for the non-invasive treatment of large and deep-lying vessels. The special accessory, based on a pulsed Nd:YAG laser, is driven by the same power source and its upgraded software package contained in the PhotoDerm system. It is available as an add-on to new PhotoDerm systems or as an upgrade to installed units. Dr. Shimon Eckhouse, president and CEO noted that in clinical development work done by the company's investigators, they successfully closed reticular and feeder leg veins non-invasively using this device. The addition to the PhotoDerm VL will expand its capability in the leg vein market.

5/20 **QLT PhotoTherapeutics** said that results of its PDT lung cancer trials were presented at the American Society of Clinical Oncology meeting held in Los Angeles. The results included as yet unpublished data that led to the FDA's approval of Photofrin in January as a treatment for microinvasive endobronchial NSLC in patients who are not candidates for surgery and radiotherapy. The trials included a total of 102 patients and were conducted in Canada and Europe. According to Dr. Stephen Lam, head of the bronchoscopy program at the British Columbia Cancer Agency in Vancouver, "It can be concluded from the results that PDT with Photofrin is an effective method for treating early-stage lung cancer which minimizes damage to surrounding healthy tissue. In our clinical trials, approximately 75% of the patients had a biopsy proving complete tumor response following treatment and about half of these patients maintained this response in long-term follow-up. Most adverse events were mild to moderate and self-limiting."

5/21 **Palomar Medical Technologies** announced that the court had granted its motion for summary judgement to invalidate **Mehl/Biophile International's** hair removal patent. The ruling by Judge Alfred M. Wolin of the U.S. District Court in NJ in favor of Palomar, invalidates Dr. Nardo Zaias' patent, which is licensed to Mehl. The court ruled that a brochure provided by **Spectrum Medical Technologies**, now a subsidiary of Palomar, in connection with sales of its Q-switched ruby laser, anticipated the Zaias patent's method of hair depilation. The court found that the manual enabled Zaias to develop his method and concluded that the Mehl patent is invalid.

Mehl responded by saying that the court had invited Mehl's counsel to present comments to the court during the next two weeks, which the company plans to accept and will attempt to show the court the error of its ruling. Mehl will await the outcome of this interaction before deciding whether to appeal the ruling. Mehl also announced that the recent settlement/license agreement with **ESC Medical** contained provisions for additional payments contingent of the outcome of certain events, including the payment of $1 million by ESC to be paid to Mehl if Palomar's motion for summary judgement was denied. The courts ruling would likely defer a determination on whether this payment would be received until the final outcome of any appeal or reconsideration of the ruling is known. In addition, under the ESC settlement, Mehl

received the right to grant an additional sublicense under the Zaias patent. This right is similarly effected. The company further announced that the unfair trade practices aspect of its lawsuit against Palomar is unaffected by the ruling.

5/21 Yet more law firms have joined the class action lawsuit fray against **Premier Laser Systems**. This time it is **Berman DeValerio & Pease**, of Boston and San Francisco, **Wechsler Harwood Halebian & Feffer**, and **Wolf Popper** both of New York.

5/21 **BioLase Technology** released its first quarter results, with sales of $262,500, an increase of 95% over the same quarter a year ago, and a net loss of $829,100 (6 cents/share). Don LaPoint, president and CEO noted some of the significant accomplishments of the past several months, the submission of clinical data to support the PMA for the Millenium's use on hard dental tissue; finalization of the design for LaserBrush; and commencement of shipment of Millenium into both Canada and Italy. Subsequent to the end of the quarter, the company received a U.S. Patent on its Hydrokinetic technology, and executed a letter of intent to acquire Laser Skin Toner, a company with proprietary non-invasive laser technology for use in the aesthetic and skin rejuvenation markets.

5/21 *NewsPage* reported that a new U.S. patent was issued to **Cynosure** titled, "Near infra-red selective photothermolysis for ectatic blood vessels", for example the treatment of blood vessels of a portwine stain birthmark.

5/21 *Dow Jones* reported that **Trimedyne's** 10Q contains information that a cash crunch could hurt its cardiovascular subsidiary. The report states that Trimedyne's **Cardiodyne** subsidiary will be the first to be shut down if additional funding cannot be secured. To resolve its cash crunch, Trimedyne has cut back operating expenses, is seeking additional financing, and even pursuing the sale of patent licenses. As of March 31st, the company had cash and marketable securities of roughly $2.4 million. The 10Q states that if current financing activities are unsuccessful, it will cease funding of operations at Cardiodyne until additional funds are received that will provide sufficient working capital to fund the company's operations through the end of the fiscal year. In October, Trimedyne invested $2 million in its Cardiodyne subsidiary and transferred all of its TMR technology, lasers, testing, and production equipment and supplies. It also granted an exclusive license to all of the present and future patents, patent applications and technology in the cardiovascular field in exchange for 9 million shares of Trimedyne stock.

5/22 **Mehl/Biophile** announced that it had been informed by NASDAQ that the company does not currently meet its requirements and will be delisted on June 2nd.

5/25 **Tyco International** and **U.S. Surgical** announced that they had signed a definitive agreement for the merger of USS with a subsidiary of Tyco. Tyco already owns **The**

**Kendall Company** and has recently acquired **Sherwood-Davis & Geck**. With the USS transaction, Tyco will have $4.5 billion in medical product sales, a solid presence in the operating room, and a greatly expanded array of products for use throughout the hospital.

5/26 **Laser Photonics** announced that it had initiated clinical trial testing of its proprietary excimer laser system for the treatment of psoriasis at the **Wellman Laboratories of Photomedicine** at **Massachusetts General Hospital**. Dr. Rox Anderson is the lead clinical investigator for the study.

5/26 **Premier Laser Systems** announced that its independent auditors, **Ernst & Young** had resigned. The company is conducting a search for replacement auditors.

**MEDICAL/SURGICAL LASER UPDATE -- JUNE 1998**

5/26 **ThermoLase** reported that a complaint regarding advertisements and representations relating to the ThermoLase SoftLight laser hair removal process had been filed in California Superior Court. The complaint, naming ThermoLase and a licensee, alleges that ThermoLase's ads and representations were misleading with respect to the results that could be expected using the SoftLight process, i.e., they were not permanent and were similar to results obtained by other, less costly methods of hair removal. Gary Weinstein, chairman, said that ThermoLase believes that the claims made in the SoftLight ads in question are accurate, and the company intends to vigorously defend against the claims.

5/27 **Premier Laser Systems** announced that it had received a request for information from NASDAQ and a notice that NASDAQ had halted trading in the company's common stock pending receipt and review of the information. This followed the announcement that the company's auditors, **Ernst & Young** had resigned because of "serious disagreements", as noted in the *Wall Street Journal*. **Price Waterhouse**, the company's auditor the two preceding years declined to stand for reappointment.

This latest dispute was precipitated by the dispute arising between Premier and its distributor, **Henry Schein**. Schein had claimed it didn't order certain laser products that Premier apparently booked as sales, amounting to nearly $7 million. *Dow Jones* said it was unclear how many dentists have actually purchased the company's hard tissue dental lasers priced at $39,000, since they were cleared for marketing last May. A spokesperson for Premier refused to answer that question, but did say that the company continued to build its own sales force and was continuing to negotiate with Henry Schein to resolve their differences. The Premier/Schein dispute has led to more that a dozen class action shareholder suits.

5/27 **Candela Corporation** announced that it had received FDA marketing clearance for a new, double-powered version of its SkinPlus dual erbium/KTP laser system, known as the 2J, which delivers two joules of laser energy for skin resurfacing and for treating facial veins and other vascular lesions. The SkinPlus 2J combines erbium:YAG for skin resurfacing with a KTP/532 laser for treatment of facial veins. The new 2J version is priced at $69,900. If combined with a computerized skin scanner (SkinScan), the price is $79,900, while the SkinPlus without the KTP laser sells for $49,900, or with SkinScan for $64,900. Candela claims to have over 2000 lasers installed worldwide with more than 500,000 aesthetic laser procedures performed annually with its systems.

5/28 **DUSA Pharmaceuticals** announced that it was re-opening discussions with potential dermatology partners following the collapse of its discussions with a major multi-national pharmaceutical company that had signed an agreement in principle. Several proposals had been made hoping to strike a deal, but DUSA was informed that the parent company of the dermatological division with which it was holding discussions had undergone changes which would preclude completion of the transaction. Therefore, DUSA was reassessing it marketing options for Levulan PDT in dermatology, including reopening discussions with potential dermatology alliance partners.

The following day, *The Financial Post* reported that DUSA's stock was hammered after the announcement of the anticipate deal coming apart, falling nearly 25%. An analyst with CIBC Wood Gundy, Lennox Gibbs, said that the deal "was quashed because it did not fit the multinational's formula."

5/28 **Laser Aesthetics** announced that it had completed a clinical study to evaluate the safety and efficacy of its new non-invasive Cool Touch system for the treatment of facial wrinkles, and had submitted the results to the FDA. The company has clearance for the use of its device in general dermatology and has begun selling internationally on that basis. The Cool Touch device allows the non-invasive treatment of the collagen layers of the skin, causing shrinkage of the collagen to remove wrinkles, in a procedure called thermescent treatment. The procedure uses gentle flash cooling synchronized with a pulse of infrared laser energy, along with active skin temperature feedback to selectively heat subsurface tissue with a particular temperature profile. This allows collagen shrinkage rather than damage, smoothing out facial wrinkles.

5/28 **Coherent Inc.** announced that it had received FDA clearance of its Versapulse Select holmium laser for the treatment of BPH in a procedure it calls Holmium Laser Resection of the Prostate (HoLRP), the first holmium laser clearance for this treatment. According to the company, BPH affects 18.5 million men in the U.S., Europe, and Asia-Pacific, with TURP being performed approximately 250,000 times annually in the U.S. alone, with a complication rate approaching 20-30%. Coherent

believes that HoLRP provides surgical results equivalent to TURP with clear benefits to the patient and surgeon, being virtually bloodless, with reduced risk of transfusion and post-operative catheter time compared to TURP. HoLRP also holds significant advantages over other currently available techniques, including RF, interstitial diode, and microwave, which essentially cook the tissue causing it to slough over time. The HoLRP technique apparently removes tissue similar to TURP, but without the TURP complications.

5/29 **American Dental Technologies** has introduced a 200 Hz dental laser, the PulseMaster 600 IQ, designed specifically for soft tissue applications, including the treatment of periodontal disease and aphthous ulcers (canker sores). This laser represents a doubling of the pulse rate allowing the dentist to surgically remove soft tissue more smoothly than before, even at lower energy levels. (No price for the system was disclosed.)

6/1 **Laserscope** announced that clinical studies recently completed at the Mayo Clinic indicate that BPH can be treated more effectively than with TURP using the new generation, more powerful, KTP/532 laser for vaporizing tissue. The doctors involved in the study reported that the Laserscope laser took less time to vaporize tissue, allowing patients to remove uncomfortable catheters far sooner, and had restored normal urinary flow far sooner than was true with earlier, less powerful laser treatments.

The company also disclosed that its new, tiny, fiberoptic laser device, the MicroADDStat, a sidefiring device that connects to the current generation of Laserscope's KTP/YAG laser systems, simplifies the treatment of upper urinary tract diseases. The system is small enough to slip through a surgeon's ureteroscope allowing doctors performing certain kidney or ureter surgery the advantage of seeing and working through the same scope. The company estimates that as many as half of the 125,000 kidney surgeries and 140,000 surgeries done on upper urinary tract conditions each year could be performed with the new 1.0 mm diameter MicroADDStat device. The device delivers up to 20 watts of 532 nm and 40 watts of 1064 nm energy from the tip laterally at 70 degrees.

6/2 **American Dental Technologies** announced that it had held its 1998 annual meeting on May 29th, re-electing the two nominees to its board. The company also said that consistent with statements in its annual and quarterly reports, it expects both North American and international sales for 1998 to increase approximately 20-25% over 1997 levels.

6/2 **Dental/Medical Diagnostic Systems** announced that it had submitted its filing of 510(k) notification with the FDA for its Apollo 95E tooth whitening and curing system. Approval should take 60-90 days. The company also announced that it had

terminated its private label agreement with **Ion Laser Technology**, which had previously said it would be unable to supply the Apollo 9500 composite curing and tooth whitening laser systems. As a result of the termination, DMDS will now receive reimbursement of all amounts paid by DMDS to ILT, which includes an inventory deposit and license fee.

6/2 *The Motley Fool*, on *Yahoo*, published an article entitled "The Daily Trouble (Archive): A review of a company whose stock price has been cut in half within the last year." The piece was about the trials and tribulations of **Premier Laser Systems**. The three-page report relates the problems encountered by Premier over its controversial distribution contract with **Henry Schein**. The writer of the piece, Rick Aristotle Munarriz, ends with the caveat that "all is not lost for Premier, even if Wall Street will take some time to be won back over," because of its diverse client base and product lines.

6/3 A report on the dental products market, "High-tech dental products proliferate in a changing market", was written by Jeffrey Berg in the *BBI Newsletter* for May. The article discusses the mature and nearly saturated market for intraoral cameras; the use of lasers and lights to cure composites; tooth whitening; lasers and air abrasion systems for removing decay; and digital x-ray imaging equipment. The report discusses the distribution deal between **Dental/Medical Diagnostics** and **Ion Laser Technology**, now dissolved (see the 6/2 brief above), and that **Premier Laser Systems** and **HGM**, in collaboration with **Kreativ**, also sell lasers for curing dental materials. Cosmetic and aesthetic dentistry are areas of increasing appeal to the U.S.'s 100,000-plus general dentists, who are increasingly offering whitening and bleaching of teeth, as well as restorative dentistry. At the time of writing, ILT had more than 100 installations in 30 states and five countries of its BriteSmile Laser tooth whitening systems, with dentists charging between $800 to $1200 for the procedure. The Apollo 9500 actinic ray discharge tube can also be used for tooth whitening, at a cost of under $300. However, it only provides about four or five shades of whitening, compared to an average of eight shades for the laser approach. The report also mentions the Premier erbium laser as the only approved laser for use on hard tissue.

6/3 **Xillix** announced it had signed an exclusive agreement with **Miravant Medical Technologies** for the co-development of devices that will integrate Xillix's LIFE Imaging Fluorescence Endoscopy System and Miravant's PhotoPoint drugs and devices for the detection and treatment of lung cancers. Miravant will make a C$7.2 million ($5 million U.S.) equity investment in Xillix, for approximately 9% ownership of Xillix, of which C$4.3 million ($3 million U.S.) will be in cash and the remainder in the form of restricted common shares. Xillix will issue 2.7 shares to Miravant at C$2.67/share. Both companies will share the R&D costs associated with the program, with the first application aimed at the detection and localization of lung cancer with Miravant's PhotoPoint drug. Future applications will target other cancers. Xillix will

receive drug royalty payments from Miravant based on the drug sales generated by the co-developed technology. Miravant also has a collaborative agreement with **Chiron Diagnostics** which is working towards developing an assay to screen high-risk patients for lung cancer. The Xillix LIFE-Lung system uses blue laser light to activate the natural fluorescence of tissue. PhotoPoint therapy can potentially be used to destroy abnormal lesions that are detected and localized by the Xillix fluorescence endoscopy.

6/3 **Mehl/Biophile International** has requested a hearing before NASDAQ in connection with the notice that it would be delisted on June 2nd. NASDAQ has further informed the company that in light of the company's history of losses, financial condition, and concerns that it did not comply with the certain requirements, its stock would not automatically be moved to the OTC Bulletin Board if it was delisted from the SmallCap Market, unless it could convince NASDAQ of its viability as a going concern and demonstrate compliance with NASDAQ's requirements. A hearing is slated for late in July. In the meantime, the company's stock will remain listed on the SmallCap Market.

6/3 *The Financial Post* contained a story about **QLT PhotoTherapuetic's** "illuminating future". As reported by Keith Damsell, the promise of a new treatment for a severe eye disease has made QLT one of the Toronto Stock Exchange's best performing stocks this year. "Shares of the Vancouver-based biotechnology firm have been on a tear since bottoming out at $15.75 last November." The stock has almost doubled in value, closing at $28.05 on June 2nd, mostly on speculation that its light-activated drug therapy may be the treatment of choice for age-related macular degeneration (AMD), the leading cause of blindness in adults over the age of 50. With the approved treatments for lung cancer, about 60 laser systems for activating Photofrin were placed, and sales of Photofrin are seeing gradual increases, with royalties from the sale of drugs increasing by 55% in QLT's first quarter. QLT appears to be the clear leader in the fight to treat AMD, ahead of competitors **Miravant** and **Scotia**, with commercial sales of its AMD drug, to be marketed by partner **Ciba Vision**, expected to begin in 2000. Analyst Christine Charette, of Nesbitt Burns, expects that QLT's AMD treatment could eventually bring in annual sales of up to $500 million.

6/4 **Cynosure** announced the first shipment of its Apogee long pulse hair removal laser, the followup product to its LPIR alexandrite system used for hair and leg vein applications. The laser was purchased by Westmoreland Dermatology Associates of Greensburg, PA.

6/5 **Coherent, Inc.** released a statement that it expected lowered profits for its fiscal third quarter, ending June 27th. The company expects results will be adversely affected by lower than anticipated revenues and two significant one-time charges. The revenue shortfall will be due to manufacturing delays with the company's Epic three-in-one ophthalmic laser system, with the delays resulting in a $1 to $1.5 million shortfall; an

additional $2 million for medical product returns; and continuing devaluation of the Japanese yen against the dollar from flat to slightly up sales in local currency. (Japanese sales account for approximately 20% of company revenues.)

The Epic problem was due to early feedback from customers that the new laser system was not functioning the same way as the lasers it replaced. The company shut down the production line for 3 weeks to correct the problem, causing the shortfall in revenues. As for the product returns, some customers receiving the Versapulse VPW's (variable pulse width) aesthetic lasers for treating leg veins complained that the lasers were user dependent and difficult to use. Approximately 10 of the 300 lasers shipped were returned, accounting for the $2 million in returns. The Versapulse VPW has now been replaced by the Versapulse V, which provides the longer pulse upgrade of the HELP-G (high energy long pulse-green) system and its associated chilled-tip delivery device. The company has offered the HELP-G upgrade to those who purchased the older Versapulse aesthetic lasers.

The two one-time charges include an additional $0.7 million to inventory reserves for medical demonstration inventory in Japan, where there has been a slowdown in converting demos to sales, and a restructuring charge for the shutdown of its Tucson research facility of $1 to $1.5 million. The activities at Tucson, including development of a new solid-state refractive laser, were transferred to Santa Clara.

6/5 *NewsPage* reports that **Eclipse Surgical Technologies** was awarded a U.S. Patent for a shaped catheter for TMR. The abstract reads in part, a shaped catheter for accessing and treating preselected surfaces of cavities and organs within the human body.

6/5 **Unicorn Financial Service** stated that during its first six months of operation, nearly 6000 patients have applied for low interest monthly payment plans to pay for their elective medical procedures. The plans are being offered through 446 doctors across the country specializing in plastic surgery, cosmetic dental surgery, and laser vision correction.

6/8 **ESC Medical Systems** announced that it had received marketing clearance from the FDA for its PhotoDerm MultiLight, a new version of the PhotoDerm pulsed light system. The integrated PhotoDerm MultiLight system enables doctors to provide long-term hair removal in addition to its traditional use in the treatment of benign vascular and pigmented lesions. Both the MultiLight and EpiLight systems will remain available as individual systems. Current PhotoDerm customers have the option of upgrading to the new dual purpose MultiLight system.

6/9 **Miravant** and **Pharmacia & Upjohn** announced that they have signed amended agreements concerning development and funding provisions of the Purlytin license agreements signed in July 1994, July 1995, and December 1996. Miravant will

manage all preclinical and U.S. clinical development programs for Purlytin in ophthalmology (for AMD), oncology, and urology. P&U will reimburse Miravant for all costs associated with trials in ophthalmology, and will pay milestones upon certain regulatory achievements. In addition, P&U will provide Miravant with $20 million of direct funding over the next two years (July 1998 through June 2000) for trials of Purlytin in oncology (major potential markets such as early stage lung cancer) and urology. P&U will direct all international clinical trials. As provided in the earlier agreements, P&U will market and distribute Purlytin worldwide once regulatory approvals are achieved, paying royalties to Miravant on sales.

6/9 **PLC Systems** announced that the required 60 patients required for enrollment in the Japanese TMR clinical study has been completed. The patients received TMR with the Heart Laser either as sole therapy or in combination with CABG. Fourteen leading research hospitals participated in the study and will continue to treat patients with the system. PLC's distribution partner, **Imatron Japan** managed and funded the study. PLC believes that the Heart Laser is the only system to complete a clinical study in Japan, which should secure a significant market lead for the company. The first ten patients have now completed the mandatory six-month followup.

6/9 **Renaissance International Group Ltd.** announced that its wholly-owned subsidiary, **RIGL Medical Systems** has entered into a management services agreement with **Meyers & Rosenberg Dermatology, Vein & Laser Institute** of Phoenix. The agreement calls for RMS to provide M&R with comprehensive practice management, financial, marketing, and technical services over the next five years.

6/9 **Laser Photonics** announced that its subsidiary **AccuLase** received a $1 million purchase order from **Baxter Healthcare** for additional lasers to support their collaborative TMR program. Shipments of the lasers are expected to begin in the third quarter, in support of the clinical studies underway.

6/10 I received a specification sheet for a new compact excimer laser, which the manufacturer claims is a "breakthrough" in excimer design. **Skandinavisk Laser Systems** of Scandinavia offers the Nexex 7 excimer laser in five wavelengths (157 nm to 351 nm), ranging in average power from 0.4 to 4.0 watts and 2 to 7 mj (depending on the wavelength). The 11 x 13 x 18 inch box is available in North America from its office in Tempe, AZ for laboratory research, micro-machining, and medical procedures. No prices are quoted. For more information, contact Eric Olson at 888-967-9968.

6/10 **Cell Robotics** announced that it had signed a letter of intent with **Chronimed** for the worldwide distribution and future development of its Lasette laser finger perforator. Chronimed provides pharmaceuticals, medical products, and services to people with

chronic conditions, such as diabetes. The two companies will feature the Lasette at the June 13-16 American Diabetes Association meeting in Chicago.

6/10 **Laserscope** announced that the registration statement filed with the SEC on May 11th covering the resale of 4.3 million shares of Laserscope stock previously held by **Heraeus Med GmbH**, in a private placement to a limited number of accredited investors was declared effective today.

6/11 The board of directors of **Surgical Laser Technologies** has authorized the company to repurchase shares of its common stock with a value up to $1 million. The company plans to buy the shares on the open market from time to time, depending on market conditions.

6/14 *The Los Angeles Times* carried a story about a new treatment for snorers. Somnoplasty, developed by **Somnus Medical Technologies** has been used on more than 1000 people since it was approved by the FDA last summer. This RF device "cooks" tissue in the back of the throat rather than the laser technique that cuts the tissue at high temperatures. Both techniques are effective in tightening the remaining tissue after excess tissue is removed, thus reducing snoring. The somnoplasty, after two treatments, has a success rate, in the one office reported in the story, of 85% to 90%. The treatment costs between $2000 and $2500, and usually is not covered by insurance.

6/15 **ThermoLase** announced that the wholly-owned ThermoLase Spa division subsidiary of the company has merged with **The Greenhouse Spa, Inc.**, which will now operate as a wholly-owned subsidiary. Located in Arlington, TX, The Greenhouse was established in 1965, and has become one of the top luxury spa destinations in the world. The current owners and operators, Gerald and Lee Katzoff, will continue to manage the facility, which will be newly renovated. In addition, the Katzoffs will also oversee the transformation of ThermoLase's Dallas Spa Thira location into the first Greenhouse Day Spa, developing a model that can be rolled out into ThermoLase's other 14 spas. ThermoLase will evaluate each of the spas to determine which may be successfully converted into Greenhouse Day Spas.

ThermoLase also announced that it intends to relocate its corporate headquarters to Dallas, TX, in order to consolidate operations with its **Creative Beauty Innovations, Inc.** subsidiary, formerly known as **CBI**, which manufactures skin care and other personal care products.

6/15 **Trimedyne** announced that it had sold a non-exclusive patent license to an unidentified party for approximately $3.6 million. The company also reported financial results for its fiscal second quarter and the six month period ending March 31st, which include the results of its 90% owned subsidiary, **Cardiodyne, Inc.**.

Revenues from continuing operations for the quarter were $1.5 million, a decrease of 13% from results for the same quarter a year ago. The net loss for the quarter were $1.9 million (17 cents/share), which included $764,000 of startup and R&D costs for Cardiodyne. This represented an increase of 16% over the loss a year ago, which included $320,000 for Cardiodyne. For the six months, revenues were $3.7 million, a 7% decrease from last year, and the net loss was $3 million (27 cents/share), (including $1.4 million in startup and R&D for Cardiodyne), an increase of 15% from last year's $2.6 million, which included only $386,000 from Cardiodyne. With the $3.6 million from the aforementioned patent license, company management believes that working capital will be sufficient to meet operating needs for both itself and Cardiodyne through early 1999, with the cut-backs in operating expenses implemented at Cardiodyne and Trimedyne. The company is seeking additional financing through the sale of equity securities of both Trimedyne and Cardiodyne, and the sale of licensing of other patent rights in order to continue funding the development of Cardiodyne's heart revascularization laser system, as well as Trimedyne's development of a new cosmetic laser.

On a June 18th appearance on **Stock-Line** (on the internet), chairman Marvin Loeb said that the company's most significant growth opportunity lied with its subsidiary, Cardiodyne. Trimedyne expects that subject to regulatory approval, human clinical trials of Cardiodyne's proprietary TMR laser system are expected to begin in late 1998, at which time the company will begin marketing the laser outside the United States.

6/15 The second issue of Volume 1 of *Photodynamics News*, an international forum for PDT, arrived with several interesting items. The cover story, written by PDT pioneer Tom Dougherty, was entitled, "Early Detection and Treatment of Lung Cancer: A PDT Success Story." The article details the developments over the past two years; **Xillix's** approval for its LIFE lung cancer detection system, and the approvals for Photofrin-PDT for the treatment of certain early-stage lung cancers in France, Germany, and the U.S. over the last two year. A second article by David Kessel provides an overview of second- and third-generation photosensitizers, including verteporfin, texaphyrins, M-THPC, ALA, and SnET2. Tom Dougherty also relates the latest PDT studies, including clinical study of a new photosensitizer (HPPH, Photochlor), underway at Roswell Park Cancer Institute, which is celebrating its 100th birthday this year, and which has been carrying out PDT studies since 1972.

6/16 **PLC Systems** announced that HCFA has published proposed medical reimbursement codes for TMR in last month's *Federal Register*. This is the first step in having reimbursement reinstated for this treatment. With PLC progressing through the final steps in obtaining FDA marketing approval for TMR, the company is hopeful that by publishing the reimbursement codes, TMR treatments with the Heart Laser will be covered by Medicaid shortly after the approval is granted, possibly later this summer.

6/16 A story in *The Los Angeles Times* relates some of the problems that the ex-auditors had at **Premier Laser Systems**. According to documents filed with the SEC, Ernst & Young said that by April 21st, it had concluded that $2.4 million of Premier's reported revenue for its fiscal third quarter was inappropriate, and that the financial statements for the period should have been restated. Ernst & Young said that it discovered that Premier was logging revenue for dental lasers that had been moved to the warehouse of a freight forwarder in Irvine, but which the distributor said it didn't order, and didn't take delivery of. The accounting firm said that Premier had no written documentation to support the assertion that **Henry Schein** had requested an arrangement under which it would be billed for products that had not been shipped. There were also no documents showing any fixed schedules for delivery or payment. Ernst & Young said it agreed to Premier's request to reconsider its stand, but that the company didn't provide any new information to alter its conclusion that the revenue was reported inappropriately. The firm recommended that a committee of independent directors and attorneys be formed to investigate. It wanted the committee to look into transactions recorded by Premier in the first three quarters of fiscal 1998 and the previous fiscal year, having identified specific revenue transactions recorded on or about March 31, 1997 that prompted it to recommend the broader investigation.

By May 22nd, the day Ernst & Young resigned as Premier's auditor, the investigation had remained limited to the $2.4 million in disputed sales in the fiscal 1998 third quarter. "The March 1997 transactions were sales that were not collected by March 1998, that we believe should have been investigated," said Ernst & Young spokesman, Don Howarth. Upon its resignation, Ernst & Young also withdrew its report on Premier's financial results for the fiscal year ended March 31, 1997. Premier has yet to report final results for fiscal 1998.

In its SEC filing, Premier said it believed "the investigation was conducted in full compliance with the former auditor's recommendations." The company said it was willing to expand the investigation, but that the committee had been limited in part because it didn't have "timely and complete access" to the Ernst & Young paperwork.

6/16 **Laserscope** announced that it had received FDA marketing clearance for its new Venus laser system and related accessories, including a unique computer-controlled scanning device, called SmartScan Plus. The initial market for this erbium laser will be the skin resurfacing market. FDA approval included multiple laser applications in dermatology, cosmetic and plastic surgery, general surgery, gynecology, ENT, and ophthalmology. The new laser is one-third the size and one-fourth the weight of other erbium lasers on the market, yet it is among the most powerful systems currently available, and one of the least expensive, according to Robert McCormick, president and CEO. "We have already taken orders for the new system and expect to begin shipments early in July." David Goldberg, MD, one of the first physicians to clinically evaluate the system said, "Venus may be the most user-friendly erbium laser system

that I have ever come across. It is very simple and easy to use, and the beam quality and degree of collimation are excellent." According to my information, the laser sells for $46,000.

6/18 The American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS) released the results of a new survey at the Seventh International Symposium of Facial Plastic and Reconstructive Surgery being held in Orlando. According to the AAFPRS president Richard Holt, MD, "Many Americans watch what they eat, exercise, and are adopting a more health-conscious lifestyle. Facial plastic and reconstructive surgery is becoming part of this overall trend as individuals desire to look young and vibrant as they feel." Technological advances bring about procedures that are less invasive, more cost-effective, and with shorter recovery times, yielding excellent results. While aesthetic procedures still outnumber reconstructive procedures in overall popularity, skin cancer reconstructive surgery still ranks highest among procedures performed on men in 1997.

Among other findings:

- On average, twice as many facial cosmetic surgeries (191.4 per surgeon surveyed) as facial reconstructive surgeries (94.5 per surgeon) were performed by AAFPRS members in 1997.
- Laser technology continues to be the leading trend in facial plastic surgery, with 40% of AAFPRS members, noting it is among their patient's top three requested procedures.
- The leading reasons cited by women for undergoing facial plastic surgery are looking younger (56%), improving overall looks (22%), and improved self-esteem (22%).
- Men cite their top three reasons as looking younger (44%), looking better/younger for work (33%), and improving overall looks (25%).
- The five procedures performed most often on women in 1997 (in descending order) were chemical peels, filler injections, blepharoplasty, rhinoplasty, and laser skin resurfacing.
- The five procedures performed most often on men in 1997 were skin cancer reconstruction, rhinoplasty, chemical peels, blepharoplasty, and hair transplants.

The AAFPRS has more than 2800 members, who specialize in cosmetic and reconstructive surgery of the face, head, and neck.

6/22 **American Dental Technologies** announced that **Prep Technology Corporation** had taken a license on ADT's patents covering its air abrasion technology for the dental field. Prep is the fifth company to license ADT's patents in the dental air abrasion field.

6/22 **Medical Industries of America** and privately-held **Physician Health Corp.** (PHC) jointly announced that they had agreed, subject to a final due diligence, on the terms of the merger of PHC into MIOA. The estimated combined revenues of these two ancillary services companies will be approximately $130 million in 1998. PHC's services and physician partners are primarily located in Orlando, FL; Cincinnati; Arlington, TX; and St. Louis, and own and manage ambulatory surgery centers, out-patient surgery centers, oncology, and cardiovascular centers, a sleep lab, and are in the process of developing other ancillary facilities including birthing centers. MIOA operates medical ancillary service businesses, multi-specialty medical group practices, primarily in Florida. (MIOA had announced in October 1997 that it intended to acquire Florida-based **Physician Laser Services**, a provider of mobile lasers. However, following an extensive due diligence and negotiation process, MIOA decided in January 1998 not to proceed with the intended acquisition.)

6/23 **Premier Laser Systems** announced that its board of directors had approved **Haskell & White LLP** as its new independent auditor, and that H&W had accepted the engagement. According to Premier president and CEO Colette Cozean, a team from the auditor was already at work on audits for the fiscal years ended March 31, 1997 and March 31, 1998. Once the audits are completed, the company would file a new 10-K for both years. Premier also announced that it had responded fully to the initial questions from NASDAQ and will file its audited financials with NASDAQ as soon as they are available.

6/24 **Candela Corporation** said that it had broken off discussions with **Advanced Medical Alliance** regarding their proposed purchase of Candela's skin care center in Boston and the closed facility in Scottsdale, AZ. Gerard Puorro, Candela's president and CEO said that they had worked hard to reach a definitive agreement but found that both the price and final financing terms were not in its best interests. As a result, Candela does not expect to hold further conversations with Advanced Medical and remains in full operating control of its Boston operation, where results continue to improve. However, at the same time, the company is actively seeking alternative solutions to implement the priorities set late last year, when it wrote off all of the costs of closing the Scottsdale spa.

6/24 **Optical Ventures, Inc.** announced that it had acquired five U.S. and four international patents covering a portfolio of technology related to the preactivation of photosensitive drugs. The patents, acquired from **Baylor Research Institute**, following the settlement of protracted litigation between the two parties, cover technology that may overcome some of the current limitations of photodynamic therapy for treating a variety of diseases, including cancers, and possibly, macular degeneration. As a result of the acquisition, Optical Ventures owns the rights to all proprietary information and test results of using these drugs under development and licensed, for potential clinical use. This technology provides the company with the information needed for drug commercialization and development.

According to Optical Ventures president and CEO Elizabeth Rogers, "We are developing preactivated drugs that will lift the restrictions currently associated with PDT. This will position us as the only company that uses a light source prior to administration of the photosensitive dye, thereby eliminating the light source during cancer treatment. In effect, we are creating new chemotherapeutic agents that will work to improve PDT for cancer and other life altering diseases."

In an interview with Ms. Rogers, I learned that her company, founded in 1987 as a technology transfer company for identifying new discoveries in optical computing, began focusing on areas of optics in medicine in 1992. With the acquisition of the Baylor patents, the company is now developing preactivated drugs to be used in the treatment of cancers, viruses, bacteria, restenosis (following angioplasty), and central nervous system diseases. One area of research involves the preactivation of Photofrin with a laser which will be administered separately, prior to Tomoxofin, to enhance sensitivity to estrogen receptor negative breast carcinoma. Ms. Rogers hopes to enhance the 40% response rate of Tomoxofin alone in the treatment of women with estrogen receptor negative breast cancer. The company is seeking joint ventures or partners to help in sponsoring some of the research.

Other drugs in the pipeline include gene-based cancer prevention drugs, anti-bacterial treatments, and biochip drug delivery products. Another area of research involves the possibility of developing an optical detection system for the forensic identification of cloned animals. All in all, very interesting technology, about which I will keep you posted.

6/25 **PLC Systems** said that the FDA had completed its inspection of the company's manufacturing facility without observing any deficiencies. This is an important step in obtaining final marketing approval for The Heart Laser.

6/25 **Pacific Pharmaceuticals** said it would excercise it right to appeal to the Board of Governers of AMEX, concerning its decision to remove the company's stock listing. AMEX has said it believes that Pacific no longer fully satisfies all of the financial guidelines of the AMEX for continued listing. The company said it was taking measures to ensure that in the event of an unnsuccessful appeal, an orderly transition will occur and that its stock would commence trading on the Electronic Bulletin Board.

**MEDICAL/SURGICAL LASER UPDATE -- July 1998**

6/30 **DUSA Pharmaceuticals** announced that it had submitted its NDA for Levulan PDT of actinic keratoses, covering the use of its 20% Levulan Kerastick applicator and its Blu-U fluorescent tube illuminator for the treatment of multiple actinic keratoses of the face and scalp. The submission incorporates the results of the treatment of lesions

in over 450 patients, including its two pivotal Phase III clinical trials involving more than 270 patients and 1700 AK lesions treated at 16 sites across the U.S. Of the patients, 91% of the AK lesions cleared with the use of Levulan versus only 25% of the placebo treated controls.

7/1 *Reuters* reports that **Ion Laser Technology** said that its net loss for fiscal 1998 (ended March 31st) widened due to a one-time impairment and write-down charge. The company reported that it lost $9.1 million ($1.62/per share) for the fiscal year, compared to a net loss of $780,000 (15 cents/share) for the year earlier. Of the 1998 loss, $4.3 million was due to a charge against earnings representing a decreased valuation of certain fixed assets, good will, patent costs, and inventories. Revenues, attributed to a decrease in dental product sales, fell to $4.6 million from $7.1 million a year ago. The company said it responded aggressively to its financial results, prompting the resignation of executive officers in April, and closing and listing for sale, its headquarters and manufacturing facility in Salt Lake City. The company has leased a new administration and manufacturing facility in Lester, PA, and an R&D facility in Evanston, IL, which is scheduled to open later this month.

The company has also sold its inventory of industrial and scientific lasers, and the rights to service its industrial laser customers, to an unnamed Salt Lake City laser maker. The sale price was for a "nominal cash payment", along with royalty payments on sales by the buyer to ILT customers, or for the use of technology, and a commitment by the buyer to service the replacement part needs of ILT customers who continue to own and operate laser systems purchased from ILT.

In a scathing article published in the *Salt Lake Tribune* on June 4th, reporter Guy Boulton tore into the company for abandoning its Utah vendors in its move to Philadelphia, and asking them to accept 50 cents on the dollar for what was owed them. One vendor, Van Pilkington of Pilkington Anodizing, a metal finishing shop, who is owed $12,500 said, "It is a strategy on their part to get out of Salt Lake City as cheaply as possible." Another said, "It is ridiculous to come in here and expect Utahns to subsidize their move to Pennsylvania." The offers for reduced payment came less than a month after the company's largest investor had put an additional $5 million into the company.

The story notes that the investment group that controls and has funded Ion Laser is headed by Tony Pilaro, one of the founders and a former chief executive of Duty Free Shoppers Group Ltd, which operates about 150 duty free shops in the Pacific Rim, and which when sold last year, Pilaro's share alone was worth an estimated $84 million. (It is also noted in the story that Pilaro, of CAP Advisers Group of Geneva, was one of the founders of **Taunton Technologies**, which acquired **VISX**.)

Apparently, the company's failure was the result of its stopping marketing of its existing tooth whitening laser products and betting the store on the next generation product, hoping to get its development done in a timely manner. When they failed to do so, with all of the first 30 to 40 units shipped failing to work properly, the balloon collapsed. Pilaro, along with the other funding partners apparently are not happy. At the end of May Ion Laser said it had hired a lawyer to evaluate suing the company's former management team for "breach of duty". And at least one of the unpaid vendors has also filed a lawsuit against the company for non-payment of monies owed. In a statement, Ron Carter of Metropolis Design, owed $46,000 said, "These venture capitalists come in and think they can shut everything down and burn everybody and head out of town with the technology. And that's crap!"

7/1 *NewsPage* reports that **CorMedica** had a patent issued on its percutaneous endomyocardial revascularization system catheter.

7/2 **Coherent** announced that Kevin Conners had resigned as president of the Medical Group and that the company was seeking a suitable replacement.

As detailed by Kathy Kincade in her writeup for an upcoming issue of *Laser Report* and next month's *Medical Laser Report*, Connors, president of Coherent Medical Group for the past year, resigned in the wake of medical-product returns and manufacturing delays that have hurt the company's overall revenues (see last month's Coherent brief of June 5th). The official word is that Connors left to pursue other interests, but company sources say that evolving market dynamics are pressuring the medical group to move from an engineering-driven strategy to one that enables them to respond to the market more quickly and efficiently--particularly in the highly competitive, consumer-oriented cosmetic field.

Connors, who had been with the company for 13 years and came from an engineering background, apparently did not quite fit with this new strategy. Coherent is now in the process of finding a suitable replacement that can bring strong leadership abilities to the medical group. The company reportedly is looking for a seasoned management professional who has marketing savvy and experience in the medical-device industry -- preferably with a large, well-established firm such as Johnson & Johnson.

In the mean time, an "office of the president" team has been established, consisting of Bernard Couillaud, Coherent president and CEO; Neil Laird, vice president of finance; Mustapha Baksh, vice president of global sales; and Ron Victor, vice president of human resources. According to Couillaud, the group will be responsible for working with senior management staff to direct Coherent Medical's day-to-day business activities and develop business strategies that will better focus the company's resources and improve performance. While there was some surprise at the announcement of Connors' leaving, it is one of several personnel changes that have

taken place at Coherent Medical in recent months. In addition to the appointment of Baksh as head of international sales, former national sales manager Mark Mazell has left the company and been replaced by Steve Duddy, former epilation-product manager. In fact, the company has been undergoing a reorganization of sorts that also includes layoffs, R&D consolidation, and relocating all operations from Palo Alto to Santa Clara. In addition to being much larger than the old facility, the new venue is expected to enable the medical group to expand and streamline manufacturing processes and move inventory through the system faster and more efficiently. At present, the medical group runs three manufacturing shifts seven days/week; the goal is to eventually have just one shift running five days/week.

Coherent's stock has fallen from 23 1/2 to around 17 since the company announced in early June that revenues for the third quarter will be lower than expected. Coherent plans to release third-quarter results July 23. Its stock closed at 17 3/8 on July 9.

7/2 **Laser Corporation** announced that it had completed preliminary testing of an improved diode-pumped solid-state laser, supplied as a component part by an outside vendor for use in its Nuvolase 532 system for dermatological use, and now believes that the useability issues experienced during the first half of this year have been resolved. The company plans to begin beta testing of a limited quantity of these improved systems during the third quarter, hoping to resume manufacturing and full sales activities shortly thereafter.

7/6 **Eclipse Surgical Technologies** announced that more than 250 patients have been enrolled in the company's ongoing U.S. percutaneous TMR clinical study. The multicenter clinical trial compares PTMR to drug therapy in patients suffering from cardiovascular disease and angina pain. Total worldwide enrollment in Eclipse PTMR studies now numbers more than 400 patients.

7/6 **Cell Robotics** said that it had received expanded FDA clearance to market its Laser Lasette laser finger perforator to healthcare professionals for collecting capillary blood samples from patients aged 5 years or above, for subsequent determination of blood glucose concentration and hematocrit. The company's previous clearance was for adults only. The new clearance allows pediatric professionals to reduce the trauma of daily multiple finger pricks with a lancet, in the treatment of juvenile diabetes.

7/7 **Miravant Medical Technologies** announced that the FDA had granted "fast track" status to Purlytin in the treatment of age-related macular degeneration, the leading cause of blindness in older adults, with more than 2 million people having advanced, vision-threatening AMD, for which there is currently no satisfactory treatment.

7/7 **BioLase Technology** announced that it had acquired the assets of **Laser Skin Toner**, including its "no-incision facelift" and stretch mark removal system, in exchange for

1.65 million shares of BioLase stock, including contingent shares for future performance. (The letter of intent had been announced last April.) According to BioLase president and CEO Donald LaPoint, the technology is protected by two issued patents and three patents pending. Once FDA marketing approval is obtained, the product line should be ready for distribution as early as the first quarter of 1999. The non-ablative, sub-surface collagen shrinking technology is applicable for facial skin rejuvenation and for the removal of abdominal and other stretch marks.

7/7 **CardioGenesis Corporation** said that it had completed the enrollment and treatment of patients in its pivotal prospective randomized Phase II trial of its Axcis percutaneous TMR system. All 290 "no option" patients had severe coronary artery disease and Class III or Class IV angina, untreatable with CABG or balloon angioplasty, and were taking the maximum recommended levels of anti-anginal drugs. The trials are being conducted at 12 major cardiovascular treatment centers in both the U.S. and Europe.

7/8 **Pacific Pharmacueticals**, and its subsidiary, **B-G Development Corporation**, announced that they had closed on a $2.5 million private placement. The proceeds are intended to fund the development of the chemosensitizing agent O6 Benzyl Guanine, and to provide capital resources for Pacific to develop its other technologies.

7/8 **QLT PhotoTherapeutics** announced that the world's first clinical study using PDT as a treatment for autoimmune diseases, which afflict 5% of adults in North America and Europe, concluded that the treatment was safe, well tolerated, and showed potential for efficacy. In a presentation to the Seventh Biennial Congress of the International Photodynamic Association, Dr. Harvey Lui of the University of British Columbia said that a Phase I study of PDT using verteporfin (BPD-MA) as a treatment for psoriasis and psoriatic arthritis prompted no serious adverse effects, with some patients showing significant decrease in total psoriasis area and severity index (PASI) score by the end of the nine-week trial. Dr. Lui noted, "We're encouraged by these positive findings and believe more than ever that photodynamic therapy could play a role as a viable alternative treatment to conventional autoimmune disease therapies, which are typically lengthy, potentially cancer causing, and often cause substantial acute and long-term side effects, including liver and renal toxicity." Five of the 19 patients showed at least a 35% decrease in total PASI scores, with one patient registering a 7% decline and another a 61% drop.

As part of its aggressive clinical trial program in the autoimmune area, QLT plans a Phase II trial in 1999 to treat psoriasis, utilizing blue fluorescent light to sidestep the potentially cancer causing attributes of UVA light. Results from QLT's Phase I trial of rheumatoid arthritis, which is now underway, are also expected in early 1999.

The following day, *The Financial Post* reported that analyst Christine Charette of **Nesbitt Burns** said that the results (on the treatment of autoimmune diseases) were

promising, but that there was still a lot of work to be done. Lennox Gibbs of **CIBC Wood Gundy** said that he viewed the results as very positive but it's still a very early stage (of development), and a good way for QLT to broaden its portfolio. Cameron Groome, an analyst at **First Marathon Securities** believes that the company is putting too much weight on its AMD/blindness treatment. "You're paying $700 million for a company with annual revenue of $10 million...So the blindness treatment better work." The company says that the clearest application for verteporfin is in the treatment of age-related blindness.

7/13 **Henley Healthcare** announced that it was retaining **Guidera Communications** to inform brokers and institutions about the revolutionary technology it is *poised* (my emphasis) to unveil for the treatment of carpel tunnel syndrome, using its MicroLight 830 diode low energy laser. The system is awaiting final marketing approval from the FDA (and has been for over four years!).

7/13 **Pacific Pharmaceuticals** reported results for its fiscal year ending March 31st. Revenues for the fourth quarter were $54,000 and the net loss was $4.1 million (39 cents/share). For the fiscal year, revenues were $348,000 and the net loss was $11.6 million ($1.25/share).

7/13 **QLT PhotoTherapuetics** announced that it had sold 1 million common shares at a price of Cdn$23 to a Canadian underwriting syndicate consisting of Nesbitt Burns and Scotia McLeod. The offering is subject to the filing of a prospectus and approval by Canadian securities authorities. Closing of the offering is expected on or before July 28th. The Cnd$22.1 million net proceedings will be used to fund the R&D of additional photosensitizers for use in the treatment of autoimmune diseases, including product formulation, toxicology studies, and early-stage clinical studies; the possible acquisition of companies, technologies, or products that would be complimentary to QLT's business; and for general corporate purposes.

7/13 **Theratechnologies** announced that it had received authorization from Health Canada's Medical Devices Bureau to begin clinical validation of its patented PDT treatment of patients suffering from chronic myeloid leukemia (CML). The trial will be conducted by Dr. Denis Claude Roy, a hematologist at Maisonneuve-Rosemont Hospital in Montreal. The Theratechnologies' ex-vivo PDT purging process (PDP) has been classified by Health Canada as a device, and not as a drug or biological product, which should cut down the clinical validation period substantially, compared to standard drug protocols. The process consists of withdrawing bone marrow or peripheral blood from patients with cancer, saturating the cancerous cells with its photosensitive TH9402 molecule and destroying them using an activated light source. The company has received notice of allowance for the U.S. patent on its photodynamic device, while its photosensitive molecule is already patented. Preclinical trials have shown that this purging technique not only destroys cancerous

cells, but allows healthy cells to survive. The healthy cells can then be reinfused into the patient through an autologous graft, thus eliminating the need to find a compatible donor. Theratechnologies is currently conducting preclinical trials for another indication, non-Hodgkin's lymphoma.

Chronic myeloid leukemia represents 11,000 new cases each year in Canada, the U.S., Europe, and Japan. The other indications which could be targeted by this unique technology platform represent 258,000 cases in these same countries, according to the company.

7/14 **Transmedica International** announced that its Laser Lancet has received broad FDA clearance for the perforation of the skin to draw capillary blood for screening purposes. The device is manufactured for Transmedica by **LaBarge** of St. Louis.

7/14 **Eclipse Surgical Technologies** released its second quarter results, with net revenues of $3.1 million, an increase of 138% over revenues for the same quarter a year ago. The net loss for the quarter were $5.7 million (34 cents/share). Richard Mueller, president and COO said that the cardiovascular market appears to be responding favorably to Eclipse's regulatory progress in TMR and to the early results of its PTMR device. Highlights for the quarter include:

- The Eclipse PMA application for TMR was accepted for filing by the FDA.
- The company passed FDA inspection of its manufacturing facilities in association with its PMA application.
- Three-month follow-up results from a second clinical trial, the TMR+Bypass study, continued to show reduction in mortality and myocardial infarction, compared with stand-alone bypass surgery.
- More than 400 patients have been enrolled worldwide in the company's PTMR studies.
- The company now has two PTMR studies in Phase II trials, stand-alone PTMR therapy and PTMR combined with balloon angioplasty and stents.

7/15 **BioLase** announced that it had received general aesthetic 510(k) clearance for the SkinLaser system acquired from **Laser Skin Toner**, and would immediately commence marketing of the system to dermatologists, plastic surgeons and gynecologists. Donald LaPoint, president and CEO, expects the systems to be in the hands of surgeons later this year, and to be available for treating patients during the first quarter of 1999. According to the developer of the system, Dr. Frank O'Donnell founder of Laser Skin Toner (and chairman of **LaserSight, Inc.**), the subsurface mechanism of action by the laser is believed to be the stimulation of new collagen and elastin growth without significant damage to the overlying epidermis. Patients experience skin tightening without significant damage, burning, redness, or cuts to the skin's surface. (The Laser Skin Toner system uses a solid-state IR laser [either diode

or YAG] to target the collagen in the dermis, causing tissue shrinkage without damage to the surface of the skin, in a manner similar to the 1.3 micron YAG laser used by **Laser Aesthetics** to potentially shrink subsurface collagen.)

7/15 **Spectranetics** reported a fourth consecutive quarter of record revenues for the second quarter. Revenues were $6.8 million and the net loss for the quarter was $985,000 (5 cents/share), down from $1.4 million for the same quarter a year ago. Joseph Largey, president and CEO reported that all of the company's domestic operations continued to demonstrate significant growth and improved gross margins. Sales of catheters for pacemaker lead removal increased 92% and angioplasty catheters increased by 28%. Laser system sales included approximately $1.2 million of TMR systems shipped to **U.S. Surgical**, part of a $6.1 million supply agreement announced in 1997. During the half year, $2.5 million of TMR lasers were shipped to USS.

For the half year, revenues were $13.3 million and the net loss was $1.8 million (9 cents/share).

7/15 **Pharmacyclics** said that two presentations on Antrin photoangioplasty were given at the recent symposium on Phototherapy in Cardiology held as part of the American Society of Photobiology meeting in Snowbird, UT. Dr. Stan Rockson of Stanford University Medical Center presented preliminary results from a Phase I dose escalation study in 14 patients with peripheral artery disease, designed to evaluate the safety and feasibility of Antrin photoangioplasty. Patients with over extremity arterial insufficiency participated and received a single intravenous dose of Antrin, followed 24 hours later by endovascular delivery of light using an optical fiber catheter. Various dose levels were evaluated for toxicity and for local arterial effects, with no serious treatment-related adverse reactions demonstrated, and increased lumen size and reduced plaque achieved.

In another presentation, Dr. Moto Hayase, also of Stanford, presented data from animal models of atherosclerosis and restenosis. Dr. Hayase showed that administration of Antrin followed by light exposure resulted in substantial reduction of atherosclerotic plaque. (Antrin is a water soluble photosensitizer that accumulates in atherosclerosis, is rapidly cleared from the blood, and is activated by 732 nm light, a wavelength able to penetrate through tissue and blood. The 732 nm laser is produced by **Laserscope**.)

7/16 **Candela** announced that the FDA had cleared its long-pulse GentleLase alexandrite laser for hair removal. The laser had been cleared for treating facial veins and other vascular lesions last December. Its selling price will be $59,500, including the dynamic cooling system, making it the lowest priced hair removal laser on the market.

7/16 **Eclipse Surgical Technologies** announced that it had received approval to market its PTMR catheter in the European Community of countries, with receipt of the CE Mark.

7/16 **ESC Medical Systems** said that it had received FDA approval to market its Silhouette product for the temporary reduction of cellulite. The Silhouette is a non-invasive, therapeutic device utilizing subdermal therapy for the treatment of cellulite.

7/16 **CardioGenesis** reported its second quarter results, with sales of $1.1 million of its intraoperative TMR and PTMR systems, including disposable components to international customers and to clinical sites in the U.S. Sales decreased from the $2.7 million achieved in last year's second quarter, but were ahead of the first quarter's $0.9 million. The net loss for the quarter was $7 million (57 cents/share). Noting president and CEO Allen Hill, "Although second quarter sales were lower than the prior year, we are very encouraged by the increased placements of laser systems in Europe. The reception by interventional cardiologists to our Axcis PMR system in both Europe and the U.S. is very positive."

7/17 **Premier Laser Systems** said that it in addition to restating revenues for the quarter ended December 31, 1997, as previously announced, the company will record an inventory reserve, estimated to be not less than $5 million, against the value of the dental lasers it built in anticipation of sales to **Henry Schein** in the third and fourth quarters of the fiscal year ended March 31, 1998. The reserve will be recorded in the quarter ended March 31st.

The company also announced that after months of negotiations, Schein has tendered payment for only a portion of the product shipped to Schein customers beginning in January 1998. In addition, more than six months after the initial shipment of inventory relating to the Schein relationship, Schein has recently disclaimed rights to the inventory. As a result, the company is using data from a recent physical inventory in order to determine how many of the systems were resold by Schein or shipped to other locations.

Colette Cozean, chairman and CEO said, "We have sustained a significant amount of damage in the dental marketplace and at large, but we have delayed seeking legal remedies as we have attempted to reach a compromise solution. The most frustrating part of this situation is that Schein has stated that they are eager to carry our product line, that they have received significant interest in our products at their booths at conventions and among their sales force, and that they have not experienced any product related problems. We have been hobbled...by the unfair presumption that since Schein is a large company and well-recognized in the dental community, we must have acted improperly in this matter. Obviously, the collapse of our relationship with Schein has been a disappointment for us, but we are now attempting to develop

direct sales and other distribution capabilities in an attempt to make up for lost time in expanding our position in the dental marketplace."

The company said that it is working diligently with its new auditors, Haskell & White, to complete the reaudit of fiscal 1997 and the audit of fiscal 1998. Once these audits are completed, the company will seek permission to resume trading on the NASDAQ.

7/17 **Surgical Laser Technologies** said it would appeal the court ruling on the patent infringement suit brought by **Trimedyne** on its sidefiring probe. The U.S. Court of Appeals for the Federal Circuit ruled on an appeal filed by Trimedyne of the decision made by the U.S. District Court of California, granting SLT's motion for summary judgement in the suit. The ruling affirmed in part and reversed in part, the lower court's judgement. The appellate court affirmed that SLT's contact laser probes do not infringe Trimedyne's U.S. Patent 4,773,413. However, the appellate court reversed summary judgement that SLT's SFB 1.0 free-beam side-firing probe did not infringe Trimedyne's U.S. Patent 5,389,317. It remanded that aspect of the case to a district court, holding that there were triable issues of fact that should be decided by a jury.

Keith Stoneback, SLT president and CEO stated that the company would re-evaluate its options in regard to the side-firing probe since it had experienced significant sales declines since 1994, and since the FDA had recently granted marketing approval for its VaporMax probe, a probe that falls within SLT's core contact tip laser patents, and that provides urologists with contact tip side-firing technology, both thermal coagulation and vaporization.

There was no direct word about the ruling from Trimedyne.

7/20 **Laserscope** announced that it expects revenues for the quarter ending June 30th to be approximately $13.1 million, lower than the $13.6 million reported for the first quarter, and each of the four quarters in 1997. The company also expects to report a net loss of approximately $2 million or 16 cents/share. The company cited an erosion of sales in its hospital equipment business and a softening of sales in the Pacific Rim, resulting from the Asian financial crisis. The company will report final results during the week of August 3rd.

7/20 **Surgical Laser Technologies** released its financial data for the second quarter and six months. Sales for the quarter were $2.3 million, compared to $2.9 million for the same quarter a year ago. The net loss for the quarter was $527,000 (5 cents/share), compared to a loss of $282,000 (3 cents/share) a year ago. For the six month period, sales were $4.7 million, down from $6 million a year ago, and the net loss was $988,000 (10 cents/share) versus a loss of only $479,000 (5 cents/share) last year.

Keith Stoneback, president and CEO noted that lower demand for YAG lasers in both the domestic and international markets continued to impact company revenues. Sales of delivery systems also declined 4% as compared to last year's second quarter. "Our development of a laser system for **CorMedica's** PTER application is progressing well, with the first shipment of clinical units planned for the third quarter. This development effort, which began 12 months ago, will result in the first substantive non-YAG related capital equipment sale in our 16 year history...Our focus on the ENT market for non-laser product opportunities has yielded several new product concepts which are currently in various stages of development...these new product ideas will be presented to the stockholders at our annual meeting tomorrow."

The following day, the company said it had presented the three new product concepts, each targeted for use in functional endoscopic sinus surgery, a segment of the otolaryngology market to its stockholders. Howeve, no specific description of the product concepts was released, other than noting that two of them would be introduced to the ENT community at the mid-September meeting of the American Association of Otolaryngology in San Antonio.

7/21 The **Thompson Cancer Survival Center** announced that it was now using PDT as a potentially curative treatment for early endobronchial lung cancer. The system being used is Photofrin, developed by **QLT PhotoTherapuetics**. Thompson is the first center in Tennessee, and among a few select cancer centers around the country to offer this technology.

7/21 **DCGR International Holdings** announced a letter of intention had been signed to acquire **New Image Centers**. The centes currently offer a full range of services for both men and women that are not typically found in the skin and hair care industry, including microdermabrasion for sun damage, wrinkled skin, line refinement, tattoo and scar removal treatments.

7/21 **ESC Medical Systems** reported its second quarter and six-month results. For the quarter, net sales grew to $63.6 million, from $44.7 million a year ago, and from $59.5 million for the previous quarter. Net income rose to $13.3 million (48 cents/share), up from $9.8 million (34 cents/share) last year, and from $12.7 million (46 cents/share) from the first quarter (excluding a one-time charge of $4.6 million associated with the acquisition of **Luxar** and a one-time charge of $29 million from the acquisition of **Laser Industries**.)

For the six-month period, net sales increased to $123.2 million, up from $84.1 million last year, while net income was $26 million (94 cents/share) compared to $17.6 million a year ago (excluding merger charges). Including non-recurring merger charges, the company incurred a net loss for the first six months of $3 million (11 cents/share).

From the news release and the teleconference that followed, it is apparent that the company has successfully integrated Laser Industries into ESC Medical. As put by Dr. Shimon Eckhouse, chairman, president and CEO, "The integration of Laser Industries into ESC has significantly strengthened our market position and favorably contributed to our financial results. The combined sales force is now fully trained to (cross) sell the entire product line and can offer our customers a one-stop shop for all their needs in aesthetic and medical devices." He went on to note that the company was "actively consolidating and streamlining the operations of the integrated company and planned to continue capitalizing on the wide range of market and business benefits of the acquisition."

Dr. Eckhouse added that ESC continued to expand its product offerings. One new product introduced during the quarter was the LAT product (?) for minimally invasive myringotomy.

During the teleconference following the financial results release, Eckhouse said that although aesthetic product sales were increasing, skin resurfacing $CO_2$ lasers sales were flat to down. He hoped that ESC's Derma K combination erbium/$CO_2$ laser would take up the slack, as its sales were on the rise. He noted that the aesthetic market was evolving and that the company's approach of bundling products appeared successful. In the future, he hoped for repeat sales to established customers as they see the benefits of using ESC's products, and sales to other specialties as they seek to get into the aesthetic market.

Dr. Eckhouse broke down sales for the quarter by product lines:

- pulsed light systems -- $32.5 million (301 units vs 236 units in the first quarter);
- laser hair removal systems -- $6.8 million (93 units vs 78 units in the first quarter);
- skin resurfacing lasers -- $12 million (down from $15.3 million last quarter, 363 units vs 447 units in the first quarter -- including 66 Derma K units in the second quarter and 60 in the first);
- silhouette -- $4.2 million (215 units vs 199 units in the first quarter); and
- other products -- $8.1 million.

Other news of note included:

- The company now has 300 sales people; 120 in the U.S., along with 80 distributors selling the doubled product line worldwide.
- The Elite diode laser should be ready later this year.
- An announcement on the integration efforts will be made at a later date.

7/22 **Palomar Medical Technologies** announced that it was the first laser company to receive clearance from the FDA to market a hair removal laser for "permanent hair reduction". The clearance was specifically for its EpiLaser system. The approval allows Palomar (and its marketing partner, **Coherent Medical**) to claim "permanent hair reduction" for its laser system.

7/22 **M.H. Meyerson'** analyst Jeffrey Berg announced a research report on **Optomedic Medical Technologies**, the Israeli producer of compact $CO_2$ laser systems, with a "buy" recommendation. (More on the report when a copy of it is received.)

7/23 **Coherent, Inc.** announced results for its third fiscal quarter ending June 27, 1998. Sales for the third quarter were $98.6 million, representing a decrease of 4% compared to the same quarter last year. The continuing strength of the dollar compared to the Japanese Yen and other major foreign currencies had a negative impact on the quarter's orders and sales. Net loss for the third quarter was $1.7 million (7 cents/share) due primarily to the poor performance of the medical group and the continued negative impact of the strengthening dollar against the Japanese Yen and other major foreign currencies. This compares to net income of $11.4 million (48 cents/share) during the same quarter last year, which included net income of $2.2 million (9 cents/share) on the sale of a building.
Sales for the nine months were $305.8 million, 6% higher than reported in the same prior year period. Sales were negatively impacted by $10.5 million, compared to the same period last year, by the strengthening of the U.S. dollar against major foreign currencies. Net income of $12.6 million (53 cents/share) for the nine months period was down 56% from the prior nine month proforma net income of $28.7 million ($1.22/share) (excluding the prior year $9.0 million charge for purchased in-process technology). This shortfall was primarily attributed to the poor performance of the medical segment in the third fiscal quarter.

The third quarter sales reported by the medical business segment was $33.1 million. This represents a sales decrease of 27% compared to the same period last year, and a 24% decrease compared to the previous quarter. The medical segment incurred a loss before income taxes of $9.0 million during the current quarter, compared to income before income taxes of $5.9 million in the same quarter last year.

Bernard Couillaud, President and Chief Executive Officer, commented, "We are very disappointed with this quarter's performance, particularly of the medical segment. Actions are being taken to both reduce costs and strengthen management within this important segment of our business. We are working with an executive search firm (Hendricks and Struggles) to assist us in identifying suitable candidates for president of the medical group and re-staffing several other senior management positions within the medical organization." As was stated in an earlier press release issued on July 2,1998, an `Office of the President' has been established as an interim measure. The

company anticipates that the recruiting process will take four to six months to complete. "Despite the issues facing us, we anticipate that the medical segment will return to moderate profitability in the fourth fiscal quarter of this year," he went on to say.

The medical business segment results reflected $12.3 million lower sales and $14.9 million lower pretax operating results than for the same quarter last year. The lower sales resulted from lower unit volume, higher sales returns and allowances, and lower average selling prices (ASP). Approximately $1.1 million of the lower ASPs was the result of the stronger U.S. dollar compared to major foreign currencies. The company incurred or accrued an additional $2.9 million in restructuring costs related to personnel actions (segment wide), the closure of the Tucson, Arizona operation, and the relocation of the medical segments' headquarters from Palo Alto, CA to a new facility in Santa Clara, CA.

The current quarter's lower medical segment sales occurred primarily in the Aesthetic business. Sales of skin resurfacing systems and VersaPulse(R) products declined $13.3 million compared to the same quarter last year and $9.5 million from the immediate preceding quarter. Contributing to the sales decline were the product returns mentioned in the press release issued on June 5, 1998. Management also believes that selling efforts associated with the highly successful introduction of the LightSheer hair removal laser manufactured by **Star Medical Technologies, Inc.**, a subsidiary of **Palomar Medical Technologies, Inc.**, detracted from similar efforts required on other longer lead-time medical products. This issue is being actively addressed by the company's sales organization. On a positive note, orders and shipments of the LightSheer laser were more than 100 units and 50 units, respectively, during the quarter. Coherent recognizes a commission for its selling efforts on this business.

During a teleconference following the release of the quarter's results, Dr. Couillaud noted that he expected medical sales to return to the $40 to $42 million range in the company's next quarter which, if electro-optical remains at the same sales level, would return the company to profitability. Commenting on returns of the aesthetic Versapulse system, he noted that about 60% of the returns were because the physicians who bought them couldn't obtain the financing needed to support them, only 40% were dissatisfied with the results obtained, which led to the upgrading of these systems with the Help G system (as noted in our June 5th brief in last month's newsletter).

7/23 **Premier Laser Systems** announced that it had received marketing clearance for its Aurora diode laser to remove diseased tissue from periodontal pockets. This is a deep-cleaning dental procedure used for soft (gum) tissue. The often painful procedure,

called sulcular debridement, removes diseased or inflamed soft tissue as part of an overall treatment plan to improve the health of gum tissue.

7/24 **QLT PhotoTherapeutics** announced the successful completion of the sale of 1 million common shares. (See the July 13th brief above.)

7/24 **Premier Laser Systems** announced that it had received notification from NASDAQ of its intention to delist its common stock and warrants effective with the opening of business on July 29th. The company intends to request a hearing to appeal the proposed action, which will have the effect of postponing the proposed delisting until NASDAQ has had an opportunity to consider the appeal.

7/24 I was able to obtain a very thorough recent report (June 10th) on **ESC Medical Systems** written by John Calcagnini of **CIBC Oppenheimer**. In it John notes that ESC has become the world's leading manufacturer of aesthetic lasers/light sources, including through the $270 million acquisition of **Laser Industries**, which "will allow the company to diversify in the new emerging and potentially large hospital and office-based medical laser markets that include photodynamic therapy (lung and esophageal cancer and possibly coronary artery disease), dental lasers for hard tissue applications (drilling cavities), endometrial ablation (abnormal uterine bleeding), and the existing market for lasers in transmyocardial revascularization." (ESC has a marketing and product development agreement with **Biosense/Johnson & Johnson**). "The growing number of new indications for lasers in medicine is expected to help smooth out the cyclicality of the industry and the company's broad product breadth should help minimize investor concerns about the "one time sale" and undue reliance on any one market segment."

The report goes on to note that the global medical laser market is estimated at $1.7 billion in size and has been growing at a 13% compound annual rate (**Spectrum Consulting**). With ESC gaining market share as sales grow, it and its competitor **Coherent** are the leading industry participants and Oppenheimer expects that the two companies will continue to consolidate the fragmented industry through the acquisition of their smaller brethren to achieve product line extensions, greater market muscle and improved economies of scale. "The vast distribution capability of these two large competitors will make it increasingly difficult for smaller players to compete."

Calcagnini estimates the global hair removal market grew to $85 million (for systems) in 1997 and will increase to $185 million in 1998. For 1997, ESC was the market leader with a 50% share, followed by **Palomar/Coherent** at 19%, **ThermoLase** at 13%, and all others with 18% shares. In 1998, he projects that Palomar/Coherent's share will drop to 14%; ESC's will go to 46%;, while **Candela** will come from nowhere in 1997 to take an 11% share in 1998. (Presumably, because of their low

pricing strategy of $60,000, announced above -- see the July 16th brief.) ThermoLase's share will drop to 4%, while all others (**Laserscope**, **Cynosure**, **Mehl/Biophile**, etc.) will split 25%. In the $150 million skin resurfacing market, Coherent and ESC have 36% and 53% respectively in 1997, according to Calcagnini, and will continue to own significant shares of this decreasing to flat $142 million market in 1998.

Calcagnini is projecting sales for ESC of $249 million in 1998, up from $196.4 million in 1997, and to reach $286 million in 1999. (I am only projecting $205 million for the combined Laser Industries/ESC Medical sales in 1998, up from closer to $193 million in 1997! The latter based on my estimate of fourth quarter sales for Laser Industries, which were never announced.)

**MEDICAL/SURGICAL LASER UPDATE -- AUGUST 1998**

7/27 I received a copy of the **M.H. Myerson** report on **Optomedic Medical Technologies**. The report basically is about the potential market opportunities for the compact $CO_2$ laser produced by this Israeli company, including skin resurfacing, transmyocardial laser revascularization, and the potential cataract removal markets (in reality, using the laser for capsulorhexis, or removal of the anterior capsule prior to phacoemulsification).

As we know, the skin resurfacing market has already surpassed its growth phase for $CO_2$ lasers, moving on to erbium:YAG systems; the TMR market is saturated with both $CO_2$ and other types of lasers; while the capsulotomy market is small compared to the removal of the cataract itself, where the erbium laser will compete directly with the YAG laser and phacoemulsification. A laser, just for removal of the anterior capsule, of itself, serves very little purpose. On the basis of this brief commentary, I see little to recommend this compact $CO_2$ laser for these applications. However, it is a useful laser for office-based surgery where a compact, low cost $CO_2$ laser is required, in the specialty of gynecology, for example.

7/28 **Medical Alliance** announced its second quarter results, with revenues of $4.2 million and a net loss of $275,000 (4 cents/share). For the six month period, revenues were $8.3 million and the loss was $924,000 (15 cents/share). The company also reported that it had performed 7,582 surgical and 13,546 aesthetic elective procedures during the quarter, down slightly from the same quarter a year ago. For the six-month period, 13,913 surgical and 26,666 aesthetic procedures were done, again, slightly down from last year's first half.

7/28 **ESC Medical Systems** announced that it was launching a new and improved Epitouch ruby laser for hair removal. The new Epitouch system has the ability to treat a broader range of skin types, and is based on ESC's proprietary multi-pulse technology. The variable and longer pulse train gives the physician a higher degree of flexibility in the

treatment of various skin types, and is associated with an enhanced ruby light tissue interaction, according to the company. No specifics for the new system were released.

7/28 **Laserscope** reported its second quarter results. Revenues for the quarter were $13.1 million, compared to $15.2 million a year ago. The company reported a net loss of $2 million (16 cents/share) compared to net income of $756,000 (6 cents/share) last year. For the six month period, revenues were $26.7 million compared to $31 million for the first half a year ago. The company reported a net loss for the six months of $2.2 million (18 cents/share) compared to net income of $1.6 million (13 cents/share) last year. Robert V. McCormick, Laserscope president and CEO, said "The two major factors contributing to these disappointing results were a decline in laser sales in the Pacific Rim resulting from the Asian financial crisis and a decline in sales in our hospital equipment business in the United States. Combined sales were off by more than $2.5 million from prior year same quarter levels. Sales of lasers in the U.S. and Europe improved during the period...Additionally, we were cash positive during the quarter and were successful in reducing both receivables and inventories, each by more than $1 million."

Two days later, the company announced a restructuring of its business, including the following:

-- The establishment of its **Ascent Medical Systems (AMS)** operations as a stand-alone business unit and movement of the AMS operations into a lower cost facility.

-- A 15 percent reduction in AMS headcount.

-- A 25 percent reduction in laser product manufacturing headcount.

-- Reorganization of Laserscope's Operations Group to improve cycle times, inventories and the cost of materials.

-- The appointment of Michael Whiteside as director of materials. Whiteside was previously U.S. controller for Laserscope.

-- The engagement of Ernst & Young as operations consultant.

-- Continuing consolidation of operations.

(For other personnel changes, see the "people-in-the-news section" following.)

7/29 **Biolase Technology** announced that it had received U.S. Patent 5,785,521, for a system that implements its fluid conditioning technology to also contain medications,

anesthetics, flavors and scents. This eliminates the necessity to use separate delivery systems for this purpose.

7/29 **ArthroCare** announced that its **Visage** division was beginning Phase II of its clinical trial of the cosmetic surgery coblation system for use in skin resurfacing and wrinkle removal. The coblation system uses radio frequency energy to remove tissue, supposedly through a significantly cooler process than that of traditional electrosurgery or lasers. The trial will be held at four U.S. sites, including the three centers that participated in the Phase I trials. These are the University of California-San Francisco; Yale University; and the University of Minnesota in Minneapolis. The fourth site will be at the office of John Yarborough, MD, of New Orleans.

7/29 **Laser Power Corporation**, a developer of microlasers and optics, reported a net loss of $24,000 for its fiscal third quarter, on revenues of $8.6 million. Product sales increased by 2% over last year's third quarter, primarily due to increased sales of military optics and microlasers, partially offset by lower sales of commercial products and contract R&D.

7/29 **Palomar Medical Technologies** announced its financial results from continuing operations. Revenues increased 28% to $9.1 million for the second quarter compared with revenues of $7.1 million during the second quarter of 1997 and a net loss of $3.9 million (7 cent/share) compared with a net loss of $11.2 million (38 cents/share) in 1997. The second quarter loss was a 42% reduction compared with the loss of $6.8 million (15 cents/share) in the preceding quarter. Additionally, Palomar's second quarter revenues were up 28% over the $7.1 million in the preceding quarter.

For the six months period, results from continuing operations showed revenues increased 64% to $16.2 million, compared with revenues of $9.9 million during the first half of 1997. The company also reported a net loss reduction of 50%, $10.8 million (21 cents/share) compared with a net loss of $21.5 million (73 cents/share) last year. For the second quarter and six months Palomar reported a net loss from discontinued operations of $2.6 million (4 cents/share) and $2.6 million (5 cents/share, respectively. Most of the 1998 second quarter loss from discontinued operations was the result of a non-cash reserve against the carrying value of the company's investment in 2.8 million shares of stock in **Nexar Technologies, Inc.**

Dan Valente, chairman and chief executive officer of Palomar said, "Approximately 100 orders were recorded for the LightSheer Diode laser system during the quarter, and we shipped over 50 units by ramping up manufacturing processes sooner than anticipated to meet the overwhelming demand. Demand remains strong, backlog continues to grow, and we look forward to improving the gross margin...through increased manufacturing capacity and efficiency."

During a teleconference accompanying the release of the financial data, Valente noted that 85% of revenues recorded during the quarter were for the diode laser system, while only 15% was for the ruby EpiLaser system, of which there are currently about 200 in place. **Star Medical** has the capacity to build 35 to 40 diode laser systems per month, while Palomar has sufficient capacity for the ruby laser to meet demand. Commenting about the ongoing relationship with **Columbia/HCA**, he noted that Palomar's **Cosmetic Technologies International** business was still on a temporary hold, while they continued to evaluate the cost sharing model. The company plans to go back into business with Columbia when it is appropriate. Valente still believes that the revenue sharing business has tremendous potential.

7/29 **PLC Systems** reported financial results for the quarter with revenues of $680,000, compared to $3.4 million a year ago. The net loss was $5.4 million (28 cents/share), compared with $2.7 million (16 cents/share) for last year's second quarter. For the six-month period, revenues were $1.6 million and the net loss was $9.3 million (49 cents/share), compared with revenues of $5 million last year. The decline in revenues for both periods reflect decreases in shipments of the Heart Laser and in contractual minimum billings. All of the six shipments during the first six months of the year were made under the company's placement program and PLC is providing its customers with relief from contractual minimum billings pending FDA approval of the laser. Management has also been working with HCFA to reinstate Medicare reimbursement for TMR using the Heart Laser following the pending FDA approval.

7/30 **Urologic** announced that the FDA has expanded approval of claims for its Targis microwave system to include treatment of the obstruction of the urethra caused by benign prostatic hyperplasia (BPH) or enlarged prostate disease. It was approved by the FDA for treating symptoms of benign prostatic hyperplasia about a year ago. Since then, a growing number of urological centers have acquired the Targis System in the United States and are reporting a high level of patient satisfaction with the Targis procedure.

7/30 **CorMedica** announced that it had been awarded U.S. Patent 5,769,843, covering a system and method for percutaneous transluminal endocardial revascularization (PTER) which uses the company's proprietary electromagnetic navigation technology. Frank Martin, president and CEO said, "The patent describes a proprietary, integrated system for catheter-based myocardial revascularization. The system's electromagnetic navigation and tracking capabilities will enable the cardiologist to accurately create channels in the ischemic tissue within the heart." (See our July 1 brief last month.) **C.R. Bard**, a strategic partner of CorMedica, has worldwide distribution rights for PTER. Bard recently announced the sale of its **Coronary Catheter Lab Business**, including the CorMedica relationship, to **Arterial Vascular Engineering**.

7/30 **Candela Corporation** announced a 25% increase in fiscal fourth quarter revenue to $12.1 million this year from $9.6 million in 1997. This enabled the company to post net income of $1.0 million (19 cents per share) for the three-month period. During the comparable quarter one year ago, Candela's lost $1.3 million, for a net loss per share of 24 cents. For the 1998 fiscal year, Candela had record revenue of $37.0 million compared with $35.5 million for the prior year. The company's net loss for the full 1998 fiscal year was $4.5 million (81 cents per share). The results reflected operating losses and major restructuring charges connected with the company's decision to close its Scottsdale, AZ, skin care center to concentrate on its core medical device business. In fiscal 1997, Candela posted net income of $238,000 (4 cents per share).

Commenting on the performance of the company, Gerard Puorro, president and CEO, said, "Our sales and backlog are now growing dramatically for new products which treat skin conditions and produce long-lasting results in removing unwanted hair with speed, safety and efficacy. Candela's advanced new GentleLase product line, which was cleared for the treatment of vascular lesions late last year by the FDA was cleared for hair removal by the FDA two weeks ago. Now physicians and other practitioners have access to the advanced technology and low cost they want and need to serve growing numbers of patients who want such services. Industry estimates suggest that worldwide demand for hair removal lasers is in excess of $1 billion. Accordingly, and with our well-established distribution network in the U.S., Asia, Europe and elsewhere, we believe we are strategically positioned to capitalize on this demand."

Discussing the company's turnaround, Mr. Puorro said that Candela had eliminated the skin care center venture's significant adverse impact on its bottom line by closing Scottsdale, and had restructured the Boston center to help ensure that it reached break-even as soon as possible this coming fiscal year. Meanwhile, the company continues to explore alternatives to find the right buyer for both locations.

8/3 **Miravant** issued a statement to clarify it S-3 Registration Statement filed on July 30th. The company said the registration was not a new offering, but related to the September 1997 private placement financing, which took effect in December 1997. The filing registered 1.125 million additional shares which may or may not be issued in the future.

8/4 **Cell Robotics International** announced that it had signed an exclusive agreement for worldwide distribution of its Lasette laser finger perforator for the glucose testing market with **Chronimed, Inc.** Chronimed, headquartered in Minneapolis, provides pharmaceuticals, medical products and services to people with chronic conditions such as diabetes. The companies have agreed to a two-year, multi-million dollar minimum purchase by Chronimed. Cell Robotics will provide Lasettes to Chronimed for an agreed upon transfer price. Chronimed will distribute the Lasette and accessories worldwide and, as part of the agreement, will assume existing

international distribution agreements with companies in China and Japan. In addition to worldwide distribution, Chronimed will make a capital investment in the development of the home use model of the Lasette consisting of a staged purchase of $600,000 of Cell Robotics' common stock based upon the achievement of certain milestones.

Chronimed's capital investment in Cell Robotics will be focused on the development of a second generation, smaller Lasette to meet the needs of the home glucose testing market. This second model of the Lasette will be manufactured at Cell Robotics' Albuquerque, NM facility. The current, professional market model, is being manufactured through an OEM agreement with **Big Sky Laser Technologies** of Bozeman, MN.

According to the company, the worldwide diabetic market is very large and continues to grow. In the U.S. alone, 2,200 new diabetics are diagnosed every day. For the $2.5 billion annual diabetic glucose monitoring market, the Lasette represents the first significant change from the pain of sampling blood with steel blades or needles since the invention of the glucose meter 20 years ago. In addition to the current FDA clearance for drawing blood for testing glucose in children and adult diabetic patients in a clinical setting, Cell Robotics has also applied to the FDA for clearance for home use by patients of all ages.

8/4 **ThermoLase** reported its fiscal third quarter results, with revenues of $8.9 million compared with $12.9 million for the same period in fiscal 1997. The net loss for the quarter was $8.3 million (22 cents/share) compared with a net loss of $3.7 million (9 cents/share) last year. Gary S. Weinstein, chairman, noted that the company had made progress in lowering expenses for the quarter, aside from a one-time $1.9 million charge associated with some corporate restructuring and moving corporate headquarters to **CBI** subsidiary's facility in Carrollton, TX. Plans are in place to begin converting Spa Thira locations into Greenhouse Day Spas. (See the June 15th brief in the June issue.)

8/4 **American Dental Technologies** announced that is was granted a summary judgment for liability against **Kreativ, Inc.** for false advertising, in the U. S. District Court for the Eastern District of Michigan. Previously, the Court had granted an injunction against Kreativ for the same false statements. The judgment firmly establishes the liability of Kreativ for making patently false statements which disparage American Dental Technologies' KCP products. A trial on damages is expected soon and American Dental Technologies will be seeking just compensation from Kreativ for its false statements.

8/4 **Fechtor, Detwiler & Co.** issued an initial report on **Palomar Medical Technologies**. The company believes that Palomar is an attractive investment opportunity for risk-

tolerant investors as it expects a dramatic increase in gross margins, and significant growth in the laser hair removal market with Palomar's products being well positioned to gain market share over the coming years. In a model for the laser hair removal market (which I helped develop with the report's author), the report projects upwards of 1600 lasers being sold in 1998 (generating $184 million in laser sales), and 2100 systems sold worldwide in 1999 (for $220.5 million in revenues). At that level, the market would only be about 15% saturated. (No specific market share for Palomar's laser systems were given.)

8/5 **ESC Medical's** new VascuLight system was the subject of a news release commenting on results reported by one of the speakers at the Summer Meeting of the American Academy of Dermatology meeting in Chicago. Dr. Robert Weiss of Johns Hopkins, discussing new concepts in intense pulsed light and laser optics noted, "We compared the various vein lasers, from the green, yellow, and near infrared wavelengths of the diode array, and found them lacking. On the upside, we learned that the versatility of the treatment parameters are key to the effectiveness of light energy on vascular structures...the more flexibility the operator has to adjust the pulse duration, pulse sequencing and spacing, and fluence of the light source relative to the vessel size and vessel depth, the better the results will be." He then went on to describe the effects obtained with the VascuLight system. He attributed its high clinical efficacy to its unique multiple synchronized pulsing, which enabled him to provide better epidermal protection while treating a full range of leg veins from 0.5 mm to 3 mm and larger, with minimal risk of epidermal injury even at high fluence levels. The VascuLight system is currently in clinical evaluation for the treatment of larger leg veins.

8/5 **Lasertec International** announced that it had been granted ISO 9001/EN 46001 certification for its medical device product line. Lasertec is currently advancing the development of its Photo Therapic Resonancy system for the diagnosis and treatment of cancers.

8/6 **Spectranetics** announced that it had received conditional approval from the FDA to commence a randomized trial at 10 medical institutions for its minimally invasive Peripheral Excimer Laser Angioplasty (PELA) catheter, designed to treat total occlusions, or blockages, in leg arteries. The PELA procedure will follow a protocol initially developed by European interventionalists and revised in accordance with FDA recommendations. Dr. John Laird, principal investigator of the PELA trial at Washington Hospital Center, Washington, DC, said, "Treatment with excimer laser angioplasty in superficial femoral arteries provides patients suffering from leg pain and disability with a minimally invasive alternative to bypass surgery."

More than 3 million people in the U.S. suffer from peripheral arterial disease. The condition can cause incapacitating pain and lead to such complications as infection,

ulcerations, gangrene and amputation. Conventional therapy for long occlusions in the lower limbs includes exercise and drug therapy or bypass surgery. The Spectranetics' PELA treatment uses fiber optic technology to deliver excimer laser energy in short, precise bursts to dissolve, or ablate, through a blockage. "The minimally invasive treatment of occluded peripheral arteries represents a potentially important, additional interventional application for our excimer laser technology," said Spectranetics president and CEO Joseph Largey. "If the trial is successful, we intend to apply for a pre-market approval application with the FDA."

8/6 **Candela** announced that it had received CE certification for its GentleLase hair removal laser. This will enable the company to sell the product in the 15 EU countries.

8/6 **Miravant** announced financial results for the second quarter with revenues and net interest income increased to $2.3 million from $874,000 for the same period in 1997. The net loss for the quarter was $9.1 million (64 cents per share) compared to a net loss of $5.7 million (46 cents per share) for the same period last year. For the six month period, revenues and net interest income was $4.2 million compared to $1.8 million last year. The net loss was $17.0 million ($1.20 per share), versus $11.2 million (90 cents per share) in 1997.

Miravant previously announced a new collaboration with **Xillix Technologies Corp.** to co-develop proprietary systems for diagnosing and treating early stage cancer and pre-malignant tissues. Under the agreement, Miravant will evaluate the integration of its PhotoPoint drugs and devices with Xillix's fluorescence imaging systems to detect and treat abnormal lesions. This agreement gives Miravant exclusive rights to Xillix's FDA approved LIFE-Lung Fluorescence Endoscopy System for use with photodynamic therapy. Miravant is planning a comprehensive clinical strategy for lung cancer with Xillix and **Chiron Diagnostics**, a business unit of **Chiron Corp.**, with which Miravant signed a letter of intent in November 1997.

8/7 **American Dental Technologies** announced the closing of the acquisition of **Dental Vision Direct**, known as DVD or "UltraCam". The purchase price was $6.9 million, consisting of $3.9 million for assets and $3 million for goodwill and intellectual properties. DVD had revenues of $8.6 million for the previous four quarters. In connection with the sale, ADT issued 5-year warrants to purchase 600,000 shares of stock at $5.50 per share to **Ultrak, Inc.**, and 60,000 to Ron Williams, former shareholder of DVD. The company received a five-year consulting agreement with Ultrak's engineering department and a royalty-free license for the dental field to implement any technology developed by Ultrak. DVD's flagship product is the UltraCam intraoral camera.

8/7 According to *Dow Jones Online*, **Clearwater Funds**, a principal unsecured creditor of **Mehl/Biophile International Corp.**, has filed a petition for involuntary bankruptcy against the struggling startup company. Mehl said that it had not been served with the petition and had no further information about it. The story notes that in February, **Palomar Medical Technologies** won a judgment to invalidate a patent for laser-hair removal held by Mehl. Palomar said a U.S. District Court found its **Spectrum Medical Technologies** unit developed a laser hair-removal method that predates Mehl/Biophile's method, covered by a different patent. The story notes further that while a consultant for Palomar, I had predicted that the overall hair-removal market could grow to $4 billion yearly, from $1 billion now. (I was referring to the service side of the business, and not the laser sales side.)

8/10 *NewsPage* reports that **Eclipse Surgical Technologies** has been awarded a U.S. Patent for "A method of non-synchronous laser assisted TMR", which involves a method of selecting laser parameters for performing TMR to avoid inducing undesirable cardiac arrhythmia without synchronization of delivery of laser energy, using the patient's cardiac cycle.

8/10 **DUSA Pharmaceuticals** announced that for the second quarter its net loss was $2.1 million (23 cents per share) compared to $1.7 million (18 cents per share) for the same period last year. Research and development costs were $1.7 million, up from $1.4 million, primarily due to costs related to the completion and filing of the NDA.

8/10 **QLT PhotoTherapeutics** released its financial results for the second quarter and six months. For the quarter, the company reported a net loss of $5.3 million (20 cents per share) compared to a net loss of $5.7 million (22 cents per share) for the same quarter last year. For the six month period, the company reported a net loss of $10.2 million (39 cents per share) compared to a net loss of $8.2 million (32 cents per share) for the corresponding period in 1997. Research and development costs for the quarter totaled $5.1 million, representing a 4% increase from the corresponding quarter in 1997, and a 5% decrease from the first quarter of 1998.

"We expect research and development spending to increase during the remainder of 1998, reflecting QLT's pivotal ongoing Phase III clinical studies of verteporfin (BPD-MA) for the treatment of age-related macular degeneration (AMD), and QLT's accelerated development programs in oncology and autoimmune disease," said Kenneth Galbraith, senior vice president and CFO. "The company's recently completed equity offering provides us with a stronger financial platform from which to accelerate these key development programs." (On July 24, 1998, QLT completed an offering of 1,000,000 common shares at a price of Cdn$23.00 per share, resulting in net proceeds to the Company of approximately $22 million. With this offering, QLT increased its current cash resources to approximately Cdn$98 million.)

QLT reported royalty revenue for the second quarter of $320,000 on end-user sales of Photofrin of approximately $1.4 million representing a 23% increase over the same period last year. Although adjustments in inventory levels among U.S. wholesalers led to lower Photofrin royalty revenues than in the previous two quarters, QLT expects growth to resume, Galbraith said.

8/11 **Thermotrex** reported fiscal results with revenues of $88.9 million and a net loss of $4.8 million. According to Gary Weinstein, chairman and CEO, the company received the largest contract in its history in May, and **Trex Medical** had another great quarter, but the impact of losses at **ThermoLase** were reflected in ThermoTrexes' net loss. He went on to state that changes were ongoing and excluding restructuring charges, the company was able to lower expenses for this quarter at ThermoLase, and had hired a new CEO to spearhead its efforts to reposition ThermoLase.

8/12 **American Dental Technologies** reported net income of $1 million (13 cents/share) for its second quarter compared to net income of $1.4 million (18 cents/share) for the same period of 1997. Revenues for the quarter were $6.4 million, up from $5.4 million a year ago. For the six month period, revenues were $12.1 million and net income was $1.8 million (25 cents/share). "The company has experienced 10 percent growth in sales during the first half of the year, primarily due to a 47 percent increase in foreign sales and an 18 percent increase in North American sales during the second quarter," said Ben Gallant, president and CEO. "Earnings continue to be in line with management's expectations and we expect continued growth in sales for the remainder of 1998."

8/12 Health-care stocks will continue to outperform the market in the future because of their superior growth prospects in the opinion of analysts specializing in the health-care industry at **Sutro & Co.**, the oldest securities firm in the Western United States. The Sutro analysts said they expect that demand for health-care products and services will "continue growing more rapidly than the economy because of worldwide population aging, continued major innovations in medical technologies and rapidly emerging markets for Western medicines in the Pacific Rim (particularly China) and the former Soviet Union states in Eastern Europe and Asia."

The Sutro analysts made their observations and predictions in the 92-page first issue of a new publication called "Vital Points". To be issued quarterly, Vital Points is written by four Sutro analysts: Eugene Melnitchenko, associate research director; Larry Smith, vice president; Bonnie Feldman; and Edward R. Vanacore. In the Sutro analysts' view, "Health care is arguably the least efficient major industry in the U.S." But it is now "in the early stages of a change that should prove to be as dramatic as those which have transformed most other major American industries into high-quality, low-cost global competitors." The report adds, "Health care is now evolving into a new way of doing business. We believe that the end game will be one in which

providers accept pre-set prices for services before they are rendered and are judged on the outcome. Health care will evolve into a new industrial-style organization in which there is a compulsion to push production to the lowest possible cost, replacing wherever possible labor with technology and increasing the division and specialization of labor."

This trend, "will lead to the creation of many publicly owned companies. In the premiere issue of Vital Points, Sutro also introduces indices for measuring the performance of health-care stocks in five sectors of the industry: biotechnology, dental, medical devices, pharmaceutical and medical services. (I received a copy of the report and it mostly covers companies on the service side of the businesses, with no laser companies involved.)

8/12 **Diomed** announced that it had acquired the business of **LaserLite LLC**, the U.S.-based distributor for Diomed's aesthetic laser products. In making the acquisition (from **Mile Creek Capital LLC**), Diomed has formed a new holding company, **Diomed Inc.**, a U.S. corporation, which will be headquartered in Boston. The new company will allow Diomed to expand its surgical and photodynamic therapy products into the U.S. market, as well as securing direct access to the rapidly growing aesthetic laser market worldwide. (The company notes that over 700 Diomed surgical diode lasers are operating in over 25 countries worldwide.)

8/13 **Ion Laser Technology** reported first fiscal quarter results with sales of $360,000, down from $2 million for the same quarter a year ago. The company incurred a net loss of $2.1 million (30 cents/share), compared to a loss of $77,000 (1 cent/share) for the same quarter last year. The loss for the quarter included a $1.1 million charge for employee termination and decreased valuation of certain fixed assets, inventories, and accounts receivable.

8/13 **Spectranetics** announced that a minimally invasive investigational coronary procedure designed to treat patients with continuous, debilitating cardiac chest pain, or angina, using an excimer laser catheter has been tested on animal subjects. Dr. Steve Ettinger, a cardiologist at the Hershey Medical Center in Hershey, Penn., performed Percutaneous Transluminal Myocardial Revascularization (PTMR) on the inside of the beating heart of a pig. Joseph Largey, Spectranetics' President and CEO said, "Our potential entry into the PTMR investigations with our excimer laser application may provide another opportunity for the use of our CVX-300, in addition to coronary angioplasty and pacing lead removal as well as our investigational studies with peripheral angioplasty, TMR and clearing restenosed stents." (Spectranetics supplies excimer lasers to **U.S.Surgical** for use in its clinical trials for TMR.)

8/14 **Pacific Pharmaceuticals, Inc.** announced results for the first fiscal quarter with revenues of $46,000 compared to $101,000 for the same period last year. The net loss for the quarter was $4.1 million (37 cents per share) compared to a loss of $2.8

million (34 cents per share) for the first quarter last year. The net loss for the quarter included a non-cash convertible preferred stock dividend of $3,294,000. During the quarter, the Company completed a private placement of equity securities of its subsidiary, **B-G Development Corp. (BGDC)**, in which it raised net proceeds of $2.6 million. The proceeds from the private placement are intended to fund BGDC's development of the recently acquired chemosensitizing agent O6 Benzyl Guanine, with a portion of the proceeds going directly to Pacific to develop its other technologies.

8/14 **Laser Corp.** announced its second quarter results with revenues of $670,000 as compared to $1.5 million for the same period in 1997. This resulted in a net loss for the period of $274,000 (32 cents/share), as compared to net income of $85,000 (10 cents/share) in 1997. For the six month period, revenues were $1.5 million as compared to $2.4 million for the same period in 1997, resulting in a net loss of $543,000 (63 cents/share), as compared to a net loss $75,000 (9 cents/share) for the same period in 1997. Joyce Wickham, president and CEO, commented that the company continued to experience downward fluctuation in demand for OEM laser products during the second quarter. She noted, however, that the company has now begun to experience an upward trend in OEM product orders. In addition as previously disclosed on July 2nd, the company introduced an improved DPSS laser which is now in beta site testing in its Nuvolase 532 medical laser system. Preliminary reports have been encouraging. Assuming continued positive results, the company intends to resume manufacturing and full sales of its Nuvolase 532 in the fourth quarter 1998.

8/14 **BriteSmile, Inc.**, which previously operated under the name **Ion Laser Technology, Inc.**, announced that it has strengthened and expanded its strategic alliance with **OraCeutical LLC**, a leading oral health care product development company. OraCeutical has developed patent pending technologies for photo-activated tooth whitening which are exclusively licensed to BriteSmile for use in the company's Tooth Whitening Centers. The BriteSmile Light Activated Tooth Whitening Gel will be used in conjunction with the BriteSmile 2000 Device presently being developed. It is expected that the BriteSmile 2000 Device and Gel will whiten teeth faster and better than all current whitening technologies. The Centers are currently scheduled to open in strategic locations in the U.S. starting in the first quarter of 1999.

In a separate agreement, BriteSmile has also licensed a patent pending dentist dispensed take home tooth whitening product developed by **Applied Dental Sciences**, an affiliate of OraCeutical. It is expected that the formula will also be the basis for a long-term maintenance product for use by individuals who have undergone the BriteSmile tooth whitening process. Both of BriteSmile's agreements with OraCeutical have a total value of approximately $500,000.

8/15 The current issue of *Laser Report* notes that the **Quantel Group** and **Big Sky Laser Technologies** have merged. According to Alain de Salaberry, Quantel's president and CEO, Big Sky will become the North American headquarters for the the Quantel Group, with Ed Teppo remaining as president and CEO, as well as becoming a director general of Quantel. Big Sky will retain its name.

8/18 **Palomar Medical Technologies** announced that it had received certification to sell its LightSheer(TM) Diode laser system with the "CE Mark" designation internationally. CE Mark is a requirement which products must meet in order to be sold in the European market. "The CE Mark designation opens up the tremendous European market to our LightSheer Diode system, which should significantly increase sales of this popular new product," said Dan Valente, chairman and CEO of Palomar. "As the only diode laser cleared by the FDA for hair removal and now as the first diode laser for hair removal to receive CE Mark status, we expect the LightSheer system to have the same overwhelming impact in Europe that it has already had here in the U.S."

Valente went on to note that the company had recently expanded the production space for LightSheer by 50% to increase its monthly capacity to meet demand.

8/18 **Excel Technology, Inc.** announced today it has acquired the assets of **Synrad, Inc.** for cash. Synrad is the world's leading manufacturer of sealed $CO_2$ lasers, generally considered to be the lowest cost laser energy source available and essential for certain applications. Synrad's installed base exceeds 20,000 worldwide. Applications are widely diversified and growing. The total cash outlay was about $22 million including payment of all Synrad bank debt and certain other obligations and expenses related to the transaction. The funds came primarily from Excel's existing cash along with some bank borrowings.

8/18 **BioLase Technology** announced the launch of its LazerSmile tooth whitening system for home use. This non-laser monochromatic light source, embedded within a battery-operated toothbrush, is used in conjunction with a clear, non-abrasive tooth whitening gel. The system can be ordered directly from the manufacturer over the internet at www.laserbrush.com, and will also be sold in dentist's offices. The internet launch will include banner ads running on several web sites and search engines, such as AOL, Excite, Yahoo, and Infoseek.

8/18 **Transmedica International, Inc.** announced that it had received allowance from the U.S. Patent Office for a patent for the use of lasers in drawing capillary blood and for the transdermal administration of pharmaceuticals. The new patent will further protect the methods of use of the company's Laser Lancet, which already has patent protection.

8/18 **Cell Robotics International, Inc.** announced financial results for its second quarter and six month period. Revenues for the quarter increased to $328,000, from $278,000. The net loss was $527,000 (10 cents per share) compared to $619,000 (12 cents per share) for the same quarter last year. For the six-month period, revenues increased 46% to $784,000, from $535,000 for 1997. The company had a net loss of $822,000 (16 cents per share) compared to a net loss of $1.1 million (22 cents per share) for the comparable period last year. Earlier this month, the company announced an agreement for the worldwide distribution of its Lasette laser finger perforator for the glucose testing market with **Chronimed**. The companies have agreed to a two-year multimillion dollar deal, which includes an investment in Cell Robotics by Chronimed. (See our August 4th brief above.)

8/19 **Palomar Medical Technologies** announced that it had a current backlog of more than $8 million in orders for its LightSheer Diode laser system for hair removal. "Halfway through the third quarter, our backlog numbers show that orders for this one-of-a-kind product continue to come in at record levels," said Dan Valente, chairman and CEO of Palomar. "Now that we have increased our monthly manufacturing capacity with newly expanded production space, we intend to ship the majority of this current $8 million backlog by the quarter's close on September 30, adding to the $5 million in orders that we have previously shipped this quarter." Valente also noted that with the Autumn selling season beginning and as the company makes inroads into the European markets with its newly won CE Mark, he anticipates even stronger sales for the remainder of the year.

8/20 **Premier Laser Systems** finally announced its restated results, along with results for its first fiscal quarter ending June 30th. For the quarter, the company had revenues of $3.5 million, up 65% compared to last years fiscal quarter, but had a net loss of $4.7 million (32 cents/share), as compared to $0.7 million or 8 cents/share last year. The increase in revenues was largely due to the sales of ophthalmic products from the company's **EyeSys Technologies** and **Ophthalmic Imaging Systems** subsidiaries. Dental product sales remained low during the period due to dental-market worries about the company's financial condition and the uncertainties following the April announcement of the disagreement with **Henry Schein**.

Chairman, president and CEO Colette Cozean said, "Following the events of the spring and summer of 1998, we have taken many remedial and forward-looking actions, substantially upgraded and tightened our internal control systems and have hired a new CFO...Most important, we are relaunching marketing and sales programs for our dental lasers...We are scheduling more dental courses...and are launching consumer-focused ads beginning to appear in publications such as *The New York Times* and *The Los Angeles Times*...ads that speak directly to dentists have been appearing in trade publications for several weeks...Our sales force is being expanded and revitalized and we are searching for a new leader for out dental products group."

For the fiscal year ended March 31, 1998, the company reported re-stated sales of $10.4 million, up from the $5.1 million reported for the previous fiscal year. The company had a net loss of $38.2 million ($3.34 per share) versus a loss of $6 million ($1.02 per share) for the 1997 fiscal year. The operating loss for fiscal 1998 was negatively impacted by $19.9 million of acquisition expenses, $7.5 million of inventory writedowns, $1.1 million of warranty costs, $480,000 of non-cash stock option expense, bad debt of $600,000, and litigation expenses of $400,000 -- all of which totaled approximately $30 million.

I have re-calculated the company's 1997 calendar year revenues as $11 million, down from the previously reported $14 million, and have downgraded my estimate for this year's revenues to $15 million -- which still may be a stretch -- down from $25 million.

8/20 **Dental/Medical Diagnostic Systems** announced that is has received 510(k) approval for the Apollo 95E tooth whitening and curing system. This allows Dental/Medical to begin marketing the Apollo 95E and shipping will commence immediately. The Apollo 95E will significantly whiten discolored teeth in less that one hour. Because the Apollo 95E is not a laser, a dental assistant can perform the procedure. The system also cures restorative composite materials in 1 to 3 seconds, making it the fastest dental curing light in the world known to the Company. DMD will be supplying its own matched composites and whitening materials to increase speed and optimize results for the dentist and the patient. Robert Gurevitch, chairman and CEO of DMD stated, "The swift approval of our 510(k) filing for the Apollo 95E supports the earlier confidence of our regulatory experts that notification wouldn't take more than 60 to 90 days. We expect the Apollo 95E to quickly garner a significant share of the market for tooth whitening devices and composite curing because of its market leading combination of price and features."

8/20 **Ion Laser Technology** said that as of August 11th, its name had become **BriteSmile, Inc.**, and effective August 24th, its stock symbol would become BWT.

8/20 **PLC Systems** announced that it has received approval from the FDA for commercial use of The Heart Laser System for TMR (transmyocardial revascularization). PLC is the first company to receive FDA approval for use of a laser product for TMR, a new surgical procedure used to treat patients suffering from severe coronary artery disease with no treatment alternative. The Heart Laser System can now be marketed throughout the U.S. and used to treat the estimated 80,000 domestic patients each year who suffer from severe coronary artery disease (CAD) but can not be treated with conventional coronary revascularization techniques such as bypass surgery or angioplasty.

"This FDA approval confirms PLC's position as the pioneer and leader in TMR," said William Dow, president and CEO of PLC. "We are the most experienced laser revascularization company in the world, based on our treatment of more than 4,000 patients and over 100 installed Heart Laser Systems worldwide. We intend to maintain our market leading position, expand our database of clinical information and seek FDA approval for expanded use of The Heart Laser System, including as an adjunctive therapy to bypass surgery." Analysts have estimated that the worldwide market potential for TMR could be as much as $1 billion annually.

PLC estimates that each year approximately 120,000 patients worldwide are diagnosed with severe CAD which is not treatable by conventional revascularization techniques. CAD is a form of heart disease caused by the blockage of blood flow into the coronary arteries which supply oxygen-rich blood to the heart muscle. Typically, severe CAD patients experience excruciating spasmodic attacks of chest pain, or angina, and often shortness of breath and fatigue. No longer candidates for traditional surgery, these patients have been placed on maximum drug therapy.

According to *Dow Jones*, U.S. clinical studies have demonstrated the TMR procedure to be safe and effective in decreasing angina by two or more classes in nearly 75% of patients and eliminating all angina in one-third of patients. One analyst with **Fechtor Detwiler Inc.** said earlier this year, sales of the laser could hit $75 million in the first year and go up to $125 million in its second year on the market. PLC's high-tech, computer-based laser system costs about $500,000 apiece. But hospitals may also rent the system for $25,000 upfront and an additional $3,000 to $3,500 each time the device is used. An estimated 120,000 to 150,000 patients suffering from advanced-stage heart disease could benefit from the laser procedure, with an additional 50,000 new patients each year, the company estimates.

The FDA said PLC's laser system is intended for treating people who suffer with severe and frequent chest pain. "Although this is not a life-saving procedure, it can provide significant relief of severe angina and improve the quality of life for a select group of patients for whom there is currently no effective treatment," said FDA Acting Commissioner Dr. Michael Friedman. Exactly how this treatment works is not understood, but may relate to reduction in the perception of pain, formation of new small blood vessels, or increased blood flow to the heart muscle. The FDA said it asked PLC Systems to conduct additional studies about mortality and long-term benefits in patients using the laser system once it is on the market. "Because of potential for major adverse events and premature death, use of the PLC laser is restricted to surgeons trained in its use and to patients with severe angina who cannot be helped by other means and who give informed consent," the FDA said.

8/21 *NewsPage* reported that **Infrared Fiber Systems** had obtained a U.S. Patent for heavy-metal oxide glass fibers for use in medical surgery. The patent relates to an improved

optical glass fiber for transmitting mid-infrared wavelength laser light in surgical instruments. The fiber includes a heavy-metal oxide component, preferably $GeO_2$ doped with heavier cations and anions.

8/21 **Trimedyne** announced a significant favorable decision by the United States District Court for the District of New Jersey in its lawsuit against **C.R. Bard**. As previously announced, Trimedyne brought an action against Bard in late 1995 for breach of contract, breach of good faith, fraud, negligent misrepresentation, account stated and an open book account/owed order. The company is seeking compensatory and punitive damages. The court's recent decision denies Bard's motion for partial summary judgment and affirms Trimedyne's claim on the open book account/owed order. Trimedyne expects a trial date to be set shortly.

8/21 **BioLase Technology** announced the results for its second quarter. Sales for the three-month period were $236,087 compared to $432,941 for the same period in 1997. The net loss for the quarter was $1.2 million (8 cents/share), compared to a net loss of $677, 862 (5 cents/share) for the second quarter of 1997. The net loss for the first half was $2.0 million (15 cents/share) on sales of $498,617 compared to a net loss of $1.4 million (11 cents/share) for the first half of 1997.

The Company reported that the decrease in sales for the second quarter as compared to the same period in 1997 was due principally to its decision to defer most deliveries of its Millennium tissue cutting system, particularly those to its German distributor, while in the process of implementing a partial redesign of the handpiece for that system. Donald La Point, president and CEO of BioLase stated, "It was a difficult decision to defer the shipment of our Millennium system to customers that have placed orders with us; however, it is in the best interest of our customers that BioLase focuses on the new design of this critical component of the Millennium. During this past quarter, we have made significant improvements to the new handpiece, which incorporates a much more flexible and robust packaging of the fiber. The new handpiece will also incorporate various sizes of disposable tips that will allow the doctor to easily change from one tip to another in a fashion similar to that already used with the dental drill." Mr. La Point added, "We fully expect to complete the partial redesign of the handpiece in the near future in time to meet, what we anticipate to be, a high demand of our Millennium system both internationally and domestically."

8/24 **BriteSmile**, formerly **Ion Laser Technology**, announced plans to open 20 BriteSmile Tooth Whitening Centers in strategic locations, concentrated primarily in Texas and on the West Coast, during the first calendar quarter of 1999. The Whitening Centers, which will be operated by dentists, will provide the latest in tooth whitening technology and products directly to consumers. Linda S. Oubre, a director of the

company, has been named president of the BriteSmile Whitening Center Division, responsible for the roll-out and marketing of the Centers.

Following the initial roll out in the first calendar quarter of 1999, BriteSmile plans to expand the Centers both domestically and internationally. The company envisions opening up to 100 BriteSmile Whitening Centers by year-end 2000.

The Whitening Centers will feature a number of new BriteSmile products, including the BriteSmile Light Activated Tooth Whitening Device and Gel. It is anticipated that the new device will provide tooth whitening at a speed and efficiency previously unavailable in a single one-hour procedure. Also at the Centers, the company expects to sell new BriteSmile tooth whitening maintenance kits for customers' follow-up care.

Working together with a number of BriteSmile's 140 current dentist partners, it is expected that many of the new Centers will be operated by certain of the partners or will be built around their existing tooth whitening operations. Financing for the Centers is expected to be provided by a $10 million line of credit, which is currently being negotiated. In addition, BriteSmile has engaged **King, Brown & Partners** to provide the company with marketing direction and expertise and **McClellan Hunter Architecture** to work on the BriteSmile Whitening Center design and build-out efforts.

8/24 **Trimedyne** reported financial results for its fiscal third quarter and the nine-month period ended June 30, 1998, which include the results of its 90 percent-owned subsidiary, **Cardiodyne** on a consolidated basis. Revenues for the quarter were $1.8 million, a decrease of 27% from revenues of $2.5 million for the same quarter one year ago.

The company's net income from continuing operations for the quarter was $2.1 (19 cent per share), including $766,000 of R&D expenses of Cardiodyne and $3.6 million income from the sale of a non-exclusive patent license, compared with a net loss of $1.7 million (15 cents per share) for last year's quarter (which included a reserve of $200,000 for excess and obsolete inventory and $486,000 of R&D expenses of Cardiodyne).

For the nine-month period, revenues from product sales were $5.5 million, a decrease of 15% from revenues of $6.4 million, for the same period one year ago. The company's net loss from continuing operations was $906,000 (8 cents per share), including $2.2 million of start-up and R&D expenses of Cardiodyne and $3.6 million from the sale of the aforementioned patent license, a decrease of 79% from the net loss of $4.3 million (39 cents per share) for the year-ago period (which included $880,000 of start-up and R&D expenses of Cardiodyne.

As of June 30, 1998, the company had $8.7 million in working capital, of which $4.4 million was in cash and equivalents and marketable securities. Management believes its existing working capital will be sufficient to meet Trimedyne's and Cardiodyne's operating needs through early 1999. The company has implemented cut-backs in Cardiodyne's operating expenses and is continuing to implement cost reductions at Trimedyne. The company is seeking additional financing through the sale of equity securities of Trimedyne or Cardiodyne and the sale or licensing of other patent rights to fund Trimedyne's and Cardiodyne's continuing operations.

8/25 **Transmedica International** announced today that **Allegiance Healthcare Corporation** has become the exclusive distributor of Transmedica's Laser Lancet to the U.S. acute care market. Allegiance is the nation's leading provider of health care products and cost management services. Allegiance demonstrated the Laser Lancet at the recent Clinical Laboratory Management Association meeting at Philadelphia. Allegiance Healthcare Corporation is the principal U.S. operating subsidiary of **Allegiance Corporation**. Through its subsidiaries, Allegiance is America's leading provider of health care products and cost management services to hospitals, laboratories, and other health care facilities.

8/25 **Laser Power**, a leading developer of microlasers, announced the issuance of two U.S. Patents. One covers a cooling system technology that enables the company's microlasers to achieve high power levels in a small compact package, through the development of an optically transparent heat sink. The other patent covers an intracavity optical frequency missing technology that allows access to frequencies that may otherwise be unobtainable in a compact solid-state laser.

8/25 The August issue of *MedPro Month* contains a cover story on the medical laser industry. Material for the story was taken from my and Kathy Kincade's coverage of the spring ASLMS meeting, presented in the April and May issues of *Medical Laser Report,* and from the just published "Worldwide Markets for Medical and Dental Lasers" study prepared for **Medical Data International**, the publishers of *MedPro Month*. The tables accompanying the article include "Worldwide Sales of Dermatology Lasers by Type" for 1997, 1998, and 1999; "1997 Estimated U.S. Dental Laser Sales by Type"; both taken from the MDI Report, and my table of hair removal lasers, taken from MLR. (Anyone wanting a copy of the article, please call or email me.)

I also received a review copy of the "Worldwide Markets for Medical and Dental Lasers" report. The report covers the important markets for medical lasers of dermatology, ophthalmology, dentistry, and transmyocardial revascularization. At a glance, there appears to be some missing information. There is no data on the overall world markets for medical lasers, or what portion of the total market, the areas above make up. In the ophthalmology section, the cataract market is overstated (perhaps by

as much as 2x!); not enough emphasis is placed on the use of lasers for secondary cataract clearance, perhaps the largest current application for medical lasers. The dermatology section lacks a good overview of laser hair removal, including projections for this important and growing market, while the cardiovascular section left out $CO_2$ lasers in its listing of important table of TMR lasers. The dental section looks OK, but doesn't address Premier's current troubles in selling erbium:YAG lasers into the dental market.

Overall, I would rate this new report with, at best, a C+.

**MEDICAL/SURGICAL LASER UPDATE -- SEPTEMBER 1998**

8/26 Upon checking in at the Arthur D. Little healthcare library to get caught up with pertinent articles from *The Gray Sheet*, I discovered an excellent profile on **Spectranetics** that appeared in last October's *In Vivo*. The eight-page article details how cardiac lasers' bright promise for laser angioplasty in the 1980s crashed in the early 1990s, but how TMR has revitalized interest in the field. (Spectranetics is partnered with **US Surgical** in this now hot field.) Spectranetics, with its recent approvals in pacemaker lead removal is also seeing a revival of interest in sales of its excimer lasers. The company estimates that the market for laser cardiac applications is in the order of $550 million, including TMR (representing about 9% of that total).

The June 29th *Gray Sheet* notes that **Mehl/Biophile** had an FDA-ordered recall of its Chromos 694 ruby lasers because of a lack of a fail-safe fiber interlock. A field correction was initiated of the 51 units in the field.

The August 3rd *Gray Sheet* noted that *The American Electrology Association* was challenging the **Palomar** 510(k) labeling allowance for "permanent hair reduction". According to the AEA, the phrase "seems contrived and intended to infer permanence without actually saying it". The association, in its letter to the FDA, said the terminology was confusing to the American public and to clinicians who perform hair removal procedures. Palomar, in its product literature, defines "permanent" as related to EpiLaser-based hair removal at fluences greater than 30 $J/cm^2$ that lasts for at least two years after a single treatment. Permanent is defined as significant and stable loss of hair for a period longer than the complete natural hair growth cycle (about one year).

The August 24th issue of *The Gray Sheet* notes that **PLC Medical Systems** is selling its Heart Laser for $400,000 following its August 20th FDA marketing approval. Other options include a standard lease based on the $400,000 price, with the cost prorated over the lease period, or a $3500 per procedure basis, following a hospital's commitment to a minimum number of treatments. Hospitals purchasing or leasing the

laser must pay about $1500 for a sterile, single-use kit for each procedure. The kit price is included in the per procedure option. The article notes that PLC has sold at least 105 lasers worldwide, with 33 of those in investigational sites in the U.S., and over 30 in Europe.

8/26 In a surprise move, **Miravant Medical Technologies** announced that it was dropping the further development of its PDT approach for the treatment of advanced cutaneous metastatic breast cancer (CMBC). According to *Dow Jones Online*, the decision was apparently made by Miravant's marketing partner, **Pharmacia & Upjohn** because the potential market was just too small. Instead, the partnership will focus on the much more lucrative market of age-related macula degeneration. Miravant said that its PDT treatment worked in CMBC, as demonstrated by substantial tumor response in late-stage clinical trials, but that the costs of launching a product for a limited market was prohibitive. The company will use the information gathered from the CMBC study in support of future FDA filings.

8/26 The third annual "Wrinkle Report: What Dermatologists Think about the Latest Advancements for Aging Skin" was released by **Ortho Dermatological**. The survey, conducted by **Louis Harris & Associates**, details patient's motivations in seeking help, most recommended treatments, and dermatologist's own skin-care practices. With the aging of the "baby-boomers", dermatologists are noting an increase in women over 30 interested in improving their facial appearance, including wrinkles, brown spots, and uneven or irregular pigmentation on the face. Men are also joining the rank of interested consumers in improving their appearances. Survey participants identified brown spots, dry skin, and wrinkles as the three aging skin conditions most frequently treated. (Since this report was sponsored by a wrinkle cream company, more than 90% of respondents cited a prescription wrinkle cream, chemical peels, and surgical intervention as most effective, rather than over-the-counter products.)

Cosmetic laser surgery (skin resurfacing) was ranked as 98% effective for wrinkle removal by the respondents, while it was recommended for some of their patients by only 84% of the responding dermatologists, most of whom ranked prescription wrinkle medications higher. In a chart accompanying the report, cosmetic laser surgery was only recommended to all or most of their patients for treating wrinkles by 6% of responding dermatologists, compared to 12% chemical peels, Rx creams 58%, OTC creams 22%, and retinol 19%. It is obvious that the dermatologists chosen for this survey were not "laser savvy", as our research shows that an increasing number of dermatologists/plastic surgeons are using both $CO_2$ and erbium:YAG lasers for removing wrinkles, with over 200,000 skin resurfacing/wrinkle removal procedures expected to be performed in 1998.

8/27 **Pharmacyclics** reported fiscal fourth quarter results showing a net loss for the quarter of $3.8 million (31 cents/share) compared to a net loss of $2.3 million a year ago.

Revenues for the quarter were $165,000. For the fiscal year, revenues were $3.5 million and the net loss was $9.7 million ($1.11 per share).

8/27 **Laserscope** announced that it had received clearance from the FDA to market its KTP-based Orion 800 Series and High-Power 800 Series Laser systems for the treatment of benign prostatic hyperplasia (BPH). The company expects to introduce the High-Power 800 Series laser in 1999, as a field upgrade on its 800 Series systems.

The question, posed by editor Kathy Kincade as the lead story in the July issue of *Medical Laser Report*, is, Are lasers too late for BPH? As Larry Haimovitch of Haimovitch Medical Technology Consultants noted, "This is a noisy market with many modalities...and in talking with urologists, they say they are confused by all of them, and continue to use TURP." In addition, because of the system-management capabilities of the various drug therapies, the actual surgical market for BPH has declined from the high of about 450,000 procedures each year, to about 200,000 annually today. And of these, no more than about 10% are being done with lasers! However, the aging population bodes well for the surgical (and laser) treatment of BPH, especially if the laser treatment becomes reimbursable. (**Coherent**, **Indigo** (for interstitial treatment), **Trimedyne** and now Laserscope all have FDA clearances.

8/28 **QLT PhotoTherapeutics** will go before an FDA advisory panel next week seeking expanded approval for its cancer drug Photofrin. QLT will seek a recommendation for using its light-activated drug in the reduction of obstruction and ease of symptoms in patients with completely or partially obstructed endobronchial non-small cell lung cancer. Photofrin was originally approved by the FDA in December 1995 for early-stage lung cancer and is also approved for advanced throat cancer. The drug generated sales of roughly $1.4 million in the second quarter. Photofrin is sold in the U.S. by **Sanofi SA's** U.S. **Sanofi Pharmaceutical** unit. According to analyst Ann Dulhanty, of Dundee Securities, even if the company gains the new approval, it would only increase sales of Photofrin in the U.S. by about 30%. Christine Charette of Nesbitt Burns agreed with Dulhanty's assessment, with the additional approvals only affecting about 20,000 to 25,000 people.

8/28 **PLC Systems** stated that the company is receiving a great deal of interest for The Heart Laser since its FDA approval last week and knows of no reason for the recent stock price activity. "We are overwhelmed by the initial impact in the market of the news of FDA approval of The Heart Laser System," stated William Dow president and CEO. "In the first week after approval, we generated more than 30 requests for quotes. We have lasers ready for shipment when the purchase orders are finalized...Doctors have indicated to our sales force that a significant number of patients have `come out of the woodwork' to inquire about TMR. In fact, a sizable number of patients have begun to contact our Franklin office directly. Given this level of interest, we are surprised that the stock is not performing better." (Perhaps it is

because those in the know realize that TMR will never be "big" until reimbursement is granted by HCFA!)

8/28 *The Los Angeles Times* reported that **Premier's** CEO received a bonus and raise prior to the company's financial woes earlier this year. Colette Cozean received a 54% increase in her compensation package for the fiscal year ended March 31st, and netted a $100,000 bonus last November, in part for helping the company win regulatory approval for its dental laser. She received a 9% salary hike to $165,000 and options exercisable at $7.97 per share to purchase 1 million shares of stock, now worthless because of the stock's slump this year. Premier's restated and reaudited results for the year ended March 31st show the company posted a loss of $38.2 million on revenues of $10.4 million, compared with a loss of $6 million on revenues of $5.1 million for the prior year.

8/30 *The New York Times* ran a style desk article entitled, "Beauty's Bomb, but How Smart?" discussing the use of lasers in cosmetic surgery. As noted in the story, lasers are showing up in salon ads and dermatologist's brochures, promising to zap away unwanted body hair, wrinkles and leg veins. But laser technology is developing so rapidly, it's difficult for consumers to discern what is safe and effective. "A laser is something you use to deliver a certain amount of energy in order to destroy a precise target," Dr. David Biro, a dermatologist in Bay Ridge, Brooklyn, said. "Like a smart bomb, it selectively attacks a site without damaging any of the surrounding tissue." But the wrong machine in the wrong hands can cause burns, scar dark skin, or just annoy consumers, who pay for permanent removal of hair only to see it grow back. Moreover, laser hair removal, tattoo removal, facials and peels don't require a medical license; the equipment can be deployed by anyone who has the $40,000 to $250,000 to buy it. "Anyone can buy a machine," Dr. Debra Jaliman, a prominent New York dermatologist, said. "But only a physician knows your medical history and can prescribe antibiotics, if necessary." But even doctors are finding that, as lasers have become more available, cosmetic dermatology has become a technology-driven field. The public, told in ads and beauty magazines about the promise of laser procedures, demands them. Doctors and others are drawn to laser procedures because they are lucrative. (Patients pay $1,000 to $3,000 for the removal of hair on the upper lip. Such elective procedures are not covered by most medical insurers.)

One concern is that some doctors might recommend a particular laser to their patients because they have a commercial relationship with the laser manufacturer. Four of the six doctors interviewed for the article said they had been offered equipment free or at a substantial discount in exchange for doing demonstrations or research with the lasers. "This is a standard industry practice," said Gary Weinstein, the chairman of the **ThermoLase Corporation**, which makes lasers for hair removal. The doctors interviewed said they had turned down the offers of free equipment.

The article concludes with a quote from Dr. Melanie Grossman, director of clinical and laser research studies for the Laser and Skin Surgery Center of New York, "In the laser race there's no clear front-runner...Choosing the right treatment ultimately depends on skin type, hair color and the energy levels being produced." Meanwhile, as the beauty smart bombs continue to drop, the waxers, electrologists and facialists across the country will undoubtedly start to lose business. On the horizon: laser manicures, pedicures, stretch mark removal, cellulite reduction and permanent hair eradication in a single session. "Lasers are going to take over, one doctor said, "Once technology advances further and the prices come down, there's no contest."

8/31 **Premier Laser Systems** announced that it had received FDA clearance to market its Pegasus YAG laser for the removal of coronal pulp in pulpotomies, and as an adjunct to root canal procedures. This is the first clearance for lasers for these types of procedures. According to the American Academy of Endodontics, more than 14 million pulpal procedures are performed annually, using reamers and files, or rotary instruments. With the use of lasers, these procedures can be performed cleaner and more comfortably, enhancing the patient's experience.

8/31 **DUSA Pharmaceuticals** announced that it had received FDA notification that its NDA application for Levulan PDT for actinic keratoses had been accepted for filing. This puts the company one step closer to gaining its first approval for marketing.

9/1 Robert Qualls, president and CEO of **ISIS Cosmetic Surgery Partners** announced that a meeting of the company's affiliated plastic surgeons was recently held at Kiawah Island, SC. The privately owned company manages only the practices of physicians board certified in plastic surgery. All surgeons affiliated with the company conduct both cosmetic and reconstructive surgical procedures, and all are members of the American Society of Plastic and Reconstructive Surgeons (ASPRS). The founding practices have combined revenues in excess of $29 million and are located from the eastern seaboard to Colorado and Nevada. Individual practices range in size from $600,000 to $4.3 million. ISIS manages plastic surgery practices and acquires the physical and other assets of medical facilities associated with the provision of plastic and reconstructive surgery procedures throughout the United States. The Company's management and marketing activities focus on changing the patient mix of individual practices to increase the private, pre-pay, cosmetic surgery component of the practice with lesser reliance on third-party- reimbursed procedures.

9/2 **ESC Medical Systems** announced that it, too, was starting a share repurchase program, with authorization of the board of directors to purchase up to 1 million shares in the open market. Because Israeli law requires prior court and shareholder approval for share repurchase, ESC has filed a motion with the Israeli District Court requesting the approval of the court. The company will also convene a shareholder's meeting to seek their approval.

9/2 **Miravant Medical Technologies** announced that the FDA had given its approval to begin a clinical study of the PhotoPoint drug Purlytin for prostate cancer. PhotoPoint is being developed as a minimally invasive procedure for the treatment of localized prostate cancer (cancer that has not spread beyond the prostate gland). "This prostate cancer study is being supported by funding from our corporate partner, **Pharmacia & Upjohn**, reflecting our focus on large potential markets where PhotoPoint may provide medical and cost benefits," said Gary Kledzik, chairman and CEO. "We were able to leverage our substantial clinical experience with cutaneous cancers into this increasingly important public health problem."

Prostate cancer is the most common malignancy in American men, and mortality from it is second only to lung cancer. Risk of prostate cancer increases with age. As a result of this high incidence, and the anticipated population growth in the older age groups, prostate cancer has major social and economic ramifications, demanding technologically advanced treatment modalities. Currently, the standard therapeutic options for men with localized prostate cancer are surgery (radical prostatectomy) and radiation therapy. Radical prostatectomy is a major surgery involving high cost ($10,000 to $18,000), hospitalization, and prolonged recovery. All treatment modalities are associated with a high level of complications and adverse effects, and there is no consensus as to the best treatment option. In animal studies Purlytin has demonstrated greater uptake in the prostate than in surrounding tissues. Miravant's light delivery technology has advanced to the stage where light can potentially be delivered to the entire prostate. Since prostate cancer generally progresses slowly, and since 58% of all prostate cancers are discovered while still localized, PhotoPoint therapy may be applicable as a minimally invasive treatment.

9/2 **Laser Corporation**, through its wholly-owned subsidiary, **American Laser Corporation**, announced an expansion of its industrial laser products sales organization through an exclusive distribution agreement reached with **Laser 2000 GmbH**, of Wessling, Germany, and its affiliates. Laser 2000 will commence the sale and promotion of the company's industrial laser products in Germany, France, Switzerland, the UK, Belgium, Netherlands and Luxembourg. In addition, Laser Corp. has entered into, or is currently negotiating laser product distribution agreements with other sales organizations in the Far East, Pacific Rim regions, South Africa, Middle East, Norway and Finland.

9/2 **Surgical Laser Technologies** announced that it has received 510(k) clearance from the FDA to market its internally developed bipolar electrosurgical sheath. The product, which enables hemostasis with the use of microdebriders, will be marketed under the brand name HemoSleeve. The HemoSleeve is approved for use with existing microdebriders that are used in Ear, Nose and Throat (ENT) surgery.

9/3 **Photogen Technologies**, at an industry conference, presented the results of research in which melanoma cells in laboratory mice were destroyed by activating naturally occurring melanin and related compounds with the company's proprietary multi-photon excitation technology. Craig Dees, Ph.D., a senior research scientist at Photogen, presented a paper on the results of this research to the *World Association for Laser Therapy* meeting in Kansas.

The tumors were treated by scanning the affected area with light from an ultrafast pulsed laser. Tumors ranging in size from 6 to 10 mm in diameter and up to 3 mm deep, when treated with ultrafast pulsed laser light, produced a visible "blanching" effect, resulting from the interaction between melanin and the light. After treatment, tumor volume was reduced by 100 percent with little or no scarring. Tumors treated with conventional, continuous wave, laser light produced only a minimal response. Results of a single treatment showed that mice with 6mm to 10 mm tumors in diameter and 3 mm deep showed no evidence of tumor recurrence after three weeks. Tumors 5 to 7 mm deep have shown some recurrence three weeks after treatment, and larger tumors reappeared even sooner. The company will evaluate the effect of multiple treatments on the larger and deeper tumors.

"These preliminary animal tests suggest that it may be possible to treat melanomas without surgery or chemotherapy," said John Smolik, Photogen's president. "If further pre-clinical results are consistent with these preliminary results, we will seek opportunities to convert these developments into an FDA-approved product that could benefit many people suffering from melanoma." The company will continue to identify optimal light doses, activation wavelength, treatment time and scan patterns for treatment of melanomas. Photogen's scientists are working toward the development of its proprietary multi-photon excitation technology to enhance the safety and efficacy of photodynamic therapy for the diagnosis and treatment of cancer, infectious diseases and other medical conditions.

9/3 The Oncologic Drugs Advisory Committee (ODAC) of the FDA recommended unanimously (eight to zero) today that the FDA expand its approval of **QLT PhotoTherapeutics'** Photofrin (porfimer sodium) to include palliation of late-stage lung cancer. Specifically, the committee voted in favor of approving PHOTOFRIN for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer. The recommendation will now be considered by the FDA as it completes its review of the revised supplemental NDA submitted by QLT in early 1998. The FDA's decision is expected no later than March 1999. Pending regulatory approval, a U.S. commercial launch by **Sanofi Pharmaceuticals** -- QLT's U.S. marketing and distribution partner -- is expected to follow shortly thereafter.

"We're very pleased with the committee's recommendation. It takes QLT one step closer to offering Photofrin as an alternative palliative therapy for patients with advanced lung cancer," said Dr. Julia Levy, QLT's president and CEO. "After such a long and rigorous review process, today's recommendation is a real accomplishment for the team of talented scientific, clinical and regulatory professionals -- led by Alexandra Mancini, our vice president of Regulatory Affairs -- who were involved in this submission.

The supplemental NDA was submitted as a four-part application for a drug-device combination consisting of QLT's Photofrin and OptiGuide cylindrical diffusers as well as laser systems manufactured by **Coherent Medical Group** and **Laserscope**.

In a separate announcement, Laserscope commented on the approval by noting that according to the National Cancer Institute, lung cancer is the leading cause of cancer mortality in the U.S., responsible for more than 160,000 deaths a year. Lung cancer was diagnosed in approximately 178,000 Americans last year. Robert McCormick, president and CEO of Laserscope said, "We are very pleased that ODAC has recommended approval of the PDT late-stage palliative cancer treatment to the FDA. As a unique, non-surgical, minimally-invasive approach to the treatment of cancer and other diseases, PDT offers a highly-desirable option for patients and physicians. As a measure of how far the PDT market has already evolved, approximately 75 cancer centers within the U.S. are now treating patients with PDT. More than 70 percent of them are using Laserscope PDT laser systems. While still modest in size, the PDT market today represents Laserscope's fastest area of growth."

Laserscope also announced that its PDT laser systems and fiber optic devices are part of two new Phase I clinical trials to evaluate additional applications of photodynamic therapy. The first is a clinical trial sponsored by U.K.-based **Scotia QuantaNova PLC** to investigate the PDT treatment of head and neck cancers using the photosensitizer drug FOSCAN. The second involves the PDT treatment of patients with malignant brain tumors using the compound BOPP (boronated porphyrin), developed and produced by San Diego-based **Pacific Pharmaceuticals**. Added McCormick, "We believe PDT has the potential to be a significant new modality for the safe, selective, and cost-effective treatment of a wide variety of diseases. At the moment, we are working with leading PDT drug developers in seven critical areas."

Among the programs:

-- Atherosclerosis, with **Pharmacyclics'** drug ANTRIN
-- Head and neck cancer, with Scotia QuantaNova's drug FOSCAN
-- Brain cancer, with Pacific Pharmaceutical's drug BOPP
-- Barrett's esophagus, with QLT PhotoTherapeutics' PHOTOFRIN
-- Late-stage lung cancer, with QLT's PHOTOFRIN

-- Early-stage lung cancer, with QLT's PHOTOFRIN (FDA Approved)
-- Esophageal cancer, with QLT's PHOTOFRIN (FDA Approved)

9/9 **Biotechnology Value Fund LP** may seek to work with **QLT PhotoTherapeutics'** management, board of directors and other company shareholders to maximize the company's shareholder value and, specifically, to protect the substantial value of funded, partnered programs from unnecessary dilution. The fund believes the external environment for small biotechnology companies are undergoing a change which may call for managements and board of directors to husband capital by significantly reducing cash burn rates and to otherwise alter preconceived business plans. These steps, if managed "pro-actively" and "intelligently" could yield attractive returns for the shareholders, according to the fund. The fund purchased its QLT common shares on the open market and in over-the-counter transactions.

9/9 **Spectranetics Corporation** announced that the FDA has cleared its 14 and 16 French (Fr) Laser Sheaths for marketing. The sheaths are designed to assist in the removal of larger-size pacemaker and implantable cardioverter defibrillator (ICD) leads. With this action, Spectranetics' entire SLS product line is FDA-approved and available to all hospitals. Release of the larger 14 and 16 Fr laser sheaths means that more patients requiring the removal of ICD leads, which are large and cannot be left in the body when non-functional, may benefit from minimally invasive, excimer-laser assisted lead removal. Each year, approximately 500,000 pacemaker and ICD leads are implanted worldwide. Spectranetics estimates that 10% of these may require removal for medical reasons.

9/10 **Henley Healthcare** said that its CEO Michael Barbour was interviewed on CNBC/Dow Jones Business Video on August 5th, and that a replay of the interview was available on its website at www.henleyhealth.com. According to the news release, one of the subjects covered was the status of the Microlight 830 diode laser for the treatment of carpel tunnel syndrome.

I was not able to access the video, but contacted a spokesperson from the firm's PR agency and was given a portion of the text from an August 19th conference call with analysts that covered the same subject. In response to the question of when the company expects FDA approval, Mike Barbour said, "I am happy to report that our Phase III clinical studies are going quite well. We expect to submit to the FDA within the next four to six weeks the results of the first 100 patients (of a 200 patient double blind study) and ask for what we call a conditional marketing release...that means...of the first 100 patients...the results are in excess of 70% for those being treated with the live laser...we think that's a compelling story for FDA to grant us the approval to market the device while we go ahead and continue to do (treat) the other 100 patients...we expect to hear back from the FDA by between Thanksgiving to

Christman, or probably by January...allowing us to have a conditional release by first quarter earliest, probably second quarter latest."

Barbour went on to explain why the FDA was now receptive to their clinical study whereas they hadn't been before. Basically, it was because their regulatory person worked closely with FDA to design the double-blind clinical study. (Maybe the end of the tunnel for the first approval of a low level laser application is in sight. I first reported on the good results being obtained in the treatment of carpel tunnel syndrome in September 1994 (in *Medical Laser Report*), after attending a General Motors/**Lasermedics** (Henley Healthcare's old name) joint news conference reporting on the results of the Microlight 830 being used on GM assembly line workers. At that time I learned that 85% to 90% of those treated with the laser were able to return to work!)

9/10 **Dental/Medical Diagnostic Systems** announced that is has already shipped 500 units of the Apollo 95E domestically since it received 510(k) clearance for the Apollo 95E tooth whitening and curing system from the FDA. The tooth whitening and composite curing system, currently marketed at $4,500 and developed internally by DMDS, significantly whitens discolored teeth in less than one hour. Because the Apollo 95E is not a laser, a dental assistant can perform the procedure.

The Apollo 95E curing light also cures restorative composite materials in 1 to 3 seconds, making it the fastest commercially available dental nonlaser curing light known to the company. DMDS will also shortly begin shipping its own branded matched composites and whitening materials, intended to offer increased speed and optimize results for the dentist and the patient.

9/10 **Genzyme Tissue Repair** announced that it had signed an exclusive licensing agreement with **PhotoBioMed Corporation**, a privately-held company located in Dallas, for the development and commercialization of PhotoBioMed's proprietary photoactive tissue welding technology for orthopedic applications. (PhotoBioMed, was formerly part of old friend Mel Judy's **MicroBioMed** company. Its technology is based on the activation of his proprietary compounds to interact with collagen fibers to cross-link the proteins and substantially weld torn tissue together.) Genzyme said that initial efforts will focus on the repair of meniscal tears and other soft tissue orthopedic applications. The company will evaluate whether photoactive tissue welding could be used in connection with the arthroscopic delivery of Carticel autologous cultured chondrocytes, its innovative treatment for articular cartilage damage. Tissue welding may be an alternative to the current method of suturing the periosteal patch to keep cartilage cells in place during knee surgery involving Carticel implantation.

With approximately 560,000 meniscal knee injuries annually in the U.S., and approximately 80% going untreated because of their location within the avascular region of the knee, this new technology may have an important place in the orthopedic surgeon's armamentarium.

Genzyme Tissue Repair also has a right of first refusal to utilize the technology for other indications, such as cardiovascular, pulmonary, wound closure, plastic surgery, ophthalmological, and in the urogenital fields.

9/11 **Reliant Technologies** announced that on September 3, 1998, Judge C. Wilken ruled that **Laser Industries/Sharplan's** U.S. patent 5,411,502 for a $CO_2$ laser scanner system was invalid. Laser Industries/Sharplan filed suit against Reliant Technologies on September 15, 1995, claiming that the now invalidated patent was being infringed by Reliant's AccuScan $CO_2$ laser scanner. In finding Laser Industries/Sharplan's patent invalid, the court also concluded that as early as December 15, 1995, the patent's inventor and Laser Industries/Sharplan's patent counsel admitted to the Patent and Trademark Office that the patent contained substantial errors, rendering it invalid. Reliant's patent counsel is of the opinion that the court's reasons for finding the `502 patent invalid casts serious doubt on the continued validity of other key patents of Laser Industries/Sharplan.

Reliant Technologies will continue to vigorously pursue its antitrust claim against Laser Industries/Sharplan. Reliant asserts that Laser Industries/Sharplan filed and continued to prosecute its infringement suit against Reliant with the intent to monopolize the laser skin resurfacing market and with the knowledge that the patent was invalid.

9/14 **ESC Medical Systems** commented on the action taken against its **Laser Industries Ltd.** subsidiary by the United States District Court for the Northern District of California in Laser Industries action alleging infringement of Laser's Patent No. 5,411,502 (the "502 Patent"), which covers its Swiftlase and SilkTouch products, against **Reliant Technologies, Inc.** (see the brief just above). In the same action, and in a separate action filed by Reliant, Reliant also asserted a number of claims against Laser Industries based, among other things, on its assertion that Laser Industries had concealed certain prior art from the U.S. Patent Office. In its ruling, the Court dismissed all of Reliant's claims, including its claim that Laser Industries fraudulently concealed prior art from the Patent Office in connection with its application for the '502 Patent. However, the Court found the '502 Patent to be invalid on other grounds, and therefore denied Reliant's and Laser's cross-motions regarding infringement. The Court also gave Reliant the right to amend its complaint to raise new claims against Laser consistent with the Court's decision.

Dr. Shimon Eckhouse, ESC Medical's chairman and CEO, stated, "We are satisfied with the Court's dismissal of all of Reliant's claims against Laser Industries, and we remain confident that Laser will prevail with respect to any new claims that Reliant might bring...While we disagree with several of the Court's rulings, including the ruling that Laser's '502 Patent is invalid, we note that none of Laser's products rely exclusively on this patent for protection. Moreover, Laser's Swiftlase and SilkTouch products, to which the '502 Patent relates, accounted for substantially less than 1% of ESC's consolidated sales during the first half of 1998. Nevertheless, we believe that the Court was mistaken in its rulings on these issues, and Laser intends to request reconsideration of, or to appeal, the Court's decision."

9/15 *NewsPage* reports that **Loma Linda University Medical Center** has been awarded a U.S. Patent covering a dental apparatus, including an instrument and a method of bleaching teeth using a laser. The patent describes an instrument, having an optical fiber for delivering UV light, an optical viewing fiber, and an irregular surface located on the exterior surface of the distal end of the instrument to provide tactile feedback.

9/15 **ESC Medical Systems** announced the start of U.S. clinical trials of its SilkLight device to determine the safety and effectiveness of temporarily modifying body shape through cellulite therapy. This study is the first of its kind to investigate the effects of cellulite therapy as a procedure for reducing inches from the body. The company also announced that the product, formerly known as Silhouette, will now be known as SilkLight. SilkLight cellulite therapy is a non-invasive form of therapeutic massage that is administered only under the supervision of a doctor. The device manipulates the fatty deposits that form cellulite, a skin sub-surface condition that affects 85% of all women. Through non-controlled studies, experienced physicians have noticed that the device has been successful in reducing body size by a combined average of eight inches from the arms, buttocks, hips and thighs. This anecdotal evidence is the impetus for further study.

9/15 **Cell Robotics International** announced that **Chronimed** had completed its due diligence on Cell Robotics' Lasette laser finger perforator for drawing blood for glucose testing in the diabetes market. Chronimed's tests have determined that the Lasette meets all of its internal expectations and based on the successful outcomes has made its first equity investment of $300,000 for 200,000 shares of Cell Robotics common stock. The capital investment will be focused on the development of a second generation, smaller Lasette to meet the needs of the home glucose testing market. Cell Robotics will also be eligible for an additional $300,000 capital investment by Chronimed at the successful conclusion of certain other agreed upon milestones. In addition, Chronimed has submitted its first Lasette purchase order to be delivered this month. Earlier in this quarter, the companies agreed to a two-year, multi-million dollar minimum purchase by Chronimed. Cell Robotics will provide

Lasettes to Chronimed for an agreed upon transfer price. Chronimed will distribute the Lasette and accessories worldwide.

9/15 The American Society of Plastic and Reconstructive Surgeons (ASPRS) announced that its 67th annual scientific meeting would be held in Boston on October 3-7. Nearly 7000 plastic surgeons, medical personnel, and guests from around the world are expected to gather to hear the latest updates on liposuction and other plastic surgery techniques. Over 190 educational courses will be given and nearly 300 exhibitors will be on hand for the event. ASPRS represents 97% of all board certified plastic surgeons. (I intend to visit the meeting and walk the exhibit hall, and will report the latest in laser-related events with next month's newsletter.)

9/16 **American Dental Technologies** announced that sales for the third quarter of 1998 remain strong and the company has received a firm order for $1.8 million in lasers from its Japanese distributor for shipments commencing in October 1998 through March 1999. "Additionally, the company has been approved for a $7.5 million revolving credit with a bank, to assist with the company's acquisition program and to provide operating capital for expanded operations," said Ben Gallant, president and CEO.

9/16 **Oscar Gruss & Son Inc.** announced that it had initiated coverage of **American Dental Technologies** with a "buy" recommendation. In a new report, analyst Alan Tuchman, MD, provides an in depth look at the business, products, and future outlook for the company. (I have requested a copy of the report and will review it upon receipt.)

9/16 *Dow Jones* reported that **Eclipse Surgical Technologies** shares surged 26.9% on investor expectation that the company's transmyocardial revascularization device will be reviewed by a FDA advisory panel next month, analysts said. The FDA posted an announcement on its Web site today that set Oct. 27 as the date the medical devices advisory panel will "discuss, make recommendations and vote on a premarket approval application for a transmyocardial revascularization device." While the agency didn't identify the company that makes the device, industry analysts said it has to be Eclipse Surgical. "There's no other company it could be," said **PaineWebber Inc.** analyst Charles Olsziewski. The company has been on track for an FDA panel meeting, Olsziewski said, adding that the expected review is both a driver and a milestone for the stock. Eclipse Surgical CFO Kenneth Bennert said the company had received no official notification from the FDA in writing about a panel review. He did say, though, that the company has been "working closely" with the agency to get through the review process. "I don't know of any other company that is in the same status as us in terms of having a filed PMA (premarket approval) application," he said.

9/17 *The Canada NewsWire* reported that interim cease trade orders, dated September 17th had been issued for **Mattan Corporation**. This same company was delisted from the American Stock Exchange last March 31st, and we reported in April of 1997 that Mattan had signed a letter of intent with **Premier Laser Systems** for the acquisition of Mattan's operating subsidiary, **The Medical Laser Institute of America (MLIA)**. (In May of 1997, Premier noted that it had made an investment in MLIA. There is no further mention of Mattan or MLIA in my records.)

9/18 **Eclipse Surgical Technologies** confirmed that indeed, the FDA would review its PMA for TMR at the Circulatory System Devices Panel on October 27th.

9/18 **Optomedic Medical Technologies Ltd.**, a developer of $CO_2$ laser systems for a variety of medical applications, released financial results for the first half of 1998. For the six months, Optomedic reported revenues of $110,321. The Company's net loss for the six months was $1.9 million (79 cents per share). Reflected in both revenues and cost of revenues for the six months were significant efforts involved in establishing **KMC Systems**, a subsidiary of **Kollsman, Inc.**, as the worldwide manufacturer and US distributor of Optomedic's PenduLaser 115. Established in 1980, KMC supplies contract development services and manufactures medical instrumentation for the clinical diagnostic industry. "We are pleased to have made substantial progress in working with KMC to accelerate their manufacturing and distribution efforts," reported Alex Harel, president, CEO, and director of Optomedic Medical. "We expect to move forward with sales of the PenduLaser 115 and to continue development efforts in several applications. These applications include ophthalmologic surgery, principally for cataract surgery, cardiac surgery, principally for transmyocardial laser revascularization (TMLR), which we believe to be an alternative to bypass surgery, and prostate surgery."

9/18 Gary Kledzik, chairman and CEO of **Miravant Medical Technologies** reported that the sale of 50,000 shares of common stock was an involuntary sale and that he had corrected the inadvertent event by purchasing 50,000 shares in the open market, at prices higher that the original selling price.

9/21 I recently noticed that ECRI had published a review of surgical diode lasers in its March 1998 issue of *Health Devices*. I requested a review copy of the article, which arrived today. The journal did a pretty comprehensive overview of surgical diode lasers, discussing their introduction into surgical medicine in 1992 (by **Diomed**), their progression from low power (5 to 15 watts) to high power (20 to 60 watts today), and their ability to replicate some of the clinical advantages and tissue effects of other types of lasers, particularly the YAGs. However, other than noting their use in ophthalmology in an accompanying table, there is no mention of their use in ophthalmology (albeit, a lower energy level application -- at a few watts), beginning in 1988, nor the many ophthalmic suppliers and developers, including **Keeler Optical**,

**Endoptics**, and **Iris Medical**. Moreover, there is no mention of the more recently introduced high powered pulsed diode lasers, now available for hair removal and leg vein removal applications from **Coherent Medical** (produced by **Palomar Medical Technologies' Star Medical Technologies** subsidiary) and **DioLite** (the Diomed subsidiary). Supplier information is presented from **Applied Optronics** (now a subsidiary of **ESC Medical**); **CeramOptec**, **Cynosure**, Diomed, and **Sharplan** (also a subsidiary of ESC Medical now).

The other omission is the bare mention of biostimulation diode lasers, especially the Microlight 830 from the former **Lasermedics**, now **Henley Healthcare**. (Note in the September 10th brief above that Henley believes it will receive FDA approval for the treatment of carpel tunnel syndrome early next year.)

An accompanying table lists 13 specialties where diode lasers are being used and the article does a good job of spelling out the comparative advantages of diodes over other types of surgical lasers, including efficiency, size and portability, reliability, low maintenance, and lower costs. In addition a comprehensive bibliography is given, including my 1994 presentation on "The Outlook for Diode Lasers in Medicine" given to the SPIE BIOS meeting in 1994.

9/21 **Miravant Medical Technologies** announced new cash management initiatives to reduce overhead costs, streamline administration and eliminate positions that are not central to the growth of the business. The cost restructuring is designed to reduce the company's annual projected net operational cash burn rate by approximately 40%, while fully sustaining current ophthalmology and oncology programs. Additionally, Miravant will continue research and preclinical programs for other selected indications. "These reductions are prudent in light of the present stock market conditions and funding environment," said Gary Kledzik, chairman and CEO. "The new measures allow us to utilize our resources for core development programs, which include age-related macular degeneration and certain oncology indications."

9/22 *Federal Filings* reports that **PLC Systems** had received an FDA warning letter last July for non-compliance with in regards to its investigational study of The Heart Laser, specifically, failing to "ensure proper monitoring of the clinical investigation as required by set guidelines" and failing to "monitor to the extent necessary to secure compliance of clinical investigators". The company responded to the violations noted in the warning letter and obviously cleared up the problems, as evidenced by the marketing clearance awarded the company on August 20th.

9/22 *NewsPage* reported that **US Surgical** had been awarded a U.S. Patent for a "lasing device", a controlled advancement laser ablation device for precise ablation of body matter.

A second patent was issued to an unnamed source for "myocardial revascularization through the endocardial surface". The abstract reads, "myocardial revascularization is performed by an apparatus and method which forms channels in the myocardium from inside the ventricular cavity without penetrating the full thickness of the ventricular wall".

9/22 **Reliant Technologies** announced that it had an overwhelming success at the AAO-HNS meeting, introducing its skin resurfacing laser system, which includes AccuScan $CO_2$ Laser Scanner and Unica $CO_2$ laser. Reliant's AccuScan $CO_2$ Laser Scanner is based on the company's patented method of transmitting and applying laser energy via a unique mirror system, allowing surgeons higher level of control and precision on the tissue. Reliant's Unica 315M $CO_2$ Laser is a compact, low-power, low-cost, battery-operated laser, which will particularly be beneficial for private office use and small medical clinics. The company plans to deliver the first units of AccuScan/Unica combination system in the fourth quarter of 1998, with full production planned in 1999. Reliant also plans to expand sales of other laser systems and delivery devices, including the Unimax 2000 and 2500 Series MicroSpot Laser Micromanipulators, already installed at over 650 hospitals and clinics in the U.S. and abroad. Reliant currently holds 20 U.S. Patents, which support its proprietary technology and products, developed for a wide range of surgical and aesthetic applications, including Otolaryngology, Plastic Surgery, Dermatology, Gynecology and Urology.

9/23 *NewsPage* reported another TMR patent issued, this time to **Eclipse Surgical Technologies**. The abstract reads, "a transmyocardial revascularization enhanced treatment for coronary artery disease and other medical procedures utilizing a source of laser energy and a laser delivery means attached thereto".

9/23 **Palomar Medical Technologies** announced that it had received a $10 million revolving line of credit for working capital from Fleet National Bank. The loan was obtained at prime rate. According to Dan Valente, chairman and CEO, the company has completed the transition from equity-based financing to traditional bank financing as it moves toward its goal of profitability.

9/24 Barbara Marsh of *The Los Angeles Times* writes that **Trimedyne** has changed its public accountants in order to cut expenses. Apparently PriceWaterhouse charged too much and the firm had hired McKennon, Wilson & Morgan in order to save some money. In its filings with the SEC noting the change, the company said it had no disagreements with PriceWaterhouse on any accounting matters during the last two fiscal years, with which the accounting firm agreed. Marvin Loeb said the company was cutting staff and other expenses in order to curb losses.

9/25 As previously noted (see the September 16th brief), Oscar Gruss analyst Dr. Alan Tuchman has begun covering **American Dental Technologies**. In his very interesting report, I learned that ADT is no longer a dental laser company, as it was when originally founded, but rather is now mostly concerned with selling air abrasion systems (its KCP line) and dental diagnostics, including dental probes and its intraoral cameras and image storage systems. The KCP products represent 70% of sales, while dental lasers and its plasma arc light curing system account for only 25% of sales. The Pulse Master YAG laser system is only approved for soft tissue applications, and although it currently holds about a 50% share of the U.S. dental laser market, according to Dr. Tuchmann, that will quickly evaporate as erbium:YAG lasers for hard tissue applications come into the market -- especially if **Premier Laser Systems** can ever get its act together!

Apparently, ADT intends to introduce a diode laser at next month's American Dental Association meeting. I expect it will be for soft tissue applications in endodontics and periodontics as well, similar to Premier's diode system. Anyone wishing to obtain a copy of Dr. Tuchman's report can contact him at 212-514-2345.

I expect, now that I know that ADT's revenues are made up mostly of its air abrasion system, that I should adjust its revenues in my yearly updates, by reducing its laser sales to approximately 20% of revenues.

9/27 *The Los Angeles Times* carried an in-depth article describing the trials and tribulations of **Premier Laser Systems** in trying to enter the dental laser market. The story, written by Patrice Apodaca, was headlined, "From Glitzy Premiere to a Performance Nightmare Analysts Say the All-Too-Common Story of a Company Whose Dental Laser Was Supposed to Take the World by Storm Is a Sobering Lesson for Others". It goes on to detail the bright future and subsequent downfall when Premier's attempt to penetrate the dental laser business was brought up short. "You're running things conservatively, the business starts growing rapidly, and then you don't have the controls," said analyst John Doss at Dominick & Dominick in New York. "I wish I had a formula for people to avoid these problems."

In the last several months, the company has endured a highly damaging dispute with a major distributor (**Henry Schein**), the resignation of its auditor (**Ernst & Young**), and the restating of nearly two years of financial results. Trading in its stock has been suspended since May. Several shareholder lawsuits have been filed, accusing the company of fraud and various securities law violations. What's more, its star product, the hard-tissue dental laser, has been slow to catch on despite the initial fanfare.

A chastened Colette Cozean, Premier's CEO, in her first in-depth interview since the troubles began, admits that "we got shoddy" and mistakes were made, though she steadfastly maintains that no one has turned up even a glint of impropriety. "It's been a

terrible three or four months," she said. But the 40-year-old executive, who holds a PhD in biomedical engineering, hasn't wavered in her belief in Premier. Premier probably lost six to 12 months that could have otherwise been spent marketing the hard-tissue laser, Cozean said. But she is intent on moving on. "What we now have to do is convince the dentists that we are still the leading dental company out there."

It won't be easy. Even aside from its image problem, Premier faces an uphill battle selling its lasers to dentists, who are generally a conservative bunch who adopt new technologies slowly. Bob Dalton, a spokesperson for **American Dental Technologies** said, "They're thinking as a dental patient, but dental patients don't buy these technologies. Dentists buy them -- and there's really nothing compelling them to buy them in a hurry."

Premier's recovery could also be complicated by lingering controversy over how -- and how much -- lasers actually will benefit dentistry. Some in the dental community believe they might pose some risk to patients and that similar results can be achieved through other technologies. The American Dental Assn. has been cautious in assessing Premier's laser, supporting its use on small and medium-sized cavities but saying it needs more data before deciding if the laser is safe and effective on deeper cavities.

Premier's goal was to capture 1% of the tooth-drilling market in the first year, amounting to about $45 million in sales. It projected it would sell 10,000 to 15,000 of the $40,000 hard-tissue laser systems in a decade. The analysts who had been so bullish on Premier's prospects were stumped by the foul-up. Cozean's initial response was that the company shouldn't have done business with Schein "on a handshake." "That sounds relatively naive," said analyst Doss, though he sees no sign of fraud. Still, the lawsuits poured in.

Cozean won't disclose just how far Premier has fallen short of its initial sales projections, but some analysts estimate the company has sold just 200 of the hard-tissue systems. Still, she insists the company has never been in danger of bankruptcy. Its other lasers continue to sell, she said, and it continues to receive new FDA clearances -- the most significant of which was the approval in August for one of its lasers to be used in root canal work. The firm also is hoping the FDA will soon give the OK for its hard-tissue laser to be used on children as well as adults -- a move it believes will help sell dentists on the product.

**MEDICAL/SURGICAL LASER UPDATE -- OCTOBER 1998**

9/7 *The Gray Sheet* reported that **QLT PhotoTherapeutics** estimated that 20,000 to 25,000 patients would be eligible for Photofrin photodynamic therapy under the expanded lung cancer indication recommended by the FDA's Oncological Drug Advisory Committee on September 3rd (see our brief of that date last month).

9/28 **ESC Medical Systems** announced that it expects revenues for the third quarter of 1998 to be approximately 15% lower than the $63 million reported in the second quarter. As a result, ESC also expects to report earnings per share on an operating basis in the range of $0.20 to $0.25 for the 1998 third quarter. The company attributes the third quarter revenue shortfall to a general slowdown in activity during the summer months, mainly in Europe, as well as lower sales volumes in South America. In addition, the uncertainty surrounding elections in Germany and Brazil has delayed the decision making of ESC's customers, thus impacting sales for the quarter.

Dr. Shimon Eckhouse, president, CEO and chairman, commented, "Despite the slowdown during the summer months, we are encouraged by the sales increase in September. Although we are not pleased with the revenue shortfall for the third quarter, we are confident in ESC's business strategy and our outlook for the future."

The day after the announcement, *Dow Jones Interactive* reported that the company's shares had plunged 52%. Analyst Heidi Huntsman of NationsBanc Montgomery Securities felt that the main concern was that European and Latin markets might be saturated, and thus fellow analyst, Kurt Kruger downgraded the stock to "hold" from "buy". Huntsman also commented that to combat the shortfall, ESC has "pulled out of Latin America a little bit...and is getting into new product areas." One of these is the use of lasers to puncture the ear drum to relieve the pressure of chronic ear infections. "While doctors seem to like the procedure, the lasers are still pretty expensive", according to Huntsman. (For more on ESC, see the third quarter results and commentary in the 10/20 brief below.)

9/29 **Thermo Electron** announced that it would be incurring approximately $53 million of pretax restructuring and other charges in its third quarter. Included in this amount would be $15 million in writeoffs for its **ThermoTrex** subsidiary, which included $8.3 million for the closing of three domestic cosmetic spas and one spa in France, of its **ThermoLase** division, and $6.7 million to write off certain tax assets. The ThermoLase locations to be closed were its Spa Thira's in Miami and Palm Beach, Florida, and the original Spa Thira in La Jolla, CA. The remaining 11 domestic spas will be converted into full-service, luxury day spas, under the Greenhouse name. (According to a spokesperson for ThermoLase, the four spas that were closed were facing strong competition and either were not profitable, or couldn't easily be switched over to Greenhouse luxury spas.)

10/1 **Cell Robotics International** announced plans to have **Hamilton Thorne Research** jointly market their infertility treatment systems. Privately-held Hamilton Thorne is a worldwide leader in sales of computer-based sperm analysis systems, with a majority of fertility clinics having these systems in place. In the marketing alliance, Hamilton Thorne will promote the Cell Robotics IVF Workstation in combination with their

sperm analysis system and identify potential customers to Cell Robotics, who will close the sales.

10/1 **Tyco International** announced that **U.S. Surgical's** shareholders had overwhelmingly approved its acquisition of U.S. Surgical, with the merger effective immediately. Leon Hirsch, U.S. Surgical founder, has been appointed non-executive chairman of **Tyco Healthcare Products Group**, which consists of U.S. Surgical, the **Kendall Company**, and **Sherwood -- Davis & Geck**. Richard Gilleland, the former chairman and CEO of the Kendall Company has been named president of Tyco Healthcare. He will report directly to Dennis Kozlowski, chairman and CEO of Tyco.

10/2 Cynosure, Inc., introduced two new lasers, for presentation at the ASPRS meeting held in Boston. The CO3, a new type of multipulsed erbium:YAG laser for skin resurfacing and wrinkle removal applications, and the Illustra, a compact, diode-pumped doubled YAG for treating facial spider veins and other vascular lesions. According to the company, the FDA approved CO3 laser provides patients with the most flexible, effective system for all types of skin resurfacing, having 4 pulsewidths -- from long to short. It combines the best features of existing $CO_2$ and erbium resurfacing lasers. Because the CO3 is a pulse tunable laser, it is capable of treating fine lines and mild sun damage. It can also be used for the treatment of more extensive sun damage with shorter healing times than carbon dioxide laser resurfacing. "Some lasers, erbium:YAG for example, remove tissue without enough heating to cause collagen shrinkage, which is considered important for effective treatment. Other lasers, $CO_2$ for example, heat tissue enough to cause this collagen shrinkage, but this treatment results in long healing times," said Bob Hubert, chief marketing officer of Cynosure. "With our new laser based on Cynosure's proprietary technology, we are offering doctors a more effective skin resurfacing protocol with reduced healing time." The CO3 laser lists at $85,000, plus the cost of a scanner.

The Illustra benefits both doctors and patients by offering a cost-efficient, effective way to remedy facial spider veins immediately, without purpura or bruising following the treatment. With the Illustra, results are immediate; there is no postoperative recovery time. Therefore, patients can now schedule laser treatments for a short time, such as a lunch hour. For dermatologists and plastic surgeons, the laser is economical to own and operate, making it an ideal complement to the technological offerings in today's most advanced vascular treatment practice. "Doctors are looking for an inexpensive, efficient vascular laser specifically to treat spider veins," said Rob Levenson, vascular product manager of Cynosure. "The Illustra is the ideal choice for patients and practice. Patients are thrilled to see instant results with no side effects such as bruising. Doctors find it remarkably cost-efficient and easy to use." The Illustra lists for $50,000.

10/5 **Optomedic Medical Technologies** announced it had received 510(k) clearance for its Pendulaser for skin resurfacing.

10/5 According to *NewsPage*, **Myocardial Stents** has been issued a patent for a stent to be inserted into the myocardial wall during TMR.

10/5 **Reliant Technologies** announced that it had filed its Second Amended Complaint in the Northern District Federal Court, against **Laser Industries/Sharplan Lasers**. The complaint asserts violations of U.S. Antitrust Laws and California statutes prohibiting unfair business practices. Reliant seeks $20 million in damages and recovery of attorney fees incurred by Reliant in defending a patent infringement suit filed in 1995 against Reliant by Laser Industries/Sharplan. The patent, upon which Laser Industries/Sharplan based its infringement action, was found invalid by Northern District Federal Court Judge Claudia Wilken on September 3, 1998. Reliant now claims that ESC filed its suit merely to drive Reliant out of the skin resurfacing market.

**ESC Medical Systems**, the parent of Laser Industries/Sharplan, denied the claims contained in the lawsuit. An ESC representative told *Dow Jones* that it expects to prevail in defending against Reliant's allegations of antitrust violations and unfair business practices. Further, ESC reiterated that its Sharplan subsidiary doesn't currently sell products that rely on the technology covered by the disputed patent.

10/5 **HealthCare Markets Group**, an advisory and investment banking firm exclusively focused on the healthcare industry, announced that its analysis of the share price performance for more than 1000 healthcare companies in 36 segments showed a decline of 14% during the third quarter, compared to end-of-year prices. The Medical Devices & Supplies Group showed a 12.5% decline, down from a 2.6% increase for the first half of the year.

10/5 **Medical Data International** found that surgical procedure volumes in hospitals decreased 2.2% in 1995, while the number of procedures performed in ambulatory surgical centers had risen by 6.1% for that same year. These results, as well as a forecast of procedure volumes by surgical application are contained in a newly issued report by the company, available for $2450. For a detailed table of contents, or more information about the report, call 800-826-5759, or visit the company's website at www.medicaldata.com.

10/7 *Medical Industry Today* ran a feature article on **Miravant**, describing the trials ahead for the company to show that its PhotoPoint light activated drug is effective for treating age-related macular degeneration. The company had recently submitted the protocols to the FDA for its Phase III trials. One of the study's objectives is to determine if a single treatment provides a permanent cure, or if the dose needs to be

repeated. Chairman and CEO Gary Kledzik made a bold strategic move early in August, stopping a metastatic breast cancer study that was underway. Buoyed by the FDA granting Fast Track review status for its Purlytin drug used in PhotoPoint, Kledzik, Miravant, and their marketing partner, **Pharmacia & Upjohn** announced age-related macular degeneration as their primary thrust to reach the U.S. market. The condition is the leading cause of blindness among people 50 and older. Also, the FDA agreed it is an "unmet medical need."

As noted by Kledzik, "Here's the seduction, there are too many applications, so we have to try hard not to be distracted. You can take it down too many roads, generate a lot of data and have nothing to show (if it doesn't reach the market)."

However, most of Miravant's clinical data for PhotoPoint was from the Phase III trials of patients with cutaneous metastatic breast cancer (CMBC). Kledzik assured people that was by design -- CMBC testing was the quickest way to show the treatment's reliability, safety and efficacy. He said the data could be used as a foundation for broader applications and, in fact, would speed approval for more uses. (See the August 26th and September 2nd briefs last month for more details about Miravant.)

10/7 *NewsPage* reported that more than 65 physicians and nurses from around the world were gathered at the Norton Hospital Cancer Treatment Center in Louisville, KY for the third training program on new developments in photodynamic therapy. To date, more than 200 physicians and nurses have been trained at Norton in techniques for using PDT. The hospital is associated with **Alliant Health Systems**, and is establishing itself as one of the leading PDT centers, now treating up to 250 patients annually. It is one of the 75 centers throughout the U.S., with others across Europe and Asia, using PDT to treat various forms of cancer.

Highlights of the two-day program were live demonstrations using leading-edge PDT cancer-fighting techniques on five patients. Performed by physicians in hospital treatment rooms, the procedures were broadcast live over closed-circuit television to an international audience of doctors and nurses watching from the hospital's auditorium. Participants in the two-day program included representatives of **Sanofi Pharmaceuticals**; **Laserscope**; and **QLT PhotoTherapeutics**.

10/8 **Cell Robotics** announced that it had commenced shipping the first 50 laser Lasette finger perforators to its exclusive marketing and distribution partner, **Chronimed**. This initial shipment is in response to Chronimed's initial purchase order for 110 units. The company also received a second purchase order for an additional 65 Lasette units.

According to Steve Crees, Chronimed senior vice president, "We have encountered strong market acceptance of the Lasette in our early marketing efforts. Selling the Lasette is an exciting marketing opportunity for Chronimed. We plan to remain in the

technological forefront of the large glucose testing market, and the Lasette will help ensure that position." The clinical market represents between 35% and 40% of the total market for glucose testing. In addition to the clinical market, Cell Robotics has submitted an application to the FDA for clearance for the home-use market, having completed an additional small study requested by the FDA. The Company considers the results of the additional study to be positive.

10/8 **PLC Systems** announced that it had entered into an exclusive agreement with a unit of **GE Capital** to provide a broad array of financing alternatives to U.S. hospitals interested in acquiring PLC's Heart Laser System. "This relationship will enable PLC to offer a broader range of financing alternatives, including leasing, for our target market of more than 900 hospitals" said William Dow, PLC president and CEO. "In addition, it provides PLC with a non-dilutive source of capital to finance placements of the Heart Laser System."

10/8 According to *Dow Jones Online News*, **Laser Corporation** was delisted by NASDAQ after failing to meet minimum net tangible asset requirements. The company said it may request a review of the action, with its shares remaining eligible for trading on the over-the-counter Bulletin Board.

10/12 **BioLase Technology** announced that it had received FDA marketing clearance for its Millenium device for hard tissue cutting in dentistry. The device uses Biolase's proprietary Hydrokinetic principle in using a laser to energize and transform atomized water droplets into microscopic, high speed, water particles capable of cutting both hard and soft tissue, in conjunction with a spray of cool, sterilized water. The marketing clearance includes cavity preparation, caries removal, and tooth etching (similar to the approval achieved by **Premier Laser Systems** in May of 1997).

The following day, *The Los Angeles Times* reported that the company's stock soared 56% following the FDA approval, with six times the normal share volume trading. According to Donald LaPoint, the company's CEO, "We are focused, we have the [regulatory] clearance, a patent, and we are moving forward." BioLase said clinical trials comparing its Millennium device with conventional high-speed drills found that 98.5% of Millennium patients had no discomfort.

Barbara Marsh of the Los Angeles Times noted that, "Although the BioLase device has advantages over conventional drills, the $40,000 to $45,000 price tag of the new system may leave many dentists open-mouthed." "Dentists, a financially conservative lot, have been slow to invest in lasers -- which can cost several thousand dollars -- when a standard drill can be had for $200 to $300," said Dr. Wayne Wozniak, an American Dental Assn. official involved in evaluating new technology. La Point said that unlike other lasers on the market, BioLase's uses water that has been energized by a laser to prepare cavities, remove decay from around old fillings and roughen the

enamel. Company studies of patients on whom the device has been used show that nearly all report painless cavity removal, he said.

10/12 *The Cincinnati Business Courier* reported that Dr. Stephen Joffe had shut down operations at the **LCA Center for Surgery**, and is looking for a buyer for the troubled outpatient facility. According to Joffe, the state-of-the-art surgery center, which he owns personally, opened last year. It had been unable to attract enough physicians willing to perform surgeries there and was losing money. Sources said Joffe is asking $1.1 million for the center. While he would not confirm the asking price, he said he had invested about twice that amount to outfit the center, which has four operating rooms and is designed to accommodate a variety of outpatient surgeries. Joffe said he has held discussions with two potential buyers; the **Health Alliance of Greater Cincinnati (Christ, Jewish, St. Luke and University hospitals)** and an Atlanta-based firm called **Specialty Surgery Centers Inc.** "I don't want to run it any more," Joffe said of the center. "For the center to be profitable, it needs to be run by a professional group. My focus needs to be totally committed to laser vision correction centers."

10/12 *The Gray Sheet* reports that researchers have found a 30-day mortality rate of 4% among study patients who have undergone percutaneous myocardial revascularization (PMR) for severe intractable angina with the **Cardiogenesis** Axcis system. This compares to a 20% rate observed in the pivotal study of **PLC Medical Systems'** Heart Laser for open-chest TMR, according to Stephen Oesterle, MD, of Massachusetts General Hospital, and as reported October 7th at the Transcatheter Cardiovascular Therapeutics Symposium in Washington, DC. Oesterle's presentation focused on preliminary results from the "roll-in" phase of the ongoing PACIFIC trial, in which 75 Class III and IV angina patients received the PMR treatment. According to Dr. Oesterle, "PMR will clearly supplant TMR, which will be used within the context of bypass surgery."

10/14 Not to be outdone by the BioLase FDA marketing approval announcement above, **Premier Laser Systems** announced that the FDA had granted the company clearance to market its Centauri erbium:YAG laser system for selected pedodontic (patients under the age of 18) tooth procedures, including decay removal, cavity preparation for restorations, and related applications. It is the first such pedodontic clearance in the United States. According to the company, Centauri systems are available for immediate shipment, and are to be showcased at the upcoming ADA convention in San Francisco October 24-28.

Since individuals under 18 make up as much as half of some dentists' patient rosters, the dental laser promises to be a definite benefit to patients, parents, and practitioners alike. Dr. Colette Cozean, company chairman and CEO commented, "Following on the extensive three-year pre-clinical and clinical studies of Centauri with adult patients, the pedodontic clinicals clearly demonstrated Centauri's overall performance

and safety advantages, together with comfort and lack of apprehension among pedodontic patients, when compared with the traditional high-speed drill."

The FDA also cleared Centauri's fiber delivery component for multiple patient uses, enhancing the dentists' opportunity for return on their laser investment. Based in part on fiber usage data obtained from company-sponsored research performed by an outside consultant and return-on-investment (ROI) studies conducted by Premier Laser, a special five-year leasing program has been developed through third-party leasing sources that results in a cost to the dentist of less than $13 per hard-tissue procedure during the first year. The program also has a three-year obsolescence protection upgrade option.

10/14 **The University of California, Irvine**, and **Candela Corporation** jointly reaffirmed Candela's exclusive license for the **UCI/Beckman Laser Institute's** patented Dynamic Cooling Device (DCD), and reached an agreement to expand application of this device to all medical and non-medical fields. Under the agreement, companies interested in the DCD are required to contact Candela to negotiate a license for using the technology, and Candela and the University will share royalties equally from any new applications for the life of the applicable patents. The Dynamic Cooling Device patent (No. 5,814,040) issued last week .

Used primarily by dermatologists, plastic surgeons and other practitioners, the DCD selectively cools the skin dynamically during laser treatments. Through its selective cooling of the upper layers of the skin by applying a squirt of cryogen an instant before applying the laser pulse, the DCD minimizes pain and thermal injury to the epidermis without decreasing laser effectiveness. Because cooling happens virtually simultaneously, the practitioner has full visibility of the skin's surface and can administer laser treatment unimpeded. Continuing research is underway to enable use of the DCD in other medical and non-medical products and processes. (The same type of cooling system, called Cool Touch, is used with the **Laser Aesthetics** Thermescent Skin Treatment system.)

10/15 **Photogen Technologies**, through its subsidiary **Photogen, Inc.**, has signed research agreements with two teaching affiliates of Harvard Medical School. The agreements came on the heels of a September announcement that the former Dean of the Harvard Medical School, Dr. Daniel Tosteson, had joined the Company's Scientific Advisory Council. One research agreement -- with Massachusetts General Hospital for work to be carried out at its *Center for Imaging and Pharmaceutical Research (CIPR)* -- will evaluate treatment of prostate and lung cancer using Photogen's simultaneous two-photon excitation technology. The other agreement -- with the *Massachusetts Eye and Ear Infirmary (MEEI)* -- will initially evaluate the technology for treatments of age-related macular degeneration (AMD). Both agreements provide that additional research projects may be undertaken with Photogen.

Dr. Gerald L. Wolf will be the Principal Investigator for the CIPR, while Dr. Joan Miller, a renown researcher in the field of macular degenerative disease will be MEEI's Principal Investigator.

Photogen intends ultimately to use the data gained through these animal studies and future clinical trials to speed submissions for regulatory approvals, although this is dependent largely upon the company's ability to secure favorable industry collaborative agreements for manufacturing and distribution. Both agreements enable Photogen to combine its technology with the scientific expertise, laboratory facilities, and personnel provided by MEEI and CIPR. MEEI and Mass General each has the right to patent any new inventions arising out of the research pursuant to their respective projects, and Photogen has the right to obtain an exclusive license concerning the invention on terms to be negotiated after development of the invention.

10/15 **Dental/Medical Diagnostic Systems Inc.** reported profitable quarterly results for its third quarter based on the successful launch of its Appollo 95E tooth whitening and composite curing system. Robert Gurevitch, chairman and CEO of Dental/Medical stated, "The acceptance of the Apollo 95E tooth whitening and composite curing system in markets around the world supports our confidence that this product will be very successful. The Apollo 95E, in conjunction with our Apollo Secret whitening materials, significantly whitens discolored teeth in less than 40 minutes. Because the Apollo 95E is not a laser, a dental assistant can perform the procedure. The Apollo 95E also acts as a curing light and is able to cure composite restorative material in 1 to 3 seconds, making it the fastest commercially available dental non-laser curing light known to the company." The company continues to ramp up production for the Apollo 95E, and is working toward the worldwide launch of its tooth whitening formulas (Apollo Secret) and composite materials (Apollo Cure) in the fourth quarter.

10/15 *NewsPage* reports that a U.S. patent had been granted to **Brown University** on an ultrasonic alternative to laser-based activation of photodynamic therapy.

10/15 **Candela Corporation** announced that it had reached an agreement with the **Massachusetts Capital Resource Company (MCRC)**, a privately owned limited partnership funded by seven Massachusetts-based life insurance companies, and had implemented a $3.7 million debt financing. Under terms of the transaction, MCRC and two other investors received eight-year, 9.75% subordinated notes. In addition, Candela will issue 370,000 warrants of the company's common stock to the note holders at an exercise price of $4.00 per share.

Commenting on the financing, Gerard Puorro, Candela's president and CEO, said, "This capital infusion adds significantly to our financial strength, so that we can capitalize more rapidly on the growing market opportunities we are seeing in our laser device business."

10/15 **Spectranetics Corporation** reported a fifth consecutive quarter of record revenues and continued strong year-over-year gains in gross margin. Consolidated revenues for the third quarter rose 12% to $7.0 million. Gross margins increased to 52% from 47% in the prior-year quarter. Net loss for the quarter was $834,000 (4 cents a share), compared with $609,000 (3 cents a share) in the 1997 quarter. For the nine months, consolidated revenues rose 32% to $20.3 million from $15.4 million last year. Gross margins increased to 53% from 46%, resulting in a narrowing of the company's net loss to $2.6 million (14 cents a share) from $3.5 million (19 cents a share) in 1997.

"During the third quarter, demand for our laser catheters in the nation's leading heart centers, coupled with the rapid growth of our Polymicro capillary tubing subsidiary, continued to lead Spectranetics to new revenue levels," said Joseph Largey, president and CEO. "Domestically, sales of our laser sheath devices for removal of pacemaker leads were up 94%, and angioplasty catheters rose 54% as compared to third quarter 1997." Revenues from service of laser systems in the U.S. also increased 52% over the previous year-quarter, reflecting the growing installed base of the CVX-300 excimer laser systems. Domestic revenue gains in these products in the third quarter more than offset weak European sales and a 28% drop in consolidated laser system sales. Actual shipments of laser systems increased 9% during the quarter; however, laser system revenues declined due to some lasers being shipped under a short-term evaluation program. For these evaluation laser systems, an initial stocking order of laser catheters and laser sheaths is received in exchange for use of the laser system during the evaluation period. At the end of the evaluation period, usually three to six months, the customer can rent, lease, return, or purchase the unit.

10/16 As reported by *Dow Jones Online News*, **BioLase Technology** expects to achieve profitability next year in the wake of the FDA approval given its Millenium device. "We feel comfortable that we will be able to turn profitable in a quarter of 1999, though we cannot at this stage forecast it for the full year," said chairman Federico Pignatelli. He expects to sell between 150 and 200 systems in the U.S. and Europe, where the device was approved in April 1997, for estimated sales of between $7 million and $10 million next year. The company is also on the verge of introducing several other new products that could provide "substantial upside" in revenues next year, including a consumer tooth brush to teeth whitening, a laser for soft tissue dermatology, and a skin rejuvination laser.

10/19 This week's issue of *Business Week* contains a blurb about **Cynosure's** newest skin resurfacing/wrinkle removal laser, the CO3, an adjustable pulse-width erbium:YAG system, including a quote from dermatologist Dr. David McDaniel, "The CO3 appears to be just as effective as earlier lasers at reducing wrinkles, but people healed quicker, with less discomfort...However, it still hurts...That's the price of looking forever young, it seems."

10/19 Citing continued strong sales of its GentleLase hair removal system, **Candela Corporation** reported record results for its fiscal 1999 first quarter. Revenue rose 37% to $10.7 million compared with $7.8 million for the same period a year ago. Net income was $910,000 for the quarter (16 cents per share). One year ago, the company had a net loss of $851,000 (16 cents per share) largely from costs associated with its now-discontinued Arizona skin care center venture. Gerard Puorro, president and CEO, commented, "The marketing excitement and customer acceptance of our GentleLase product line here in the United States were clearly the primary reasons for our solid first quarter. We are now continuing to work hard to maintain this momentum domestically and spread it throughout the world."

Candela derives about half of its sales and service revenues from non-U.S. customers.

10/19 **LaBarge, Inc.** announced that certain disputes have arisen between it and **TRANSMEDICA International, Inc.** relating to the respective obligations of the parties under their agreements wherein LaBarge has developed and is manufacturing the Laser Lancet for skin perforation to draw capillary blood. LaBarge indicated that when it completes manufacture of units currently in production, it will reach the limit of credit it had agreed to extend to TRANSMEDICA. The issues relate primarily to LaBarge's rights to develop and manufacture new laser products and determination of the number of Laser Lancet devices TRANSMEDICA is presently obligated to purchase from LaBarge. LaBarge has filed a Petition for Specific Performance and Declaratory Judgment in the Circuit Court for St. Louis County, Missouri, seeking resolution of these issues.

10/19 **Eclipse Surgical Technologies** announced results for the third quarter. Net revenues were $2.0 million, compared to $1.4 million in the third quarter of 1997. Net loss for the quarter was $5.5 million (32 cents per share), compared to $4.5 million (27 cents per share) in the third quarter of 1997.

10/20 **ESC Medical Systems** announced third quarter and nine month results with net sales For the third quarter increasing modestly to $53.8 million from $51.2 million for the same quarter last year. Net income was $8.0 million (29 cents per share), compared to $10.9 million (40 cents per share) for the 1997 third quarter. For the nine-month period net sales increased to $177.0 million from $135.3 million for the comparable period last year. Net income was $34.0 million ($1.23 per share), compared to $28.5 million ($1.05 per share) for the first nine months of 1997, excluding merger expenses.

The 1997 first quarter results exclude a one-time charge of $4.6 million associated with the acquisition of **Luxar Corporation** and the 1998 first quarter results exclude a one-time charge of $29.0 million associated with the acquisition of **Laser Industries**

**Limited**. Including these non-recurring merger expenses, net income for the first nine months of 1998 was $5.1 million (18 cents per share). The 1997 third quarter and nine-month results are restated to include Laser Industries results.

As reported in ESC's preliminary news release on September 28th, revenues for the third quarter were affected by lower sales volumes in certain international markets. The company stated that its business fundamentals remain sound and ESC continues to gain market share in its four main product lines. Dr. Shimon Eckhouse, president, CEO and chairman, commented, "Although sales activity slowed in the third quarter, we remain confident in our strong competitive position and continue to see growing market acceptance of our products in key regions. We were particularly pleased with the demand for our new VascuLight and MultiLight products, which strengthened our PhotoDerm business. Additionally, our Otolam laser for myringotomies, which was officially launched during the month of September, has generated significant interest in the marketplace."

During the teleconference following release of the financial data, Dr. Shimon Eckhouse broke out ESC's sales by product line -- similar to what was reported in our July 21st brief following the release of second quarter results (as estimated by me based on his remarks on average selling prices and units sold during the quarter):

- intense pulsed light systems -- $27.8 million on 257 units at an ASP of $108K. (This is down about 45 units from the second quarter, but at the same ASP.)

- laser hair removal systems -- $5.9 million on 81 units at $74K; down 12 units.

- skin resurfacing systems -- $9.2 million on 322 units at $28.5K; down 41 units, but also at a reduced ASP of $28.5K.

- silhouette -- $3.9 million on 200 units at $19.5K; down about 15 units.

- service and accessories -- $7 million, down from $8.1 million in the second quarter.

New products that began selling during the quarter included two pulsed light systems, the MultiLight and the VascuLight. Also, the new laser for otolaryngology, the Otolam, a $CO_2$ laser to create a hole in eardrums to alleviate the pressure buildup of chronic infection of the inner ear. This product was introduced at an otolaryngology meeting in September to a good reception. The company expects to begin selling this device in the fourth quarter to the tune of $1 to $2 million in sales. Another new product, in an earlier stage of development is the Elite, an office-based diode laser system for endometrial ablation -- stopping the excessive endometrial bleeding that

some women experience. Eckhouse also noted that the company was working on a "next generation" hair removal system.

10/20 **PLC Systems** announced financial results for the third quarter and nine months. Total revenues for the quarter were $1.6 million compared to revenues of $1.9 million for the corresponding quarter in 1997. The net loss for the quarter was $4.0 million (21 cents per share), compared with a net loss of $3.6 million (21 cents per share), for the third quarter of 1997. Total revenues for the nine month period were $3.2 million compared to revenues of $6.9 million for the last year. The net loss for the nine months was $13.3 million (70 cents per share), compared with a net loss of $9.3 million (56 cents per share) last year.

The decline in revenue for the nine month period reflects decreases in shipments of the Heart Laser System, and in contractual minimum billings under placement contracts. PLC provided its customers with relief from contractual minimum billings pending FDA approval. The company has both a placement strategy and a direct/distributor sales strategy for purchases of its laser system. The placement program allows the company to receive recurring revenue based on the usage of the Heart Laser rather than one-time revenue from the sale of each system. Under the placement model, an installation fee is paid when the laser is installed and the company then receives a fee per use.

"We made great progress toward establishing PLC as a viable commercial entity during the third quarter, most importantly by obtaining FDA approval for the Heart Laser," said William Dow, president and CEO of PLC. "Third quarter revenue increased significantly from the preceding quarter, and quarterly operating expenses declined by nearly $900,000, reducing our quarterly operating loss by nearly 30%. Achieving profitability will continue to be the primary goal of PLC management."

Following the FDA approval, an increase in domestic TMR procedures ocurred, with twice the number of procedures performed in August being completed in September. Also, the company's U.S. sales force made more than 300 sales calls to leading open heart surgery centers, resulting in the submission of over 50 proposals for the acquisition of the Heart Laser to prospective customers.

Other highlights of the quarter include:

-- Reimbursement for TMR using the Heart Laser by a number of private insurers.

-- Progress in efforts to obtain Medicare reimbursement for TMR, with reimbursement codes implemented by HCFA despite its continuation of a "non-coverage" instruction for TMR.

-- A submission to the Ministry of Health and Welfare (MHW) in Japan which included clinical data describing 30 Japanese patients that received TMR.

"We are excited about the market opportunity which lies ahead," stated Mr. Dow. "Our recently announced agreement with **GE Capital** gives PLC the ability to provide new domestic customers with a broad range of financing options for the Heart Laser and a non-dilutive source of capital to finance our placement program. We anticipate a number of new shipments during the fourth quarter of 1998 in both the U.S and Europe. In Asia, we anticipate approval to sell the Heart Laser in Korea and Taiwan by the end of the first quarter of 1999. In Japan, which is the largest medical device market outside the U.S., our distributor anticipates MHW approval in the second quarter of 1999."

10/21 **Dental/Medical Diagnostic Systems** announced the introduction of its revolutionary new tooth-whitening product, Apollo Secret, for use with its Apollo 95E tooth-whitening and composite curing lamp, the fastest commercially available curing light, including lasers, known to the company. DMD has the exclusive worldwide distribution rights for the Apollo Secret whitening agents and composite curing materials, and plans to begin shipping them to dentists in the fourth quarter of 1998.

The benefits of Apollo Secret Power Whitening include a unique desensitizing formulation that substantially reduces patient discomfort, allows the procedure to be performed by a dental assistant or hygienist, generally in less than 40 minutes, and provides the patient with prompt gratification by whitening the patient's teeth up to ten shades lighter. Apollo Secret is the subject of a pending patent application by its developer.

10/21 **Laserscope** announced results for the third quarter and nine months. Revenues in the quarter were $12.8 million compared to $15.7 million in the same period a year ago. The company reported a net loss for the quarter of $737,000 (6 cents per share), compared to net income of $901,000 (7 cents per share) last year.

Revenues for the nine-month period were $39.5 million compared to $46.7 million in the same period a year ago. The Company reported a net loss for the nine-month period of $2.9 million (24 cents per share), compared to net income of $2.5 (20 cents per share) last year. In making the announcement, Robert McCormick, Laserscope president and CEO, noted, "While sales of Laserscope products in Europe grew at a healthy pace, these achievements were offset by continued weakness in Pacific Rim markets. Our quarterly and nine-month results were also affected by continued slow moving sales in our hospital equipment business in the U.S. and by a decline in U.S. laser sales. While we continue to look at the entire Asia-Pacific market as one with considerable long-term growth potential for the company, the region at the present time represents less than 8 percent of total sales...Even though our results to date have

been unsatisfying, we are encouraged by several achievements and prospects for improvement going forward. Substantially all of the costs associated with the restructuring have been taken, and we will continue to work aggressively to reduce costs and improve our balance sheet. The restructuring goals announced in July should be complete by the end of this month and their impact is expected be felt in future quarters."

"Additionally, the three new lasers systems we introduced at trade shows earlier this year now have been commercially launched, and we expect to see their contribution in the months ahead. We continue to invest a significant portion of our resources in R&D and in the development of new medical laser procedures. We also anticipate submitting data in early 1999 to the FDA from our clinical trials on laser hair removal, and, we await a ruling that could come very shortly from the FDA on the photodynamic therapy (PDT) treatment of late-stage lung cancer, following the Oncologic Drugs Advisory Committee's unanimous recommendation of approval on September 3...We are a strong believer in PDT as a highly-desirable approach to the treatment of cancer and other diseases," McCormick added. He also noted that approximately 75 cancer centers within the U.S. are now treating patients with PDT, and more than 70 percent of them are using Laserscope PDT laser systems.

10/22 **Premier Laser Systems** reported that it had received correspondence from NASDAQ notifying the company that its common stock and warrants were to resume trading immediately.

10/22 **CardioGenesis Corporation** reported results for the third quarter and nine months. Sales for the third quarter were $1.1 million, resulting from sales of the company's Intraoperative Transmyocardial Revascularization (ITMR) and Percutaneous Myocardial Revascularization (PMR) Systems, including disposable components, to international customers and to clinical trial sites in the United States. Third quarter 1998 sales decreased slightly from sales of $1.2 million for the third quarter of 1997. The net loss for the quarter was $6.9 million (57 cents per share), versus a net loss of $5.1 million (42 cents per share) for the third quarter of 1997. The increase in the net loss is due primarily to additional R&D expenditures and higher clinical expenses for increased activity in clinical trials as well as higher marketing expenses.

For the nine month period sales decreased to $3.0 million from $5.5 million in the same period a year ago. This reduction in sales is due primarily to constraints on capital equipment purchases resulting from hospital budgets and government overview outside the U.S., and by the limited current availability of reimbursement for TMR procedures in Europe. The net loss for the nine-month period was $19.5 million ($1.60 per share), compared to a net loss of $12.4 million ($1.03 per share) for the first nine months of 1997.

"Although sales were basically flat with last year, we are pleased with the progress of PMR and the reception to the PMR results reported by Steven Oesterle, M.D., at the Transcatheter Cardiovascular Therapeutics conference in Washington, D.C. this month. Dr. Oesterle's conclusion that the CardioGenesis Axcis PMR System provides patients a clinical benefit is encouraging," said Allen Hill, CardioGenesis president and CEO. "We are eager to complete our modular PMA submission of data to the FDA on the surgical CardioSync System. The FDA has requested that we delay submission of the final clinical package until they catch up with their September 30, 1998 fiscal year end backlog. Our relationship with the FDA remains strong, and we are not aware of any issues with our modular submissions to date and do not believe that this request will slow our progress toward the panel date or ultimate FDA approval."

10/22 In a surprise announcement, **Eclipse Surgical Technologies** and **CardioGenesis Corporation** announced the signing of a definitive agreement that provides for the business combination of the two companies. Under the terms of the agreement, each share of CardioGenesis common stock will be converted into the right to receive 0.8 shares of Eclipse common stock, and Eclipse will assume all outstanding CardioGenesis stock options. CardioGenesis will survive as a wholly-owned subsidiary of Eclipse. As a result of the transaction, Eclipse will increase its shares outstanding by approximately 9.8 million shares, which will be issued to CardioGenesis stockholders. These shares will represent approximately 36% of Eclipse's outstanding shares after the transaction.

The boards of directors of Eclipse and CardioGenesis have approved the definitive agreement, but the combination is subject to approval by the shareholders of each company and to certain other customary conditions to closing. Certain affiliates of both Eclipse and CardioGenesis have agreed to vote their shares in favor of the combination. The parties anticipate the transaction will close in the first calendar quarter of 1999.

"We believe the combined entity will have a multi-year lead in FDA clinical trial progress over any other fiberoptic TMR competitor," said Douglas Murphy-Chutorian, M.D., chairman and CEO of Eclipse. "The combined patent portfolio of the two companies will be very strong, and our market share will rise to over 300 installed laser systems -- many of which are in the largest or most influential cardiovascular centers in the world." "The combination of these two companies leverages leading positions in percutaneous and surgical TMR, talented employees, and capital resources, and will provide an excellent product platform to best serve our customers' needs," said Allen Hill, president and CEO of CardioGenesis. "We look forward to working together with Eclipse to create the clear "full play" leader in the TMR market."

Dr. Murphy-Chutorian, Eclipse's current chairman and CEO, will remain Eclipse's chairman of the board. Mr. Hill, CardioGenesis current president and CEO, will become Eclipse's CEO. Eclipse's board of directors will consist of four directors from the current Eclipse board and three directors from the current CardioGenesis board.

(I wonder how they will work out their marketing/partnering relationships with **Boston Scientific** (CardioGenesis) and **Sorin Biomedica** (Eclipse)?)

10/23 Two law firms, **Wechsler Harwood Halebian & Feffer LLP** and the **Law Offices of Lionel Glancy** announced that they had filed a class action suit in the United States District Court for the Southern District of New York, on behalf of a class consisting of all persons who purchased the common stock of **ESC Medical Systems, Ltd.** on Monday, September 28, 1998 inclusive. The complaint charged ESC, and its chief financial officer, with disseminating material inside information regarding ESC's business prospects to **Salomon Smith Barney** during the course of the day of September 28, 1998. Allegedly, this permitted Salomon Smith Barney to inform its institutional clients and let them sell shares of ESC prior to full and proper disclosure of such information on a widespread basis to the investing public. Only after the market closed did ESC purportedly inform the investing public of the downward forecast of the company's prospects.

10/23 **Trimedyne** announced it had formed a strategic marketing alliance with **Surgical Innovations and Services** for the states of Florida, Alabama, Arkansas, Mississippi, Louisiana, Tennessee, Virginia, North and South Carolina, Kentucky, and Maryland. Through a comprehensive service approach, SIS provides hospitals and surgery centers in the South with lasers, technicians to operate the lasers, and disposable laser fibers, tips and hand pieces at one low "fee per case" charge. SIS' contract guarantees laser availability when the hospital or surgery center requests it, with no minimum monthly fees or case volumes.

10/23 **Laser Corp.** announced that it has completed a private placement of 521,739 shares of its common stock for the purchase price of $600,000. The investor in this private placement is a European businessman who has developed several medical lasers and other devices for his own companies and has had an ongoing business relationship with the company for many years.

10/26 **American Dental Technologies** reported its third quarter results. Revenues increased 62% to $6.6 million, up from $4.1 million for the same period a year ago. Income from operations increased 261% to $583,100 from $161,360 a year ago, while net income was $549,900 (7 cents/share). For the nine month period, revenues were $18.7 million and net income was $2.4 million (32 cents/share). (Based on the recently established formula -- see last month's September 25th brief -- that laser sales

represent about 20%-25% of total sales, I estimate that the company's laser sales were about $1.3 million for the quarter, and $4.9 million for the nine months.)

"The Company has experienced a 62% increase in sales during the third quarter, which is primarily due to a 34% increase in our core business of air abrasion and lasers plus the addition of the Ultracam sales since the acquisition on August 1st. Domestic air abrasion and laser sales increased 33% and foreign air abrasion and laser sales increased by 8% in the quarter compared to 1997...Earnings continue to be in line with management's expectations and we expect continued growth in sales for the remainder of 1998," said Ben Gallant, President and CEO.

**MEDICAL/SURGICAL LASER UPDATE -- NOVEMBER 1998**

10/26 I received a copy of the complaint in the class action suit against **ESC Medical**, filed by three law firms. Basically, the complaint charges that trading in ESC's common stock opened at 21 1/8 on Monday, September 28th, and closed at 14 5/8, with an unusual number of shares trading -- 3,211,600. On the following day, the asking price at the opening was 7 1/2, and the closing price was 6 1/2, on a whopping 15,532,800 shares traded. The argument alleges that **Salomon Smith Barney** was informed about the potential downturn in company revenues and profits prior to the public announcement over the PR Newswire at 4:33 PM on the 28th, giving Smith Barney the opportunity to tell certain of its institutional clients about the expected lower revenue and earnings, allowing them to sell or lighten their positions in the company's stock.

10/26 **Paulson Investment Company** has released a research update on **Cell Robotics**. I have requested a copy of the report and will review it upon receipt.

10/26 **Spectranetics** will be a presenter at the upcoming **Robertson Stephens** medical conference to be held in New York City on November 30 - December 3rd.

10/27 **Laser Power Corporation** released several announcements: 1) it had received a purchase order from a European customer for $500,000 worth of its green and blue microlasers for laser light show applications; 2) it had received a $750,000 Phase II SBIR grant from the Department of Defense to continue development of its microlaser-based 3D displays, which could eventually be used by the military for land or sea visualization, and commercial applications in medicine, entertainment, and air traffic control; and 3) the company released preliminary results for its fiscal fourth quarter. Laser Power expects to report a loss of $3.8 million to $4 million on revenues of approximately $7.5 million for the quarter, and a loss of approximately $6.5 - 6.7 million on revenues of $34.7 million for the fiscal year.

10/28 **Eclipse Surgical Technologies** announced that the Circulatory System Devices Advisory Panel of the FDA had recommended approval of its PMA for its TMR 2000 Holmium Laser System for the treatment of severe angina. The panel, which voted 6-1 in favor, requested that the company conduct post-market surveillance in a manner to be decided in discussions with the FDA. The data presented to the FDA Panel showed that TMR using the Eclipse system reduced severe angina pain in patients with advanced coronary artery disease. The randomized prospective study compared patients treated with TMR to a control group of patients who received maximal drug therapy. The TMR patients had significantly better freedom from treatment failure, from cardiac events, and free from re-hospitalizations. TMR patients were also able to reduce their medications and increase their exercise tolerance while substantially improving their quality of life. It is expected that full marketing approval could be obtained in approximately three to six months, providing competition to **PLC Systems**, which won approval in August.

10/28 **Spectranetics** reported that an excimer laser angioplasty procedure successfully opened a 14-cm long total occlusion in an artery in the upper leg of a patient at the Washington Hospital Center. The procedure, using Spectranetics' proprietary technology, was performed in conjunction with the recent *Transcatheter Cardiovascular Therapeutic (TCT) Conference* held in Washington, D.C. Patients with long lesions of this nature are typically not candidates for angioplasty treatment.

Referring to the live procedure, Professor Giancarlo Biamino of Hamburg, Germany, said: "This case clearly shows the effectiveness of using the excimer laser to treat complex peripheral vascular disease. Stenting was not required due to excellent results with laser and balloon alone." Prof. Biamino has performed more than 4,000 peripheral procedures in Europe, where Spectranetics' peripheral products received CE Mark approval in March 1997. More than 3 million people in the U.S. suffer from peripheral arterial disease. The condition can cause incapacitating pain and, in extreme cases, leads to such complications as infection, ulcerations, gangrene and amputation. Conventional therapy for long occlusions in the lower limbs includes exercise and drug therapy, or bypass surgery. The Spectranetics' peripheral excimer laser angioplasty (PELA) treatment uses fiber optic technology to deliver excimer laser energy in short, precise bursts to dissolve, or ablate through a blockage.

10/28 **Coherent, Inc.** announced financial results for its fiscal fourth quarter and year ended September 26, 1998. Sales and net income were $104.6 million and $6.2 million (26 cents per share), respectively. Net income included a $2.7 million (11 cents per share) non-recurring tax benefit. Sales increased by $6.1 million (6.2%) and net income (exclusive of the non-recurring tax benefit) increased by $5.2 million compared to the fiscal third quarter. Sales increased by $0.8 million (0.8%) and net income, exclusive of the aforementioned tax benefit, decreased by $3.1 million compared to the fourth quarter last year.

Sales for the fiscal year were $410.4 million, a 5% increase from last year. Net income, exclusive of the $2.7 million tax benefit, was $16.1 million, a 54% decrease from last year's income, excluding the $9.0 million write-off of purchased in-process technology. Comparative sales were adversely impacted by more than $12 million as a result of changes in the relative strength of the U.S. dollar against major foreign currencies. Net income for the year was negatively impacted by (i) poor performance in the **Coherent Medical Group** during the second half of the year; (ii) continued investments by **Lambda Physik** in DUV lithography systems for the next generation of semiconductor equipment; (iii) continued investments by the company's **Auburn Group** to establish a catalog distribution system; and (iv) a decrease in the gross profit rate due to lower sales of higher margin medical products and the impact of the strengthening of the U.S. dollar against major foreign currencies. Gross profit rates for the fourth quarter and fiscal year were 45.9% and 48.2% compared to 50.9% and 52.6% for the corresponding prior year periods.

The Medical Group's revenues for the quarter were $36.8 million, up from the previous quarter, but down significantly from last year's same quarter of $44.1 million. As put by CEO Bernard Couillaud, the Medical Group "had a breakdown in the fiscal third quarter, stabilization in fiscal Q4, and hopefully, recovery in fiscal Q1 next year." He attributed the stabilization to a better balance of sales, including increased sales of ophthalmic products and reduced expenses, including a downsizing of about 60 people.

Couillaud said, "While I am pleased that we were able to quickly recover from the 7 cents per share loss of last quarter, I do not believe that this past year's financial results are indicative of our business or prospects. The reorganizational efforts are continuing within the Coherent Medical Group and I am satisfied that the process we have started is in the best interest of our shareholders, customers and employees. We managed to reduce the loss in Coherent Medical Group from $9 million in the third quarter to approximately $1 million in the fourth quarter. I expect that the Group will return to profitability and I remain confident that we will successfully conclude our search for a new Medical Group president within the current quarter." (In a meeting with Couillaud at the American Academy of Ophthalmology in New Orleans, he mentioned that the company was close to naming a new president for its Medical Group, indicating it would do so within about a month.) Other bright spots in medical laser sales included continued good sales of hair removal lasers and the sales of systems for the treatment of BPH. In the cosmetic arena, he believes that the sales of skin resurfacing lasers may be reaching saturation, the vascular market has not yet been properly addressed, while the hair removal market is in a growth stage. Discussing the sale of erbium lasers for skin resurfacing, Couillaud thought that these systems were not "holding their promise", that sales were flat to down, with some indications that dermatologists and plastic surgeons were going back to $CO_2$ laser systems for this application. As for hair removal systems, he felt that about 2000

systems had been sold into this market, which should be three times the skin resurfacing potential of 5000 systems, or close to 15,000 laser systems.

10/28 Speaking at the *American Academy of Dermatology's Derm Update '98*, Harold Brody, MD, Department of Dermatology, Emory University School of Medicine, Atlanta, GA, discussed the refinement of skin resurfacing techniques using a combination of modern skin correctional approaches. Though chemical peeling and resurfacing have been in existence for over 100 years, the last several years have led to refinements in alpha and beta-hydroxy acids and the reestablishment of tried and true techniques. "Laser resurfacing techniques in the last year have established the $CO_2$ laser to be superb for deepest resurfacing and the erbium laser to be valuable for lesser skin damage," Dr. Brody said. By combining these lasers with the lasers for pigment and blood vessel removal, skin rejuvenation can be accomplished simultaneously and efficiently.

10/29 Also speaking at the *American Academy of Dermatology's Derm Update '98*, Melanie Grossman, M.D., Cornell University Medical School, New York, NY, discussed new laser technologies that are emerging in the treatment of unwanted body hair. "Recent improvements in the understanding of laser skin interactions and advances in laser technology have afforded the development of several laser-assisted hair removal strategies. Coupled with our existing knowledge, this gives way to new and exciting possibilities into future testing and research development," Dr. Grossman said.

Lasers enable the treatment of large surface areas in a short time span, allowing treatment of an entire back, leg or chest in one treatment session. While in many cases results are excellent compared to existing alternatives, it is easier to induce a growth delay than to induce permanent hair removal. Success varies depending upon the individual and the location of the hair on the body. Currently, FDA-approved methods of hair removal include: the Long Pulsed Ruby Laser; the Q-Switched Nd:YAG Laser in combination with a carbon suspension; Long Pulsed Alexandrite Laser; Diode Laser; and the Non-coherent light source.

The Q-Switched Nd:YAG Laser works in combination with a carbon-based topical suspension. Hair is removed from the skin surface by shaving the day before treatment. The day of treatment, the carbon suspension is applied and low energy laser pulses are delivered to the treatment area, which directs the carbon into the hair follicles. Higher fluence pulses are then delivered to the skin surface and target the carbon-filled follicles. Areas of treatment include the face, trunk and extremities. Various body sites and individuals respond differently.

The Long Pulsed Alexandrite Laser is another FDA-approved method which is used to treat the trunk, the extremities and the face. Hair-bearing areas must be shaved prior to treatment. In addition, a Non-coherent broad-spectrum light source is also

used to treat areas shaved prior to treatment. A cooling gel is applied to the surface of the skin and then laser light pulses are delivered.

The newest FDA-cleared method is the Diode Laser. Under investigation are several additional sources for the treatment of hair removal: a Long Pulsed YAG Laser; and photodynamic therapy light therapy which utilizes a topical drug Amino Levulonic Acid (ALA), which targets hair follicles for destruction using a red light. "With the development of new treatments underway and the refining of existing technologies, the dermatological advancement of hair removal is successfully moving forward," Dr. Grossman concluded.

10/29 **Premier Laser Systems** reported enthusiastic response at the 1998 ADA conference to its recent FDA clearance for "all ages" hard-tissue laser dentistry, deep cleaning procedures, and endodontic procedures for their dental laser products. Dentists were also very responsive to a new leasing program that was designed in response to market demand for a low per-procedure cost and to alleviate return-on-investment concerns for dentists. The company reported excellent booth traffic and near-capacity attendance at 40 presentations by seven dentists on hard-tissue dentistry, soft-tissue dentistry, dental hygiene applications, such as deep cleaning/debridement, endodontics, and teeth whitening. Orders taken on the floor of the exhibit hall crossed all three dental-laser product lines: Centauri (hard tissue), Aurora (soft tissue and hygiene), and Arago (teeth whitening and composite curing).

The new Premier Laser dental laser leasing program is designed to offer break-even usage levels as low as one procedure every month for the Aurora diode laser and just six total teeth whitening procedures for the Arago argon system. Practitioners using Premier's top-of-the-line Centauri erbium:YAG laser system should also benefit from a new leasing program with per-procedure costs of $13 or less cited. Estimated per-procedure costs for this special five-year Centauri leasing program are based on 100 hard-tissue procedures per month. The program includes the monthly lease cost of the laser with a three-year warranty, obsolescence protection and the estimated number of fibers and tips required over the term of the lease.

10/29 **MW Medical**, a private firm located in Scottsdale, AZ, announced that it was scheduled to begin Phase III clinical trials of a microwave device to remove unwanted hair for cosmetic purposes, and also for treatment of spider veins. MW president and CEO Paul Banko believes its microwave technology offers advantages over laser systems. Whereas laser hair removal systems require retreatment in 40% to 50% of cases, the microwave system is designed to destroy the hair follicle on the first application. Early trials on a small number of patients have indicated success, the company said. In addition, the treatment shows no difference on a range of skin colors nor does it discolor certain skin types, according to MW medical director Dr. Robert B. Spertell.

MW applies a cream and cooling gas on the patient's skin to help avoid burning. The microwave, funneled from a standard microwave generator through a specially designed handpiece, is applied either in a dime-sized area or "paint brush" style to a depth of 4 to 5 mm. The company found that the depth stops growth in the follicle without burning the skin. MW Medical hopes to complete the Phase III trials in 60 to 90 days and submit a 510(k) application for marketing clearance to the FDA by April. The Phase III trials will begin this week and will eventually include U.S. and European sites by the end of next month.

10/29 **Palomar Medical Technologies** announced the first profitable quarter in the history of the company, with a net profit from continuing operations for the third quarter of $539,000 (1 cent per share), compared with a net loss from continuing operations of $22 million (68 cents per share) for the third quarter of 1997. Revenues from continuing operations increased 136% to $13.8 million compared with revenues of $5.8 million during the third quarter of 1997. The third quarter net profit of $539,000 compares with the loss of $4.0 million in the preceding quarter. Additionally, Palomar's third quarter revenues of $13.8 million increased 52% over revenues of $9.1 million in the preceding quarter.

For the nine month period, results from continuing operations showed revenues increased 91% to $30 million, compared with revenues of $15.7 million during the same period a year ago. Palomar also reduced its net loss 76% for the first nine months to $10.3 million (19 cents per share), compared with a net loss of $43.5 million ($1.43 per share), for the first nine months of 1997.

"Achieving profitability is indeed a significant event for Palomar as we accomplish our stated goal of turning the company around by the end of 1998," said Dan Valente, chairman and CEO of Palomar. "We achieved this milestone sooner than expected due to the dedication of our employees and the guidance of our directors, all the while investing the necessary resources in R&D to maintain our technology leadership position." Valente added, "This technology emphasis has yielded our current products already on the market, and we are developing a number of other products, including next-generation, that should provide excellent growth opportunities in the future. To further enhance shareholder value, we will also consider intellectual property licensing agreements, the sale of intellectual property rights that the company does not intend to exploit, the sale of operating subsidiaries, and mergers, acquisitions, or other transactions."

10/30 **Surgical Laser Technologies** announced its financial results for the third quarter and first nine months of 1998. Sales for the quarter were $2.2 million compared to sales of $3.0 million in the third quarter of 1997. The net loss was $527,000 (5 cents per share) compared to a net profit in the third quarter of 1997 of $47,000, which included an aggregate non-recurring credit of $177,000. The non-recurring credit included $1.0

million received in settlement of a lawsuit offset in part by charges amounting to $0.8 million for facility-related items.

For the first nine months of 1998, sales were $6.9 million compared to sales of $9.0 million in 1997. The net loss was $1.5 million (15 cents per share) versus $432,000 (4 cents per share), which included the above-mentioned non-recurring credit of $177,000.

Commenting on the results, Keith Stoneback, SLT's president and CEO stated, "The sales level that we have experienced over the last several quarters continues to reflect weak demand for Nd:YAG lasers in both domestic and international markets. We expect that demand for these lasers will continue to be depressed in the foreseeable future. In an effort to reduce our dependency on this single product line, we have implemented a focused strategy in the ENT surgical market, expanding our product offering beyond lasers. Our first two internally developed, non-laser, ENT products were introduced to the ENT community in mid-September at an American Academy of Otolaryngologists meeting and we believe have generated sincere interest. We expect to make our first commercial shipments of both products in early November."

In addition, Stoneback added: "The third quarter included the initial limited shipment of clinical units resulting from our development of a laser system for **CorMedica's** PTER application. We are on schedule to meet our target of delivering the next several laser systems in the fourth quarter."

11/2 **Premier Laser Systems** said it would be one of 16 prospective high growth microcap companies co-hosting the 21st Annual Westergaard Microcap Conference on November 5th at the Waldorf Astoria in New York City. CEO Colette Cozean was scheduled to make six presentations during the day, and was to be awarded the Westergaard Online's Kjakan award at the Thursday luncheon for her contribution to the spirit of entrepreneurial capitalism.

11/2 **Palomar Medical Technologies**, and **Coherent, Inc.** announced that they were negotiating the sale of Palomar's majority owned subsidiary, **Star Medical Technologies** to Coherent. Star, based in Pleasanton, CA, manufactures the LightSheer Diode laser system distributed exclusively by Coherent. The sale price is expected to be in the range of $60 to $65 million, payable in cash. However, the parties have not agreed to all of the terms of the transaction. If an agreement is reached, consummation of the transaction would be subject to the approval of the stockholders of Palomar, as well as certain regulatory approvals and other standard closing conditions.

As reported in the November issue of *Medical Laser Report*, editor Kathy Kincade wrote that according to Dan Valente, Palomar chairman and CEO, "While the

LightSheer is currently one of Palomar's leading revenue generators, selling Star to Coherent would not leave Palomar without significant diode-laser resources...We retain substantially all licenses and patents if this sale goes through...and we are moving along in other advanced products, including looking at new products using our ruby laser technology." Valente also said that Palomar has diode laser technology separate from the technology used in the LightSheer that would enable it to develop other diode laser products. "We do not want to make a knock-off of the diode laser Coherent would be purchasing from Star, and we do not want to compete with them. We believe that the future is in the low-cost arena, and we see ways of producing new products and developing many applications beyond hair removal."

11/2 **Donner Corp. International** announced that it had initiated coverage and had issued a report on **Trimedyne**, with a "speculative buy" recommendation. Donner analyst Libby Weber says that the lasers manufactured by Trimedyne "have distinct advantages over other types of medical lasers". (See my review of the Donner research report in the 11/16 brief below.)

11/2 *Wall Street Corporate Reporter* conducted an interview with Joseph Largey, president and CEO of **Spectranetics**. The article reviewed Largey's background and his reasons for taking on the position of leadership at the company. He noted that Spectranetics had placed laser systems in over 250 medical institutions worldwide, with approximately 175 in the U.S., and close to 70 in Western Europe. He commented on the company's relationship with **U.S. Surgical** in the field of TMR and PTMR, which will allow Spectranetics to be the exclusive supplier of their disposables and to sell his lasers through their distribution channels.

11/3 According to *Federal Filings*, **Premier Laser Systems** was issued a "warning letter" by the FDA for violating the Federal Food, Drug and Cosmetic Act, making the company's devices "adulterated." Specifically, in an inspection conducted between June 26 and July 14, the September 24 letter states that Premier Laser's devices "are adulterated...in that methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacturing Practice requirements." Premier Laser was cited for failing to maintain records of investigations of all complaints regarding the possible failure of a device or records describing why there was no investigation. In addition, the company was also charged for misbranding its laser system, due to promotional materials that claim the device performs certain functions without having premarket approval for that indication. The letter states that the laser system was further misbranded because the company failed to "furnish information required under the MDR regulations," requiring that manufacturing facilities report within 30 days whenever the manufacturer becomes aware that its device may have caused some degree of injury or loss, or has malfunctioned and would likely result in causing some degree of injury or loss.

The agency acknowledged receipt of two responses submitted by Premier Laser, which were deemed adequate. However, the agency stated that further verification will be necessary during a reinspection of the facility.

11/3 *Federal Filings* reported that the merger between **Cardiogenesis Corp.** and **Eclipse Surgical Technologies** may be canceled if it is not completed by Feb. 28, 1999. The deal is also contingent on mutual shareholder approval, no governmental interference, and the accuracy of both parties' representations and warranties. The merger is further conditioned on the deal qualifying as a reorganization for income tax purposes. Either company must pay the other a $3 million termination fee if it decides to accept a superior offer within nine months after mutually terminating the deal with the other company. Both parties are prohibited from soliciting third party bids, though Cardiogenesis may enter into negotiations if it receives a superior offer. Cardiogenesis must then promptly notify Eclipse Surgical of such developments.

11/4 **Reliant Technologies** introduced its newest product, the AccuScan LVO, an innovative, fully integrated laser-video-otoscope scanning system, designed primarily for laser treatment of otitis media. Based on Reliant's proprietary technology, the AccuScan LVO employs a combination of a precise laser delivery system coupled with a built-in CCD video camera and four-inch color LCD video monitor. Otitis media represents an extremely common medical illness, especially in children, which not only can be very painful, but also can lead to long term complications including permanent hearing impairment. Approximately 80% of children will have had at least one episode of otitis media by the age of three years. Essentially all cases of otitis media require medical evaluation and intervention. Otitis media is the most common reason for visits to pediatricians. Recurrent otitis media is also very common; unless appropriately treated, it may be associated with delay in speech and language development in infants and children. The annual direct cost of medical care for otitis media nationally is estimated to be $2 billion.

With the use of AccuScan LVO, the laser fenestration is accurately calculated to a predetermined size and placed precisely in the desired area of the tympanic membrane. Its unique configuration brings to the surgeon a fully integrated, convenient, video-monitored, precisely delivered and safely performed laser treatment of the middle ear. Reliant plans to offer its AccuScan LVO system either together with its Unica $CO_2$ Laser (a portable, low-power, low cost $CO_2$ laser, useful primarily for private offices and small outpatient clinics), or separately as a cost-effective attachment to the physician's existing laser.

11/4 **Chronimed** announced that it had begun shipping its new Lasette Laser Lancing Device to both domestic and international customers. As previously announced on August 4, Chronimed has exclusive worldwide rights to market and sell the patent-protected Lasette laser technology products through its development and

distribution agreement with **Cell Robotics International**. The Lasette laser finger perforator is designed for drawing blood from fingertips in a nearly painless manner for glucose testing. It utilizes a laser beam that penetrates the skin to obtain a capillary blood sample, instead of traditional lancets that tear the skin. In addition to minimizing immediate and residual pain, the Lasette eliminates accidental needle sticks, reduces cross contamination, eliminates sharps disposal, and can be used for testing glucose with any standard blood glucose meter. The currently available institutional model of the Lasette is designed for use in clinical settings, such as hospitals, clinics, blood banks and doctors' offices. The planned, second-generation model of the Lasette is a smaller unit designed for convenient in-home use by consumers, and is pending regulatory approval.

11/5 **Pacific Pharmaceuticals** and **Procept Inc.** announced that they have signed a letter of intent which contemplates the merger of Pacific into Procept. The proposed merger would consolidate the two companies resources and drug development expertise to further advance ongoing research programs at both companies.

11/5 The law firms of **Wechsler Harwood** and **Lionel Glancy** announced that they had amended their class action suit, re-filed on October 30th, against **ESC Medical** to include the time period of January 27, 1998 through September 28th as the inclusive period. The amended period goes back to the date of acquisition of **Laser Industries** by ESC. The amended complaint alleges that "certain of the defendants adopted a scheme to overstate the company's revenue through the improper acceleration of revenues and improper recognition of revenues". This is in addition to the alleged disclosure of inside information to a representative of **Salomon Smith Barney** prior to the public dissemination of information about adverse revenues for the fiscal third quarter on September 28th.

11/5 **ESC Medical** responded to the filing of the class action law suits, by stating that it had not yet received copies of the amended complaint nor the second complaint and would respond to both when served. However, the company vigorously denied the claims as described in the complaint as well as those in media reports. Dr. Shimon Eckhouse, president, CEO and co-chairman of the board of the company stated, "The claims are completely meritless. The company did not violate the securities laws in any manner, including specifically its announcements to the public concerning its business growth prospects and product demand as alleged. Furthermore, the company's acquisition of Laser Industries, which is the subject of one suit, was highly beneficial to the shareholders of both companies and will continue to strengthen the company's place in the market. In addition to denying these claims, the company will use all legal means at its disposal, to defend itself against these baseless allegations."

11/6 *CNBC/Dow Jones Business Video* conducted an interview with **Premier Laser Systems** CEO Colette Cozean. In the interview, she explained how the company's new

products would help patients visits to the dentist be less painful. During the interview, Cozean said the company had overcome past accounting problems. She also said the standard curve for dentists is very conservative, they slowly buy anything new. From a price perspective, a study of the first 50 users showed that they made $148,000 after they paid for their laser. "It comes down to only $13 per procedure. So it's very affordable but I think it's scary [for them] to try a new technology". Cozean said Premier has been doubling its revenues almost every year.

11/6 A new treatment, developed by Los Gatos, CA dermatologists Patrick Bitter Sr., M.D. and Patrick Bitter Jr., M.D. of the *Institute for Dermatology & Cosmetic Surgery*, uses pulses of light to eliminate the redness and flushing of rosacea. In a study of sixteen patients with rosacea, Dr. Bitter treated the facial redness using intense pulses of light from a PhotoDerm non-laser system from **ESC Medical**. This laser-like medical device allowed the doctor to precisely set the characteristics of the light energy for each patient's skin, permitting exact treatment of the dilated blood vessels and redness without injuring the remainder of the skin. With the PhotoFacial treatment, the entire face was treated within 20 minutes using repetitive flashes of light. No anesthesia was necessary and patients experienced only mild redness immediately after treatment.

11/7 Within a few days following the announcement of the amended class action suit against **ESC Medical**, several other law firms jumped on the bandwagon, including: **Milberg Weiss Bershad Hynes & Lerach**; **Schiffrin Craig & Barroway**; **Schatz & Nobel**; and **The Law Office of Leo Desmond**.

11/9 **Brentwood Venture Capital** announced the closing of its largest venture capital fund, *Brentwood Associates IX*, totaling $300 million. Brentwood Venture Capital is a leading West Coast venture capital partner for early-stage companies, focusing on information technology and health care. Brentwood's newest fund will enjoy a strong and diverse group of Limited Partner investors. Returning investors include long-time supporters **Harvard Management Co.**, **Brinson Partners**, **Horsley Bridge Partners**, **St. Paul Venture Capital**, **ARCO**, **Mellon Bank**, **The Walt Disney Company**, **Pfizer**, **TIFF**, **Memorial Sloan-Kettering Cancer Center**, and **The Duke Foundation**. Ross Jaffe, Brian Atwood and old friend Bill Link (formerly president of **American Medical Optics**) lead Brentwood's health care investment practice.

11/9 **Laserscope** announced that it had sold its hospital equipment business unit to **Heraeus Medical Inc.**, a newly established division of **Heraeus Holding, GmbH**. Laserscope acquired the hospital equipment business, later renamed **Ascent Medical Systems**, as part of its acquisition in 1996 of **Heraeus Surgical Inc.** from **Heraeus MED GmbH**, a subsidiary of Heraeus Holding. "The sale of AMS is the planned outcome of the corporate restructuring goals announced in July when we established AMS as a stand-alone business unit," said Robert McCormick, Laserscope president and CEO. "The divestiture of AMS returns Laserscope to a pure laser company. It allows

management to concentrate its full attention on Laserscope's core business of leading-edge laser systems and energy delivery devices for the office, outpatient center and hospital markets." Laserscope will receive approximately $1 million in cash, subject to the release of $200,000 from a related escrow account, and a settlement of $1.5 million in associated liabilities. Laserscope also said it expects to take a non-operating charge in the range of up to $1 million in the current quarter directly related to the divestiture.

11/10 **ThermoLase Corporation** reported that revenues for the year ended October 3, 1998, were $40 million, compared with $45.2 million in fiscal 1997. Net loss for the year was $41.2 million ($1.07 per share) compared with a net loss of $12.4 million (31 cents per share) last year. "Fiscal 1998 was an extremely difficult year, but we are working hard to make 1999 a turning point for our company," said Gerald Feldman, president and CEO of ThermoLase. "We have begun to implement significant changes. Laser-based services -- including hair removal and our new SoftLight Laser Peel -- will be integrated with **Greenhouse** traditional spa services. In addition, we are redesigning our licensing programs in the U.S. and overseas, and diversifying **CBI's** business to include our own higher-margin branded products."

For the fiscal fourth quarter, revenues were $9.6 million and the net loss was $22.3 million (57 cents per share).

11/10 **QLT PhotoTherapeutics** released its financial results for the third quarter and nine month period. For the quarter, the company reported a net loss of $6.4 million (24 cents per share) compared to a net loss of $3.7 million (14 cents per share) for the same quarter last year. For the nine month period, the company reported a net loss of $16.6 million (63 cents per share), compared to a net loss of $11.9 million (46 cents per share for the corresponding period in 1997. QLT reported royalty revenue for the third quarter of $529,000 on end-user sales of PHOTOFRIN of approximately $2.6 million. This represents a 150% increase over the same period last year and a 65% increase over the second quarter of 1998. Worldwide unit sales rose 89% in the third quarter of 1998 compared to the previous quarter, predominantly due to strong growth in the United States. R&D costs for the third quarter of 1998 totaled $5.9 million representing a 22% increase from the corresponding quarter in 1997, and a 14% increase over the second quarter of 1998. "We expect R&D spending to rise in the fourth quarter of 1998, as we prepare to assess the results from our pivotal Phase III clinical studies of verteporfin (BPD-MA) for the treatment of age-related macular degeneration (AMD), and as QLT expands its development programs in oncology and autoimmune disease," said Kenneth Galbraith. "Pending the completion of the analysis, an announcement regarding preliminary results of these Phase III trials in AMD is expected to be released in the first quarter of 1999."

11/10 **Cell Robotics International** announced financial results for the third quarter and the nine month period. Revenues for the quarter were $273,900 compared to $293,700 in the comparable quarter of the previous year. Revenues during the quarter were $237,400 compared to $188,000 during the same quarter in 1997; an increase of 26%. The company reported a net loss for the quarter of $672,000 (13 cents per share) compared to a net loss of $712,700 (14 cents per share) for the same quarter last year.

For the nine-month period, revenues increased 27% to $1.1 million up from $828,600 for the same period in 1997. Revenues for the nine-month period increased 24% from the same period last year. Year to date total revenues exceeded total fiscal year 1997 sales figures. The company reported a net loss for the nine-month period of $1.5 million (29 cents per share), compared to a net loss of $1.8 million (36 cents per share), for the comparable period last year.

During the quarter the company shipped the first order of its leading-edge laser finger perforator for the blood glucose testing market, the Lasette, to its strategic marketing partner **Chronimed**. In addition, Chronimed made an initial equity investment in Cell Robotics for the joint development of a home use version of the Lasette for the rapidly growing worldwide diabetic market. Cell Robotics goes into the fourth quarter with a backlog of orders for its three main product lines: the Cell Robotics Workstation, the In Vitro Fertilization Workstation and the Lasette. This will be the first quarter in which the company will be shipping all three product lines.

11/10 Dr. Keith Horvath of **Northwestern University Medical Center** presented three year results of transmyocardial revascularization (TMR) using The Heart Laser System, developed by **PLC Systems**, at the American Heart Association (AHA) Meeting in Dallas. The long-term TMR analysis included 70 patients and eight hospitals. Each patient suffered from severe, chronic angina (chest pain) before receiving treatment with The Heart Laser System. The average age of the patients at enrollment was 63. The average preoperative angina class for the group was 3.8. Angina is measured in classes ranging from one to four, one being the least painful and four being the most painful. After an average of 34 months following the TMR procedure, the group's average angina class was significantly improved to 1.5. This was virtually unchanged from the 1.4 average angina class reported at 12 months postoperatively. In fact, 23% of the patients reported having no angina and 58% were in class 1 or 2, three years after TMR with The Heart Laser System.

11/10 According to a report in *The Wall Street Journal*, a new study also presented at the AHA meeting, suggests that patients undergoing coronary artery bypass surgery may have a significantly better outcome if they also get laser TMR. Keith Allen, MD, at St. Vincent Hospital and Health Care Center in Indianapolis, reported on a randomized study of 266 patients that just 1% of those who also received laser treatment died within 30 days of the procedure, compared to 7% of those who had

bypass surgery alone. Timothy Gardner, chief of cardiothoracic surgery at the University of Pennsylvania in Philadelphia, called the findings "startling" and indicated that if they held up in further studies, they would provide validation for the laser technique. Dr. Allen used **Eclipse Surgical Technologies'** TMR laser system.

11/11 **Medical Alliance**, announced results for its third quarter and nine month period. For the quarter, revenues were $3.9 million compared with $4.6 million a year ago. The company achieved break-even, compared with a net loss of $275,000 (5 cents per share), in the prior year period. For the nine months revenues were $12.2 million compared with $14.7 million a year ago. Net loss for the nine month period was $922,000 (15 cents per share), compared with a net loss of $2.1 million (34 cents per share) in the prior year period.

The company reported that it had conducted 8,625 medical/surgical procedures and 9,910 aesthetic elective procedures in the third quarter. The aesthetic procedures were down from 12,674 procedures performed in last year's same quarter. For the nine month period, 24,816 surgical procedures and 34,298 aesthetic procedures were performed, down from 27,186 surgical and 38,042 aesthetic procedures in the same period last year.

11/11 **DUSA Pharmaceuticals** reported a significant narrowing in its loss for the third quarter due to a decrease in expenditures following the filing of its first NDA at the end of the second quarter. Since that time, the company has focused its development efforts primarily on manufacturing and scale-up for its lead indication, Levulan PDT for Actinic Keratoses (AKs), and its Phase I/II clinical trial on Levulan photodetection (PD) of bladder cancer. During the quarter, the company also continued the evaluation of its marketing options for Levulan PDT of AKs, including discussions with potential dermatology marketing partners. The company intends to continue to tightly control costs until it has finalized its AK marketing arrangements. However, it will expend the funds necessary for the scale-up and manufacture of its Levulan Kerastick applicators and Blu-U light sources in order to be ready for the commercial launch of the AK indication, subject to FDA approval.

For the three month period, the company's loss totaled $1.1 million (12 cents per share), compared to a loss of $1.9 million (20 cents per share) for the same period last year, and $2.1 million (23 cents per share) for the prior quarter ended June 30, 1998. At the end of the quarter, the company's cash and U.S. government securities position was $7.7 million, compared to $14.5 million at the same time last year.

11/12 **ABIOMED** announced that it had received approximately $750,000 from the National Institute of Diabetes and Digestive and Kidney Diseases to develop a laser-based tissue welding system. The funding was awarded as a Phase II grant under the SBIR program. ABIOMED's program is directed toward the development of products for

sutureless tissue closure. Laser-based systems have the potential advantage of minimal foreign body reaction. ABIOMED's patented technology provides automatic feedback to the surgeon to insure reproducible closures and prevent tissue damage. The ABIOMED system creates a bioactive structure using ultrapure biological carrier proteins and recombinant growth hormones to enhance healing and the strength of the closures.

11/12 **Pharmacyclics, Inc.** reported financial results for its first fiscal quarter with a net loss for the period of $4.0 million (32 cents per share), compared to a net loss of $2.7 million (26 cents per share) in the comparable period of fiscal 1998. During the first quarter of fiscal 1999, revenue was $235,000 compared to no revenue during the first quarter of the prior fiscal year. Revenue consisted of contract research and development related to one of the company's collaborative agreements. As of September 30, 1998, the company had cash, cash equivalents and investments totaling $66.6 million compared to $70.4 million at June 30, 1998.

11/12 **Miravant Medical Technologies** announced financial results for the third quarter with revenues and net interest income increasing to $4.8 million from $1.3 million for the same period in 1997. The net loss for the quarter was $4.1 million (30 cents per share) compared to a net loss of $7.8 million (63 cents per share), for the same period last year. For the nine month period, revenues and net interest income was $8.9 million compared to $3.1 million for the same period in 1997. The net loss for the nine months was $21.0 million ($1.51 per share), versus $19.0 million ($1.53 per share) for the same period last year.

During the third quarter, Miravant announced a shift in its development programs to focus on disease indications with large potential market opportunities such as ophthalmology and oncology. The company also announced that it had safety and treatment data on over 300 patients with its PhotoPoint drug SnET2, a database that is being leveraged into various diseases, such as age-related macular degeneration (AMD), where the opportunities for sales and profitability are strong. The company initiated a restructuring of costs and resources designed to focus on the company's core development programs while reducing the company's annual net operational cash burn rate. As a result of these initiatives, the company reduced this quarters expenses by $2.6 million compared to second quarter 1998. Also during the quarter, new reimbursement programs commenced under the June 1998 amended oncology and ophthalmology license agreements with Pharmacia & Upjohn. Revenues from these reimbursements increased by $2.4 million over second quarter while losses in the third quarter decreased to $4.1 million compared to $9.1 million in the second quarter.

Miravant has commenced phase I clinical trials for prostate cancer, the most common malignancy in American men, and is prepared to begin enrolling patients in phase III clinical trials for AMD during the fourth quarter.

11/13 **Premier Laser Systems** reported that sales for its second fiscal quarter were $3.3 million, up from the $3.1 million reported for the second quarter of the previous fiscal year. For this year's second quarter, the company reported a net loss of $5.5 million (38 cents per share), compared with a net loss of $12.0 million ($1.11 per share) for the comparable period in fiscal 1998. The majority of the net loss reported in last year's second quarter was due to a charge of approximately $11.3 million of in-process R&D and integration costs in connection with the acquisition of **EyeSys Technologies**, now a Premier subsidiary doing business as **EyeSys.Premier**. The increase in selling, general, and administrative expense in this period over last year's comparable period was due to, in large part, accounting fees related to the reaudit of financial statements, legal fees including those related to shareholder litigation, and the relaunch, training and development of a direct sales force. Approximately one-third of the increase was associated with costs related to the 51 percent acquisition of **Ophthalmic Imaging Systems**. Losses generated by OIS are 100 percent consolidated into the results of the company, due to the financial position of OIS. The company also booked an inventory reserve in the quarter totaling $580,000.

For the first six months of this fiscal year, the company reported a net loss of $10.3 million (70 cents per share), as compared with a net loss of $12.7 million ($1.30 per share) for the same period last year.

Chairman, president and CEO Colette Cozean, commented, "Summer is a slow time in our industry in general, and particularly in our overseas markets. We accomplished a lot of rebuilding over the summer, relaunching our dental laser marketing programs and our direct sales force. We are pleased that sales reached the level they did; this allowed us to build some momentum for the busier fall quarter and the important product introductions announced last week.

11/16 I received the **Donner Corporation International** research report on **Trimedyne**, and to my surprise, it posed a positive story about the company. Although the company has had declining sales and earnings over the past few years, the author, Libby Weber has found encouraging information about which to write. Trimedyne has become an established supplier to both the orthopedic and urology markets, with its two holmium lasers, the OmniPulse-Max 80, an 80 watt, 7 joule device, which features a double-pulse mode, enabling the surgeon to double the amount of energy delivered to, for example, a bony structure for cutting or ablation; and the OmniPulse Jr 30 watt, 2.5 joule system, useful for fracturing stones in urological applications, creating smaller residual pieces than the pulsed dye systems usually used. The holmium systems also find use in ENT, gynecology, and certain other specialty applications.

But orthopedics and urology applications remain the major revenue producers for the company. Trimedyne is still working on its Monarch cosmetic laser, which has yet to be identified as to laser type. According to a company source, the original device has

been redesigned to deliver two wavelengths, either together, separately, or in trains of pulses, and should be ready for marketing mid-1999. However, the potential "home run", so to speak, is the TMR Laser System being developed by its **Cardiodyne** subsidiary, which uses an 80 watt holmium laser able to make larger channels more quickly that the 6 to 20 watt holmium systems from **Eclipse**, **Cardiogenesis**, **Cormedica**, and **Laser Industries/ESC Medical**, and is further differentiated by the addition of an injection system which will be used to add angiogenic growth factors, genes, or genes plus a virus (to cause the expression of the growth factor) -- at the physician's discretion -- during the procedure, to enhance the growth of capillaries along with the formed TMR channels. The question posed is, will Cardiodyne's system be enough to turn Trimedyne around, since it is years behind several of its competitors, like the recently panel approved Eclipse system. An IDE is on file and the company expects to start clinical trials in February. The company expects to file for its PTMR system early in 1999 and begin those trials by mid-year. (It should be noted that an export license is in hand, and as soon as CE Mark approval is obtained, hopefully early next year, the company can begin shipping its TMR laser internationally, to fill a backlog of orders that it has obtained.) As noted in a news release shown below, the system was on display at the American Heart Association meeting, and generated a lot of interest. However, the cost of running human clinical studies is substantial and will require Cardiodyne to either raise a substantial amount of money, or enter into a collaborative/marketing arrangement with an established cardiovascular device company.

For a company whose revenues have been decreasing over the past several years, and which has yet to show a profit (except for an extraordinary payment for the licensing of technology in its last reported quarter), the Donner report was quite upbeat.

11/16 **Laser Corp.** announced results for the third quarter with revenues of $850,883 as compared to $1.3 million for the same period in 1997. This resulted in a net loss for the period of $241,572 (28 cents per share) as compared to net income of $16,241 (2 cents per share) in 1997. For the first nine months of 1998, revenues were $2.4 million as compared to $3.7 million for 1997, which resulted in a net loss of $784,466 (90 cents per share) versus a net loss $58,708 (9 cents per share) for the same period in 1997.

Joyce Wickham, president and CEO commented that while the company's progress towards its goals of intermediate and long term growth was not reflected in its third quarter results, the company is continuing its efforts to expand its industrial laser product sales and medical product sales organizations, to complete the beta site testing of its NuvoLase 532 medical laser system, and to develop and broaden its medical and OEM product base through its ongoing engineering activities. (Also note the corporate developments reported from the AAO meeting, where **ARC Corporation** became a

subsidiary of Laser Corporation, for the purpose of selling both cataract removal and dermatological lasers to the ophthalmic community.)

11/16 **Trimedyne** announced that its 90% owned subsidiary, **Cardiodyne Inc.**, displayed its proprietary Angiogenic Injection and Laser TMR System at the American Heart Association meeting in Dallas. Marvin Loeb, chairman, said, "Cardiodyne's Angiogenic Injection and Laser TMR System received considerable interest from cardiologists and cardiac surgeons at the American Heart Association meeting last week. TMR is believed to stimulate the growth of new vessels in the heart (angiogenesis), and supplementing the body's supply of angiogenic growth factors by injecting such agents along with Laser TMR is a logical next step in the treatment of coronary artery disease." Loeb continued, "Several papers on animal studies were presented by independent researchers which showed the injection of angiogenic growth factors or genes along with TMR using lasers of other companies produced better results than either the injection of angiogenic agents or laser TMR alone...In one such animal study, after intentionally closing a major coronary artery, angiogenic injection plus laser TMR caused sufficient vessel growth to completely normalize the animals' heart function, in effect a `natural bypass'. If these results can be duplicated in humans, bypass surgery and balloon angioplasty may not be needed by many persons suffering from angina pectoris. Angina affects an estimated 4 million people in the U.S. and causes severe chest pain due to a blockage in one or more of the coronary arteries."

Cardiodyne has completed its initial series of animal studies and submitted an application to the FDA to test its Laser TMR System in angina patients who have failed all other available therapies. If animal studies of its Angiogenic Injection System are successful, Cardiodyne plans to amend its application and seek FDA approval to test its Angiogenic Injection System with Laser TMR in humans in early 1999.

11/18 Scott Baily, senior analyst and vice president at **BlueStone Capital Partners LP** issued his long-awaited medical laser industry report, initiating coverage of several medical laser companies, including **Laserscope**, **ESC Medical**, **Coherent Inc.**, and **American Dental Technologies**. The firm has previously written about both **Premier Laser Systems**, and **BioLase**. This report, nearly 100 pages in length, covers all aspects of the medical laser industry except ophthalmology (which Scott hopes to cover at a later date). From providing a brief history of the medical laser industry, to explaining how lasers work, to tissue interactions, to major trends facing the industry, to covering the "hot" application areas (aesthetic/cosmetic, dentistry, TMR and photodynamic therapy), the report is as thorough as I have seen. Entitled "Medical Lasers: Shedding Light on an Attractive Small Cap Industry", the report looks at the new markets and technologies that are spurring growth, to values and attractive prices of the several companies covered.

As he notes in his introduction, "With a number of innovative medical applications on the horizon that require new lasers to perform the procedures, we believe small cap investors can outperform the market by investing in the best companies of the medical laser industry."

Scott initiates coverage of the firms listed above by rating American Dental with a "buy" rating; Coherent, and ESC Medical as "long-term buys"; Laserscope and Premier Laser as "holds"; and BioLase with a "strong buy" rating.

As with the **Dain Rauscher** report on laser refractive surgery, this report is also "must reading" for anyone who wants to know what's going on in the medical/surgical side of the business. (Scott Baily can be reached at 212-850-0558, or by email at sbaily@bluestonecapital.com.)

11/18 Both *Laser Focus World* and *Biophotonics International* contain articles on the suddenly "hot" laser cardiology market. Kathy Kincade, editor of *Medical Laser Report*, in her Medicalwatch column in LFW, writes about the various companies working on TMR in her "Heart patients find new hope in transmyocardial revascularization" article. About the only company she is missing (because I didn't tell her about it until after she submitted the piece) is **Clinicon** and its new LaserDrill probe for TMR. (As reviewed in my attachment to last month's newsletter.)

Kevin Robinson, writing in BioPhotonics discusses some of the clinical results of TMR in his piece, "Laser Heart Treatment Wins FDA Approval, but Questions Remain". As he puts it, "In the wake of the FDA's approval of the use of $CO_2$ lasers for transmyocardial revascularization, other companies using Ho:YAG and excimer lasers are queuing up for their turns at the approval process. No one yet knows whether the procedure actually improves the heart's function, or whether the reduction in chest pain associated with the procedure comes from another quarter."

Also in the same issue of *BioPhotonics International*, **SDL, Inc.**, a producer of OEM diode lasers, announced the availability of a 3 watt, 630 nm OEM laser for photodynamic therapy applications. This laser was specifically developed to replace the much more costly dye lasers for the activation of Photofrin in the treatment of cancers. (Companies with developed diode laser systems for activating Photofrin include **Ceramoptic**, **Diomed** and **Zeiss** in Europe, all of which hope to bring their systems into the U.S. in 1999. **Laserscope** is also believed to be working on such a system for the U.S. market.)

11/18 A company called **The Next Phase** has announced the availability of an overview report of the arterial restenosis industry. The study is entitled, "Developments and Trends in Arterial Restenosis: Prevention and Treatment". The company claims that this is the first in a planned series of market overviews called Situational Market

Analysis Reports covering various aspects of the medical/pharma industries. For information, contact Victoria Hunsicker Sanko, president of The Next Phase at 425-869-8724, or by email at info@thenextphase.com.

11/19 **Trimedyne** announced it had settled its lawsuit against **C.R. Bard Inc.** The net proceeds to Trimedyne, after legal fees and costs, is expected to be approximately $6.5 million. Bard has agreed to pay the full amount by Nov. 30, 1998. Marvin Loeb, chairman of Trimedyne, said, "Settling this matter before the trial will save considerable cost and management time. It will also enable us to concentrate on expanding our present business, complete the Heart Revascularization System being developed by our subsidiary, **Cardiodyne Inc.**, and allow us to continue the development of other new laser devices for use in urology, cosmetic surgery, gynecology and neurosurgery."

11/20 **Lasertec International** announced it had completed a private placement for $4.3 million. The proceeds of the private placement will be added to working capital, principally to continue the development of its laser-based products.

11/23 **Surgical Laser Technologies** announced that it has received the necessary Japanese regulatory approvals to begin selling its laser delivery systems and accessories in Japan. This regulatory approval, referred to as a Shonin, applies to the company's laser fiber-optic delivery systems, probes and scalpels, and related accessories. The company is currently in the process of implementing the necessary packaging and labeling revisions required by **Olympus Japan Co. LTD**, the holder of SLT's Japanese distribution rights. Olympus will market the SLT products in Japan under the **Diomed** label, for use with a diode laser manufactured for Olympus by **Diomed Limited** of Cambridge, UK. SLT and Diomed entered into a private label agreement in June 1997. Commenting on the announcement, Keith Stoneback, SLT's president and CEO stated, "This Shonin represents the culmination of our efforts to enter the laser fiber delivery system market in Japan. Our previously announced private label agreement with Diomed provided SLT access to the very strong marketing and distribution resources of Olympus. We are anxious to complete the final packaging and labeling revisions required by Diomed and Olympus, enter the Japanese market and receive, what we believe will be, positive customer response to our fiber delivery system product lines in Japan."

11/23 **Eclipse Surgical Technologies** announced that **U.S. Venture Partners** (Menlo Park, CA) and **Venrock Associates** (New York, NY) had made a $5.5 million equity investment in **MicroHeart Holding, Inc.** Following this investment, Eclipse contributed certain licenses, patents, and other intellectual property related to MicroHeart's business in exchange for stock and warrants in MicroHeart. In addition, Eclipse has agreed to perform research and development activities over the next year, for which it will be reimbursed by MicroHeart. "We are pleased to collaborate with

two of the top venture capital firms in the country," said Dr. Douglas Murphy-Chutorian, Chairman and CEO of Eclipse. "U.S. Venture Partners and Venrock Associates bring to MicroHeart a wealth of experience in the biotechnology and medical device industries." Eclipse now owns less than 20% of the outstanding shares of MicroHeart. On a fully diluted basis, if Eclipse were to exercise all of its warrants, Eclipse would then own a majority position in MicroHeart, which designs and develops devices for drug delivery of growth factors to promote angiogenesis in the heart. Myocardial revascularization utilizing angiogenic drugs and growth factors is a nascent technology intended to provide a new therapeutic approach to the treatment of coronary artery disease and associated symptoms such as angina. (Note: Trimedyne is also actively working in this area, with the development of an injection system to inject angiogenesis agents into the heart in conjunction with its TMR laser system -- see the November 16th brief above.)

11/23 **BioLase Technology** announced the results of operations for the third quarter and nine-month period. Sales for the quarter were $87,686 compared with $604,681 for the comparable 1997 quarter. Sales for the nine month period were $586,303, compared with $1.2 million for the comparable 1997 period. The decrease in sales for both the three and nine-month periods in 1998 was primarily the result of the deferral of most deliveries of the Millennium laser-based HydroKinetic tissue cutting system, particularly those to the company's German distributor which had been the most significant customer for Millennium systems, while the company was in the process of completing a partial redesign of the hand piece for that system. The net loss for the third quarter was $6.7 million (41 cents per share) compared with a net loss of $513,247 (4 cents per share) for the third quarter of 1997. The net loss for the first nine months of 1998 was $8.7 million (59 cents per share) compared with a net loss of $2.0 million (15 cents per share) for the comparable 1997 period. The net loss for both 1998 periods included a non-cash charge of $5.1 million for the write-off of purchased research and development costs principally associated with the July 1998 acquisition of the assets from **Laser Skin Toner Inc.**, a development stage company. Excluding that write-off, the net loss for the three and nine-month periods in 1998 would have been $1.5 million (9 cents per share) and $3.5 million (24 cents per share), respectively. In addition to the write-off of purchased research and development costs, the increased loss is attributable principally to the decreased 1998 sales and the higher 1998 overhead costs incurred to prepare the company for higher production levels.

11/24 **American Dental Technologies** announced that sales for the fiscal fourth quarter of 1998 remain strong and are in line with management's expectations for a year of record sales.

11/24 *News Page* reports that an unassigned patent was issued covering hair removal with a laser system and waveguide, probe, or needle, which is apparently inserted into a hair follicle and pulsed laser energy used to destroy said follicle.

11/30 **Diomed**, a world leader in medical diode laser technology, launched the LaserLite compact and lightweight aesthetic laser in the European market following award of the CE Mark under the Medical Devices Directive. Operating at a wavelength of 810 nm, the LaserLite diode-based system is used by physicians for hair removal and treatment of pigmented and vascular lesions, including leg veins and telangiectasia (spider veins).

**MEDICAL/SURGICAL LASER UPDATE -- DECEMBER 1998**

11/18 A notice on the **Westergaard** web page provided some of **Premier Laser Systems'** CEO Colette Cozean's remarks at a recent Westergaard Conference. Apparently, the company now has 93 patents issued and pending covering their dental laser products, and has "captured" more than 70% of the market for dental lasers (?). Included in the patent portfolio is a patent on the use of water with their erbium:YAG laser (similar to technology patented by competitor, **BioLase**). Colette also noted that its tooth whitening laser, the Arago is priced at $5,500, and should pay for itself within six months of purchase. She also said that some 30,000 U.S. dentists have now attended some kind of seminar or class on dental lasers, three times the number just a year ago. Word of mouth about dental lasers is bringing in eight new patients a month to dentists who are using them.

11/30 According to *The Gray Sheet*, the announcement earlier this month (see the November 23rd brief) by **Eclipse Surgical Technologies** about **MicroHeart Holdings**, didn't make the point that MicroHeart had been a subsidiary of Eclipse until the spin-off made possible by the equity investment by two venture capital companies. MicroHeart was formed by Eclipse in October 1997.

11/30 A news note about a new microwave (?) device being used to cure snoring and nasal congestion caught my attention. Upon looking into it, I learned that the device was the Somnoplasty radiofrequency surgical system from **Somnus Medical**, that was 510(k) cleared on November 4th for the treatment of obstructive sleep apnea. The company has launched the product and expects to have a network of 25 company representatives and 15 distributors in place by the end of 1999, with anticipate placement of 1500 systems, up from 400 at the end of this year. The device had already been cleared for the treatment of nasal obstruction and snoring. The radiofrequency device sells for $15,000-$20,000, while handpieces range from $100 to $300.

11/30 **Pharmacyclics** said that updated interim results from its Phase I study with ANTRIN photoangioplasty for patients with atherosclerotic peripheral arterial disease were reported at the meeting of the Radiological Society of North America (RSNA) in Chicago, as a "hot topic" discussion in the cardiovascular session. Eighteen patients had been treated at Stanford University Medical Center in the ongoing Phase I study.

The trial was designed primarily to evaluate the safety of ANTRIN followed by photoangioplasty in patients with severe symptomatic arterial insufficiency involving the major arteries of the lower extremities. Successive groups of patients received a single treatment with increasing doses of ANTRIN followed 24 hours later by photoangioplasty of a critical lesion. Patients were evaluated both for systemic toxicity and local arterial responses by follow-up intravascular ultrasound (IVUS) and angiograms. ANTRIN was given intravenously and light was delivered to the diseased artery through a 0.89 mm optical fiber catheter using standard percutaneous endovascular techniques.

The data presented update and confirm the statistical significance of results recently presented at the meeting of the American Heart Association in Dallas on November 9th. Response to treatment, defined as an increase of greater than ten percent in the blood vessel opening (minimal luminal diameter, "MLD"), was particularly evident in patients evaluated with IVUS, where responding patients' MLD increases ranged from 10% to 74%.

12/1 *Laser Report* noted that **Spectranetics** was involved in a legal dispute with **White Star Holdings**, concerning a patent license originally given to Spectranetics by **Pillco** in 1993. The license covered the Fox/Coster intraluminal patents (pulsed laser energy within a body lumen). In looking into this matter, I have learned that not all is as it seems. According to the complaint, Pillco assigned all rights to the Fox/Coster patents to an entity called **Interlase Limited Partnership** in 1996, and this was transferred to White Star Holdings on September 11, 1998. White Star filed the complaint on October 15, 1998, claiming that Spectranetics had failed to make a royalty payment of at least $64,827 on July 30, 1998. Now for the interesting part. According to Spectranetics, the reason that they did not make the called for royalty payment was because they had been served with a Garnishment Summons in July, from an Arlington, VA court on behalf of Ken Fox's wife, Wendy Fox. Apparently, she and the good doctor are tied up in a divorce battle, and she wants her fair share! So, not knowing who were the legal owners of the patents -- White Star or Wendy Fox -- the company put the royalty payment into an escrow account and has filed an Interpleader counterclaim against White Star, calling on the court to determine which entity or individuals are entitled to some or all of the royalty payments! I'll keep you posted as this intriguing story unfolds.

12/1 **Spectranetics** reported that two excimer laser angioplasty procedures to open total occlusions (blockages) in the upper leg arteries of two patients were successfully performed at the Cleveland Clinic, in conjunction with the Cleveland Clinic's Peripheral Vascular and Carotid Stenting meeting. Dr. Bruce Gray of the Cleveland Clinic said, "Patients with arterial disease in their legs can experience pain with walking, ulceration, and ultimately gangrene with limb loss. The Spectranetics excimer laser allows for safe traversal of extremely long arterial blockages. These

difficult occlusions typically require bypass surgery; however, the excimer laser coupled with balloon angioplasty can provide excellent results, reestablishing flow within one hour's time. Importantly, patients' clinical symptoms are dramatically improved with the assistance of the Spectranetics excimer laser." More than 3 million people in the U.S. suffer from peripheral arterial disease.

12/1 **Cynosure** announced the release of its Apogee-40, its newest laser for hair removal. The Apogee-40 is a long-pulsed alexandrite system and is the follow-up generation to Cynosure's Apogee laser, used for both hair removal and leg vein treatments. The Apogee-40 has a pulse width of 40 milliseconds, allowing high fluences to be delivered, while avoiding damage to the skin, even in darker skin types. "We've enhanced our position with a 40-millisecond laser that goes beyond the capability of any other hair removal laser on the market," said Robert Hubert, senior vice president and chief marketing officer of Cynosure. "The Apogee-40 ensures that patients can receive a safer, more effective treatment by giving physicians the flexibility they need to match the laser pulse width to the patient skin type."

12/2 **CardioGenesis** reported developments in its contining research into the use of growth factors in conjunction with TMR. The company announced that US. Patent No. 5,840,059, "Therapeutic and Diagnostic Agent Delivery" had issued to the company on November 24, 1998. The patent is directed to the administration of angiogenic growth factors as part of a therapy for severe angina (chest pain) resulting from severe coronary artery disease. The company also announced agreements for exclusive licenses to the patent rights held by co-developers of the technology, **Indiana University and Columbia University**, where researchers had validated the techniques. Terms of the agreements were not disclosed.

"We are very pleased to have obtained this important piece of intellectual property and to have reached agreement with our research partners. We intend to continue exploring the potential of growth factors used in combination with TMR as a therapeutic strategy," stated Allen Hill, president and CEO. The patent is directed to the company's research into the use of growth factors as part of a revascularization treatment. The patent addresses both surgical and percutaneous approaches to combination TMR and growth factor therapies.

12/2 As reported in *The Chicago Tribune*, a new laser treatment apparently can zap small breast tumors without leaving scars or disfiguration. A researcher reported on the new technology, which marries magnetic resonance imaging with lasers, at the Radiological Society of North America (RSNA), meeting in Chicago. Other reports previewed new ways of treating prostate cancer, artery disease and lung cancer. The new breast treatment was described by Dr. Steven Harms, a radiologist at the University of Arkansas, who said it improves upon the concept of the lumpectomy, a cancer treatment that spares the patient's breast but can still be disfiguring. By using

magnetic resonance imaging, Harms said his team has been able to pinpoint breast tumors with unprecedented clarity, enabling physicians to insert a small needle inside the tumor and deliver laser energy to destroy the tumor cells. So far this technique has been applied only to women scheduled to have their cancer treated surgically. Analysis of breast tissue after surgery showed that in all cases the laser treatment had already destroyed the cancerous cells, Harms reported. The next step will be to treat several patients with lasers only and then watch them to compare the rate of cancer recurrence with other patients treated by lumpectomy or the more radical surgery, mastectomy, Harms said. It will take five years to complete that study, he estimated.

12/2 **Photogen, Inc.**, a subsidiary of **Photogen Technologies** has been awarded two U.S. Patents. Patent 5,829,448 covers methods in photoactivation of molecular agents. It recognizes Photogen's innovations for the treatment of plant or animal tissue with two-photon excitation (TPE) of at least one photoactive molecular agent. Other methods claimed in the patent include the treatment of cancer in plant or animal tissue, and for the production at least one photoactivated molecular agent in a particular volume of a material. Not all of the claimed methods recite simultaneous TPE, however, and some are for deep tissue photoactivation.

Patent 5,832,931 covers a method for improved selectivity in photo-activation and detection of molecular diagnostic agents. It recognizes that Photogen has a method for the imaging of plant or animal tissue containing photoactive molecular agents. The method includes treating the tissue with light sufficient to promote TPE of the photoactive agent. This process causes the photoactive agent to emit energy that can be detected as a signal. The present invention also includes a method for imaging of a particular volume of material containing photoactive molecular agents.

12/2 **Rare Earth Medical** announced that it had been awarded U.S. patent, 5,843,073 covering the surgical use of holmium and other mid-infrared lasers delivered through low OH-content silica fibers to facilitate removal and/or repair of biological tissue. The invention is based on work done by Rare Earth Medical's founder, Dr. Edward Sinofsky, in early 1985. To date, the FDA has granted clearance for use of holmium laser systems to treat herniated disks, kidney stones, and benign prostatic hyperplasia (BPH), and in arthroscopic, gynecology and endoscopic sinus surgery procedures. Subsequent to the regulatory clearances, a number of laser manufacturers have sold holmium laser systems into surgical suites across the country, claiming as a key advantage the versatility and wide range of clinical applications for the system. In addition, several companies are in various stages of clinical investigation using holmium laser systems to perform transmyocardial revascularization (TMR and/or PMR). Rare Earth Medical believes the allowed patent claims will have broad applicability to surgical procedures using fiber delivered holmium laser energy. The Company intends to pursue licensing of its rights to the patent to companies currently marketing holmium lasers and/or delivery systems for use in surgical applications.

12/2 **Cell Robotics International** announced that **TransMedica** had withdrawn its appeal to the Federal Circuit Court. On October 15, 1997, TransMedica (formerly **Venisect**) filed a lawsuit claiming that Cell Robotics had infringed its patent for laser perforation of the skin for capillary blood draws. On March 23, 1998 the United States District Court for the Eastern District of Arkansas granted Cell Robotics International Inc.'s motion to dismiss the lawsuit due to lack of personal jurisdiction and improper venue. This ruling was appealed by TransMedica to the United States Court of Appeals for the Federal Circuit in Washington D.C. However, on December 1, 1998, TransMedica withdrew their appeal. Although Cell Robotics believed that no infringement had occurred, the company is satisfied with the TransMedica decision. This action does not prevent any future filings by either company.

12/2 *The New York Daily News* contained a story about dental lasers in conjunction with the Greater New York Dental Meeting taking place in that city. According to the story, "painless lasers are poised to replace delirium-inducing drills as the cavity cleaners of choice." Jinder Khurana, a New York City periodontist noted that, "Everybody's excited about it...The approval just came from the FDA, so that's what everyone's talking about." Khurana went on to say that lasers are silent and you can avoid encroaching on live tissue and thus avoid pain.

12/5 Florida's *Sun Sentinel* reported that Florida's top doctors have urged the state's Board of Medicine to quickly adopt tough new regulations to improve the safety of cosmetic surgery performed in doctors' offices. Dr. James T. Howell, secretary of the Florida Department of Health, lent his support to a set of medical-quality proposals approved by the board's surgical care committee. "We need to move forward quickly," Howell said. Howell said he was concerned about rising numbers of deaths and injuries following common cosmetic surgery, such as facelifts to smooth away wrinkles and liposuctions to remove fat. Hundreds of Florida doctors now perform cosmetic procedures in their offices, and when patients have more than one operation at a time, risks of injury may increase, many experts believe.

The proposed changes include: limiting planned operating times in an office to eight hours and prohibiting patients from staying overnight to recuperate; making all physicians who perform complicated cosmetic surgery in an office register with the medical board and have their offices accredited by an independent group of experts; requiring surgeons to report any deaths or serious injuries that occur in their offices to the state within 15 days and to keep a log of all surgeries they perform.

12/7 **Trimedyne** announced it received the $6.5 million payment from **C.R. Bard Inc.** due under the settlement agreement reached in late November. Receipt of the funds will enable Trimedyne to complete the Angiogenic Injection and Laser Heart Revascularization System being developed by its 90% owned subsidiary, **Cardiodyne**

**Inc.**, as well as continuing Trimedyne's development of new products in urology, cosmetic surgery, neurosurgery and gynecology.

12/7 **BriteSmile** announced that its largest shareholder, **LCO Investments Limited**, had signed a binding agreement to invest an additional $10 million in the company in exchange for 9,302,326 shares of additional common stock. The parties have agreed to issue the new shares against transfer of the funds on December 8, 1998. Anthony Pilaro, a director of BriteSmile, is also a director of LCO and **CAP Advisers Limited**, the sole trustee of a trust which owns all of the interests in LCO.

The BriteSmile board of directors approved the private placement to LCO in order to provide additional capital for the upcoming roll-out of the **BriteSmile Tooth Whitening Centers**. The company is currently scheduled to begin opening the Whitening Centers during the first calendar quarter of 1999 in several strategic locations in California. The Whitening Centers, which will be operated by dentists, will provide the latest in tooth whitening technology directly to consumers, and feature the company's proprietary BriteSmile 2000 Light Activated Tooth Whitening Device and Gel.

12/8 **Cell Robotics International** announced that the FDA had approved the use of its Lasette laser finger perforator for home use by diabetics. The device will be available by prescription from its exclusive distributor, **Chronimed, Inc.** The Lasette is the first laser-based medical device cleared by the FDA for use in the home. In its release, the FDA stated:

"The FDA today granted market clearance to a first-of-a-kind device that offers people with diabetes a means of drawing blood without using traditional lancets (small, razor-sharp devices for puncturing the skin). The device, the Cell Robotics' Lasette, is a portable, battery operated erbium:YAG laser that can be used in the home after patients have received a prescription and requisite instruction from their health care provider. `Today's action may improve the quality of life for many Americans who suffer from diabetes,' said Dr. Donald B. Burlington, director of FDA's Center for Devices and Radiological Health. `It highlights the many important ways that advanced technologies can contribute to our everyday health care needs.' The Cell Robotics' Lasette uses laser energy to penetrate the skin. Clinical testing has shown that adequately trained patients can perform finger pin-pricks with the laser device as easily and accurately as with lancets. The Lasette has been proven effective with both adults and juveniles who have diabetes."

Ronald Lohrding, chairman and CEO of Cell Robotics, commented, "We are very pleased that the FDA has cleared the Lasette for home use. Many people with diabetes avoid conducting daily glucose tests because of the pain associated with the needle sticks necessary to draw adequate blood, resulting in a deterioration of health. The

Lasette will permit people with diabetes to avoid daily painful needle sticks and consequently they may monitor their glucose levels more consistently, leading to improved health."

Diabetics' bodies cannot regulate glucose, or blood sugar. Millions stay alive by controlling their glucose with insulin shots, which they time by pricking their fingers to check their blood sugar. The repeated finger-pricks are painful, particularly on children's tiny fingers. But an estimated 70% of diabetics fail to test themselves daily. That neglect is dangerous because the tighter control diabetics maintain on their blood sugar, the less likely they are to suffer blindness, heart disease and other complications of the disease. However, diabetes experts warned the laser may prove too expensive for many patients. And even though it's just the size of a VCR tape, it's still too big for many people to conveniently carry around all day. "If it's atrociously expensive, it will not be accessible," warned Dr. Bob Goldstein of the Juvenile Diabetes Foundation.

Cell Robotics actually makes two types of the laser. Shipping of a specially sized, at-home version won't begin until next year. But diabetics who don't want to wait can immediately begin buying a larger, more complex version the company sells to doctors' offices, for $2,000. The special at-home version will probably cost less, according to a company spokesperson.

12/8 **Spectranetics** announced it had received CE Mark approval for its Vitesse COS coronary angioplasty laser catheter. The Vitesse COS is a next-generation, rapid-exchange laser catheter designed with enhanced optical fiber distribution to create a larger opening in a blocked coronary artery.

12/8 **Palomar Medical Technologies** announced it planned to introduce the new Palomar E2000 Ruby Laser system for hair removal in the first quarter of 1999. The new system is faster than any other hair removal laser on the market and, according to the company, this speed of treatment, combined with safety and efficient use of laser energy, will set the new industry standard. The Palomar E2000 Ruby Laser, which has already been cleared by the FDA, is the successor to the well-known EpiLaser system, still the only laser in the world cleared by the FDA for "permanent hair reduction." Palomar has filed an application with the FDA seeking this same clearance for its new product, which has been in clinical trials since August.

**Coherent, Inc.** will have the right to distribute the new product on a non- exclusive basis, and additional non-exclusive distributors will be announced when agreements are reached with Palomar. The new system's unparalleled speed is particularly important in the treatment of large areas such as back and legs; being capable of treating a pair of female legs in under an hour, or a man's back in about half that time. The new product uses patented contact-cooling technology to protect the skin,

advancing lasers to a new level of safety with the introduction of "Super Cooling" and "Twin Pulse."

Another technological advance and safety feature in this "Smart Laser" technology is "Contact Sensing", in which the laser energy is triggered by sensing optimal epidermal temperature, assisting the user in developing the most desirable long-term effect, while also maximizing laser safety. Additionally, the Palomar E2000 Ruby Laser offers other new and unique characteristics that make it useful for treating a wide range of hair colors and thicknesses, as well as skin types. With these features together in one laser for the first time, the Palomar E2000 Ruby Laser allows the user to dramatically increase patient flow which potentially lowers the cost per treatment.

In a second announcement, Palomar said that it had reached an agreement to sell its majority owned subsidiary, **Star Medical Technologies, Inc.**, to Coherent for $65 million in cash. Under the terms of the transaction, Coherent will also pay an ongoing 7.5% royalty to Palomar on the sale of hair removal products, including Star's current LightSheer Diode laser system. Star, based in Pleasanton, Calif., manufactures the LightSheer Diode system distributed exclusively by Coherent, which will continue to have the right to distribute Palomar's future hair removal products on a non-exclusive basis.

"We created a tremendously valuable asset by aggressively developing Star and its technology during the past few years after forming the unit for less than a million dollars in 1992," said Dan Valente, chairman and CEO of Palomar. "The proceeds from the sale, which we believe are minimally impacted by taxes due to the company's net operating loss carry-forwards, will provide Palomar with a solid financial foundation on which to build our future. The timing of the sale is optimal as we continue to focus our operation on Palomar's strength: developing key technology in large cosmetic and medical markets." Palomar will retain its portfolio of intellectual property, while pursuant to the terms of the agreement with Coherent, patents associated with Star will be transferred to Coherent. Palomar also has worldwide exclusive licensing agreements with **Massachusetts General Hospital (MGH)** and the **Institute of Fine Mechanics and Optics Laser Center** in St. Petersburg, Russia. Palomar will continue to leverage these partnerships to capitalize on new products and new business opportunities.

Bernard Couillaud, Coherent's president and CEO stated, "While we are excited about owning the rights to the LightSheer product, we are not acquiring Star for one product. We view Star as a semiconductor laser company with proven laser diode stacking technology waiting to be applied into commercial and other medical markets. Star's proprietary technology will play a strategic role in the expansion of our Semiconductor Group's laser diode markets. Star's stacking capabilities will broaden

Coherent's applications in a variety of other medical fields and material processing such as soldering, welding and thermal treating, laser pumping, and illuminators."

12/9 **Candela Corporation** announced that its GentleLase alexandrite hair removal laser has become faster acting by means of a new 15 mm spot for increased coverage and faster hair removal times, with lower fluences for treating darker skin types, and an easier to use distance gauge kit. The FDA-cleared system is also used for treating facial veins and other vascular lesions. "The enhancements that we've added further differentiate GentleLase and give us an even greater edge over the competition," said Burt Salkin, Candela product manager. "It's a feature-rich package that delivers outstanding performance -- including Candela's patented Dynamic Cooling Device (DCD) -- at a fraction of the cost of other hair removal devices."

In making the announcement, Candela released the following data from practitioners reports about typical treatment times for the new 15 mm spot size device, but the company notes that the figures are for demonstration purposes only and that actual experiences may differ:

| Area of Treatment | Procedure Time |
|---|---|
| Upper Lip/Chin | 30 seconds to 2 minutes |
| Underarm (Axilla) | less than 5 minutes |
| Forearms | less than 30 minutes |
| "Bikini" | 6-10 minutes |
| Lower Legs | 30-40 minutes |
| Full Legs | less than 60 minutes |
| Full Back/Chest | 30-50 minutes |

12/8 Today's *New York Times* Science section contained an article about dental lasers. Science writer Holcomb Noble wrote, "Much of the dread in the dreaded trip to the dentist is being removed: New treatments are bringing patients freedom from drilling, freedom from anesthesia, and freedom from pain. Moreover, they appear to be, in their initial stages, safer, more accurate, and faster than traditional methods.

Technological advances have, after decades of scientific and engineering effort, produced laser beams that can cut efficiently and without pain into the hardest surface of the body -- teeth -- to remove decay and prepare cavities for filling." He notes that the dental laser was approved for use on adults in May 1997, and for children in October of this year.

Holcomb writes, "The lasers, used with a stream of water sprayed on the teeth, have been successful in dental work done on 1,800 people in clinical trials. All but 1%

reported no pain or need for anesthesia, compared with 70% of those treated with drills."

The development of technology that would apply laser light to the repair of decaying teeth is the culmination of nearly four decades of research and development. A variety of obstacles presented themselves, chief among them the heat generated by the laser that could damage the nerve of the tooth and destroy the fiber optic material needed to deliver the laser beam to the tooth in the first place. A race to harness the new technology had been on since 1964, when Dr. Leo Goldman, director of the dermatology department at the University of Cincinnati, began experimenting with lasers -- powerful, highly focused beams of light. He tried placing various combinations of chemical elements or compounds -- holmium, neodymium, yttrium and lithium among them -- in crystalline cylinders and shooting rays of ordinary light at them. It was not until the 1980s that a team of researchers from academic and private business research groups, led by Dr. Myron Wohlbarsht at Duke University and Dr. Robert Freiberg representing academic and private research groups, hit upon erbium, which in combination with other elements, produced the correct wave length to cut tooth enamel, and the team received a patent for the idea in 1987. But the overheating problem persisted when they tried to use it in animal studies. In the following four years Freiberg, and his team came up with the idea of adding water to absorb enough of the heat before the laser was shot out of the cylinder. The team also reported applying air or water spray to the teeth during its experiments and clinical trials for added cooling and to make the cutting more efficient.

Dr. Colette Cozean, CEO of Premier Laser Systems, and an original member of Freiberg's team, said that the FDA then began a review of the laser data and found it supported the claims made for it. Premier was granted approval for the treatment of adults and later for children. A second manufacturer, Biolase of San Clemente, Calif., which developed a slightly different technology, was given the go-ahead in October for laser work on some but not all types of adult cavities.

Following the publication of the New York Times article, **Westergaard Broadcasting Network**, which covers Premier Laser Systems, came out with its own statement about the Times article, "Five years from today, when every town in America of any size will have at least one dentist employing laser technology to excavate cavities, accepted wisdom will have it that Holcomb Noble's article was a seminal moment in dental history. It will be seen as the defining event which forced the dental profession to come to grips with the reality that the conventional dental drill is a dinosaur...From this moment forward, no dentist can in good conscience treat children for removal of tooth decay by conventional means. Nor will any mother in good conscience drag her child to a dentist that does not employ the 'safer more accurate and faster' technology of lasers as described by Mr. Noble."

12/9 *NewsPage* reports that the Japanese Health and Welfare Ministry has decided to create a Japanese version of the FDA when the government ministries are reorganized in the year 2001.

12/9 Dr. Abdel Fustok, chairman of the **Institute of Cosmetic Surgery**, based in Houston, announced the completion of Phase I of its business plan which projects the development of ICS surgical clinics throughout the U.S. There are currently 3 centers in operation and Dr. Fustok anticipates opening as many as 60 centers over the next 3-4 years. Dr. Fustok recently completed negotiations for the addition of three new surgeons to the ICS staff in early 1999. They will be trained by Dr. Fustok and be assigned to one of the ICS facilities. After familiarization and training, each new surgeon is expected to generate an additional $2 million in revenues. The company has also completed negotiations for the newest surgical clinic, to be located in southwest Houston.

12/9 The first photodynamic therapy treatment for early-stage lung cancer in the Boston area was performed at the Beth Israel Deaconess Hospital by Drs. Armin Ernst, director or Interventional Pulmonology, and Joseph Locicero, a thoracic surgeon. Now that the first procedure has been performed, the doctors believe that a large number of patients in the New England area will benefit from the procedure.

12/11 **Cell Robotics International** announced that it had received ISO 9001 and EN46001 certification by ISO qualifying agency, **TUV Essen**. The award of this certification insures that Cell Robotics' products meet quality standards that have been accepted by over 100 countries and thousands of organizations throughout the world.

12/11 *NewsPage* reports that **Eclipse Surgical Technologies** had received a U.S. Patent covering a method and apparatus for performing TMR which utilizes two laser sources.

12/11 **Pacific Pharmaceuticals** and **Procept, Inc.** announced that they have signed a definitive agreement contemplating the merger of the two companies. The combined company, Procept, Inc., will have a product portfolio with a focus in anti-infectives and oncology, including three novel technologies in human clinical trials which may be candidates for accelerated regulatory approval and funding, anticipated to propel the company's development agenda forward.

The management of both companies believe that the merger strengthens the combined company's ability to leverage its collective resources, research expertise, and intellectual property, into successful product development, and attract corporate partnerships more readily than either company alone.

12/14 **Palomar Medical Technologies** reports that the investment firm **Fechtor, Detwiler & Co.** had reiterated its "speculative buy" recommendation for Palomar, following the announcement that Palomar had reached an agreement to sell its subsidiary, **Star Medical Technologies** to **Coherent, Inc.**

12/14 The November issue of *Photonics Spectra* contains a letter to the editor explaining that past problems with sapphire fiber delivery systems for **Premier's** Centauri erbium:YAG dental laser have been solved. Premier, working with its sapphire fiber supplier, **Saphikon, Inc.**, have collaborated on a redesign of the fiber optic delivery system, leading to a far more reliable system, according to Jeremiah Fitzgibbon, director of sales & marketing for Saphikon. (The original article on dental lasers appeared in the August issue of Photonics Spectra.)

12/15 **Clinicon Corporation** announced that its patented Diamond LaserKnife had received FDA clearance for use as a scalpel for incision or excision, with or without cauterization/coagulation, in multiple medical specialties such as dermatology, general surgery, plastic surgery, neurosurgery, ophthalmology, otolaryngology, and urology.

The patent protected Diamond LaserKnife, creates and controls a uniform field of laser energy for even hemostasis at the scalpel/tissue interface, while providing the surgeon with highly sensitive tactile feedback. Energy penetration into tissue to cause reliable cauterization can be as shallow as a single cell layer, and can be finely regulated to the level needed so that collateral tissue damage is minimized. And, when used for cosmetic surgery, the significantly improved post-operative results show less bruising, leading to faster healing and recovery.

The new diamond laser scalpel is designed to work in conjunction with the company's SureFlex wave-guide delivery system. The Diamond LaserKnife and SureFlex wave-guide will work with most installed $CO_2$ laser systems, or with Clinicon's new 9.3 micron $CO_2$ system.

"This revolutionary and unique proprietary product, for the first time combines the superior cutting capability of diamonds, with a uniform and controllable field of laser energy at the diamond interface, while providing the surgeons with tactile feedback", said Fritz Brauer, president and CEO of Clinicon. "This product will revolutionize the way surgery is performed since it allows controlled hemostasis in anatomical regions and on organs of the body where electrocautery is not feasible".

(For more on this unique diamond scalpel product, and the other exciting new Clinicon products about to be introduced into the market, see the bonus writeup included with the October newsletter, or contact me for another copy.)

12/16 **ESC Medical Systems Ltd.** announced that it had acquired the VNX radiofrequency technology, including certain patents and other intellectual property, used for the minimally invasive treatment of large, deep varicose veins from **Ballard Medical Products**. This acquisition demonstrates the company's commitment to creating comprehensive solutions for the large number of patients with leg vein problems. Terms of the transaction were not disclosed. VNX along with the light based PhotoDerm (for the non-invasive treatment of superficial vascular lesions) and The VascuLight (for the non-invasive treatment of the deeper vascular lesions) will provide ESC with a full range of complementary technologies and products to treat the entire scope of vascular lesions including leg veins and varicose veins. The VNX technology uses a radio frequency based energy source transferred through disposable catheters. It is estimated that approximately 600,000 invasive procedures per year are performed in the US to treat vascular indications which can be treated by the VNX minimally invasive technology in the vascular surgery office.

12/16 **Abbott Northwestern's Laser and Cosmetic Care Center** is developing a new laser treatment for removing wrinkles from sun-damaged skin. The center's medical director Brian Zelickson, M.D., released a study that provides hope that pulsed dye laser treatment would have milder side effects than skin resurfacing. The FDA has not approved the pulsed dye laser for wrinkle reduction, but it is routinely used to treat port wine stain birth marks. Zelickson has found that this particular laser appears to reduce wrinkles by stimulating changes in skin cells. He studied ten adults who had moderate to severe sun-induced facial wrinkles. Each received one laser treatment and was examined at six weeks, twelve weeks and fourteen months after treatment. "Five patients had gradual observable improvements, which can be seen in before and after photographs. And, under an electron microscope, skin biopsies from all of the patients showed growth of new tissue," Zelickson said. "The changes might be due to the stimulatory effects of electromagnetic energy on wound healing." (No mention was made of whose pulsed dye laser was used, but Dr. Zelickson is a clinical investigator for the **Candela Corporation** laser systems.)

12/17 **The Oschner Clinic** in New Orleans became the 80th United States site to perform laser assisted cardiac lead removal using the **Spectranetics** Laser Sheath. The SLS is the only device which has received pre-market approval from the FDA for the minimally invasive removal of non-functioning pacemaker and implantable cardioverter defibrillator (ICD) leads which may pose medical complications.

12/17 **Cell Robotics International** announced that the FDA had approved the new smaller Personal Lasette technology for marketing and sale. The development cycle for the Personal Lasette is being completed and it should be available through Cell Robotics' exclusive distributor, **Chronimed, Inc.** in mid 1999, by prescription, for all previously cleared applications. The FDA cleared the Professional Lasette for home-use on December 7th. The Personal Lasette engineering design data was submitted to the

FDA Office of Device Evaluation to explain the modifications that differentiated it from the Professional Lasette. After reviewing the engineering and safety data, the FDA notified the company, based on the information supplied, the safety and efficacy of the Personal Lasette was no different from the previously cleared Professional Lasette. The Personal Lasette will be smaller and less expensive than the Professional model and both can be obtained for home-use with a prescription. A Chronimed company official notified me that the Professional model is priced at $2000, and that the Personal model, which is due to be available in mid-1999, will be priced at $1000.

According to the American Diabetes Association, there are 15.7 million people, or 5.9% of the population in the United States who have diabetes. Approximately 2,200 people are diagnosed with diabetes each day, this is equivalent to more than one person per minute. Worldwide there are over 100 million people with diabetes.

12/18 **Trimedyne** reported financial results for its fiscal year, which included the financial results of its 90% owned subsidiary, **Cardiodyne** on a consolidated basis. Revenues from continuing operations for the fiscal year ended Sept. 30, 1998 were $7.0 million, a decrease of 24% from revenues of $9.3 million for the preceding year. The company's net loss from continuing operations for the current fiscal year was $2.5 million (23 cents per share), including $2.9 million of R&D costs of Cardiodyne, 54% less than the net loss of $5.5 million (51 cents per share) for the prior year. Had the company not incurred Cardiodyne's R&D costs, the company would have had $281,000 of net income for the current year, largely as a result of the company's having sold a non-exclusive patent license for net proceeds of $3.6 million. For the fiscal quarter, the company had net revenues of $1.6 million, compared to $2.8 million for last year's fiscal quarter, and from $1.8 million in the proceeding quarter. The company is in line to have a $6.5 million calendar year, down from last year's $9.2 million.

Marvin Loeb, chairman of Trimedyne, said, "While we are not pleased with these financial results, we believe our investment in the development of Cardiodyne's MLR System and our continued development of other new laser products is vital to our future success...Our financial condition remains strong. In addition to the $6.5 million of net proceeds we received in early December from the settlement of our lawsuit against **C.R. Bard Inc.**, we had nearly $3 million in cash and securities, $1.7 million of receivables and $3.5 million of inventories, with no long term debt and only $1.3 million of current liabilities."

12/21 **Premier Laser Systems** announced that the FDA had granted the company clearance to market its Aurora diode laser for the removal of coronal pulp in pulpotomies and as an adjunct to root canal procedures. This clearance follows the announcement in August that the Pegasus YAG laser had been cleared for these procedures. This announcement is especially important since the Aurora diode laser is widely used for

a range of FDA cleared soft tissue (gum) procedures including sulcular debridement (deep cleaning). The company also announced that Aurora will now include the new pulpotomy upgrade as standard equipment to enable dentists to perform this FDA approved procedure. The feature will include a special optical coupler that enables the use of a 200 micron fiber and handpiece with Aurora, as well as enhanced software and other accessories. The list price of Aurora with the standard pulpotomy feature is $25,000 and deliveries of Aurora with the feature are planned to commence in January. Installed Aurora diode lasers can be upgraded in the field with the pulpotomy feature kit. List price of the field upgrade kit is $2,750, with deliveries also planned to start in January.

According to The American Academy of Endodontics, more than 14 million pulpal procedures are performed each year in the United States. Conventional cleaning and shaping of the pulpal cavity in these endodontic procedures are performed using reamers and files or rotary instruments. With the advent of dental laser systems, these procedures can be cleaner and more comfortable for the patient, enhancing the overall patient experience.

12/21 **Donner Corp. International**, a Santa Ana, CA-based investment banking firm reiterated its "speculative buy" recommendation on **Trimedyne Inc.** Donner analyst Libby Weber said that Trimedyne, which has established itself as a leader in lasers for the urology, orthopedic, ENT, gynecology and general surgery markets, has recently settled a lawsuit against **C. R. Bard Inc.** This settlement resulted in a payment of $6.5 million to Trimedyne, increasing the stock price to approximately $1.50. This settlement will allow Trimedyne, through its 90% owned subsidiary, **Cardiodyne**, to complete the Angiogenic Injection and Laser Heart Revascularization System. This technology may potentially revolutionize the treatment of coronary artery disease.

12/22 According to a writeup in *Medical Industries Today*, **Theratechnologies** of Montreal, Quebec, is screening and enrolling patients for an in vivo clinical trial of photodynamic therapy to treat chronic myeloid leukemia (CML). The study, designed to determine safety and efficacy, will enroll 20 patients during 1999 at Maisonneuve-Rosemont Hospital, a designated provincial transplant center. Hematologists Dr. Denis Claude Roy and Dr. Robert Belanger are the principal investigators. The patients need to have chronic myeloid leukemia but be unable to receive a graft from histocompatible donors. The photodynamic purging process developed by Theratechnologies is a patented technology that allows the patient's own healthy stem cells to be reintroduced after the cancer cells in the graft are destroyed or purged.

Doctors draw a sample of bone marrow or peripheral blood before exposing the patient to a radiotherapy or chemotherapy treatment. Theratechnologies said its method is unique because of the incubation of the cells with a photosensitive agent

(TH 9402) directed against the malignant cells. When the agent is activated by a light source, the graft is depleted significantly of cancer cells. The treated sample is then reintroduced to the patient, who becomes his or her own donor (autograft). Theratechnologies said it has demonstrated the efficacy of the treatment in ex vivo studies. The in vivo trials will measure safety by the time to engraftment and clinical efficacy by the percentage of relapse.

Canadian government regulators classified the treatment as a medical device, reducing the clinical validation period compared with drug approval. The company hopes to commercialize and launch the treatment in 2000.

12/22 **Premier Laser Systems** announced that it will substantially lower the price of Centauri hard-tissue erbium:YAG dental lasers in order to clear out excess inventory that was initially manufactured for a large U.S.-based dental products distributor (**Henry Schein**) earlier in 1998, and with whom the company had a dispute. Centauri lasers, which were the first lasers cleared by the FDA for certain hard-tissue dental procedures, are the only lasers cleared to market for all classes of cavities in adults and children, and have been in use by dentists for more than 18 months. According to the announcement by Premier chairman, president, and CEO Colette Cozean, the lasers in inventory will be priced at $24,950, reduced more than 40% from the current list price of $44,950. This price is only available on Centauri lasers currently in inventory and once those lasers are sold, the price will be re-adjusted upward. (This may be difficult to accomplish. Usually, once a price has been brought down, it is difficult to put it back up!)

Cozean stated: "We have made a commitment to redeploy assets that are now imbedded in inventory by converting that inventory to cash. The company's inventory surplus is now a piece of good fortune for dentists who have considered acquiring a Centauri, but had not yet committed the funds."

12/22 I received an update about the fate of **Mehl/Biophile** from a former executive with the firm. Apparently, the company has been broken up into three separate entities: **SLS Wales**, the ruby laser producer, has bought itself back and is operating independently of Mehl; the consumer product division has rescued the Mehl name and is operating in California; and the laser division, which was supposedly about to enter bankruptcy, was rescued from that fate by its major creditor/shareholder, **Clearwater Funds**, and is trying to decide what to do with the laser assets it still has in storage. (Perhaps this might be an opportunity for another firm to purchase these ruby hair removal lasers?)

12/22 **BioLase Technology** announced that its board of directors had adopted a Stockholder Rights Plan designed to assure that all BioLase stockholders would receive fair treatment in connection with any effort made to take over control of the company. The Plan provides for the distribution of one Right for each share of common stock

outstanding on Dec. 31, 1998. In making the announcement, Federico Pignatelli, chairman, stated, "The Rights are designed to provide the board of directors with adequate time and tools to represent the interests of the stockholders in the event of an unsolicited bid to acquire control of the company. The Plan is not designed to prevent or discourage any offer for the company that is commensurate with its value and is presented in a manner permitting full review and negotiation." The Plan is triggered in the event that any person becomes the beneficial owner of 15% or more of the company's stock, and expires on December 31, 2008!

12/22 *The Wall Street Transcript* has published a special 270 page Health Care edition, for the December 14-16 **ING Baring Furman Selz** Health Care '98 Conference. It features interviews with 11 leading research analysts, and CEOs or top management from 65 Health Care firms. Furman Selz Medical Device & Technology analyst Sam Navarro is quoted as saying, "Because most medical technology breakthroughs and innovations come from small companies, the unspoken rule of "big-is-better" and "small-begets
-breakthroughs" continues to exist." In scanning the list of companies, I found no medical laser companies or medical laser-affiliated companies on the list. Separate copies of the special edition are available from The Wall Street Transcript for $395.

12/22 *The Financial Post* carried a brief story about **QLT PhotoTherapeutics**, noting that its stock price had risen to a 52-week high. The article's author, Garry Marr, speculates that the new high is in anticipation of pre-Christmas approval by the FDA of the use of Photofrin for the palliation of late-stage lung cancer. (As it turns out, the writer was correct, as the announcement was made the following day!)

12/23 Both **QLT PhotoTherapeutics** and **Sanofi Pharmaceuticals** announced that the FDA had indeed cleared Photofrin for the palliation of late-stage lung cancer. Specifically, the approval was for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC). This followed a unanimous recommendation in early September by the FDA's Oncology Drug Advisory Committee. Sanofi, the U.S. marketing partner for QLT, currently markets Photofrin in the U.S. for use in photodynamic therapy (PDT) as a treatment for certain types of early-stage microinvasive lung cancer, and as a palliative treatment for certain patients suffering from esophageal cancer. Photofrin is now available for the new indication to physicians and the nearly 80 medical centers currently conducting PDT procedures in the U.S.

According to the American Cancer Society, it is estimated that 171,500 patients in the U.S. will be diagnosed with lung cancer this year. Approximately 20,000 to 25,000 patients may be candidates for palliative treatment with Photofrin for relief from the debilitating symptoms associated with obstruction of the airways in late-stage NSCLC.

The FDA approval includes marketing clearance for laser systems and a fiber optic used to activate the drug. The device approvals include: **Laserscope's** Series 600 and 630 PDT Dye Modules and Laserscope's Series 800 Laserscope Surgical Laser Systems; the **Coherent** Lambda Plus PDL1 and PDL2 photodynamic lasers; and the OPTIGUIDE Cylindrical Fiber Optic Diffusers.

"Today's FDA decision, the second U.S. regulatory approval for Photofrin this year, and the third since 1995, reflects our steady evolution toward commercial success," said Dr. Julia Levy, QLT's president and CEO. "It also marks another building block in QLT's campaign to widen the availability of photodynamic therapy to patients who can benefit from our innovative technology, and to expand our oncology franchise in the U.S."

"Unfortunately, most of the estimated 171,500 Americans who will be diagnosed with lung cancer this year will be diagnosed at a fairly late stage in the progression of this deadly disease," said Dr. Harvey Pass, Professor of Surgery and Oncology at the Karmanos Cancer Institute, Wayne State University, in Detroit, Michigan. "A significant number of these lung cancer patients will eventually suffer bronchial obstruction and hemorrhaging as the disease progresses, and photodynamic therapy with Photofrin offers patients and oncologists alike an effective alternative palliative treatment."

Commenting on the announcement, Robert McCormick, president and CEO of Laserscope said, "PDT has the potential to be a significant new modality for the safe, selective, and cost-effective treatment of cancer and other diseases. At present, more than 75 healthcare organizations in the U.S. are providing PDT treatment to their patient base, and more than 70 percent of them are using Laserscope's PDT laser systems." McCormick said the company expects to begin its marketing launch for the new indication in conjunction with the launch of the drug by Sanofi Pharmaceuticals, U.S. distributor of Photofrin.

12/23 **BioLase Technology** announced the addition of a diode laser, the BioLase LD-15, to its dental product line. Dentists who have used the product have found it particularly effective for many soft tissue procedures as well as bacteria reduction. BioLase has commenced sales, with several of the new laser systems shipping immediately. The retail price of the new diode system is $24,000.00. Jeffrey W. Jones, newly appointed president and CEO of BioLase, remarked "This new product has won the respect and acceptance of leading dentists. The diode laser, as a soft tissue laser, is a strategically sound addition to the newly approved hard tissue Millennium. Having both systems further strengthens BioLase's position in the dental market."

12/23 **Computer Motion** and **U.S. Surgical**, a division of **Tyco Healthcare Group**, announced that they have formed a strategic alliance to jointly develop instruments for

robotic heart surgery. USS will manufacture and sell cardiac surgery suturing devices for use with Computer Motion's ZEUS Robotic Surgical System. The single-use, ZEUS-Ready instruments will be designed to help surgeons with the challenging task of sewing together small cardiac vessels in minimally invasive bypass procedures. USS will manufacture the devices under a royalty-bearing license and distribute them through its worldwide sales force. (USS is also developing excimer lasers for use in transmyocardial revascularization.)

12/23 As it turns out, Kathy Kincade's Medical Watch column in this month's issue of *LaserFocus World* is quite timely, addressing the subject of the use of lasers for both diagnosis and treatment of high-risk cancers. The article looks at some of the newer laser-based techniques for diagnosing breast cancer and melanoma and other skin cancers.

12/23 The November/December issue of *MedPro Month* discussed the FDA's report on "Trends in Device Technology", released earlier this year. Based on a survey of outside experts, including physicians, engineers, healthcare policymakers, manufacturers, futurists, and technology analysts, the study attempted to identify major anticipated trends in medical device technology over the next ten years, in order to identify areas in which new or significantly increased product development activity was likely. It is interesting to note that on a ranked scale of probability and importance, medical lasers used in surgery ranked ninth (out of 36 ranked device types), with an importance of 4.25 out of a potential score of 5.00, making it almost certain to have a significant impact.

12/24 Canada's *Globe and Mail* ran a story on the latest clearance for Photofrin, discussing the increase in stock price of **QLT PhotoTherapeutics** after achieving clearance for the palliative treatment of lung cancer. The newspaper noted that the company's stock had risen more than 40% since the beginning of November to $33.90, almost near its record high of $38 per share. The story said that according to analysts, the wider approval could double the market for the drug. Another factor for increased interest in the stock might be the **Warburg Dillon Read** recent report, with its "strong buy" recommendation, and featuring bullish comments about BPD, QLT's second generation photosensitizer's potential use in treating age-related macular degeneration.

Some analysts believe that BPD will be the driver of QLT's sales and profit -- and the share price. "That's where all the interest and potential is," said Ezra Lwowski, a Toronto-based analyst who follows the company for **Yorkton Securities Inc.** Michael Lorimer who follows health care stocks for **Scotia Capital Markets**, told clients that photodynamic therapy is one of the most promising new therapeutic techniques in medicine and QLT is a leader in the field. In an earlier report, **ScotiaMcLeod** estimated the global market for BPD at $1.3 billion. Mr. Lorimer noted that QLT's new photodynamic eye therapy drug is competing with a product being developed by U.S.-based **Miravant Medical Technology**. "In our view, Miravant is two years

behind QLT." Under a profit-sharing arrangement with **Novartis**, QLT is going to get 35 cents of every $1 of sales of the new drug to the medical community, Mr. Lorimer said, describing the deal as "above average."

12/24 According to *NewsPage*, a German company, **W&H Dentalwerk, GmbH**, has been issued a U.S. Patent for a laser dental system to provide direct laser radiation to a desired location within a patient's mouth without the use of an optical fiber. (However, the abstract does not say how exactly this is accomplished.)