

## MEDICAL/SURGICAL LASER UPDATE -- January 2004

I somehow managed to miss two press releases from Cynosure during December. To correct that mistake, here they are:

12/2 **Cynosure, Inc.**, announced that it had signed **Europe Skin Care Avenue Corp./Europelab** as distributor of its cosmetic product line for the rapidly growing U.S. salon and spa market. Europelab, headquartered in Montreal, has been commercializing salon/spa products successfully in the U.S. since 1996 and is recognized for its comprehensive technical and educational programs.

"One of the founders of Europelab and their Director of Education, Manon Pilon, has been at the forefront of the skin care industry for nearly 20 years," said Michael Davin, CEO of Cynosure. "We are fortunate to have her company introduce Cynosure's cosmetic products into this new market for us. To continue our success world-wide in existing and promising new markets, we need proven market-specific distribution channels such as Europelab."

In the U.S., overall U.S. spa revenues doubled from 1991 to 2001, jumping from \$5 billion to \$10.7 billion, while the number of spa outlets increased from 5,300 in 1999 to 9,632 in 2001. Consumers paid 156 million spa visits in 2001, up 71% since 1999, according to a study conducted by **PriceWaterhouseCoopers** for the *International Spa Association* and recently reported on **www.trendsetters.com**. According to figures recently stated by the *Spa & Resort Expo and Conference*, both medical spas and resort/hotel spas have increased by over 140% between 1997 and 2002. **Mintel International Group's** US Day Spas Market Report predicts that, "day spas with medical physicians will be in demand as clients seek botox injections or collagen to stave off the signs of aging."

"Our customers are always looking for new services for their clients," commented Pilon. "New services mean growth. And Cynosure's products are designed especially for our high-end spa and salon customers, particularly those with aesthetic medical affiliations."

Europelab will distribute several of Cynosure's cosmetic products, including:

-- The TriActive for LaserDermology combines the actions of 6 diode lasers, localized cooling and mechanical massage to smooth and tighten skin, on the face and full-body.

-- The Smartepil II Nd:YAG system is a multi-purpose laser for hair removal, facial and leg vein, and skin treatments.

About Europe Skin Care Avenue Corp./Europelab:

Europe Skin Care Avenue Corp./Europelab is headquartered in Montreal, Canada, and is an exclusive distributor of specialized European Skin Care Products and services to the

beauty professionals; Day Spas, Spas, Clinics and Beauty Centers, throughout North America.

Europelab provides the best Skin Care Products and services presently available in the industry, along with comprehensive technical and educational programs. The co-founder and Director of Education for Europelab, Mrs. Manon Pilon, has been commercializing exclusively, the Physioderme Methode across the United States since 1996.

Pilon has engaged nearly 20 years in the skin care industry as an aesthetician spa owner, morpho-lymphatic drainage and morpho-digestive specialist, massage therapist, founder of the most prestigious day spa chain and of a renowned school of esthetics in Montreal. She is also the international educator for the Physioderme Swiss line, one of the most recognized motivational speakers on advanced skin care and marketing and has lead conferences in Europe, Japan, Asia and South America. She also consults for spas around the world. She has been a guest speaker at Les Nouvelles Esthetiques in Paris. She has developed an advanced skin care program for private school consisting of 1,350 hours on skin only. She was named Business Woman in 1992 and 1996, is the award-winner of the Marketing Alpha 1997, the Distribution Alpha 1999 and has been a finalist in the 1999 Canadian Woman Entrepreneur of the Year Awards.

- 12/15 **Cynosure Inc.** announced that it had received additional government clearance for the pulsed dye laser (PDL) for the treatment of acne. The PhotoGenica family of lasers has long been recognized throughout the world for the effective treatment of a wide variety of difficult vascular conditions, including port wine stain birthmarks in infants and children. Now, these same lasers can be used to deliver a gentle pulse of light that causes a self-destructive reaction in acne bacteria, reducing the number of lesions. In addition, the PDL reduces redness associated with inflammatory acne improving the patient's skin.

According to the *American Academy of Dermatology*, there are more than 20 million teenagers who suffer from acne and 10% of them say it is the worst thing about being a teenager. In addition, about 15% of women and 5% of men continue to have acne as adults.

"We are very pleased to receive clearance for the treatment of acne. Many patients, including their parents, are seeking newer and safer ways of controlling this condition," said Michael Davin, president and CEO of Cynosure. "Controlling acne can help prevent disfiguring acne scars that can effect a person's self esteem now and in the future. Now, physicians can offer their patients an safer more gentle treatment using the V-Star, pulsed dye laser."

"Initial published studies show a 52% improvement of acne lesions treated with the PDL," said George Cho, senior vice president, Medical Technologies. "We are looking forward to results of a larger study and to studies conducted by dermatologists with our V-Star lasers throughout the U.S.,"

12/29 **BriteSmile Inc.** announced that it had entered into a strategic alliance with image consulting firm **Professional Polish** to raise awareness among Houston-area consumers of the impact of image on both their social life and their income. Professional Polish Founder and CEO Jeanette Coon, who has over 20 years of cumulative experience as an image consultant, corporate trainer and personal coach, said that research studies show a strong correlation between image and success. A great smile is a good starting point, she said, which is why she endorses BriteSmile.

"My goal is to show people, especially those in the business community, how important image is as a success factor," Coon said. "First impressions are critical. That's why it's easy to justify a teeth whitening treatment like BriteSmile -- it can literally give an instant return on investment."

Lin Zhang, Houston Center Manager for BriteSmile, said she chose to partner with Professional Polish because of the natural fit between teeth whitening and professional image. "No one understands the importance of a beautiful smile more than an image consultant," said Zhang. "Jeanette's business is centered around helping people improve their personal and professional relationships by sharpening their looks, etiquette and communication skills. BriteSmile is an important component of the overall package."

12/30 **Spectranetics Corporation** announced it had reached a settlement with the Special Receiver for **Interlase Limited Partnership** related to litigation involving a royalty dispute. The settlement includes a one-time payment of \$200,000 and no change to the original 1993 license agreement.

Interlase originally claimed it was owed in excess of \$1.1 million in back royalties for certain products used in connection with the removal of pacemaker and defibrillator leads, training services provided to Spectranetics customers, and future royalties on these products and services.

The settlement agreement states that lead removal products are not within the scope of the license agreement and that training services are not royalty-bearing, provided they do not exceed a certain percentage of total royalty-bearing revenue. As a result, future royalty expenses are not expected to be impacted by the settlement and all litigation between the parties has been dismissed. Since the \$200,000 one-time payment has been recorded as an accrued liability in prior periods, the payment will not have an impact on Spectranetics' income statement for the quarter ended December 31, 2003.

"We are pleased to have reached this settlement, which preserves forward royalties at the same rate and on the same products as set forth in the original license agreement," said John Schulte, president and CEO of Spectranetics.

1/2 **BriteSmile Inc.** announced the sale of 369,577 shares of unregistered common stock at \$23 per share for total proceeds of approximately \$8.5 million. Proceeds from the private placement will be used to retire the \$2 million bridge loan announced by the company

on November 26, 2003 and for working capital purposes. The company agreed to file a registration statement covering the shares purchased in this transaction.

**Adams, Harkness & Hill, Inc.** acted as Placement Agent in the private placement of the shares to a group of institutional investors.

The company also announced a 5 for 2 stock split of shares of its common stock with each shareholder of record on January 16, 2004 being entitled to receive 5 shares of common stock of the company for each two shares of common stock held as of the record date.

Subsequent to the sale of the 369,577 shares of common stock in the private placement, the company will have outstanding approximately 4.053 million shares. After the stock split, the company will have outstanding approximately 10.134 million shares.

1/5 According to *The T Sector Online*, **RA Medical Systems** won part of its lawsuit against **PhotoMedex**. In a case alleging theft of trade secrets by a former employee scheduled to go to trial today, Monday, 5 January 2004, that pitted RA Medical, a small local San Diego County-based medical device company against PhotoMedex, one of the largest companies in its industry, was dismissed when the larger company voluntarily dismissed its complaint on New Year's Eve in San Diego County Superior Court. RA Medical Systems Inc., an emerging, medical device company based in Carlsbad, was dragged through lengthy legal action by PhotoMedex, a Pennsylvania-based company with manufacturing facilities in Carlsbad. PhotoMedex has made several claims against RA Medical and Dean Irwin, RA Medical's founder and former PhotoMedex employee, including conversion, misappropriation of trade secrets, breach of contract, and interference with existing PhotoMedex contracts - all of which have been dismissed.

The San Diego County Superior Court on 13 November 2003 ruled in favor of RA Medical and Dean Irwin, the defendants, against PhotoMedex, granting summary adjudication in three of five causes of action, as requested. Remaining causes of action for misappropriation of trade secrets and unfair competition were scheduled for trial this week.

Entrepreneurial Rights at Issue -- Potentially at stake was the ability of a generation of California entrepreneurs to move on from a former employer to new business ventures. "What they have been trying to do is prevent me from practicing my profession," said Dean Irwin, founder of RA Medical, and a former vice president of Research and Development for PhotoMedex.

"I took a lifetime of work, study and knowledge, and, during my four years at PhotoMedex, created the first-generation excimer laser for the treatment of dermatological diseases. In my role at RA Medical, I have applied my laser expertise, and principles and technologies available in the public domain, to create the

second-generation excimer laser. As a scientist, my job is to advance technology, it's what I do."

"We won this case" said Irwin. "PhotoMedex' case was totally without merit, a point the Superior Court Judge made on November 13 when he dismissed most of the claims, and a point that was confirmed by PhotoMedex' voluntary withdrawal of the rest of its complaint on New Year's Eve just as we were about to go to trial. PhotoMedex had approached us to settle and we declined, based on the strength of our case. PhotoMedex then surrendered."

Irwin began developing the second-generation excimer laser for RA Medical about a year after leaving PhotoMedex.

Early Court Decisions Favored RA -- In his 13 November 2003 ruling, the Honorable Michael Anello of the San Diego County Superior Court ruled in favor of RA Medical Systems and Mr. Dean Irwin, the defendants, in three of five causes of action by granting summary adjudication as requested.

The Honorable Judge Anello ruled in favor of RA Medical for three of the five causes due to speculative and insufficient testimony and PhotoMedex's lack of ability to raise triable issues. PhotoMedex was unable to produce evidence of conversion, intentional interference with PhotoMedex's contractual relationships, or breach of contract by Irwin.

1/6 The following day, **PhotoMedex, Inc.** put its spin on the proceedings, announcing that it had brought a civil action against **RA Medical Systems, Inc.** and Dean Stewart Irwin in the Federal District Court for the Southern District of California. PhotoMedex seeks damages and injunctive relief for alleged violations related to false advertising and unfair competition under the Lanham Act and various California statutes. In related news, on December 31, 2003, PhotoMedex withdrew, voluntarily and without conceding its pending claims, from its previous action against RA Medical and Irwin that had been brought in California Superior Court for San Diego County in favor of its case in Federal District Court.

Commenting on the new suit, Jeffrey O'Donnell, president and CEO of PhotoMedex said, "We have brought this action in Federal court on grounds related to false advertising and unfair competition because we believe it will afford PhotoMedex a venue specific to the damages it has sustained to date. We are committed to defending our stockholders' investment in excimer technology, and will take all appropriate steps to do so."

In April 2003, PhotoMedex had brought its state court action against RA Medical and Irwin - its former vice president of technology - based on, among other things, alleged misappropriation of its proprietary information and technology.

1/7 **Lumenis Ltd.** announced that it had reached an agreement with **RH Technologies Ltd.** to outsource its manufacturing and service operations at its Pleasanton, CA site. Currently

Lumenis' landmark Lightsheer System for hair removal with over 2,000 systems installed worldwide, and the Relume and B-Clear Systems for aesthetic and medical-aesthetic applications, are being manufactured in Pleasanton. This agreement is one of the milestones of the company's Turnaround Plan, whereby Lumenis intends to close sites and reduce costs. The company expects to save approximately \$5 million over the next four years as a result of this agreement. The Research and Development and Marketing activities previously based in Pleasanton will be transferred to the company's offices in Santa Clara, CA.

Avner Raz, president and CEO, commented: "RH has a proven track record in running manufacturing operations for medical devices and other high tech products. This new agreement will allow us to reduce costs while maintaining the expertise and highest standards developed over the years in Pleasanton, and at the same time providing continuation of employment for our employees."

RH Technologies Ltd. is a public company traded at TASE (Tel Aviv Stock Exchange), and is considered to be the largest contract manufacturer in Israel. RH will operate at the existing site in Pleasanton, and will supply Lumenis with products and the related parts and service. The agreement is for an initial term of four years and covers approximately 45 employees who will be transferred to RH. RH will also purchase certain inventory from Lumenis. The transaction is expected to close next week.

1/7 **Diomed, Inc.**, a subsidiary of **Diomed Holdings, Inc.** announced that it had commenced legal action in the United States Federal District Court for the District of Massachusetts against **AngioDynamics, Inc.**, a subsidiary of **E-Z-EM, Inc.**, seeking injunctive relief and damages for infringement of Diomed's United States Patent Number 6,398,777 covering the endovascular laser treatment of varicose veins. Diomed, a leading developer and marketer of minimally invasive medical technologies, including EVLT for the laser treatment of varicose veins, acquired exclusive rights to the patent from the five inventors of the procedure in September 2003.

"Diomed has invested more than \$20 million in the commercialization of EVLT over the last three years and we will aggressively protect this investment," stated James Wylie, president and CEO of Diomed Holdings, Inc. "Most importantly, we are fully committed to providing all physicians with open access to Diomed's EVLT technology, thereby ensuring the full range of benefits for patients and the medical community on a long-term basis."

It is estimated that between 25-40 million Americans suffer from venous insufficiency. EVLT represents the next generation of minimally invasive treatment of varicose veins. The procedure takes less than 45 minutes without the need for general anesthesia or hospitalization, and patients experience only minimal discomfort with no scarring. Published clinical studies indicate that EVLT has a 93.4% long-term success rate, and is superior to surgery and alternative technologies used for the treatment of varicose veins.

In a final comment, Wylie went on to say, "Diomed's EVLT system has been successfully used in more than 10,000 procedures since the FDA granted clearance for the procedure in January 2002. Clearly, EVLT is rapidly developing as the standard of care in minimally invasive treatment of varicose veins."

The company declined further comment on the pending action.

- 1/13 A new technology developed by Israeli dermatologists that has been proven safe and effective in treating psoriasis, vitiligo, atopic dermatitis and leukoderma has been cleared by the FDA to be marketed in this country. MultiClear, manufactured by **CureLight Ltd** of Or Akiva, Israel, is the first computer-controlled, targeted phototherapy system which utilizes both UVB and UVA rays. It will be widely available in the U.S. by March 2004, according to company officials.

"This system is a breakthrough treatment for psoriasis, vitiligo, atopic dermatitis and leukoderma," said Dr. Yoram Harth, medical director of CureLight. "It is an effective non-drug alternative, combining the emissions of UVB and UVA from a single optical delivery system, allowing optimal high- intensity, targeted UV band selection for the treatment of these common skin disorders. It protects patients from exposing their entire bodies to harsh and risky treatments of the past," he said.

"Oral tablets, injections, or full-body light boxes cannot zero in on the affected areas, and thus they run the risk of harming the patient systemically or damaging other parts of the skin. Our technology acts only on the affected area," said Harth. "The MultiClear's computerized system allows the exact matching of wavelengths and doses to optimally treat specific skin disorders."

Dr. David Friedman, board-certified dermatologist and former Brown University assistant professor, currently uses MultiClear for his patients. He said, "It's safe, responsive and gets good aesthetic results as well. The choice between using UVB, UVA or tailored combinations of UVB and UVA in one system results in fast improvement of psoriasis, and repigmentation of hypopigmented lesions such as vitiligo and stretch marks. In some vitiligo patients repigmentation may start after the fourth treatment. Typical treatment lasts about five minutes and that's another real plus. Usually less than 10 treatments are needed."

Psoriasis is one of most common skin disorders treated by MultiClear. It affects more than 7 million people worldwide and 200,000 cases are diagnosed each year in the U.S. alone. Current therapies include prolonged use of topical creams, full-body lightbox treatments repeated 30-40 times or life-long weekly injections. Vitiligo is a pigmentation disorder affecting roughly 50 million people or about two percent of the world's population. Atopic dermatitis is a common eczema disorder that also affects millions, usually appearing first in childhood and then persisting throughout an adult's life. Leukoderma or hypopigmented skin appears in stretch marks and acne and surgical scars, and cannot be treated effectively topically or systemically.

MultiClear will be featured at a forum sponsored by the *Aesthetic Buyers Guide*, concurrent with the *American Academy of Dermatology's* annual meeting in Washington, D.C., February 9.

CureLight Ltd is a leader in the development, manufacturing and marketing of technologically advanced, effective and safe phototherapy systems for key medical disorders. CureLight has developed the first light-based systems to ever receive FDA treatment of moderate inflammatory acne. ClearLight, the company's award-winning product, is the first light-based, FDA-approved acne treatment device to be introduced to the U.S. market. iClear, another CureLight Ltd product, is also approved by the FDA for moderate inflammatory acne and is now being marketed to physicians and Medi-Spas around the world. More than 600 clinics worldwide are currently using ClearLight and iClear.

- 1/14 **Spectranetics Corporation** announced that it had submitted a 510(k) application to the FDA, seeking clearance to treat critical limb ischemia patients suffering from total occlusions (blockages) in their leg arteries with proprietary Spectranetics excimer laser catheters. The FDA typically responds to 510(k) submissions within 90 days, although a final decision may take longer. The submission contains supporting clinical data obtained from a subset of the LACI (Laser Angioplasty for Critical limb Ischemia) trial, and was supplemented by data obtained from other similar clinical studies in the U.S. and Europe. In those studies, the 47 patients treated were poor surgical candidates and were not amenable to other minimally invasive percutaneous procedures, such as balloon angioplasty, since the lesions were not crossable with a guidewire. The data reveal limb salvage was observed in 95% of patients surviving for six months with no increase in serious adverse events as compared with the LACI study.

"Patients with total occlusions refractory to guidewire crossing, who are poor candidates for bypass surgery, have so few treatment options that amputation is nearly inevitable," stated John Schulte, Spectranetics' president and CEO. "We have worked with the FDA during the preparation of this 510(k) application, and have made every effort to address the issues raised at the FDA advisory panel review last October. We look forward to FDA's review and the opportunity to provide a new treatment option for patients with this debilitating condition."

#### About Critical Limb Ischemia and the LACI Trial

Critical Limb Ischemia (CLI) is associated with multi-level arterial disease in the vasculature between the thigh and the ankle, and is dominated by occlusions (total blockages) rather than stenoses (partial blockages). The extent and location of the disease make arterial reconstruction, including surgery and balloon angioplasty, difficult. Approximately 1.5 to 2 million people in the U.S. and Europe suffer from CLI, which can often lead to amputation.



The LACI trial enrolled 145 patients (155 limbs) at 15 sites in the U.S. and Germany. Clinical results from the trial showed that CLI patients who are poor surgical candidates can be successfully treated with laser assisted therapy. The primary endpoint of six-month survival with limb salvage (i.e., no amputation) was achieved in 93% of the limbs (legs) treated, compared with 87% in the control group. The control group was comprised of 789 patients with critical limb ischemia who were treated with a variety of standard therapies. Outcomes for this group were published in *The Annals of Internal Medicine* vol. 130 pp 412 - 421, (1999). Additionally, surgery was performed in only 2% of the LACI group compared with 34% in the control group.

On October 2, 2003, a Circulatory System Devices Panel, which is an advisory panel to the FDA, voted 9-1 for nonapproval of the company's pre-market approval (PMA) supplement, citing concerns with the use of a historical control group from a foreign country and the lack of data showing the specific benefits of the laser treatment, which was an adjunctive treatment to balloon angioplasty in most cases and stents in some cases.

- 1/14 **Trimeddyne, Inc.** reported a net profit of \$1.0 million (8 cents per share) on revenues of \$6.5 million for the fiscal year ended September 30, 2003, compared to a loss before income taxes of \$1.2 million (9 cents per share) on revenues of \$7.1 million for the prior fiscal year. Net profit for quarter ended September 30, 2003 was \$172,000 (2 cents per share) on net revenues of \$1.6 million, compared to a loss before income taxes of \$165,000 (1 cent per share) on revenues of \$1.6 million for the year earlier period. Income taxes for both periods were not significant.

This is the company's fourth, consecutive, profitable quarter. The company's cost of goods, G&A, sales and R&D expenses were significantly lower in the current fiscal year and quarter than in the prior fiscal year and quarter, as a result of management's aggressive cost control efforts. Gross profit for the fiscal year was 48.0% of sales, compared to 40.6% of sales in the prior year. Please see the company's Annual Report on Form 10K for audited financial statements.

- 1/15 **DUSA Pharmaceuticals, Inc.** announced a number of new developments. DUSA reported that preliminary Q4 2003 end-user Levulan Kerastick net sales to physicians from its distributors totaled 5,478 Kerastick units, versus 1,938 in Q3 2003 (a 183% sequential increase), and versus 1,722 in Q4 2002 (a 218% year-over-year increase). These increases follow the October 2003 launch of DUSA's sales force, and the signing of various independent sales agency agreements. The preliminary number of BLU-U units placed in doctors' offices has also increased to 406, compared with 360 at the end of Q3 2003 and 329 at the end of Q4 2002.

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "We are delighted to report this significant increase in sales following the launch of our initial sales force, and the continued increase in awareness of our therapy among dermatologists, as highlighted in numerous scientific and educational presentations and publications. Although the costs

related to the addition of our initial sales force and related marketing activities are expected to be greater than the gross profit generated from this level of increased sales, we are very encouraged with the initial increase in sales, and believe that our efforts to penetrate the market are working."

With the increased demand for our products from dermatologists, we have also recently added an additional U.S. distributor for the Levulan Kerastick, in order to handle the broader market. While continuing to work with **Moore Medical**, we have also commenced distributing our product through **Delasco**, a dermatology specialty distribution company that is widely used by the dermatology community. Both companies have also been authorized to sell the BLU-U on DUSA's behalf, in addition to DUSA's direct sales efforts.

- 1/15 **CardioGenesis Corporation** announced that conclusive new data on the long-term benefits of TMR when performed in conjunction with coronary artery bypass grafting (CABG) surgery compared to patients undergoing CABG alone will be presented by Keith Allen, MD at the annual meeting of *The Society of Thoracic Surgeons (STS)* on Jan. 27 in San Antonio, TX. The five-year data presented by Dr. Allen, a cardiothoracic surgeon at Heart Center of Indiana, is a follow-up to the prospective, randomized, multi-center trial data originally published in 2000 in *The Journal of Thoracic and Cardiovascular Surgery*. That published data, which was compiled a year after the surgeries, showed TMR plus CABG provided significantly reduced 30-day mortality when compared to CABG alone (1.5% versus 7.6%).

"We are quickly building on the tremendous five-year data presented at the recent American Heart Association (AHA) meeting," said chairman and CEO Michael Quinn. "At the AHA the data presented showed the substantial angina relief provided by CardioGenesis TMR not only persists to five years, but also helps patients live longer. At the upcoming STS meeting, Dr. Allen and CardioGenesis will, for the first time, provide the cardiothoracic surgical and referring community conclusive data demonstrating the significant patient benefits of TMR achieved as an adjunctive procedure, when used for patients who cannot be completely revascularized with bypass grafting alone."

CardioGenesis also announced that a new minimally-invasive, robotically-assisted approach to TMR will be highlighted at the STS meeting. The company will present the successes of surgeons who have experience in the new minimally-invasive procedure, which also significantly improves patient recovery time. "CardioGenesis will be highlighting at the meeting our exciting new tools designed for the innovative cardiothoracic surgeons who are serious about responding to the competitive pressures in their practice," Quinn said. "Patients and referring physicians are demanding less risky and less invasive procedures and CardioGenesis is providing the minimally invasive solution for TMR."

- 1/20 **Lumenis Ltd. and Syneron Medical Ltd.** announced that they had agreed to a settlement and license agreement resolving the litigation between them that has been carried out in Israeli and US courts. Under the terms of the agreement, which commenced January 1, 2004, Lumenis grants Syneron unlimited non-exclusive worldwide licenses for Lumenis patents relating to the use of incoherent light in aesthetic and medical applications, including all of its IPL related patents. Syneron will pay Lumenis royalties up to a predetermined cap with an upfront payment of \$1.5 million. The two parties reached agreement in order to avoid the cost of ongoing litigation, and agreed that there would be no admission of wrongdoing or liability on the part of either company. The settlement and licensing agreement includes certain other confidential terms.

Avner Raz, president and CEO of Lumenis and Moshe Mizrahy, CEO of Syneron Medical, said: "We are happy we have reached an agreement which allows both companies to resolve the costly litigation on fair terms. We look forward to moving onward and further strengthening the market position of both our companies."

- 1/21 **Candela Corporation** announced that it had received additional clearances from the FDA to market its Vbeam and its Cbeam for the non-invasive treatment of acne. Vbeam and Cbeam represent the gold standard in pulsed dye lasers to treat facial veins, rosacea, leg veins, port wine stains, scars, wrinkles, psoriasis, stretch marks and warts.

Gerard Puorro, Candela's president and CEO, said, "For physicians interested in treating only the bacterial component of acne, pulsed dye lasers have been shown to temporarily reduce acne lesions by targeting P.Acnes (bacteria) in the skin. This clearance comes soon after Candela's FDA clearance for acne for Smoothbeam, Candela's premier acne treatment option."

Tina Alster MD, Director, Washington Institute of Dermatologic Laser Surgery comments, "The FDA clearances are great news for Candela. However, of all the laser and light-based treatment options I have investigated, Smoothbeam demonstrates the best clinical results with greater than six month remission times and an 83% lesion clearance rate. I also prefer to use it for atrophic acne scars, giving patients a two-for-one treatment option."

The Smoothbeam laser offers a long-term acne solution by treating the root cause of acne -- the sebaceous glands. By directly altering the structure and function of the sebaceous glands, Smoothbeam drastically reduces acne lesions without significant side effects while offering longer remission times and improved efficacy rates when compared to other light-based devices.

Acne affects roughly 80% of the population worldwide in some form, is the most commonly diagnosed skin disorder in the U.S., and is the #1 reason why patients visit a dermatologist. Acne can have a crippling effect on a patient's self esteem and is often a source of anxiety, low self-confidence and even depression.

- 1/21 **Palomar Medical Technologies Inc.** announced that it will be presenting its latest products at the *American Academy of Dermatology's 62nd Annual Meeting (AAD)*, in Washington, DC, from February 7 to 10, 2004.

At the meeting, Palomar will introduce its next generation of Lux pulsed-light system. The Palomar portfolio currently includes the MediLux, EsteLux and NeoLux, which are sold with the LuxY handpiece for hair removal and pigmented lesion treatment on large body areas; the LuxG handpiece for photofacial treatments on vascular and pigmented lesions; the LuxR handpiece for large-area hair removal on all skin types; the LuxRs handpiece for permanent hair reduction on all skin types with fewer treatments; the LuxV handpiece for fast treatment of pigmented lesions and mild to moderate acne (pending FDA clearance); and the LuxB handpiece for treatment of lighter pigmented lesions on fair skin as well as leg and spider veins. With the various Lux handpieces, physicians can tailor a system to their existing practice or offer additional applications to their patients at a fraction of competing systems. The market acceptance of the Lux family of products has helped the company increase its revenues, profit and cash position over the last two years. The company also sells the Palomar Q-YAG 5 laser system for tattoo and pigmented lesion removal.

Palomar's light-based cosmetic technology is among the most advanced in the industry. Palomar invested considerable resources to ensure that its patent portfolio and other intellectual property provide strong protection of its technology.

- 1/22 **Candela Corporation** announced that it had launched its new GentleYAG laser. The company said with a peak power exceeding 26,000 watts, more than twice the power of any other competitive YAG on the market, the new GentleYAG is the fastest, most versatile and user friendly device on the market today. The GentleYAG will offer superior capability for the treatment of unwanted leg veins and for hair removal on dark and tanned skin over any other YAG laser on the market today.

Gerard Puorro, Candela's president and CEO, said, "The entry of the new GentleYAG is a disruptive technology to all other competitive lasers being offered. This device is faster, more versatile, and is priced below competitive devices. We introduced this laser at the *IMCAS Meeting* in Paris two weeks ago and received rave reviews. We will feature the GentleYAG at the *62nd Annual Meeting of the American Academy of Dermatology* on February 7, 2004 at the Washington Convention Center."

- 1/22 **CardioGenesis Corporation** announced that it had executed a private placement of approximately 3.1 million shares of newly issued, restricted and unregistered common stock to institutional investors, raising gross proceeds of \$2.7 million. The net proceeds of the placement will primarily be used to support the company's introduction and launch of a number of new technologies and products for its growing TMR business.

Chairman, president and CEO Michael Quinn said the completion of this financing follows a successful fourth quarter for the company, which showed a significant

improvement in bottom line performance as gross margins as a percent of revenue increased and operating expenses declined. He said the company expects to report a net profit for the fourth quarter ended December 31, 2003 in the range of \$400,000 to \$500,000 on revenues between \$3.3 million and \$3.4 million.

"I have never been more excited and optimistic about the prospects of CardioGenesis and our potential for profitable growth," Quinn said. "The fact that we were profitable during the quarter, clearly demonstrates that TMR continues to gain traction in the market and that our efforts to build TMR into a growing and profitable business are beginning to pay off. I am extremely pleased with our accomplishments on all fronts and my compliments to our entire team for a job well done. In addition to being the current market leader for TMR, we are on the threshold of extending our leadership further with the introduction this year of a number of breakthrough technologies and products for TMR, which will include the latest in robotic applications, as well as new products to support minimally invasive techniques for TMR. This financing will help ensure the timely introduction of these products, which we believe can dramatically increase the number of TMR procedures being performed worldwide, providing a growing number of patients suffering from severe angina the opportunity to get relief from their debilitating pain."

The approximately 3.1 million shares of newly issued common stock were sold to the investors at a price of \$0.86 per share, which was based on a 15% discount from the volume weighted average closing bid price of the stock for ten consecutive trading days ended January 13, 2004. The investors also received warrants to purchase approximately 3.1 million additional shares of common stock at a price of \$1.37 per share. These warrants are immediately exercisable and have a term of five years. The company has agreed to file a registration statement covering the resale of the shares within 50 days from the date of closing. The private placement agreement includes additional warrants providing the investors the ability to purchase approximately 1.57 million shares of CardioGenesis common stock at \$1.00 per share for a period of six months following the effective date of the registration statement.

The company also amended its Shareholder Rights Agreement dated August 17, 2001, as amended, to provide that the initial issuance of the securities to the investors would not trigger the Rights Agreement and to exclude the warrants from the calculation of beneficial ownership under the Rights Agreement unless and until the warrants are exercised.

1/23 **BioLase Technology, Inc.** announced it had acquired **PAClive**, a premier dental teaching institute, from **Discus Dental, Inc.**, a leading direct distribution manufacturer of dental products. PAClive, one of dentistry's premier live-patient, hands-on continuing education programs in the United States, was established in 1998 by Dr. William Dorfman, founder of Discus Dental. "We're proud of PAClive's accomplishments over the past 6 years. We've helped change the lives of thousands of dental professionals, as well as their patients," says Dr. Dorfman. "We're pleased to hand over the reigns of the program to a solid organization. We believe BioLase is going to continue to uphold the standards of

excellence that have defined the PAClive experience, and help take the program to new heights."

Jeffrey Jones, BioLase president and CEO, commented, "PAClive is a respected forum, well known in the industry for advancing dentistry to the benefit of both practitioners and patients. PAClive has a strong contingent of instructors, sponsors and suppliers that BioLase plans to continue working with to grow the PAClive tradition and to broaden its course offerings. Additionally, PAClive is an ideal forum to showcase BioLase's Waterlase and LaserSmile dental laser systems."

About Discus Dental, Inc. -- Founded in 1993, Discus Dental is one of the leading direct manufacturing sellers of dental products in North America. The company is a leading manufacturer and direct distributor of professional dental products in the areas of tooth whitening and breath control; a leader in the areas of impression materials, site registration materials, curing lights, restorative materials, prescription home fluorides, continuing education, practice enhancement services and practice management software. Discus Dental is headquartered in Culver City, California. More information is available at [www.discusdental.com](http://www.discusdental.com).

- 1/23 **AngioDynamics, Inc.**, a wholly owned subsidiary of **E-Z-EM, Inc.**, announced that **Diomed, Inc.**, a subsidiary of **Diomed Holdings, Inc.**, had filed a lawsuit against the company in the federal district court in Massachusetts alleging patent infringement related to AngioDynamics' ELVS endovascular laser venous system. This system is used for the treatment of severe varicose veins. The suit involves a single patent, Number 6,398,777, covering the endovascular laser treatment of varicose veins.

"The company has analyzed the Diomed patent, and has a written opinion of non-infringement from outside patent counsel," said Eamonn Hobbs, president and CEO of AngioDynamics. "We believe our ELVS product does not infringe the Diomed patent, and we intend to vigorously defend this action."

About ELVS -- The ELVS endovascular laser venous system is a patient friendly, minimally invasive alternative for the treatment of severe varicose veins. The ELVS procedure, which lasts about 45 minutes, offers patients an effective out-patient alternative to surgical ligation and vein stripping. The company markets and sells the ELVS system throughout the United States.

#### **MEDICAL/SURGICAL LASER UPDATE -- February 2004**

- 1/20 **Cynosure, Inc.** announced that its parent, **El. En.**, headquartered in Florence, Italy, had provided the laser technology used in the recent restoration of Verrocchio's David. In preparation for exhibition in the U.S., the 4-foot bronze sculpture from the National Museum of the Bargello in Florence was restored for the first time since its creation in the mid-15th century. Conservator Ludovica Nicolai at the Bargello conducted the

restoration, which was made possible through collaboration between the Bargello and the High Museum in Atlanta, Georgia.

A surgically-precise Nd:YAG laser was reconfigured by El.En.'s engineers into the EOS 1000. The EOS 1000, adapted to work on stone and metal, was used to remove centuries of varnish and dirt that covered the sculpture's surface. This laser was capable of penetrating precisely to the level of the fine gold leaf gilding, which highlighted the sculpture's surface, without damage. El. En.'s lasers been used in several restorations throughout Italy including Giambologna's "The Rape of the Sabine Women" sculpture, Donatello's "Prophet Abacus" statue, the Cupola and Pisano's reliefs of Santa Maria del Fiore (the Duomo), the facades of the Church of St. Frediano and the Priory of Povia, as well as the bas reliefs of the Church of the Holy Sepulchre in Jerusalem.

The restoration of David has significantly altered the interpretation of the piece by art historians, reinforcing the theory that it is most probably a portrait by Verrocchio of his most famous pupil, Leonardo da Vinci. The sculpture, one of the most important and influential masterpieces of the Renaissance, is now on exhibit until February 8, 2004, at the High Museum of Art in Atlanta. It will then travel to the National Gallery of Art, Washington, DC, for exhibit from February 13 to March 21, 2004. Both exhibits are being supported by **Worldspan, L.P.**

- 1/27 **Cynosure, Inc.** announced that it will unveil its new logo, visual identity and product design at the upcoming *American Academy of Dermatology* meeting, February 6- 11, in Washington, D.C. The corporate re-branding takes effect immediately throughout Cynosure's worldwide offices.

**Why a new logo?** -- While the original logo adopted in 1991 served Cynosure well, the new logo more effectively represents the new product design and the company's strategic direction. The company developed its first laser, the PhotoGenica V pulsed dye for treatment of vascular conditions such as port wine stain birthmarks, in 1991. Since then it has continually expanded the product line to offer laser hair removal, "lunch time" facial treatments, therapeutic laser massage and treatments for leg and facial veins, photo-damaged skin, acne and pigmented lesions. In 2002 Cynosure partnered with **El. En.**, Italy's leading laser developer and manufacturer, when El. En. acquired a majority position of Cynosure, Inc.

The new corporate image better reflects Cynosure's increasingly competitive market position, with the new management and development teams prepared to meet ever changing market demands. Cynosure also sees the re-branding as a chance to expand its businesses beyond its traditional market segments, while reinforcing its commitment to the core aesthetic medicine business that has driven its growth all along. Michael Davin, CEO, said, "I would like the Cynosure brand to be one that physicians throughout the world recognize and consider their first choice. We are committed to producing effective medical technology of the highest quality and value, enabling our customers to improve

the health and well being of their patients. Our strategy is to do this through the art of innovation and a relentless pursuit for excellence."

The new logo and visual identity will first be featured on the following products: Apogee 5500, Acclaim 7000m Apogee Elite and the PhotoGenica V. Cynosure worked closely with **M + M Design**, based in Connecticut, to develop its new logo and visual identity and with **Herbst LaZar Bell** to develop its new product design.

1/27 **Candela Corporation** reported results for its second fiscal quarter ended December 27, 2003. The company said that revenues for the quarter were \$23.9 million, a 33% growth compared to \$18.0 million for the same quarter a year earlier. For the first six months of the fiscal year, the company reported revenues of \$42.6 million, a 36% growth, compared to \$31.3 million for the same period last year. Income for the quarter from continuing operations was \$2.4 million (22 cents per share) compared to \$800,000 (8 cents per share), increases of 203% and 175% respectively over the same quarter a year earlier. For the six-month period, income from continuing operations was \$4.2 million (38 cents per share) versus \$1.8 million (18 cents per share), increases of 140% and 111% respectively over the same period last year.

Gerard Puorro, Candela's president and CEO, commented: "Our best in class products coupled with our ever strengthening worldwide distribution channels continue to drive the significant revenue and profit growth we have been enjoying. We continue to add new products, and expanded regulatory approvals as we head into next month's 62nd *Annual Meeting of the American Academy of Dermatology*." Puorro added: "We remain quite optimistic as we move into the second half of our fiscal year."

Simultaneous with its earning announcement, the company also announced that its Board of Directors had approved a two-for-one stock split, payable in the form of a 100% stock dividend. All shareholders of record at the close of business on February 16, 2004 will receive one additional share for each share of common stock owned. The additional shares will be distributed to shareholders on or about March 16, 2004. Upon completion of this split, Candela will have approximately 22 million shares of common stock outstanding.

Regarding the company's stock split, Puorro said: "We believe the increase in shares outstanding from this split could enhance the liquidity of Candela shares, and is beneficial to our shareholders over term."

Following the analyst teleconference, Dalton Chandler of **Needham & Co.** issued an update report on the company, "**Candela tops our revenue and earnings estimates again; raising estimates and price target.**" Some of his comments included:

**Investment Conclusion** -- This morning Candela posted F2Q04 results that easily topped our estimates. On the strength of these results we are raising our estimates and our 12-month price target to \$30 from \$20 and reiterating our Buy rating.



## **Summary:**

- This morning Candela reported revenue of \$23.9 million (up 29% Y/Y) versus our estimate of \$21.0 million.
- The earnings per share were \$0.22 versus our estimate of \$0.18, up from \$0.05 in the year ago period.
- The GentleLASE, which is primarily used for hair removal, led the way in the quarter at 47% of total sales.
- During the quarter Candela received FDA clearance for acne treatment using its Smoothbeam laser and estimated the worldwide market potential for the unit at 10,000-15,000 compared to the current installed base of just 350.
- Subsequent to the close of the quarter Candela announced the launch of the GentleYAG, a high-powered laser that sells at the lowest price point in the industry. We think this price-performance profile has the potential to dramatically alter the competitive landscape in Candela's favor.
- Candela has announced a 2:1 stock split for shareholders at 2/16/04. This should increase the liquidity of the stock and could launch the shares higher.
- The balance sheet is strong and improving with \$32.4 million in cash (\$2.87 per share), up from \$30.1 million last quarter, and just \$6.6 million in long-term obligations.
- We have updated our earnings model to reflect the continued superior performance of Candela in the quarter and we are raising our estimates accordingly. Based on these higher numbers we are raising our 12-month price target to \$30 from \$20 and reiterating our Buy rating.
- **RISKS:** In the near-term we see the potential for disruptive marketing tactics from Lumenis as it struggles to stay out of bankruptcy. In the longer term we think the need to meet the challenge of new technology as the greatest risk.

**Quarterly Discussion** -- Candela has turned in another strong quarter, significantly exceeding our top and bottom line estimates for the third consecutive quarter, which is as long as we've covered the stock. The company also had two recent developments that we view as significant and positive. In mid-December Candela announced full clearance for acne and acne scar treatment from the FDA for its Smoothbeam laser. The advantage of the Smoothbeam compared to other light-based treatments for acne is that at its 1450 nm wavelength it modifies the sebaceous glands where acne originates, while the other primarily eradicate bacteria that are a product of acne. The economics of the laser appear to be compelling for the physician, who would typically charge \$1,500-3,000 for a course of treatment, usually consisting of three sessions lasting 10-30 minutes each. The list

price of the laser is \$49,900, indicating the payback for the laser is probably somewhere between 20 and 25 patients.

We think this is also appealing to physicians because payments for such cosmetic procedures are generally “out of pocket”, which means no managed care hassles and pricing pressures. An independent study commissioned by Candela indicates that the worldwide demand for Smoothbeam, laser systems is 10,000-15,000 units. The current installed base is just 350, indicating a long growth ramp. In what may be an even more significant development, just last week Candela launched its GentleYAG for hair removal and other cosmetic applications. This laser appears to have redefined the cost/performance relationship in the cosmetic laser category. And management reports that they have already received domestic orders that will be in revenue in the March quarter despite the fact that the formal launch won't occur until next weeks *American Academy of Dermatology* meeting in Washington, D.C. In looking at the technical specifications of cosmetic laser systems it is difficult to differentiate among on the basis of power, pulse width and spot size, all of which are key indicators of potential clinical performance. With the introduction of the GentleYAG it appears that Candela has broken out of the pack.

Its 24,000 watts of peak power is nearly double that claimed by its nearest rival. The higher power means that the treatment spot size can also double. The GentleYAG will have a maximum spot size of 18 mm while most rivals claim 9-10 mm. Since doubling diameter of a circle increases its area more than 6 times the time to treat large areas (back hair, for example) will be significantly reduced. Not only has Candela developed a product that appears to offer superior clinical performance, its engineering is such that its list price will be about 10% below most current low-end YAG laser prices, which typically start around \$80,000, and it will be able to maintain its 50% gross margins. It is well know that Candela and other players in the cosmetic laser industry have been taking market share from **Lumenis** as a result of that company's financial difficulties. We think that having redefined the price/performance curve Candela is likely to start taking market share from others as well. The cosmetic laser market is difficult to size because some significant players are privately held or their results are buried in the financials of much larger parent companies. We estimate that the 2003 market from participants whose results we can identify will be about \$260 million and the total market is around \$310 million. We think that Candela will have 30% of this market, up from 24% in 2002. This means that 1% of market share is worth about \$3 million in incremental revenue. If Candela can gain market share while maintaining its margins each 1% would add about \$0.03 per share to earnings.

**Changes to Our Financial Model** -- We believe that the overall cosmetic laser market is growing in the “low double digit” range. If we use 12% as our industry growth rate then our new assumption that Candela can grow its top line means it is growing 50% faster than its competition. This is consistent with our view that the new GentleYAG will enable Candela to take market share from rivals other than Lumenis.

Below the bottom line we have made few changes. We have assumed that gross margins will top out at 52%, which is slightly above recent results, but below the 53-54% management believes to be achievable and well below historical levels that approached 60%. We have assumed that the operating margin can get to 19%, again well below historical levels that have reached as high as 23%. We did bump up our tax rate assumption to 36% for fiscal 2005 from the 33% level still expected for 2004 because some tax advantages from historical transactions will expire.

Our estimates have increased substantially as a result of these new assumptions. Our fiscal 2004 revenue estimate is now \$100 million, up from \$95 million and our 2005 estimate is \$118 million, up from \$107 million. Our EPS estimate for fiscal 2004 is now \$1.00, up from \$0.93 and our 2005 estimate is now \$1.15, up from \$1.00. The comparable company analysis described in our Valuation section is based on calendar year estimates, which are also up substantially. Our calendar 2004 revenue estimate is now \$107 million, up from \$100 million and our EPS estimate for the year is now \$1.06, up from \$1.00. We are introducing calendar 2005 estimates of \$127 million in revenue and EPS of \$1.30.

- 1/27 **AngioDynamics, Inc.**, a wholly-owned subsidiary of **E-Z-EM, Inc.** announced the launch of the new ELVS Procedure kit. The kit features a new 65cm sheath and a double-distal-tipped guidewire, and represents the next generation of ELVS Procedure kits. The ELVS system is a patient-friendly, minimally invasive alternative for the treatment of severe varicose veins. Current treatment options for these types of varicose veins include surgical ligation and vein stripping, invasive procedures that require an overnight hospital stay. In most cases, the entire ELVS therapy takes less than an hour to perform and visual results can be immediate. Patients who undergo the ELVS treatment can experience a rapid recovery time with no scarring, and generally can return to normal activities once they leave the doctor's office. AngioDynamics first introduced ELVS in November 2002.

The new sheath will provide physicians the flexibility to treat those patients with longer refluxing vein segments. The new double-distal-tipped guidewire provides the physician a choice between a straight-tipped or j-tipped guidewire for more tortuous veins during the ELVS procedure. Commenting for AngioDynamics, David Doster, Product Manager for the ELVS Laser, said, "The 65cm ELVS Procedure kit is another example of innovation from AngioDynamics. AngioDynamics is in the business of providing solutions for vascular care, and we are committed to developing procedure kits that meet the changing needs of the ELVS System user."

ELVS is a trademark of **Biolitec, Inc.**

- 1/27 Kirk Shinkle, writing in *Investor's Business Daily*, wrote about, "**Demand For Hair-Removal Gear Has It Sitting Pretty**", featuring the **Palomar Medical** hair removal devices.

Never underestimate the power of vanity. Consider: an estimated \$2.2 billion is spent every year on laser hair removal procedures, experts say. That figure is expected to grow to \$5 billion by 2007. Angling for a bigger piece of the business is Palomar Medical Technologies Inc., which makes laser hair removal machines. The Burlington, Mass.-based firm pioneered laser systems in the mid-1990s. Its products are used to treat or remove hair, facial and leg veins, lesions and sun or age spots.

Around 1,000 Palomar machines are in doctor offices. The treatments are pricey, costing between \$150 and \$250 per visit. Most patients need four to six treatments, depending on the condition. The key to growing the business is to help spread awareness of the technology, says CFO Paul Weiner. "Earlier on, these procedures were much more aggressive," he said. "Now they're lunchtime procedures where you can go right back to work. Nobody even knows about these treatments."

Palomar has three systems on the market. The latest, dubbed the NeoLux, sells for around \$32,000 and can handle hair removal and simple lesion removals. Two higher-end products - MediLux and EsteLux - have price points in the \$42,000 to \$52,000 range. They can handle more intense treatments such as acne and large areas of body hair.

Palomar's line is unique among rivals, thanks to interchangeable hand pieces that can be used for specific treatments. Doctors using rival machines have to buy new, much more costly machines for each job. The handsets sell for about \$10,000, Weiner says, and last about two years.

Palomar has sold enough of its gear to run off five straight quarters of double- or triple-digit revenue growth. Third-quarter sales last year rose 25% to \$9.2 million. Earnings doubled to 2 cents a share. Analysts polled by First Call expect the firm to post a 10-cent profit for all 2003. They see earnings this year rising 110% to 21 cents a share.

For future growth, Palomar will rely in part on a deal it signed last year with shaving giant **Gillette Co.** In February, Gillette agreed to give Palomar \$7 million to develop a hair removal system for women that can be used at home. For Palomar, the deal means about \$700,000 in quarterly sales and gives it the muscle of Gillette's brand name. The plan is to unveil the product sometime in the next two years. Analysts expect a debut sometime in 2005 or 2006. Of course, there are the usual spate of FDA approvals and other factors that could affect that time frame.

"That could be very compelling," said analyst Daniel Morgan of **Noble Financial Group**. "It's hard to say how that will piece together. They are receiving money for working (on the product), so it's not a waste." Research and development on the project are moving along on schedule, Weiner says. He declined to give specifics, however, citing Gillette's notoriously tight lips when it comes to new products.

"We are moving ahead," Weiner said. "But until it's ready for launch, you won't hear many details." If a product is approved, Palomar gets another \$2.5 million. It gets further

development deals that could translate into tens of millions of dollars if the product succeeds. Either way, the deal will add a few million in revenue for the next couple of years.

Another potential growth area is tattoo removal. Palomar and analysts are betting that a few years down the road, heavily inked members of generations X and Y will rethink that ying-yang symbol they got below their navel during sophomore year. "The theory is when you finally get a real job or get out in the real world, you want to get them removed," Morgan said.

Palomar has one of only two systems designed for the job. Rival **Candela Corp.** has the other. The overall market leader is **Lumenis Ltd.**, with an estimated 30% share. Candela ranks No. 2. Palomar's share hovers near the 15% range, Weiner says.

- 1/28 **Trimedyn, Inc.** announced its chairman, Marvin Loeb, was interviewed by **MacReport.Net**. The interview will be available by visiting [www.macreport.net/](http://www.macreport.net/) and entering 'TMED' in the public companies section. Loeb discussed Trimedyn's business, including its current product lines, new products in development and the company's plans for the future.

Commenting on the interview, Loeb said, "We are pleased that MacReport chose to interview us, and we are gratified by the attention being paid to Trimedyn's continued profitability and the potential of its new products. Trimedyn has demonstrated its ability to develop innovative, patented products, effectively market them and earn \$1 million or \$.07 per share, fully diluted, in the year ended September 30, 2003."

- 1/29 **PhotoMedex, Inc.** announced that it had filed a lawsuit against **Edwards Lifesciences Corporation** and its former parent company **Baxter Healthcare Corporation** in the Superior Court of the State of California for Orange County. PhotoMedex seeks the return of \$4 million plus costs and interest. The lawsuit alleges that Edwards has breached a series of agreements between the companies for a project to develop and commercialize PhotoMedex's patented excimer laser technology to treat heart-related diseases. The lawsuit further alleges that Edwards improperly granted to a competitor certain rights to the heart-related proprietary technology which belongs to PhotoMedex under the agreements and which PhotoMedex had acquired at Baxter's insistence for \$4 million.

Commenting on the suit, Jeffrey O'Donnell, president and CEO of PhotoMedex, said, "Edwards did not fulfill its obligations under our agreements and has abandoned the project related to cardiovascular diseases. We have been damaged financially and competitively by Edwards' actions. We are now in a position to seek appropriate relief and remedy for Edwards' improper conduct."

- 2/2 **BriteSmile** announced that its 5:2 stock split had taken effect. On January 2, 2004, the company announced a 5 for 2 stock split of shares of its common stock with each

shareholder of record on January 16, 2004 being entitled to receive 5 shares for 2 that were held.

2/2 **CardioGenesis Corporation** announced that new, conclusive five-year data demonstrates the enduring benefits of TMR when performed on patients with diffuse coronary disease in conjunction with coronary bypass artery grafting (CABG) surgery. The data, which was presented by Keith Allen, MD at the recent annual *Society of Thoracic Surgery (STS)* scientific sessions in San Antonio, showed that the combined procedure significantly reduces crippling chest pain called angina, even more than in patients who receive CABG alone. An analysis of the new data also showed that TMR in conjunction with CABG is particularly effective in reducing angina in patients who are diabetic.

Dr. Allen, a cardiothoracic surgeon at Heart Center of Indiana in Indianapolis, presented data showing that two groups of patients, including 110 who received TMR with CABG and 108 who received CABG alone, both experienced significant reduction in angina five years after their surgery, but the CABG/TMR patients enjoyed a significantly lower mean angina score (0.4 versus 0.7). In addition, no patients who received TMR in conjunction with CABG suffered from severe angina (Class III or IV) after five years while 10% of the CABG alone patients did. Of the diabetic patients, 93% were angina free after five years compared to 63% who received CABG alone.

"This is a very impressive result for TMR therapy in that CABG is, and has long been, the gold standard of care for these patients," Dr. Allen said. "To achieve even better long-term angina relief with CABG and TMR in this difficult subset of CABG patients is significant."

Robert Guyton, MD, president of the STS and Chief of Cardiothoracic Surgery, Emory Clinic, in Atlanta, specifically included TMR in his address to the surgeons at the conference noting that TMR is an innovation that "is Here today" and he presented data that predicted the 5,000 TMR procedures performed in the U.S. in 2003 will grow to 7,000 by 2005. "Innovation is not just our future, it is today," Dr. Guyton told the gathering. Consistent with the "Innovation" theme of the conference, CardioGenesis also generated considerable interest at the meeting by highlighting its new, minimally-invasive, robotically-assisted or thoracoscopic approach to TMR, which employs a proprietary fiberoptic delivery system and greatly reduces the surgical risk and patients' recovery time.

In conjunction with the STS meeting, CardioGenesis conducted a TMR user's conference that was attended by surgeons with significant TMR experience and others now considering TMR. It was moderated by Robert Emery, MD and included discussions by Sudhir Srivastava MD on minimally invasive techniques, Race Kao, PhD on TMR and stem cell therapy and Dr. Allen on long-term clinical outcomes.

Michael Quinn, CardioGenesis chairman and CEO said that the attendance and feedback at the company's TMR user's conference was most gratifying. He said the enthusiastic,

standing-room-only crowd showed significant interest in TMR and the company's new thoracoscopic and robotic delivery systems, which were presented and discussed at the user's conference, as well as the STS exhibit. "As the clinical and market leader in TMR, CardioGenesis is actively pursuing collaboration with the innovators and thought leaders of cardiothoracic surgery in bringing TMR to the forefront. The conclusive results of our five-year studies show the impressive impact of our TMR system on patient outcomes. Clearly, based on the five-year results presented at the STS meeting in San Antonio and the recent AHA meeting in Orlando, patients suffering from advanced coronary artery disease can benefit from TMR. In addition to relieving severe angina and providing benefits that are significant and enduring, for the first time, as demonstrated at the AHA meeting, we have seen a positive effect on long-term survival."

"As a result of these clinical results and our innovative efforts," Quinn added, "we are well-positioned to take advantage of the demand by patients and referring physicians to provide minimally invasive techniques with robust and enduring clinical outcomes."

2/2 **Telsar Laboratories** announced that it would introduce two lotions to prevent over or under treating specific areas of the skin with any light source at the *American Academy of Dermatology* annual meeting in Washington, D.C. "Often, physicians forget what areas they have already treated during a session," said Nikolai Tankovich, MD, founder and president of **ParadigmTrex, LLC** (San Diego, Calif.), which developed the two lotions. "You don't want to over treat and cause side effects such as burning and hyperpigmentation."

Telsar Laser Tracking Lotion contains very small particles of carbon. "Carbon absorbs any laser light. It is the best absorbent material for any light source," Dr. Tankovich stated. The lotion is applied prior to treatment. The carbon makes the skin gray, but when you treat that area with light, the carbon is evaporated and the area returns to skin color." According to Dr. Tankovich, this is the first treatment tracking lotion on the market.

In contrast, Telsar Laser Shielding Lotion contains a much higher concentration of carbon particles. This is also applied before treatment. "If you accidentally expose light to an area that you don't want to treat, the carbon will absorb and vaporize," Dr. Tankovich said. "But there will still be a lot of carbon left on the skin. You would have to activate the carbon five times before affecting the skin."

DermaChiller -- The fourth generation DermaChiller from Telsar Laboratories is a handheld skin cooling device that allows physicians to safely treat darker skin. Pain sensitivity and pigmentation changes are also reduced in all skin types. "This is a new product for us to manufacture," said Peter Zimmer, founder and president of Telsar. "Most laser systems require some sort of cooling device. A lot of companies have gone to a cryogen spray, but the physician really has no temperature control with the cryogen technique." In contrast, the DermaChiller's sapphire window has an immense heat sinking ability. Skin temperature can be maintained at 5°C or 0°C, for example. "It doesn't get

colder or warmer," Zimmer noted. In addition, because the laser is fired through the sapphire window, "this obviously helps considerably in directing the laser energy."

The battery powered device with recharger sells for less than \$2,000 and each disposable cooling canister (under \$10) provides 30 to 50 minutes of continuous cooling power. "One canister will cover numerous patients," Zimmer said. The DermaChiller also numbs the skin prior to injecting collagen or Botox. "DermaChiller should alleviate any apprehension a patient may have about pain, so this will improve a physician's revenue stream. When given a choice, patients normally opt for anesthesia."

According to Nikolai Tankovich, MD, the co-inventor of the DermaChiller, "If the skin starts heating up, the device immediately and automatically lowers the cooling temperature." Dr. Tankovich is widely considered the inventor of laser hair reduction technology. "With hair, it is necessary to protect the skin, especially the pigmentation," said Dr. Tankovich, who is founder and president of ParadigmTrex, LLC (San Diego, Calif.), which developed the DermaChiller. "I tried different ways to cool the skin, but found that the best method was contact cooling, even though I have a patent on spray cooling as well."

Physicians can now treat a wider range of patients. "People with skin types III, IV, V and VI are well protected from the heat," said Dr. Tankovich, noting that treating hair, blood vessels and wrinkles are the three most popular procedures that use the DermaChiller. "Patients really appreciate the increased comfort," Dr. Tankovich observed. Especially in tattoo removal, "once patients have experienced the DermaChiller, they don't want to return to other cooling devices."

2/2 Elizabeth Dinan, writing in *Mass High Tech*, wrote about **Cynosure** and some of its new products, "**Cynosure aims its lasers at hair removal industry**"

When Michael Davin attends social events, his wife's friends are inclined to show him their age spots, scars and facial veins. As the new president of Cynosure, a developer of cosmetic and medical lasers, Davin gets cornered for advice about making those and similar flaws vanish. In professional circles, Davin and Cynosure are announcing that the company has received FDA approval for use of its lasers for the treatment of acne. In addition, Italian parent company El.En. performed cosmetic laser treatment on the historic Verrocchio statue of David, not to be confused with Michelangelo's sculpture of the same name.

Cynosure's bread and butter, or most popular laser product, is hair removal technology and accompanying hardware delivery systems, for an industry performing hundreds of thousands of procedures a year. Part of the ballooning aesthetic laser market, hair and abnormality removal, in addition to skin 'rejuvenation' technology, represents 95% of Cynosure's business, as it nurtures the other 5% in medical lasers.



Laser hair removal is a young procedure, but according to Davin it is growing rapidly as people see it as affordable, permanent and safe. He markets it to the medical and spa industries as a cash business (not covered by insurance) to bolster revenue. A 17-year veteran of the cosmetic laser industry, Davin said that South American and wealthier American demographics are hot laser hair removal markets today, but with costs lowering, the demographics are growing and becoming mainstream.

“We have an aging population with disposable income and the prices are coming down,” he says. “The generation of today wants to look good.”

Cynosure’s business proves looking good often includes the removal of age spots, hair and acne, as well as stretch marks, warts, scars, tattoos, rosacea, port wine stains and varicose veins. The skin rejuvenation process is said to reduce the appearance of fine lines, pores and sun damage by removing top layers of damaged skin. In Massachusetts, most of these procedures do not have to be performed by a physician and, Davin says, are being administered as “a lunchtime approach.”

What lasers can’t do, he says, is lift faces. But his company is conducting research into the use of laser technology for diminishing the appearance of cellulite. “It’s a very important area of interest,” he says.

Cynosure has a competitor in Burlington’s **Palomar Medical Technologies**, and a January corporate backgrounder prepared by New York investor relations firm **Allen and Caron**, predicts the market for cosmetic laser procedures will reach \$19 billion by 2007. **PricewaterhouseCoopers** conducted similar research for the *International Spa Association* showing spa revenues (including laser treatments) doubling to \$10.7 billion in the last 10 years, as consumers made 156 million spa visits, or an increase of 140% between 1997 and 2002.

Palomar reports an agreement with **Gillette** for the development of an at-home, light-based hair removal system. Meanwhile Wayland’s **Candela Corp.**, another Cynosure competitor, has an agreement with **Mass General Hospital** for joint development of cosmetic laser devices.

Cynosure has agreements with physicians for cosmetic laser research and with Mass General Hospital for the development of laser-based medical devices. According to Davin, Cynosure is under FDA review for a laser treatment for glaucoma with a “unique disposable” component and received FDA clearance for laser technology paired with fiber optics (also designed and manufactured in Chelmsford) for the treatment of recurrent respiratory papilloma. The technology is a fiberoptic-based system for outpatient laser surgery.

Meantime, Verrocchio’s David is rejuvenated and on an American tour, in part because of the recent laser removal of grit from the 4-foot bronze masterpiece. It’s the first time

the sculpture, believed to be designed after the likeness of a young Leonardo da Vinci, has been restored since its mid-15th century creation.

Davin says business for his private, 100-employee company is seeing faster growth in the aesthetics market, but he says the medical aspect is “emerging.” The company was founded in 1991 by Dr. Horace Furumoto after a career in the laser weaponry field. Furumoto retired last fall after Davin was hired to replace him. Cynosure’s Chelmsford headquarters conducts research and development, engineering, regulatory compliance, quality control, manufacturing and field service. It has affiliates throughout Europe and is in discussions about an initial public offering.

2/3 **Cynosure, Inc.** will demonstrate its two newest products at the February *American Academy of Dermatology (AAD)* Meeting in Washington, DC. "These two systems provide today's cosmetic dermatology practices with multi-application capability in aesthetic space-saving designs, As the number of cosmetic surgery procedures continues to grow annually at double-digit rates, it is important to provide 'turn-key' solutions for practices starting or expanding their practices", said Marina Kamenakis, Director of Marketing.

The new TriStar Aesthetic Workstation includes 3 lasers in the same footprint as previous 1-laser systems, building on the V Star pulse dye technology framework. With the 3 “most popular” wavelengths (595nm, 1064nm, 1320nm), the dermatologist can provide the most requested aesthetic patient treatments. These include treatment of acne and acne scarring, leg and facial veins, pigmented lesions and non-ablative skin treatments, wrinkle treatments and treatment of vascular conditions. The range of wavelengths along with pulse widths and spot sizes allows physicians to combine treatments for the best results. For example, non-ablative skin treatment can include using 595nm for overall skin redness and pigment reduction, 1064nm for larger facial veins, and 1320nm for deeper collagen remodeling. And it can all be accomplished with one device, in a single treatment room, saving time and space.

The Apogee Elite, Cynosure’s new combined Alexandrite + Nd:YAG, has the ideal wavelengths for laser hair removal. The Alexandrite (755nm) and the Nd:YAG (1064nm) can treat the broadest spectrum of skin and hair types, including tanned skin. The combined therapy of both wavelengths for the same patient will treat the most persistent conditions. In addition the 1064 nm wavelength provides a highly versatile treatment for vascular conditions, such as facial and leg veins. With the micro second technology of the 1064 nm, this wavelength plus the 755 nm can be combined to treat both redness and brown pigment resulting in healthier looking skin. The Apogee Elite combines these 2 versatile wavelengths in a new, compact size, at an economical price.

Michael Davin, CEO, said: "We are pleased to introduce two new systems engineered at Cynosure. The TriStar is designed for the new practice, providing full aesthetic laser capability. This “Aesthetic Workstation” is the result of a scientific breakthrough by our award-winning R&D Group, combining for the first time these 3 lasers in 1 box. The Apogee Elite ends the debate of which laser is ideal for hair removal. We combined the

optimal laser wavelengths in one system. The Apogee Elite is designed for the practice that wants to add hair removal or upgrade their older system to treat all skin types, while adding other cosmetic treatments.”

- 2/3 **CardioGenesis Corporation** announced the creation of three new business units, the promotion of Richard Lanigan to senior vice president, Marketing and the promotion of three other senior managers to lead those units. Each of the new business units will have full top- and bottom-line accountability with two of them responsible for domestic and international sales and marketing in their respective geographies and the third providing maintenance and repair services to the company's worldwide customer base. Lanigan and the other newly-promoted vice presidents all report directly to chairman, president and CEO Michael Quinn.

"We took a fresh look at our organization because this is an incredibly important time for CardioGenesis, given that we are launching a number of new products to support our new minimally-invasive approach to TMR, and that the lengthy FDA review of PMR should be coming to a close in the upcoming months. Our entire senior management team, which collectively has more than 100 years of industry experience, is more bullish than ever about our business. With this new structure, senior management will be closer to where the action is and can better focus our resources on the market and the needs of all of our customers, including cardiac care hospitals, cardiothoracic surgeons, cardiologists and the patients they serve. This structure can also help us continue to develop the kinds of professional relationships necessary to sustain and build our business and provide an effective means to ensure market acceptance and utilization of our entire product line, especially as we bring new products and procedures to the market in the months ahead."

"With the creation of a Worldwide Services Division, we are also focused on profitably expanding our service and maintenance business with existing customers and can provide cost effective technical services to support new products and customers, as well," Quinn added.

The Pacific Division, to be led by newly-promoted vice president, general manager Lorrie Orton, will be responsible for a territory that includes all of North America west of the Mississippi River, as well as key markets in the Pacific Rim. The Atlantic Division includes all of North America east of the Mississippi River, as well as Europe and the Middle East, and it will be led by senior vice president Henry Rossell, who was named general manager of the division. Both the Pacific and Atlantic Divisions will include 14 regional sales territories, each staffed with experienced regional sales and clinical support professionals. The Worldwide Services Division will be run by Gerard Arthur, recently named vice president, general manager.

- 2/4 **Palomar Medical Technologies Inc.** announced financial results for the fourth quarter and year ended December 31, 2003. For the fourth quarter ended December 31, 2003, the company's total revenues increased by 35%, its product revenues increased by 26% and its gross profit from product sales improved by 34%, compared to the fourth quarter of

2002. For the year ended December 31, 2003, the company's total revenues increased by 37%, its product revenues increased by 39% and its gross profit from product sales improved by 61%, compared to the year ended December 31, 2002. The company realized a significant increase in net income to \$1.0 million, a 137% improvement over the fourth quarter of 2002 and for the year increased 85 times to \$3.3 million from \$39,000. Over the past year, product gross margins have improved significantly due to a higher margin product mix and the effects of increased sales volume. The company has also strengthened its balance sheet since the end of last year, including more than doubling its cash position and more than tripling stockholders' equity. The current ratio is now 2.9x, up substantially from 1.5x at the end of 2002, and there is no long-term debt.

CEO Joseph Caruso commented, "I am pleased to report on Palomar's progress during the fourth quarter of 2003 and the full fiscal year, which included some major milestones. A year ago, the company announced an agreement with **The Gillette company** to complete development and commercialize a patented home-use, light-based hair removal device for women. In our base business, gross margins on product sales reached 60%, which compares quite favorably with our competitors' margins. And thanks to the market's enthusiastic reception of our expanding Lux line of products, we doubled the size of our domestic sales force at the end of the year. Especially encouraging is the fact that our revenues continue to increase at a rapid rate, allowing us to maintain our research and development effort. Our reputation for leading-edge technology and product reliability has resulted in increased market share for Palomar over the past two years in the expanding market for light-based cosmetic procedures, a trend we think will continue in 2004. We also expect to keep extending the applications of our technology during upcoming quarters, and the strength of our balance sheet should allow us to continue to compete strongly in this dynamic market."

Revenues for the quarter ended December 31, 2003, were \$10.1 million, up from \$7.5 million in the fourth quarter of 2002. Gross profit from product sales increased to \$5.5 million (60% of product revenues), up from \$4.1 million (57% of product revenues) in the year-earlier quarter. The company reported net income of \$1.0 million, or \$0.06 per diluted share, for the fourth quarter of this year, versus net income of \$437,000, or \$0.04 per diluted share, for the fourth quarter of last year.

Revenues for the year ended December 31, 2003, were \$34.8 million, up from \$25.4 million for the year ended December 31, 2002. Gross profit from product sales increased to \$18.3 million (58% of revenues), up from \$11.3 million (50% of revenues) in the year-earlier period. The company reported net income of \$3.4 million, or \$0.21 per diluted share, for the year ended December 31, 2003, versus net income of \$39,000, or \$0.00 per diluted share, for the year ended December 31, 2002.

Commenting on Palomar's ongoing program to expand its shareholder base, CFO Paul Weiner concluded, "The recent strong operating and financial performance at Palomar have been noticed by the investment community, and during 2003 we substantially increased the institutional following of the company. We are continuing our efforts to

expand our shareholder base with an ongoing program of meetings with professional money managers and analysts nationwide. We are currently scheduling our next round of meetings at this year's *Annual Meeting of the American Academy of Dermatology (AAD)*, to be held in Washington, DC, from February 7 to 10, 2004. At the meeting, Palomar will introduce its next generation of Lux pulsed-light system."

Following the financial release and analyst teleconference call, Anthony K. Green of **Craig-Hallum Capital Group** released an updated research report, **Flawless December quarter. Raising estimates and price target**. Some of his comments included:

### **Investment highlights**

- Palomar Medical reported December-quarter results that were well above expectations. Sales of \$10.1 million beat our \$9.3 million estimate and the \$9.5 million consensus forecast. EPS were \$0.06 (\$0.04 fully taxed), \$0.03 better than consensus and our \$0.03 estimate (\$0.02 fully taxed).
- The company outperformed across the board and gave a very positive outlook on its quarterly conference call.
- We maintain our 2004 and 2005 sales estimates and raise our EPS forecasts based on margin expansion. For this year, we now look for fully-taxed earnings of \$0.24 per share (up from \$0.17) and our 2005 revised estimate is \$0.40 (from \$0.33).
- Upcoming catalysts include imminent FDA approval for acne treatment and this weekend's annual meeting of the American Academy of Dermatology (AAD) in Washington D.C., where Palomar will roll out a new product for leg vein treatment.
- Development efforts on the Gillette home-use hair removal product for women remain on track and we continue to look for a 2H05 product approval.
- We reiterate our Buy rating on PMTI shares and increase our 12-month price target to \$17 (from \$13). Our target is based on the sum of 35x (up from 30x) our taxed 2005 EPS forecast of \$0.40 for the core business (\$14) plus a \$3 premium for the Gillette opportunity.

**Our point of view** -- Palomar Medical reported an exceptional December quarter, with upside to revenue, margin and earnings expectations. We remain excited about the opportunity for the company's affordable, light-based treatments that are expanding their footprint from hair removal into new applications. Palomar's strategy of being the low-cost leader to expand the market into price-sensitive segments appears to be paying off based on continued excellent financial results. The company's unique interchangeable handpieces allow practitioners to inexpensively grow their businesses by purchasing additional handpieces for \$7,000 or so rather than buying a whole new system at \$50,000 or more, as is the case with competing laser systems. The handpieces last about two

years, adding a recurring revenue component and visibility to the company's income statement. Imminent FDA approval for acne, which accounts for 75% of all dermatology visits, further broadens the available patient population.

Although PMTI shares have more than doubled since our December 8, 2003 initiation, we believe that they should continue to trade higher on positive news flow and continued strong financial results. Palomar has a fast-growing, profitable business with high gross margins and a building consumable stream. The company has no debt, is generating cash and is led by an enthusiastic and motivated management team. The October 2003 addition of 11 direct sales representatives is paying off earlier than expected. The development agreement with Gillette—the world leader in hair removal products—for a home-use pulsed light product for women is unique in the industry and the company is seeking additional partners for other potential consumer applications such as skin rejuvenation, acne and fat removal. Palomar is doing all the right things, in our opinion, and we continue to recommend purchase of these shares.

2/4 **BIOLASE Technology, Inc.** announced that it intends to release its financial results for the fourth quarter and year ended December 31, 2003 on or before March 3, 2004. "Our unaudited results indicate that we finished the year on a strong note, and we expect to report that our fourth quarter and year end sales met or exceeded the high range of our previously stated sales guidance of 40% to 50% increase over the same periods in 2002," stated Jeffrey Jones, president and CEO of BIOLASE.

The company also announced it had received clearance from the FDA for its patented Waterlase technology for several new bone, periodontal and soft tissue procedures. The new clearance paves the way for dentists to perform additional procedures with the Waterlase system. The Waterlase is the first laser to receive clearance for these new bone, periodontal and general soft tissue surgical indications: Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours); Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc); Osseous crown lengthening; Flap preparation -- incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions); Full thickness flap; Partial thickness flap; Split thickness flap; Removal of granulation tissue from bony defects; and laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery.

Additionally, the Waterlase is the first hard tissue laser (YSGG or Er:YAG) to receive clearance for laser soft tissue curettage. BIOLASE's LaserSmile diode laser was previously cleared for laser soft tissue curettage in October 2003.

According to a report by the *American Dental Association* titled "1999 Survey of Dental Services Rendered" (updated in 2002), over 2.6 million osseous (bone) and gingival (gum) surgeries are performed each year by general practitioners, oral and maxillofacial surgeons and periodontists.

The clearance also covers soft tissue curettage for post extraction tooth socket. According to the ADA report more than 30 million tooth extractions are performed per year, which can now be treated with the Waterlase. A 1998 press release from the *American Academy of Periodontology* reported "A new analysis of recent research has revealed gum disease may represent a far more serious threat to the health of millions of Americans than previously realized. These studies found that periodontal (gum) infection may contribute to the development of heart disease, the nation's number one cause of death, increase the risk of premature, underweight births, and pose a serious threat to people whose health is already compromised due to diabetes and respiratory diseases."

Lawrence Nurin, DDS, commented, "These new indications are a major advancement for periodontists, general dentists and patients since procedures done with the Waterlase can be faster, cause significantly less post-operative pain and swelling and usually require little or no pain medication. The Waterlase gives dentists a way to avoid using scalpels and high speed drills. For example, instead of using a bur to grind bone to expose the underlying blood supply that will nourish a bone graft, now you can do the same procedure with the Waterlase without creating a smear layer, vibration or detrimental heat that will negatively impact tissue healing." Dr. Nurin has been practicing periodontics in Annapolis, Maryland since 1973.

Bret Dyer, DDS, added, "In addition to doing periodontal, soft tissue and bone procedures faster, with less trauma, less pain and with better, more predictable results than traditional methods, the Waterlase allows us to use techniques that were not previously possible. When performing Waterlase surgery there is less bleeding giving the doctor better visibility. Additionally, with the Waterlase we can now perform all of the following procedures -- cutting flaps, degranulating bone, recontouring bone, osseous surgery and perforating the bone to access the blood supply that previously would have required several different instruments. Another advantage of the new clearance and procedures is they allow practitioners to perform several procedures in one appointment in what previously may have required several appointments."

"With the Waterlase I not only can do much more for my patients, but I prescribe fewer pain medications and antibiotics and my patients love me for it." Dr. Dyer is a Board Certified Periodontist practicing in Sugarland, Texas.

Jeffrey Jones, president and CEO of BIOLASE, noted, "BIOLASE's efforts to continually improve the standard of patient care are evidenced by the new clearance for the Waterlase. The clearance further expands the utility of the Waterlase for both periodontists and general dentists, providing them with the opportunity to perform more procedures in fewer appointments with less need for anesthesia, shots, scalpels and drills. Practitioners report that many of their patients are also more comfortable both during and after Waterlase procedures, experience much less swelling and pain and a reduced need of pain medication when compared to traditional methods."

2/4 **Cynosure, Inc.** announced that it had received government clearance for the treatment of cellulite using its TriActive LaserDermology device. The TriActive is also used for therapeutic laser massage. "This clearance allows us to expand our marketing of the TriActive. Physicians and medical spas will be able to offer treatments to a wider category of individuals. We know how concerned women are about the appearance of cellulite. Each day on the internet alone, hundreds of searches are made for information on treatment," said Marina Kamenakis, Director of Marketing.

"In addition, the *American Academy of Dermatology* has noted that, 'increasing numbers of dermatologists are realizing it's an important issue to their patients.' We are pleased to be able to offer this newest treatment modality to physicians and their patients."

"The TriActive is used not only to tighten cellulite on the body, but can be used to tighten facial skin. It is the entry-level system for any aesthetic medicine practice or medical spa," said Michael Davin, president and CEO. "Patients can also combine TriActive LaserDermology treatments with other laser facial treatments, liposuction, and other procedures as they wish."

At the 20th Annual Meeting of the *American Academy of Cosmetic Surgery (AACS)*, recently held in Hollywood, FL, Susan Boyce, MD, presented two abstracts on the TriActive: "Intraoperative Treatment of Cellulite with Liposuction of the Thighs" and "A Comparison Study: Triactive With and Without the 800nm Diode Laser Component". In the latter abstract she showed that " ... both modalities can offer some benefit to patients who are bothered by their cellulite. However, the added benefit of the 800-nm laser component makes a significant difference for patients." During these studies, Dr. Boyce was a fellow with Dr. Mitchell Goldman, Dermatology-Cosmetic Laser Associates and SpaMD in La Jolla, CA. She is currently in practice at the Ferguson Medical Group in Sikeston, MO.

2/4 **CardioGenesis Corporation** announced that the company will meet with the FDA in March as part of the ongoing interactive review of the Premarket Approval (PMA) Supplement for the company's Axcis PMR system. The review process has been extended beyond the company's original timeframe to insure the participation of the key clinical experts and investigators on behalf of the CardioGenesis PMR therapy. CardioGenesis now has a firm schedule and commitment from David Feigal, MD, Director of the FDA's Center for Devices and Radiological Health, for the final steps of review and consideration, said CardioGenesis chairman, president and CEO Michael Quinn. Quinn added that he remains optimistic that the issues raised by the FDA as part of the review process can be worked out.

"We share the FDA's commitment to vigilance in protecting the public's well being in regards to new technology," Quinn said, "and we feel the data we have provided demonstrates the safety and efficacy of PMR. We are committed to finding a solution that addresses the concerns of the FDA's medical reviewers and that ultimately provides PMR



as a minimally invasive option for patients suffering from debilitating coronary artery disease who currently have very limited treatment options."

PMR is a less invasive, catheter-based version of the FDA-approved surgical TMR system, which is designed to trigger the mechanisms of angiogenesis or the creation of new blood vessels in the heart to relieve the often crippling chest pain called angina.

Quinn added that if a favorable outcome cannot be reached as a result of this interactive review process, a hearing before the FDA's Medical Devices Dispute Resolution Panel remains an option for the company. There can be no assurance that the company's PMA Supplement for PMR will be approved.

2/5 **Spectranetics Corporation** announced financial results for the quarter and year ended December 31, 2003. Total revenue for the 2003 fourth quarter was \$7.4 million, essentially unchanged from \$7.4 million in the comparable prior-year quarter and up 8% from \$6.9 million in the immediately preceding quarter. Net income was \$378,000 (1 cent per share) compared with net income of \$488,000 (2 cents per share) in the fourth quarter of 2002. This marks the sixth consecutive quarter of profitability for Spectranetics.

Disposable product revenue (which includes coronary and lead removal products) for the 2003 fourth quarter rose 9% to a record \$5.8 million, compared with \$5.3 million in the 2002 fourth quarter and up 12% from \$5.1 million in the immediately preceding quarter. Laser revenue for the 2003 fourth quarter was \$565,000, compared with \$1.3 million in the 2002 fourth quarter, and reflects the company's re-deployment of field sales resources from laser equipment sales to higher-margin, recurring disposable revenue. Service revenue, which is associated with laser equipment repair and maintenance services provided by the company's field service engineers, was \$1.1 million in the 2003 fourth quarter, up 7% from \$1.0 million in the 2002 fourth quarter.

The company's worldwide installed base of lasers increased to 383 at December 31, 2003, a net increase of seven during the fourth quarter, compared with six new placements during the fourth quarter of 2002.

Fourth quarter 2003 gross margin rose to 73%, up from 69% in the year-ago quarter reflecting a product mix favoring disposable products.

"Against the backdrop of a difficult capital equipment spending environment in 2003, we were successful in shifting our sales focus to the more profitable disposable revenue business. The growth in disposables in 2003 reflects continued growth in our lead removal business and stabilization of our coronary atherectomy product line," said John Schulte, president and CEO. "Looking to the future, with our recent 510(k) submission to the FDA, we remain cautiously optimistic about the possibility of extending the application of our platform laser technology in 2004 to treat critical limb ischemia patients who have total occlusions. This, in turn, would enable us to fully shift our

research, development and clinical resources toward the promising area of a laser-based treatment for heart attacks."

Full-year 2003 total revenue was \$27.9 million, down slightly from \$28.1 million in 2002. Net income for 2003 was \$929,000 (4 cents per share) compared with a net loss for 2002 of \$1.6 million (7 cents per share). Exclusive of costs associated with the proxy contest and settlement obligations in 2002, 2002 income was \$276,000 (1 cent per share).

By product line comparing 2003 with 2002, disposable product revenue rose 10% to \$21.1 million, while laser revenue declined 44% to \$2.8 million, reflecting increased sales emphasis on more profitable disposable products. The worldwide installed base grew by 23 laser systems in 2003 compared with 33 in 2002. Service revenue increased 4% to \$4.0 million. The gross margin for 2003 increased to 72%, compared with 68% in 2002, again reflecting a product mix favoring disposable products. Cash, cash equivalents and investment securities totaled \$13.3 million at December 31, 2003, which reflects a net increase of \$1.9 million compared with December 31, 2002.

**2004 Financial Guidance** -- For 2004, the company is projecting revenue growth of approximately 5% to 7% compared with 2003, driven primarily by increased disposable product sales and reflecting 25 to 30 new laser placements. Net income is projected to be in the range of \$500,000 to \$1 million. This financial guidance assumes no revenue contribution from the treatment of totally occluded arteries in patients with critical limb ischemia. However, it does reflect costs associated with the hiring of at least three new clinical account managers and the advancement of clinical research focused on a laser-based treatment of heart attacks.

2/5 **Syneron Medical Ltd.**, and its North American subsidiary **Syneron Inc.**, announced that the FDA had granted 510K marketing clearance to Syneron's Aurora AC system for treatment of moderate inflammatory acne vulgaris. The system, comprising a special applicator for acne treatment and the Aurora medical aesthetic treatment platform, has already received CE Mark approval, enabling it to be marketed in Europe and other regions.

Over the past year and a half, Syneron has secured FDA approval for systems that treat a wide range of medical aesthetic conditions, including the Aurora SR skin renewal system and the Aurora DS hair removal system. Its other product family, Polaris, addresses wrinkle treatment, hair removal, and vascular lesion and leg vein treatment.

Aurora AC utilizes Syneron's proprietary ELOS (Electro-Optical Synergy) technology, which combines optical energy and electrical energy to enable a wide range of highly efficient, safe and cost-effective medical aesthetic treatment systems. Like all Aurora systems, Aurora AC uses light and conducted RF energies.

"This FDA approval is an important step as it establishes Syneron as the only company that can offer skin renewal, hair removal and acne treatment via a single platform," said

Domenic Serafino, president of Syneron Medical Inc. "This means that our customers can cost effectively treat a wide range of patients and conditions."

- 2/5 **Laserscope** announced that it would introduce the Gemini Dual-Wavelength Laser System at the *American Academy of Dermatology (AAD)* Annual Meeting, being held in Washington, D.C. Laserscope's Gemini system stands out in the rapidly growing non-invasive aesthetic laser market due to its tremendous clinical versatility, ease-of-use and speed. The Gemini is currently FDA cleared for 17 different clinical applications and is awaiting clearance on the treatment of acne, wrinkle reduction and permanent hair reduction on all skin types. Once all FDA clearances are received, the Gemini will support over 20 of today's fastest growing major cosmetic applications.

The Gemini combines both the wavelengths and pulsing characteristics of Laserscope's two leading aesthetic products, the Aura and Lyra laser systems, into a single, higher power and faster product platform. The Gemini additionally incorporates a number of innovative features including computer controlled continuously adjustable spot sizes, patented continuous parallel contact cooling for patient safety and comfort, an intuitive touch-screen interface and ergonomic handpieces designed specifically to reduce operator fatigue and improve treatment visibility.

"We believe the Gemini will set the standard for versatility, performance and value in the market," said Eric Reuter, Laserscope's president and CEO. "We currently know of no other system available that can offer this wide range of discrete aesthetic clinical applications, ease-of-use and speed in a single product offering. Furthermore, the Gemini has a legacy of peer-reviewed and clinical results validating its superior effectiveness. We are targeting a wide range of physicians with this product, including those who do not want to purchase multiple laser systems, those who are looking to purchase their first system and those who are looking to upgrade their existing systems to this state-of-the-art technology."

"It is the synergy of the two different wavelengths that I believe work best at treating the widest variety of problems that we see in dermatology and aesthetic surgery," said Christine Lee, MD of Walnut Creek, California and a pioneer in enhanced skin rejuvenation procedures. "There's a tremendous switch in the patient population's desire to have a 'no downtime' treatment," said Robert Weiss, MD of Hunt Valley, Maryland. "People want smoother skin, more uniform pigmentation and removal of blotchy pigmentation and broken blood vessels. The Gemini allows us to do all of that and to do it very efficiently to satisfy exactly what the patients are demanding."

"Many customers have asked for a single-platform system combining all the great features and benefits of our Aura and Lyra systems but with more power and speed," continued Reuter. "For a physician offering cosmetic procedures, patient safety, clinical efficacy and speed are constant concerns. With the Gemini, we have incorporated and enhanced the clinical and technical capabilities of our two hottest selling aesthetic products to meet the needs of those physicians who choose an integrated platform."

2/5 **Lumenis Ltd.** announced that it had received notice that the company's ordinary shares would be delisted from The Nasdaq National Market (Nasdaq) prior to the market opening on Friday, February 6, 2004. Following delisting, the company expects that its ordinary shares will be quoted on the Pink Sheets Electronic Quotation Service under the symbol LUME.

The notice was contained in a decision by the Nasdaq Listing Qualifications Panel (the Panel) denying the company's request for an appeal from the determination of the Staff of Nasdaq stating that its securities are subject to delisting pursuant to Nasdaq Rule 4310(c)(14) since the interim financials in the company's Form 10-Q for the quarter ended September 30, 2003 had not been reviewed by the company's independent auditors in accordance with SEC Rules due to an ongoing independent investigation being conducted by its Audit Committee.

Avner Raz, president and CEO of Lumenis, said, "We are disappointed with the decision of the Panel and intend to appeal the Panel's decision to the Nasdaq Listing and Hearing Review Council. In the meantime, we will continue our efforts to complete the previously announced ongoing independent investigation being conducted by the Audit Committee as quickly as possible and focus on completing our turnaround plan for the company. The change in the trading venue of our ordinary shares does not affect our compliance with the covenants in our bank financing agreements."

The company expects that its ordinary shares will be quoted on the Pink Sheets Electronic Quotation Service. Information regarding the Pink Sheets Electronic Quotation Service is available at [www.pinksheets.com](http://www.pinksheets.com). Investors should be aware that trading in the "pink sheets" may result in a reduction in the liquidity and trading volume of the company's common stock.

Following the above announcement, one research firm decided to drop coverage of the company. John Calcagnini of **CIBC World Markets** said that his firm had dropped coverage of Lumenis for the following reasons:

Effective 2/6, we are dropping coverage of Lumenis. The company announced yesterday that its shares would be delisted from the NASDAQ National Market effective February 5 and would begin trading on the Pink Sheets. Our last rating (SU-Spec) and estimates should no longer be relied upon.

The stock was delisted because the interim financials for the quarter ended September 30, 2003, had not been reviewed by the company's independent auditors in accordance with SEC rules owing to an ongoing independent investigation being conducted by its Audit Committee.

We believe the company's prospects are grim due to a weak business environment and high debt burden. As of 3Q03 the company's debt was \$210 million. Though the

company has reached an agreement to restructure its existing debt, we believe cash flow will still be an issue.

With a very competitive medical laser markets, the company's market cap of approximately \$44 million (based on NASDAQ closing price on February 5) and the stock being delisted, we do not see a reason to continue covering the company.

We believe the company's prospects are grim owing to a weak business environment and a high debt burden. As of September 30, 2003, the company's debt was \$210 million. Though the company has reached an agreement to restructure its existing debt, we believe cash flow will still be an issue. Our most recent cash flow model has the company's cash dropping from \$16 million at September 30, 2003 to \$3-\$4 million at the end of 2004 even without paying down any debt. For the quarter ended September 30, 2003, the company reported a net loss of \$15.3 million and negative operating cash flow of \$1 million. Revenues declined 26% to \$66.2M from \$90M a year ago due to lower aesthetic, ophthalmic and surgical laser system sales. The company reported an operating loss of \$10.5 million versus \$3.6 million in earnings a year ago. Gross profit margin in 3Q03 was 40% versus 52% a year ago, slightly higher than our 38% estimate but not an encouraging trend.

We believe that the medical laser markets remain very competitive and that the company will have difficulty reaching profitability while maintaining sales focus. We believe that the company's poor liquidity picture is cause for concern. With a market cap of approximately \$44 million (based on NASDAQ closing price on February 5) and the stock being delisted, we do not see a reason to continue covering the company. Our last rating (Sector Underperformer Speculative) and estimates should not be relied upon going forward.

2/6 **PhotoMedex** announced its attendance at the upcoming 62nd Annual Meeting of the *American Academy of Dermatology* being held in Washington, DC where it will exhibit the XTRAC XL Plus. The Conference is the largest, most prestigious in its field, and typically is very well attended by its membership, including a majority of the practicing dermatologists in the United States and a large number of their international counterparts. The Conference features product demonstrations, hands-on training, workshops, and numerous presentations by leading medical and technical experts in the development and utilization of treatments for skin diseases.

Jeff O'Donnell, PhotoMedex' CEO said, "We expect that the XTRAC will be discussed in at least nine of the scheduled podium presentations being delivered by esteemed key opinion leaders in Dermatology...We believe the XTRAC will become the standard of care for treating mild to moderate psoriasis."

To date, the excimer laser has been supported by 13 clinical studies that establish its safety and efficacy. In addition, **Thomson Health Economics Research** has produced an

economic model and study of the XTRAC therapy, comparing it to the other treatment alternatives available for mild-to-moderate recalcitrant plaque psoriasis. The study, based on peer-reviewed literature and input from several psoriasis experts from leading universities and private practice, confirmed that the XTRAC procedure compares favorably, from both a cost and efficacy standpoint, to other treatment alternatives. The study, performed from an insurance company perspective, establishes the cost-effectiveness of XTRAC therapy for psoriasis.

The addition of the Thomson study to its compendium of clinical data supporting the XTRAC laser, provides the company with a strong and persuasive case for managed care organizations throughout the United States to include XTRAC laser therapy as an approved procedure reimbursable to their members. To date, XTRAC claims have been paid by 79 private insurance companies, along with 24 Medicare plans throughout the country. While Medicare consistently covers the procedure, many of the private payers have been inconsistent in claim reimbursement. As a result of the significant interest in this procedure by dermatologists and their patients and the new economic study, private payers are currently updating their medical policies regarding the use of the excimer laser for the treatment of psoriasis. The Data Compendium, including the Thomson Health Economics Research report, has been recently sent to all plan providers throughout the country. We believe the economic study and model will provide significant evidence for the inclusion of the XTRAC procedure as a covered benefit.

O'Donnell further added, "In the fourth quarter of 2003, the company sold over 10,000 procedures, a ten-fold increase from the comparable quarter in 2002. Insurance reimbursement is taking root and we expect the economic study will contribute to accelerating this ramp."

2/9 **Palomar Medical Technologies Inc.** announced the introduction of its next generation pulsed-light and laser system, the Palomar StarLux, this past weekend at the *American Academy of Dermatology's (AAD) 62nd Annual Meeting* in Washington, DC. The StarLux includes all of the pulsed light handpieces available on prior Palomar pulsed light systems plus the new Lux1064 YAG laser handpiece to treat vascular lesions including leg veins.

The Palomar StarLux pulsed-light and laser system is computer controlled for easy operation and provides physicians with an adjustable "smooth pulse" energy output and integrated contact cooling at the sapphire tip for added safety and patient comfort. Optimum spectrum selection plus higher power and fast repetition rate have been incorporated into this ultra-compact pulsed light design to rival the performance of much higher priced, single application laser technology. Like the MediLux, EsteLux and NeoLux systems, the StarLux has many versatile handpieces that can be used for the removal of hair, treatment of acne (pending FDA clearance) and for photofacial applications for the treatment of pigmented and vascular lesions to improve skin tone and texture. In addition, the StarLux has the new Lux1064 YAG laser handpiece to treat vascular lesions including leg veins.

CEO Joseph Caruso commented, "Palomar came to this year's AAD meeting feeling invigorated having just announced the company's outstanding financial results for the calendar year ended 2003 as well as earlier in 2003 announcing a major strategic agreement with **The Gillette company** to complete development and commercialize a patented home-use, light-based hair removal device for women. Along with this momentum, we were able to announce at the AAD the next generation Lux system. Needless to say, we believe 2004 will be a very exciting year for Palomar."

Caruso continued, "Palomar is proud of its continued improvement to the Lux system platform. Palomar has kept its commitment to continually provide value to customers who invest in our Lux system platform. The StarLux, MediLux, EsteLux and NeoLux systems are the most affordable and versatile cosmetic light-based systems on the market. The Lux platform enables us to custom tailor our products to fit almost any professional medical office or spa location. These systems offer a suite of applications at a fraction of the cost of other competing systems."

CFO Paul Weiner commented, "We have recently completed a very successful investor relation's roadshow at the AAD where we met with managers of numerous investment funds and analysts to discuss Palomar's strategic initiative and growth potential. The tremendous interest generated in Palomar through these meetings is not surprising given the recent financial results and successful implementation of our overall business strategy. We look forward to continued positive meetings with investors and fund managers in 2004."

2/9 Tri-Active LaserDermology (**Cynosure** -- see the February 4 brief from Cynosure above) is the result of the newest FDA-approved technology incorporating Triple-Action methodology for restoring a normal balance to the skin and outer layers, including smoothing and tightening. This new FDA-approved treatment reduces the appearance of cellulite through the combined action of mechanical massage, localized cooling and deep laser stimulation. The **Cellulite Endermologie Center** in Manhattan is one of the first facilities to possess this new FDA-cleared treatment in the U.S., and the only center in New York City with the technology. As the center's director Paulette Long explains, "The primary reasons for cellulite are related to prolonged inflammatory response and insufficient circulation. These three mechanisms work together to optimize results." LaserDermology can be used for the following applications:

- Cellulite treatment
- Pre and post-liposuction
- Facial smoothing
- Body smoothing and contouring
- Enhancing microcirculation
- Therapeutic massage

The Triple Action technology employs deep laser action from six diode lasers that enhance microcirculation. The treatment's mechanical massage brings deep massaging

and stimulating action on the subcutaneous tissue, which results in a tighter appearance in the treated areas. This cutting-edge treatment, when done in a series of sessions, offers an effective way to significantly reduce the appearance of cellulite and enhance overall body contouring.

The Tri-Active LaserDermology system is the answer for cellulite treatment, liposuction support before and after procedures. LaserDermology targets body areas that include the midriff, larger areas prone to cellulite such as thighs and buttocks, and small areas such as the face and neck. Most other parts of the body can be treated as well, including the love handles, abdomen, upper arms, and neck. The procedure is painless and not even as strenuous as traditional massage. The procedure is typically done in a series of 10-15 treatments spaced as closely as three times per week, or as far apart as once a week. Facial tissue will also appear more relaxed and balanced with a fresh glow. Perfect just before and important event, such as a wedding or class reunion!

Results - Individual results can depend on several factors such as:

- Areas being treated
- Whether the treatment is being combined with liposuction or Endermologie (**LPG Systems** of France)
- If treatment has been combined with diet and/or exercise
- Age of patient and general condition
- The number of treatments

Maintenance - Normally the series can be done annually with follow-up monthly maintenance treatments. Tri-Active systems were originally developed three years ago by laser scientists in Italy and are in use all over the world. Physicians, spas, and other health specialists have used this innovative technology in thousands of individuals to uncover glowing skin. Tri-Active LaserDermology enhances the appearance of skin, making it feel smoother, more radiant and cellulite free.

2/9 **Candela Corporation** announced that it was the recipient of several awards for its laser technology at the *Aesthetic Trends & Technologies* Editor's Choice Awards ceremony held on Sunday evening, February 8, 2004 in Washington, D.C.

*Aesthetic Trends & Technologies*, an aesthetic trade journal for physicians, developed The Editor's Choice Awards to give recognition and credit to those devices which are outstanding in their treatment categories. These awards are based on survey results from over 1,000 Board Certified Dermatologists and Plastic Surgeons who are renowned experts in laser and light-based devices.

Candela was honored for best in class with the following awards:

- Best laser for acne - Smoothbeam
- Best non-ablative laser for wrinkle reduction - Smoothbeam



- Best laser for telangiectasia - Vbeam
- Best laser for specialized vascular disorders - Vbeam
- Best laser for hair removal (light skin types) - GentleLASE

Commenting on the awards, Gerard Puorro, Candela's president and CEO, said: "We are delighted to have been recognized with these awards for our superior products. Indicative of this recognition, we are experiencing a very high level of activity and excitement at the Candela booth at the *American Academy of Dermatology's* annual meeting this week in Washington, D.C."

2/10 **Diomed Holdings, Inc.** announced that the resale registration statement filed on behalf of the selling stockholders of Diomed's common stock has been declared effective by the Securities and Exchange Commission. The registration statement registers for resale 327,917,434 shares of Diomed common stock by the selling stockholders named therein at prices to be determined from time-to-time based on the market price of the common stock on the American Stock Exchange, the prices agreed in privately negotiated transactions or otherwise as described in the registration statement. The resale of these shares does not represent a new financing by Diomed.

2/10 Lumenis Ltd. issued the following letter to its customers (published on its website):

Letter to our Customers

February 10, 2004

Dear Customer,

I wanted to use this opportunity to provide you with additional information relating to recent events at Lumenis. We understand that, as you consider the purchase of our equipment, you may have some questions regarding the recent change in the trading venue of the company's stock from the Nasdaq National Market to the Pink Sheets. While we are disappointed in the decision we recently received from Nasdaq giving rise to this change, we want to reassure you that this change in trading venue should have no impact on our operations or ability to serve you, nor does it impact our financing arrangements. In short, it should have no effect on our ability to meet all of our commitments to you as a customer.

First, I would like to explain why the change occurred, what it means and, hopefully, dispel some unfounded rumors.

Why it happened:

\* Nasdaq delisted our stock because we were unable to file the auditor's report for our third quarter financial statements in a timely manner, as required by Nasdaq's rules.

\* We were unable to file the auditor's report because the auditors have not performed any reviews until our Audit Committee completes an internal investigation that was requested by the auditors.

\* The auditors requested the review because of questions raised during the course of the previously announced SEC investigation regarding the company's relationship with its distributors and accounting matters relating thereto.

\* While the Audit Committee is continuing its efforts to complete the investigation, it, unfortunately, was not able to do so in time to retain our listing on Nasdaq.

What the change means:

\* Our shares will now trade on the Pink Sheets. The Pink Sheets is the leading provider of pricing and financial information for the over-the-counter (OTC) securities markets. Approximately 5,000 companies trade in the OTC market.

\* The company will continue its practice of issuing press releases on significant events and keeping investors informed.

What happens next:

\* The Audit Committee will continue its efforts to complete the investigation as promptly as practicable and, thereafter, review the results of the investigation with our auditors, in an effort to become current in our SEC filings.

\* In the meantime, we intend to appeal the delisting decision.

Importantly, **Bank Hapoalim**, our sole lender, is aware of our situation and is fully supportive of the company and its plans. We remain in compliance with all of our covenants in our agreements with them.

We remain committed to delivering to our customers the best technology and products in the market today and to continuing to improve on the service and support that is so important to your practices. While our share price has performed very poorly recently and the delisting is a disappointment to our shareholders, and us, it is unrelated to, and should have no impact on, our ability to provide you with the best products or our financial viability for the long term.

In light of the facts highlighted above, I hope you feel more comfortable and confident about Lumenis' future. If you have any additional questions or concerns, please contact Kevin Morano, our CFO, or myself.

In closing, I want you to know Lumenis appreciates your interest in our products and your support of our company. We look forward to serving you for many years to come.

Sincerely,

Avner Raz  
President and Chief Executive Officer  
Lumenis Ltd.  
**araz@lumenis.com**  
(212) 515-4187

- 2/12 **DUSA Pharmaceuticals, Inc.** announced that DUSA's Levulan PDT generated considerable excitement at the recent *American Academy of Dermatology (AAD)* 2004 Annual Meeting in Washington, D.C. February 6-11. This meeting is widely considered to be the largest and most important dermatology conference of the year.

In the scientific sessions, there were 29 lectures and presentations that were focused on, or included, Levulan PDT, and/or aminolevulinic acid (ALA) PDT (ALA is the active ingredient in DUSA's Levulan). This included presentations and posters based on both DUSA sponsored and independent investigator studies. The topics ranged from Levulan PDT's FDA-approved use in the treatment of actinic keratoses (AKs), to a wide variety of other potential uses, and were based on both DUSA sponsored and independent investigator studies. Over the course of the meeting, thousands of dermatologists and dermatology residents attended these presentations. As a result, many dermatologists informed DUSA employees that Levulan PDT was "the hot topic" of the whole conference.

The increased physician interest in both our Levulan Kerastick and our BLU-U brand light source at the DUSA booth and in the technical exhibits exceeded company expectations. Many physicians placed orders for the company's products at the booth, and many others asked for a DUSA sales representative to call on them in the near future. Dr. Geoffrey Shulman, DUSA's President and CEO, stated "We couldn't have been more pleased with the scientific sessions, as well as the level of physician feedback and interest at the 2004 AAD meeting, and the company intends to keep the momentum going. For example, the company is being well represented at the *2004 South Beach Symposium* hosted by the *Florida Society of Dermatology and Dermatologic Surgery*, which starts February 12, 2004 and runs through February 15. This important meeting, with over 400 dermatologists registered, features Levulan PDT live patient treatment sessions for treatment of AKs and other potential indications as an integral part of its program. DUSA will also be represented at numerous other society and educational meetings throughout the year."

- 2/12 **Laserscope** reported that revenues for its fourth quarter ended December 31, 2003 increased 41% to \$17.8 million from \$12.7 million in the year-ago quarter. Sequentially, revenues increased 25% from \$14.3 million for the quarter ended September 30, 2003. Net income was \$1.5 million (7 cents per share) compared with net income of \$50,000,

or break-even per share, in the same quarter last year, and net income of \$533,000 (3 cents per share) for the third quarter of 2003.

"Our strong fourth quarter revenues were driven by the explosive growth of our urology product line and very solid domestic growth of our aesthetics products," said Eric Reuter, Laserscope's President and CEO. "We believe our results clearly demonstrate the successful execution of our growth strategy, which is to drive the rapid adoption of our innovative Photo-Selective Vaporization of the Prostate (PVP) procedure. Our GreenLight PV revenues and utilization rates continue to exceed our expectations. Total 2003 GreenLight PV revenues for the year were \$15.1 million, or 26% of total revenues, compared with \$4.3 million, or 10% of total revenues, in 2002."

Gross margin was approximately 54%, compared with approximately 51% for the fourth quarter of fiscal 2002. Sequentially, the gross margin improved from approximately 52% for the third quarter. Selling, general and administrative expenses were \$6.8 million, or 38% of net revenues, compared with \$5.3 million, or 42% of net revenues, in the year-ago quarter. Increased spending in this area came primarily from higher sales and marketing expenses relating to the GreenLight PV products as well as higher direct selling expenses for domestic aesthetic products.

Reuter continued, "During the quarter, we sold 39 GreenLight PV laser systems and 5,364 fibers, compared with 34 systems and 3,414 fibers in the prior quarter. This represented an approximately 57% sequential increase in fiber volume and sales were higher to all customer types. For the full year, 2003 GreenLight PV fiber shipments grew 284% over 2002's levels. Additionally, backlog increased to 19 systems at the end of the fourth quarter, compared with 12 systems at the close of the third quarter. These results continue to indicate that PVP adoption is growing at a significant pace in both our domestic and international markets."

"Domestic aesthetic revenues grew 37% over the fourth quarter last year. During the fourth quarter, we received FDA clearance for active acne treatment using our Aura laser system. We believe that this additional FDA clearance, along with the recent launch of our versatile Gemini aesthetic laser system, will continue to support ongoing growth in our aesthetic business domestically and internationally. We are looking forward to a very exciting 2004."

The company had no short-term bank borrowings and increased its cash position to \$7.2 million at December 31, 2003 from \$4.7 million at the end of 2002.

**Full Year 2003 Results** -- For the year ended December 31, 2003, the company reported revenues of \$57.4 million and net income of \$2.5 million, or \$0.13 per diluted share, compared with revenues of \$43.1 million and net income of \$323,000, or \$0.02 per diluted share, for the full year 2002.

**Update on Reimbursement** -- In November 2003, the company announced that the Centers for Medicare and Medicaid Services (CMS) had notified Laserscope that its application for assignment of the PVP procedure to treat Benign Prostatic Hyperplasia (BPH) had been accepted. In determining that PVP meets the new technology APC qualification criteria, CMS noted that the new code would be effective April 1, 2004.

"As of today, we have not yet been informed by CMS of the level of reimbursement under the new code," stated Reuter. "As we mentioned previously, we continue to work with CMS and the American Urological Association (AUA) to ensure that the hospital outpatient and physician reimbursement rates for furnishing PVP reflect the appropriate costs of performing the procedure. We will announce the new rates as soon as they are released by CMS."

**Guidance** -- The company is updating its guidance for fiscal year 2004 and will further revise its guidance when news from CMS is released regarding the new technology APC reimbursement rate. The following is the updated guidance:

- \* First quarter revenues are expected to be in the range of \$15 - \$16 million due to seasonal patterns in elective surgeries. The company expects the seasonality to result in a sequential decrease in fiber volume. Additionally, first quarter sales and marketing expenses will include costs associated with the launch of the Gemini laser.

- \* Expecting continued adoption of the PVP procedure to drive further sales growth of the GreenLight PV products, the company is upwardly revising its 2004 revenue forecast to \$70 million with growth increasing in the latter half of the year.

- \* Gross margin, as a percentage of 2004 revenues, is expected to be in the range of 53% to 55%.

- \* The company expects to achieve 2004 net income of \$0.32 - \$0.34 per diluted share, higher than the \$0.30 per diluted share provided previously. The company expects the majority of earnings growth to be generated in the second half of the year.

2/13 **Celsion Corporation** announced that it is naming its Transurethral Microwave Thermotherapy System, which is currently under PMA review by the FDA, the Prolieve Thermodilatation system. Upon approval by the FDA, the system, formerly known as the Microfocus BPH 800 Microwave Urethroplasty system, will be distributed and marketed by **Boston Scientific Corporation**.

Dan Reale, Celsion's executive vice president, said, "The Prolieve Thermodilatation name was chosen as it describes our unique mechanism of action in which BPH symptoms are relieved through the dual techniques of applying heat to the prostate while simultaneously dilating the urethra with a balloon catheter."

Benign Prostatic Hyperplasia (BPH), otherwise known as enlarged prostate, affects men as they age, resulting in frequent urination and other difficulties. Current treatments, which include drug therapy and minimally invasive treatments, are such that seven million of the nine million American men affected choose not to be treated.

In January 2003, Celsion entered into a strategic alliance with Boston Scientific Corporation in which Boston Scientific will initially distribute the Prolieve Thermodilatation system in the United States.

- 2/13 The Board of Directors of **El.En. SpA**, met and approved the financial report for the fourth quarter of year 2003. During the fourth quarter the **El.En. Group** consolidated revenues were 20.140 thousands of Euro, up 4% from the revenues of the corresponding quarter in 2002, while the revenues for the year reached 68.120 thousands of Euro up 26% with respect to 2002. The increase in revenues was mainly driven by sales in the medical/aesthetic segment which marks a 40% revenues increase, and in the customer service revenues, up 54% on 2002's results. The Gross Margin for the fourth quarter 2003 was 11.379 thousands of Euro, up 18% on the fourth quarter of Q4 2002, while on a twelve month basis the Gross Margin was 37.598 thousands of Euro, up 37% over year 2002 and with a 51% impact on the value of production, increased as an effect of the higher margin on sales performed by **Cynosure**.

EBITDA in the fourth quarter 2003 was 1.816 thousands of Euro, down 37% with respect to the fourth quarter of 2002, while the 5.508 thousands of Euro EBITDA of year 2003 marks a 22% decrease on 2002's result. Earnings have been hit by the enduring crisis in the manufacturing market and by the US dollar's weakness which helped consolidating the crisis. EBIT for the fourth quarter 2003 is 462 thousands of Euro, down 70% on 2002's 1.553 thousands of Euro. EBIT for the year 2003 was 1.440 thousands of Euro, marking a 64% decrease on the 3.971 thousands of Euro of year 2002. The Net Financial Position as of December 31, 2003 is positive for 13 millions, decreasing from end of year 2002 but up 600 thousands of Euro in the fourth quarter of 2003. The strong negative conjuncture in the manufacturing segment and the weakness of the US dollars had a negative impact on revenues and profits of the Group. The Budget for year 2004, prepared within such a negative framework, nevertheless show a strong growth rate in revenues, achieved with the help of the complete consolidation of the financials of **Quanta System SpA**, **Asclepion Laser Technologies GmbH** and **Lasercut Inc.**, and of the strong increase in Cynosure's sales on the medical market. El.En. estimates consolidated revenues of 89 thousands of Euro for 2004, up 30%.

The revenue growth in the medical segment will be 35%, while the industrial will mark a 30% growth. The forecasted EBIT is 4,2 millions of Euro, up 130%.

- 2/17 **BriteSmile Inc.** announced that the *Screen Actors Guild Awards Committee* had selected BriteSmile as one of the top-of-the-line gift items that will be included in the coveted gift baskets for presenters at the 2004 Screen Actors Guild Awards (SAG). This is the second year that BriteSmile has worked with the Screen Actors Guild Awards presenter gift baskets. Presenters at this year's awards will receive the BriteSmile Whitening Care Kit,

which includes a complimentary BriteSmile light activated teeth whitening treatment at any of the company's luxurious BriteSmile Spas, and BriteSmile's complete line of maintenance products, including BriteSmile whitening toothpaste, BriteSmile crystal clear mouth wash, BriteSmile sugar free gum and BriteSmile's newest product offering, the BriteSmile To Go Whitening Pen.

"We are extremely honored that a prestigious organization like the Screen Actors Guild Awards Committee has chosen BriteSmile to be a part of this year's SAG Awards(TM) presenter gift baskets," said John Reed, BriteSmile CEO. "From the runway to the red carpet, BriteSmile goes hand-in-hand with some of America's most famous smiles. We are thrilled to be a part of this award's season."

- 2/18 **Palomar Medical Technologies Inc.** announced that it had been awarded a \$2.5 million research contract by the *Department of the Army* to develop a light-based self-treatment device for Pseudofolliculitis Barbae (PFB). The project begins on February 23, 2004 and is scheduled to last for nineteen months, through September 22, 2005. PFB, commonly known as "razor bumps", has been called "the most significant dermatologic disease in the US Army"; affecting combat readiness, unit cohesion, and individual morale of over 50% of African American and Hispanic military personnel. The importance of a solution to the PFB problem is increasing along with the changing demographics of the military; the percentage of African-Americans and Hispanics in the services is currently twice that in the civilian population and growing. This contract is awarded by the Department of Defense Peer Reviewed Medical Research Program (PRMRP) of the Office of the Congressionally Directed Medical Research Programs (CDMRP) to private and public organizations having demonstrated capability in solving "Military Relevant" medical problems.

In commenting on the impact of the PFB award, Dr. Michael Smotrich, Palomar's Chief Technical Officer said, "Over the past six years, Palomar has invested in the development of technology necessary for the realization of a compact, safe, cost effective, self-treatment light-based system having applications in dermatology. The PFB program is an ideal extension of this technology to address a military problem. We are honored to have been selected to assist our armed forces through this award."

- 2/19 **Diomed Holdings, Inc.** announced financial results for the year ended December 31, 2003. For the year ended December 31, 2003, Diomed delivered revenue of \$9.2 million, an increase of \$3.6 million, or 66% over the year ended December 31, 2002. Revenue from EVLT disposable procedure kits increased 220%, representing a volume increase of more than three times the number of kits sold in FY2002, when the Company received FDA clearance. (That means, for the fourth quarter, revenues were \$2.6 million.) Loss from operations decreased by \$1.7 million, or 22%, to \$6.0 million compared to FY2002. Net loss applicable to common stockholders was \$19.9 million (36 cents per share) compared to a net loss of \$8.0 million (59 cents per share) for FY2002. The FY2003 net loss included \$12.7 million in non-cash interest expense arising from debt discounts and

beneficial conversion features related to the bridge financings in December 2002 through September 2003.

"Diomed delivered a strong performance in 2003 while achieving a number of critical strategic initiatives," commented James Wylie, president and CEO. "The company achieved a record sales performance since becoming public in 2002, raised \$23.2 million in an equity financing and acquired the exclusive rights to the U.S. Patent No. 6,398,777 covering the endovenous laser treatment of varicose veins. We estimate that since the launch of EVLT more than 10,000 EVLT procedures have been successfully performed on more than 350 installed EVLT laser systems, a clear demonstration of the growing acceptance of EVLT in the medical field."

### **Liquidity and Capital Resources**

"The recent \$23.2 million equity financing leaves the company well positioned to fund key sales and marketing initiatives, to implement its intellectual property strategy, and to retire existing debt," further commented Wylie. The \$23.2 million equity financing included \$21.0 million in new cash proceeds and \$1.2 million in the form of conversion of existing debt. Of the new cash proceeds, the company utilized \$2.3 million in initial payments to acquire the exclusive rights to the EVLT patent, \$2.1 million to retire the December 2002 notes, \$438,000 to retire short-term notes, \$1.2 million in equity financing costs, \$1.1 million in the reduction of trade payables, \$150,000 in the Augenbaum settlement, and \$1.3 million in working capital from September through December. On January 2, 2004, the company retired its \$936,000 promissory note to **Axcan Pharma**, eliminating bank indebtedness from its balance sheet.

- 2/19 **Cynosure, Inc.** announced that its Aesthetic Medicine Group had selected **Herbst LaZar Bell (HLB)** to redesign its products for the office-based physician market. The Aesthetic Medicine Group markets these cosmetic surgery products to over 60,000 office-based physician practices in the U.S., including dermatologists, plastic surgeons, facial plastic surgeons, oculoplastic surgeons, family practice, gynecologists, and other specialties.

The newly designed products include those for laser hair removal, "lunch time" facial treatments, leg and facial veins, photodamaged skin, acne and pigmented lesions. The products will be released at this year's annual meetings of the *American Academy of Dermatology (AAD)*, *American Society of Aesthetic Plastic Surgeons (ASAPS)*, *American College of Obstetrics and Gynecology (ACOG)*, and other associations. These products fulfill a broad range of office-based physician market requirements, which combine optimal clinical results and artistic presentation for the cosmetic patient.

"We have chosen HLB as our product designer because of their extensive track record in identifying dominant design trends," said Michael Davin, CEO. "We are pleased with this partnership because it supports our strategy to focus Cynosure's resources where the greatest value is added. This decision to redesign our aesthetic medicine products was based in large part to market input. Our customers need high technology products that



provide important cosmetic procedures but in aesthetic, artistic packaging that meet patients' expectations."

2/23 **Frost & Sullivan ([www.MedicalDevices.frost.com](http://www.MedicalDevices.frost.com))** has published a new report on the medical laser industry, "*U.S. Medical Lasers Market*," that reveals that revenue in this industry totaled \$546.3 million in 2003 and is projected to reach \$672.4 million by 2009. (My numbers indicate that the market is at least twice that size, at \$1479 million for 2004.)

The spurt of newer technologies in the U.S. medical laser devices market has made possible the treatment of various critical health conditions, which were previously considered difficult to treat. In a bid to encourage adoption, participants are focusing on creating awareness among end users. Lasers are now widely used among patients who cannot undergo a bypass surgery. Similarly, the quick rehabilitation period and minimal post-operative pain involved with laser in situ keratomileusis (LASIK) procedures in ophthalmology has contributed to their extensive use. Expansion to areas such as Cardiology for Transmyocardial Revascularization and Urology for BPH treatment would ensure long-term growth of laser markets.

If you are interested in a virtual brochure, which provides manufacturers, end-users and other industry participants an overview of the latest analysis of the "U.S. Medical Lasers Market," then send an e-mail to Danielle White, healthcare media relations executive, at **[dwhite@frost.com](mailto:dwhite@frost.com)**.

The increase in demand for different types of lasers can be partially attributed to the growing baby boomer population. Age-related diseases such as presbyopia, macular degeneration and diabetic retinopathy have positively influenced the market. With the average number of baby boomers suffering from such diseases going up, there has also been a corresponding rise in technologies that can effectively combat them.

Sophisticated, vision correction techniques such as Customcornea are capable of providing "customized" treatments by mapping the cornea of an individual patient. This would naturally increase the accuracy and precision of the treatment. "Several patients are opting for lasers mainly because it reduces the complications involved with many diseases," says Frost & Sullivan industry analyst Dhiraj Ajmani. "Since lasers are non-invasive, a patient tends to perceive it as being less dangerous and non-threatening."

However, the lack of sufficient clinical data is likely to slow down market growth. Even while procedures such as laser-assisted lead removal, excimer laser angioplasty and transmyocardial revascularization (TMR) offers great potential in the cardiology segment, surgeons remain unclear as to the clinical end points and long-term implications.

The frequent introduction of new techniques also challenges the expertise among surgeons. In many instances, they prefer to opt for the comfortable familiarity of older

modalities. "Generating awareness among physicians is central to the growth of the laser devices market," says Ajmani. "It is essential to provide training to surgeons and practitioners to encourage uptake."

Another factor that is likely to restrain growth is that many healthcare facilities are still paying for older equipment. For instance, many renal centers are financially committed to the high-priced extracorporeal shock wave lithotripsy (ESWL) platforms even though they are keen to try the newer laser modality of treatment. Additionally, the lengthy turnaround time involved with an FDA approval also acts in the favor of older procedures and seriously incapacitates new entrants. In an effort to reduce FDA paperwork and increase their market share, many participants have started focusing on overseas markets.

"U.S. Medical Lasers Market" is part of the Surgical and Infection Control Products subscription, and provides a comprehensive insight of the competitive landscape of the U.S. medical laser devices market in four segments: ophthalmology, aesthetic, cardiology and urology. It evaluates the drivers and restraints affecting each of these segments and assesses the potential growth opportunities in each. It also outlines the winning strategies adopted by leading participants, which would give new comers an indication of how they could position themselves.

The following is a list of key industry participants: **Advanced Medical Inc., Alcon Inc., American Society of Plastic Surgeons, Bausch & Lomb, Candela Corp., Cardiogenesis Corp., Carl Zeiss Meditec AG, Convergent Laser Technologies, Diomed Inc., Dornier Medtech, IntraLase Corp., IRIDEX Corp., LadarVision** (? I thought that LadarVision was a brand from Alcon, not a company!), **Laserex, LaserSight Technologies Inc., NIDEK, Palomer Medical Technologies Inc., PhotoMedex, PLC Medical Systems Inc., Spectranetics, Trimedyne Inc., VISX Inc.**

Frost & Sullivan, an international growth consultancy, has been supporting clients' expansion for more than four decades. Our market expertise covers a broad spectrum of industries, while our portfolio of advisory competencies includes custom strategic consulting, market intelligence and management training. Our mission is to forge partnerships with our clients' management teams to deliver market insights and to create value and drive growth through innovative approaches. Frost & Sullivan's network of consultants, industry experts, corporate trainers and support staff spans the globe with offices in every major country around the world.

## **MEDICAL/SURGICAL LASER UPDATE -- March 2004**

2/24 **BIOLASE Technology, Inc.** reported results of operations for the fourth quarter and year. Net sales for the quarter and year were \$16.1 million and \$49.1 million respectively. Net sales for the quarter and year ended December 31, 2002 were \$8.1 million and \$27.3 million respectively. As discussed in the company's Report on Form 10-Q for the quarter ended September 30, 2003, results of operations between periods are not directly comparable due to the change in accounting for revenue recognition in August 2003.

During the fourth quarter of 2003, the company recognized approximately \$400,000 of the revenue that was previously deferred at September 30, 2003.

Net income for the quarter and year was \$14.3 million and \$19.1 million, respectively, and includes a one-time tax benefit of \$11.4 million. At December 31, 2003, an estimated \$32.5 million in net operating loss carryforwards was available to offset federal taxable income in future years. Income before taxes for the quarter and year ended December 31, 2003 was \$2.9 million and \$7.7 million respectively. Income before taxes for the quarter and year ended December 31, 2002 was \$332,000 and \$1.5 million, respectively. Cash flow from operating activities for the year ended December 31, 2003 was \$6.3 million compared to \$477,000 for the year ended December 31, 2002.

Net income per share for the fourth quarter and year was \$0.61 and \$0.83 respectively. The per-share information for 2003 includes the one-time tax benefit as discussed above. Net income per share for the quarter and year ended December 31, 2002 was \$0.02 and \$0.07 respectively.

At December 31, 2003, the company had cash of \$11.1 million, working capital of \$10.7 million, stockholders' equity of \$31.8 million and total assets of \$44.5 million.

Jeffrey Jones, BIOLASE president and CEO stated: "We were very pleased with our performance for the fourth quarter and 2003 overall. During the fourth quarter we experienced strong revenue and earnings growth, while increasing our cash position by approximately \$5 million. Our operating margin reached a new high of 17.5%, during this seasonally strong quarter. As we grow, we expect our annual operating margin to expand from the 15% annual rate achieved in 2003. However, our current strategic priority remains on market penetration and our quarterly operating margins could fluctuate due to sales and marketing activities and other factors. During 2004, we expect strong sales growth consistent with our historical guidance of 40% to 50% and we expect our profitability will continue to increase as we execute our business strategy."

2/24 **PhotoMedex, Inc.** announced the results of their operations for the fourth quarter and year ended December 31, 2003. Revenues for the fourth quarter were \$3.7 million, an increase of 12.2% over the third quarter 2003. Included in this amount was \$2.9 million from operations of **Surgical Laser Technologies, Inc. (SLT)**, a company acquired by PhotoMedex on December 27, 2002. Revenues for the same quarter last year were \$647,341, including revenues of \$37,075 from SLT (for a period of 2 days following the closing of the merger of PhotoMedex and SLT on December 27, 2002). The net loss for the quarter was \$2.2 million (6 cents per share). The net loss for the fourth quarter of 2002 was \$2.6 million (9 cents per share).

Revenues for the year were \$14.3 million. Included in this amount was \$11.8 million from operations of SLT. Revenues for 2002 were \$3.3 million, including \$37,075 from SLT (for a period of 2 days following the closing of the merger of PhotoMedex and SLT on December 27, 2002). The net loss for the year was \$7.4 million (21 cents per share).

The net loss for 2002 was \$9.1 million (34 cents per share). As of December 31, 2003, the company had cash and cash equivalents of \$6.6 million.

Jeffrey O'Donnell, PhotoMedex CEO and president, commented, "I am pleased with our total shipments that again exceeded \$4 million, resulting in \$3.7 million of recognized revenue. Our domestic dermatology business continues to increase. The number of XTRAC procedures performed in the quarter increased by over 17% to approximately 10,600 procedures from approximately 9,000 procedures in the third quarter. This represents more than a ten-fold increase from the same period last year. More importantly, I am proud of the acceptance PhotoMedex once again received at the *Annual Meeting of the American Academy of Dermatology (AAD)* earlier this month. We were represented in over 10 podium presentations leading to significant inquiry by practicing dermatologists. We are still at the early stage of awareness among the medical community. Widespread reimbursement will allow us to make the next major step in market awareness moving us toward our goal of becoming a preferred treatment for mild to moderate psoriasis and other inflammatory skin disorders."

O'Donnell further added, "With a recently completed mailing to over 1,800 insurance providers, we have been active in discussions with medical directors across the country analyzing the merits of including XTRAC as a covered benefit..."

### **2003 Highlights:**

- CPT Codes for Medicare and Medicaid become effective March 1, 2003;
- December 2002 Acquisition of Surgical Laser Technologies, Inc. quickly integrated with substantial economies realized;
- Dermatological XTRAC procedures increased ten-fold;
- Pursuit of Private Payer adoption leads to completion of Economic Study on the cost effectiveness of XTRAC;
- Data Compendium, including the economic study mailed to over 1,800 insurance providers;
- Completion of \$10.1 million Private Equity Placement;
- Obtained further validation, both nationally and internationally, from such premier medical conference podiums as the 62nd Annual Meeting of the *American Academy of Dermatology (AAD)* and the *21st World Congress of Dermatology Meeting*, attesting to the clinical superiority of the XTRAC therapy;

-- Received prominent exposure in peer review journals, supporting the XTRAC laser's claims of clinical superiority; equal or superior level of symptom remissions, multiple uses for dermatology indications, and safe and effective treatment for patients.

2/25 **PLC Systems Inc.** reported positive financial results for the three months and year ended December 31, 2003. The company also announced that it earned a profit for the seventh consecutive quarter, which led to PLC achieving its second consecutive profitable year.

In a separate news release (see below) PLC Systems and **Edwards Lifesciences Corporation** announced that the two companies had entered into an exclusive, multi-year agreement to develop and manufacture Edwards' Optimaze surgical ablation system, a cardiac laser technology that treats cardiac arrhythmias. Edwards is the exclusive U.S. sales and marketing partner of PLC's TMR Heart Laser system for cardiac revascularization.

Total revenues for the fourth quarter of 2003 increased 4% to \$2.3 million compared with \$2.2 million for the fourth quarter of 2002. PLC generated fourth quarter 2003 operating income of \$309,000, which is a record for PLC since the company entered into its TMR partnership with Edwards Lifesciences in January 2001. PLC's fourth-quarter net income was affected by the company's decision to liquidate one of its international subsidiaries. In closing its Swiss subsidiary, the company realized a non-recurring foreign translation currency loss of \$257,000. Fourth quarter 2003 net income, after giving effect to this non-recurring foreign currency charge, was \$74,000 compared with fourth quarter 2002 net income of \$210,000.

Total revenues for the year were \$8.3 million compared to total revenues of \$8.8 million for 2002. Net income was \$517,000 compared to net income of \$305,000 for 2002. During the year, PLC improved its cash position by approximately \$450,000 and ended 2003 with cash and cash equivalents totaling approximately \$6.4 million.

"PLC's profitable fourth quarter and full year are important achievements," stated Mark Tauscher, president and CEO of PLC Systems. "With Edwards' clinical and educational capabilities behind our TMR technology, we believe it has the potential to become the technology of choice for surgeons and cardiologists who want to achieve more complete revascularization for their patients."

During the fourth quarter of 2003, PLC shipped 10 CO<sub>2</sub> Heart Lasers worldwide. Nine next-generation CO<sub>2</sub> Heart Lasers (HL2) were delivered to United States hospitals through Edwards. Additionally, PLC shipped one first generation CO<sub>2</sub> Heart Laser (HL1) to an international hospital.

PLC ended the fourth quarter of 2003 with 156 CO<sub>2</sub> Heart Lasers located at heart centers throughout the U.S., comprised of 106 HL2 customers and 50 HL1 customers. As of December 31, 2003, PLC's U.S. total laser base (HL1 and HL2) had increased by 18 percent during the preceding twelve months. More significantly, PLC's U.S. HL2

installed base grew to 106 lasers as of December 31, 2003, up 39% from December 31, 2002.

PLC believes that a leading indicator for the adoption rate of the CO<sub>2</sub> TMR therapy is disposable kit shipments to hospitals. During the fourth quarter of 2003, a total of 476 disposable kits were shipped worldwide. Edwards Lifesciences delivered 471 disposable kits to United States hospitals and PLC shipped an additional 5 disposable kits to international hospitals. The 471 domestic kits delivered by Edwards Lifesciences represents a 41% increase over the comparable fourth quarter a year ago. A total of 452 disposable kits were delivered worldwide during the fourth quarter of 2002.

In the second press release, noted above, PLC and Edwards said the following:

PLC Systems Inc. announced that the company had entered into an exclusive, multi-year agreement with Edwards Lifesciences Corporation for the development and manufacture of Edwards' Optimaze surgical ablation system, a cardiac laser technology designed to treat cardiac arrhythmias, or heart rhythm disorders. The most common cardiac arrhythmia is atrial fibrillation -- a disease that affects more than 2.2 million Americans and causes approximately 15% of all strokes in the United States.

The Optimaze system, which has received FDA clearance, utilizes a proprietary fiber optic and diffuser technology to give clinicians a flexible tool to create a rise in tissue temperature resulting in thermal ablation of the cardiac tissue. It is believed that the lesions created in this process block the conduction of errant electrical signals in the heart. PLC and Edwards plan to develop the Optimaze technology platform as a basis for future, less-invasive products that enable minimally invasive ablation treatment of cardiac arrhythmia.

"This expanded agreement with Edwards is important to PLC," stated Mark Tauscher, president and CEO of PLC Systems. "It marks a significant milestone in our long-term strategy to expand beyond TMR and make PLC a multi-product, multi-platform company. We have extended and deepened our relationship with Edwards, a recognized industry leader. And lastly, we seized an opportunity to enter the cardiac ablation marketplace, which is vastly underserved and currently in search of improved technology solutions."

"The decision to expand the relationship with our partners at PLC was a natural one given the continuing success with our TMR partnership," said Michael Mussallem, Edwards' chairman and CEO. "By combining the development activities of the Optimaze laser and disposable components within a focused organization that specializes in laser technologies, we believe we can further enhance the technology and accelerate the development of less invasive approaches to this therapy."

Under the exclusive, multi-year agreement, Edwards Lifesciences will transfer to PLC assets and technologies related to its Optimaze surgical laser ablation program. PLC will

assume the responsibility of ongoing product development and manufacturing of the Optimaze system and disposable components. Edwards will be the exclusive worldwide distributor of these products. PLC and Edwards will jointly own all surgical cardiac ablation intellectual property developed under the agreement. The companies have entered into a revenue sharing agreement for Optimaze disposables, whereby Edwards retains approximately 65% and PLC receives approximately 35% of all customer-generated revenue.

As part of this agreement, PLC and Edwards also modified their existing TMR relationship, which included lengthening the term of the distribution agreement and adjusting the domestic TMR disposable revenue sharing arrangement, in exchange for an upfront payment of \$4.5 million from Edwards. PLC adjusted its TMR disposable revenue share from 45% of customer-generated revenue to 36.5%. PLC will recognize the \$4.5 million payment as revenue over the next seven years. All other material terms of the agreement, including domestic TMR laser revenue sharing and PLC's retention of all rights to its international TMR business, remain the same.

Tauscher continued, "With today's announcement, PLC has taken a major step forward in expanding our revenue generation opportunities with an attractive, synergistic second business. We believe, based on other recent transactions for cardiac ablation technologies, the value created within PLC for our shareholders as a result of this transaction is exceptional. We have positioned PLC for stronger growth in 2005 and beyond. The cardiac ablation laser opportunity with Edwards is a major first step in our strategic plan to diversify PLC's products and target new markets. While we anticipate that our research and development investments in 2004 will contribute to an overall net loss this year, we expect that PLC's TMR business will continue to be profitable on a standalone basis this year. We believe the Optimaze product will generate incremental revenues for PLC beginning in early 2005. The \$4.5 million payment, combined with our existing cash, provides us with additional flexibility to execute our long term strategy and pursue further strategic initiatives to create value for our shareholders."

The Edwards news release added: The arrangement builds upon Edwards' existing relationship with PLC as the exclusive distributor of PLC's TMR Heart Laser system for cardiac revascularization. "The decision to expand the relationship with our partners at PLC was a natural one given the continuing success of our TMR partnership," said Michael Mussallem, Edwards' chairman and CEO. "By combining the development activities of the Optimaze laser and disposable components within a focused organization that specializes in laser technologies, we believe we can further enhance the technology and accelerate the development of less invasive approaches to this therapy." Edwards Lifesciences announced in December 2003 at its annual investor conference its intent to expand the development of its Optimaze program to include products that can be used on a beating heart. The company plans to begin market introduction of the redesigned surgical product line in the second half of 2004.

2/26 **Candela Corporation** announced that its Vbeam pulsed dye laser was featured on CBS's "The Early Show" on Wednesday, February 25th and Thursday, February 26th during a two-part birthmark treatment procedure series. Dr. Roy Geronemus of the Laser & Skin Surgery Center of New York, a leading surgeon in the treatment of birthmarks, demonstrated the Vbeam laser as a treatment option for the removal of birthmarks. Each year, one in ten children is born with a vascular birthmark, commonly referred to as a "port wine stain." These birthmarks can range in color from pale pink to dark purple, and vary in size. Treatments for port wine stains have drastically improved in recent years with the advancement of laser technologies, such as the Vbeam from Candela.

Gerard Puorro, Candela's president and CEO, commented, "It's admirable that CBS and Hannah Storm decided to raise awareness about the treatment of port wine stains, as it is a topic not easily discussed. Now, many children and their parents can be better informed about the treatment options currently available for this condition."

2/26 **CardioGenesis Corporation** announced results for its fourth quarter and year ended December 31, 2003. Chairman and CEO Michael Quinn reported total annual revenues were higher in 2003 compared to the prior year. In addition, as gross margin percentages for the quarter and year increased, the loss from operations for 2003 declined sharply and the company reported a profitable fourth quarter.

"We ended 2003 and have begun 2004 on a very optimistic note for several reasons, but most importantly because we believe our Holmium:YAG TMR procedure came of age in the past year, both clinically and as a business enterprise," said Quinn. "In recent weeks we have seen conclusive clinical evidence, in the form of two long-term and very high-profile studies, that Holmium:YAG TMR not only provides significant and enduring benefits for patients suffering from advanced coronary artery disease, but it also improves long-term survival. Looking forward, we intend to build on our recent Holmium:YAG TMR successes with the introduction of a number of new products in the coming year including new minimally-invasive and robotically-assisted approaches to TMR."

Net income for the quarter was up more than 261% to \$538,000 (1 cent per share) compared to \$149,000 (0 per share) in the prior year fourth quarter. Net revenues in the fourth quarter of 2003 were \$3.4 million compared to \$3.7 million in the same period in 2002. Net revenues in the 2002 fourth quarter included a higher number of handpiece sales worldwide than in the 2003 fourth quarter as throughout 2003 the company focused on increasing utilization of in-place lasers and handpieces in the US installed base, which also resulted in a year-over-year decline in international sales.

For the full year of 2003, the loss from operations declined sharply to \$336,000 from \$2.8 million in 2002 and the net loss for 2003 was \$348,000 (1 cent per share) compared to a net loss of \$530,000 (1 cent per share) for the prior year. Net revenues in 2003 increased to \$13.5 million from \$13.0 million in 2002.



The fourth quarters of 2003 and 2002 included \$309,000 and \$598,000, respectively, for the reduction of accrued liabilities established in prior periods for research and development costs associated with estimated clinical trial obligations. For all of 2003 and 2002, accrued liabilities established in prior periods for these research and development costs were reduced by \$605,000 and \$1.3 million, respectively. The 2002 fourth quarter included a \$567,000 reduction in accrued liabilities recorded earlier in that year in connection with the company's management incentive program. The results for 2002 also included a \$2.3 million one-time gain recorded in the second quarter from the sale of the company's minority interest in a privately held medical company.

Gross profit margins, as a percentage of sales in 2003 continued to improve, increasing to a record 84% in the fourth quarter and 83% for the full year, up from 80% and 78%, respectively, for the 2002 fourth quarter and full year. Sales, general and administrative expenses in this year's fourth quarter declined approximately \$500,000 from the prior year period to \$2.2 million, and for the full year declined \$2.7 million to \$9.6 million due primarily to improvements in operating expenses resulting from headcount reductions and related expenses.

Additional R&D expenses associated with getting FDA clearance for PMR were \$193,000 for the fourth quarter and \$1.4 million for all of 2003. Quinn noted that without those expenses the company would have been profitable for the year.

The year also saw a renewed focus on innovation at CardioGenesis that resulted in the introduction last month of its new, minimally-invasive, robotically-assisted or thorascopic approach to TMR, which employs a proprietary fiberoptic delivery system that greatly reduces the surgical risk and a patient's recovery time. "We are the clinical and market leaders of TMR and we are actively pursuing new approaches to the therapy," Quinn said. "These new minimally invasive delivery systems are where modern technology is headed and we intend to be leaders in this effort. Obviously, when we reduce the surgical risk to patients who undergo our therapies, the added benefit will be a much quicker recovery and a faster return to a more vital lifestyle. That's the goal of all of our innovations."

Among the highlights of 2003 was the data from a five-year follow-up clinical study of the company's pivotal TMR vs. Medical Therapy trial presented by Keith Allen, MD at the *American Heart Association* Scientific Sessions in November. Dr. Allen's data showed that not only do the overwhelming majority of patients (88%) treated with TMR continue to experience significant reduction in angina pain after five years, but that the TMR patients had a better survival rate (65% after five years) than those patients on maximum drug therapy. That study was followed several weeks later by another study presented by Dr. Allen in January 2004 to the *Society of Thoracic Surgeons (STS)* showing conclusive long-term evidence of the enduring benefits of TMR when performed in conjunction with coronary artery bypass grafting (CABG) surgery. The data showed that the benefits of the combined procedures are superior to the benefits for patients receiving CABG alone to reduce angina.

"Obviously these studies can be key drivers for our business and our market intelligence tells us that more and more cardiothoracic surgeons are getting the message," Quinn said. "It's very encouraging to see adoption and training rates for TMR trending up and the fact that TMR is a profitable, stand-alone product line in its own right is a testament to the benefits of the procedure and the hard work and commitment of our team."

Quinn also said the company remains committed to PMR, its catheter-based version of TMR, noting that a meeting has been scheduled with the FDA in March as part of the ongoing interactive review of the Premarket Approval (PMA) Supplement for the company's Axcis PMR system.

"The cardiology community understands the potential value inherent in this innovative procedure as a minimally invasive option for patients suffering from coronary artery disease," Quinn said. "We look forward to our meeting with the FDA in March and to working closely with their regulatory staff to address any concerns they may have regarding the safety and efficacy of this procedure. We remain committed to finding a solution that addresses any of these concerns." Quinn added that if a favorable result cannot be reached as a result of this interactive process, a hearing before the FDA's Medical Devices Dispute Resolution Panel remains an option.

The company also announced that in January of this year it had completed a private placement of approximately 3.1 million shares of newly issued, restricted and unregistered common stock to institutional investors, raising gross proceeds of \$2.7 million. The net proceeds of the placement strengthen the company's balance sheet and will primarily be used to support the company's introduction and launch of a number of new technologies and products for the growing TMR business.

As a way to enhance the momentum the company has generated over the past year, Quinn recently reorganized the business unit structure into two regional divisions, called the Pacific and Atlantic divisions, and a Worldwide Services Division to expand its technical service and maintenance business. The result will bring the company staff closer to its customers to better develop professional relationships and provide more cost effective technical support, Quinn said.

During the fourth quarter of 2003, the company shipped three lasers and converted five installed lasers to sale and worldwide disposable sales was 666 units; for the year 25 lasers were shipped, 7 lasers were converted to sale and worldwide disposable sales were 2,895 units. This compares to the shipment of 6 lasers, the conversion of 3 installed lasers to sale and worldwide disposable sales of 820 units in the fourth quarter of 2002; for all of 2002, 21 lasers were shipped, 7 installed lasers were converted to sale and worldwide disposable sales were 3,034 units.

2/27 **DUSA Pharmaceuticals, Inc.** announced that it had entered into definitive agreements with certain new and existing institutional and other accredited investors for the private placement of 2.25 million shares of its common stock at a purchase price of \$11.00 per

share resulting in gross proceeds to DUSA of \$24.75 million. In addition, the company has granted the investors the right to purchase up to an aggregate of an additional 337,500 shares of common stock at \$11.00 per share. These additional investment rights expire 30 trading days from closing.

The placement agent's commission will be paid in shares of common stock calculated at the offering price. The company will use the proceeds from the sale of the securities to expand its sales force, for possible product acquisitions and for general working capital purposes, including research and development opportunities.

2/27 **BioLase Technology, Inc.** announced the pricing of its previously announced public offering of common stock at \$18.50 per share, before underwriting discounts and commissions. The offering consists of 2.8 million shares of common stock, including 2.5 million newly issued shares offered by the company and 307,500 shares offered by a selling stockholder. The offering is expected to close on March 3, 2004. In addition, the underwriters have a 30-day period in which to exercise an option to purchase from the company up to 421,125 additional newly issued shares of common stock to cover over-allotments, if any. **Needham & company, Inc.** is acting as lead manager in the offering, and the co-managers are **William Blair & company, LLC** and **Oppenheimer & Co. Inc.** A registration statement relating to these securities was filed and declared effective by the Securities and Exchange Commission on February 26, 2004.

3/1 **Palomar Medical Technologies Inc.** announced that the United States District Court for the District of Massachusetts had issued a "Markman" ruling Friday, February 27, 2004 in the ongoing patent infringement action between Palomar and **Cutera, Inc.** (formerly **Altus Medical Inc.**). The ruling represents a major step in Palomar's efforts to enforce its patent portfolio and will have considerable impact on the case as it proceeds toward trial. If Palomar prevails at trial, Cutera may be ordered to pay millions in damages for past sales and may also be ordered to stop selling any products that perform hair removal. In the ruling, the District Court largely embraced Palomar's position, finding for Palomar on critical issues dealing with U.S. patent 5,735,844. The ruling arises from a Markman Hearing, where both sides presented their arguments to the Court on the interpretation of the patent claims at issue. The Markman ruling establishes the scope of the patent claims and how the patent terms should be constructed or defined. A copy of the Court's Markman Order is available at:  
<http://pacer.mad.uscourts.gov/recentopinions.html>.

The legal precedent from a Markman Hearing can be determinative of the outcome at trial on issues of validity and infringement of patents. For example, the District Court ruled in favor of Palomar over Cutera that one of the patent claims at issue does not require contact between the hair removal device and the skin. Chief Executive Officer Joseph Caruso commented, "We are very pleased with the Court's interpretation of the scope of the claims we are asserting against Cutera. We believe the Judge's claim construction ruling is a clear win for Palomar."

General Counsel Patricia Davis, a registered patent attorney, commented, "The Court's ruling validates our belief not only in the strength of this patent but also in the corresponding family of patents. The family of patents associated with U.S. Patent 5,735,844 includes another U.S. patent 5,595,568, a European patent EP 0 806 913 B1 and additional corresponding foreign patent applications. Palomar has also been notified that a second European Patent will be granted and, like the patent at issue, includes claims that cover Cutera's products."

Palomar currently sub-licenses two competitors to this patent family for a 7.5% royalty on their products. In addition, Palomar has filed a claim against Lumenis, Inc. for patent infringement of both U.S. patents 5,595,568 and 5,735,844 in the United States District Court for the Northern District of California.

3/4 **Diomed Holdings, Inc.** announced that it had commenced an offering to those persons who held shares of its common stock on August 29, 2003. The offering is for up to 29.7 million shares of Diomed's common stock. Diomed stockholders as of August 29, 2003 may purchase from Diomed one share of Diomed common stock for each share of common stock held on August 29, 2003, at a purchase price of \$0.10 per share. The offering period will be 45 days, commencing on March 3, 2004 and ending at 5:00 p.m. EST on April 16, 2004, unless Diomed elects to extend the offering period.

The company also announced that it had commenced legal action in the United States Federal District Court for the District of Massachusetts against **Vascular Solutions, Inc.**, seeking injunctive relief and damages for infringement of Diomed's United States Patent Number 6,398,777 covering the endovascular laser treatment of varicose veins. Diomed filed a similar legal action against **AngioDynamics, Inc.** a subsidiary of **E-Z-EM, Inc.** on January 6, 2004. "Diomed has committed to invest \$4.5 million in the acquisition of sole and exclusive rights to the key patent in the field." stated James Wylie, president and CEO of Diomed Holdings, Inc. "Accordingly, we plan to defend our legal rights under U.S. patent law while ensuring the full range of benefits for patients and the medical community on a long term basis."

It is estimated that between 25-40 million Americans suffer from venous insufficiency. EVLT represents the next generation of minimally invasive treatment of varicose veins. The procedure takes less than 45 minutes without the need for general anesthesia or hospitalization, and patients experience only minimal discomfort with no scarring. Published clinical studies indicate that EVLT has a 93.4% long-term success rate, and is superior to surgery and alternative technologies used for the treatment of varicose veins.

In a final comment, Wylie went on to say, "Diomed's EVLT system has been successfully used in more than 10,000 procedures since the FDA granted clearance for the procedure in January 2002. Clearly, EVLT is rapidly developing as the standard of care in minimally invasive treatment of varicose veins." The company declined further comment on the pending action.

3/4 **Vascular Solutions, Inc.** responded to the announcement by **Diomed Holdings, Inc.** of the initiation of a patent infringement lawsuit against Vascular Solutions, Inc. in the United States District Court for the District of Massachusetts related to the company's Vari-Lase endovenous laser business. Howard Root, CEO of Vascular Solutions, commented, "Once again, Diomed has announced a litigation without, to my knowledge, serving Vascular Solutions with a summons and complaint to properly commence the action. Therefore, we have not had the opportunity to review the allegations other than what is disclosed in Diomed's press release. We can state, however, that we have analyzed the single Diomed licensed patent in this area, and we have a written opinion of non-infringement from our outside intellectual property counsel. We believe that our Vari-Lase products do not infringe any validly existing patent, and we intend to vigorously defend this action."

3/4 **Trimeddyne, Inc.** announced the U.S. Patent Office had allowed 17 claims of its patent application on a new Laser Balloon Catheter intended to treat mitral valve prolapse in a minimally invasive procedure. The patent should issue in a few months. Mitral valve prolapse occurs when the leaflets of the mitral valve of the heart fail to close properly. Approximately 125,000 people undergo surgery to treat this condition each year in the United States, and many live with the condition because they do not wish to suffer the trauma and risk of death of the surgical procedure.

Lasers are widely used to shrink facial tissues to reduce or remove wrinkles. The laser energy passes through the upper layers of the skin, which is commonly cooled by a refrigerated fluid, and shrinks the underlying tissues. In laboratory tests, the proper wavelength and amount of laser energy was able to shrink the chordae tendonae, long tendons of cartilage which close the leaflets of the mitral valve, up to 30%. While the patent application also covers high intensity light, radiofrequency (RF), microwave, electrical and ultrasound energy, the company believes the uniform penetration of laser energy will cause a longer lasting shrinkage effect. Trimeddyne's Side-Firing Laser Balloon Catheter is designed to be used either by surgeons during bypass surgery or Cardiologists by advancing it through the arterial system to the heart from a tiny incision in the groin. The balloon may be filled with a cold fluid to cool the tissue while laser energy is applied to shrink it. Clinical trials of these devices will be required to obtain FDA marketing approval, the success of which cannot be assured.

Trimeddyne earlier acquired an issued U.S. Patent covering the principle of applying thermal energy to shrink the chordae tendonae of the mitral valve. The new patent expands Trimeddyne's proprietary position in this area.

3/8 Cosmetic surgery and related procedures in the United States jumped 32% last year to 8.7 million, led by a surge in injections of Botox anti-wrinkle treatments, according to the *American Society of Plastic Surgeons (ASPS)*. The organization said the number of surgical procedures grew by five%, while minimally invasive procedures jumped 41% over 2002. Leading the rise in these in-office procedures was the use of Botox, a form

of the botulism toxin that can reduce facial wrinkles, up 157% from 2002 to 2003 to 2.9 million procedures. Collagen injections were up 30%, the group said.

The ASPS said these procedures could grow even more with the US approval of Restylane, or hyaluronic acid, a jelly-like material that can be used in conjunction with Botox for wrinkle treatment. "The concept of cosmetic injectables has become more mainstream and accepted," the organization said. "It is gratifying to see that more and more people are choosing plastic surgery, knowing the surgery can produce the outcome they desire," said ASPS president Rod Rohrich.

"It's important for the general public to understand, however, the serious nature of elective cosmetic surgical procedures. At the highest level of care, every surgery has risks as well as benefits." Women made up 86% of those who had minimally invasive cosmetic plastic surgery procedures and 82% of the surgical procedures.

The organization said the top five surgical cosmetic plastic surgery procedures in 2003 were nose reshaping (356,554), liposuction (320,022), breast augmentation (254,140), eyelid surgery (246,633), and facelift (128,667). The top five surgery procedures men were nose reshaping, eyelid surgery, liposuction, hair transplantation and facelifts. The figures shows breast augmentations up seven percent from 2002 to 2003, even though US health authorities were still debating where to allow the reintroduction of silicone breast implants - a public endorsement to the safety of saline-filled implants.

The number of procedures for lip augmentation grew 21%, with tummy tucks up 18%, breast lifts 17%, liposuction 13% facelifts nine percent and eyelid surgery (seven%. Forehead lifts were down 24%, reflecting the growing popularity of Botox, which is used for forehead wrinkles.

3/8 **BioLase Technology, Inc.** announced that it had successfully completed its secondary public offering of 2.8 million shares at a price of \$18.50 per share. The offering included 2.5 million newly issued shares sold by the company, and 307,500 shares sold by **American Medical Technologies**, a stockholder of the company. The proceeds of the offering were received by the company on March 3, 2004.

Federico Pignatelli, chairman of the Board of Directors of BIOLASE commented, "We are pleased to have completed this important milestone in the company's development. During the years I have been the chairman of the company, BioLase has come a very long way. It is my belief that the next years will be very exciting and rewarding."

Jeffrey Jones, CEO and president said, "With the offering behind us, we can focus our resources on the business. We believe our balance sheet is now more in line with our sales growth. We intend to use the proceeds of the offering to add strength to our growth, and flexibility to capture marketing leverage, and grow the company in a healthy fashion."

3/8 **Miravant Medical Technologies** announced preclinical data that may support the future treatment of patients with atherosclerosis and atherosclerotic vulnerable plaque. The presentations at the *American College of Cardiology (ACC)*, New Orleans LA, represent the culmination of a series of experimental cardiovascular studies done in collaborations with Dr. Ron Waksman of the Washington Hospital Center and Dr. Renu Virmani of the Armed Forces Institute of Pathology. The following results were demonstrated in atherosclerosis models at 28 days after PDT treatment:

\* Plaque reduction: Intravascular PhotoPoint PDT promotes plaque stabilization by removing the inflammatory cells responsible for disease progression. This was determined to be a sustained event that also yielded up to 40% reduction in plaque volume.

\* Plaque stabilization: Following PhotoPoint treatment, the plaque matrix is replaced with stable, non-proliferating smooth muscle cells, suggesting that the tendency for plaque re-growth is limited. These results are indicative of appropriate healing and repair of the artery walls.

Robert Scott, MD, president of **Miravant Cardiovascular, Inc.**, stated, "Many atherosclerotic plaques are vulnerable to rupture, triggering life threatening cardiovascular events. Inflammation seems to contribute to the unstable properties of these plaques. The PhotoPoint results presented at ACC are extremely encouraging. In repeated studies, we have found that PhotoPoint PDT removes problematic inflammatory cells and induces positive mechanisms of healing and repair that are consistent with true plaque stabilization."

These experimental studies were conducted under the direction of Ron Waksman, MD, Professor of Medicine (Cardiology), Georgetown University and Associate Chief of Cardiology at the Washington Hospital Center; and analyzed under the direction of Renu Virmani, MD, Chair, Cardiovascular Pathology, Armed Forces Institute of Pathology, Washington DC.

Additional studies in target vessel coronary arteries, also presented at the ACC meeting, analyzed arterial healing responses at acute (3 days post-PDT) and long time points (14-90 days). The studies, conducted at the Washington Hospital Center, measured the effects of Intracoronary PDT on vascular cellular populations (smooth muscle cells and endothelial cells). The coronary artery wall displayed positive healing responses and normalization at 30-90 days post-treatment. These results provide further evidence of a potentially beneficial aspect of the treatment for atherosclerotic plaque and/or restenosis, suggesting stabilization of the artery wall over time.

3/9 **BioLase Technology, Inc.** announced it had expanded its international distribution channels, added to its North American sales force, and leased additional office and production space. BIOLASE continues to grow and expand its international sales channel and recently appointed new international distributors in countries including Switzerland,

Holland, Belgium, Russia, Portugal, Brazil, Caribbean/Puerto Rico, Lebanon and Israel. Additionally, the company replaced several independent sales people in Germany with direct sales people dedicated to and exclusively focused on selling BIOLASE products.

During the end of 2003 and the first two months of 2004 BIOLASE has expanded its North American direct sales force from 25 sales representatives to a current total of 32. This expansion was necessitated by growing demand for the flagship Waterlase product and was accomplished by splitting several existing territories into smaller geographic areas and recruiting additional experienced sales people with strong track records. Additional sales territories will be created and representatives hired on a controlled growth basis, paced to maximize sales while keeping marketing expenses at an acceptable level, growing the bottom line over prior year same quarters, while prioritizing top line growth year over year.

BIOLASE has just leased additional office and manufacturing space next door to its headquarters in San Clemente. This facility gives the company added capacity in manufacturing, customer support, and marketing to support its continued growth. This move brings the company's leased facilities in the US to approximately 40,000 sq ft in addition to 20,000 sq ft of space in Germany owned by BIOLASE.

Jeffrey Jones, BIOLASE CEO and president commented, "BioLase is experiencing robust sales growth. Consistent with the business plan we have expressed, we are expanding our sales channels both internationally and domestically and adding facilities as necessary to support growing demand and streamline our infrastructure. We are pleased to have leased the building adjacent to BioLase, in the same business park. The building is well suited because it was used for hi-tech telecommunications production, requiring only minor cosmetic renovations. This facility will help our efficiency for the needed capacity expansion. We expect the facility to be fully operational by the first of May."

3/9 **William Blair & company** announced that it had initiated research coverage of **BioLase Technology, Inc.**, with an Outperform rating and company profile of Aggressive Growth. Analyst Ben Andrew estimated that the company would earn \$0.26 per share in 2004 and \$0.37 per share in 2005 on a fully taxed basis. BioLase thus far has penetrated less than 2% of the total dental population with its unique Waterlase product, which can perform a wide range of procedures (cutting soft gum tissue as well as hard tooth enamel and bone). "The market for dental capital equipment has been robust in recent periods, and we believe this will continue, as penetration is low, product utility is high, and patient preference remains strong," Andrew said. "BioLase management has a proven record with this product and market opportunity, and we expect continued execution as the company expands its sales efforts."

In his initiation research report, Andrews wrote:



- BioLase is the leading maker of dental lasers, but fewer than 2% of dentists currently use the company's flagship product, the Waterlase system.
- The market for dental capital equipment has been robust in recent periods, and we believe this will continue, as penetration is low, product utility is high, and patient preference remains strong.
- Management has a proven record with this product and market opportunity, and we expect continued execution as the company expands its sales efforts.
- Revenue grew roughly 90% in the seasonally strong fourth quarter and 68% for fiscal 2003; we project 49.5% growth in 2004, to \$68.5 million (excluding the \$3.2 million positive impact on 2003 revenue from the restatement), with EPS climbing 70%, to \$0.26, on a fully taxed basis.
- With strong business momentum, a still wide-open market opportunity for the Waterlase product, and the stock's trading at 6.6 times our 2004 revenue target of \$68.5 million, we are initiating coverage on BioLase with an Outperform rating.

3/9 **Medtech Insight LLC**, a leading provider of medical technology business information, announced the publication of a new report entitled: "**The U.S. Aesthetics Marketplace**," which details the U.S. markets for surgical and nonsurgical cosmetic surgery products, including topical and injectable aesthetics products, aesthetic facial surgery, and breast and body sculpting products. Americans of all ages are driving the demand for aesthetic procedures and growth in nonsurgical treatments such as botulinum toxin injections, chemical peels, microdermabrasion, laser hair removal and sclerotherapy, which accounted for over three-quarters of the 6.6 million cosmetic procedures performed in 2002. Cosmetic surgery products will generate \$1.2 billion in U.S. sales in 2004, and will more than triple to over \$4.3 billion in 2012, according to Medtech Insight's new report. Injectable aesthetic products such as botulinum toxin and new facial fillers such as collagen and hyaluronic acid will continue to experience strong growth, particularly as the aging Baby Boomer segment increases in number.

This new, detailed 181-page report includes analyses of technologies, market forecasts, competitors, and opportunities in: microdermabrasion; dermal, hair and vein removal lasers; botulinum toxin products; facial fillers; facial surgery products including implants and fixation devices; breast augmentation implants; and liposuction products.

Companies detailed in this report include: **Allergan, ArthroCare, Biomet, Candela, DePuy Mitek/Ethicon/Johnson & Johnson, Elan, INAMED, IRIDEX, Laserscope, LifeCell, Lumenis, Medicis Pharmaceutical, Medtronic, Mentor, Palomar Medical Technologies, and Porex/WedMD**, among many others. A full table of contents for this report and ordering information can be viewed at:  
[www.medtechinsight.com/ReportA580.html](http://www.medtechinsight.com/ReportA580.html).

- 3/15 **Vascular Solutions, Inc.** announced that CE Mark approval had been received for the Vari-Lase laser console and procedure kit used in the endovenous laser treatment of varicose veins. Receipt of the CE Mark will allow commercialization of the Vari-Lase procedure to commence through the company's direct sales force in Germany and through the company's independent distributors in other European countries.

Howard Root, CEO of Vascular Solutions, commented, "We are encouraged concerning the prospects for our Vari-Lase business in Europe in general, and in Germany in particular where our clinical evaluation to demonstrate the procedure's effectiveness is continuing at three centers. The overall response to this procedure in Germany has been exceptional, and we believe that with this CE Mark approval, our independent distributors will make substantial progress in 2004 in introducing this new procedure in their respective countries."

The Vari-Lase product line consists of a laser console and a custom designed procedural kit used in endovenous laser therapy for reflux of the great saphenous vein, commonly referred to as varicose veins. Left untreated, varicose veins can result in serious clinical consequences, including limited mobility and venous ulcers. Historically, an invasive surgical procedure known as vein stripping was the only treatment for severe varicose veins. Recently, the non-surgical use of endovenous laser energy to treat and close the diseased vein has emerged as a preferred alternative to vein stripping. Recent clinical data on endovenous laser therapy has demonstrated excellent clinical results and outstanding patient satisfaction.

- 3/15 **Blueshine Srl** introduced its next generation combined Laser Systems: ALEX SHINE PLUS, combining 755 nm and Intense Pulsed Light and DUAL SHINE PLUS combining 1064 nm, 755 nm and Intense Pulsed Light.

In addition to easily removing unwanted hairs and vascular lesions BLUESHINE Alex Shine Plus is suitable for Skin Rejuvenation and Acne treatment.

Adding the capability of treating leg veins and epilate suntanned skin types, BLUESHINE Dual Shine Plus is indicated for customers requesting high performing Laser Systems for specialistic solutions and complete range of applications.

- 3/15 **BriteSmile, Inc.** released results for the year ended December 27, 2003. Total revenue for 2003 was \$43.8 million as compared with \$39.3 million for 2002 -- representing an 11% increase. In 2003, 163,857 procedures were performed compared with 156,149 in 2002 -- representing a 5% increase. The growth in revenue can be in part attributed to the fourth quarter launch of the company's innovative BriteSmile To Go take-home whitening pen. The efficacy, ease and superior performance of BriteSmile To Go over other products in this market segment is generating strong demand. BriteSmile To Go is offered through BriteSmile Associated Center dentists, in BriteSmile spas, on the company's website, and through the company's previously announced partnership with

**Sullivan-Schein Dental**, which currently serves more than 75% of the dental practices in the United States.

The growth in procedures was driven by both increased demand in the U.S. market and by growth in the company's International Associated Center dentist network. By year end, the company had over 4,900 Associated Center dental offices worldwide, compared to over 4,600 the previous year end. There were 1,827 Associated Centers operating in over 70 countries outside of the U.S., compared with 1,315 at the end of 2002. In the fourth quarter 2003, the company launched its proprietary BriteSmile Magic Mirror, which, by showing potential customers their "before" and "after" picture, is driving productivity of the existing footprint.

For 2003, the company reported a net loss of \$15.2 million compared with \$18.8 million net loss for 2002, representing a 19% improvement. For 2003, the loss per share was \$2.25 compared with \$3.14 for 2002 (both per share numbers reflect the 5:2 stock split which was effective January 30, 2004).

Revenues in the fourth quarter 2003 were 38% higher than revenues in the same period 2002. This improvement was driven by broad-based procedure growth in the Associated Center network and the spas, and sales of BriteSmile To Go.

For the first quarter 2004, revenues are forecasted to exceed growth of 25% over first quarter 2003, and the company is on target to meet its expectation of being cash flow positive in the first half of the year.

During 2003, the company was able to achieve an expansion of its revenue base, grow procedure volume, reduce expenses, and implement operational efficiencies. In 2003, total Selling, General and Administrative expenses decreased \$2.9 million to \$31.6 million from \$34.5 million in 2002. This decrease is largely the result of a significant reduction in advertising expense that was achieved while increasing revenues.

During 2003, the company converted \$15.3 million of debt into equity, reducing total interest bearing liabilities from \$23.6 million to \$8.3 million. "2003 was a pivotal year for BriteSmile. We were able to significantly grow the top line and successfully launch our BriteSmile To Go product, while increasing efficiency and improving our capital structure," said John Reed, CEO, BriteSmile, Inc. "BriteSmile is well positioned to maintain its leadership of the teeth whitening category and continues to grow its domestic and international footprint both with respect to professional teeth whitening and at home products."

3/15 **Candela Corporation** announced that it had been awarded the **Frost & Sullivan** Product Quality Leadership Award for the United States medical laser markets. This award was given for Candela's GentleLASE family of products, which offers fast treatment times, high efficacy, and great flexibility for hair removal, wrinkles, pigmented lesions and

vascular lesions. The GentleLASE family has found wide-spread acceptance and is the laser of choice.

Gerard Puorro, Candela's president and CEO, commented: "We welcome this award from Frost & Sullivan in recognition of our GentleLASE product family as lasers of choice, providing the best in efficacy and economics across various applications. We will continue to listen to our customers and fill their needs."

- 3/15 **Trimeddyne, Inc.** announced that the U.S. Patent Office had allowed 24 claims of its patent application on a new Laser Angioplasty Catheter designed to open blocked coronary arteries of the heart without damage to the artery wall. The patent should issue in a few months. Blockages, due to the build-up of plaque in the coronary arteries, cause severe chest pain on exertion and, if they close a vessel almost completely, a heart attack. The most common treatments for this condition are bypass surgery and balloon angioplasty. While 800,000 balloon angioplasties are performed each year in the United States, many blockages cannot be treated by angioplasty. In addition, many blocked vessels are too small to admit a balloon catheter or to be bypassed.

Some years ago, Trimeddyne developed a bullet-shaped metal-tipped laser catheter and a large, 300 pound, \$100,000 laser whose energy was used to heat the metal tip while it was advanced through a blocked vessel. Sales of these devices exceeded \$30 million in both 1989 and 1990. However, heat radiating sideways from the metal tip of the laser catheter could damage the artery wall, and sales declined in later years.

Instead of a metal tip, Trimeddyne's new Laser Catheter uses a proprietary glass tip, through which laser energy is transmitted to melt or vaporize the blockage. Little or no heat is radiated sideways, reducing the risk of damage to the artery wall. The new Laser Catheter can be made as small as 1 millimeter in diameter to enable totally blocked or very small vessels to be opened. Clinical trials of these devices will be required to obtain FDA marketing approval, the success of which cannot be assured.

- 3/16 **DUSA Pharmaceuticals, Inc.** announced its fourth quarter and full year 2003 financial results and corporate highlights. During the fourth quarter, the company's revenues from product sales increased to \$516,000, compared to \$162,000 in 2002, based on the previously reported increase in sales of our Levulan Kerastick, as well as increased sales of the company's BLU-U brand light source. Other highlights of the fourth quarter included the launch of DUSA's direct sales force, along with the signing of a number of independent sales representative agreements. We also added a second drug distribution channel, enjoyed strong representation at a number of dermatology educational meetings, and completed our Phase IV long term actinic keratoses (AK) tracking study.

Subsequent to year-end, we reported a very solid response to Levulan Photodynamic Therapy (PDT) at the annual meeting of the *American Academy of Dermatology (AAD)*; the start-up of Kerastick manufacturing at our Wilmington, MA facility; the reacquisition of full Canadian rights to our technology; and the decision to increase the size of the sales

force based on significantly increased demand for our therapy. Recently, we also strengthened our financial position with a private placement of 2.25 million shares of our common stock that raised gross proceeds of \$24.8 million. The company will use the proceeds from the sale of these securities to expand our sales force and for working capital purposes, including research and development activities, and for potential product acquisitions.

The company also was pleased to be able to report that the positive sales trends achieved in Q4 have continued in the first quarter of 2004. Interest in its therapy at the *South Beach Symposium*, held immediately after the AAD meeting, was very strong, and we have since supported a number of continuing medical education (CME) meetings across the country. The actual number of Kerastick sales to customers during Q1 04 will be reported after the end of the quarter.

In light of the increased demand for its therapy, the company decided to at least double the size of its direct sales force of area managers and representatives, from the current level of 8 to 16, with the potential for additional hires as the year progresses. We have also continued to make excellent progress in obtaining private insurance coverage for our therapy so that patients may be reimbursed for their Levulan PDT treatment of AKs.

The company also continued to make progress on our new indication development programs. These included a proposed Phase II short drug contact photodamaged skin study, a new Phase II short drug contact study for the treatment of moderate to severe acne vulgaris with Levulan and the BLU-U, and a pilot Phase II Barretts esophagus high-grade dysplasia trial designed to test its new proprietary endoscopic light delivery device. In addition, it received approval from Health Canada to amend our medical device license to market the BLU-U for light alone treatment of acne.

Since year-end, there has also been a positive development on the patent front. The company had previously received notice that its Netherlands patent was being formally challenged by an anonymous agent, and had filed a formal response to the opposition. After receiving submissions from both parties, the Netherlands Patent Office issued a notice that the company's patent was upheld and granted in amended form. Although the opposing party had the right to appeal the decision, the company is now pleased to report that the deadline for the appeal has expired. Meanwhile, the Australian patent dispute is scheduled to go to trial during April of this year.

**Financial Highlights:** For the three months ended December 31, 2003, DUSA's net loss was \$3.8 million (27 cents per share) compared to a loss of \$3.7 million (27 cents per share) for 2002. For the twelve months ended December 31, 2003, the company incurred a net loss of \$14.8 million (\$1.06 per share) as compared to a net income for 2002 of \$5.8 million (42 cents per share). The prior year period included the one-time recognition of certain items as a result of the September 2002 termination of our former marketing and development collaboration, including \$21.0 million of research grant and milestone revenue, and charges to cost of product sales and research and development costs totaling

\$2.6 million and \$639,000, respectively. As a result of the recognition of these items, net income for 2002 was increased by approximately \$17.7 million (\$1.28 per share).

Revenues for the three months ended December 31, 2003 increased to \$516,000, compared to \$162,000 in 2002, due primarily to higher Kerastick end-user sales. In addition, the company began selling the BLU-U during the quarter following our receipt of market clearance from the FDA in September 2003 to market the BLU-U as a stand alone device for the treatment of moderate inflammatory acne vulgaris. Revenues for the twelve months ended December 31, 2003 were comprised of \$970,000 in product sales, as compared to product sales of \$319,000 in 2002. Revenues for 2002 also included research grant and milestone revenues of \$22.3 million and co-development revenue of \$2.9 million that was earned under our former marketing and development collaboration.

Research and development expenses for the three months ended December 31, 2003 decreased to \$1.3 million, compared to \$2.8 million in 2002. This decrease was mainly attributable to the re-assignment of resources as of January 1, 2003 to marketing and sales functions that were previously functioning in research and development roles. Research and development costs for the twelve months ended December 31, 2003 decreased to \$5.4 million, compared to \$12.1 million in 2002, due primarily to the absence of co-sponsored project costs under our former marketing and development collaboration, and the aforementioned re-assignment of resources to marketing and sales functions. The 2002 period also included the write-off of \$639,000 of previously deferred costs as a result of the collaboration termination, and a \$500,000 milestone payment under a license agreement signed in December 2002 for proprietary technology related to ALA for systemic dosing in the field of brain cancer.

Marketing and sales costs for the three and twelve months ended December 31, 2003 were \$896,000 and \$2.5 million, which includes \$517,000 and \$924,000, respectively, of payroll related costs, including direct and indirect commissions. As of January 1, 2003, we reassigned resources that were previously functioning in research and development roles to our marketing and sales function. In August 2003, DUSA hired an Associate Vice President of Sales, and in October 2003 we hired, trained, and deployed a regional sales force. In 2002, there were no marketing and sales expenses incurred directly by DUSA as all rights and activities associated with the marketing and sales of our products were the sole responsibility of our former partner. We anticipate that the level of marketing and sales expenses will continue to increase in 2004 as we expand our sales capacity to keep pace with the success of our sales initiatives.

General and administrative expenses for the three months ended December 31, 2003 increased to \$1.6 million, compared to \$1.5 million in 2002, due primarily to the legal costs associated with the challenge to our Australian patent and related patent issues. General and administrative expenses for the twelve months ended December 31, 2003 increased to \$6.3 million, compared to \$5.6 million in 2002, due mainly to higher legal expenses of \$3.3 million, compared to \$2.0 million in 2002. Increased legal expenses were partly offset by lower 2003 staffing related costs of approximately \$458,000, due

primarily to employee separations during 2002. It is expected that legal costs will stay elevated as long as the patent dispute continues.

As of December 31, 2003, total cash, cash equivalents, and United States government securities, including long-term instruments, were \$38.0 million, compared to \$52.9 million at the end of 2002. Long-term debt, including current maturities, as of December 31, 2003 was \$1.5 million, compared to \$1.8 million at the end of 2002.

- 3/18 **Palomar Medical Technologies Inc.** reported its common stock had begun trading on the Nasdaq National Market System. Palomar has met all the requirements for listing on the Nasdaq National Market and has upgraded from the Nasdaq Small Cap Market System while retaining the same ticker symbol, PMTI.

"We are extremely proud of Palomar's ability to meet the listing criteria for the Nasdaq National Market," stated CEO Joseph Caruso. "The listing serves as an endorsement that Palomar has met the stringent requirements outlined by Nasdaq for listing on its national market and reiterates our growing position on Wall Street." Chief Financial Officer Paul Weiner commented, "Trading on the Nasdaq National Market could result in increased visibility among institutional investors with listing restrictions and additional analyst coverage."

- 3/25 **CardioGenesis Corporation** announced that the FDA was unable to reach a favorable outcome on the company's supplemental premarket approval application (PMA) for PMR following a meeting earlier this month with the agency's Center for Devices and Radiological Health. The meeting was held as part of the interactive review process for the PMR application.

The company expects to meet with the FDA in the near future in order to clarify any needs for additional clinical data on PMR. The Company has determined not to proceed to a Medical Devices Dispute Resolution Panel review of the application at this time, although that option remains available.

CardioGenesis chairman, president and CEO Michael Quinn stated that while he was disappointed, the company has been working for the past year on minimally invasive surgical tools to increase the patient population eligible to receive laser myocardial revascularization -- regardless of how the FDA might rule on PMR. He noted that as a result of the company's concentration on its TMR business throughout the past year, CardioGenesis achieved profitability in the fourth quarter of 2003 based largely on the success and growth of TMR.

"While there is definitely a scientific disagreement between prominent experts speaking on behalf of PMR and the FDA experts, we are committed to supporting PMR in Europe, Canada, Australia and the other countries where PMR is approved," Quinn said. "We have an ongoing base of clinical support for PMR outside the U.S. that continues to treat patients and collect data. We are committed to our current customers and to providing

PMR to patients in need. As for TMR, our team is focused on growing that business in the cardiac surgery market with new products, techniques and impressive new five-year clinical data and we have made great strides in the past year. TMR is the core of our business and we are working with innovative surgeons to identify additional new opportunities that will fuel growth now and in the future."

- 3/29 **Danaher Corporation** announced that it had signed a definitive agreement to purchase **Kaltenbach & Voigt GmbH (KaVo)** for approximately 350 million Euro in cash (\$425 million), including transaction costs and net of cash acquired. The acquisition remains subject to regulatory approval and other customary closing conditions. KaVo, headquartered in Biberach, Germany, with 2003 revenues of approximately \$450 million, is a worldwide leader in the design, manufacture and sale of dental equipment, including handpieces, treatment units and diagnostic systems and laboratory equipment. ([www.kavo.com/en](http://www.kavo.com/en)) Earnings accretion is expected to be minimal for 2004. (KaVo is the distributor of **Carl Zeiss Meditec** line of dental lasers.)

Danaher's president and CEO, Lawrence Culp, Jr. said, "The acquisition of KaVo brings a premier brand name to Danaher's newest platform, Medical Technology. The company is an excellent fit with our Gendex acquisition, completed in February, and allows us to offer a complete portfolio of equipment for dental professionals. In addition, we believe each company will benefit from strong geographic sales channel synergies. We look forward to working with the associates and management of KaVo as we continue to build on the strong foundation already established in this attractive market."

Danaher Corporation is a leading manufacturer of Process/Environmental Controls and Tools and Components. ([www.danaher.com](http://www.danaher.com))

- 3/29 **CBS MarketWatch** reported that **Cutera** was the IPO of the week according to **Renaissance Capital**, which runs IPO Plus.

While medical device makers had disappeared from the IPO radar screen for a while, they are back in vogue. Bribane, CA-based medical laser maker Cutera has applied to the Nasdaq to trade under the symbol, "CUTR."

Cutera plans to offer roughly 3.5 million shares at a proposed price range of \$14 to \$16. **Piper Jaffray** is the lead underwriter for the deal and will be assisted by **SG Cowen** and **RBC Capital Markets**.

Cutera, formerly known as **Altus Medical**, provides laser systems for the removal of hair, leg and facial veins, wrinkles and benign pigmented lesions under the "CoolGlide" brand to dermatologists, plastic surgeons, gynecologists and primary care physicians. The company sells about 77% of its products in the U.S. but sees opportunities to expand its presence in international markets, such as Asia and Europe.



Each of its seven systems consists of one or more hand pieces and a console and can be upgraded for use in multiple applications. The average selling price for its systems ranges between \$70,000 and \$155,000. To date, Cutera has sold more than 1,200 systems and 240 upgrades and plans to introduce at least one new product per year going forward.

**Booming laser surgery market.** The surge in aesthetic procedures is driven by three key factors: increasing demand for cosmetic surgery by aging baby boomers, technological advancements that provide for safer and more effective treatments, and physicians' incentives to provide treatments paid for directly by the patient. Procedure costs can range anywhere from a few hundred dollars to several thousand, depending on the size of the treatment area and the physician. **Millennium Research Group** estimates that more than 2.6 million aesthetic laser procedures were performed in the U.S. in 2002.

This number is expected to grow to 4.4 million in 2005, which translates into a compound annual growth rate of over 19%. The hair removal market (Cutera's primary source of revenue) is expected to grow from \$2.4 billion in 2002 to \$3.3 billion by 2005, or 11% annually, according to the 2002 Epilation Market Report.

Cutera hopes to gain share in this market through the introduction of new products and upgrades to its existing installed base.

**Pending lawsuit concern.** In February 2002, Cutera's competitor **Palomar** filed a patent infringement suit against the company. While the lawsuit is still early stage, it is costly and could ultimately force Cutera to pay damages and product royalties on its hair removal systems, which could significantly cut into profits. The court issued an initial Markman ruling in late February. While Cutera cannot comment on the ruling since it is in the quiet period, Palomar seemed pleased with the outcome of the initial ruling. The case is now proceeding to trial.

Despite the overall market correction, the group of recent medical device IPOs, as well as Cutera's peers, are white hot. Cutera's publicly traded competitors (excluding **Lumenis**) have generated a 41% return year-to-date, and institutional money flow continues to be strong. Renaissance Capital stated, "While it is one of many small fish in a competitive pond and we are concerned about a pending lawsuit, Cutera has been profitable since 2000, demand for aesthetic laser procedures is booming and the firm gets credit for its strong corporate governance. In addition, the laser group is hot and that should help Cutera off to a good start."

## **MEDICAL/SURGICAL LASER UPDATE -- April 2004**

3/29 **BriteSmile, Inc.** released an addendum to its earnings release previously issued on March 15, 2004 providing updated results for the year ended December 27, 2003.

Net loss decreased from \$15.2 million as previously reported to \$14.6 million with a resulting decrease in net loss per share from \$2.25 to \$2.15. This is a result of two

adjustments: a decrease to Product Sales of \$27,000, offset by a decrease to Operating and Occupancy Costs of \$704,000. These adjustments result from a correction in accounting policy for Magic Mirrors offered to customers who sign a contract to purchase a minimum number of key cards per month. Subsequent to the release of our earnings on March 15, 2004, we determined that these costs should be capitalized and amortized over the life of the contract. Previously, revenue and cost attributable to these Magic Mirrors was recognized at the time of shipment to the customer.

- 3/30 **Axcan Pharma Inc.** announced that the Committee of Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products had granted Axcan a Marketing Authorization for use in the European Union of its photodynamic therapy (PDT), PHOTOBARR (porfimer sodium), in the ablation of High-Grade Dysplasia associated with Barrett's Esophagus. PHOTOBARR PDT was also granted an orphan medical product status at the time of its submission, which guarantees Axcan exclusive marketing rights for PHOTOBARR PDT in the European Union for a ten-year period.

It is estimated that High-Grade Dysplasia associated with Barrett's Esophagus affects 25,000 to 35,000 people in Europe, and an additional 5,000 to 7,000 people in Europe are diagnosed with this condition each year.

"We are pleased with the CPMP's approval of PHOTOBARR PDT for the treatment of High-Grade Dysplasia associated with Barrett's Esophagus. This approval, which is the first one for Axcan in Europe, is very important since it demonstrates our ability to navigate the European regulatory process," said Leon Gosselin, president and CEO of Axcan. "We expect to launch PHOTOBARR PDT in the second half of fiscal 2004," he concluded.

- 3/30 **Cutera, Inc.** (formerly **Altus Medical**) announced the initial public offering of 3.5 million shares of common stock at a price of \$14 per share. The company is selling 3.1 million shares of the offering and Cutera stockholders are selling 432,000 shares. Cutera has granted the underwriters an option to purchase up to an additional 529,800 shares at the initial public offering price to cover over-allotments, if any. The common stock will trade on the Nasdaq National Market under the symbol "CUTR."

**Piper Jaffray** is the book-running manager for the offering. **SG Cowen** and **RBC Capital Markets** are co-managers.

A registration statement relating to these securities has been filed with, and declared effective by, the Securities and Exchange Commission. Copies of the final prospectus may be obtained from the offices of Piper Jaffray & Co., U.S. Bancorp Center, 800 Nicollet Mall, Suite 800, Minneapolis, MN 55402; SG Cowen Securities Corporation, Two International Place, 27th Floor, Boston, MA 02110; or RBC Capital Markets Corporation, 60 South Sixth Street, Minneapolis, MN 55402.

3/30 **Cynosure, Inc.** announced that it had received FDA clearance for its new Apogee Elite product, a combination of Alexandrite + Nd:YAG lasers. "This clearance allows us to offer a "one-for-all" system that permanently removes hair regardless of skin type, eliminating the need for two separate lasers. The Elite combines 2 highly versatile wavelengths in a new, compact size. In addition, it is designed to be used for multiple applications, including Cynosure's popular LaserFACIAL, as well as leg and facial veins", said Marina Kamenakis, Director of Marketing.

"For the first time, the Apogee Elite offers complete hair removal in a single unit," said Dr. Robert Weiss, Dermatology Associates, Maryland Laser, Skin, and Vein Institute. "The combination of the 755nm and 1064nm wavelengths are essential for treating all skin types. The 1064nm wavelength has proven effective in treating facial and leg veins. The 755nm wavelength can be used to treat solar lentigines. In addition, the air-cooling system used with the laser is preferred by our patients."

"The number of laser hair removal treatments in the U.S. continues to grow by 25% per year and will exceed 1 million in 2004, according to the 2003 ASAPS statistics," said Michael Davin, president and CEO. "Laser hair removal is the second most popular treatment after Botox injections and, therefore, is one of the core services for the cosmetic practice. Other non-ablative treatments, such as the LaserFACIAL, are growing significantly as well."

3/30 For the first time in its 40-year history, the *Society of Thoracic Surgeons (STS)* has established guidelines to assist heart surgeons in their use of Transmyocardial Revascularization (TMR) therapy to treat angina, a debilitating condition involving heart and chest pain stemming from cardiovascular disease. **Edwards Lifesciences Corporation** is the exclusive U.S. distributor of the CO2 TMR Heart Laser manufactured by **PLC Systems, Inc.**, and one of the technologies referenced in the new guidelines. The device is used during open-heart surgery on the left ventricle of a beating heart to create channels which are believed to promote the development and formation of new blood vessels, thereby improving blood flow to the heart muscle and alleviating angina pain.

"The TMR guidelines are the first-ever practice guidelines published by the Society of Thoracic Surgeons' Workforce on Evidence-Based Medicine," said Dr. Robert Guyton, professor of cardiothoracic surgery at Emory University School of Medicine and the immediate past president of the Society of Thoracic Surgeons. "This is a significant milestone in clarifying the standard of care in the diagnosis, management, and surgical treatment of patients with angina."

The STS guidelines will be published in the April 1, 2004 issue of the *Annals of Thoracic Surgery*. In its guidelines, STS concludes that with proper patient selection and observance of surgical technique, TMR therapy provides noticeable symptomatic improvement in patients suffering from angina.

"STS's development of these guidelines further substantiates CO2 TMR as an important, emerging therapy," said Anita Bessler, Edwards' corporate vice president of Global Franchise Management. "Edwards remains confident that this technology provides significant benefits to people suffering from angina."

A clinical trial published in the *New England Journal of Medicine* in September 1999 demonstrated that, at 12 months, myocardial perfusion had improved by 20 percent in CO2 TMR patients. A long-term, five-year follow-up of CO2 TMR patients, published in the September 2001 issue of the *American Heart Association* journal *Circulation*, indicated that 68% of treated patients had an improvement of at least two angina classes, as classified by the *Canadian Cardiovascular Society*. To date, more than 10,000 patients have been successfully treated with the CO2 TMR Heart Laser.

3/31 **Trimeddyne, Inc.** announced that Marvin Loeb, chairman of Trimeddyne, was interviewed by Diane Reynolds of *CEO/CFO Interviews*. A transcript of the interview will be posted on their website, **[www.ceocfointerviews.com](http://www.ceocfointerviews.com)** on Thursday, April 8, 2004. To see a summary of the interview, click on "Interviews". Loeb discussed the company's current business, financial condition and business strategy, the markets for the company's products, the company's "fee per case" laser rental service and new products the company is developing.

3/31 **Laserscope** said that the Centers for Medicare and Medicaid Services (CMS) announced the assignment of the company's Photoselective Vaporization of the Prostate (PVP) procedure for the treatment of Benign Prostatic Hyperplasia (BPH), or enlarged prostate, to New Technology Ambulatory Payment Classification (APC) 1525 (CMS Transmittal 132, Publication 100-04). The new classification carries with it a payment rate of \$3,750.00, approximately twice that of the old rate.

"We are very pleased with today's news," said Eric Reuter, president and CEO of Laserscope. "We believe that the response by the CMS to our request for a new APC code for our GreenLight PVP procedure, clearly demonstrates the effectiveness and safety profile that makes this BPH treatment unique and unlike any other known technology in the world. The increased payment rate now more accurately reflects the costs of performing the procedure. We expect that the new payment rate dictated by the CMS will encourage performance of the PVP procedure at those hospitals, where previously, due to economics, it would not have been made available to patients. We plan to provide additional details and revised guidance for the remainder of 2004 in the near future."

The company said that effective April 1, 2004, according to the CMS, PVP procedures performed in an outpatient hospital site of service should be coded using new Healthcare Common Procedure Coding System (HCPCS) code C9713 and will be grouped to APC 1525. The description for HCPCS code C9713 is "non-contact laser vaporization of prostate, including coagulation control of intraoperative and post-operative bleeding." The minimum unadjusted co-payment amount for the procedure is \$750.00. In addition,

non-contact laser vaporization has an "S" payment status, which means that the multiple procedure discount does not apply to PVP.

4/1 Lawrence Carrel of **SmartMoney.com** wrote about the Laserscope announcement above:  
**Just What the Doctor Ordered: THANK YOU, Uncle Sam.**

At least that's what investors in Laserscope (LSCP) should've been saying on Thursday. Shares of the maker of medical lasers jumped 29% to \$25.59 after the San Jose, Calif., company announced that the federal government was significantly increasing the amount it paid for one of Laserscope's prostate procedures.

"This is big news," says Adina Dodi, an analyst at **B. Riley & Co.**, an institutional brokerage in Los Angeles. "We see the increased reimbursement level as a catalyst. By increasing the reimbursement level, physicians and hospitals will receive more financial benefit from using the procedure, and this should increase revenue for Laserscope's urology segment."

Late Wednesday, Laserscope, which also makes advanced fiber-optic devices, said the Centers for Medicare and Medicaid Services boosted the payment level for the laser procedure on enlarged prostates to \$3,750. That's about double what the government health-care programs had been paying to treat the condition formally known as benign prostatic hyperplasia, or BHP. While the company doesn't receive direct compensation for each treatment from the government — treating physicians do — the pumped-up reimbursement level encourages doctors and hospitals to order more of the lasers and related equipment from Laserscope.

Laserscope's procedure, called photoselective vaporization of the prostate, is a minimally invasive surgical technique that targets troublesome tissue without harming the surrounding area. The laser is administered to the prostate via a fiber-optic delivery system inserted through the urethra.

The urology unit that sells this laser makes up 25% of the revenue of the 22-year-old company, which holds more than 30 U.S. patents pertaining to surgical laser systems, delivery devices, calibration inserts and laser resonators. Laserscope manufactures four other laser systems for its aesthetics business, which sells devices to plastic surgeons and dermatologists for pigment lesions, hair removal and leg and facial vein treatments. That unit makes up 50% of Laserscope's sales. About 25% of revenue comes from its service unit, and the remainder is generated from the sale of the nearly 350 disposable pieces that can be used with the devices.

For 2003, Laserscope posted a profit of \$2.5 million, or 13 cents a share, a 674% increase from \$323,000, or two cents a share, earned in 2002. Revenues leapt 33% year-over-year to \$57.4 million.

"Doubling the reimbursement will have a favorable effect on the ability of hospitals to adopt the technology," says Eric Reuter, Laserscope's president and chief executive.

Since its release in February 2002, Laserscope has shipped 160 of the urology lasers world-wide, with 110 in the U.S. Still, the potential pool of hospitals is quite large. According to Reuter, nearly 2.2 million men have BPH in the U.S., and there are almost 150,000 procedures done domestically every year. The world-wide market could be three times larger than the U.S. market, he says. In 2003, Laserscope's laser was used in 11,000 treatments.

As the laser business grows, so will sales of the single-use disposable fiber-optics needed for each procedure. Reuter says the disposables for the urology laser cost between \$800 and \$850, with a margin well above 60%. The company's corporate margin rate is in the mid-50% range.

Reuter took the reins in late 1999, when the company was losing money and its shares traded at 68 cents. Since then, Laserscope has turned profitable and currently holds no debt. In February, the company forecast 2004 net income of between 32 cents and 34 cents a share on sales of \$70 million. Gross margins are expected in the range of 53% to 55%. Reuter wouldn't offer an update on the company's financials Thursday, but said he would provide new guidance in the near future.

"We haven't made any changes to our model yet," says Dodi of B. Riley. "As of Wednesday, our projection for the urology unit was \$25.1 million in 2004 and \$32.4 million in 2005, which would account for 36% and 38% of total revenue, respectively." (Dodi doesn't own shares of Laserscope; B. Riley & Co. doesn't have an investment-banking relationship with the company.)

Quote: "The really exciting story is the BPH urology product: the size of the market, the characteristics of a minimally invasive procedure and our penetration in the market," says Laserscope CEO Reuter. "We've seen dramatic growth over the last two years."

In a private interchange with Ms. Dodi, she sent along the following update:

"Just spoke with LSCP's CEO. The company may have a conference call to discuss the potential impact of the increased CMS reimbursement level prior to the actual Q1 '04 earnings call. He mentioned that the new reimbursement level (for outpatient procedure) was better than expected (it sure exceeded our expectations). We anticipate the new APC code to act as a catalyst, driving both revenue from sales of the GreenLight PV laser system and recurring revenue from sales of the disposable optical fibers. We point out that revenues for the urology segment (systems and fibers) accounted for 26% of company's revenues in 2003 and for 33% in Q4 '03. We believe LSCP has enough capacity to accommodate any increase in demand triggered by the new APC code. Our current revenue projections call for urology segment sales of \$25.1MM and \$32.4MM, which translate to 36% and 38% revenue contributions for 2004 and 2005, respectively."

4/1 **CardioGenesis Corporation** announced that the five-year follow-up results of its TMR vs. Maximum Medical Management trial are to be published in the April 2004 edition of *The Annals of Thoracic Surgery*, the official journal of the *Society of Thoracic Surgeons (STS)*.

In addition to this data, the journal's April issue also published specific guidelines on the usage of TMR for the treatment of severe angina as established by the STS and concluded that "with proper patient selection and observance of appropriate surgical technique, TMR provides very gratifying symptomatic improvement to desperately ill patients who otherwise would be crippled by unrelenting angina pectoris."

Robert Guyton, MD, Chief of Cardiothoracic Surgery at The Emory Clinic in Atlanta noted that the TMR guidelines are the first practice guidelines published by the *Society of Thoracic Surgeons' Workforce on Evidence-Based Medicine*. "This is a significant milestone in clarifying the standard of care in the diagnosis, management, and surgical treatment of patients with angina," Dr. Guyton said.

The follow-up study data published in the journal, originally presented by Keith Allen MD of the Indiana Heart Hospital at the *American Heart Association* meeting in November 2003, demonstrated a significant survival benefit in patients receiving TMR compared to those randomized to medical management, as well as significant angina benefits.

Michael Quinn, CardioGenesis chairman and CEO, added, "It is a significant accomplishment for TMR therapy to be recognized as part of the standard of care in the treatment of patients with severe angina by a leading medical society such as STS. It is also significant that a prominent medical journal such as *The Annals of Thoracic Surgery* accepted for publication the results of our TMR vs. Medical Management trial. Such recognition of the science and value of TMR therapy confirms what we are seeing at hospitals worldwide, namely keen interest in TMR as an important part of any cardiac treatment regimen."

4/5 **Diomed, Inc.**, a subsidiary of **Diomed Holdings, Inc.** announced that it had commenced legal action in the United States Federal District Court for the District of Massachusetts against **Total Vein Solutions, LLC.**, of Houston, Texas, seeking injunctive relief and damages for infringement of Diomed's United States Patent Number 6,398,777 covering the endovascular laser treatment of varicose veins. Earlier this year, Diomed filed patent infringement actions against **AngioDynamics, Inc.**, a subsidiary of **E-Z-EM, Inc.**, and **Vascular Solutions, Inc.**

Diomed is a leading developer and marketer of minimally invasive medical technologies, including EVLT for the laser treatment of varicose veins, and acquired exclusive rights to the patent from the five inventors of the procedure in September 2003.

"Total Vein Solutions has ignored Diomed's patent rights in the field of endovenous laser treatment of venous incompetence and is openly promoting and marketing laser fibers and associated procedure kit components without a license from us", stated James Wylie, president and CEO of Diomed Holdings, Inc. "As we stated in earlier press releases, Diomed has invested more than \$20 million in developing and launching EVLT and we will defend our legal rights under U.S. patent law."

The company declined further comment on the pending action.

4/5 **Palomar Medical Technologies Inc.** announced that it had received clearance from the FDA to market the LuxV handpiece for the treatment of acne. Prior to this clearance, Palomar marketed and sold the LuxV handpiece for the treatment of pigmented lesions. With this new clearance, Palomar can now market the LuxV handpiece for the treatment of mild to moderate inflammatory acne vulgaris. The LuxV is a handpiece attachment for use with Palomar's family of Lux Pulsed Light systems, including the StarLux, MediLux, and EsteLux system. The LuxV is Palomar's first handpiece to treat acne.

According to the *American Academy of Dermatology*, it is estimated that acne affects more than 80% of the world's population at some point in their lives. In the past, a combination of over the counter cleansers and prescribed topical medications including topical antibiotics, peroxide compounds and topical retinoids have been traditionally recommended to treat acne. Unfortunately, many topical and oral acne treatments provide inconsistent results and are known to cause side effects. These factors, combined with an aversion to long-term dependence on antibiotics, have made light-based acne treatments increasingly appealing to the general public.

Christine Dierickx, MD, a world renowned dermatologist and Director of the Boom Laser Clinic in Belgium commented, "The advantage of Palomar's approach to the treatment of acne is that it doesn't involve medication and can be performed in the office without relying on the patient's compliance at home. Use of the LuxV handpiece offers acne sufferers a non-drug, easy and effective alternative without the side effects commonly found with drugs. Patients have been extremely happy with the results and enjoy benefits of long lasting clear skin after just a few treatments."

Joseph Caruso, CEO of Palomar added, "We are extremely pleased to receive the additional FDA clearance for the treatment of acne with the LuxV handpiece. This clearance, combined with the recent addition of the StarLux system, could dramatically increase consumer interest in Palomar's light-based cosmetic technology, and propel us to an even greater market share in this growing worldwide market."

The LuxV handpiece offers a long-term acne solution by treating the root cause of acne which is the sebaceous glands. The LuxV emits pulses of intense light that alter the structure and function of the sebaceous glands to reduce acne lesions without the many side effects common to drugs while offering longer remission times and improved efficacy rates when compared to other treatments. Acne treatment is the most rapidly



growing therapeutic category in the dermatology sector and in the U.S. alone; more than \$1.4 billion annually is spent on anti-acne medication and treatment.

- 4/6 **Cynosure, Inc.** announced that two members of its scientific team presented at the *American Society for Laser Medicine and Surgery (ASLMS)* meeting, which was held March 31 - April 4, in Dallas, TX. The company also announced that one of its newest products, the V Star pulse dye laser with SixPulse Technology, was the subject of two presentations and two panel sessions at the meeting. The new TriStar, PhotoLight and Apogee Elite systems were also included in the discussions.

Rafael Sierra, Cynosure chief technology officer, appeared on the panel discussion entitled, "Leg Vein: Bridging the Gap." Evan Sherr, Cynosure director, Clinical Studies, was an invited panelist for the session, "Skin Rejuvenation: Bridging the Gap," which included the V Star and other products.

"We are pleased to have the opportunity for our scientists to discuss Cynosure's unique technologies, such as the V Star SixPulse, especially at a luminary-led meeting such as the ASLMS. We are focused on developing the most clinically effective systems for all the key cosmetic applications," said Michael Davin, CEO and president.

The V Star also recently won the 2003 Editor's Choice Award for treatment of striae (stretch marks).

- 4/6 **Laserscope** reported that the FDA had cleared Laserscope's Gemini laser system for three major additional indications, including acne treatment, permanent hair reduction, and wrinkle reduction. Including these new clearances, Laserscope's Gemini laser system is FDA-cleared to perform 21 total procedures.

"We are very pleased and excited with this news, and believe the three new FDA clearances validate the tremendous versatility of the Gemini product platform," said Eric Reuter, Laserscope's president and CEO. "Using the Gemini, a physician can now perform over 90% of all aesthetic laser procedures currently available in the physician's office. Because of its versatility, we believe the Gemini will have significant appeal to those physicians who prefer to use a single product platform rather than several different and disparate laser systems."

"This is especially important and appealing in the so-called 'non-traditional' aesthetic market segment which includes physicians such as gynecologists, family practitioners, and other physicians who are seeking additional fee-for-service revenue streams such as those offered by cosmetic laser procedures. These physicians typically do not have space or finances to purchase several laser systems and would prefer to devote only a single treatment room in which to perform cosmetic treatments."

The Gemini laser system combines, via an intuitive touch-screen display, two of the most versatile and clinically proven laser wavelengths, 532 nanometers and 1064 nanometers,

in one powerful system with two easily selectable, ergonomically designed treatment handpieces. The innovative, continuously adjustable Versastat handpiece allows for the physician to choose up to 42 different spot sizes, enabling very precise treatment control of isolated vascularities and/or pigmentation areas. Unlike Intense Pulse Light (IPL) and some other laser sources which are typically only available in a single spot or several discrete spot sizes and are often heavy, bulky and difficult to use around certain areas of the body, the Gemini's treatment flexibility allows for precise treatment control around the face, nose, and other contoured areas as well as large treatment areas.

The Gemini is additionally complemented by a large spot handpiece which allows for fast laser coverage of large areas, making treatments for Acne, Skin Rejuvenation and Hair Removal less tedious and more cost-effective for the physician. Additionally, the Gemini incorporates the same continuous contact cooling technology as the Aura and Lyra lasers to aid in physician and patient safety and comfort.

The Gemini's technology platform is based in part on the GreenLight PV surgical laser system which was released in early 2002 and is being used in many areas of the world for the pioneering new treatment alternative for Benign Prostatic Hyperplasia (BPH) called Photoselective Vaporization of the Prostate (PVP).

4/7 **Spectranetics Corporation** announced that **Northland Securities, Inc.**, Minneapolis, Minn., had initiated coverage on the company with an "Outperform" rating. Suraj Kalia, CFA, wrote the initial report that outlined his firm's perspective on investing in Spectranetics. "Northland provides both institutional and individual investors with quality research on companies for which we believe significant investor opportunities exist," stated Kalia. "Spectranetics is well positioned for strong growth as we believe its excimer laser technology has the potential to become a standard of care for clearing complex blockages in the vascular system."

In his initiation coverage of Spectranetics, Suraj Kalia included the following:

Spectranetics has the only laser system approved by the FDA that uses ultraviolet light to send short pulses of high energy through catheters and clear blocked arteries. Over 50,000 procedures have already been safely carried out using this technology and reimbursed through third party payers. By establishing this technology as an adjunctive treatment to stenting, the firm has positioned itself for excellent growth. Clinical data showing reduced re-blockage in arteries using drug eluting stents has renewed the focus on using excimer laser technology as an adjunctive treatment in totally blocked arteries. The focus is shifting away from expensive bypass surgeries and has opened up new markets upwards of \$200 million for this technology. We believe Spectranetics' products can be used in over 350,000 of the 1 million percutaneous procedures performed annually in the U.S., a market opportunity upwards of \$1 billion. Strong clinical data was recently presented in treating blockages in leg extremities. We believe a 510(k) approval in treating blockages in the leg arteries is crucial for tapping into a market upwards of \$200 million. Excimer laser technology holds the promise of improving the quality of human

lives and reduced healthcare costs. *We believe this opportunity has not been recognized by the market and we are initiating coverage with an Outperform rating and a 12 month price range of \$7-\$9.*

#### **The Northland Perspective on this Investment:**

**Pending 510(k) for Critical Limb Ischemia.** We believe the company has presented compelling evidence in resubmitting its 510(k) application for using excimer lasers in critical limb ischemia (CLI). The company stands to post significant top line growth if it receives 510(k) approval.

**Dedicated Management Team.** Led by John Schulte and Guy Childs, the firm has recorded seven consecutive profitable quarters since 2002.

**Drug Eluting Stents.** The lower restenosis rates shown by drug eluting stents has renewed the focus on using lasers to open up chronic blockages rather than expensive bypass surgeries. This represents a \$175 million opportunity.

**Attractive Valuations.** The stock is currently valued at \$5. We believe the base business is worth \$6-\$7 per share. Assuming that the company receives a 510(k) approval, our discounted cash flow models show a \$7-\$9 price per share valuation.

- 4/12 Michael Moretti, Editor of the *Aesthetic Buyers Guide*, recently wrote about how **DUSA Pharmaceuticals, Inc.** will expand its promotion of Levulan ALA aminolevulinic acid for photodynamic therapy (PDT) to plastic surgeons. This month, DUSA will make its first exhibition to this group at the annual meeting of *ASAPS, the American Society of Aesthetic Plastic Surgeons*, in Vancouver, BC, April 15-21.

DUSA's pharmaceutical product, the Levulan Kerastick, as well as its BLU-U Blue Light Photodynamic Therapy Illuminator, have drawn great interest at recent regional and national dermatology and aesthetic medicine meetings. In addition, many highly regarded opinion leaders and cosmetic procedure experts have contributed lectures, workshops, and scientific articles to the growing interest in Levulan ALA PDT applications.

The new wave of interest in the DUSA product is generally not due to its approved application (treatment of actinic keratosis), but to the innovative techniques that surround the use of Levulan in cosmetic procedures. These new photodynamic treatments utilize the BLU-U or any of a number of other appropriate lasers and light sources, such as IPL's or pulsed dye lasers, already in widespread use in the offices of physicians and surgeons. Topics such as acne treatments, or "enhanced photorejuvenation" with Levulan PDT are present on the agendas of every major scientific meeting that addresses progressive cosmetic developments.

The new promotion to cosmetic and plastic surgeons at the ASAPS meeting will undoubtedly impact the expansion of Levulan use. According to the ASAPS website

([www.surgery.org](http://www.surgery.org)), plastic surgeons currently perform more than 495,000 chemical peel procedures yearly. This type of treatment produces very similar results as new off-label non-invasive Levulan applications that have been described, using the safe topical ALA activated by light or laser. The plastic surgeon segment of the aesthetic market is expected to account for significant growth of this cosmetic PDT procedure in the coming year.

- 4/12 **PhotoMedex** announced that **The Regence Group**, with nearly 3 million medical members and over 44,000 **Blue Cross/Blue Shield** providers had adopted a medical policy approving payment for medically necessary treatment of mild to moderate psoriasis using the PhotoMedex XTRAC laser system.

Jeff O'Donnell, PhotoMedex' CEO said, "We are pleased with the continued progress we are making on the insurance reimbursement front. We have always believed in the clinical superiority of the XTRAC. Regence's decision not only affirms that view, but further demonstrates that our XTRAC therapy cost-effectively provides those outcomes."

The Regence Group includes Blue Shield of Washington, Blue Cross Blue Shield of Oregon, Blue Cross Blue Shield of Utah, and Blue Shield of Idaho. The medical policy covering the XTRAC can be found at: [www.regence.com/trgmedpol/medicine/med98.html](http://www.regence.com/trgmedpol/medicine/med98.html).

- 4/14 **PLC Systems Inc.** announced that a cardiac surgical team from the Good Samaritan Hospital in Cincinnati, OH had completed the first carbon dioxide (CO<sub>2</sub>) Transmyocardial Revascularization (TMR) procedure with robotic assistance. Dr. Michael Smith, a cardiac surgeon and director of Robotic Surgery at Good Samaritan Hospital, performed the operation using an innovative combination of these two cutting-edge technologies. The CO<sub>2</sub> Heart Laser was utilized to create new blood-flow channels in the heart of a 66 year-old angina patient. The patient was discharged after only two days and is doing well. The CO<sub>2</sub> Heart Laser system, manufactured by PLC Systems Inc. and distributed by **Edwards Lifesciences Corporation** has already been used to successfully treat more than 10,000 patients suffering from angina.

Dr. Smith utilized the robot to provide visualization during the "closed- chest" procedure. With visualization and several small incisions a surgeon can perform TMR with the CO<sub>2</sub> Heart Laser less invasively than through an open chest or thoracotomy. Such less invasive technologies provide the same benefit to patients' and reduce hospital stays and recovery time.

"CO<sub>2</sub> TMR has proven to be an effective therapy for severe angina patients," stated Dr. Michael Smith. "In addition, robotic-assisted technology is gaining a pivotal role in the cardiac surgical community. We believe providing this established angina relief therapy through less invasive methods will be beneficial for patients."

- 4/14 **DUSA Pharmaceuticals, Inc.** announced first quarter sales, and a positive response at a recent medical meeting. DUSA reported that Q1 2004 end-user Levulan Kerastick sales to physicians totaled 12,054 Kerastick units, versus 5,478 in Q4 2003, and versus 1,842 in Q1 2003. The number of BLU-U units placed in doctors' offices also increased, to 534, compared with 406 at the end of Q4 2003 and 324 at the end of Q1 2003. The increased sales resulted from dermatology conferences such as the *American Academy of Dermatology* meeting (as previously reported), and from both new and existing customers across the country.

Subsequent to the end of the quarter, the company also participated in the 2004 annual meeting of the *American Society of Laser Medicine and Surgery (ASLMS)*, held in Dallas. There were numerous presentations and posters on Levulan PDT, generating a positive response that resulted in our booth being busy throughout the meeting,

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "We are delighted to report the increase in Q1 sales, and the continued increase in awareness of our therapy among dermatologists. Although the costs related to the addition of our sales force and related marketing activities are still greater than the gross profit generated from this level of Kerastick sales, we are very encouraged with the increasing sales trend, and believe that our efforts to penetrate the market are working."

- 4/15 **Spectranetics Corporation** announced that it expected a decision within 30 days from the FDA regarding the status of the company's 510(k) application to treat total occlusions (blockages) in the leg not crossable with standard guidewires. "We have worked closely with the FDA officials who are reviewing our 510(k) application, and have had recent discussions with them regarding the status of our application," said John Schulte, Spectranetics' president and CEO. "Based on the interactive review and recent communications with the FDA review team, we expect their decision will be made and communicated to us within 30 days."
- 4/15 **Vascular Solutions, Inc.** announced record quarterly net sales in its results for the first quarter ended March 31, 2004 and also provided an update on new product development projects and re-affirmed its sales guidance for 2004.

Net sales during the first quarter were \$4.4 million, an increase of 50% from net sales of \$3.0 million in the first quarter of 2003. The 50% increase in net sales primarily resulted from expanding sales of the D-Stat Dry hemostatic bandage which was launched worldwide in September 2003 for the topical control of bleeding in interventional procedures. In addition, the growth in first quarter sales benefitted from the initial U.S. sales of the Pronto extraction catheter and the Vari-Lase endovenous laser console, both of which were launched in January 2004.

Net sales of the Vari-Lase endovenous laser product line increased to \$370,626 in the first quarter as sales of the laser console component of the Vari-Lase product line commenced. "With the U.S. clearance of our laser console and the introduction of several

new versions of our Vari-Lase procedural kit, we now have a complete line of products for the endovenous laser treatment of varicose veins," commented Howard Root, CEO of Vascular Solutions. "At the recently completed *Society of Interventional Radiology* meeting, the growth and interest in this procedure among Interventional Radiologists was unmistakable, and with improving reimbursement and growing clinical data, our Vari-Lase business has substantial growth potential."

Vascular Solutions also re-affirmed its guidance on its sales estimates for 2004. "We believe that our net sales for the year 2004 will increase by 100% or more over net sales for 2003 to \$25 million or possibly higher. Projected revenue by product line is estimated at between \$3 million and \$4 million for the Vari-Lase."

- 4/20 **Diomed Holdings, Inc.** announced that it had successfully completed its offering to those persons who held shares of its common stock on August 29, 2003, raising approximately \$3.0 million in additional equity financing. "Given the company's ongoing commitment to its stockholders, we believed it important to provide existing stockholders the right to invest alongside the institutional investors in our recently completed \$23.2 million equity financing," noted David Swank, the company's CFO.

"The demand for the offering exceeded the allotted shares by 30%, demonstrating a continued solid endorsement of the company and its management," added Swank. "The additional funding adds to the already solid capital base the company has accumulated to support its growth and intellectual property protection strategies."

- 4/20 **PhotoMedex** announced that **WellPoint**, the nation's second largest health plan, covering more than 15 million medical members and 46 million specialty members, has adopted a medical policy approving payment for medically necessary treatment of mild to moderate psoriasis using the PhotoMedex XTRAC laser system.

Jeff O'Donnell, PhotoMedex' CEO said, "This is a major event for PhotoMedex. The favorable decision by one of the largest healthcare plans supports our view that our XTRAC therapy cost-effectively provides superior clinical outcomes. We believe this will have a catalytic impact on other insurers and will trigger deployment of XTRAC laser systems and marketing programs in the geographies covered by WellPoint."

WellPoint serves its members through Blue Cross of California, Blue Cross and Blue Shield of Georgia (the largest healthcare insurance entity in Georgia), Blue Cross and Blue Shield of Missouri, Blue Cross Blue Shield of Wisconsin, and throughout various parts of the country as UNICARE, HealthLink, and MethodistCare, Inc. (one of the largest HMOs in Houston). WellPoint is included in the S&P 500 Index. The medical policy covering XTRAC can be found at [http://medpolicy.bluecrossca.com/alpha\\_index.html](http://medpolicy.bluecrossca.com/alpha_index.html), or any of the other WellPoint company websites.

- 4/21 **Spectranetics Corporation** announced that revenue for the quarter ended March 31, 2004 rose 11% to \$7.8 million from \$7.0 million in the comparable prior-year quarter, and rose

5% from \$7.4 million in the seasonally strong immediately preceding quarter. Net income for the first quarter of 2004 was \$135,000 (1 cent per share) compared with net income of \$141,000 (1 cent per share) in the first quarter of 2003.

For the 2004 first quarter, disposable product revenue (which includes coronary atherectomy and lead removal products) rose 14% to \$5.7 million from \$5.0 million in the same quarter last year, due primarily to a 25% increase in coronary atherectomy revenue. Laser equipment revenue (which includes laser system sales and rental fees) declined from the year-ago period, and was \$761,000 in the 2004 first quarter, compared with \$1.1 million in the 2003 first quarter. This decline is consistent with the focus of field sales resources on disposable product sales and a continued shift towards evaluation and rental placements as opposed to outright sales.

Gross margin for the first quarter of 2004 was 73%, up from 70% in the year-ago quarter reflecting a product mix favoring disposable products.

The company's worldwide installed base of lasers increased by a net of five lasers during the quarter ended March 31, 2004, compared with a net increase of one new laser placement during the first quarter of 2003. The worldwide installed laser base at March 31, 2004 totals 388 systems, which includes 287 laser systems in the United States.

"We are very pleased with this quarter's top-line growth, which was driven by solid execution of our strategy to increase disposable product sales. The strength of our coronary atherectomy business is particularly encouraging and reflects positive customer response to a live laser case at the first-ever 'CTO Club' meeting, at which many of the world's top interventional cardiologists convened to view developments in the treatment of chronic total occlusions," said John Schulte, president and CEO. "We believe this favorable response, along with the growing base of clinical evidence supporting use of lasers in treating saphenous vein grafts and acute myocardial infarction, contributed to heightened awareness of the effectiveness of laser technology in complex atherectomy procedures.

"We remain confident as we await a determination from the FDA on our 510(k) application for use of our laser to treat totally occluded arteries in patients with symptomatic peripheral vascular disease, including critical limb ischemia," Schulte continued. "FDA marketing clearance would mark another important milestone for the company, would open up an important new market for our laser system and would enable us to commence a product launch of the new larger diameter catheters immediately."

**Company Reiterates 2004 Financial Guidance:** Spectranetics today reiterated its 2004 financial guidance, which projects annual revenue growth of 5% to 7% driven primarily by an increase in disposable product sales and by the placement of 25 to 30 new lasers. Net income is expected to be \$500,000 to \$1 million. This financial guidance assumes no revenue contribution from the treatment of patients with critical limb ischemia. However, it does reflect costs associated with the hiring of at least three new clinical

account managers and the advancement of clinical research focused on a laser-based treatment of heart attacks.

4/22 **Laserscope** reported record revenues of \$18.8 million for its first quarter ended March 31, 2004, a 51% increase from \$12.5 million in the year-ago quarter. Sequentially, revenues increased 5% from \$17.8 million for the quarter ended December 31, 2003. First quarter 2004 net income was \$2.2 million (10 cents per share) compared with net income of \$135,000 (1 cent per share) in the same quarter last year, and net income of \$1.5 million (7 cents per share) for the fourth quarter of 2003.

"We had a stellar quarter, driven primarily by strong growth in our GreenLight PVP urology business," said Eric Reuter, president and CEO. "Our innovative procedure for the treatment of Benign Prostatic Hyperplasia (BPH), or enlarged prostate, continues to gain traction at a rapid pace both domestically and internationally. Recent substantial increases to the Medicare reimbursement rate for this procedure done in outpatient hospitals in the United States should further encourage utilization of our treatment going forward."

Gross margin for the first quarter of 2004 was approximately 56%, compared with approximately 50% for the first quarter of fiscal 2003 and approximately 54% for the fourth quarter of 2003, primarily as the result of changes in product mix and better ASPs for the company's GreenLight lasers. Selling, general and administrative expenses were \$6.7 million, or 36% of revenues, in the first quarter of 2004, compared with \$5.1 million, or 41% of revenues, in the year-ago quarter. Increased SG&A spending resulted primarily from higher sales and marketing expenses relating to the company's GreenLight PV products, as well as higher direct selling expenses for domestic aesthetic products.

The company strengthened its balance sheet during the quarter. At March 31, 2004, the company had no short-term bank borrowings and a cash position of \$8.7 million, up from \$7.2 million at the end of 2003.

"During the first quarter, we sold a total of 49 GreenLight PV laser systems and increased sequential fiber volume by 19% to 6,403 fibers, compared to 39 systems and 5,364 fibers sold in the fourth quarter," continued Reuter. "This performance was accomplished in spite of the normal seasonality experienced during the Holiday period and is further indication of the accelerating adoption of the PVP procedure. Additionally, our GreenLight PV system backlog remained strong at 19 systems at the end of the first quarter, the same as at the end of the fourth quarter of 2003.

"Although first quarter revenues in our aesthetics business were up only about 4% compared to the prior year, we have a very strong aesthetic backlog, especially for our newest Gemini Laser," said Reuter. "The Gemini, which was recently FDA-approved for the treatment of acne, permanent hair reduction and wrinkle reduction, is now approved for a total of 21 different procedures, and can perform over 90% of all aesthetic laser



procedures available in a physician's office. We are seeing strong preliminary acceptance and demand for the product in the market.

"We are continuing to successfully execute on our business plan in both our urology and aesthetics businesses and have built considerable momentum over the last several quarters. We believe we are on track for a strong year."

**Guidance:** In recognition of strengthening adoption of the company's GreenLight PVP treatment for enlarged prostate and the recently launched Gemini aesthetic laser system, Laserscope is revising its financial forecast for fiscal year 2004 as follows:

\* Revenue is expected to be approximately \$86 million in 2004, up from a previous forecast of \$70 million.

\* Gross margin, as a percentage of 2004 revenues, is expected to be in the range of 57% to 60% for the full year.

\* Net income per share is expected to be in the range of \$0.50 - \$0.55 per share assuming a tax rate of approximately 13%, up from a previous forecast of \$0.32 - \$0.34 per diluted share. The company expects continued growth in profitability with the highest growth occurring in the traditionally strong fourth quarter.

\* GreenLight fiber sales worldwide are expected to be in the range of 31,000 - 33,000 for the full year.

4/26 **Cutera, Inc.** announced that the underwriters of its initial public offering exercised their over-allotment option to purchase an additional 529,800 shares of its common stock at \$14.00 per share. The option was granted in connection with the company's initial public offering of 3,532,000 shares on March 31, 2004. The company granted the underwriters an option to purchase up to an additional 529,800 shares to cover over-allotments. **Piper Jaffray** is the book-running manager for the offering. **SG Cowen** and **RBC Capital Markets** are co-managers.

A registration statement relating to these securities was declared effective by the Securities and Exchange Commission on March 30, 2004. Copies of the final prospectus may be obtained from the offices of Piper Jaffray & Co., U.S. Bancorp Center, 800 Nicollet Mall, Suite 800, Minneapolis, MN 55402; SG Cowen Securities Corporation, Two International Place, 27th Floor, Boston, MA 02110; or RBC Capital Markets Corporation, 60 South Sixth Street, Minneapolis, MN 55402.

#### **MEDICAL/SURGICAL LASER UPDATE -- May 2004**

4/27 **BIOLASE Technology, Inc.** reported financial results for the three month period ended March 31, 2004. Net sales for the first quarter of 2004 were \$14.4 million compared to net sales of \$9.2 million for the three months ended March 31, 2003. Sales of the

company's principal product, the Waterlase system, for the first quarter of 2004 comprised 78% of sales, which is the same percentage of sales that the Waterlase system comprised in the first quarter of 2003. For the year ended December 31, 2003 Waterlase sales comprised 83% of total sales, including recognized deferred revenues.

Gross profit for the first quarter of 2004 was \$9.3 million, an increase of approximately 58% over gross profit of \$5.9 million for the first quarter of 2003. Gross margin was 64.4% for the first quarter of 2004 compared to 63.7% for the first quarter of 2003.

Operating expenses were \$8.1 million for the first quarter of 2004 compared to \$5.0 million for the first quarter of 2003. Sales and marketing expenses increased 58% and were 40% of sales for the first quarter of 2004 compared to 39% of sales for the first quarter of 2003. The increase is consistent with the company's commitment to rapid market penetration, particularly in launching its marketing activities for the new year. Increases in absolute dollars included an increase in the number of new sales representatives in North America and additional investment in international sales and marketing events and infrastructure. Sales and marketing expenses in the first quarter have historically been higher as a percentage of sales. General and administrative costs were \$1.6 million, an increase of 90% over the first quarter of 2003 but in line with expenses in the prior two quarters. Increases in general and administrative costs are due mostly to legal, including legal fees related to the **Diodem** patent litigation, insurance accounting and auditing fees. Engineering and development costs for the first quarter increased 51% compared to the first quarter of 2003; however, they were also in line with expense levels in the prior quarter. Increases relate to additional investment in product development activities.

Operating income was \$1.2 million for the first quarter of 2004 compared with \$886,000 for the first quarter of 2003, an increase of 32%.

In the fourth quarter of 2003, based on the historical level of taxable income and the projection for future taxable income, it was determined that deferred tax assets, which previously had been fully reserved due to the uncertainty of their future realization, would more likely than not be realized. As a result, the valuation reserves on deferred tax assets were reduced and an income tax benefit was recognized. Consequently, a provision for income tax of \$437,000 was recorded against taxable income, although actual income tax payments will not be made until the estimated \$32.5 million in net operating loss carryforwards are utilized. The provision was based on the company's estimated effective tax rate of 39%, which represents the combined federal and state tax rates.

After the provision for income tax of \$437,000, net income for the first quarter of 2004 was \$672,000 (3 cents per share). For the first quarter of 2003, net income with no provision for income tax was \$940,000 (4 cents per share).

4/27 **Candela Corporation** reported that its third fiscal quarter revenue of \$27.6 million, increased by 29% over revenue for the same quarter one year earlier, and increased 33%

over the same nine-month period in the prior year. Net income for the quarter was \$1.96 million, or \$.09 per share, compared to \$2.62 million, or \$.13 per share, for the prior year quarter in accordance with GAAP. The prior year net income for the quarter includes the effect of a favorable arbitration result in such quarter of \$.76 million, or \$.04 per share. The company reported that its gross margin for the third fiscal quarter was impacted by approximately \$.9 million in aggressive pricing terms it implemented to launch a new product to gain market share.

Gerard Puorro, Candela's president and CEO, commented: "We saw a window of opportunity to take market share for the long term by building a significant referral base in a short period of time through initial aggressive pricing terms. We now have over 100 referral sites of physicians who are happy with this product. We accomplished this product rollout in less than eight weeks. We have since that time raised the price to the level we expected to offer the product over a longer selling period, but now have the benefit of an early adopter referral base, attracted by the aggressive pricing terms, who will attest to the value added of this device. In the past, we have provided only limited guidance as to our expectations of growth. Given the obvious question of how this increased pricing strategy will impact our future results, we offer the following: We currently believe that our fourth fiscal quarter will bring our full year to approximately \$100 million in revenues. We believe that gross margin in our fourth quarter will exceed that of each of the previous three quarters, and that our expenses will hold steady."

- 4/28 **Lumenis Ltd.** announced that the company had entered into a 3-year agreement with **MedAssets HSCA** to become a supplier for laser, light-based devices, and services to their 22,000 hospitals, sub-acute care facilities and physician practices nationwide. Lumenis is the leading provider of surgical, ophthalmic, aesthetic lasers and intense pulsed light systems in the medical industry. In this agreement, Lumenis will offer convenient access and procurement of the company's surgical and ophthalmic lasers, accessories, delivery devices, as well as service to hospitals, clinics and doctor offices at negotiated prices. The three-year contract will take effect on April 1, 2004 and run through March 31, 2007.

President and CEO Avner Raz commented, "We are very pleased with this vote of confidence from MedAssets HSCA and its customers. The MedAssets HSCA contract is an important account for Lumenis and is due in large part to the concentrated effort and investment Lumenis has made to develop our National Contracting business over the last two years. We look forward to serving the customers of MedAssets HSCA".

"We are pleased to bring Lumenis' line of surgical and ophthalmic lasers to MedAssets members," said Joe Dysko, Executive Director Engineering & Capital Resource Group at MedAssets HSCA, "and look forward to this mutually beneficial partnership."

- 4/29 **Diomed Holdings, Inc.** announced financial results for the first quarter ended March 31, 2004. In the first quarter of 2004, Diomed delivered revenue of \$2.9 million, a 39% increase over Q1 2003. Revenue from the EVLT product line increased 53% over the

same period last year, including growth of more than 100% in disposable procedure products.

"Diomed continued its strong pace through the first quarter of 2004," stated James Wylie, president and CEO of Diomed Holdings, Inc. "Our first quarter performance clearly establishes Diomed as the leader in the endovenous laser treatment of varicose veins. We now estimate that over 15,000 procedures have been successfully performed on a worldwide basis.

"This year we also initiated litigation against **Angiodynamics, Vascular Solutions** and **Total Vein Solutions** for the infringement of U.S. Patent No. 6,398,777 covering the endovenous laser treatment of varicose veins," Wylie added. "We have invested more than \$20 million in the commercialization of EVLT over the last three years and we are aggressively protecting this investment."

Gross profit for Q1 2004 was \$1.0 million, an increase of \$281,000, or 39%, over Q1 2003. However, at the cost of revenues line, improvement from fixed manufacturing cost leverage on incremental 2004 volume was partially offset by the foreign exchange impact on raw material purchases and the impact of patent royalties not in effect in the prior year. Research and development expenditures for Q1 2004 increased \$108,000, or 57%, to \$296,000 compared to Q1 2003. R&D expenditures are expected to remain at an elevated level through year-end as we strive to improve the feature-function of our products and continue to reduce product costs.

Selling and marketing expenses for Q1 2004 were \$1.6 million, an increase of \$463,000, or 40%, over Q1 2003. The increase was driven by a significant expansion in the size of the sales force, higher sales commissions resulting from the increased sales volume, and increased marketing expenditures in support of the sales efforts. General and administrative expenses for Q1 2004 were \$1.4 million, an increase of \$598,000, or 75%, over Q1 2003. The increase was driven by incremental legal fees, sales volume-based product liability insurance costs, infrastructure enhancements, and a non-cash charge for stock options granted to a third-party service provider. Legal costs included the initiation of patent litigation against both Angiodynamics and Vascular Solutions, and continuing costs of litigation against Vascular Solutions in the theft of trade secrets suit filed in the fourth quarter of 2003.

Loss from operations for Q1 2004 increased by \$888,000, or 63%, to \$2.3 million compared to Q1 2003. Net loss applicable to common stockholders for Q1 2004 was \$2.3 million (1 cent per share) compared to a net loss of \$2.0 million (13 cents per share) for Q1 2003.

**Liquidity and Capital Resources:** The ending cash balance of \$8.3 million reflected a \$5.1 million reduction in cash during the quarter and included \$2.3 million in payments not expected to recur in FY04; specifically \$1.2 million in debt repayments, \$261,000 in

costs related to the 2003 equity financing, and \$875,000 in annual insurance premiums and other annual costs which benefit future quarters.

On April 20, 2004, Diomed announced the completion of its offering to shareholders of record as of August 29, 2003, raising approximately \$3.0 million in additional equity financing. Proceeds from the offering will be included in the second quarter 2004 balances and used to support the company's continued growth and intellectual property protection strategies. The company's preliminary proxy to the 2003 annual shareholders' meeting filed with the SEC on April 23, 2004 details a proposal recommending a reverse split of the company's shares. "The proposed reverse split completes the last in a series of initiatives launched in 2003. Those initiatives include recruitment of key executive management and Board members, recapitalization of the balance sheet through \$26.2 million in equity financings, acquisition of exclusive rights to the key EVLT patent, and initiation of litigation to enforce those patents," stated David Swank, CFO. "The reverse stock split is proposed at a ratio of one new share for every twenty-five existing shares."

4/29 **PhotoMedex, Inc.** announced the results of their operations for the quarter ended March 31, 2004. Revenues for the quarter were \$4.0 million, an increase of 15.9% over the same period last year and 8.7% increase over the fourth quarter of 2003. The net loss for the quarter ended March 31, 2004 was \$1.4 million (4 cents per share). The net loss for the quarter ended March 31, 2003 was \$1.7 million (5 cents per share). As of March 31, 2004, the company had cash and cash equivalents of \$5,825,956.

Jeffrey O'Donnell, PhotoMedex CEO and president, commented, "We are pleased with the recent decisions by key private health insurers approving the XTRAC for reimbursement. We believe this is just the beginning, and anticipate that the other large health insurance providers will be reaching the same conclusion. This is a major milestone for PhotoMedex and further substantiates our belief that our psoriasis laser therapy provides superior clinical outcomes in a cost effective manner. We look forward to our conference call today, as it provides us with an opportunity to not only advise you of the first quarter results, but also to discuss our plans for the rollout of the XTRAC in the new regions covered by reimbursement."

4/29 **PLC Systems Inc.** reported financial results for the three months ended March 31, 2004. First quarter total revenues increased to \$1.9 million compared with \$1.7 million in the first quarter of 2003. The net loss for the quarter was \$350,000 (1 cent per share) compared to net income of \$15,000 (0 cents per share) in the first quarter of 2003.

During the first quarter, PLC Systems and **Edwards Lifesciences Corporation** announced that the two companies entered into an exclusive, multi- year agreement to develop and manufacture Edwards' Optimaze surgical ablation system, a cardiac laser technology designed to treat cardiac arrhythmias.

"PLC entered 2004 with a growth strategy to pursue opportunities that would provide the company with product diversification," stated Mark Tauscher, president and CEO of PLC

Systems. "By executing our strategy, we have positioned PLC for future growth. Our first quarter research and development investments of \$529,000 are a clear indication of our commitment to this strategy. In February, we expanded our product portfolio by adding the Optimaze system. This first step provides the foundation for the new PLC, a multi-product company focused on creating innovative technologies for the cardiac and vascular markets."

Prior to the expanded relationship between Edwards and PLC, Optimaze was an ongoing program within Edwards. During the next three quarters, the research and development, as well as the manufacturing of the entire Optimaze system, will be transitioned to PLC. Edwards expects to introduce the Optimaze system in the second half of 2004.

Tauscher commented on the new opportunity, "We are very pleased with the progress of our new Optimaze project. We have been aggressive in ramping up our capabilities to finish the research and development phase as well as positioning ourselves to manufacture both the laser and disposable components of the Optimaze system. In order to track our performance, we believe it is important to establish project milestones that are expected to be completed in the next three quarters. As we drive toward generating revenue in 2005, our key objectives are as follows: infrastructure build out completed in the third quarter; infrastructure validation completed in the fourth quarter; Optimaze laser product release in the fourth quarter; and Optimaze disposable hand piece product release in the first quarter of 2005."

Commenting on the first quarter TMR results, "During the first quarter, the demand for our CO2 TMR laser system continued to be healthy, which is evident by the number of new lasers shipped to hospitals and the conversion of previously placed lasers into sales. We believe that the recently issued *Society of Thoracic Surgeons'* practice guidelines for TMR will be a positive influence on the adoption of the TMR therapy."

During the first quarter of 2004, PLC shipped eight next-generation CO2 Heart Lasers (HL2) to United States hospitals through Edwards Lifesciences, PLC's exclusive U.S. sales and marketing partner. Six of the eight HL2 shipments were new lasers and two were redeployed lasers.

PLC ended the first quarter of 2004 with 163 CO2 Heart Lasers located at heart centers throughout the U.S., comprised of 114 HL2 customers and 49 HL1 customers. As of March 31, 2004, PLC's U.S. laser base (HL1 and HL2) had increased by more than 18% during the preceding twelve months

During the first quarter of 2004, a total of 427 disposable kits were shipped worldwide. Edwards delivered 382 disposable kits to United States hospitals and PLC shipped 45 disposable kits to international hospitals. In comparison, a total of 413 disposable kits were delivered worldwide during the quarter ended March 31, 2003.

Tauscher concluded, "Our vision is to build a world-class multi-product, multi-platform medical technology company, focused on creating innovative technologies for the cardiac and vascular markets. We are making great strides toward this goal. We believe that our TMR business can and will continue to grow. The Optimaze project is on course and should generate revenues for PLC in early 2005. In addition, we continue to investigate additional business opportunities that can provide greater revenue growth and diversification. By executing our strategy, we believe PLC's future is bright."

4/29 **Spectranetics Corporation** announced it had received market clearance from the FDA to treat patients suffering from total occlusions (blockages) in their leg arteries with Spectranetics' proprietary excimer laser catheters. The market clearance, which was supported by clinical data from a subset of patients enrolled in the LACI (Laser Angioplasty for Critical limb Ischemia) trial, applies to most of the company's coronary catheters ranging in diameter from 0.9 millimeters to 2.0 millimeters in addition to new 2.2 and 2.5 millimeter diameter catheters specifically designed for treating blockages in the peripheral vasculature.

Professor Giancarlo Biamino, Director of the Department of Clinical and Interventional Angiology at the University of Leipzig Heart Center, and a pioneer in laser-assisted endovascular intervention for peripheral vascular disease, commented, "It is an ethical must to treat patients with symptomatic ischemic peripheral vascular disease using aggressive endovascular revascularization procedures. The excimer laser is an essential tool to recanalize total occlusions and remove obstructive material to transform diffuse disease into more easily ballooned stenoses. Clinical studies with the excimer laser demonstrate that this approach results in excellent limb salvage rates with a low risk of distal embolization. We have been using the excimer laser to treat complex peripheral vascular disease in Europe with excellent results for over a decade."

"We are delighted with the favorable response from FDA to our 510(k) application, and look forward to bringing this important new treatment option to certain patients suffering from critical limb ischemia, a debilitating condition," said John Schulte, Spectranetics' president and CEO. "Patients with total occlusions refractory to guidewire have so few treatment options that surgery -- either bypass or amputation -- is nearly inevitable," he added. "Our research indicates that approximately 1.5 to 2 million people in the U.S. and Europe suffer from critical limb ischemia, and that more than 200,000 patients may benefit from laser treatment. We plan to immediately launch the CLiRpath product line to our customers who already have a laser and an active interventional peripheral program. We will solicit an initial stocking order of four to six catheters in these 100 accounts and plan to complete this phase of our launch within 90 days. We will update our financial guidance sometime after the initial 90-day period when we have a better view of re-order rates."

**About Critical Limb Ischemia and the LACI Trial:** Critical Limb Ischemia (CLI) is associated with multi-level arterial disease between the thigh and the ankle, and is dominated by occlusions (total blockages) rather than stenoses (partial blockages). The

extent and location of the disease often make arterial reconstruction, including surgery and balloon angioplasty, difficult.

The Spectranetics 510(k) submission contained clinical data obtained from a subset of the LACI trial, and was supplemented by data obtained from other similar clinical studies in the U.S. and Europe. In those studies, the 47 patients treated were poor surgical candidates and were not amenable to other minimally invasive percutaneous procedures, such as balloon angioplasty, since the lesions were not crossable with a guidewire. Limb salvage was observed in 95% of patients surviving for six months with no increase in serious adverse events as compared with other patients in the LACI study.

4/29 **Palomar Medical Technologies Inc.** announced financial results for the first quarter ended March 31, 2004. The company's total revenues and product revenues each increased by 58% and its gross profit from product sales improved by 80% as compared to the first quarter of 2003. Due to growing sales of the company's family of Lux Pulsed Light systems, revenues have increased, product gross margins have improved and the company has realized net income for the past two years, with a net income improvement of more than three times the net income for the first quarter of 2003. The improvement in product gross margins is primarily due to a higher margin product mix and the effects of increased sales volume. The increase in net income has allowed the company to improve its cash position over the past year.

CEO Joseph Caruso commented, "This has been an exciting and rewarding quarter for Palomar. We continue to enjoy increased market acceptance of our new product offerings, and we believe we are maintaining our leadership position as an innovator in our markets. Our reputation for leading-edge technology and product reliability has resulted in increased revenue for Palomar over the past two years in the expanding market for light-based cosmetic procedures; a trend we think will continue throughout 2004."

Revenues for the quarter ended March 31, 2004, were \$10.8 million, up from \$6.8 million in the first quarter of 2003. Gross profit from product sales increased to \$6.2 million (64% of product revenues), up from \$3.5 million (57% of product revenues) in the year-earlier quarter. The company reported net income of \$1.2 million (7 cents per share) for the first quarter of this year, compared to net income of \$358,000 (3 per share) for the first quarter of last year.

During the first quarter of 2004, the company announced the following events:

\* Received clearance from the FDA to market the LuxV handpiece for the treatment of acne. The LuxV is a handpiece attachment for use with Palomar's family of Lux Pulsed Light systems. The LuxV handpiece offers a long-term acne solution by treating the root cause of acne. The LuxV emits pulses of intense light that alter the structure and function of the sebaceous glands to reduce acne lesions without the many side effects common to drugs while offering longer remission times and improved efficacy rates when compared



to other treatments. Acne treatment is the most rapidly growing therapeutic category in the dermatology sector and in the U.S. alone; more than \$1.4 billion annually is spent on anti-acne medication and treatment.

- \* Awarded a \$2.5 million research contract by the Department of the Army to develop a light-based self-treatment device for Pseudofolliculitis Barbae (PFB). PFB, commonly known as "razor bumps", has been called "the most significant dermatologic disease in the US Army"; affecting combat readiness, unit cohesion, and individual morale of over 50% of African American and Hispanic military personnel.

- \* Results of a Markman ruling in the ongoing patent infringement action brought by Palomar against **Cutera, Inc.** The ruling represents a major step in Palomar's efforts to enforce its patent portfolio and will have considerable impact on the case as it proceeds toward trial. If Palomar prevails at trial, Cutera may be ordered to pay millions in damages for past sales and may also be ordered to stop selling any products that perform hair removal. In the ruling, the District Court largely embraced Palomar's position, finding for Palomar on critical issues.

- \* Palomar's common stock began trading on the Nasdaq National Market System. After meeting all the requirements for listing on the Nasdaq National Market, Palomar upgraded from the Nasdaq Small Cap Market System while retaining the same ticker symbol, PMTI.

- \* Launch of its next generation pulsed-light and laser system, the Palomar StarLux, at the *American Academy of Dermatology's (AAD) Annual Meeting* in February. The StarLux is capable of operating all of the pulsed-light handpieces available on prior Palomar pulsed light systems plus the new Lux1064 YAG laser handpiece to treat vascular lesions including leg veins.

4/30 Increasing numbers of women and men are seeking cosmetic procedures to turn back the clock of time and erase telltale wrinkles, often spending large amounts of money and enduring painful procedures, with mixed results. The revolutionary new ELOS (electro-optical synergy) technology (from **Syneron Medical**) is now being offered by Dr. Kovak of **Midwest Dermatologic Laser and Vein Centre** in Elmhurst, IL. It offers the safest, most effective and comfortable solution for smoothing fine lines and deeper wrinkles.

The ELOS technology is a breakthrough in cosmetic lasers as it is the first to use a unique combination of Radio Frequency and Diode Laser to treat wrinkles. With ELOS, we can isolate the treatment area and leave the surrounding skin free from potentially harmful side effects. Using gentle pulses of two targeted energies means better results with lower overall energy output -- assuring the highest level of safety and comfort. ELOS has been proven to deliver superior results, and marks a major leap forward in cosmetic laser technology

5/3 **Lumenis Ltd.** announced the results of the ongoing internal investigation being conducted on behalf of the Audit Committee of its Board of Directors. The company also announced that it will be reorganizing certain of its financial reporting functions. Avner Raz, Lumenis' president and CEO, stated, "We are committed to completing any remaining investigation action items, as well as the reorganization of certain of our financial reporting functions, as expeditiously as possible. In addition, as CEO, I want to assure you that as the Audit Committee and its advisors continue their work to complete the investigation, the company will remain focused on serving our customers and growing and revitalizing our business. Our products continue to be recognized as worldwide market leaders, the implementation of our previously announced turn-around program continues on schedule and cash resources remain available and sufficient to execute our plans."

**Summary of Results of Internal Investigation:** As previously disclosed, the Audit Committee commenced an internal investigation in October 2003 in response to a request from **Deloitte & Touche Brightman Almagor**. The internal investigation, which was conducted for the Audit Committee by **Debevoise & Plimpton LLP** and accounting advisors retained by that firm, initially focused on accounting and disclosure issues related to the company's relationship with one of its domestic distributors. It was subsequently expanded to include a comprehensive review of the company's revenue recognition practices during 2002 and 2003. Certain transactions recorded in 2001 were also reviewed during the internal investigation.

The report prepared for the Audit Committee concludes that the timing of the company's revenue recognition was inappropriate with respect to certain identified transactions. The aggregate effect of the company's accounting for the transactions identified in the report was to cause revenues in 2001 to be overstated by approximately \$1.7 million or 0.6%, revenues in 2002 to be overstated by approximately \$4.4 million or 1.3%, and revenues in 2003 to be understated by approximately \$5.9 million or 2.1%. The effect on quarterly periods was as follows:

	Amount of Overstatement/(Understatement) Of Revenue by Quarter (In 000's)			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2001	N/A	\$345	\$423	\$931
2002	\$2,827	\$1,234	\$2,182	(\$1,873)
2003	\$1,561	(\$3,079)	(\$1,022)	(\$3,362)

The effect of such overstatement/understatement of revenues on previously reported earnings (loss), while not included in the report, is estimated, on a preliminary basis and subject to further adjustment, to increase the net loss as reported in 2001 by approximately \$0.9 million or 0.6%, to increase the net loss as reported in 2002 by approximately \$2.9 million or 6.5%, and to reduce the net loss as reported in 2003 by

approximately \$3.8 million or 4.6%. The impact on particular quarterly periods may vary on a percentage basis.

The Audit Committee intends to undertake further investigative steps, including a more comprehensive review of transactions recorded in the company's fiscal year ended December 31, 2001. The Audit Committee anticipates that a restatement of previously reported financial results may be appropriate, but intends to defer making a final decision pending completion of the additional investigative steps.

Based on the information obtained to date, the adjustments made in any such restatement would primarily affect the timing of revenue recognition, and it is not anticipated that they would have a material effect on the financial position of the company as currently reported. In addition, because the report does not identify any transactions in which revenue was recorded prematurely after the first quarter of fiscal 2003, the company does not expect that a restatement would have a meaningful effect on future reporting periods.

The company has shared the results of its investigation and its plans to reorganize certain of its financial reporting functions with Deloitte. That firm has made no commitment to continue serving as the company's auditor, and it has advised the company that it will not be in a position to evaluate whether it is willing to do so until after the company's reorganization has taken place, and the further investigative steps have been completed.

The company has also shared the information concerning the results of the investigation and the financial reporting function reorganization with **Bank Hapoalim B.M.**, which continues to be supportive of the company.

**Fourth Quarter Results:** The company also announced preliminary unaudited results for the fourth quarter of \$75.4 million in revenue, excluding the effect of the understatement noted above. Preliminary unaudited net loss for the fourth quarter, including approximately \$16.5 million in charges or provisions for inventory, bad debt and severance related matters, but excluding the effect of any possible restatement as noted above, was approximately \$28 million, while net cash flow from operations was negative by approximately \$1 million. The company intends to provide additional financial information on its fourth quarter results as soon as practicable.

5/3 **Cutera, Inc.** reported financial results for the first quarter ended March 31, 2004. First quarter revenue was \$11.6 million, a 76% increase over the \$6.6 million recorded in the same period last year. Net income for the first quarter was \$221,000 (2 cents per share) compared to a net loss of \$72,000 (4 cents per share) reported in the first quarter of 2003. Included in the first quarter results is \$372,000 of pre-tax, non-cash, stock-based compensation charges, compared to charges of \$220,000 in the first quarter of 2003. First quarter results also reflect G&A costs associated with a facilities move, IPO accounting fees, and settlement of the **Allied Health** lawsuit.

"We are very pleased with our first quarter results, particularly as a newly public company," said Kevin Connors, president and CEO. "As consumer demand continues to grow for non-invasive aesthetic treatments, dermatologists, plastic surgeons and other emerging physician groups are turning to Cutera for our high performance, expandable technology platforms. We believe the market for our products is significant, as we have recently experienced exciting growth in the primary care physician segment. The shift in product mix towards our premier offering is evidence that the market recognizes the value and performance of our versatile technology platforms and our multi-application systems."

Based on the current outlook, Cutera believes that second quarter revenue will be approximately \$11.8 million with corresponding earnings per diluted share of \$0.03. Weighted average shares for diluted EPS in the second quarter are estimated to increase by 3.8 million shares to approximately 13.2 million shares, primarily resulting from the issuance of shares due to the company's IPO and the exercise in full of the over-allotment of shares by the underwriters. For the full year, Cutera expects revenue of \$49.5 to \$50.5 million and earnings per diluted share of \$0.15 to \$0.17.

- 5/3 **Trimedyne, Inc.** announced its 80 Watt Holmium Laser and Re-usable Optical Fibers were eligible for Medicare's new reimbursement rate for laser procedures to treat Benign Prostatic Hyperplasia (BPH), commonly referred to as an enlarged prostate, a condition affecting approximately 50% of men over age 55. An estimated 2 million Americans require treatment for BPH annually, and almost 200,000 surgical procedures to treat BPH are performed each year in the United States.

The new \$3,750 Medicare reimbursement rate is approximately twice the previous rate. The procedure is defined under HCPCS Code Number C9713 as "Non-contact laser vaporization of the prostate, including coagulation control of intra-operative and post-operative bleeding". The higher reimbursement rate is due to the procedure being classified under New Technology Ambulatory Classification Number 1525. The maximum patient co-pay is \$750.

Trimedyne's Holmium Laser enables prostate tissue to be vaporized and coagulated with less risk of thermal damage to adjoining tissues than other lasers, such as KTP or Nd:YAG. In addition, Trimedyne's reusable optical fibers can bring the cost of the fiber down to less than \$100 per case. Competitive disposable fiber-optic devices can cost \$700 or more per case.

- 5/4 **BIOLASE Technology, Inc.** officially opened its new manufacturing facility in San Clemente. Jeffrey Jones, BIOLASE CEO and president, reported, "The company opened its facility on schedule today, fully operational and successfully producing its first lasers. The new facility utilizes the Kanban inventory system for the delivery of parts to the line, and the KAIZEN principals to improve the manufacturing processes, pursuing the world class manufacturing environment."

The operation is part of a capital expansion program to significantly increase the company's manufacturing capacity, international distribution channels and domestic sales force as previously announced in March 2004. This expansion has been necessitated by growing demand for BIOLASE's lasers and related products. The new facility is located within the same business park in San Clemente, adjacent to BIOLASE's headquarters. The building will bring the company's U.S. leased facility capacity to approximately 40,000 sq. ft., providing extensive operating leverage in the form of manufacturing efficiencies, which will help contribute to the company's profitability going forward. In addition, the company owns approximately 20,000 sq. ft. of office and manufacturing space in Germany.

Jones further commented, "With our expanded manufacturing capacity and robust sales forecast, this is going to be an exciting year for BIOLASE, both internationally and here in the United States. I feel that with the added capacity that we have in the U.S., together with the support from our expanded sales force team, BIOLASE should significantly increase its market penetration and be in a better position to support its growing demand in 2004 and beyond."

5/4 **Cynosure, Inc.** announced that its TriActive LaserDermology device was featured in the April 27th issue of *Woman's World* magazine, the number one woman's weekly with a circulation of over 1.6 million. Robert Pitera, MD, medical director of the Cellulite Endermologie Center of New York, which offers the TriActive treatments in Manhattan, comments on the causes of cellulite which include heredity, female hormones and poor circulation. Mitchel Goldman, MD, a dermatologist and the medical director of La Jolla Spa MD in San Diego, notes that "Many patients actually fall asleep during the treatment" because it is painless.

In January 2004, the TriActive received government clearance as an exempt device for the treatment of cellulite. The device is also used for therapeutic massages. Cellulite affects nearly all adult women and a smaller percentage of men, especially body-builders. Cellulite centers, spas and medical practices that now offer TriActive LaserDermology treatment report that their clients find the treatment relaxing and a complement to their other stress, and weight reduction regimens. It is also less time consuming than alternative massage technologies.

"We are pleased to have received this recognition in the consumer media, especially since it will benefit our customer base by helping to publicize the benefits of the TriActive. It is yet another acknowledgement that our products are performing well in the marketplace and helping our customers address their clients' most important body profiling needs," said Michael Davin, Cynosure CEO and president.

5/4 **DUSA Pharmaceuticals, Inc.** reported that its registration statement on Form S-3 with respect to the 2.6 million shares issued to investors, and the 155,250 shares issued to the placement agent as commissions and non-refundable retainer, in connection with the recent private placement was declared effective today. This action allows the resale of

shares of the company by certain selling shareholders from time to time. DUSA will not receive any proceeds from the resale by the selling shareholders.

The company also reported its corporate highlights and financial results for the first quarter ended March 31, 2004.

**Corporate Highlights:** As reported earlier, Q1 2004 end-user Levulan Kerastick net sales to physicians totaled 12,054 Kerastick units, versus 1,842 in Q1 2003. BLU-U units in doctors' offices at quarter-end totaled 534, compared with 324 at the end of Q1 2003. Total revenues for the quarter were \$1.26 million, up from \$143,000 in Q1 2003. The company also reported a continuing increase in interest in our therapy during the quarter, demonstrated primarily by new inquiries and orders at various dermatology and laser conferences.

Due to the increased demand for our products, we commenced production of the Kerastick at our Wilmington manufacturing facility during the quarter. Initial production runs have proceeded smoothly. Also during the quarter, DUSA signed an exclusive Canadian distribution agreement with **Coherent-AMT**, a leading medical laser and medical device distribution company in Canada. Coherent is already marketing the BLU-U, and expects to market the Kerastick in Canada by Q3 2004.

**Financial Highlights:** For the three months ended March 31, 2004, DUSA's net loss was \$4.4 million (30 cents per share) compared to a loss of \$3.6 million (26 cents per share) for the comparable 2003 period. This increased loss was primarily due to a higher level of legal and marketing and sales expenses offset, in part, by an increase in Kerastick and BLU-U product sales.

Revenues for the quarter were \$1.3 million compared to \$143,000 in 2003. During the current quarter Kerastick and BLU-U sales to physicians were \$896,000 and \$360,000, respectively, whereas revenues for 2003 were totally comprised of Kerastick sales to physicians. These increases are largely the result of the efforts of our sales force since its launch in October 2003, and have been positively affected by dermatology conferences including the *American Academy of Dermatology* meeting from February 6-11, 2004, which is the largest and most important dermatology conference each year. In addition, the increase in BLU-U placements was caused, in part, by our ability to sell the BLU-U to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris. Although the level of Kerastick sales to end-users for 2004 is much higher than those in the prior year, Kerastick sales must continue to increase significantly in order for DUSA to become profitable.

Research and development costs for the three months ended March 31, 2004 were \$1.7 million as compared to \$1.5 million for 2003. This increase was primarily due to \$241,000 of compensation recognized to reflect the fair value of 30,000 fully vested stock options issued to three consultants for services, partly offset by lower expenditures

following the completion of our FDA mandated Phase IV clinical study of the long-term efficacy of our marketed product.

Marketing and sales costs for the three months ended March 31, 2004 were \$1.4 million as compared to \$531,000 for 2003. This increase is mainly attributable to the hiring and launch of our direct sales force in the fourth quarter of 2003, and related marketing and sales activities. As of March 31, 2004, our sales force was comprised of 8 direct representatives and various independent representatives in key target markets. We anticipate that the level of marketing and sales expenses and related support functions will continue to increase in 2004 as we expand our sales force to at least 16 representatives.

General and administrative costs for the three months ended March 31, 2004 increased to \$2.2 million as compared to \$1.5 million for 2003. This increase is mainly attributable to higher legal expenses of \$1.2 million incurred in 2004 as compared to \$684,000 in 2003, primarily due to patent litigation costs. It is expected that legal expenses will remain at elevated levels as long as DUSA is involved in active patent disputes. In particular, the final hearing relating to our Australian patent litigation with **PhotoCure ASA** and **Galderma SA** was held during April 2004. Therefore, legal expenses are expected to be higher during April, but lower during subsequent quarters unless new litigation is initiated. Based upon the judge's current backlog, an opinion in this matter is not expected to be rendered until late 2004.

As of March 31, 2004, total cash, cash equivalents, and United States government securities, including long-term instruments, were \$58.9 million compared to \$38.0 million at the end of 2003. This increase is primarily due to \$24.8 million of gross proceeds raised from the private placement in March 2004. Subsequent to the end of the quarter, an additional \$3.7 million of gross proceeds was raised as all of the Additional Investment Rights from the private placement were exercised. Long-term debt, including current maturities, as of March 31, 2004 was \$1.5 million compared to \$1.5 million at the end of 2003.

5/5 **CardioGenesis Corporation** announced results for the first quarter ended March 31, 2004. Driven by sales of the company's Holmium:YAG cardiac laser system for the treatment of severe angina pain, revenue for this year's first quarter increased 18% and net income more than doubled from the prior year period as gross profit margins reached record levels. First quarter 2004 revenues grew to \$4.0 million from \$3.4 million in the same period last year and net income increased 121% to \$267,000 (1 cent per share) from net income of \$121,000 (0 cents per share) for the first quarter of 2003.

Gross profit margins as a percentage of sales in this year's first quarter rose to record levels increasing to 86%, up from 82% in the prior year's first quarter and 84 percent in the 2003 fourth quarter.

The company's March 31, 2004 balance sheet reported the highest cash position in the past 11 quarters with cash and cash equivalents of \$3.1 million, total assets of \$9.2 million, shareholders' equity of \$6.7 million and no long-term debt.

Chairman and CEO Michael Quinn said that the results for the 2004 first quarter reflect the positive impact of the company's increased concentration on its core business, surgical products and accessories for the TMR procedure, and the growing acceptance in the surgical community of TMR. "Our focus on expanding awareness within the cardiac surgery market of TMR as an effective treatment for patients suffering from severe angina pain is beginning to pay off and has established our TMR product line as a viable, stand-alone business," Quinn said.

"We are cash flow positive and have a significantly improved balance sheet," Quinn added. "As we look to the future, with the momentum we are building in our TMR business, especially in the area of minimally-invasive TMR, and the \$2.7 million we raised in the private placement of common stock early in the first quarter, I believe we are now positioned with the resources, talent and product pipeline to build a substantially larger and more profitable company."

To bolster its TMR franchise, CardioGenesis is moving aggressively forward with its plans to introduce a range of innovative new products, particularly in the area of minimally-invasive and robotically-assisted approaches to TMR. "We are very pleased to begin to see the innovation in minimally invasive technology with our proprietary fiber-optic delivery technology. We are bringing to market innovative new tools to support the thoracoscopic and robotically-assisted approaches to TMR. We are also very enthusiastic about delivering to the market later this year our new TMR laser system that provides the cardiac surgeon and the operating room staff important new features and flexibility," Quinn said. "The system is less than one-third the size of our current laser footprint, requires no special wiring or power source and can be utilized in any operating room and readily moved between operating rooms."

The company has increased its sales force by adding six new Region Managers in the first quarter to further penetrate the market for its new laser system, and anticipates that its new product initiatives will have a positive impact on sales and profitability starting later this year.

Total operating expenses in this year's first quarter increased to \$3.2 million from \$2.7 million in the prior year's first quarter. The increase was primarily due to expenses associated with the sales force expansion, sales and marketing expenses associated with a major sales meeting and the marketing initiatives related to the presentation and promotion of the exciting new five-year CardioGenesis patient outcomes.

During this year's first quarter, the company shipped nine lasers and had worldwide disposable sales of 739 units, compared to the shipment of eight lasers and worldwide disposable sales of 721 units in the first quarter of 2003. At the end of the 2004 first



quarter, there were 437 sites with CardioGenesis lasers for myocardial revascularization, compared to 425 sites at the end of the first quarter of 2003. The total number of surgeons trained as of March 31, 2004, had risen to 1,171, compared to 1,133 trained at the end of the prior year's first quarter.

Although the FDA was unable to reach a favorable outcome on the company's supplemental Pre Market Approval application (PMA) in March, CardioGenesis continues to work closely with the FDA as part of an ongoing interactive review of the company's Axcis PMR system. The company is working together with the FDA to establish a near term date to meet with Dr. Dan Schultz, Acting Director of the Center for Devices and Radiological Health (CDRH) and other key members of the CDRH. "We are encouraged by the FDA's willingness to define a pathway for the approval of PMR," Quinn said. Although the company does not currently intend to pursue dispute resolution, the company has the option of pursuing a hearing with the Medical Device Dispute Resolution Panel in the future.

CardioGenesis' management believes that the strength of its existing clinical data and the significant quality of life enhancing benefits of PMR should ultimately lead to clearance from the FDA to market PMR in the United States. In the meantime, CardioGenesis continues to support PMR in Europe, Canada, Australia and other countries where PMR is approved.

5/5 **Lumenis Ltd.** announced that the Centers for Medicare and Medicaid Services (CMS) had assigned a New Technology Ambulatory Payment Classification code for its Holmium Ablation Procedure for the treatment of Enlarged Prostate. The new Ambulatory Payment Classification (APC) 1525, (CMS Transmittal 132, Publication 100-04) carries with it a payment rate of \$3,750.00. The company said that effective April 1, 2004, according to the CMS, Holmium Ablation of the Prostate performed in an outpatient hospital site of service should be coded using new Healthcare Common Procedure Coding System (HCPCS) code C9713 and will be grouped to APC 1525. The description for HCPCS code C9713 in "non-contact laser vaporization of prostate, including coagulation control of intraoperative and post-operative bleeding."

Avner Raz, president and CEO, said, "We are very pleased with the CMS's decision to increase the reimbursement for this procedure and recognize that this decision will encourage many facilities to pursue our less invasive approach to benign prostatic hyperplasia (BPH) management. Our Holmium laser system has been the market leader and the ideal choice for the treatment of BPH because it vaporizes, cuts, coagulates, and penetrates tissue superficially. It can also efficiently fragment stones."

In May of 1998, Lumenis was the first company to receive FDA clearance for Holmium Laser Resection of the Prostate for BPH, a condition that affects over 20 million men in the U.S., Europe and Asia-Pacific. Since 1998, Lumenis continued to develop this technology and placed over 2,000 Holmium Lasers worldwide. In March of 2000, Lumenis introduced the first and only 100-watt Holmium laser system designed for the

treatment of enlarged prostates. This system, when combined with its proprietary side fire delivery device, provides a superficial vaporization of tissue with minimal adverse post-operative complications. The VersaPulse PowerSuite holmium laser and DuoTome SideLite Fibers can be purchased directly from Lumenis or through our strategic distribution partner **Boston Scientific Corporation**.

Dr. James Lingeman, Clinical Professor of Urology at Indiana University School of Medicine and Director of Research, Methodist Hospital Institute for Kidney Disease, Indianapolis, Ind., stated, "Holmium Ablation of the Prostate has proven to be an effective and simple to learn and perform procedure in our hospital. Patients are released within 24 hours with symptoms relieved and are back to normal activities soon afterward. Because the High Power Holmium laser is used to treat both stones and BPH, two of the most common conditions urologists treat, it is an essential tool in my operating room."

Dr. Akhil Das, attending Urologist, Northeastern Regional Hospital, Las Vegas, NM commented, "There has been a resurgence in laser ablation of the prostate to treat bladder outlet obstruction secondary to BPH. The question is, which laser to use? The ideal laser should be easy and safe, and useful for a variety of urologic diseases. The Holmium laser has been shown to be safe and effective for the treatment of urinary stones, urinary strictures, urothelial tumors and BPH, and is the ideal choice."

5/6 **Spectranetics Corporation** announced that the first successful CLiRpath procedures using new Extreme Excimer Laser Catheters recently cleared by the FDA were performed by Craig Walker, MD, Mohammed Khan, MD and David Allie, MD at Cardiovascular Institute of the South in Louisiana and by John R. Laird, MD at the Washington Hospital Center in Washington, DC. The physicians utilized the larger, 2.3 mm and 2.5 mm CLiRpath Catheters that were introduced into the U.S. market on Tuesday, May 4. Dr. Laird was Principal Investigator of the LACI (Laser Angioplasty for Critical Limb Ischemia) trial. Dr. Allie and Dr. Walker were principal investigators in the Louisiana LACI Case Series. Clinical data from a subset of patients enrolled in these trials were used to support the 510(k) market clearance.

Dr. Laird utilized a 2.3 mm CLiRpath Catheter to successfully recanalize a 30 cm occlusion in the superficial femoral artery in a patient with an ischemic ulcer. After successful laser atherectomy, balloon angioplasty was performed without the need for a stent. Dr. Laird commented, "As an investigator in the LACI trials, I am gratified that we have obtained market clearance for these catheters. The data used to support the submission included critical limb ischemia patients who were poor surgical candidates and who could not be treated with standard balloon angioplasty because a wire could not cross the occlusion. Despite the severity of the disease, we achieved a limb salvage rate of 95% in survivors in a patient group that historically would have been almost assured of an amputation."

Dr. Walker, Dr. Allie and Dr. Khan performed CLiRpath procedures at Opelouses General Hospital in Opelouses, Louisiana and Southwest Medical Center in Lafayette,

Louisiana. They included two successful limb salvage procedures using the 2.5 mm CLiRpath Catheters to recanalize the superficial femoral artery (SFA), popliteal artery and the proximal peroneal artery. Dr. Walker commented, "The bigger laser catheter made a significant impact in the vessels we treated, especially where there was predominantly thrombus. In one case where we treated an occluded SFA, we accomplished a stand-alone laser result with no need for ballooning or stenting." He added, "We have been using the excimer laser in our practice to treat critical limb ischemia with limb salvage rates in excess of 90%. The larger catheters are important additions that allow us to more efficiently treat larger vessels. The new catheters worked very well and we are looking forward to using more of them."

"We are extremely pleased with the initial feedback following the CLiRpath product introduction on Tuesday, May 4," said John Schulte, Spectranetics' president and CEO. "We were able to begin shipping within one week of FDA clearance and initial orders have been encouraging."

CLiRpath Excimer Laser Catheters are indicated for use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions cannot be crossed with standard guide wires.

5/6 **BIOLASE Technology, Inc.** launched a new dental laser product for cosmetic, soft tissue and hygiene dental procedures, the DIOLASE PLUS, priced at \$10,900. The DIOLASE PLUS is a newly upgraded, fully-featured, entry level cosmetic, soft tissue and periodontal laser that is based on the DIOLASE acquired by BIOLASE in its asset purchase of **American Dental Technologies, Inc.** in May 2003.

Jeffrey Jones, BIOLASE CEO and president, commented, "DIOLASE PLUS is the company's first dental laser product that comes as a result of the integration of the American Dental Laser and BIOLASE technology. We believe this product is excellent for multi-laser practices where dentists would like a laser for each hygienist. In addition, we expect this product will also result in many up-sale opportunities, where dentists contact us for a DIOLASE laser, who then after become more informed and subsequently purchase our market leading Waterlase system."

BIOLASE will focus its sales and marketing efforts for the DIOLASE PLUS on cosmetic dentists and general dentists using the laser for cosmetic smile design, treating gum disease and other soft tissue procedures as well as on hygienists for laser hygiene procedures. The DIOLASE PLUS delivers more power and features than competing entry-level diode lasers. DIOLASE PLUS has 7 watts of power vs. 3-5 watts found in competing systems. It also offers important differences such as easy to use, programmable presets for various clinical procedures, fully adjustable pulse modes, basic and advanced training through the World Clinical Laser Institute and factory-direct service and support.

DIOLASE PLUS has many cosmetic and soft-tissue applications; soft tissue curettage; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; and removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium. BIOLASE also offers guaranteed upgrade options with the purchase of a DIOLASE PLUS, giving the clinician flexibility to upgrade to either the LaserSmile Soft Tissue and Whitening laser or the market leading Waterlase Hard and Soft Tissue system.

Jones further commented, "BIOLASE is committed to launching at least one new significant product every year and we believe this product will substantially leverage our marketing dollar. DIOLASE PLUS is our first major new product this year and complements our LaserSmile and Waterlase systems, giving dentists and hygienists a well-featured, quality diode laser at an entry-level price. This new product will expand our market share reaching dental professionals who are more price sensitive."

5/7 **Lumenis Ltd.** announced that **Brightman Almagor & Co.** (a member firm of **Deloitte Touche Tohmatsu**) (Deloitte) had resigned as the company's independent auditors. The Audit Committee is in the process of interviewing potential new auditors and hopes to be in a position to announce a selection shortly. As previously disclosed, the Audit Committee commenced an internal investigation in October 2003 in response to a request from Deloitte. The investigation initially focused on accounting and disclosure issues related to the company's relationship with one of its domestic distributors, but was subsequently expanded to include a review of the company's revenue recognition practices during 2002 and 2003. Deloitte's action follows the company's issuance of a press release on May 3, 2004 reporting on the initial results of the investigation and the reorganization of certain of its financial reporting functions.

5/10 **Lumenis Ltd.** announced preliminary unaudited financial results for the fourth quarter and year ended December 31, 2003. Revenues in the fourth quarter were \$75.4 million, compared to revenues in the fourth quarter 2002 of \$76.9 million and compared to \$66.2 million in the third quarter of 2003. The net loss for the fourth quarter was \$28.2 million (76 cents per share) compared to \$39.7 million (\$1.07 per share) in the fourth quarter 2002. For the fiscal year ended December 31, 2003 revenues were \$287.2 million compared to \$337.7 million in 2002. The net loss was \$83.6 million for the year 2003 (\$2.25 per share) and \$44.1 million for 2002 (\$1.19 per share).

Lumenis president and CEO, Avner Raz, commented, "The new organizational structure has provided us with the necessary framework to reduce costs significantly and provide customers with the products and services they demand. We have implemented the core components of the Turnaround Plan, including the final phase of headcount reductions, closure of several sites and a reduction in management layers. We expect to realize the results of these changes over the next several quarters. While the reported loss in the fourth quarter is disappointing, we believe that the recovery in revenue and the improvement in operating cash flow, which for the fourth quarter was only slightly negative, reflects a stabilization of our business."

**Results of Investigation:** As previously reported, a report prepared for the Audit Committee with respect to the company's internal investigation had concluded that the timing of the company's revenue recognition was inappropriate with respect to certain identified transactions. The aggregate effect of the company's accounting for the transactions identified in the report was to cause revenues in 2001 to be overstated by approximately \$1.7 million or 0.6%, revenues in 2002 to be overstated by approximately \$4.4 million or 1.3%, and revenues in 2003 to be understated by approximately \$5.9 million or 2.1%. The effect on quarterly periods was as follows:

Amount of Overstatement/(Understatement) Of Revenue by Quarter (In 000's)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2001	N/A	\$345	\$423	\$931
2002	\$2,827	\$1,234	\$2,182	(\$1,873)
2003	\$1,561	(\$3,079)	(\$1,022)	(\$3,362)

The effect of such overstatement/understatement of revenues on previously reported earnings (loss), while not included in the report, is estimated, on a preliminary basis and subject to further adjustment, to increase the net loss as reported in 2001 by approximately \$0.9 million or 0.6%, to increase the net loss as reported in 2002 by approximately 2.9 million or 6.5%, and to reduce the net loss as reported in 2003 by approximately \$3.8 million or 4.6%. The impact on particular quarterly periods may vary on a percentage basis.

The Audit Committee anticipates that a restatement of previously reported financial results may be appropriate, but intends to defer making a final decision pending further review of fiscal 2001 transactions. As recently announced, our auditor has notified us that they have resigned and the company has commenced the process for selection of a new auditor.

**Additional Information Concerning Q4 Results:** The company's operating cash flow was negative \$1.0 million in the fourth quarter despite the large operating loss due to reductions in working capital and the fact that a large part of the operating loss resulted from write downs and provisions for inventory and certain receivables.

The operating loss for the fourth quarter of 2003 of \$21.1 million included provisions and write downs of inventories of \$9.9 million. These write downs mainly related to additional provisions for excess and obsolete inventory and physical inventory losses. A provision in the amount of \$4.9 million was also established for potential bad debts mainly related to certain foreign distributors and severance costs of \$1.7 million associated with the Turnaround Plan was also accrued. Operating expenses for the quarter were \$47.5 million including the aforementioned bad debt provisions and severance.

The net loss for the fourth quarter of 2003 also included a provision of \$1.2 million for the expected final settlement of working capital related to the sale of the company's industrial laser business reported as loss on sale of discontinued operations. The fourth quarter 2002 net loss included \$19.8 million of charges principally for asset write-downs and litigation reserves.

In the fourth quarter of 2003, sales in Europe were \$16.6 million, compared to \$13.7 million a year ago and \$12.7 million in the third quarter of 2003. The Americas region had sales of \$35.0 million, down compared to revenue in the fourth quarter 2002 of \$37.8 million and up from the \$30.5 million in the third quarter 2003. Sales for Asia Pacific, China and Japan were \$23.8 million compared to the previous year revenue of \$25.4 million and \$23.0 million in the third quarter.

The Surgical product line had total sales of \$14.0 million in the fourth quarter, compared to \$16.6 million in the same quarter a year ago and \$10.7 million in the third quarter. In the past we always took the vet out of the surgical, and only on the fact sheet combine together. The numbers were OK if we want to show separately and OK after the change if we want to show together The dental business had sales of \$2.6 million, compared with \$1.3 million in the fourth quarter of 2002.

Fourth quarter sales from our Aesthetic products were \$24.4 million, a decrease of \$4.7 million compared to the fourth quarter of 2002 and an increase of 2% compared to the third quarter. Ophthalmic products had fourth quarter sales of \$21.2 million compared to \$19.4 million in the same quarter a year ago and \$16.6 million in the third quarter.

The service business had revenues of \$13.2 million up 25.7% compared with \$10.5 million in the same quarter a year ago.

The company had approximately \$20 million in backlog at December 31, 2003 compared to \$19 million at September 30, 2003. At December 31, 2003, the company's cash position was \$18.2 million and borrowing capacity under its committed lines of credit was an additional \$7.2 million. Total debt was \$212.4 million at year-end.

5/10 **BriteSmile, Inc.** released results for the quarter ended March 27, 2004. Total revenues increased by \$2.8 million, or 31%, to \$11.8 million for the first quarter ended March 27, 2004, from \$9.0 million for the first quarter ended March 29, 2003. For the same period, the loss per share was \$0.12 compared with \$0.41 for 2003 (both per share numbers reflect the 5:2 stock split which was effective January 30, 2004). The loss from operations fell to \$1 million, compared to \$2.4 million for the previous year, while depreciation and amortization expense was \$1.7 million.

Product sales increased 164% to \$2.4 million from \$0.9 million primarily due to the continuing momentum of the company's innovative BriteSmile To Go take-home whitening pen which was launched in the third quarter of 2003. The efficacy, ease and superior performance of BriteSmile To Go over other products in this market segment

is generating strong demand. BriteSmile To Go is offered through BriteSmile Associated Center dentists, in BriteSmile spas, on the company's website, and through the company's previously announced partnership with **Sullivan-Schein Dental**, which currently serves more than 75% of the dental practices in the United States.

In addition, Center whitening fees increased by \$1.2 million or 38% to \$4.3 million in the first quarter of 2004, from \$3.2 million for the corresponding quarter in 2003. The number of procedures performed in the Centers increased 31% to 8,818, compared to 6,747 in the same quarter of 2003. The opening of the company's newest spa in SoHo in New York contributed to the revenue increase. Associated Center whitening fees increased by \$101,000, or 2%, to \$5.0 million for the first quarter, compared to \$4.9 million for the same period last year. The net increase was primarily due to an increase in procedures in International Associated Centers offset by a slight decrease in Domestic Associated Centers. The total number of procedures in Associated Centers increased 9% to 30,870 procedures, compared to 28,240 procedures in the same quarter of 2003.

"With strong first quarter revenue growth of 31% and relative containment of operating expenses dramatically narrowing our operating loss, and the completion of our recent private placement in January, BriteSmile has now arrived at a fundamentally stronger cash flow position," said Bruce Fleming, CEO, BriteSmile, Inc. "And with the recent signing of leases for three new spas, BriteSmile is already set to build on this new platform." For the second quarter 2004, revenues are forecast to grow 12-17% over second quarter 2003, and the company is on target to meet its expectation of being cash flow positive in the first half of the year.

- 5/11 Phil Nalbone, Sam Chang, and Jennifer Hsui of **RBC Capital Markets** initiated coverage of **Cutera** with an Outperform rating with Speculative Risk.

\* **A Big Market In Aesthetic Medicine:** The "Baby Boom" generation is aging, and we are a culture obsessed with youth and beauty. While there has always been a desire for cosmetic surgery, the more recent introduction of a broad range of minimally-invasive treatment options has opened the market to vastly more candidates. Last year, according to the *American Society of Plastic Surgeons*, minimally-invasive cosmetic surgery procedures in the U.S. grew 43%. The worldwide market for laser and light-based hair removal products alone is approaching the \$3 billion level this year.

\* **Technology Leader In Aesthetic Lasers:** The aesthetic laser market is intensely competitive. But the market for hair removal and other cosmetic procedures such as wrinkle and pigmented lesion reduction is significantly under-penetrated, suggesting an opportunity for multiple successful players. In addition, we believe Cutera has two major competitive advantages: the ability to treat the widest range of skin types (both light and dark) and the ability to combine multiple functions (hair removal + wrinkles + pigmented lesions + veins) in a single system.

\* **Valuation:** Our \$18 price target represents a multiple of approximately 38x our calendar 2005 cash EPS estimate (excludes deferred compensation charges) of \$0.48 and a market cap that is approximately 4 times our 2005 sales estimate of \$60.2 million. Cutera is rated Outperform with Speculative Risk.

We are initiating coverage of Cutera with an \$18 per share price target. Our \$18 price target represents a multiple of approximately 38x our calendar 2005 cash EPS estimate (excludes deferred compensation charges) of \$0.48 and a market cap that is approximately 4 times our 2005 sales estimate of \$60.2 million. The earnings multiple represents a premium to the current average forward earnings multiple of our universe of medical device companies (now trading at approximately 25x). We believe the premium multiple is justified given the greater than 40% bottom line growth that we project will be posted by the company over the next several years. On a multiple of sales basis, our price target would imply a multiple that is in line with other profitable medical device stocks. Our earnings projections reflect our expectations that the demand for aesthetic procedures will continue to grow which will translate into increased demand for Cutera's class leading products. If growth in aesthetic procedures ends up being lower than we projected or if a new competitive product appears in the marketplace that challenges Cutera's class leading products, both scenarios could serve as an impediment to our EPS forecasts and price target.

5/11 Entrepreneur Craig Nabat, a Detroit native known for inventing the infomercial product The FINDIT Keyfinder has brought low-level laser therapy for treatment of nicotine addiction to the United States. Nabat's company, **Freedom Laser Therapy** is turning smokers into non-smokers in 30-minutes. Nabat says, "From our follow up treatment phone calls we are learning 9 out of 10 Freedom clients are tell us they quit." "Clients are raving about how easily it is to end their smoking addiction and are referring other smokers to our clinic."

Nabat learned about low-level laser therapy after being treated in Canada for his addiction to nicotine. Amazed at the ease of kicking his cigarette smoking habit, Nabat has turned into a "LASER-PRENEUR" and dedicated himself to establishing Freedom Laser Therapy Clinics around the United States. The entire Freedom Laser Therapy staff is dedicated to freeing the world from nicotine addiction.

In May 2003, an Institutional Review Board (IRB) authorized investigational clinical trials using low-level laser therapy in compliance with FDA regulations. Clinical trials are being set up to measure the safety and effectiveness of low-level laser therapy to treat nicotine addiction. The IRB is an organization chartered by the Food and Drug Administration (FDA) to oversee clinical trials, which collect data on new medical treatments. Institutional Review Boards exist to ensure the rights of human study subjects protecting them by being in accordance with FDA guidelines; all treatment being offered must be safe, as well as ethical. The FDA has already ruled low-level laser therapy as a "non-significant risk" and the US investigational trials are being funded through patient



participation. Freedom Laser Therapy is the first full scale nicotine addiction based clinic participating in this research study to test the efficacy of smoking cessation treatment.

Low-level laser therapy works on a specific energy points along the body's central nervous system. Laser therapy is thought of as a highly effective modern form of acupuncture. A soft laser light is used to stimulate specific energy points in the ear, face, and hands relating to the addiction. When the laser makes contact with the body's various energy points, a person experiences a feeling of relaxation and a state of well being, as well as a boost to their metabolism, combating the common occurrence of weight gain often associated with quitting smoking.

For the past 30 years, this specific application in treating addiction has been available in Europe and Canada. After decades of use in these other countries, the treatment has been proven successful in treating smokers and other substance abusers, as well as those suffering from eating disorders. International practitioners of low-level laser therapy have also documented amazing recovery results as high as 85% with alcohol, cocaine, and heroin addictions. Treatment with a laser helps to promote the release of endorphins in the body. Endorphins are the body's natural chemicals, which help keep a person calm and relaxed, making it significantly easier to cope with their addiction, withdrawal symptoms, and cravings that arise from giving up nicotine.

Laser therapy mimics a similar type of endorphin release in the body, which a person receives from smoking cigarettes. After laser therapy treatment is administered, the client will lose almost all physical urges to smoke. This is the marriage of two great technologies, the ancient form of Chinese acupuncture and the modern form of the laser. The 30-minute treatment includes education on nicotine addiction, advice on coping with cravings and withdrawal, nutritional recommendations, a vitamin detoxification regimen, and detailed instructions on how to maintain a nicotine free lifestyle.

Freedom Laser Therapy, Inc. is the first full scale nicotine addiction based clinic in the United States to legally treat nicotine addiction with low-level laser therapy under IRB investigational trials. Presently, Freedom Laser Therapy has clinics operating in Santa Monica, California and Royal Oak, Michigan. In upcoming months, additional clinics are scheduled for Arizona, Massachusetts, Florida, Illinois, and Texas.

- 5/14 The board of Directors of **El.En. S.p.A.** approved the consolidated financials for the first quarter of 2004, which reported consolidated revenues of about 19 millions of euro, up more than 45% with respect to the first quarter of 2003, and a significant growth in Europe (up 78%). Revenue analysis by market segment revealed an excellent performance in the medical area (+62%) and a lighter growth (+7%) in the industrial segment. In both cases recently acquired companies supported the revenue growth. In the quarter the Value of Production marked 20.5 millions of euro with a 37% growth on the previous year.

The consolidated Gross Margin was more than 10.6 millions, up 47% with respect to 2003. Also EBITDA improved markedly to 1.3 millions of euro, more than doubled from 2003, with an increase of its impact on the value of production, from 3,7% to 6,5%. EBIT was positive of 158 euro thousands, as opposed of a 221 thousands euro loss in the first quarter of 2003; pre tax income was more than 1.2 euro millions, it was 612 thousands of euro in 2003, and had a 5,9% impact on Value of production.

The results, in terms both of revenues and operating profit, are on track in respect to the yearly forecasts. The Net financials position was positive for more than 9.5 millions of euro.

5/20 **DUSA Pharmaceuticals, Inc.** reported the initiation of a new multicenter Phase II clinical study using the company's Levulan photodynamic therapy (PDT) for the treatment of facial photodamage. The study will utilize broad area, short contact drug application, combined with 3 light sources: Intense Pulsed Light (IPL), Long Pulsed Dye Laser (LPDL) and DUSA's BLU-U brand blue light. DUSA announced that it has signed development agreements with **Lumenis Inc.** of Yokneam, Israel, and **Cynosure Corp.** of Chelmsford, MA, providing for the inclusion of Lumenis' IPL Quantum and Cynosure's PhotoGenica V-Star LPDL in the study, along with the BLU-U.

Dr. Geoffrey Shulman, DUSA's president and CEO, stated, "Since receiving our initial FDA approval for Levulan PDT with the BLU-U for the treatment of actinic keratoses, results from independent investigator studies conducted by leading physicians(a) (see references below) in laser and cosmetic dermatology have indicated that one of the best opportunities for Levulan PDT may be in the treatment of photodamaged skin. For this common condition caused by excessive exposure to the sun, the most prevalent treatment is non-ablative photo-rejuvenation using multiple sessions with IPL or laser. Based on information from these studies, we decided to test short contact Levulan, combined with IPL, LPDL and/or the BLU-U, looking for potential improvement over treatment with IPL or LPDL alone. Our goal is that all 3 light sources will eventually be approved with Levulan for this indication."

The present study, which will be carried out at 4 clinical trial sites in the United States, consists of two phases. The first phase, with up to 64 patients, will evaluate the V-Star LPDL and the IPL Quantum to establish the best light dosages for PDT using these devices. The second phase, with up to 60 patients, will include up to three treatments per patient for photodamaged skin, given at three-week intervals, using fixed light doses with one of the light sources (BLU-U, PDL or IPL). In both phases of the study, prior to treatment with any light source, the left and right sides of each subject's face will be randomized to receive topical Levulan using DUSA's Kerastick on one side and vehicle on the other (split-face study). Efficacy at each visit will be assessed on each side of the face using standard markers of photodamage. Safety and tolerability will be assessed throughout the study.

"Leading dermatologists consider Levulan PDT one of the most exciting developments impacting their medical and aesthetic practices", said Michael Davin, CEO of Cynosure. "As our population ages, the interest in non-ablative procedures to treat sun damaged skin will grow tremendously. We are pleased that we can play a role in helping DUSA explore these opportunities with our pulse dye laser technology."

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "With the rapidly growing interest in Levulan PDT, dermatologists and other physicians are eager to see it developed for use in additional indications. After investigator-initiated studies using Levulan PDT with the V-Star for treating photodamaged skin reported promising patient outcomes, DUSA's became interested in incorporating the V-Star into our new Phase II trial. We are delighted to be working with Cynosure, a pioneer in this field."

Dr. Roy Geronemus, past president of the *American Society of Dermatologic Surgery (ASDS)*, referencing ASDS statistics, noted that "The number of non-ablative photorejuvenation (NAPR) treatments for photoaging has increased by 60% over the last 3 years. In this study, the goal is to determine whether the addition of Levulan to NAPR will provide even better results for patients." Mark Nestor, MD, an advisor to both companies, stated that "Levulan PDT is now being routinely used in our practice with the V-Star for the treatment of the entire face, with excellent cosmetic results. This includes patients with significant sun damage, rosacea and even severe cystic acne."

5/20 **BIOLASE Technology, Inc.** announced the new introduction of its next generation, proprietary whitening gel LaserWhite10. Jeffrey Jones, BIOLASE CEO and president, commented, "LaserWhite10 is a valuable addition to our consumables strategy that will help drive our business going forward."

The LaserWhite10 further enhances the performance of the LaserSmile Whitening System, featuring dramatic whitening results in one appointment. Through its use with BIOLASE's proprietary LaserSmile whitening technology, LaserWhite10 produces one of the shortest treatment times on the market, taking just 24 - 32 minutes of treatment time. LaserSmile's laser wavelength output has been synchronized to the proprietary whitening gel's chemical formulation, resulting in increased efficiency and minimized energy levels required to produce maximum whitening. The procedure requires very little exposure of EM energy to the teeth -- about three minutes per quadrant -- compared with other whitening systems on the market. In addition, LaserWhite10 does not require refrigeration and features an easy to apply, self-mixing dual barrel delivery syringe.

Jones further commented, "As a company, we expect BIOLASE's presence in the laser whitening market to be a healthy contributor in a strong 2004. We have seen a growing patient demand for accelerated in-office whitening treatments and our introduction of LaserWhite10 points to our commitment to continually improve our proprietary LaserSmile Whitening System. We believe that as dentists experience the enhanced clinical results together with the fast treatment times, they will be eager to replicate this

same success, helping BIOLASE leverage consumer awareness and passion, and drive the adoption of its other dental laser systems."

Over the past several months, participating dentists have used the new LaserWhite10 gel on patients to provide the company with important clinical data. Dr. Douglas Sakurai, practicing dentist in Santa Ana, California, commented on the product saying, "The new gel is much more convenient and easier to apply, leading to rapid treatment times and improved clinical results. My patients have been experiencing reduced sensitivity, typically lasting less than 24 hours. All in all, my patients love the fast, zero-maintenance LaserSmile whitening treatment."

"My patients love the immediate results. The gel is very convenient and easy to use. It works great with very little sensitivity," said Dr. Randolph Cockrell, practicing dentist in Anaheim Hills, California, reflecting on his experience with the LaserWhite10 whitening gel.

- 5/20 A negative blurb about **Laserscope** appeared in *Forbes Magazine*. Written by Daniel Kruger, and entitled, "Laser Burn", it attacked laser company's laser device for treating BPH.

"Having the best product doesn't always guarantee riches. Such is the case at LASERSCOPE, maker of medical lasers to treat dermatological conditions. It is placing a big bet on a laser device that reduces swollen prostates, a condition called benign prostatic hyperplasia. While 10 million men suffer from BPH, the number who seek treatment is much smaller. There's real concern about how readily most prostate docs, who prefer traditional surgery, will take to the laser. Anthony Vendetti, a **Maxim Group** analyst, says Laserscope has the best device for the problem, but the market is valuing the company at an overoptimistic 148 times trailing earnings. We say short it; cover at \$24."

- 5/21 I received a note from a new, recently started company in the cosmetic laser field, **Med-Surge Holdings**. Med-Surge Holdings is the parent company, newly formed within past couple of years, covering **Med-Surge Technologies, Inc.**, **MS Skincare, Inc.**, **MS Finance**, and other divisions as the company moves up and forward. It is comprised of laser industry executives including Paul Herchman, a current board member of the *American Society of Lasers in Medicine and Surgery (ASLMS)*, and the former CEO of **Medical Alliance, Inc.**, out of Dallas, Texas. Medical Alliance was the nationwide owner and renter of aesthetic lasers to physicians in the U.S. It owned more lasers than any one company in the world at one point. It was then sold to **ICN Pharmaceuticals**, now **Valeant Pharmaceuticals**.

Med-Surge Technologies currently distributes the Aramis 1540nm Laser, Viridis 532 KTP, both from **Quantel Medical** of France, the MeDioStar 810 Diode laser from **Asclepion** an **El. En. Company** from Germany and also has an Erbium, 1064, IPL, and a micro-derm unit.

The company just recently formed MS Skincare, Inc. and will be launching its new cosmeceutical skincare line called BelleDerm in a couple of weeks and it will be sold only through physician offices in the U.S.

Med-Surge Technologies, Inc. is a group of laser industry executives with big plans, big ideas and is growing at a rapid pace.

5/21 **Trimeddyne, Inc.** reported a net profit of \$149,000 (1 cent per share) on net revenues from sales and other income received of \$1.5 million for the quarter ended March 31, 2004, compared to a net profit of \$207,000 (2 cents per share) on net revenues from sales and other income received of \$1.7 million for the same quarter of the prior year. This represents the company's sixth, consecutive, profitable quarter. However, the company had a loss from operations of \$24,000 in the current quarter, compared to an operating profit of \$210,000 in the prior year quarter. Proceeds from royalties and the settlement of litigation were \$181,000 in the current quarter.

Revenues in the current quarter were 23% less than in the same period of the prior year, primarily due to a decline in laser sales. However, sales of lasers are expected to increase in the coming quarter, as we intend to expand our laser product offering. With lasers selling for \$40,000 to \$100,000, an increase or decrease in the number of lasers sold in a quarter can have a significant impact on revenues and profits. Sales of disposable and reusable fiber optic devices remained relatively stable in the quarter ended March 31, 2004, compared to the prior year quarter.

As a percentage of sales, the company's cost of goods was comparable in both quarters, SG&A increased from 35% to 42%, R&D expenses rose to 7% from 2% and gross profit declined to 48% in the current quarter from 50% in the same period of the prior year. A \$4,000 provision for income tax was required in the current quarter, while \$26,000 in income tax was incurred in the prior year quarter.

During the quarter ended March 31, 2004, net revenues were \$1.3 million as compared to \$1.7 million for the same period of the previous year, a \$379,000 or 23% decrease. This overall decrease was the result of lower laser sales during the current period. Lasers typically sell between \$35,000 and \$110,000, depending upon the type of laser. The number of lasers sold in a typical quarter during the past two years has ranged from one to six per quarter. Net sales from delivery and disposable devices increased by \$9,000 or 1% to \$741,000 in the current quarter from \$732,000 in the same quarter of the prior year. Net sales from service and rental increased by \$73,000 or 20% to \$437,000 from \$364,000 for the same quarters. This increase was primarily due to the growth of the company's subsidiary MST, which is expanding its territory into other states.

Cost of sales during the quarter ended March 31, 2004 was 52% of net sales as compared to 50% of net sales during the quarter ended March 31, 2003.

Selling, general and administrative expenses decreased in the current quarter to \$540,000 from \$580,000 in the prior year quarter, a decrease of \$40,000 or 7%. The decrease in selling, general and administrative expenses was primarily the result of the following: decreases of \$42,000 in bad debt expense, \$36,000 in commissions expense due to a decrease in sales, \$16,000 in administrative payroll and \$13,000 in miscellaneous administration expenses offset by increases of \$36,000 in depreciation expense, \$17,000 in audit and tax preparation expense and \$11,000 in rent expense. Research and development expenditures for the quarter ended March 31, 2004, increased \$58,000 to \$94,000 as compared to \$36,000 in the quarter ended March 31, 2003. This increase was a result of Trimedyne increasing its efforts to develop new delivery systems and Holmium lasers.

Other income increased by \$154,000 or 670% from \$23,000 in the second quarter of fiscal 2003 to \$177,000 in the second quarter of 2004. During the three months ended December 31, 2003, the company settled litigation with a competitor which resulted in the receipt of \$155,000 in technology fees and royalties of \$26,000 during the current quarter offset by interest accrued on notes due to the CEO.

For the current quarter, the company had net income of \$149,000 (1 cent per share), based on 14.6 million basic weighted average number of common shares outstanding, as compared to net income of \$207,000 (2 cents per share) based on 13.7 million basic weighted average number of common shares outstanding in the same quarter of the previous year.

Six months ended March 31, 2004 compared to six months ended March 31, 2003:

During the six months ended March 31, 2004, net revenues were \$2.7 million as compared to \$3.3 million for the same period of the previous year, a \$684,000 or 20% decrease. Net sales from lasers and accessories decreased by \$774,000 or 23% to \$1.8 million during the six months ended March 31, 2004 from \$2.6 million in the same period of the prior year. Export sales also decreased by \$187,000 or 31% due to a reduction in laser sales in Asia and Latin America. Net revenues from delivery and disposable devices increased by \$33,000 or 2% to \$1.6 million during the six months ended March 31, 2003 from \$1.5 million for the same period of the prior year. Net sales from service and rental increased by \$90,000 or 11% to \$852,000 from \$762,000 for the same quarters in the prior year. This increase was primarily due to the growth of the company's subsidiary MST, which is expanding its territory into other states.

Cost of sales remained relatively unchanged at 52% of net sales in the six months ended March 31, 2004 compared to 51% for the six months ended March 2003.

For the six months ended March 31, 2004, selling, general and administrative expenses totaled \$1.1 million as compared to \$1.1 million for the same period of the previous year, a \$52,000 or 5% increase. This increase in selling, general and administrative expenses since the prior year period is the result of the following: the company being named in an

additional product liability lawsuit and accruing a charge of \$50,000 representing the contingency for insurance deductible, a rent increase of \$18,000 per the leasing contract of the company's Irvine location, a \$47,000 increase in salaries and wages due to the hiring of additional operations staff, the increase of insurance expense of \$17,000, and an increase of repairs and maintenance of \$23,000 and depreciation of \$30,000 due to the purchase of additional assets for the company's subsidiary, MST, all offset by reductions in bad debt expense of \$42,000, commissions expense of \$67,000, telephone expense of \$13,000 and reductions in miscellaneous administration expenses of \$10,000.

Research and development expenditures for the six months ended March 31, 2004, increased \$58,000 or 56% to \$161,000 from \$103,000. The increase is primarily due to Trimedyne increasing its product development efforts which include the testing and research of new and current products, along with preparation of regulatory submissions.

Other income increased by \$268,000 to \$300,000 in the current six-month period from \$32,000 in the six-month period of fiscal 2003. In November 2003, the company settled litigation with **Lumenis, Inc.** which resulted in the reduction of \$88,000 in the liability for royalties in the previous quarter ended December 31, 2003 and the receipt of \$155,000 in technology fees and royalties of \$26,000 during the current quarter ended March 31, 2004. During the previous year's quarter ended December 31, 2003 the company also received \$53,000 for an unrelated cash insurance settlement for a damaged laser. Other income was primarily offset by interest accrued on notes due to the CEO.

For the six months ended March 31, 2004, Trimedyne had net income of \$314,000 (2 cents per share) based on 14.5 million basic weighted average number of common shares outstanding, as compared to a net income of \$497,000 (4 cents per share) based on 13.7 million basic weighted average number of common shares outstanding in the same period of the previous year, resulting from the above mentioned factors.

5/25 **BIOLASE Technology, Inc.** announced the launch of the *1st Asian World Clinical Laser Institute (WCLI) Regional Symposium*. Although the WCLI has held various chapter-level meetings in Asia, the 1st Asian WCLI Regional Symposium was held on May 13th - 16th at the Phuket Arcadia Beach Resort in Phuket, Thailand. BIOLASE formed the WCLI organization to accelerate the use of its Waterlase and LaserSmile systems in dentistry. The mission of the Institute is to provide advanced clinical laser education for dental professionals as well as training to current customers on how they can maximize the clinical, marketing and financial benefits of BIOLASE products. The WCLI is open to newcomers to the field of laser dentistry and general practitioners investigating the purchase of a laser.

Over 200 dental professionals attended the three-day event, traveling from over 17 countries around the globe, including Singapore, Australia, New Zealand, Thailand, Japan, South Korea, Taiwan, China, Hong Kong, Indonesia, South Africa and Vietnam. Approximately one-half of the attendees were prospective buyers of BIOLASE's Waterlase technology, with all attendees paying tuition for the event. In addition, there

were a number of VIP attendees that participated in the event, including the vice governor of Phuket, Nirund Kalayanamitr, who greeted the delegates from around the world to this meeting. Professor Prathip Phantumvanit, professor emeritus of Thammasat University Dental School in Thailand, Dr. John Chen, the Former chairman of the *International Congress of Oral Implantologists-Asia Pacific*, Dr. Tatsuya Ishikawa, the Dean of Tokyo Dental College and Dr. Jong-Jin Suh, Professor of Yonsei University-College of Dentistry, Department of Periodontology, were among the various luminaries in attendance. The 1st Asian WCLI Regional Symposium was also featured on several television programs as well as printed news stories in the Asia Pacific region, especially in Thailand as the host country.

Jeffrey Jones, BIOLASE CEO and president, commented, "These symposiums are incredible gatherings of the brightest and most advanced laser dentists and universities the world has to offer, helping us to change a medical profession unlike any other laser from the past."

The symposium offered a broad range of hands-on clinical seminar meetings and educational programs. Some of the topics covered included "The Evolution of Dental Lasers," "Hard and Soft Tissue Procedures," "Advanced Procedures in Laser Oral Surgery," "Lasers and Microdentistry," "Lasers in Cosmetic Surgery" and "Advanced Laser Endodontics." Additionally, there was a considerable amount of interest and discussion surrounding the Waterlase technology and its expanding applications as well as presentations in plenary sessions.

Jones further commented, "The 1st Annual Asian WCLI Regional Symposium was extremely beneficial to all of our customers and prospective buyers in this part of the world. The symposium offered a variety of essential support services to our laser owners, including ongoing education, after-sale support and an excellent platform for current and future customers to fully investigate laser technology. In addition, these meetings gave future customers the opportunity to discuss the clinical and financial benefits with hundreds of laser dentists."

5/25 **PhotoMedex** announced that **Aetna**, one of the nation's leading providers of healthcare benefits, has adopted a medical policy approving payment for medically necessary treatment of mild to moderate psoriasis using the PhotoMedex XTRAC laser system. Aetna provides benefits through employers in all 50 states, with products and services specifically targeted to small, mid-sized and large multi-state national employers, serving more Fortune 1,000 companies than any of its competitors. The company also serves individuals and Medicare beneficiaries in certain markets.

Jeff O'Donnell, PhotoMedex' CEO said, "We are pleased to announce that Aetna has joined the ranks of those prestigious healthcare insurers that have recognized the XTRAC as an appropriate reimbursable therapy by including it in its subscriber offerings. Aetna subscribers will now have the opportunity to avail themselves of this clinically superior treatment for mild to moderate psoriasis. Aetna is one of the Nation's leaders in the



healthcare insurance industry and we believe this favorable decision will continue to support and encourage industry peers to follow suit."

Aetna's nationwide network includes more than 600,000 healthcare service providers, including over 370,000 primary care and specialist physicians and 3,783 hospitals. The medical policy covering the XTRAC can be found at [www.aetna.com/cpb/data/CPBA0577.html](http://www.aetna.com/cpb/data/CPBA0577.html).

- 5/26 **Laserscope** announced that it had signed an exclusive, eighteen month distribution agreement with **Dornier MedTech Europe** for its proprietary GreenLight PVP (Photoselective Vaporization of the Prostate) laser systems and disposable fiber optics. Dornier MedTech Europe, a division of **Dornier MedTech**, will be responsible for the distribution, service, and clinical support of Laserscope's GreenLight PVP business throughout Germany and Russia.

"We are very pleased to have an industry leader like Dornier representing Laserscope's new, innovative procedure for the treatment of Benign Prostatic Hyperplasia (BPH), or enlarged prostate," said Eric Reuter, president and CEO of Laserscope. "Dornier is a very well respected company in the field of urology with vast experience in the sales and marketing of innovative, high technology capital equipment. We believe that Dornier's experience and relationships will help accelerate our growth in Germany and Russia. In Europe, as is typical in other parts of the world, the TURP, or transurethral resection of the prostate, is by far the leading surgical treatment for BPH. The combined total number of these procedures done annually in Germany and Russia is estimated to be nearly equal to the total number done in the United States. Additionally, it is estimated that the total number of TURPs done outside the U.S. ranges from 1.5 million to over 2 million annually."

"As we drive toward our corporate goal of replacing the TURP with PVP as the worldwide standard of care for treating BPH, this agreement with a respected worldwide leader in urology, such as Dornier, is indicative of the respect that PVP is gaining. The relationship allows us to take advantage of a very large and exciting international market opportunity."

Michael Lerch, General Manager, Dornier MedTech Europe said, "We are excited to represent Laserscope in Germany and Russia for their innovative GreenLight PVP laser and fibers. The clinical results and growth of PVP to date have been impressive, and we believe that PVP will be recognized as the standard of care for treating BPH. We feel this procedure will allow us to broaden our ability to offer current and future customers in the urology field the finest equipment they need for the most common procedures performed in a hospital or outpatient setting."

- 5/27 **Laserscope** announced results from four separate presentations made at the 2004 *American Urological Association (AUA)*'s 99th Annual Meeting, in San Francisco.

Physicians presented findings from four studies conducted using Laserscope's Photo-Selective Vaporization of the Prostate (PVP) procedure and GreenLight PV laser system and disposable fiber optic devices, including, among others:

- \* Better long-term clinical efficacy, lower overall side effects, and best cost-effectiveness for the healthcare system when compared to all other minimally invasive and surgical treatment options for enlarged prostate.
- \* Excellent safety and viability for patients with very large prostates.
- \* Enhanced safety as compared to electrovaporization of the prostate.
- \* Continued safety, durability, and clinical efficacy from multi-site clinical study at two year follow-up.

**Case Western and John's Hopkins University Researchers Prove Cost-effectiveness and Better Clinical Outcomes:** Presented by: Dr. Mark Stovsky, Assistant Professor of Urology, Case Western Reserve School of Medicine.

Highlights: The newest PVP study reported at the annual Urological Association conference summarized a clinical cost and outcomes analysis that compared PVP to other forms of minimally invasive surgical treatment for BPH including Interstitial Laser Coagulation (ILC), Trans-urethral Microwave Therapy (TUMT), Trans-urethral Needle Ablation (TUNA(TM)), and Trans-urethral Resection of the Prostate (TURP). The analysis showed PVP to be the most cost-effective treatment modality for the health care system, and also illustrated a substantially better clinical outcome profile, including lower complication rates when compared to these other modalities.

Dr. Stovsky presented costs for various modalities from a period of three months to two years post procedure. The data compared the direct and post-operative costs from complication rates and re-treatment rates, and was based on a critical review of almost 2,500 patients in 35 series of peer reviewed literature. The cost estimates were derived using complication rates from the most recently available Medicare claims data from 1999-2001 and the 2003 Medicare reimbursement rates for each procedure.

The analysis showed that there was a significant differentiation between PVP and other surgical treatments for BPH in both clinical efficacy and cost. When compared to the other treatment options, PVP offered better clinical outcomes, translating into lower initial and downstream costs to the health care system. The total cost savings using PVP ranged from \$1,079 to \$2,604 per treatment at the two-year follow-up period.

**Two Separate Cornell University Studies Demonstrate Excellent Efficacy and Safety:** Presented by: Dr. Jaspreet Sandu, Weill Medical College of Cornell University.

Highlights: At the end of a one-year follow up period, this study demonstrated excellent efficacy and safety of the PVP procedure for patients with very large prostates. Often, patients with very large prostates have had to undergo an open prostatectomy to treat their symptoms. This important clinical series revealed that for patients who do not wish to undergo such an invasive procedure and associated risk of complications, PVP is a viable alternative that can now be considered for all patients with enlarged prostates, regardless of size.

Presented by: Dr. Alexis Te, Weill Medical College of Cornell University.

Highlights: In this second study from Weill Medical College, the PVP procedure was demonstrated to be as efficacious, and in some respects safer, than electrovaporization of the prostate. Dr. Te also presented one-year follow-up data indicating that PVP procedures performed in an outpatient setting could provide results as good, or better, than an inpatient electrosurgical trans-urethral resection (TUR) of the prostate.

**Six-center Clinical Study Highlights Long-term Clinical Efficacy:** Presented by: Dr. Terrance R. Malloy, Vice Chairman, Department of Urology, University of Pennsylvania Health Care Systems.

Highlights: Results from this two-year, six-center clinical trial demonstrated the long-term clinical efficacy of Laserscope's PVP procedure using its GreenLight PV(TM) laser system and disposable fiber optic devices.

After treatment with the PVP procedure, patient outcomes were greatly enhanced with improvements of more than 90% recorded in the key clinical metrics of the AUA Symptom Score, the Quality of Life score, and Post Void Residual volumes. Further, the study showed nearly 200% improvement in peak urinary flow rates at the two-year follow up period. The clinical metrics indicated by this study continue to show the superiority and durability of PVP over any known technology for the treatment of Benign Prostatic Hyperplasia (BPH) or enlarged prostate.

"The clinical information presented at the AUA Annual Meeting has further strengthened the fact that PVP is the technology of choice for treating BPH for the widest range of patients," said Eric Reuter, president and CEO of Laserscope. "The results of the two-year follow-up from the multi-site clinical study were very encouraging as they continued to validate that PVP is a very durable treatment with a very low side-effect profile that can typically be done on an outpatient basis and often without catheterization. Additionally, the large gland study demonstrates that PVP, unlike other minimally invasive techniques such as the thermal therapies, can actually be used on patients that would otherwise have to undergo an open prostatectomy. Further, unlike other vaporization laser technologies that have been on the market for years, PVP is relatively fast and simple to learn and can be used on a wide range of gland sizes using the same surgical technique."

"Dr. Stovsky's presentation was extremely exciting because it verified, using published data and statistical methods, that PVP not only has a significant advantage clinically, but that it is also a dramatically more cost-effective treatment solution when compared with all the other major BPH surgical therapies," continued Reuter. "This information will be used to help insurance payors, including Medicare and large hospital groups recognize the strategic value of encouraging widespread adoption of the PVP procedure. It will also help us in international markets as we demonstrate that in many socialized medicine environments, PVP is not only the finest surgical treatment available but is also the most cost-effective. We plan on encouraging that medical therapy, or drugs, as well as several other lesser known and used treatment therapies be included in future evaluations to make the study even more comprehensive of all BPH therapies."

5/28 **Microwave Medical** issued its Quarterly Report.

We were in the business of manufacturing and selling our primary product, the MW2000. We also were in the business of designing and developing microwave technologies for dermatological applications. Due to our financial condition and filing for bankruptcy, we wrote off our entire inventory and currently have no business activities.

**Reverse Stock Split:** Currently our operations are at a standstill and we wrote off our entire inventory last year. In addition, as of the end of the reporting period we had issued a total of 99,822,434 out of 100,000,000 authorized common shares and were therefore unable to issue additional shares without increasing the authorized shares or reducing the total issued shares through a reverse stocksplit. After the close of the reported quarter, we filed a Schedule 14A and called a shareholders meeting which was held on May 10, 2004. At this meeting, the shareholders approved a reverse stock split of our common stock on a basis of one new share for every 500 shares presently outstanding.

**Need for financing, Name Change and Potential Acquisition:** Management has determined that it must seek additional funding or other business relationships such as a merger or reverse acquisition in order to proceed with an active business operation. Recently, after the close of the reported quarter, management has been in negotiations to acquire a skin care company known as **Davi Skin, Inc.** While no agreement has been signed, management believes that an acquisition such as this under the right terms would be in the best interests of the company and is aggressively pursuing this and similar options. In this regard and in anticipation of being able to reach such an agreement shortly, the company has processed a name change with the state of Nevada to Davi Skin, Inc.

**Plan of Operations:** We currently have no business activities. Unless we can secure financing, we will not be able to restart our operations. With the economic downturn, we have been unable to raise additional capital from outside sources and management is unaware of any reasonable prospects for financing. We are in the process of evaluating and negotiating the acquisition of a skin care company and hope to be able to enter into

an agreement with this company shortly. Upon entering into the agreement, we expect to announce the terms and conditions in a follow up filing.

**Assets:** Our total assets as of March 31, 2004 were \$15, compared to total assets in the amount of \$48 on December 31, 2003. Our only asset is cash in the amount of \$15.

**Liabilities and Stockholders Equity:** Our total liabilities as of March 31, 2004 were \$1.3 million, compared to total liabilities in the amount of \$1.2 million as of December 31, 2003. Our total current liabilities consisted of: (a) \$84,875 in accounts payable; (b) accrued expenses of \$280,141; and (c) notes payable in the amount of \$973,034. The notes payable consist of a promissory note issued pursuant to an agreement with Ms. Wallace discussed below, unpaid management fees owed to Ms. Wallace, and unpaid management fees owed to Grace Sim, our Chief Financial Officer.

On March 15, 2003, we entered into a loan agreement with Ms. Wallace. In accordance with this agreement, Ms. Wallace agreed to provide further financial support for a period of 90 days in an amount of no more than \$50,000 and to accept a new promissory note for a reduced amount of \$945,775.30, which extended the due date for payment to June 15, 2003. The company is continuing to negotiate with Ms. Wallace to extend the due date of the note. The balance owing on this promissory note is currently past due.

On March 31, 2004, we had a working capital deficit of \$1.3 million, compared to a working capital deficit of \$1.2 million on December 31, 2003.

**Results of Operations:** Due to our financial condition and the filing of bankruptcy, we had no business operations in the three month period ended March 31, 2004. Therefore, we had no revenue for the three month period ended March 31, 2004.

Our operating expenses were \$93,671 for the three month period ended March 31, 2004, compared to operating expenses of \$99,092 for the same three month period in the prior year. Our operating expenses in the three month period ended March 31, 2004 consisted of only general and administrative expenses. We did incur \$22,327 in interest expense in the three month period ended March 31, 2004, compared to interest expense of \$395,619 for the same three month period of the prior year.

We incurred a net loss of \$115,998 for the three month period ended March 31, 2004, compared to a net loss of \$494,711 for the same three month period in the prior year.

**Liquidity and Capital Resources:** On March 31, 2004 we had cash in the amount of \$15, compared to \$48 in cash on December 31, 2003. We wrote off our inventory and assigned it to Ms. Wallace in 2003 to repay a portion of the secured debt owed to her. Therefore, our only asset is cash at this time. Unless we can secure financing, we will not be able to restart our operations. With the economic downturn, the company has been unable to raise additional capital from outside sources and management is unaware of any reasonable prospects for financing.

5/28 **PLC Systems** reported that the Center for Medicare and Medicaid Services (CMS) announced in today's Federal Register that on July 14, 2004 it will convene the Medicare Coverage Advisory Committee (MCAC). The MCAC will discuss and make recommendations regarding using transmyocardial revascularization (TMR) and percutaneous myocardial revascularization (PMR) as it relates to Medicare patients with severe angina. The July 14 MCAC meeting will be open to the public, so that individuals may have an opportunity to express their views.

The MCAC is advisory in nature, and consists of clinicians and other medical experts as well as non-voting industry and consumer representatives. The MCAC advises CMS on whether specific medical items and services are reasonable and necessary. Final decisions related to medical coverage policies rest with CMS.

"Working closely with our partners we will deliver to the MCAC panel the data, the evidence, and the personal experiences that support the use of the efficacious and beneficial TMR therapy," stated Mark Tauscher, president and CEO of PLC Systems. "We believe that the scientific data demonstrates that the TMR therapy provides positive outcomes for patients and improves their quality of life."

#### **MEDICAL/SURGICAL LASER UPDATE -- June 2004**

6/6 **Lumenis Ltd.** announced preliminary unaudited financial results for the first quarter ended March 31, 2004. Revenues in the quarter were \$65.1 million compared with revenues in the first quarter 2003 of \$77.4 million. The net loss for the quarter was \$4.1 million (11 cents per share) compared with \$6.9 million (19 cents per share) in the first quarter 2003. Net operating cash flow from operations was positive \$2.8 million compared with a negative \$8.2 million net operating cash flow in the first quarter 2003.

Commenting on the results, Avner Raz, Lumenis president and CEO, said, "The first quarter results are the first full quarter reflecting our new organization. We have implemented the core components of the Turnaround Plan, including the final phase of headcount reductions, closure of several sites and a reduction in management layers. We expect to realize the full benefit of these changes over the next several quarters. While we still reported a loss in the first quarter, we are encouraged by the reduced operating costs and good operating cash flow despite the lower revenue experienced in the first quarter. Our new organization is now focusing on improving operational efficiencies, customer satisfaction and growth in our markets."

The operating loss for the quarter was \$1.4 million and included restructuring expenses related to implementation of the Turnaround Plan of \$1.0 million. Operating expenses, including restructuring costs of \$1.0 million, for the quarter were \$32.0 million compared with \$38.8 million in the first quarter 2003.

The net loss for the quarter also included other income of \$1.5 million from the settlement of the patent litigation with **Syneron**. The company will also receive future royalties from Syneron.

In the quarter, sales in Europe were \$17.9 million, compared to \$17.2 million a year ago and \$16.6 million in the fourth quarter of 2003. The Americas region had sales of \$27.8 million, down compared to revenue in the first quarter 2003 of \$35.9 million and from the \$35.0 million in the fourth quarter 2003. Sales for Asia Pacific, China and Japan were \$19.4 million compared to the previous year revenue of \$24.3 million and \$23.8 million in the fourth quarter 2003.

First quarter sales for our Aesthetic products were \$20.3 million, down compared to \$29.4 million a year ago and the \$24.4 million in the fourth quarter of 2003. The Surgical product line had total sales of \$12.4 million in the first quarter, compared to \$12.1 million in the same quarter a year ago and \$14.0 million in the fourth quarter 2003. The dental business had sales of \$1.8 million, compared with \$2.4 million a year ago and \$2.6 million in the fourth quarter of 2003. Ophthalmic products had first quarter sales of \$16.1 million compared to \$20.0 million in the same quarter a year ago and \$21.2 million in the fourth quarter 2003. The service business had revenues of \$14.4 million compared with \$13.5 million in the same quarter a year ago.

The company had approximately \$20 million in backlog at March 31, 2004 compared to \$20 million at December 31, 2003. At March 31, 2004, the company's cash position was \$18.4 million and borrowing capacity under its committed lines of credit was an additional \$9.6 million. Total debt was \$210.0 million.

As previously reported, a report prepared for the Audit Committee with respect to the company's internal investigation had concluded that the timing of the company's revenue recognition was inappropriate with respect to certain identified transactions. The aggregate effect of the company's accounting for the transactions identified in the report, as described more fully in the company's press release of May 3, 2004, was to cause revenues in 2001 and 2002 to be overstated, and revenues in 2003 to be understated.

The effect of the foregoing on the results of operations for the three-month period ended March 31, 2003 was to cause revenues to be overstated by approximately \$1.6 million or 2.0%. The effect of such overstatement of revenues on previously reported earnings (loss), while not included in the report, is estimated, on a preliminary basis and subject to further adjustment, to increase the net loss as reported in such period by approximately \$1.1 million. Such adjustments are not reflected in the attached financial statements.

As previously reported, the Audit Committee anticipates that a restatement of previously reported financial results may be appropriate, but intends to defer making a final decision pending the engagement of its new auditors. As recently announced, the company is in the process of the selection of a new auditor.

6/7     The booming aesthetic procedure market is generating a wide array of new business development opportunities, according to a new research report released by **Medical Insight, Inc.** this week. Light-based treatments are now mainstays of medical and aesthetic practices. In 2003, nearly 20 million hair removal, skin rejuvenation, tattoo/pigmented lesion removal, acne treatment and photodynamic therapy procedures were performed. These earned almost \$6.5 billion for practitioners and \$372 million in revenue for equipment manufacturers. By 2008, this will grow to over 53 million treatments annually earning practitioners \$10.4 billion and manufacturers more than \$500 million.

Botox and similar treatments are also popular. In 2003, approximately four million procedures were performed worldwide, generating over \$2.1 billion in procedure fees. By 2008, more than 10 million procedures will be performed annually, generating treatment revenue of \$4.4 billion. Revenues to suppliers will grow from \$656 million in 2003 to \$1.6 billion in 2008. Dermal filler use isn't far behind. More than two million procedures were performed in 2003, earning practitioners \$1.2 billion and suppliers \$196 million. In 2008, this will rise to almost five million treatments generating \$2.3 billion for physicians and \$398 million for suppliers.

Microdermabrasion, chemical peels and emerging skin rejuvenation treatments are also rising. In 2003, over 16 million treatments were performed, accounting for almost \$3 billion in fees to practitioners. Equipment manufacturers and suppliers earned about \$101 million. By 2008, this will grow to more than 41 million procedures earning over \$6 billion for practitioners and \$230 million for manufacturers.

The greatest growth and largest opportunity, however, remains anti-aging topicals. In 2003, sales of all brands through all outlets accounted for \$4.1 billion. This will grow to more than \$5.6 billion in 2008. According to study author Michael Moretti, president of Medical Insight, Inc. and Editor of the *Aesthetic Buyers Guide*, the Global Aesthetic Market study provides the only available comprehensive market analysis and five-year forecast related to emerging and high-growth aesthetic market segments.

In addition to releasing the Global Aesthetic Market Study, Moretti has identified a priority list of current business development and investment opportunities, which is available upon request. "This Strategic Opportunities Summary is designed to give business development executives, investors and R&D managers immediate access to a select group of the most promising new concepts in this exciting, high-growth field," explained Moretti.

6/8     **DUSA Pharmaceuticals, Inc.** announced the initiation of a pilot Phase II clinical trial for the treatment of high-grade dysplasia (HGD) within Barrett's Esophagus (BE), using Levulan (ALA, or aminolevulinic acid) photodynamic therapy (PDT). This single site U.S. trial is being carried out in order to gather pilot treatment data using DUSA's proprietary new endoscopic light delivery system.



Independent investigator studies have reported that orally administered ALA followed by red laser light selectively treats the epithelial (lining) layer of the esophagus, making it effective in ablating HGD without causing strictures (circumferential scarring) or prolonged skin photosensitivity. In DUSA's earlier small clinical trial on the removal of HGD in BE using Levulan PDT, patients received 60 mg/kg Levulan orally, followed 4 to 6 hours later by 200 J/cm<sup>2</sup> of red laser light delivered through a clear balloon catheter. Of the 5 (of 6) patients that have been followed for a median of 12 months after the last Levulan PDT treatment (with an average of 2 treatments per patient), complete ablation of HGD was seen in all of them (100%), with no strictures reported.

In the new pilot Phase II clinical trial, at least 8 patients with HGD will receive 60 mg/kg Levulan orally, followed 4 to 6 hours later by 150 J/cm<sup>2</sup> of 635 nm of red laser light delivered using DUSA's proprietary new endoscopic sheath device. The DUSA sheath device was designed in order to allow direct visualization of the target area for optimal placement of the light-carrying fiber optic. The design is also meant to deliver light evenly and circumferentially, all with only a single insertion of the endoscope. This compares with current methods of light delivery involving balloon catheterization which require multiple endoscope insertions and imprecise light placement.

Barrett's esophagus is an acquired condition affecting up to 700,000 patients in the United States, in which the normal esophageal lining is replaced by an abnormal lining that can then become dysplastic. Patients with confirmed high-grade dysplasia (HGD) often undergo major surgery to remove the affected portion of the esophagus. An alternative medical treatment for these patients using PDT was recently approved by the FDA. The approved drug, porfimer sodium (Photofrin, **Axcan Pharmaceuticals**), was effective in Phase III clinical trials, but was associated with skin photosensitivity for up to 4 to 6 weeks, and strictures resulting in the need for repeated esophageal dilatation in 38% of the patients.

Stuart Marcus, MD, DUSA's CSO and CMO, stated "Published independent studies and DUSA's earlier small study have suggested a significant and prolonged effect of ALA PDT on dysplasia within BE. DUSA's new study will gather pilot treatment data using Levulan and DUSA's proprietary new endoscopic light delivery system, which we believe could lead to a simple, safe and effective treatment for this dangerous condition."

6/9 **Trimeddyne, Inc.** announced the issuance of U.S. Patent No. 6,740,107, which covers new, minimally invasive laser devices designed to treat mitral valve regurgitation. An estimated 4 million Americans suffer from this condition. Each year in the United States, approximately 50,000 people undergo open-heart surgery to repair or replace a mitral valve. In addition, an estimated 75,000 mitral valve repairs or replacements are performed during bypass surgery. In many people who have both mitral valve regurgitation and heart failure, the condition is not treated, as they are too ill to undergo surgery.

Mitral valve regurgitation or "prolapse" occurs when the valve does not fully close and blood leaks backward into the left atrium with each heartbeat, causing the heart to work harder, and possibly leading to heart failure. Traditional open-heart surgery requires the patient's chest to be opened, the heart stopped, a heart-lung machine to be used, a 5 to 7 day hospital stay and a long recuperation period.

Trimedyne's patent covers designs for two new laser devices to treat this condition; one for use by surgeons during bypass surgery, and one for use by cardiologists in the catheter lab through a puncture in an artery in the groin. The device for use by surgeons will consist of a patented, side-firing optical fiber encased in a balloon. The balloon is designed to be inflated in the annulus or "collar" of the valve. Laser energy is then emitted from the device as it is rotated, like the beacon of a lighthouse. The laser energy shrinks the annulus and the leaflets of the valve, just as laser energy is used to shrink facial tissues to treat wrinkles. The device may also be positioned in the left ventricle to shrink the tendons that close the valve, but which may become stretched over time. The device is designed to significantly reduce the surgical trauma of conventional valve repair or replacement.

The device for use by cardiologists will consist of a catheter designed to be inserted into the patient's femoral artery and positioned in the annulus of the mitral valve or the left ventricle. In this device, the balloon is intentionally made lop-sided, with the side from which laser energy will be emitted significantly larger in diameter than the opposite side. When the balloon is inflated with a fluid opaque to x-rays or ultrasound energy, the cardiologist can see the shape of the balloon and determine the direction in which laser energy will be emitted.

Trimedyne earlier acquired U.S. Patent No. 5,989,284, which covers the use of laser, radiofrequency, electrical or microwave energy to shrink the mitral valve. The new patent covers specific devices designed for use with these and other forms of thermal energy to treat mitral valve regurgitation, expanding Trimedyne's patent position in this field.

Clinical trials at substantial cost and FDA approval will be required before any of the above devices can be marketed in the United States. However, with modest sized clinical trials, such devices may be marketed in Europe, when CE Marked, and most countries in Asia, the Middle East and South America.

- 6/14 **CardioGenesis Corporation** announced that the Medicare Coverage Advisory Committee (MCAC) will meet on July 14, 2004 to review the clinical evidence regarding laser myocardial revascularization as a treatment option that is reasonable and necessary for Medicare patients. The MCAC meeting is a non-binding public hearing to consider the body of scientific evidence and to provide advice and recommendations to the Centers for Medicare & Medicaid Services (CMS) on clinical issues.

"We believe this meeting presents an excellent opportunity for an open and objective public hearing covering all of the relevant scientific and clinical evidence regarding

TMR," CardioGenesis chairman and CEO, Michael Quinn said, "and we are looking forward to participating. While there have been many new and exciting treatments recently approved to treat the epidemic of cardiovascular disease, there remains a significant and growing patient population whose chronic, debilitating angina symptoms cannot be resolved by traditional revascularization methods. Even though nearly 30,000 of those patients have been treated with laser myocardial revascularization since the first FDA approval in 1998, there are many tens of thousands of needy patients that remain untreated. This hearing is about a technology that is not only relevant to Medicare patients today and in the future, but that has already relieved the suffering and improved the quality of life of a vast number of severe angina sufferers."

Since the Medicare coverage decision regarding TMR in 1999 and the addendum to that decision in 2000, there have been a number of important new published clinical studies, including peer reviewed long term follow-up studies that show the lasting effectiveness of the procedure. The company believes the most current published evidence regarding TMR, specifically the recently published studies demonstrating the enduring patient benefit of TMR to five years, clearly support the current Medicare coverage decisions regarding TMR.

"Our company sees this upcoming public forum as a tremendous opportunity and an excellent setting to highlight the magnitude of the entire body of evidence supporting the clinical importance of TMR," Quinn said. "We and our industry peers have an obligation to encourage and support Medicare stakeholders by directly participating as requested by CMS in this important public process, and to ensure that the significant body of scientific evidence on TMR is effectively presented to and considered by the MCAC in the formulation of their recommendations."

In regards to Percutaneous Myocardial Revascularization being included on the agenda for the meeting, Quinn said that the company had not requested any such review of PMR at this time and is requesting clarification from CMS regarding that topic.

6/14 **Dynatronics Corporation** announced the FDA had given marketing clearance for the company's new Solaris D890 low-power laser probe. The laser treats muscle and joint pain, including the pain and stiffness associated with arthritis. The Solaris D890 is the second probe designed for use as an accessory to the company's popular new Solaris Series products. The probe is expected to be ready for shipment within 30 to 60 days.

"We are thrilled with the FDA's decision to allow us to begin marketing this laser probe," stated Kelynn Cullimore, president of Dynatronics. "Our first attempt to obtain approval for a laser probe was over 20 years ago. That makes this clearance even more satisfying."

According to Larry Beardall, Dynatronics' executive vice president of marketing and sales, "The new D890 probe will expand the foundation of success our Solaris product line has already achieved. With two decades of clinical research behind them, lasers have been of keen interest to the medical community and have found many applications in

medical settings. Hundreds of people around the country have already benefitted from light therapy. The results have been remarkable."

- 6/15 **Diomed Holdings, Inc.** announced that it had secured a two year revolving line of credit of \$2.5 million from **Silicon Valley Bank**, the primary banking subsidiary of **Silicon Valley Bancshares**. "This line of credit strengthens our financial position and is a further reflection of the credit worthiness created by the significant turnaround achieved by our organization," stated James Wylie, president and CEO of Diomed. "While there is no immediate need for the proceeds, the credit facility provides additional flexibility in funding the company as our drive for growth continues. We are very pleased to be initiating our relationship with Silicon Valley Bank in this capacity and we look forward to collaborating with them as we continue to build shareholder value," Wylie concluded.

"We look forward to providing financial support to Diomed as it solidifies its position in the medical technology market," stated Doug Marshall, vice president, Northeast Life Science Team, Silicon Valley Bank. "Our mission is to help emerging and established life science companies, like Diomed, succeed by providing the diversified financial services that will help them grow."

- 6/16 **Diomed Holdings, Inc.** announced that it had completed a one-for-twenty five reverse split of its common stock. As a result of the reverse stock split, every twenty five (25) shares of common stock will be combined into one (1) share of common stock and the total number of issued and outstanding shares of common stock will be reduced to approximately 14,600,000 shares as of the market opening on June 17, 2004. The reverse split will affect all shares of Diomed Holdings, Inc. common stock, including those shares underlying stock options and warrants outstanding immediately prior to the effective date of the reverse split.

"As a logical follow-up to our recent \$26 million in financings, Diomed's investors, voted overwhelmingly in favor of the reverse stock split," stated James Wylie, president and CEO for Diomed Holdings, Inc. "This much anticipated action will reduce the number of shares outstanding from 365 million to 14.6 million and is expected to bring the company's share price into a range more acceptable to both retail and institutional investors. Importantly, the reverse split eliminates a significant hurdle to obtaining coverage of Diomed by analysts within the financial community."

As of June 17, 2004 shares of common stock of Diomed Holdings, Inc. will begin trading on a split-adjusted basis with its same ticker symbol "DIO".

- 6/17 **Spectranetics Corporation** announced that it had received conditional approval from the FDA to commence the Extended FAMILI clinical trial, which will study the use of the company's proprietary excimer laser catheters to treat heart attack patients. The goal of the study is to determine if treating the heart attack with the laser restores blood flow and reduces the infarct size, or amount of dead heart muscle. The feasibility trial will enroll 80 patients at up to 20 multi-national sites. The trial has been initiated in Europe and 13

patients have been enrolled at five European sites. For each patient, study endpoints include the re-establishment of blood flow in the blocked artery creating the heart attack (TIMI flow), the ability of blood to flow into the heart muscle as seen on the electrocardiogram (S-T segment resolution), and the amount of tissue damaged by the heart attack (infarct size).

The trial has been initiated in Europe and 13 patients have been enrolled at five sites in Europe.

Dr. Jeffrey Moses, Chief of Interventional Cardiology at Lenox Hill Hospital in New York City and U.S. principal investigator of the trial, said "The Extended FAMILI study will help us understand the clinical impact of using the excimer laser to photoablate thrombus in AMI patients prior to stenting. Safe removal of thrombus with the laser may help restore blood flow more rapidly and potentially reduce heart muscle damage measured by infarct size."

"We have commenced this important feasibility trial with a high degree of confidence and enthusiasm for the laser's ability to ablate all types of thrombus as well as underlying plaque and therefore see significant potential to provide a solution to the 150,000 heart attack patients treated each year with percutaneous techniques. We are particularly pleased to have Dr. Moses, an eminent interventional cardiologist, as a principal investigator. This Extended FAMILI trial is expected to be completed in late 2004 or early 2005 and, if successful, a multi-center randomized trial is likely to begin in 2005," stated John Schulte, Spectranetics' president and CEO.

6/18 **CardioGenesis Corporation** announced that it held its Annual Meeting of Shareholders, Thursday, June 17, 2004, at the company's headquarters, as scheduled. A quorum of shareholders was present in person or by proxy. All proposals submitted to the shareholders were approved, including the reelection of six Directors to the Board of Directors, which fills all Board seats; ratification of the appointment of **PricewaterhouseCoopers LLP** as the company's independent auditors for the year ending December 31, 2004; and certain amendments to the company's Stock Option Plan, Employee Stock Purchase Plan and Articles of Incorporation.

The Directors reelected to serve until the next annual meeting were Michael J. Quinn, CardioGenesis chairman, president and CEO; Joseph Kletzel, former COO of **Advanced Tissue Sciences**; Robert Mortensen, Board member and retired chairman of the Board and president of **Lightwave Electronics**; Robert Strauss, chairman, president and CEO of **Noven Pharmaceuticals**; Marvin Slepian, MD, founder and CEO of **SynCardia Systems, Inc.**; and Kurt Wehberg, MD, Director of the Multidisciplinary Thoracic Oncology Center and the TMR program at Peninsula Regional Medical Center in Salisbury, MD.

The shareholders approved an amendment to the Stock Option Plan to increase the number of shares of Common Stock for issuance under the Plan by 1.5 million shares and

they approved an amendment to the Employee Stock Purchase Plan to increase by 150,000 the number of shares of Common Stock reserved for issuance under that Plan. In addition, the shareholders approved an amendment to the Director Stock Option Plan to increase the number of authorized Common Stock by 300,000 shares.

6/22 **Lumenis Ltd. and Palomar Medical Technologies Inc.** announced that they had reached a settlement resolving their on-going litigation concerning both patent infringement and contractual matters. Palomar accused the LightSheer Diode Laser System, a product initially developed by Palomar and now marketed by Lumenis, and various Lumenis IPL systems of infringing claims in two U.S. patents (5,595,568 and 5,735,844). Palomar has an exclusive license to these patents from the **General Hospital Corporation** in Boston, MA. Pursuant to the settlement, the parties will dismiss with prejudice both the federal action in the Northern District of California as well as the state court action in Massachusetts.

Under the terms of the settlement, Lumenis will pay \$4.09 million over the next six quarters for royalties due on sales of the LightSheer made between July 1, 2002 and December 31, 2003. Beginning on January 1, 2004, Lumenis will pay Palomar a 5% royalty on sales of the LightSheer and other professional laser hair removal devices and modules. In addition, Lumenis has granted Palomar a paid up license to a variety of Lumenis' patents for Palomar's light based devices. Palomar has also granted Lumenis a paid up license to the '568 and '844 patents for Lumenis' lamp based devices. Importantly, both parties have agreed to the validity and enforceability of each others patents and not to challenge such validity and enforceability in the future.

CEO Joseph Caruso of Palomar commented. "The settlement benefits both parties and eliminates the costs and distractions of continuing litigation. The strength of Palomar's patent portfolio is validated by this settlement along with the favorable claims construction rulings Palomar received in this lawsuit as well as our patent infringement lawsuit against **Cutera Inc.**" Caruso continued, "Palomar intends to continue its strategy of vigorously enforcing its patent portfolio."

Avner Raz, president and CEO of Lumenis, stated, "The terms of this agreement are beneficial for both companies and will avoid protracted and costly litigation. It represents one more step toward resolving past legal issues and enables us to have an even more intense focus on our long tradition of providing leading-edge laser and light-based systems, and quality customer care."

6/22 **Spectranetics Corporation** management reviewed the CLiRpath launch plans and current status at its Annual Meeting of Shareholders held today. The CLiRpath product line received FDA marketing clearance on April 29, 2004 and sales commenced on May 1, 2004. "I'm pleased with the progress of the initial CLiRpath product launch, which is focused on the 120 hospitals with identified potential users that already have an excimer laser system. We are now 35 selling days into the launch and 85 of our target accounts have ordered the newer, larger diameter catheters," said John Schulte, Spectranetics'

president and CEO. "We have an elegant marketing launch that will include marketing communications, physician training, podiatry outreach, public relations aimed at assisting hospitals in their local markets, and economic outcomes study results. The full marketing launch will commence in August as originally planned. We expect to update our financial guidance after we obtain better visibility on the re-order rates and the impact of the marketing launch, which most likely will occur in connection with our third quarter earnings release and investor call in mid-October."

The three items on the ballot at the Annual Meeting of Shareholders were approved by an overwhelming majority of affirmative shareholder votes. They included the re-election of Cornelius Bond, Martin Hart, and Joseph Ruggio, MD to the Board of Directors, the appointment of **KPMG** as independent auditors for the current fiscal year, and an amendment to the Employee Stock Purchase Plan increasing the number of authorized shares of common stock available to the plan from 850,000 to 1.35 million.

6/22 **CardioGenesis Corporation** announced that a team of leading physicians who have performed and developed a variety of approaches to TMR, including minimally invasive thoracoscopic and robotically assisted techniques, concluded in an article featured in the June 2004 edition of *The Heart Surgery Forum*, that TMR is a clinically proven, safe and effective therapy for physicians addressing some of the most difficult angina and revascularization cases. Angina is the often crippling pain associated with severe cardiovascular disease.

The authors of the article, titled "Transmyocardial Laser Therapy; A Strategic Approach," also noted after reviewing several case studies that, "the use of TMR has added another important dimension to the overall management of angina patients, particularly those with no other treatment options."

The comprehensive article in *The Heart Surgery Forum*, the official journal of *The International Society for Minimally Invasive Cardiac Surgery (ISMICS)*, provided a detailed patient selection algorithm and case studies on the variety of approaches to TMR, including using TMR as a sole therapy, as an adjunctive therapy to coronary artery bypass grafting (CABG) and promising new, minimally invasive methods such as robot-assisted TMR.

The article's featured author was Louis Samuels, MD of Lankenau Hospital of Wynnewood, PA, who shared the byline with eight other physicians from centers around the U.S. who are actively utilizing TMR in their cardiothoracic programs. Dr. Samuels underscored how TMR is evolving as surgeons become more familiar with the technology and experiment with new, minimally invasive approaches.

"Minimally invasive approaches (to TMR), including off-pump approaches and limited thoracotomies to enhance patient benefit and expand patient eligibility, are becoming a routine part of TMR strategy," Dr. Samuels wrote. "Future applications in this regard

include the use of port access (thoracoscopic approach) to minimize patient pain and recovery time and to avoid sternotomy in young patients."

Chairman and CEO, Michael Quinn, said that publication of this important article on TMR in the current edition of The Heart Surgery Forum is particularly timely for the company as it has been published in conjunction with the annual ISMICS meeting being held in London later this month. "During the past year there have been important new publications of clinical data regarding the enduring benefits of TMR, including publication of a five-year follow-up study demonstrating that patients treated with the procedure continued to experience reductions in angina pain after one year. The study also showed that TMR had a beneficial impact on long-term survivability."

The Society of Thoracic Surgeons Workforce on Evidence-Based Surgery recently endorsed the procedure in its published Practice Guidelines for TMR. "The publication by Dr. Samuels et al builds upon the scientific evidence supporting the therapy, by providing a thorough and thoughtful review of a significant body of clinical experience in outlining patient selection and procedural considerations," Quinn added.

CardioGenesis is working with the physicians who are studying new and advanced approaches to TMR, including minimally invasive methods. These innovative approaches to TMR are much easier on the patient and lead to much quicker recovery times. "This is where TMR is headed and we have a number of new products on the way to assist in these approaches," Quinn said.

6/23 **Diomed Holdings, Inc.** acknowledged that, with recently issued health insurance policies, the number of eligible covered lives for the EVLT procedure now exceeds 80 million Americans. "The list of insurance providers with positive coverage policies has grown and now includes private regional and national companies, in addition to Medicare (Part B) carriers," stated John Welch, vice president of Marketing for Diomed Holdings, Inc. "Recently, the **Blue Cross Blue Shield Association** offered guidance to its membership favoring coverage for EVLT. Currently, eighteen independent Blue Cross Blue Shield Carriers have positive coverage policies with most others conducting active assessments. Other national policies include **Aetna US Healthcare** and **Humana**. We are pleased to note that with at least one positive policy in each state, increasing numbers of patients now have access to this breakthrough technology and procedure."

It is estimated that at least 25 million Americans suffer from some form of varicose veins due to venous insufficiency. This disorder has a dramatic affect upon quality of life, is often unsightly, painful and, if left untreated, may lead to serious complications. EVLT offers patients afflicted with venous insufficiency a relatively pain free and affordable treatment alternative. Unlike traditional varicose vein surgery that can require expensive hospitalization and general anesthesia, EVLT is an outpatient procedure that requires only local anesthesia. Employers recognize an economic benefit because EVLT allows people to return to work within 24 hours or less when compared to traditional surgery, which can require weeks of painful recovery.



James Wylie, president and CEO of Diomed commented, "Positive coverage policies are being driven by the growing body of clinical and scientific evidence attesting to the safety and efficacy of the EVLT procedure and by the strong economic advantages offered by this minimally invasive technology. Diomed is committed to continuing its active support of physicians and hospitals through proactive education and advocacy with health insurance carriers on a national basis to facilitate access to EVLT with adequate reimbursement for all appropriate patients."

- 6/28 **Palomar Medical Technologies Inc.** and **The Gillette Company** said that they had completed the initial phase of their agreement, and both parties will move into the next phase. Palomar will now disclose additional proprietary information to assist the parties in completing the development and commercialization of a patented home-use, light-based hair removal device for women. In conjunction with entering this next phase, the parties have amended the agreement to provide for additional development funding to further technical innovations.

The original agreement provided for \$7 million in development funding from Gillette. Under the amendment, Gillette will provide \$2.1 million in additional development funding over a 9-month extension of the development phase, which is now planned to be completed by August 31, 2006.

Commenting on the agreement, Palomar CEO Joseph Caruso said, "We have had a fantastic first year. With excellent collaboration between research groups and complementary expertise on both sides, we have been able to accomplish our goals. Gillette has enhanced our approach and knowledge of the consumer market, and we are looking forward to the next phase."

Michael Buckley, Director of Emerging Technology Ventures for The Gillette Company commented, "We are pleased with the progress made and results observed during the first phase. The long-term potential of a light-based hair-removal product for use at home by women remains exciting."

#### **MEDICAL/SURGICAL LASER UPDATE -- July 2004**

- 6/23 **Thermage Inc.** announced that the FDA had cleared its radiofrequency ThermoCool device for the non-invasive treatment of facial wrinkles and rhytids. Previously cleared for the treatment of periorbital (around the eyes) wrinkles and rhytids, the ThermoCool system is the only technology proven to tighten and contour skin and its underlying structures without incisional surgery.

For the majority of people who prefer a more natural, tightened look and don't have the time, money or interest for major plastic surgery, the Thermage procedure is a welcome and more subtle alternative. This non-invasive choice is particularly attractive for the many patients with only mild symptoms of loose skin who are not yet ready -- mentally

or physically -- for the more drastic effects of a facelift and its associated recovery period.

Bob Byrnes, president and CEO of Thermage stated: "We are very pleased to receive FDA clearance for treatment of the full-face with the Thermage procedure. With the market potential for cosmetic treatments of the mid and lower face estimated to be four to five times greater than the demand for periorbital procedures, this additional regulatory clearance presents a tremendous growth opportunity for our company."

The Thermage patented capacitive radiofrequency (RF) technology deploys deep, uniform and volumetric heating to tighten both skin and underlying tissue, while protecting the skin's outer layer with a cooling cryogen spray. The deep heating action promotes immediate collagen contraction beneath the skin surface and generates new collagen growth over time. The new regulatory clearance for the full-face indication was based on a submission of clinical data from 48 patients who received Thermage treatment on facial skin. The multi-site study was conducted by leading dermatologic surgeons: Dr. Roy Geronemus of New York City, Dr. Tina Alster of Washington, DC, and Dr. Michael Kaminer of Boston, MA.

Summarizing the research findings, Dr. Kaminer commented: "When treating the cheeks, jawline and chin areas using a multiple-pass approach, we observed a substantial reduction in laxity with just one treatment session in most cases. Further, there were no reports of adverse events. And although pain medications were used, most patients found the treatment to be quite tolerable." In addition, Dr. Alster noted that "these study findings of facial skin treatment validate what researchers at our clinical center have long considered to be one of the most useful applications of Thermage technology -- sagging and drooping of the mid and lower facial region. Laxity reduction, particularly in the area just underneath the chin and along the jawline, is a frequent request from cosmetic patients. The Thermage procedure is the only proven non-invasive choice for tightening skin in this region."

Dr. Alster cited similar evidence from her peer-reviewed clinical study published in the April 2004 issue of *Dermatologic Surgery*. Based on long-term results, Drs. Alster and Elizabeth Tanzi demonstrated that improvement from a single Thermage treatment was sustained for at least the 12-month post treatment evaluation period, with the greatest improvement observed at three to six months post-treatment.

6/29 **Norwood Abbey Limited** announced that its subsidiary **Norwood Devices (ND)** was forecasting to achieve revenues of more than \$1 million for FY 03/04 and in excess of \$14 million for FY 04/05. Norwood Devices CEO Richard Walmsley, said, "We are extremely pleased with the customer response received to date. The infrastructure changes that we are implementing will allow us to take the next steps in the marketing of our products to achieve our future revenue targets."

ND has a portfolio of innovative drug delivery technologies including the Laser Assisted Drug Delivery product (currently marketed in the USA and Asia) and the Needle Free and Micro-needle technologies both under development at MIT. ND has also recently introduced the new **Norwood Eye Care** products Centurion SES System and EpiEdge (epikeratome separator) to the market. This technology was acquired by Norwood Abbey Limited from **Ciba Vision** (a subsidiary of **Novartis**) at the beginning of May.

In order to achieve its strategic and financial goals in 2004/2005, the Devices Division is expanding its USA based infrastructure and has:

1. Appointed a US president of Drug Delivery: Jeff Spielman, who has had a very impressive career in medical devices including seven years with **Baxter Travenol Laboratories** in sales and marketing and 18 years with **Portex, Inc.**, the last eight of these as President. Spielman will be responsible for managing the US and European commercialization of all the ND drug delivery technology platforms. One of his first tasks will be to oversee the expansion of the marketing activities for the LAD product in the USA. This will include the development and implementation of a range of exciting interactive web-based marketing tools to target clinicians. In addition to LAD marketing, Spielman will be managing the development program at MIT and actively seeking strategic partners for the needle-free and micro-needle based technologies. Spielman will be located in the US and will report to the CEO of ND, Richard Walmsley.

2. Appointed 8 additional staff to varying roles.

3. Established an office in Atlanta, Georgia to manage the US and European sales and marketing activities for the Norwood EyeCare products.

4. Appointed a team of commissioned-based sales representatives in the US to aggressively market the EyeCare product. Discussions with regard to the appointment of a number of European representatives are progressing well and it is expected that a network of distributors in Europe will progressively be appointed over coming months.

Richard Walmsley said, "These additional sales and marketing appointments as well as establishment of a sales and marketing office in Atlanta, will greatly assist in achieving our strategic and revenue goals. We expect to further strengthen the US team as appropriate over the coming months."

6/30 The worldwide market for cosmetic surgery and facial cosmetic rejuvenation, now representing nearly \$12 billion in sales, is growing at \$1 billion a year, according to a new study released today from **Kalorama Information**. Injectable fillers such as Allergan's Botox, new laser treatments for wrinkles and hair removal, resurfacing techniques, and increased acceptance of traditional cosmetic procedures such as face lifts, are creating a booming market with fierce competition.

The new study, *Facial Cosmetic Surgery and Rejuvenation Markets*, predicts that found that over 15 million procedures from simple botulinum toxin injections to full surgical rhinoplasty will be preformed this year, and that by 2006, that number will be well over 21 million. Furthermore, the majority of the procedures will be simple injections or laser treatments for wrinkles.

"While rapid technological changes in dermal fillers, lasers, and other light sources are creating a frenzy of competition," notes Steven Heffner, acquisitions editor for Kalorama Information, "manufacturers are riding the wave of the real market drivers: the providers hungry for a cash business in their managed care practices and the aging public's demand for less invasive, more effective treatments."

The report details U.S. and the international procedure volumes, dollar volumes, unit sales (treatment systems and drugs), competitive market share, and market channel estimates for wrinkles treatments such as dermal fillers and lasers, ablative procedures such as dermabrasion and resurfacing, the top five restorative cosmetic surgeries, and hair removal, among other segments. Extensive analysis of clinical, market, and regulatory trends, along with the competitive profiles of 36 leading companies rounds out the 400+ page report.

This new report is priced at \$3500 and is available for purchase at [www.kaloramainformation.com/pub/849260.html](http://www.kaloramainformation.com/pub/849260.html).

6/30 **CardioGenesis Corporation** announced that The Johns Hopkins Hospital in Baltimore had installed a CardioGenesis TMR laser system and is using it to treat patients suffering from the often crippling effects of severe angina pain. CardioGenesis chairman and CEO Michael Quinn, said that based on the hospital's commitment to TMR as a viable treatment option for severe angina, the company hopes to see the development of an extensive clinical research program at Johns Hopkins, focusing on minimally invasive approaches to the procedure, such as the use of a surgical robot, and on TMR's mechanism of action.

"We believe the selection of the CardioGenesis Holmium:YAG laser for TMR by a medical institution with the high standards of excellence of Johns Hopkins is a strong statement about the quality of our product and the clinical benefits of the procedure," Quinn said. "The value of TMR in relieving angina pain has been well documented and adding new minimally invasive approaches could greatly expand the potential population of patients who could benefit from the procedure."

When performed with the CardioGenesis Holmium:YAG fiberoptic delivery system, TMR is a procedure that can be readily adapted to innovative minimally invasive approaches, which should be encouraging to cardiothoracic surgeons as these less invasive approaches can improve recovery time and dramatically reduce procedural morbidity and risk.

"We are working closely with the Johns Hopkins clinical and research teams and believe that thanks to the efforts of leading surgeons the potential of the minimally invasive approaches to TMR can truly be realized," Quinn added. "These minimally invasive approaches can make TMR a much more viable treatment option for needy patients and referring physicians, opening up this beneficial treatment to a greater number of patients suffering from severe cardiovascular disease."

6/30 **Medical Makeover Corporation of America** announced that it had opened its corporate office as well as its sales and marketing campaign with both print advertising and television commercial spots. The company expects to begin serving clients on an on going basis. When asked about this key event in the company's history, Dr. Leonard Weinstein, the president, CEO, and chairman stated: "We are very excited about the initiation of operations for Medical Makeover Corporation of America. This continues to demonstrate our commitment to swiftly achieving full operations in line with our forecasts."

Medical Makeover Corporation of America was incorporated under the laws of the State of Delaware and has entered into business in the medical makeover/anti-aging industry. MMAM provides a comprehensive approach to looking and feeling better through the modalities of cosmetic plastic surgery, dermatological surgery, cosmetic dentistry, hairstyling, fashion, and makeup services. MMAM is the first in the field to provide a comprehensive, team-based approach to our patients.

MMAM will primarily be serving the population between 35 and 75 years of age, or potentially 115 million people in the United States. The company will serve these clients through a contracted network of providers, initially in Miami-Dade, Broward, and Palm Beach Counties in the State of Florida. Through an aggressive marketing campaign, the company expects to generate significant customer volume for itself and its affiliated providers. These clients/patients will receive the benefit of the MMAM panel of board certified providers, as well as the convenience of the company's scheduling and concierge services.

MMAM's initial foray into the Florida market is a test of its concept and business model. After establishing the validity of its concept and business model, MMAM will evaluate specific markets in which to expand its business model. Assuming positive results, MMAM will expand into additional markets as Los Angeles, New York, and Atlanta. MMAM is also raising additional capital to establish its plan and concept as well as to enable it to expand into further markets.

7/1 **Diomed Holdings, Inc.** announced that the company had completed its realignment and expansion of its U.S. sales organization. Under the direction of Leo Griffin, vice president of North American Sales, the new organization includes two regional managers, twenty field sales representatives (recognized as EVLT Consultants) and two Field Clinical Specialists. "We have doubled the size of our field sales organization over the last six months," stated Griffin. "Our expanded sales organization is now strategically

located in all of the major population centers across the United States. Diomed's highly trained EVLT Consultants and Clinical Specialists are positioned to provide unparalleled post-sale physician training, reimbursement support and practice enhancement, including patient referral, advertising and promotion, to its rapidly expanding physician base."

"Achievement of this critical milestone will drive implementation of Diomed's strategic initiatives and accelerate EVLT market penetration," added James Wylie, president and CEO of Diomed. "We have assembled an exceptional team --- one of the finest with which I have ever been associated."

7/6 **Guidant Corporation** announced an agreement with **Miravant Medical Technologies**. According to the terms of the agreement, Guidant will collaborate with Miravant to develop photodynamic therapy for cardiovascular applications, including potential treatments for vulnerable plaque. Guidant also will make a staged equity investment in the company.

Miravant is developing photodynamic therapy as a minimally invasive interventional procedure for the treatment of patients with coronary artery disease. The therapy is approved in the United States for ophthalmology, oncology and dermatology applications. Currently under preclinical investigation, the company's catheter-based PhotoPoint technology uses a low-power, non-thermal light to activate an intravenously delivered light-reactive drug to treat regions of atherosclerotic plaque in blood vessel walls. In preclinical studies, photodynamic therapy has been shown to deplete inflammatory cells believed to be involved in cardiovascular disease progression, yielding up to 40% reduction in plaque volume. In addition, following treatment, studies showed that plaque had been replaced with non-proliferating smooth muscle cells, indicating a healing response and possibly limiting plaque re-growth.

"Vulnerable plaque is a silent killer that can cause a heart attack without warning. Guidant is actively pursuing interventional device-based therapies to treat the millions of patients with cardiac and vascular disease who have these potentially deadly lesions," said Dana Mead, president, **Vascular Intervention**, Guidant Corporation. "We are encouraged by Miravant's preclinical results, and look forward to collaborating with the company to further develop the potential of photodynamic therapy for vulnerable plaque applications."

According to Miravant, Guidant agreed to provide up to \$7 million capital in support of Miravant's PhotoPoint cardiovascular programs, including an upfront payment of \$3 million and additional staged investments based on the achievement of certain milestones through Phase I clinical trials. The development programs include regional treatments for atherosclerosis and atherosclerotic vulnerable plaque, representing large potential markets. Miravant plans to collaborate with Guidant on clinical development from facilities in Santa Barbara and Indianapolis.

"We are extremely pleased with Guidant's support and endorsement of PhotoPoint PDT as a potential treatment for patients with serious coronary artery diseases," said Gary Kledzik, Miravant chairman and CEO. "The benefit of Guidant's experience and consultation should focus our development efforts and help facilitate our progress towards human clinical studies."

7/7 As reported by the *Aesthetic Buyers Guide*: **Levulan Photodynamic Therapy Offers Effective Acne Treatment Alternative**

The rapidly increasing interest in Levulan photodynamic therapy (PDT) from **DUSA Pharmaceuticals, Inc.** to treat acne and other medical conditions can largely be traced back to the efforts of Rox Anderson, MD, research director of photomedicine at the Wellman Center, Massachusetts General Hospital, Boston. "I think light-activated drugs are extremely powerful," Dr. Anderson said. "The use of topical 5-aminolevulinic acid (ALA) is one of the early examples of what I expect to become a growing number of diverse drugs in the near future. I believe we are near the beginning of this cycle

It was four years ago, at the 2000 annual meeting of the *American Society for Laser Medicine and Surgery (ASLMS)*, that Dr. Anderson presented his seminal research on ALA PDT to treat acne. "This was the first paper to demonstrate that ALA would act as a light-activated drug against acne. There are basically two mechanisms involved at different doses. In the study, we were able to demonstrate that treatment inactivates the bacteria in the hair follicles that is part of the reason people develop acne. But much more exciting is that we were able to show that at high doses, treatment actually shuts down the sebaceous gland in the skin. This is great news because it has a long lasting effect. There was a strong effectiveness against even severe acne."

Dr. Anderson's original exposure to the novel compound was as an investigator for skin cancer. "When ALA enters the skin, it becomes metabolized. The skin cells turn it into a photosensitizer called porphyrin. Earlier, we had conducted a study showing that sebaceous glands were the most active part of the skin for producing porphyrins. Sebaceous glands are the root cause for the formation of acne."

"Although there are many different treatments for acne, we have no cures," observed Dr. Anderson. "We really need a cure, something that has a very long-term effect and treats the activity of the sebaceous gland. Drugs like isotretinoin (Accutane) are the only proven therapy to markedly impact the sebaceous gland. However, Accutane has fairly toxic side effects. We felt with our 2000 meeting presentation that we were on to something that could be used with a better safety profile and would have a long lasting effect against the disease."

A separate study of ALA, around the same time, was conducted in Japan by Yoshiyasu Itoh, MD. "Those results were similar to ours," Dr. Anderson conveyed. "However, back in 2000, ALA was not approved for anything. It was an experimental drug. Since then, the drug is on its way to being embraced by the aesthetic community. ALA is now FDA

approved for the treatment of actinic keratoses. Because the drug is approved, physicians can actually order it and many have begun off-label use to treat acne. I'm also optimistic about the recent work of looking at different light sources to activate ALA. The potential to use flashlamps, which are very fast treatment sources, with ALA to treat acne is certainly exciting."

As a physician, Dr. Anderson considers himself somewhere in the middle when it comes to implementing a wide range of applications for new technologies. "I like to undertake experiments and come up with new approaches to things, but it takes awhile before we really understand where it fits into the whole picture. Because Levulan PDT has shown that it can be very effective in treating acne, physicians are now starting to incorporate this therapy creatively into their practices. There is a kind of clinical creativity going on. ALA PDT actually treats a number of aspects of chronic sunlight injury to the skin. But I don't ever expect ALA to be able to remove blood vessels. PDT therapy really is meant to be used synergistically with lasers and other modalities of treatment."

Overall, Dr. Anderson believes that the use of Levulan PDT will continue to grow. "I think it will be useful for acne and other follicular disorders of the skin. My guess is that it will be used in two different modes. One is a low dose maintenance mode. I can even imagine combining ALA with sunscreens and letting the sun do the work for you. This would be a totally different approach. The other mode would be a high dose, office based procedure. I predict this approach will someday be used for severe acne. I also believe ALA has the potential to be as effective as oral retinoids. So ALA will likely become a very popular approach. But I don't think we will see ALA replacing our use of creams, topical retinoids, antibiotics and benzoyl peroxide."

7/7 A news release from **Cynosure**, provided some statistics from the 2003 *American Society of Aesthetic Plastic Surgeons* report on cosmetic surgery:

- The number of surgical and nonsurgical cosmetic procedures in the U.S. increased by 20% in 2003 to a total of nearly 8.3 million, nearly 4 times the 2.1 million procedures done in 1997. (And 6.9 million done in 2002.)
- Botox injections ranked first of all procedures, with an increase of 37%. Laser hair removal ranked second, with an increase of 25%. Other non-surgical procedure increases of note were: laser treatment of leg veins, up 222%; and laser skin resurfacing, up 76%.
- Non-surgical procedures accounted for 78% of the total, up 22% over 2002. Total expenditures for non-surgical procedures accounted for over 30% or nearly \$3 billion of the total physician fees.

Procedures, such as non-ablative facial rejuvenation including treatment of wrinkles, pigmented lesions and facial spider veins were not included in the ASAPS survey. Earlier, the *American Society of Dermatologic Surgeons (ASDS)* reported a 30% average



annual increase in non-ablative skin rejuvenation procedures performed by their 3500 members in the last 2 years.

Procedures done in selected categories in 2003 were:

- Laser skin resurfacing -- 127,470
- Laser treatment of leg veins -- 170,358
- Non-Ablative skin rejuvenation -- 233,964
- Laser hair removal -- 923,260
- Botox -- 2,272,080

7/9 **Spectranetics Corporation** announced that a successful case of a difficult to treat saphenous vein graft blockage was featured on the TCTMD website at [www.tctmd.com](http://www.tctmd.com). The treated patient was a 71 year-old male who had several blockages in multiple vessels, including the saphenous vein bypass graft. Blood flow was re-established using a 1.4 mm laser catheter followed by a 2.0 mm laser catheter and a balloon-mounted stent. No angiographic evidence of embolization or other types of complications were noted. "Complex cases of this nature are ideal laser cases and we are pleased this case was featured on the TCTMD website, given their large physician subscriber base and the significant number of cases submitted to TCTMD for their consideration on a weekly basis," said John Schulte, Spectranetics' president and CEO.

TCTMD is an outgrowth of the annual *Transcatheter Cardiovascular Therapeutics (TCT)* conference, which is sponsored by the *Cardiovascular Research Foundation* in New York City. The TCT conference is the largest international symposium designed for physicians and other healthcare professionals with a special interest in the field of interventional vascular therapy and vascular medicine.

7/12 **DUSA Pharmaceuticals, Inc.** announced increased second quarter Kerastick and BLU-U sales volumes, including initial sales in Canada. For Q2 2004, end-user Levulan Kerastick sales to physicians totaled 17,910, including 1,908 sold by **Coherent-AMT**, the Canadian marketing and distribution partner. This compared to 12,054 Kerastick units sold during Q1 2004 and 1,914 during Q2 2003, neither of which included any Canadian sales.

The number of BLU-U units placed in doctors' offices during the quarter also increased significantly, by 241, including 58 in Canada, compared with 128 during Q1 2004 and zero during Q2 2003. At the end of Q2 2004, there were 775 BLU-U units in doctors' offices, as compared to 534 at the end of Q1 2004, and 323 at the end of Q2 2003.

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "We are very pleased with the continuing strong increases in Kerastick and BLU-U sales. In fact, BLU-U placements nearly doubled compared to the prior quarter, and Kerastick volumes increased nearly 50%, which was especially impressive since the prior quarter included significant sales made during the *American Academy of Dermatology* meeting, the largest dermatology

conference of the year. Naturally, as we continue to invest in the development of our sales force, our sales and marketing costs will also continue to increase, but overall, we believe that DUSA is now well positioned to take advantage of the strong and increasing interest in our products during the remainder of 2004 and beyond."

- 7/13 The **Reliant** FRAXEL SR laser has now gained additional 510(k) clearances to treat pigmented lesions (including age spots, sun spots and skin discoloration) at any location on the body and periorbital (around the eye) wrinkles, joining the clearance obtained in 2003 for dermatological conditions requiring the coagulation of soft tissue.

As of July 1, 2004, the Reliant FRAXEL SR laser had FDA 510(k) clearance for:

- Dermatological procedures requiring the coagulation of soft tissue.
- Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and dyschromia.
- Treatment of periorbital wrinkles.

Reliant FRAXEL Laser Treatment is a breakthrough technology based on a new science of "fractional" skin repair. By treating a fraction of the skin's surface at a time, FRAXEL Laser Treatment provides the positive results of traditional skin resurfacing without the down time and risks. The first FRAXEL laser installations across the U.S. are scheduled for the fourth quarter of 2004, with widespread treatment available by January 2005.

The FDA clearances are based upon the clinical study of 30 patients with skin types I-III. These patients showed improvement in periorbital wrinkles and linear shrinkage in tissue as early as one week post-treatment. Minimal swelling and redness were the only side effects reported, and these resolved within 1-2 days. Treatment was well tolerated with minimal pain scores, largely due to spared tissue that remains between microthermal treatment zones.

"These three FDA clearances are based on two of six studies planned for completion in 2004," said Len DeBenedictis, Reliant president and CTO. "Patients, investigators and prominent, expert dermatologists agreed that there were compelling improvements in wrinkles, texture and discoloration after FRAXEL treatment, which is a powerful endorsement of the versatility and functionality of this new science and technology."

Reliant Technologies is positioned for growth and poised to become a new market leader in aesthetic laser medicine, surgery and biomedical technologies. Reliant is dedicated to fulfilling the promise of laser medicine by creating breakthrough systems focused on FRAXEL Laser Treatment. Reliant employs 50 professionals in two primary locations, San Diego and Palo Alto, California. For more information, visit **[www.reliant-tech.com](http://www.reliant-tech.com)**.

- 7/15 **PLC Systems** reported that the Center for Medicare and Medicaid Services (CMS) convened the Medicare Coverage Advisory Committee (MCAC) yesterday to review and discuss the evidence and clinical data regarding transmyocardial revascularization (TMR)

as it relates to Medicare patients with severe angina. The MCAC is an advisory panel consisting of clinicians and other medical experts which is used to supplement CMS's internal expertise. During the meeting, surgeons representing the *Society of Thoracic Surgeons (STS)* discussed with the MCAC panel the clinical data, evidence, and personal experiences that support the use of the TMR therapy.

"TMR has always enjoyed an active dialogue in the medical community, which fostered the lively discussions at today's meeting," said Mark Tauscher, president and CEO of PLC Systems. "We believe that the MCAC process provided valuable information to the Panel, to industry participants and to clinicians. We look forward to working with the medical community in this process to continue to add to the clinical body of evidence that supports the use of TMR for patients suffering from severe angina."

Since FDA approval in 1998 and CMS's reimbursement coverage decision in 1999, several well-qualified technical assessment bodies and physician specialty societies have analyzed available TMR data. These organizations have concluded that the evidence favorably supports TMR for certain patients, and/or that TMR provides significant angina relief in certain patients. These assessments or practice guidelines include:

- \* Society of Thoracic Surgeons (STS) Workforce on Evidence-Based Surgery 2004;
- \* American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines 2002 (published 2003);
- \* Blue Cross and Blue Shield Association (BCBSA) Technology Evaluation Center Assessment on TMR as an Adjunct to CABG Surgery for the Treatment of Coronary Artery Disease 2001, reviewed in 2004;
- \* The Agency for Healthcare Research and Quality (AHRQ) Technology Assessment of Percutaneous Myocardial Laser Revascularization and Transmyocardial Laser Revascularization 2004;
- \* ECRI Technology Assessment Report on Transmyocardial Laser Revascularization (TMR)/ Percutaneous Myocardial Laser Revascularization (PMR) for Treatment of Refractory Angina 2004.

7/15 *The Vascular Disease Foundation (VDF)* announced that **Diomed Holdings, Inc.**, is the inaugural member of the Foundation's new National Advisory Board and will sponsor a portion of the Foundation's website dedicated to venous disease. Diomed's president and CEO, James Wylie, Jr., will serve on behalf of the company on the Foundation's Advisory Board.

"We are delighted to announce that Diomed has made a significant commitment to the Vascular Disease Foundation's future," said Peter Gloviczki, MD, president of VDF's board of directors. "The goal of the Vascular Disease Foundation's new National Advisory Board is to reduce the mortality and morbidity from vascular diseases. The Advisory Board is allied with the Foundation in the belief that patient quality of life and longevity can be improved through education and prevention, prompt diagnosis, comprehensive treatment and effective rehabilitation of arterial and venous disease. The

VDF website offers guidance to thousands of visitors each month with educational support from companies such as Diomed."

Founded in 1998, VDF is one of the country's leading nonprofit information and education resource on the diagnosis and management of vascular diseases.

Commenting on the Advisory Board inauguration and web site sponsorship, James Wylie, Diomed president and CEO, said, "It is really an honor to be working with the VDF in their endeavor to provide useful, timely and accurate information to thousands of patients. The VDF's mandate to inform patients about the array of vascular diseases is perfectly in line with Diomed's mandate to provide the latest in chronic venous disease treatment alternatives."

Wylie said that it is estimated that more than 25 million Americans are affected by varicose veins or more severe forms of chronic venous disease and that Diomed is committed to provide solutions to this issue. "Our membership in the VDF National Advisory Board and our VDF website sponsorship is part of a broader Diomed initiative to help advance patient education while supporting worthy causes surrounding vascular disease."

- 7/15 Kathy Kincade, editor of **Medical Laser Report**, wrote the following article on laser dentistry that appeared in the July issue of the newsletter: **Diode-laser use expands in dentistry**

For years, technology developers and market analysts have considered the dental field to be a goldmine for lasers. But with 600,000 dentists worldwide—170,000 of them in the United States—and only 3% market penetration so far, dental-laser systems manufacturers have clearly met with limited success.

These days, however, it appears that their optimism might finally pay off. End-user interest in lasers for dental applications is on the rise, due in large part to growing public demand (the Biolase investment in marketing and advertising of its Waterlase technology has been a boon to the entire dental-laser industry, according to several manufacturers) and to technological advances that have yielded more reliable products with increased energy levels and more application-specific accessories. The result is that more dentists are now able to perform a wider variety of applications, and often at lower cost.

In particular, diode-laser systems are finding increasing favor in the dental market. Suppliers of diode lasers say they are experiencing steady growth in demand for their products from dental-laser system manufacturers, and several companies are now marketing diode-laser systems for hard- and soft-tissue dental applications:

— **OpusDent**, a subsidiary of **Lumenis** (Yokneam, Israel), offers a complete line of dental lasers, including the Opus 5, a 5-W 830- nm diode laser, and the Opus 10, a 10-W 830- nm diode laser for soft tissue management and tooth whitening.

— **ZAP Lasers** (Pleasant Hill, CA) is targeting dental hygienists with its SoftLase diode-laser system, which sells for under \$10,000.

— **Ivoclar/Vivadent** (Amherst, NY) is marketing its Odyssey diode laser system for \$11,000. The Odyssey soft-tissue diode laser can be used for a variety of procedures, including:

- Gingivectomy, gingivoplasty, operculectomy
- Crown lengthening
- Recovering dental implants
- Treating inflammation around implants
- Troughing for impressions
- Frenectomy
- Reducing sulcular oral bacteria and other flora
- Recontouring interproximal tissue
- Accelerating healing for split lips
- Soft tissue debridement
- Reducing hyperplasia

— **BioLase** (San Clemente, CA) launched a new dental laser product in May for cosmetic, soft tissue, and periodontal dental procedures. The Diolase Plus, priced at \$10,900, delivers 7 W of power and, according to the company, has many cosmetic and soft-tissue applications, including soft tissue curettage; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; and removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

"Dentists are increasingly reluctant to sit on the sidelines with all the push-pull advertising that is going on," said Bob Gregg, co-founder of **Millenium Dental Technologies** (Cerritos, CA), which offers pulsed Nd:YAG lasers for periodontal applications. "Diodes are inexpensive and allow the less committed dentists to get in on the trend without spending a lot of money."

Looking ahead, additional advances in diode-laser technology will further impact the capabilities and adoption of diode lasers for dentistry. For example, according to Jeff Manni, head of **JGM Associates** (Burlington, MA) -- which published the market/technology report, "Dental Applications of Advanced Lasers," in 2003 -- single-emitter diode lasers may soon be available that provide as much as 8W of CW out-put power; single-emitter diode lasers are much easier to fiber-couple than diode laser bars, or "half-bars. This could pave the way for fiber-coupled diode lasers that deliver 6–7 W through a standard 320- $\mu$ m, 0.22 NA fiber, as is typically used in dentistry for soft-tissue surgical procedures. More important, the sell price of such a laser to dentists could be well under \$10,000, while still providing an attractive profit for the dental laser supplier."

According to Manni, a sell price substantially less than \$10,000 should help diode lasers further penetrate the dental market and bring the benefits of laser soft tissue management to a wider patient base.

- 7/15 **WaveLight Laser Technologie AG** announced that it had received FDA clearance to market its MYDON and SINON aesthetics laser systems on the US medical laser market. The 510(k) marketing clearance was based on the positive review and approval of the aesthetic applications in accordance with the Food, Drug and Cosmetic Act. Effective immediately, the MYDON and SINON laser systems can be marketed and used in treatment by hospitals and doctor's clinics in the USA, providing US practitioners with a broad range of cosmetic-aesthetic laser treatment options. SINON is a versatile ruby laser system used for the treatment of pigmented skin alterations such as age and pigment spots as well as tattoo removal. The MYDON Neodymium YAG laser is recommended for the removal of vascular skin alterations such as spider veins. The system is also suited for skin rejuvenation. In practical applications, both laser systems produced excellent patient results coupled with very flexible handling.

Following the October 2003 FDA approval of ALLEGRETTO WAVE for refractive surgery in the US market, the approval of the MYDON and SINON aesthetic lasers is another important step for WaveLight Laser Technologie AG on its dynamic global growth path. Marketing clearance for the world's most lucrative medical laser market is dependent on compliance with high quality and safety standards and is therefore regarded as an international "seal of approval" for particularly well-developed and safe medical technology.

"The successful US market launch of ALLEGRETTO WAVE last fall was an important milestone in the history of our young company. Marketing clearance for our MYDON and SINON lasers is a further step in our sustainable growth strategy. We will continue to expand our international market presence in the aesthetics segment," said Max Reindl, founder and CEO of WaveLight Laser Technologie AG, commenting on the successful news from the division. As part of its US marketing strategy, WaveLight will supply its newly approved aesthetic applications to a number of highly experienced specialized physicians. These luminaries will actively support the Erlangen, Germany based laser manufacturer in evaluating patient results as well as quality control. In addition, they will act as important market multipliers worldwide.

- 7/16 **CardioGenesis Corporation** announced that the Medicare Coverage Advisory Committee (MCAC) reviewed more than six years of clinical evidence regarding laser myocardial revascularization as a treatment for patients suffering from severe angina pain. The committee members' assessments of the clinical evidence will be forwarded to the Centers for Medicare & Medicaid Services (CMS), the government agency charged with making medical coverage decisions for Medicare. CMS does not have any pending National Coverage Analysis relating to laser myocardial revascularization.

Medicare has covered TMR since 1999 for patients with severe angina who do not respond to standard medical therapy. The U.S. Food and Drug Administration approved the CardioGenesis TMR system in 1999.

The MCAC members responded individually to a set of questions designed to elicit their assessment of an evaluative survey of the body of scientific evidence concerning the safety and effectiveness of laser myocardial revascularization. The evidence was contained in a technology assessment presented by the Agency for Healthcare Quality & Research of the various forms of myocardial revascularization therapy.

As part of its deliberations, the committee heard testimony from a group of leading physicians regarding TMR. The group included Robert Guyton, MD, immediate past president of the *Society of Thoracic Surgeons (STS)* and Chief of Cardiothoracic Surgery, Emory University School of Medicine; Bruce Ferguson Jr., MD, Chief of Cardiac Surgery at New Orleans-based LSU Health Sciences Center; Keith Horvath, MD, Associate Professor of Cardiothoracic Surgery, Northwestern University Medical School; and Kurt Wehberg, MD, Director of the Multidisciplinary Thoracic Oncology Center and the TMR program at Peninsula Regional Medical Center in Salisbury, MD.

"The public meeting provided an excellent opportunity to present and explain to the Medicare community the scientific and clinical evidence regarding TMR -- from the clinicians who treat the patients," said CardioGenesis chairman and CEO Michael Quinn. "These clinicians, who work closely with patients suffering from angina and have first-hand experience with TMR, are perhaps in the best position to assess the therapy's life-enhancing potential. Certainly the assessment of TMR presented by the leadership of the Society of Thoracic Surgeons indicates the progress achieved in recognizing the clinical importance of the therapy by the physicians who perform the procedure."

Quinn added, "It is encouraging to us to see all of the participants in this CMS process clearly focused on patient care and outcomes in this review and assessment of TMR. We look forward to working in cooperation with health care providers (including STS and the American College of Cardiology), payors (including CMS and Blue Cross) and the FDA in continuing to develop the body of evidence regarding laser myocardial revascularization."

7/16 **Medical Makeover Corporation of America** announced that Walter Birch, CFO, had been featured on **Wallstreetcorner.com**.

Medical Makeover has current operations in the Florida market which are a test of its concept and business model. After thorough evaluation, and assuming positive results, Medical Makeover will look to expand the business model into additional markets, primarily Los Angeles, New York, and Atlanta.

In his article, Larry Oakley explained the products and services Medical Makeover Corporation of America offered, including cosmetic plastic surgery, dermatological

surgery, cosmetic surgery, and many others. According to Oakley, "This is a hot industry that has grown at a rate of over 30% per year."

Walter Birch, CFO, stated, "Our key advantages are that we create a pleasant, one-on-one experience for the customer, and act as an effective marketing service for the professional providers with whom we contract the services required. Customers like the way they are treated. It's a very pleasant experience for both customer and provider."

7/16 **BIOLASE Technology, Inc.** announced preliminary results for the second quarter ended June 30, 2004. Total revenue was anticipated to be in the range of \$14.6 million to \$14.8 million. Earnings for the second quarter 2004 were expected to be similar to first quarter 2004. Revenue for the first half of 2004 was expected to be approximately \$29.0 million to \$29.3 million, representing a year-over-year growth rate of approximately 48% to 50% when compared to first half revenue for 2003 of \$19.6 million.

Jeffrey Jones, CEO and president, stated, "Although our preliminary results for the second quarter are below analyst expectations, we ended the quarter on a strong note with solid momentum heading into the second half of 2004. The company exceeded analyst expectations in the first quarter while second quarter preliminary results reflect lower than analyst expectations. We historically generate approximately 42% to 43% of our sales in the first half of the year, so we anticipate our year-over-year sales growth for fiscal 2004 to be in the range of 40% to 50%. We are confident in the continued success and growth of our technology and products."

The second quarter outlook announced today was preliminary and subject to change as a result of final review by management and closing adjustments for the quarter. BIOLASE expects to report final second quarter results on July 27, 2004.

**Second Half Guidance for 2004:** Revenue for the third quarter of 2004 is expected to be in the range of \$15 million to \$16 million and for the fourth quarter is expected to be in the range of \$23 million to \$25 million. This compares with non-GAAP revenue of \$10.7 million for the third quarter of 2003 and non-GAAP revenue of \$15.7 million for the fourth quarter of 2003, which excludes \$2.7 million and \$0.4 million of revenue that was deferred to the third and fourth quarter of 2003 as a result of the restatement of revenues, respectively. The non-GAAP revenue numbers presented are not in accordance with generally accepted principles but are presented to provide a clearer understanding of the impact to the company's results for changes in revenue recognition. You should not consider this presentation in isolation or as a substitute for analyzing our results under GAAP.

7/19 **BIOLASE Technology, Inc.** announced that BIOLASE's Board of Directors had authorized a 1.25 million share repurchase program. Pursuant to the authorization, BIOLASE may purchase shares from time to time in the open market or through privately negotiated transactions over the next 12 months.



"Given the company's long-term outlook, cash flow generation and solid balance sheet, the Board believes a share repurchase program represents an excellent use of capital that will greatly enhance shareholder value over the long term," said Federico Pignatelli, BIOLASE's chairman. BIOLASE currently has approximately \$50 million in cash. The company has no obligation to repurchase shares under the share repurchase program, and the timing, actual number and value of shares to be purchased will depend on market conditions. BIOLASE has approximately 24.3 million shares outstanding and has an approximate public float of 23.7 million shares.

7/20 **Spectranetics Corporation** reported financial results for the second quarter ended June 30, 2004. Revenue totaled a record \$8.7 million, a 32% increase over \$6.5 million during the second quarter of 2003. Net income during the second quarter was \$401,000 (1 cent per share) up sharply from \$53,000 (0 cents per share) last year. The increase in second quarter revenue was led by disposable product revenue (which includes atherectomy and lead removal product sales), which increased 27% to \$6.6 million compared with \$5.2 million last year. Atherectomy and lead removal sales were up 43% and 13%, respectively. Atherectomy revenue included sales of \$1.0 million from the recently FDA-approved larger diameter catheters which range in size from 2.0 to 2.6 mm in diameter and which are marketed under the CLiRpath brand. FDA clearance for these new products was received on April 29, 2004 for use in total occlusions in the legs that cannot be crossed with a guidewire.

Equipment product revenue (which includes laser hardware sales and rental fees) for the quarter was \$0.7 million, up from \$0.4 million for the same period last year. The worldwide installed base grew to 394 laser systems at June 30, 2004 (293 in the United States), a net increase of six units during the quarter, versus seven units sold during the same quarter last year. Service and other revenue rose 47% to \$1.3 million, compared with \$0.9 million during the same quarter last year.

Gross margins strengthened to 75% for the second quarter of 2004, up from 73% last year, reflecting improved margins across all product lines, which included the benefit of manufacturing efficiencies realized as a result of the higher volume of catheters produced and sold. Operating expenses for the second quarter of 2004 rose 30% to \$6.2 million from \$4.7 million during the same quarter last year, due to the planned CLiRpath product launch that commenced in May 2004, higher royalties and commissions related to higher sales, increased general and administrative costs associated with Sarbanes-Oxley compliance and increased costs as a result of clinical trial activities in the area of a laser-based treatment for heart attacks.

John Schulte, president and CEO, said, "This quarter we delivered record revenue and continued sequential-quarter revenue growth reflecting improvement in all areas of our business. This strong performance is a reflection of our strategy to focus on disposable growth through increased penetration of our current markets in coronary atherectomy and lead removal, coupled with expansion into a new market segment -- peripheral vascular disease." Schulte added, "Our near-term clinical efforts are focused on extending the

application of our laser catheters to treat heart attacks, which is a potential \$200 million market in the U.S. alone. This quarter we received FDA clearance for the FAMILI study. The goal of this feasibility study is to determine if treating heart attacks with the laser restores blood flow and reduces the infarct size, or amount of dead heart muscle. If the clinical data warrants, it is likely we will initiate a randomized trial during 2005.

"This year's financial guidance, which was introduced in February, projects revenue growth of 5% to 7% driven primarily by an increase in disposable product sales, and did not include revenue contributions from our then yet-to-be-approved CLiRpath catheters. Net income projections of between \$500,000 and \$1 million did, however, reflect certain costs in anticipation of the CLiRpath product launch and a continued focus on product development and clinical research programs. By the time we report our third quarter financial results in October, we believe we will have sufficient data on sales trends and re-order rates for CLiRpath to allow us to provide an update on the current 2004 financial guidance," Schulte concluded.

**Year-to-Date Financial Results:** Net income for the six months ended June 30, 2004 was \$536,000 (2 cents per share) compared with \$194,000 (1 cent per share) during the first half of 2003. Revenue for the first half of 2004 rose 22% to \$16.4 million from \$13.5 million for the first half of 2003. Year-to-date 2004 disposable product revenue was \$12.3 million, up 20% compared with the same period last year. Atherectomy and lead removal revenue increased 34% and 8%, respectively. Laser equipment placements totaled 11 compared with 8 for the same period last year, and equipment revenue was essentially flat at \$1.5 million in both periods. Service and other revenue rose 47% to \$2.7 million from \$1.9 million for the 2003 six-month period.

Gross margins for the first half of 2004 were 74% compared with 71% in the first half of 2003, and were favorably impacted by product mix and manufacturing efficiencies resulting from higher volumes. Cash, cash equivalents and investment securities totaled \$16.0 million at June 30, 2004, up from \$13.2 million at December 31, 2003.

## **MEDICAL/SURGICAL LASER UPDATE -- August 2004**

7/20 As published by Rich Duprey of *Motley Fool*: **Lasers Lose Focus**

It didn't take Austin Powers' Dr. Evil using a "lay-zer" to singe **Biolase Technology's** stock price. It was only necessary for the maker of dental, cosmetic, and surgical lasers to report that second-quarter earnings will be flat for investors to be scared off. Biolase's premier product, the Waterlase, is a dental laser that spins and explodes a blast of water, light, and air without the noise -- or pain -- of a traditional drill. Despite being popular, distributors have plenty in stock, and sales are expected to be flat. As much as the markets don't like uncertainty, they don't like to be certainly wrong, either. Analysts had expected EPS of \$.06 next quarter, and the company was forecasting \$.03 per share. Biolase fell by more than 25% on the news. It seems as though painless dentistry can still be painful to shareholders.

Still, it's an industry built upon technological improvements, a game of one-upmanship. What is the market leader today may very well be the market laggard tomorrow. Dental and cosmetic laser companies are a competitive bunch, and the industry has seen lots of consolidation even as the sector has been under strain lately. Leaders such as **Candela** missed analyst projections but gave higher guidance for the year and still saw the stock knocked down. **Palomar Medical Technologies** and **LaserScope** did Mini Me routines, reporting good numbers but sliding nonetheless. **BriteSmile**, which traded as high as almost \$20 last year, has seen its stock price halved.

The industry is still primed for growth, with expectations as high as 45% or more. The cost of owning a laser is shrinking, opening up opportunities for more small businesses, including non-medical offices, to own one. It's profitable, too. Margins tend to be high, 50%-60% or more, which makes it attractive for competitors wanting to get in on the game. There are a lot of smaller players in the field, companies that trade on the OTC bulletin board, such as **Valley Forge Scientific**, or in the pink sheets, such as **Lumenis** and **American Medical Technologies**.

At the same time as the earnings announcement, Biolase reported a 1.25 million share repurchase program over the next 12 months. Share buybacks, at least ones that are done to reduce the number of shares outstanding and not merely offset stock option programs, can significantly increase shareholder value and are a good use of cash. Considering that investors did not like the company's earnings report, it looks as though they gave management an excellent opportunity to begin buying right away.

Biolase sports trailing structural free cash flow of more than \$20 million. It has no long-term debt and more than \$50 million cash in the bank. It's a strong, clean balance sheet. If the company can avert any more disasters (it's in litigation over patent infringement of its Waterlase; it had to restate earnings going back to 2000; and the SEC contacted it regarding an informal inquiry), this could eventually be a company with some good potential.

7/26 **Lumenis Ltd.** announced that its IPL Quantum SR is the only Intense Pulsed Light (IPL) system that will be used as part of a new multicenter Phase II clinical study to be carried out at four locations in the U.S. by **DUSA Pharmaceuticals, Inc.**, with whom Lumenis has signed a development agreement. Lumenis was the first to introduce IPL technology into the aesthetic market. IPL provides gentle, non-ablative treatments that remove sun-induced freckles, most benign brown pigments, and redness caused by broken capillaries.

The multicenter study will focus on rejuvenation of photodamaged skin, a condition commonly resulting from exposure to sunlight. Published reports from leading physicians indicate that the DUSA drug Levulan, when used in conjunction with the IPL Quantum SR, may optimize non-ablative photorejuvenation of damaged skin.

Dr. Mitchel Goldman (La Jolla, CA), co-author of one of the published reports, stated, "As the developer of IPL and the continued leader in the creation of the most innovative IPL systems, Lumenis was the logical choice as the only IPL partner with DUSA in these very important clinical studies. We expect these studies to clearly demonstrate the significant enhancing effect of Levulan on skin treatments using photorejuvenation. As a result, millions of patients worldwide will benefit from the efforts of these two industry leaders."

The first of two phases in the clinical study will involve up to 64 patients and will establish the best light dosages for photodynamic therapy using the IPL Quantum SR. The second phase will involve up to 60 patients who will receive multiple treatments of fixed light doses. In both phases of the study, one side of each patient's face will be selected at random to receive a control treatment. The alternate side will be treated topically with Levulan.

The study will seek to demonstrate that treatment is improved when IPL is used in conjunction with Levulan. The combined procedure potentially brings great advantages to the thousands of Lumenis IPL systems now in use worldwide.

7/27 **BIOLASE Technology, Inc.** reported financial results for the three month and six month periods ended June 30, 2004. Net sales for the second quarter of 2004 were \$14.8 million compared to net sales of \$10.4 million for the three months ended June 30, 2003. Sales of the company's principal product, the Waterlase system, for the second quarter of 2004 comprised 82% of sales, compared to 81% of sales in the second quarter of 2003.

Net sales for the first half of 2004 were \$29.2 million, representing a year-over-year growth rate of 49% when compared to first half net sales for 2003 of \$19.6 million.

Gross profit for the second quarter of 2004 was \$9.7 million, an increase of approximately 53% over gross profit of \$6.4 million for the prior year same period. Gross margin was 66% for the second quarter of 2004 compared to 61% for the second quarter of 2003.

Operating expenses were \$8.7 million for the second quarter of 2004 compared to \$5.2 million for the second quarter of 2003. Sales and marketing expenses were \$6.2 million for the second quarter of 2004 or 42% of sales, as compared to \$3.6 million for the prior year same period or 35% of sales. The increase in sales and marketing is related to the expansion of our sales force as well as increased marketing expenses related to new and ongoing associations with education and dental institutes. General and administrative costs were \$1.8 million for the second quarter of 2004 or 12% of sales, as compared to \$1.0 million for the second quarter of 2003 or 10% of sales. Increases in general and administrative expenses are due mostly to increased costs associated with legal and professional fees, insurance costs and shareholder communication expenses associated with the company's proxy and annual report distribution. Engineering and development

costs were \$706,000 for the second quarter of 2004 or 5% of sales, as compared to \$521,000 for the prior year same period or 5% of sales.

Income before income taxes was \$1.2 million for the second quarter of 2004 compared with \$1.3 million for the second quarter of 2003. After the provision for income tax of \$461,000, net income for the second quarter of 2004 was \$716,000 (3 cents per share). For the second quarter of 2003, net income with no provision for income tax was \$1.3 million (5 cents per share).

When comparing the second quarter of 2004 to the prior year same quarter, the results are not directly comparable. In the second quarter of 2003, we recognized revenue essentially on a cash basis for domestic sales; whereas we currently recognize revenue on an accrual basis at the time of shipment.

Additionally, no income tax expense was recognized in the second quarter of 2003 because the company had not determined at that time that the realization of its deferred tax assets were more likely than not realizable.

Jeffrey Jones, CEO and president, stated, "Although our results for the second quarter are below analyst expectations, we ended the quarter on a strong note with solid momentum heading into the second half of 2004. The company exceeded analyst expectations in the first quarter while second quarter results reflect lower than analyst expectations. For the past three years, we historically generated approximately 42% to 43% of our sales in the first half of the year, so we anticipate our year-over-year sales growth for fiscal 2004 to be in the range of 40% to 50%. We expect revenue for the third quarter of 2004 to be in the range of \$15 million to \$16 million and for the fourth quarter to be in the range of \$23 million to \$25 million. Based on the fact that 57% to 58% of our revenue is generated in the second half of the year, we believe our first half revenue and guidance for the coming quarters are in line with achieving our fiscal year revenue targets of \$68 million to \$69 million for 2004."

"We are focusing on increased penetration to the largest potential market for medical lasers. We believe the mid- and long-term success and health of the company requires a continued investment in education, sales and marketing and product development. And as we continue our expected revenue growth, we anticipate that our mid- and long-term gross and operating margins will expand accordingly."

"We are pleased to report on the company's two recent corporate finance initiatives. First, the company has been active in the market over the past week in repurchasing shares. As a management team, we firmly believe in the company's long-term outlook and believe that a share repurchase represents a great use of the company's capital today. Second, we announced the Board's decision to declare a regular cash dividend of \$0.01 per share every other month. We believe that a consistent dividend program is a strong sign of BIOLASE's financial strength."

As noted above, the company's Board of Directors voted to change the company's dividend policy to pay a regular cash dividend of \$0.01 per share every other month. The first dividend will be payable August 30, 2004 to shareholders of record on August 16, 2004. "We are very pleased to announce a regular dividend program for the first time in the company's history. We believe that a consistent dividend program is a further sign of BIOLASE's financial strength and improved business outlook. It is our objective to reward our shareholders with cash dividends as well as increasing share appreciation. Additionally, we believe that a regular dividend program will attract long-term institutional investors that are interested in emerging growth companies like BIOLASE, but are constrained by investment charters requiring regular dividend payments," said Federico Pignatelli, BIOLASE's chairman.

7/28 **Laserscope** reported record revenues of \$21.4 million for its second quarter ended June 30, 2004, a 67% increase in revenues from \$12.9 million in the year-ago quarter. Sequentially, revenues increased 14% from \$18.8 million for the quarter ended March 31, 2004. Second quarter 2004 net income was \$3.0 million, or \$0.13 per diluted share, compared with net income of \$348,000, or \$0.02 per diluted share, in the same quarter last year, and net income of \$2.2 million, or \$0.10 per diluted share, for the first quarter of 2004.

"We are very pleased with our performance this quarter as we executed well in all areas of our business," said Eric Reuter, president and CEO of Laserscope. "As a result, we are continuing to see solid and accelerating improvements in our core metrics of revenue, gross margins and profitability. During the quarter, we had very strong growth in our PVP urology business. PVP, or Photo-Selective Vaporization of the prostate, is our innovative solution for treating Benign Prostatic Hyperplasia (BPH) using our proprietary GreenLight PVP system. This procedure is being increasingly recognized by leading medical authorities and industry experts around the world as the new standard of care for treating BPH.

"GreenLight PVP system and disposable fiber optic sales are continuing to drive impressive financial performance both domestically and internationally, and we believe that the combination of fast growing acceptance of PVP and a large worldwide market for the procedure will continue to fuel significant additional growth in the future."

Gross margin for the second quarter of 2004 was approximately 57%, compared with approximately 50% for the second quarter of fiscal 2003 and approximately 56% for the first quarter of 2004, primarily as the result of changes in product mix. Selling, general and administrative expenses were \$8.2 million, or 38% of revenues, in the second quarter of 2004, compared with \$5.0 million, or 39% of revenues, in the year-ago quarter. Increased SG&A spending resulted primarily from higher sales and marketing expenses relating to the company's GreenLight PV products, as well as higher direct selling expenses for the company's domestic aesthetic products and higher expenses relating to ensuring Sarbanes-Oxley compliance.

The company further strengthened its balance sheet during the quarter. At June 30, 2004, Laserscope had no short-term bank borrowings and a cash position of \$10.4 million, up from \$7.2 million at the end of 2003.

**Urology Business:** "During the second quarter we sold a record 58 GreenLight PV laser systems and increased sequential fiber volume by 33% to 8,490 fibers, outpacing our first quarter successes during which we sold 49 systems and 6,403 fibers. We believe this quarter's rapid fiber sales continue to validate the procedure's increased worldwide adoption. We are also seeing an increasing level of excitement and performance in our international urology business and are looking forward to a record year from our international team."

Beginning July 1, 2004, Laserscope raised the price of its fibers in the U.S. from per unit list prices of \$670 to \$820, depending on region, to a uniform list price of \$875 per unit throughout the United States.

"We believe that certain of our customers may have built inventory during the second quarter in anticipation of the price increase," said Reuter. "Although this may affect the rate of U.S. fiber revenue growth during the third quarter relative to the second, we don't expect that it will materially impact the business or our financial results for the year. Our practice is to encourage our customers not to hold inventory, but rather order fibers based on actual procedure demand."

**Aesthetics Business:** "In addition to the substantial gains in our urology business, revenues in our aesthetics business were up strongly as well, increasing about 22% worldwide compared to the prior year. This growth was led by our newest aesthetic product, the versatile Gemini Laser and another fine performance by our U.S. sales and marketing organization," said Reuter. "The Gemini was recently FDA-cleared for the treatment of acne, permanent hair reduction and wrinkle reduction, and is now FDA-cleared for a total of 21 different procedures. This laser system can perform over 90% of all aesthetic laser procedures now available in a physician's office and we continue to see strong preliminary acceptance and demand for the product in the marketplace."

**Six-Month Results:** For the six months ended June 30, 2004, the company reported revenues of \$40.2 million and net income of \$5.2 million (23 cents per share) compared with revenues of \$25.3 million and net income of \$483,000 (2 cents per share) for the same period in 2003. "Clearly, the momentum in our business has not slowed down, and has, in fact, accelerated over the past several quarters" said Reuter. "Our business plan is highly focused and our team is successfully executing against it. As we continue to work toward increasing the visibility of our outstanding product line in the market, we look forward to a strong and productive year."

**Guidance:** As the result of its continued strong performance, Laserscope is increasing its previous 2004 guidance in the areas of revenues, gross margin, profitability and worldwide GreenLight fiber sales:

- \* Revenue is expected to be approximately \$88 million in 2004, with most of the revenue growth for the balance of the year occurring in the traditionally strong fourth quarter.

- \* Gross margin, as a percentage of 2004 revenues, is expected to be in the range of 58% - 61% for the full year.

- \* Net income per share is expected to be in the range of \$0.55 - \$0.60 per diluted share due to enhanced business prospects and also assuming a tax rate of approximately 9% (previously 13%). The company expects continued growth in profitability with the highest level of growth occurring in the traditionally strong fourth quarter.

- \* GreenLight fiber sales worldwide are expected to be in the range of 33,000 - 35,000 for the full year.

7/28 **PLC Systems Inc.** reported financial results for the three and six months ended June 30, 2004. Second quarter total revenues were \$1.8 million compared with \$2.0 million in the second quarter of 2003. The net loss for the second quarter of 2004 was \$251,000 (1 cent per share) compared to net income of \$203,000 (1 cent per share) in the second quarter of 2003.

Total revenues for the six months ended June 30, 2004 were \$3.7 million compared to total revenues of \$3.7 million for the six months ended June 30, 2003. The net loss for the six months ended June 30, 2004 was \$601,000 (2 cents per share) compared to net income of \$218,000 (1 cent per share) for the six months ended June 30, 2003.

"We made significant progress in executing our plan to grow PLC beyond its single product focus during the past two quarters," stated Mark Tauscher, president and CEO of PLC Systems. "As we entered this year, PLC was a single product medical device company. As a result of our efforts, we believe that PLC is on target to enter next year as a company with an expanded product portfolio and a bright future. During the quarter, the TMR business continued at a reasonable pace and we made positive advancements in our new business initiatives. The Optimaze project is on schedule and we believe that it will generate revenue for PLC in the first quarter of 2005."

During the second quarter of 2004, 11 next-generation CO2 Heart Lasers (HL2) were delivered to United States hospitals through **Edwards Lifesciences Corporation**, PLC's exclusive U.S. sales and marketing partner. Six of the 11 HL2 shipments were new lasers and five were redeployed lasers. PLC ended the second quarter of 2004 with 168 CO2 Heart Lasers located at heart centers throughout the U.S., comprised of 120 HL2



customers and 48 HL1 customers. As of June 30, 2004, PLC's U.S. laser base (HL1 and HL2) had increased by 17% during the preceding twelve months. More significantly, PLC's U.S. HL2 installed base grew to 120 lasers as of June 30, 2004, up 35% from June 30, 2003.

During the second quarter of 2004, Edwards delivered 502 disposable kits to United States hospitals. In the second quarter of 2003, a total of 524 disposable kits were shipped to United States hospitals. A total of 382 disposable kits were delivered domestically during the first quarter of 2004.

Tauscher concluded, "As we drive toward generating revenue in 2005 from the Optimize project, our key objectives are as follows: infrastructure build out completed in the third quarter; infrastructure validation completed in the fourth quarter; Optimize laser product release in the fourth quarter; and Optimize disposable hand piece product release in the first quarter of 2005."

7/29 **Diomed Holdings, Inc.** announced results for the second quarter ended June 30, 2004. Diomed delivered revenue of \$3.2 million, an increase of \$1.0 million, or 48%, over the second quarter of fiscal year 2003. Revenue from the EVLT product line increased by 65%, including an 89% increase in revenue from EVLT disposable procedure products during the period.

"Our strong second quarter performance reflects significant progress towards the global commercialization of our EVLT product line", commented James Wylie, president and CEO of Diomed Holdings. "Diomed's installed EVLT base now exceeds 450 systems worldwide."

Revenue for the six-months-ended June 30, 2004 of \$6.1 million increased \$1.9 million, or 44% over the first six-months of 2003, while EVLT sales increased 59%. Revenue from EVLT disposable procedure products increased 96% during the six month period.

"We have achieved six quarters of consecutive revenue growth since reorganizing the executive management team during the first quarter of 2003," added Wylie. "Second quarter revenue increased 8% sequentially, concurrent with the retooling of our US sales organization. With our new team of 20 sales reps and 2 clinical specialists in place, we look forward to realizing the full potential of this revitalized organization."

Net loss applicable to common stockholders, adjusted for the one-for-twenty-five reverse stock split effective June 17, 2004, for Q2 2004 was \$2.1 million (14 cents per share) compared to \$1.8 million (\$1.48 per share) in the second quarter of 2003, and \$4.4 million (31 cents per share) for the six months ended June 30, 2004, compared to \$3.8 million (\$4.11 per share) for the same period 2003.

**Liquidity and Capital Resources:** The ending cash balance of \$9.2 million reflected a \$4.2 million reduction in cash during the six months and included \$2.3 million in Q1

2004 payments not expected to recur in the remaining quarters of 2004; specifically \$1.2 million in debt repayments, \$261,000 in costs related to the 2003 equity financing, and \$875,000 in annual insurance premiums and other annual costs which benefit future quarters.

On April 20, 2004, Diomed announced the completion of its offering to shareholders of record as of August 29, 2003, raising approximately \$3.0 million in additional equity financing. Proceeds from the offering are being used to support the company's continued growth and intellectual property protection strategies.

"Importantly, Diomed completed a one-for-twenty-five reverse stock split during the quarter," stated David Swank, the company's CFO. "We were quite pleased by the overwhelming support of our shareholders in bringing our share count more in line with companies of comparable size. The reverse split also eliminates a significant hurdle to obtaining coverage of Diomed by analysts within the financial community."

"We also secured a two year revolving line of credit of \$2.5 million from **Silicon Valley Bank** during the quarter," added Swank. "The credit facility provides additional flexibility in funding the company's program to protect its intellectual property and its continued drive for growth."

7/29 **Palomar Medical Technologies Inc.** announced financial results for the second quarter ended June 30, 2004. Revenues for the quarter ended June 30, 2004, were \$13.2 million, up from \$8.7 million in the second quarter of 2003. Gross profit from product sales increased to \$6.9 million (64% of product revenues), up from \$4.5 million (58% of product revenues) in the year-earlier quarter. The company reported net income of \$2.0 million (12 cents per share) for the second quarter of this year, versus net income of \$1.1 million (7 cents per share) for the second quarter of last year.

Revenues for the six months ended June 30, 2004, were \$24.1 million, up from \$15.5 million for the six months ended June 30, 2003. Gross profit from product sales increased to \$13.1 million (64% of revenues), up from \$8.0 million (58% of revenues) in the year-earlier period. The company reported net income of \$3.2 million (18 cents per share) for the six months ended June 30, 2004, versus net income of \$1.4 million (10 cents per share) for the six months ended June 30, 2003.

The company's total revenues increased by 53%, product revenues increased by 38%, and its gross profit from product sales improved by 52% as compared to the second quarter of 2003. The company realized a significant increase in operating income of \$1.4 million, or 228%, and a net income improvement of \$961,000, or 90%, as compared to the second quarter of 2003.

CEO Joseph Caruso commented, "We are pleased to report another strong quarter with a substantial increase in profitability, and are especially encouraged that our revenues continue to grow. As we disclosed earlier in the quarter, Palomar and **Lumenis, Ltd.**

reached a settlement resolving their on-going litigation concerning both patent infringement and contractual matters. As a result of this settlement, royalty revenues increased by \$1.2 million, or 525%."

Caruso continued, "Over the past year, product gross margins have improved significantly due to a higher margin product mix and increased sales volume. The company has also strengthened its balance sheet since the end of last year with a 62% increase in its cash position. We anticipate this trend to continue as we concentrate on increasing distribution both domestically and internationally. This is all being achieved while investing the necessary resources in research and development to maintain our technology leadership position."

During the second quarter of 2004, the company announced the following events:

\* The company and **The Gillette company** completed the initial phase of their agreement and will move into the next phase. In conjunction with entering this next phase, the parties have amended the agreement to provide for additional development funding to further technical innovations. The original agreement provided for \$7 million in development funding from Gillette. Under the amendment, Gillette will provide \$2.1 million in additional development funding over a nine month extension of the development phase, which is planned to be completed by August 31, 2006.

\* The company and Lumenis Ltd. reached a settlement resolving their on-going litigation concerning both patent infringement and contractual matters. Under the terms of the settlement, Lumenis paid \$868,000 in the second quarter for sales of the LightSheer made prior to July 1, 2002 and agreed to pay \$3.225 million over the next six quarters, or \$537,500 per quarter, for royalties due on sales of the LightSheer made between July 1, 2002 and December 31, 2003. Beginning on January 1, 2004, Lumenis agreed to pay Palomar a 5% royalty on sales of the LightSheer and other professional laser hair removal devices and modules. Lumenis made their first payment of \$457,000 in the second quarter for sales made in the first quarter. In addition, Lumenis granted Palomar a paid up license to a variety of Lumenis' patents for Palomar's light based devices. Palomar granted Lumenis a paid up license to the '568 and '844 patents for Lumenis' lamp based devices. Both parties have agreed to the validity and enforceability of each others patents and not to challenge such validity and enforceability in the future.

7/30 The booming aesthetic procedure market is generating a wide array of new business development opportunities, according to a new research report released by **Medical Insight, Inc.** this week. Light-based treatments are now mainstays of medical aesthetic practices. In 2003, nearly 20 million hair removal, skin rejuvenation, tattoo and pigmented lesion removal, acne reduction and photodynamic therapy treatments were performed. These earned almost \$6.5 billion for practitioners and \$372 million in revenue for equipment manufacturers. By 2008, this will grow to over 53 million treatments annually earning practitioners \$10.4 billion and manufacturers more than \$612 million.

Botox treatments are also popular. In 2003, four million procedures were performed worldwide, generating over \$2.1 billion in procedure fees. By 2008, more than 10 million procedures will be performed annually, generating treatment revenue of \$4.4 billion. Revenue to suppliers will grow from \$656 million in 2003 to \$1.6 billion in 2008.

Dermal filler use isn't far behind. More than two million procedures were performed in 2003, earning practitioners \$1.2 billion and suppliers \$196 million. In 2008, this will rise to almost five million treatments generating \$2.3 billion for physicians and \$398 million for suppliers.

Microdermabrasion, chemical peels and emerging skin rejuvenation treatments are also rising. In 2003, over 16 million treatments were performed, accounting for almost \$3.3 billion in fees to practitioners. Equipment manufacturers and suppliers earned about \$108 million. By 2008, this will grow to more than 41 million procedures earning over \$6 billion for practitioners and \$185 million for manufacturers.

The greatest growth and largest opportunity, however, remains anti-aging topicals. In 2003, sales of all brands through all outlets accounted for \$4.1 billion. This will grow to more than \$5.6 billion in 2008.

According to study author Michael Moretti, president of Medical Insight, Inc. and Editor of the *Aesthetic Buyers Guide*, the Global Aesthetic Market study provides the only available comprehensive market analysis and five-year forecast related to emerging and high-growth aesthetic market segments. In addition to releasing the Global Aesthetic Market Study, Moretti has identified a priority list of current business development and investment opportunities, which is available upon request. "This Strategic Opportunities Summary is designed to give business development executives, investors and R&D managers immediate access to a select group of the most promising new concepts in this exciting, high-growth field," explained Moretti.

To obtain an Executive Summary of the Global Aesthetic Market Study, or receive the Strategic Opportunities Summary, contact Michael Moretti at: **Mmoretti@MiiNews.com**

8/2 **Cutera, Inc.** reported financial results for the second quarter and six-month period ending June 30, 2004. Second quarter revenue was \$12.3 million, a 36% increase over the \$9.0 million recorded in the same period last year. Net income for the second quarter was \$591,000 (5 cents per share) compared to net income of \$695,000 reported in the second quarter of 2003. Included in the second quarter 2004 results was \$355,000 of pre-tax, non-cash, stock-based compensation charges, compared to charges of \$242,000 in the second quarter of 2003.

The company's revenue for the six months ended June 30, 2004 was \$23.8 million, a 53% increase compared to \$15.6 million recorded in the same period last year. Net income for the first six months was \$812,000 (7 cents per share) compared to net income of \$624,000 reported in the same period last year. Included in the first six months of 2004

results was \$727,000 of pre-tax, non-cash, stock-based compensation charges, compared to charges of \$462,000 in the same period last year.

"We are pleased with our progress in the first half of 2004 as a public company," said Kevin Connors, president and CEO. "Our second quarter results confirm the growing market acceptance of our versatile technology platforms and our multi-application systems. We will continue to focus on our fundamental growth initiatives, including the introduction of innovative products that expand our range of aesthetic applications and aggressive expansion of our direct global sales organization, with particular emphasis on our international sales."

Management believes that third quarter revenue will be approximately \$12.5 million with corresponding earnings per share of \$0.05. For the full year, Cutera is raising guidance and now expects revenue of \$50.0 to \$52.0 million and earnings per share of \$0.16 to \$0.19, up from a range of \$49.5 to \$50.5 million and \$0.15 to \$0.17, respectively, based on an average share count of approximately 12.3 million shares.

- 8/2 As published in the Israeli newspaper, *Maariv*: **FITE proposes acquiring control over Lumenis — In discussions with Bank Hapoalim, Lumenis' principle creditor. Bank: no deal at price proposed by FITE**

**First Israel Turnover Enterprise**, or FITE, founded by businessmen Ishai Davidi and Ron Zuckerman, recently contacted Bank Hapoalim with a proposal to acquire controlling interest of **Lumenis**, *Maariv* has learned. **Bank Hapoalim** is the company's largest creditor (company owes the bank \$230 million) and is in effect responsible for any significant business transaction made by the company. In a meeting between Hapoalim representatives and the potential buyers, headed by Davidi, the bank clarified that there would be no deal under the terms of the current proposal.

The crux of the dispute is the stock price by which the transaction would be carried out, as well as additional terms that FITE included: potential obliteration of Lumenis debts to the bank. Banking industry sources believe that Hapoalim has already implemented a doubtful debt provision totaling at least \$50 million for Lumenis debts, thus obliterating this debt and making it an irrevocable debt.

The bank, however, remains optimistic regarding the chance of recovery by Lumenis, which is managed by Avner Raz. The bank apparently has no intention of conducting any significant business transaction, including sale of controlling interest in the company. According to estimates, Lumenis Q2 2004 reports will indicate improved profitability. FITE was founded six months ago in order to acquire export businesses experiencing difficulties. The Fund, directed by Roy Machnes, has not issued a response.

- 8/3 **Lumenis Ltd.** announced that it had retained **BDO Ziv Haft** as its independent accountants. The company's Audit Committee and Board of Directors approved BDO Ziv Haft's selection. The company intends, in accordance with Israeli law, to seek ratification

of such approval by the company's shareholders as promptly as practicable. Avner Raz, Lumenis president and CEO, said, "We are pleased with the appointment of BDO Ziv Haft as the company's independent accountants. They will proceed with completing the audits to help the company bring its financial statement filings up to date.

8/3 **CardioGenesis Corporation** announced results for its second quarter and first six months ended June 30, 2004. Chairman and CEO Michael Quinn said that revenues for the 2004 second quarter and first six months rose 9% and 14%, respectively, compared to revenues in the same periods last year, as year over year the gross margins increased and the bottom line improved significantly in both periods.

Quinn noted that TMR continues to gain acceptance among leading cardiothoracic surgeons as a very important and viable treatment option for severe angina. This factor, combined with a number of key developments that highlighted the second quarter, make the outlook for the company's TMR business very positive. These developments include physician-driven advancements in the procedure, including minimally invasive and robotically assisted TMR; the recent installation of a CardioGenesis TMR laser system at The Johns Hopkins Hospital, one of the nation's leading medical institutions; and the publication of significant long-term follow-up data on the clinical efficacy of TMR in the *Annals of Thoracic Surgery*, the official journal of the Society of Thoracic Surgeons.

Revenues in this year's second quarter increased to \$3.4 million from \$3.1 million in the prior year period. The net loss in the 2004 second quarter declined to \$264,000 (1 cent per share) from a net loss of \$878,000 (2 cents per share) in the 2003 second quarter. For the first six months of 2004, revenues increased to \$7.4 million, from revenues of \$6.5 million in the same period last year. Net income for the first half of 2004 was \$3,000 (0 per share), compared to a net loss of \$757,000 (2 cents per share) in the prior year period.

"The recently published enduring benefits of TMR beyond five years, and the progress we are making with key surgeon innovators on our minimally invasive devices are clearly reinvigorating our customers and attracting additional interest throughout the cardiothoracic community," Quinn said. "Indicative of this increased awareness is the recent action by Johns Hopkins Hospital, one of our country's biggest and most prestigious medical institutions, to purchase our TMR system and integrate it into their cardiovascular therapeutic formula. We believe this is a significant milestone for TMR and for our company."

Quinn noted that questions raised in the marketplace about the July review of laser myocardial revascularization by the Medicare Coverage Advisory Committee (MCAC), which was first announced in early June, clearly impacted sales towards the end of second quarter.

"Many of our prospects and customers waited for the outcome of the Medicare advisory panel review before making a final decision about adopting TMR or purchasing a laser, which caused a fall off in revenue from this year's first quarter and negatively impacted

our bottom line. But we are confident this is only temporary," Quinn said. "We came out of the Medicare advisory panel meeting encouraged and energized. The clinicians, particularly the leadership of the Society of Thoracic Surgeons, presented a very clear and compelling case based on the substantial scientific and clinical evidence on the efficacy and safety of TMR."

"We remain confident in the clinical and commercial viability of PMR, and are committed to achieving FDA approval. While we did not incur the level of expense in our continued pursuit of PMR approval as in previous periods, we are actively working with the FDA in specifying exactly what additional clinical data are required to achieve approval," Quinn said. "We expect to achieve clarification from the FDA in the near future, and will be able to then determine the necessary steps and resources to attain approval."

"Our operational focus right now is TMR. We will be delivering to the cardiothoracic market the first new important TMR product initiatives (since approval in 1999) in the second half of 2004," Quinn added. These new products, developed with innovative surgeons across the country, have been designed to support minimally invasive techniques that are intended to reduce the morbidity associated with standard open surgical procedures. They will enable more patients suffering from severe angina to consider TMR due to significantly reduced procedural morbidity.

"These initiatives with minimally invasive TMR are essential to making it a viable procedure for a much greater proportion of these extremely sick patients," Quinn said. "The published preliminary results utilizing minimally invasive techniques with our technology show that hospital stays are reduced from an average of five to six days for a standard TMR procedure through a thoracotomy -- to under two days. We believe that such advancements in patient-centered outcomes, coupled with the recently published significant long-term benefits of TMR, are of utmost importance to the cardiothoracic community today."

During the year's second quarter, the company shipped three lasers and had worldwide disposable sales of 742 units, compared to the shipment of five lasers and worldwide disposable sales of 730 units in the second quarter of 2003. At the end of the second quarter there were 440 sites with CardioGenesis lasers for myocardial revascularization compared to 428 sites at the end of the second quarter of 2003.

8/3 **PhotoMedex, Inc.** announced the results of its operations for the quarter ended June 30, 2004. Revenues for the second quarter ended June 30, 2004 were \$4.3 million, an increase of 12.5% over the same period last year and 7.4% increase over the first quarter of 2004. The net loss for the quarter ended June 30, 2004 was \$1.2 million (3 cents per share). The net loss for the quarter ended June 30, 2003 was \$1.7 million (5 cents per share).

The revenue and net loss for the six months ended June 30, 2004 were \$8.3 million and \$2.6 million, respectively (7 cents per share). The revenue and net loss for the six months ended June 30, 2003 were \$7.3 million and \$3.4 million, respectively (10 cents per share). As of June 30, 2004, the company had cash and cash equivalents of \$5.7 million, a decrease of \$137,981 from March 31, 2004.

Jeffrey O'Donnell, PhotoMedex CEO and president, commented, "We are pleased with the results of our core business segments, as well as with the recent medical policy approvals put in place for our XTRAC laser therapy system by some of the nation's leading health insurers. Our team has accomplished a great deal over this past quarter in terms of expanding the size of our addressable markets and creating a more attractive product offering in those markets. We are now focused on pure execution and positioning ourselves to build on those successes. We look forward to today's conference call and the opportunity to review with our shareholders our increased revenues, improved margins and the impact of reimbursement on our business."

The following were among the more notable recent achievements:

**Reimbursement:**

- \* **WellPoint Blue Cross and Blue Shield Plans**, the nation's 2nd largest health plan with 15 million medical members, adopts XTRAC reimbursement
- \* **Aetna**, with 13.6 million medical members, adopts XTRAC reimbursement
- \* **The Regence Group**, with 3 million medical members, adopts XTRAC reimbursement

**Financial:**

- \* Domestic XTRAC yields 21.6% growth over first quarter 2004
- \* Surgical Services yields 18.0% growth over first quarter 2004
- \* **GE Capital** makes available \$2.5 million lease line of credit
- \* Stock warrants exercised, amounting to \$904,886 incremental cash

**New Product Development:**

- \* FDA market clearance and CE mark obtained for the manufacture and distribution of a CO2 surgical laser which will lower the cost of delivery for the Surgical Services group
- \* FDA market clearance and CE mark obtained for the manufacture and distribution of a Diode laser indicated for use in General Surgery, Neurosurgery, ENT, GYN, and LEG VEIN Procedures. Our previously FDA cleared Venous Fiber can be used with our Diode Laser.

**Business Development:**

- \* Entered into a Product Development agreement with **AzurTec, Inc.** for the design of a cancer detection device and process to be marketed to MOHS Surgeons in Dermatology



## Corporate Governance:

- \* Appointment of David Anderson to the board of directors

8/3 Kathy Kincade, editor of *Medical Laser Report*, wrote the following article for MLR's August issue: **Photodynamic therapy targets dental bacteria**

The dental-laser market has been dominated by applications that involve cutting and ablating soft and hard tissue. But many related applications hold strong end-user potential as well, such as tooth whitening, cleaning, and diagnostic imaging. An emerging nonsurgical application for lasers involves a form of photodynamic therapy designed to disinfect and kill bacteria in the mouth.

**Denfotex** (Inverkeithing, Scotland), a spin-off of **Carl-Zeiss** (Jena, Germany) that has developed a photo-activated disinfection (PAD) technique the company says kills the bacteria associated with cavities, reducing the time and unpleasantness of many dental procedures. There are two principal components to PAD: a solution containing pharmaceutical-grade tolonium chloride, and the SaveDent laser, a 635-nm diode laser that activates the solution through a disposable handpiece. The solution is applied to the tooth by brushing it on for caries or injecting it from a syringe for root canals. When exposed to the low-power (100 mW) laser, the solution disinfects the tooth by releasing reactive oxygen species that disrupt the membrane of the microorganism, eliminating the need to further scrape, clean, or overdrill the tooth. According to the company, within 1 to 2½ minutes PAD achieves over 99.9% kill of all bacteria types found in caries and root canals; other disinfection techniques -- chemical, thermal, or physical -- pose risks by the use of disinfecting agents that can be toxic, not specific to bacteria, or depend on a mechanism that is inherently harmful to surrounding tissue.

In addition to the SaveDent for PAD, Denfotex offers a blue LED (450-470 nm) attachment for curing applications; according to the company, the blue LED sets white fillings instantly, reducing the risk of contamination during the few minutes it normally takes for filler to set.

A Canadian company, **Ondine Biopharma** (Vancouver), has developed a similar technology the company calls photodynamic disinfection (PDD), which is designed to kill periodontal bacteria and ease gum disease. Periodontal disease affects one-in-three adults in North America, generating a US\$6 billion treatment and services market. The Ondine approach involves "painting" a Photocidex compound onto infected gums and then exposing the gums to low-level red-laser energy.

If the company's 250-person clinical trial next year is successful, the PDD system could be on the market in 2006, with the system selling for about \$2000; the company says the FDA has determined that PDD will be reviewed as a medical device instead of a new drug application. Ondine went public in April through a reverse takeover of **Springbank Ventures** on the TSX Venture Exchange. PDD was developed at the **Eastman Dental**

**Institute** in England by microbiologist Michael Wilson, who is now a member of Ondine's scientific advisory board. In 1998, a group of Canadian investors formed Ondine to acquire the rights to Wilson's patents. The patents were subsequently challenged by **Gillette Co.'s** Braun oral hygiene division; that litigation was settled in late 2001. In addition to dentistry, Ondine is in the early stages of developing PDD systems as an alternative to antibiotics for skin wounds, hospital-acquired infections and fungal infections.

In the same issue, Kathy Kincade also wrote the following article about **Syneron**:  
**Syneron goes public, but draws fire**

Even as it ages, the medical-laser field remains a small world in many ways. The same names seem to pop up over and over. Such is the case with Syneron Medical (Yokneam, Israel), a medical-laser company whose founder, Shimon Eckhouse, was once the CEO of **ESC Medical** before ESC acquired **Coherent Medical** and became **Lumenis**. In early August, Eckhouse -- who owns about 24% of Syneron -- was back in the public eye, working to make the investment community aware of Syneron as the company prepared to go public on the Nasdaq stock exchange under the ticker symbol ELOS. The company hopes to sell 5 million shares at \$14-\$16 each, raising \$70 million to \$80 million. The company's shareholders, including founder Shimon Eckhouse, will piggyback with another 500,000 shares. The issues underwriters, **Citigroup Global Markets**, **CIBC World Markets**, and **Stephens Inc.** have been granted an option to purchase up to 825,000 additional shares to cover over-allotments. In its prospectus, Syneron said its net income for the first quarter was \$5.5 million, up from \$2.3 million in the same quarter a year ago. The company had a profit of \$8.6 million in 2003 and \$2 million in 2002, after losing \$1.1 million in 2001.

Founded in 1999, Syneron primarily makes laser systems for hair and wrinkle removal. In late 2002, Lumenis filed a \$6.3 million lawsuit against Syneron, claiming that Syneron stole the technology used in their products. This past January, the two parties reached the agreement under which Lumenis granted Syneron unlimited non-exclusive worldwide licenses for some of its patents, while Syneron agreed to pay Lumenis royalties up to a pre-determined amount. The two agreed that there would be no admission of wrongdoing or liability on the part of either company.

Lumenis is not the only thorn in Syneron's side. In late July the company was hit with more patent litigation. **Thermage** (Hayward, CA) filed a lawsuit against Syneron in San Francisco, CA, seeking damages and injunctive relief for infringement of a Thermage patent that is infringed by Syneron's systems for non-invasively treating skin. The Thermage patent addressed in the lawsuit is U.S. Patent #6,749,624, which issued on June 15, 2004. This patent covers methods and devices for treating skin using either light or radiofrequency energy or both. Thermage commercially launched its ThermaCool System for tightening skin in July 2002 and has more than 1000 systems installed worldwide. The ThermaCool System uses capacitive RF technology to generate deep,

uniform volumetric heating of surface tissue to tighten both skin and underlying tissue in conjunction with a cryogen spray.

"It is clear to us that Syneron has copied some of our patented concepts," said Thermage president and CEO Bob Byrnes. "Our investors have spent more than \$47 million to develop these concepts into medical devices that offer real clinical benefits to our customers. We had hoped that Syneron would accept our recent offer of a limited license because we really didn't want to have to litigate this matter. But when they refused, we had no choice but to defend the inventions we worked so hard to develop."

Moshe Mizrahy, Syneron CEO, says Syneron has conducted an initial review of the Thermage patent and firmly believes that its products do not infringe any valid claim of the patent. "The assertion in Thermage's press release that Syneron copied Thermage's recently issued patent is demonstratively false and misleading. The claims in Thermage's patent were not submitted to the U.S. patent office until March of 2003, over 18 months after Syneron's ELOS products were already on the market and three years after Syneron filed its patents. Thermage has no device on the market that uses a combination of light and RF energy. We regret that Thermage has chosen to compete with our company in the courts rather than in the marketplace."

Another patent-infringement lawsuit has been filed against Syneron by a nonlaser company, **Shladot Metal Works** (Haifa Bay, Israel), that reportedly has an investment in a biotech venture that uses light for healing purposes. The company claims to own a patent covering the use of broadband light on skin for hair removal, skin rejuvenation, and acne treatment. According to reports in the Israeli newspaper *Haaretz*, Shladot president Arie Fridenson and Eckhouse had discussions in 1999 about commercializing this technology; Shladot says that Eckhouse signed a confidentiality agreement at that time and that Syneron's products clearly breach that agreement.

8/5 **AngioDynamics, Inc.** announced that it was changing the name of its endovascular laser venous system to VenaCure Laser Vein Treatment. To support the change, the company is launching a new web site **www.venacure.com** along with updated marketing materials.

VenaCure is a minimally invasive alternative for the treatment of severe varicose veins. The procedure lasts about 45 minutes and offers patients an effective out-patient alternative to surgical ligation and vein stripping.

AngioDynamics developed the name VenaCure as a way to establish name recognition for the products used in a procedure that is becoming more and more popular with patients as well as doctors. The company will use the patient friendly name in conjunction with its marketing welcome kit, to further assist physicians in developing and marketing this aspect of their practice.

The current kit, an all-inclusive marketing package, recently received the "Award of Excellence" in the Dealer/Distributor Materials Category at the 29th Annual Pro-Comm

Awards -- the longest running and most respected business-to-business marketing communications awards program in the U.S.

Commenting for AngioDynamics, Product Manager David Doster, said, "We are excited to launch the new VenaCure brand name, a change that reflects our ongoing commitment to increase public awareness of this important procedure. Through programs like the new VenaCure web site and our award-winning 'business in a box' welcome kit, we will continue to support physicians who partner with us with patient information and services."

8/5 **Axcan Pharma Inc.** announced operating results for the quarter ended June 30, 2004, the company's third quarter of the fiscal year ending September 30, 2004. The company reported revenue growth of 32.3% to \$62.0 million. Net income was \$12.6 million (25 cents per share) representing 98.0% growth in net income, as compared to third quarter fiscal 2003. Excluding takeover bid expenses and related income taxes from third quarter fiscal 2003 net income, net income for the fiscal quarter ended June 30, 2004 rose by 43.5%.

"Axcan's growth strategy is clearly working," stated Leon Gosselin, president and CEO of Axcan. "Our revenue met our expectations and our net income has increased proportionally compared to the third quarter a year ago. This indicates that while we have increased the size of our sales force both in the United States and in France, we have been able, nevertheless, to absorb many of the operating expenses related to our recent acquisitions within our current infrastructure, building real value for our shareholders."

**PHOTOBARR - European Union Market Authorization** In March 2004, the European Commission granted Axcan market authorization for use in the European Union of PHOTOBARR (porfimer sodium), its photodynamic therapy for the ablation of High-Grade Dysplasia associated with Barrett's Esophagus. PHOTOBARR was also granted orphan medical product status at the time of its submission, which guarantees Axcan exclusive marketing rights for PHOTOBARR in the European Union for a ten-year period from March 2004. This represents a significant milestone for Axcan, because this is its first regulatory approval in Europe. The launch of PHOTOBARR in major EU markets is expected near the end of the current fiscal year.

**PHOTOFRIN** PHOTOFRIN is approved in a number of countries for the treatment of different forms of cancers. Axcan is currently investigating the use of PHOTOFRIN for the treatment of cholangiocarcinoma, a serious bile duct (liver) cancer with a high morbidity rate. The treatment under investigation combines PHOTOFRIN with PDT and the stenting of the bile ducts. The proposed Phase III study will start in the fourth quarter of fiscal 2004.

8/9 Responding to the filing of several shareholder lawsuits, **BIOLASE Technology, Inc.** announced that it intended to vigorously defend lawsuits accusing BIOLASE and its officers of violating federal securities laws. The complaints, filed in the U.S. District

Court for the Central District of California, allege that BIOLASE and its officers failed to disclose material information about demand for the company's products and the fact that the company would not achieve the financial growth forecasted. The suit seeks damages on behalf of an alleged class of investors who purchased BIOLASE shares during the period from October 29, 2003 to July 16, 2004. The complaint does not specify any amount of claimed damages.

BIOLASE stated that it believes the lawsuit is without merit and appears to have been filed in response to a recent decrease in the market price of BIOLASE's stock. The company is confident that it has complied with applicable laws and properly disclosed its business and financial information to stockholders. The company intends to defend the action vigorously and to request the court to dismiss the cases at the earliest opportunity.

"We have reviewed the complaint and believe the claims are unfounded and the lawsuit is without merit. We believe this lawsuit represents the very type of baseless suits instigated by class action plaintiff's lawyers that Congress has recognized as abusive. BIOLASE will vigorously defend itself against this litigation," said Jeffrey Jones, BIOLASE's president and CEO.

In addition, the company announced that BIOLASE's Board of Directors had authorized an additional 750,000 shares, increasing the total share repurchase program to 2.0 million shares. Pursuant to the authorization, BIOLASE may purchase shares from time to time in the open market or through privately negotiated transactions over the next 12 months.

"At current levels, we believe BIOLASE's stock represents an excellent use of capital that will greatly enhance shareholder value over the long term. Furthermore, this action affirms our commitment to increasing shareholder value and reflects confidence in the strength of our business model and expanded market penetration. We have already actively been repurchasing shares since the initial announcement of the repurchase program and intend to continue to do so," said Federico Pignatelli, BIOLASE's chairman. The company has no obligation to repurchase shares under the share repurchase program, and the timing, actual number and value of shares to be purchased will depend on market conditions. BIOLASE has approximately 24.3 million shares outstanding and has an approximate public float of 23.7 million shares.

8/9 **Lumenis Ltd.** announced preliminary unaudited financial results for the second quarter and six months ended June 30, 2004. Revenues in the second quarter were \$70.3 million compared with revenues in the second quarter of 2003 of \$68.1 million. Net earnings for the second quarter were \$1.1 million (3 cents per share). The company had a net loss from continuing operations of \$29.5 million in the second quarter of 2003 (79 cents per share) and a net loss of \$33.3 million (89 cents per share) after deducting a \$3.8 million loss from discontinued operations. Net cash flow from operating activities was a positive \$6.6 million in the second quarter of 2004 compared with a positive \$6.0 million in the second quarter of 2003.

Commenting on the results, Avner Raz, Lumenis president and CEO said, "The second quarter results are encouraging as they continue to reflect the benefits of our new organization. We are particularly encouraged by the reduced operating costs, good operating cash flow and modest improvement in revenue which allowed us to report positive operating income for the second quarter. While we were also able to report a small profit in the second quarter, these results included one-time or special gains associated with our **WaveLight** agreements. Our new organization continues to focus on improving operational efficiencies, customer service and positioning us for growth in our markets."

Operating income for the second quarter of 2004 was \$4.4 million and included expenses related to implementation of the Turnaround Plan of \$0.5 million and a gain in cost of sales of \$0.9 million from the settlement of two patent disputes. Operating expenses in the quarter, including restructuring costs of \$0.5 million, were \$31.4 million compared with \$41.8 million in the second quarter 2003. Operating expenses in the second quarter of 2003 included provisions of \$2.2 million for severance and litigation expenses.

Net income for the second quarter of 2004 of \$1.1 million included Other Income of \$1.8 million as a result of the company's new sales and marketing agreements with **WaveLight Laser Technologie AG** ("Wavelight") of Erlangen, Germany. Under the new agreements, Lumenis will continue to be the exclusive distributor for the ALLEGRETTO WAVE Excimer Laser in China, Hong Kong, Taiwan and Japan. Lumenis will no longer sell this product in the U.S. or in Europe. The Other Income included payment by Wavelight for the distribution rights in the U.S. and Europe, release from previously provided liabilities and other costs associated with the termination of the earlier agreements. Net loss for the second quarter of 2003 of \$33.3 million included charges for inventory adjustments of \$8.9 million primarily due to the processing of excess inventory in the second quarter, which was recovered at a lower value than previously estimated and a loss of \$3.8 million related to the sale of **Spectron**, the company's industrial laser business. Additional charges in the second quarter of 2003 included \$1.3 million for severance and an accrual for certain legal matters of \$0.9 million.

In the second quarter of 2004, sales in the Americas were \$34.1 million, compared to \$30.4 million a year ago and \$27.8 million in the first quarter of 2004. The Europe region had sales of \$15.0 million, compared to revenue in the second quarter of 2003 of \$15.3 million and to \$17.9 million in the first quarter 2004. Second quarter sales in the Asia Pacific, China and Japan regions were \$21.2 million compared with \$22.3 million and \$19.4 million in the second quarter of 2003 and the first quarter 2004, respectively.

Second quarter sales of Aesthetic products were \$24.8 million, compared to \$22.7 million in the year earlier period and \$20.4 million in the first quarter of 2004. The improvement in second quarter sales reflects growth in the Americas largely due to sales of the new Lumenis One, for which deliveries began in the second quarter.

The Surgical product line had total sales of \$11.2 million in the second quarter, compared to \$11.6 million in the same quarter a year ago and \$12.4 million in the first quarter 2004. The Dental business had sales of \$2.4 million, compared with \$1.6 million in the second quarter of 2003 and \$1.8 million in the first quarter of 2004.

Sales of Ophthalmic products in the second quarter were \$16.3 million compared to \$19.1 million in the same quarter a year ago and \$16.1 million in the first quarter of 2004.

Service revenues were \$15.4 million in the second quarter compared with \$13.0 million in the same quarter a year ago and \$14.5 million in the first quarter of 2004.

The company had approximately \$15 million in backlog at June 30, 2004 compared to \$20 million at March 31, 2004.

Net cash flow from operating activities was \$6.6 million in the second quarter of 2004. Net cash flow from investment activities also included a positive \$1.7 million as a result of the WaveLight transaction.

At June 30, 2004, the company's cash position was \$16.7 million and borrowing capacity under its committed lines of credit was an additional \$19.2 million. Total debt was \$200.5 million. Based on the preliminary unaudited results for the first and second quarters of 2004, the company is in compliance with its covenants under its bank agreements.

As previously reported, a report prepared for the Audit Committee with respect to the company's internal investigation had concluded that the timing of the company's revenue recognition was inappropriate with respect to certain identified transactions. The aggregate effect of the company's accounting for the transactions identified in the report, as described more fully in the company's press release of May 3, 2004, was to cause revenues in 2001 and 2002 to be overstated, and revenues in 2003 to be understated.

The effect of the foregoing on the results of operations for the three and six-month periods ended June 30, 2003 was to cause revenues to be understated by approximately \$3.1 million or 4.6% and \$1.5 million or 1.0%, respectively. The effect of such understatement of revenues on previously reported earnings (loss), while not included in the report, is estimated, on a preliminary basis and subject to further adjustment, to decrease the net loss as reported in such periods by approximately \$2.0 million and \$0.9 million, respectively. Such adjustments, as well as any other adjustments which may arise from any further investigative activities, are not reflected in the attached financial statements.

As previously reported, the Audit Committee anticipates that a restatement of previously reported financial results may be appropriate, but intends to defer making a final decision pending completion of the audit by the company's independent accountants. As previously announced, the company has recently engaged **BDO Ziv Haft** as its independent accountants.

8/9 **Medical Insight, Inc.** announced the launch of the *European Aesthetic Buyers Guide*, a unique and progressive publication focusing solely on the exploration of new products, procedures, technologies and trends in the European medical aesthetics market. The premier issue will reach more than 10,000 leading plastic surgeons and dermatologists across Europe in early November, with additional distribution at the *EADV* annual meeting in Florence, Italy. European Aesthetic Buyers Guide will cover all areas of medical aesthetics, including equipment and supplies, pharmaceuticals, cosmeceuticals and skincare products.

According to Michael Moretti, Editor, the European Aesthetic Buyers Guide will be a "progressive resource for the medical community, enabling manufacturers to market products and services directly to aesthetic professionals through editorial partnerships, advertising and other sponsorship opportunities. Our research shows that Europe is a high growth market, tracking the trends in aesthetic procedures that we have witnessed in the U.S. over the past several years. Moreover, many technologies and procedures that are blocked by the FDA in this country are widely available there."

Amy Coronato, Director of Business Development for Medical Insight, will oversee the launch of the European Aesthetic Buyers Guide in addition to managing a series of new projects in the North American market. Coronato comes to Medical Insight, Inc. from **The Walt Disney company**, where she developed and managed promotional programs and marketing partnerships for **ABC Radio Networks**. Prior to joining Disney, she managed media sales in a news weekly for **Reed Business Information**.

For more information regarding editorial projects or advertising in European Aesthetic Buyers Guide or Aesthetic Buyers Guide, contact Amy Coronato at 949-683-8026 or via e-mail at [acoronato@miinews.com](mailto:acoronato@miinews.com).

Public companies participating in the aesthetic market include: Allergan (NYSE:AGN), Biolase (Nasdaq:BLTI), Candela (Nasdaq:CLZR), Cutera (Nasdaq:CUTR), Dusa (Nasdaq:DUSA), Inamed (Nasdaq:IMDC), Isolagen (AMEX:ILE), Laserscope (Nasdaq:LSCP), Medicis (NYSE:MRX), and Palomar (Nasdaq:PMTI).

8/9 **BriteSmile, Inc.** released results for the quarter ended June 26, 2004. Total revenues increased by \$1.7 million, or 16%, to \$12.7 million for the second quarter ended June 26, 2004, from \$11.0 million in the second quarter of 2003. Earnings before interest, tax, depreciation, and amortization (EBITDA) was \$1.1 million in the second quarter 2004 compared to an EBITDA of \$(0.6) million in the second quarter of last year. EBITDA is a Non-GAAP financial measure. More information regarding this Non-GAAP financial measure, and a reconciliation of EBITDA to net loss, the most directly comparable GAAP measure, is provided below in this press release.

The net loss was \$0.7 million (7 cents per share) in the second quarter compared with \$2.5 million (40 cents per share) in 2003 (both per share numbers reflect the 5:2 stock split which was effective January 30, 2004).



Other key financial highlights for the second quarter were:

- \* Center whitening fees of \$4.9 million were 16% higher than last year.
- \* Associated Center whitening fees of \$6.0 million were 6% higher than 2003.
- \* Product sales of \$1.9 million were 68% higher than last year, primarily due to sales of the BriteSmile to Go take-home whitening pen which was launched in the third quarter of 2003.

"We are very pleased with our cash earnings improvement and continued revenue growth in the second quarter," said Bruce Fleming, CEO. "We look forward to opening new spas, additional retail channel distribution, and increased Associated Center penetration."

In terms of forward guidance, third quarter revenue is projected to grow in the low to mid single digit range compared to last year as the company faces the pipeline fill associated with last year's new product introductions.

8/10 **CardioGenesis Corporation** announced that the company and the FDA have agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMR. Chairman and CEO Michael Quinn said that the company views last week's meeting and its outcome as a significant step forward with the FDA and its efforts to gain clearance of PMR. Directly assisted by Marvin Slepian, MD, Professor of Medicine (Cardiology) and Director of Interventional Cardiology at the University of Arizona's Sarver Heart Center, officials from CardioGenesis and the FDA's Center for Devices and Radiological Health met on August 5. The purpose of the meeting was to discuss the company's supplemental premarket approval (PMA) application for PMR and to determine if there was a workable clinical path to move the application forward to gain clearance to market the percutaneous procedure in the United States.

Quinn said the meeting was a scientifically-based discussion of clinical results and the company's percutaneous technology for treating angina. It was a productive session that went a long way in defining a specific clinical trial protocol for addressing the remaining questions for the FDA. Quinn stated that he expects the company should be able to submit a final protocol for review by the FDA before the end of the quarter. The final design and size of the trial will determine the resources required to support the trial, an issue that Quinn says he is prepared to address to "ensure the future of this important technology."

Quinn also noted that in advance of the meeting the company decided to rename its percutaneous platform as Percutaneous Myocardial Channeling (PMC). The new name more literally depicts the immediate physiologic tissue effect of the CardioGenesis Axcis Percutaneous Myocardial Channeling (PMC) system to ablate precise, partial thickness channels into the heart muscle from the inside of the left ventricle.

Dr. Slepian, who joined CardioGenesis as a Board Member in December of last year, commented, "My interest in the company is based upon my experience with myocardial channeling for the treatment of angina, and my belief in the potential of this platform in developing treatments for advanced cardiovascular disease. I am pleased to be supporting the company in defining and executing the definitive trial for PMC. This is necessary for medical, regulatory and payor acceptance. This new clinical work importantly provides the opportunity to further the understanding and awareness by the cardiology community of the significant body of scientific evidence regarding the surgical procedure (TMR) and to clarify the results from previous trials of differing percutaneous laser systems. Ultimately, laser myocardial channeling is a tool that can provide important patient benefits as performed by both the cardiologist and the cardiothoracic surgeon, and provides a platform for important new treatments in both arenas."

CardioGenesis enlisted the counsel and direct participation of Dr. Slepian for its meeting with the FDA. "He not only has over 10 years of experience with laser myocardial channeling to treat angina," said Quinn, "he has been involved in research and clinical implementation of innovative medical devices for over 20 years." Dr. Slepian has also been directly involved in successful PMA approvals of new and innovative medical devices, most recently having obtained a recommendation for approval from an FDA Advisory Panel for the SynCardia CardioWest Total Artificial Heart (TAH), designed for end-stage congestive heart failure.

"The FDA gave us important guidance and insight as to the most direct path to approval to market Percutaneous Myocardial Channeling in the U.S. We are committed to doing what needs to be done to bring this important therapy to market." Quinn added, "The commitment by the agency to consider the least burdensome pathway is absolutely critical for our company. Based upon the substantive progress made during our meeting last week, we should now be able to quickly formalize a clinical protocol and begin the definitive trial of Percutaneous Myocardial Channeling in the near future."

8/10 **DUSA Pharmaceuticals, Inc.** reported its corporate highlights and financial results for the second quarter ended June 30th, 2004.

**Corporate Highlights:** As reported earlier, Q2 2004 end-user Levulan Kerastick(R) net sales to physicians totaled 17,910, including 1,908 sold by Coherent-AMT, our Canadian marketing and distribution partner. This compared to 12,054 Kerastick units sold during Q1 2004 and 1,914 during Q2 2003, neither of which included any Canadian sales. The number of BLU-U units placed in doctors' offices during the quarter also increased significantly, by 241, including 58 in Canada, compared with 128 during Q1 2004 and zero during Q2 2003. At the end of Q2 2004, there were 775 BLU-U units in doctors' offices, as compared to 534 at the end of Q1 2004, and 323 at the end of Q2 2003.

By the end of the current quarter, DUSA reached its previously announced target of 16 sales representatives and area managers. In light of the continued strong growth in sales, management has decided to continue hiring, in order to reach a total sales force of

approximately 23 individuals (including sales representatives, area managers and an Associate VP of sales) by the end of Q3. Management believes that this number will allow DUSA to serve all of its current key markets with direct representatives. We expect to maintain approximately this number for at least the remainder of 2004.

Due to the demand caused by increasing sales volumes, DUSA is also pleased to announce that during the current quarter, we began producing and shipping Kerastick units from our FDA-approved manufacturing facility at our Wilmington, MA headquarters. There were no significant start-up issues, and production will be gradually ramped up as sales continue to increase.

On June 21, 2004, DUSA signed an Amended and Restated Purchase and Supply Agreement with **National Biological Corporation (NBC)**, the manufacturer of our BLU-U light source. This agreement eliminated certain exclusivity clauses and made other modifications to the original agreement, giving both parties greater flexibility related to the development and manufacture of new light sources, and the associated technology within the field of PDT. DUSA also maintains the ability to order additional BLU-U light sources from NBC, if we so choose. DUSA paid \$110,000 to NBC upon execution of the agreement, which will be amortized over the remaining term of the agreement, expiring November 5, 2008.

In light of the growing interest in blue light treatment of acne, and the significant increase in BLU-U sales during the first half of 2004, our inventory of original BLU-U units has been depleted more rapidly than initially expected (approximately 160 units remained in stock at the end of Q2). Therefore, the company is aggressively evaluating its options with respect to reclaiming any DUSA-owned light units in the field that are not being actively used, ordering more BLU-U units, and/or developing alternative light sources. However, until new light sources are available, likely in H1 2005, BLU-U revenues are expected to be limited by supply constraints.

During the quarter, DUSA announced the initiation of a Phase II clinical trial on Levulan PDT in the treatment of photodamaged skin, and a Phase II pilot study using Levulan PDT for the treatment of high-grade dysplasia in Barrett's esophagus. The company expects to initiate a Phase II study on Levulan PDT for the treatment of acne vulgaris during the third quarter. There were also a number of peer-reviewed scientific articles related to the use of Levulan published in the dermatology literature, as well as numerous lectures and presentations at scientific meetings and CME events.

Other developments during the quarter included an announcement from CMS of improved reimbursement for our procedure when the treatment is administered in hospital out-patient clinics; agreements with **Cynosure** and **Lumenis** related to the use of their light sources as part of our Phase II photodamage skin trial; and the addition of DUSA's stock to the Russell 3000 index.

Dr. D. Geoffrey Shulman, DUSA's president and CEO, stated "We are very pleased with the strong increases in Kerastick and BLU-U sales this quarter. With the March 2004 financing, we are well-positioned to make the key short-term investments needed to add significant long-term value, including expanding our sales force, developing the photodamaged skin and acne indications, and defending our intellectual property as required. Other than the unknown effect of seasonal factors on sales during the upcoming third quarter, we look forward to continued strong sales growth as we become a significant competitor in the field of dermatology and beyond."

**Financial Highlights:** For the three months ended June 30, 2004, DUSA's net loss was \$4.2 million (25 cents per share) compared to a net loss of \$3.8 million (27 cents per share) in 2003. This higher loss is primarily due to a significant increase in legal and marketing & sales expenses, partially offset by the increase in Kerastick and BLU-U product sales (net of a related increase in cost of product sales). The legal expenses were primarily related to the costs of the patent litigation trial in Australia, which ended in April. A court decision in this matter is not expected to be rendered until late 2004. However, legal costs are expected to decline during the second half of the year, unless DUSA enters into additional significant legal activities. On the other hand, the increased marketing & sales expenses were directly related to the increased size of the sales force, and these expenses are expected to continue to rise through the remainder of 2004, until the number of representatives stabilizes.

Revenues for the three months ended June 30, 2004 were \$2.2 million, compared to \$147,000 in 2003. During the current quarter, Kerastick and BLU-U sales to physicians were \$1.3 million and \$872,000 respectively, including initial sales in Canada by **Coherent-AMT**, our Canadian marketing and distribution partner, whereas revenues for 2003 were totally comprised of Kerastick sales to physicians by our US distribution channels. This significant increase in revenues is largely the result of the efforts of our sales force since its launch in October 2003. In addition, the increase in BLU-U placements was caused, in part, by our ability to sell the BLU-U to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris. Although the level of Kerastick sales to end-users for 2004 is much higher than those in the prior year, Kerastick sales must continue to increase significantly in order for DUSA to become profitable.

- 8/11 **Lumenis Ltd. and Danish Dermatologic Development A/S (DDD)** announced that they have agreed to a settlement and license agreement resolving certain patent litigation. Under the terms of the agreement, which commenced July 1, 2004, Lumenis granted DDD unlimited, non-exclusive, worldwide licenses for Lumenis patents relating to the use of intense pulsed light in aesthetic and medical applications including all of its IPL-related patents. DDD will pay Lumenis royalties on its product sales up to a predetermined cap. In addition, DDD granted Lumenis a fully-paid up, worldwide, non-exclusive license to DDD's patents. The settlement and license agreement includes other confidential terms.

Avner Raz, president and CEO of Lumenis, stated, "We are pleased this litigation has been resolved on mutually beneficial terms. This agreement reflects our determination to resolve ongoing legal disputes and protect Lumenis' valuable intellectual property."

- 8/12 **BIOLASE Technology, Inc.** provided an update on the *World Clinical Laser Institute's (WCLI) 2004* progress. To date, the WCLI has held five major symposiums in San Diego, CA, Phuket, Thailand, New York City, NY, Chicago, IL and Vail, CO with over 1,300 total attendees. The WCLI plans to host additional symposiums, including Orlando, FL in August 2004 and Munich, Germany in October 2004. The WCLI expects an additional 300 to 350 total attendees at these meetings. Last year, the WCLI hosted three major symposiums in San Diego, CA, Atlantic City, NJ and Sardinia, Italy with approximately 900 total attendees.

Jeffrey Jones, BIOLASE's president and CEO commented, "The significant increased attendance rates at the WCLI events signal the strong growth of the dental laser market." Dr. Scott Lybrook of Fruita, CO commented, "Every time I go to one of these WCLI events, it just amazes me how dentistry is advancing. Its better dentistry and its good for my patients."

BIOLASE formed the WCLI organization to accelerate the use of its Waterlase and LaserSmile systems in dentistry. The mission of the Institute is to provide advanced clinical laser education for dental professionals as well as training to current customers on how they can maximize the clinical, marketing and financial benefits of BIOLASE products. The WCLI is open to newcomers to the field of laser dentistry and general practitioners investigating the purchase of a laser.

Dr. Ashley Goodman of San Diego, CA commented, "The Waterlase and LaserSmile dental lasers have transformed my dental practice and my patients' enjoyment of their dental treatment. Working with a responsive and responsible company like BIOLASE, which sponsors the WCLI continuing training, has made my transition from a 'drilling dentist' to a 'laser dentist' smooth, exciting and professionally reinvigorating."

The symposiums offer a broad range of hands-on clinical seminar meetings and educational programs. Some of the topics covered include "The Evolution of Dental Lasers," "Hard and Soft Tissue Procedures," "Advanced Procedures in Laser Oral Surgery," "Lasers and Microdentistry," "Lasers in Cosmetic Surgery" and "Advanced Laser Endodontics."

Dr. Lawrence Nurin, a periodontist from Annapolis, MD commented, "If someone took my Waterlase system away, I would have to shut down my office. The biggest advantage of using BIOLASE's products is providing patients with virtually painless dentistry."

- 8/12 **Trimeddyne Inc.** reported a net profit of \$158,000 (1 cent per share) on revenues of \$1.7 million for the quarter ended June 30, 2004, compared to a net profit of \$331,000 (2 cents

per share) on revenues of \$1.5 million for the same quarter of the prior year. This represents the company's seventh consecutive profitable quarter.

Revenues in the current quarter were 13% higher than in the same period of the prior year, primarily due to an increase in laser sales. With lasers selling for \$40,000 to \$100,000, an increase or decrease in the number of lasers sold in a quarter can have a significant impact on revenues and profits. Sales of disposable and reusable fiber optic devices remained relatively stable in the quarter ended June 30, 2004, compared to the prior year quarter.

As a percentage of sales, compared to the same quarter of the prior year, the company's cost of goods increased to 51% from 43%, SG&A increased to 34% from 32%, R&D expenses rose to 5% from 2%, and gross profit declined to 49% from 57%. A \$20,000 provision for income tax was made in the current quarter, while \$17,000 of income tax was incurred in the prior year quarter.

In the current quarter, the increase of cost of goods and decrease in gross profit was largely due to slightly lower selling prices for lasers, a higher proportion of new lasers being sold, versus older, partially amortized units, and the cost of expanding operations of the company's wholly owned laser rental subsidiary, which is expected to result in increased revenues in the future.

For the nine months ended June 30, 2004, the company had a net profit of \$472,000 (3 cents per share) on revenues of \$4.4 million compared to a net profit of \$828,000 (6 cents per share) on revenues of \$4.8 million in the same period of the prior year. As a percentage of sales, compared to the same period of the prior year, the cost of goods increased to 51% from 48%, SG&A increased to 39% from 32%, R&D expenses increased to 6% from 3% and gross profit decreased to 49% from 52%. Provisions for income tax were \$24,000 in the current nine-month period, versus \$43,000 in the prior year period.

8/13 **Miravant Medical Technologies** announced consolidated financial results for the second quarter ended June 30, 2004. The net loss for the quarter was \$3.7 million (11 cents per share) compared to a net loss of \$3.7 million (15 cents per share) for the same period in 2003. The net loss for the six months ended June 30, 2004, was \$9.2 million (30 cents per share) compared to a net loss of \$7.1 million (29 cents per share) for the same period in 2003. The company had cash and marketable securities of \$8.4 million at June 30, 2004, and received an additional \$3.0 million through an equity investment in July 2004.

Gary Kledzik, chairman and CEO, stated, "This is a very exciting time at Miravant as the FDA reviews our application for approval of SnET2, a new treatment for macular degeneration. We were very pleased that our application was granted a Priority Review designation, and we are working diligently with the FDA to accomplish the accelerated review. Following the close of the quarter, we were proud to announce a new cardiovascular collaboration with **Guidant Corporation**, a world leader in the treatment

of cardiac and vascular disease. Our mutual goal is to optimize PhotoPoint PDT to treat serious coronary artery diseases, especially vulnerable plaque, the primary cause of fatal heart attacks."

On June 1, 2004, Miravant announced that the FDA accepted for filing the company's New Drug Application (NDA) for drug SnET2 and granted a Priority Review designation. Acceptance of the filing means that the FDA has made a determination that the NDA meets the standard for substantive review, and the Priority Review designation expedites the review period. Also in June, the FDA accepted for filing the associated Premarket Approval Application (PMA) for the laser device used to activate the drug SnET2 and granted Expedited Review Status. The NDA and PMA were simultaneously submitted to the FDA on March 31, 2004, and are being concurrently reviewed by the respective FDA drug and device divisions.

On April 27, 2004, SnET2 clinical investigators presented safety and efficacy results at the Association for Research in Vision and Ophthalmology (ARVO) meeting, Ft. Lauderdale, FL. In two independent phase III clinical trials of patients with wet AMD, SnET2 demonstrated a visual acuity benefit and slowed disease progression in the per protocol study population, the basis of the NDA filing. Wet AMD is a common eye disease that causes severe loss of central vision in older adults.

On April 27, 2004, the company announced a \$10,269,000 private placement of 4,564,000 shares of common stock with a group of institutional investors, with full proceeds to the company. There were no warrants or placement fees associated with the offering.

Subsequent to the end of the quarter, on July 6, 2004, Miravant announced a Collaboration Agreement and a Securities Purchase Agreement (SPA) with Guidant Corporation. Guidant agreed to provide up to \$7.0 million in equity capital in support of Miravant's PhotoPoint cardiovascular programs, consisting of an upfront equity investment of \$3.0 million and additional staged investments based on the achievement of certain milestones through Phase I clinical trials. The development programs include PhotoPoint treatments for atherosclerosis and atherosclerotic vulnerable plaque, representing large potential markets in coronary artery disease.

8/16 David Landis of **Kiplinger.com** writing about: **Young Companies on a Roll**, included a few paragraphs about **Cutera**.

**Laser upgrader:** If popular TV shows like Extreme Makeover are any indication, Americans like to believe that ugly ducklings can indeed turn into swans. Last year, U.S. plastic surgeons treated nearly nine million patients, up 32% from 2002. About one million of those patients were treated nonsurgically with lasers for hair removal, skin rejuvenation and other therapies.

Cutera offers a new wrinkle to physicians and other practitioners who use cosmetic lasers, or want to: upgradeable laser systems. Buyers of its products, which are designed mainly for hair removal, can update their technology or add new treatment options without purchasing entirely new systems, which cost \$70,000 and up. Since its start in 1999, Cutera has sold more than 1,200 laser systems and 240 upgrades in the U.S. and abroad.

Competition among sellers of aesthetic laser equipment is intense, with five public companies and dozens of private firms fighting for a share of a market still in its infancy. Analyst Mark Taylor of investment bank **Roth Capital Partners** estimates that laser-equipped doctors serve less than 4% of the potential market. For the full year, Cutera expects revenues of about \$50 million, up 29% from 2003.

Dermatologists and plastic surgeons have been the traditional customers for cosmetic laser devices. But now more than half of sales are to general practitioners, gynecologists and other primary-care physicians looking for new business as reimbursements from health insurers fall. Insurance doesn't cover aesthetic procedures, but aging baby-boomers -- the target market -- "tend to have disposable income and want to improve their looks and slow down the aging process," says Ron Santilli, Cutera's chief financial officer.

Cutera went public in March at \$14. It has since slipped to \$13, even though it holds more than \$5 per share in cash. The stock sells for a lofty 81 times estimated 2004 earnings. If Roth Capital's Taylor is even close to the mark with his call that earnings will grow 65% per year through 2007, the stock isn't excessively priced.

- 8/17 **DUSA Pharmaceuticals, Inc.**, Queens University at Kingston, **Galderma S.A.**, and **PhotoCure ASA** announced that they had entered into a Mediation Agreement designed to facilitate resolution of the parties' potential patent disputes concerning PhotoCure and Galderma's methyl aminolevulinate product.

PhotoCure received approval from the FDA on July 27, 2004 to market methyl aminolevulinate for the treatment of actinic keratoses. DUSA's product, the Levulan Kerastick has been approved for treatment of actinic keratoses using photodynamic therapy since September, 2000.

In order to avoid litigation, PhotoCure and Galderma agree to notify DUSA and Queens University 45 days in advance of launching methyl aminolevulinate in the United States.

- 8/17 Robert Davis, writing in the "Aches & Claims" column in the *Wall Street Journal*, wrote about "lunchtime face lifts". In the column, he addressed the procedure done by **Thermage**, which involves using radiofrequency to heat underlying facial tissue to tighten loose skin, following using a cooling spray to protect the outer layer of skin.

All in all, he wasn't very impressed with the procedure, saying that results varied from person to person, with it being hard to predict who would or would not benefit. In



general, he said, the treatment appeared to work best in younger people -- those in their 30s, 40s, and early 50s, with minimal side effects. The procedure is not typically as effective for older people with severely sagging skin.

As with all types of cosmetic procedures, he said that anyone considering the procedure should select a highly experienced doctor.

8/19 **Syneron Medical Ltd.** announced its 2004 second quarter results, for the period ended June 30, 2004. Revenues for the second quarter of 2004 were \$13.7 million, a 70% increase over the \$8.1 million recorded in the second quarter of 2003. Net income for the second quarter was \$6.4 million (30 cents per share) compared to net income of \$2.8 million reported in the second quarter of 2003. Expenses during the second quarter of 2003 included \$0.6 million settlement and legal costs associated with litigation with **Lumenis Ltd.**, which was settled in March 2004.

The company's revenues for the six months ended June 30, 2004 were \$26.1 million, a 77% increase compared to \$14.7 million recorded in the same period last year. Net income for the first six months was \$11.9 million, compared to net income of \$5.1 million reported in the same period last year. Expenses during the first six months of 2004 included \$1 million settlement and legal costs associated with the Lumenis litigation.

Management believes that the full year 2004 revenues will be approximately \$55 million.

"We are pleased with our progress in the first half of 2004," said Moshe Mizrahy, Syneron's CEO. "Our second quarter results confirm the growing market acceptance of our ELOS technology. We will continue to introduce new products into the market based on our ELOS technology and we will continue to expand and strengthen our worldwide sales and marketing network."

8/24 **Candela Corporation** reported that revenues for its fourth quarter were \$34.2 million, a 32% increase over the same quarter a year earlier. For the full year, the company reported \$104.4 million in revenues, also a 32% increase over the same period last year. Earnings from continuing operations for the quarter were \$4,321,000, or \$0.19 per share. Earnings from continuing operations for the full year were \$10,512,000, or \$0.46 per share.

Gerard Puorro, Candela's president and CEO, commented: "We continue to grow at a healthy pace. The market investment we made in prior quarters is paying off as we see increased penetration into larger markets including family practitioners and general practitioners, particularly in North America. During the quarter, those markets represented approximately 47% of North American sales." Puorro continued: "All of our geographic distribution channels are poised for continued growth. As we begin a new year, we are optimistic that we will remain the market leader and look forward to increasing our lead."

## MEDICAL/SURGICAL LASER UPDATE -- September 2004

- 9/1 **Natus Medical Incorporated** announced the addition of the new neoBLUE mini LED Phototherapy device to the company's line of jaundice management products. Natus recently previewed the neoBLUE mini system at the *Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)* Convention in Tampa, Florida, where it was well received. The international launch of the neoBLUE mini light is scheduled to take place September 18, 2004 at the *European Society of Paediatric Research* meeting in Stockholm, Sweden.

Designed as a smaller counterpart to Natus' existing overhead neoBLUE LED Phototherapy Light, the neoBLUE mini system offers clinicians a more compact and portable alternative to other brands of phototherapy devices currently on the market. The neoBLUE mini device's adjustable arm with pole mount facilitates attachment to a variety of patient care apparatuses such as incubators and radiant warmers, often used during phototherapy treatment. Using special light-emitting diodes (LEDs), the neoBLUE mini device emits blue light, which is clinically proven to be most effective in the breakdown of bilirubin and treatment of newborn jaundice.

Jim Hawkins, president and CEO of Natus, commented, "With its small size and flexible mounting options, the neoBLUE mini is well-suited for a variety of patient care settings. More importantly, the neoBLUE system allows clinicians to comply with the recently published *American Academy of Pediatrics* guidelines for phototherapy. We are also excited to introduce this product at a lower price point, which we believe will be an excellent value to our customers."

- 9/1 **Trimedyne Inc.** announced that its chairman, Marvin Loeb, was interviewed by the *Wall Street Reporter*. Loeb described the company's products, medical applications and financial results. Trimedyne recently reported its seventh consecutive quarterly profit. It manufactures Holmium Lasers and Optical Fibers for fragmenting stones in the kidney, ureter or bladder, and Laser Needles for use in new, outpatient procedures to treat herniated or ruptured discs in the spine.

"In our disc procedures, the patient's back pain usually disappears during or shortly after the approximate 20 to 40 minute procedure, and the patient typically walks out with only a band-aid on the puncture, no stitches, and is back to light activities in a few days. Surgery to treat these conditions generally requires a two-to-seven day hospital stay, a lengthy, recuperation period and a long absence from work," Loeb said. "An estimated 10 million people in the United States suffer from back pain, most often from a damaged or diseased spinal disc," Loeb added.

- 9/2 **BIOLASE Technology, Inc.** provided an update on its anticipated operating expenses for the second half of 2004. The company estimates professional fees and costs associated with Sarbanes-Oxley implementation, **Diodem** patent lawsuit and shareholder class action

litigation will incrementally impact operating expenses by approximately \$900,000 in the third quarter and approximately \$950,000 in the fourth quarter.

Jeffrey Jones, BIOLASE's president and CEO commented, "Although these one-time professional expenses and other related costs for Sarbanes-Oxley implementation are affecting our short-term bottom-line as we move toward the completion date, we believe it is an important investment in the future of the company. BIOLASE has appropriate insurance with a deductible of \$250,000 that applies to legal fees related to the shareholder class action litigation. BIOLASE also expects to incur an estimated \$850,000 of additional legal fees related to the Diodem patent lawsuit in the second half of 2004. We believe it is in our best interest to step up the legal activities related to the Diodem matter and move towards a final resolution of this matter, with the goal of allowing management to put this distracting litigation behind us."

- 9/7 **Palomar Medical Technologies Inc.** said that they had signed an agreement with **Johnson & Johnson Consumer Companies, Inc.**, a **Johnson & Johnson Company**, to develop, clinically test and potentially commercialize home-use, light-based devices for (i) reducing or reshaping body fat including cellulite; (ii) reducing appearance of skin aging; and (iii) reducing or preventing acne. The agreement provides for JJCC to fund Palomar's development and clinical studies during an initial proof-of-principle phase.

Commenting on the agreement, Palomar CEO Joseph Caruso said, "This agreement with JJCC enables Palomar to continue early-stage research and development of light-based technology in a wide-array of fields for introduction to the consumer market. We are positioned with the best possible partner in these fields."

The agreement provides for continued research and development of light-based technology and even possible product commercialization, if testing and regulatory requirements are met. Further details of the agreement are contained in a corresponding filing with the Securities and Exchange Commission.

- 9/8 **BIOLASE Technology, Inc.** announced the selection of **Richter7**, a nationally-acclaimed public relations and advertising agency. Richter7 has been engaged to raise consumer awareness of its world leading Waterlase dental laser system. A national public relations campaign will be designed to generate awareness and educate consumers and dental professionals about the benefits of using Waterlase technology. The Waterlase is the #1 choice and fastest selling dental laser system, and gives dentists the ability to offer world-class, pain-free dentistry for dozens of hard and soft-tissue procedures.

Jeffrey Jones, BIOLASE's president and CEO commented, "Richter7 has impressed us with their ability to effectively showcase the unique benefits of previous clients' products to millions of consumers. And we believe an effective consumer PR campaign will leverage our marketing dollar by strategically raising the company's visibility on a more cost-effective basis. Additionally, we believe now is the time to step up our consumer

awareness initiatives, given that we have reached enough critical mass with over 2,800 Waterlase systems sold."

"BIOLASE will be a significant client to Richter7 and we are excited to help BIOLASE raise awareness of the clinically superior results offered by Waterlase technology," said Richter7 executive vice president of Public Relations Tim Brown. "Today it is essential for patients to be aware of options that are available and our national campaign will bring this information directly to consumers."

9/9 **PhotoMedex** announced that it had acquired, through an asset purchase agreement, exclusive worldwide rights to certain proprietary technology from **Stern Laser srl** of Italy. The technology is expected to expand PhotoMedex' product offerings in the dermatology field, and is the subject of a patent application filed in the European Union with an application in the United States expected in the near term.

Commenting on the technology acquisition, Jeffrey O'Donnell, PhotoMedex' president and CEO, stated, "We are constantly monitoring activities throughout the world related to our markets. We are pleased to have identified a technology that we believe will add appreciably to our offerings in dermatology as we expand the deployment of the XTRAC excimer laser throughout 2005. We believe the acceptance of the XTRAC as an integral part of the dermatologist's practice has opened the door for the deployment of additional technologies that can add significant value to these same practices. It is anticipated that the specific introduction of the technologies based on these newly acquired rights is expected to be made by the second half of 2005. Consequently, we have structured this transaction with milestone common stock payments."

**About the Transaction:** On September 7, 2004, PhotoMedex closed the transaction with Stern Laser in accordance with a Master Asset Purchase Agreement (the "Master Agreement"). PhotoMedex issued 92,464 shares of its common stock, valued at \$200,000, at the closing and committed up to an additional \$1.2 million upon the completion of certain milestones related to the development and commercialization of the products contemplated by the Master Agreement. The company has reserved the right under the Agreement to make the additional milestone payments in cash or through the additional issuance of its common stock. If in stock, the number of shares would be determined at the milestone dates based on an agreed formula to determine the price of the stock to be used in calculating the number of shares to be issued. PhotoMedex will file a registration statement to register the shares of common stock issued and which may be issuable under the Master Agreement. In connection with the Master Agreement, PhotoMedex also acquired certain assets and agreed to assume certain contractual rights and obligations of Stern Laser relating to the manufacture of medical products utilizing the licensed technology. Under a related License Agreement, PhotoMedex will pay to Stern Laser a royalty of 4 percent on sales of licensed products through 2008. The license is worldwide in scope and is exclusive to PhotoMedex for applications technology in the medical field.

In checking out the web site of Stern Laser, it was learned that the company is primarily a distributor of dermatological lasers from **Sciton**, PhotoMedex and **Cynosure**. According to a PhotoMedex representative, "They are acquiring the rights to new technologies in the dermatology space. Keep in mind the purchase price is rather modest, especially if the product(s) become even moderately impactful to revenues." Further, he said, "The company has decided to hold off on specific marketing or application information until a later date. Stern does have valuable technology that we believe will extend our abilities in dermatology and will better utilize the distribution channel into the dermatologists office that we are building through XTRAC."

- 9/14 **BIOLASE Technology, Inc.** provided an update on its share repurchase program originally announced on July 19, 2004 and subsequently expanded to a total of 2.0 million shares on August 9, 2004. As of August 31, 2004, the company had repurchased 1,477,000 shares. Timing of repurchases and exact number of shares of common stock to be purchased in the future will depend upon prevailing market conditions and other factors.

Federico Pignatelli, BIOLASE's chairman commented, "We believe that our shares continue to offer us an attractive investment opportunity in today's market. Although the market's pendulum swings from optimism to pessimism at times unjustifiably, we believe the combination of the cash dividend and the repurchase program demonstrates our commitment to long-term shareholder value. Furthermore, the Board's actions affirm the company's confidence in its future growth and its ability to generate future cash flows. Accordingly, BIOLASE has been actively repurchasing shares since the initial announcement of the repurchase program."

- 9/15 **PhotoMedex** announced that **Anthem**, the fourth largest publicly traded health benefits company in the United States and an independent licensee of the **Blue Cross and Blue Shield Association**, had adopted a medical policy approving payment for medically necessary treatment of mild to moderate psoriasis using the PhotoMedex XTRAC laser system. Anthem, through its subsidiary companies, provides healthcare benefits to more than 12.6 million people. Anthem is the Blue Cross and Blue Shield licensee for the states of Indiana, Kentucky, Ohio, Connecticut, New Hampshire, Colorado, Nevada, Maine and Virginia, excluding the Northern Virginia suburbs of Washington D.C.

Jeff O'Donnell, president and CEO of PhotoMedex, commented, "Our reimbursement team, including our physician partners, continue to make significant progress toward a fully reimbursed environment for the XTRAC. With the addition of the Anthem companies, more than half of the 41 plans in the Blue Cross Blue Shield National Network have now adopted coverage for the medically necessary treatment of mild to moderate psoriasis with the XTRAC system. We believe a fully reimbursed environment in the near term is a realizable goal."

- 9/17 John Calcagnini of **CIBC World Markets** initiated coverage of **Syneron Medical: ELOS: Initiating With Sector Outperformer Rating and \$21 Target**

Effective 9/17, we are initiating coverage of Syneron Medical with a Sector Outperformer rating and 12- to 18-month price target of \$21. ELOS presently trades at a P/E of 12.6X estimated 2005 EPS and fits in nicely with our "Global Mainstreaming of Plastic Surgery/Dermatology" theme.

Revenue for 2004 is estimated to grow 57% to \$55M, while earnings are forecast to jump 69% to \$25M, or \$1.06 per share. This growth will likely be driven by the global introduction of new and proprietary laser-based devices that combine optical light and radio frequency (RF) energy.

Syneron's products include lasers for hair removal, photo-rejuvenation, wrinkles, leg veins and new emerging indications like cellulite and acne. The company is also working on a non-invasive liposuction technology, expected to be launched in the U.S. in 2006.

Syneron maintains the highest profitability (gross margin of 87%) through outsourcing mfg, combining RF with optical energy to reduce COGS and taking advantage of "approved enterprise zone" benefits in Israel to pay very little in taxes. Competitors have margins in the 50%-65% range.

(In addition to providing a comprehensive overview of Syneron and its products, the report also provides an overview of the Aesthetic Market and Syneron's competitive position in that market.)

- 9/17 **CardioGenesis Corporation** announced that the minutes of the July Medicare Coverage Advisory Committee (MCAC) meeting, called to review the scientific evidence on laser myocardial revascularization, were now available on the Centers for Medicare & Medicaid Services (CMS) website. After speaking with CMS at the time of the posting of the minutes, CardioGenesis does not expect any action regarding the current TMR coverage by CMS at this time. The minutes of the meeting, which was convened by CMS, can be viewed on the CMS website at [www.cms.hhs.gov/mcac/id125b.pdf](http://www.cms.hhs.gov/mcac/id125b.pdf).

Medicare has covered TMR since 1999 for patients with severe angina who do not respond to standard medical therapy. The FDA approved the CardioGenesis TMR system in 1999.

- 9/21 **El. En.** reported their six-month results, for the period ending June 30, 2004. For that period, the company had sales volume of E45,018 thousand compared to E30,242 thousand for the same period a year ago, for an increase of 49%. Within the medical-cosmetic sector, which represents about 65% of the sales of the group, sales were E29,082 thousand, compared to E18,524 thousand, an increase of 57%.

In the cosmetic sector, which represents more than 70% of sales in this field, a considerable increase has been registered again, thanks to the contributions of all the companies of the Group operating in this area: **Deka, Cynosure, Asclepion and Quanta System**; these brands, which the Group manages with particular attention towards the

safeguarding of the independence and the particular characteristics of the individual firms, represent a very significant presence on the global market with products like Triactive for the treatment of cellulitis, Photosilk and Photolight for hair removal, and photo Rejuvenation (Deka), Mediostar (Asclepion), Light C and "Eterna Giovinezza" (Quanta System) and Apogee Elite (Cynosure) for hair removal and vascular treatments.

The dental sector also showed an exceptional growth, most of which came from the additional sales of Asclepion through its distributor **KaVo**, from Quanta System which has been very active in the field with its low-powered diode systems, and the success of the American subsidiary, **Deka Laser Technologies** which bases its distributing operations on the CO2 US 20D laser; the dental sector therefore has also benefitted from the innovations in the range of CO<sub>2</sub> lasers. The distribution of these devices in Italy through **Anthos Impianti** remains at an excellent level. Moreover, FDA approval has recently been obtained for our innovative Smartlite device for tooth whitening, as well as the formal authorization necessary for selling it in the USA. The FDA approval also represents an official recognition of the efficacy of the treatment which is useful on a world wide level.

In the category of "Other lasers" growth has been sustained by a variety of products offered and by the good results, in particular those of Cynosure and their Dye Lasers and of Asclepion with its new MCL30 version of its Erbium lasers for skin ablation. Along with the dental uses, the Smartlite system also obtained FDA approval for its elective applications in dermatology and vascular treatments, which, when used in connection with the Hi-Scan scanner represent a product of extreme interest for this sector. A new device for the treatment of psoriasis has also been introduced; this device is an appealing portable version with similar performance levels, of its predecessor Excilite. The Group has also continued its work on projects more directly related to hospital applications, and interesting developments are expected soon thanks to the results obtained from experiments for uses based on the technologies available to the companies in the Group.

It should also be noted that after the change in the supplying relationship between Cynosure and Sona which was negotiated as part of the sale of the equity, Cynosure will sell half of the equipment used by **Sona** for its activity in cosmetic laser treatments, and in return the amount paid by Sona in proportion to the sales volumes of its centers will be decreased. This will mean that there will be an increase in the sales volume for laser systems in the cosmetic field, and a decrease in the sales volume for services, of which the "revenue sharing" is part.

9/24 Thomas Kouchoukos and Gregory Simpson of **Stifel, Nicolas** initiated coverage of **Laserscope: Giving the "GreenLight" to an Impressive BPH Technology; Initiating Coverage with a Market Outperform Rating.**

We are initiating coverage of Laserscope with a Market Outperform rating and a twelve-month price target of \$26.00. LSCP manufactures and distributes advanced laser systems for aesthetic surgery and urology applications. While LSCP historically tended to focus its resources on developing and marketing laser systems for aesthetic applications, the Company has been aggressively pursuing the rapidly growing BPH segment of the urology market since launching its GreenLight laser system during the first quarter of 2002. Sales of the GreenLight system have been robust, with LSCP selling more than 270 systems and 31,500 disposable fibers since product launch.

**\* GreenLight PVP Is Poised to Replace TURP as the Gold Standard BPH Therapy.** The current "gold standard" surgical therapy for treating severe benign prostatic hyperplasia (BPH) is transurethral resection of the prostate (TURP), which is an effective but invasive procedure that carries high morbidity and complication rates. LSCP's GreenLight PVP procedure is a minimally invasive, laser-based BPH procedure that provides equivalent, if not better, clinical outcomes than TURP, with virtually none of the associated side effects or complications. We believe LSCP's GreenLight PVP procedure is well-positioned to replace TURP as the gold standard treatment for severe BPH.

**\* BPH Offers a Huge, Yet Dramatically Underserved Market Opportunity.** While more than 13 million American men live with BPH, including about 6 million that experience noticeable symptoms of the condition, only about 2 million actually seek treatment for their symptoms each year. The market opportunity is even larger in the international markets, where approximately 17 million men are afflicted with the condition, and TURP is the most common interventional treatment. We estimate that there are a minimum of 500,000 TURP procedures performed in the international markets each year, providing LSCP with a vast target market for its GreenLight PVP procedure.

**\* Favorable Demographics, Improved Reimbursement Provide a Powerful Combination for LSCP.** Aging Baby Boomers and increasing life expectancies are driving the BPH market opportunity. Reimbursement also represents a significant positive for LSCP, as the CMS recently doubled its Medicare payment for the GreenLight PVP procedure in the hospital outpatient setting. Going forward, we believe that this increase will be a significant catalyst in driving adoption of LSCP's GreenLight laser system.

**\* Mix Shift from Aesthetic to Urology Products Continues to Enhance Gross Margins.** Urology revenues are steadily increasing as a percentage of LSCP's consolidated sales mix, as GreenLight sales continue to rapidly penetrate the BPH market. Given the fact that GreenLight products offer a recurring revenue stream and carry higher margins than the Company's aesthetics products, we expect to see continued gross margin expansion at the corporate level as GreenLight represents a larger share of the revenue pie.

## **MEDICAL/SURGICAL LASER UPDATE -- October 2004**

9/28 **Diomed Holdings, Inc.** announced that it had entered into definitive agreements for \$10.6 million in financing through a private placement. James Wylie, president and CEO of Diomed Holdings, Inc., stated, "The completion of this financing helps to increase and solidify Diomed's position as a global market leader in the area of endovenous laser treatment of varicose veins with our patented EVLT technology. As evidenced by the greater market acceptance and awareness of the procedure by an increasing number of insurers across the US, we continue to be excited about the future prospects of our company and our industry in general."

The private placement financing consists of \$7 million in senior convertible debt and \$3.6 million in common stock. The debt is convertible at \$2.29 per share, which is a 20% premium over yesterday's closing price of \$1.91 per share and bears interest at the six month LIBOR rate plus 400 basis points. The convertible debt has a four-year term and is payable at maturity in cash or stock, subject to certain restrictions.

The \$3.6 million in common stock will be purchased at \$1.53 per share, a 20% discount to yesterday's closing price. The terms of the transaction include 50% warrant coverage for both equity and debt components. The warrants have a 5-year term, with an exercise price of \$2.10 per share, a premium of 10% to yesterday's closing price.

"Our decision to take advantage of this financing opportunity was based on our desire to continue to expand our business, maintain our competitive advantage, and to continue to vigorously protect our intellectual property rights under US patent law," Wylie added. "Coupled with our continued strong business fundamentals, this financing strengthens our balance sheet and positions the company to further expand its key sales and marketing initiatives, taking advantage of a rapidly growing market."



The company has agreed to register the underlying shares with the Securities and Exchange Commission. Closing is subject to the satisfaction of certain conditions, including the listing of the shares with the American Stock Exchange.

- 9/28 **Provectus Pharmaceuticals, Inc.** announced it had received a notice of allowance for what is anticipated to be the company's thirteenth U.S. patent and the fourth patent for a therapeutic medical device. The invention, which enhances multiphoton methods for therapeutic treatment, greatly expands the scope of the company's device technologies for treatment of certain cancers and other pigmented lesions, such as melanoma, as well as for precision surgical applications.

"These technologies are fundamental to a range of new laser-based medical devices that should dramatically enhance the precision and effectiveness of treatments for important skin, eye and neurological disorders, and are now the subject of intensive research and development in laboratories around the world," said Eric Wachter, Provectus executive vice president and co-inventor. "Together with our earlier therapeutic device patents, such as U.S. patents 5,829,448, 5,998,597 and 6,042,603, we continue to assemble an attractive portfolio of technologies that are available for licensure to the medical device industry."

Provectus' laser technology harnesses the energy of ultrashort laser pulses in a precise manner that minimizes damage to tissue surrounding the targeted surgical area. In addition, Provectus' technologies enable the selective destruction of cancerous areas and non-cancerous lesions based on the tissue's inherent light absorption. In certain cases, this may also elicit an anti-tumor immune response that can control or eliminate metastases.

A notice of allowance is an interim designation from the Patent and Trademark Office indicating that one or more of the patent's claims have been approved.

- 9/28 **Syneron Medical Ltd. and Syneron Inc.** won a significant legal victory in their defense of a patent infringement lawsuit brought by **Thermage Inc.** in the United States District Court for the Northern District of California. In the lawsuit, Thermage sought a preliminary injunction against the sale of Syneron's Polaris WR wrinkle treatment device in the United States. In a 12-page opinion, the court denied Thermage's motion for a preliminary injunction. The court found that Thermage had failed to establish a likelihood of success on the merits and was therefore not entitled to a preliminary injunction. Moshe Mizrahy, Syneron's CEO, said that the company was "extremely pleased that the court found that Syneron's challenge to the validity of the patent at issue has substantial merit."

The decision was particularly important to Syneron, the first and only company in the world to combine the use of light and radiofrequency energy in a medical device for dermatological and medical aesthetic treatments. The court found that there was substantial merit to Syneron's position that Thermage's patent claim, which Thermage filed after it saw Syneron's products on the market, was not supported by the written description of the patent, and that Syneron had raised a substantial question regarding

whether the claim was "enabled." The court also held that Thermage's patent claim was vulnerable to invalidation based on two prior art references. "The court clearly saw Thermage's action as an attempt to claim that which it did not invent, and rejected it," said Mizrahy. "Syneron will continue to vigorously defend itself against this lawsuit by Thermage who has chosen to litigate rather than compete in the market place," Mizrahy added.

9/30 **BIOLASE Technology, Inc.** announced the introduction of the Waterlase MD, a new clinical and technological platform for dentistry. The company plans to officially launch the new product at the *American Dental Association's (ADA) 2004 Scientific Session* in Orlando, Florida on October 1, 2004. The Waterlase MD, which features exclusive, proprietary technology from BIOLASE, has a very broad range of clinical capabilities both in dentistry and other medical disciplines.

The Waterlase MD platform delivers on the "wish list" of clinical capabilities requested by dentists and comfort sought by patients. Notable features include the HydroBeam LED illumination with a contra-angle 360-degree rotating handpiece as well as a SensaTouch laser control system with easy touch screen functionality. The new system provides powerful cutting action, allowing the dentist to select up to 50 pulses per second. Another key advancement of the new system is two distinct pulse modes. Dual-mode capability gives the dentist the ability to do procedures with more comfort and control. These new features coupled with innovative, ergonomic styling and design are part of BIOLASE's proprietary MD technology platform upon which the Waterlase MD is based.

The Waterlase MD all-tissue dental laser is the new premium price-point product of BIOLASE's comprehensive dental laser product portfolio, serving to expand the company's existing dental laser product line. BIOLASE's other product offerings include the Waterlase YSGG laser, LaserSmile soft tissue and whitening laser and DioLase Plus hygiene and periodontal laser.

"The suite of new features gives me a degree of control to cut tissue far more effectively and precisely than ever before. This instrument is finely tuned for supreme patient comfort, which my patients highly appreciate," said Dr. James Jesse, practicing dentist and consultant to BIOLASE, reflecting on his experience with the Waterlase MD. "After using the Waterlase MD, I cannot think of any objection or rationale that isn't completely addressed by the new features of this laser."

Jeffrey Jones, BIOLASE's president and CEO commented, "The Waterlase MD is a product that brings customer feedback and innovative engineering together in development of an instrument with exceptional utility, effectiveness and 21st century design. Our primary goal was to introduce a new type of all-tissue dental laser that offers mass appeal while raising the bar to a new level of clinical excellence. This new platform demonstrates BIOLASE's continuing commitment to research and product development."

9/30 **Spectranetics Corporation** announced its products were used in two separate live case sessions at the *Transcatheter Cardiovascular Therapeutics (TCT)* convention, which is being held this week in Washington, D.C., and which is attended by more than 9,000 physicians. The first live case session featured a 2.3 millimeter diameter CLiRpath excimer laser catheter recently cleared in the United States by the FDA to treat a total occlusion in the popliteal artery of the leg. The blockage was successfully treated by Professor Giancarlo Biamino, MD and Dierk Schienert, MD of Leipzig Heart Center in Leipzig, Germany. Dr. Biamino pioneered the use of laser technology for the treatment of peripheral vascular disease and has performed more than 5,000 peripheral cases utilizing the excimer laser system.

The second live case featured a patient with a chronic total occlusion (CTO) in the left anterior descending (LAD) coronary artery that was successfully crossed using a Prima Laser Wire and a Quick-Cross support catheter. The female patient treated had triple-vessel disease, with the target lesion having previously failed crossing attempts with mechanical wires. Jaap Hamburger, MD, of Vancouver General Hospital, British Columbia, performed the successful crossing of the CTO, which was approximately 20 millimeters in length, in roughly 10 minutes.

Dr. Hamburger commented, "I'm excited about the re-emergence of the Prima Laser Wire technology. The treatment of chronic total occlusions continues to be a challenging indication for interventionalists. Today's procedure clearly demonstrated the capability of the device to cross otherwise resistant chronic total occlusions."

10/4 **DUSA Pharmaceuticals, Inc.** reported at the annual meeting of the *American Society for Dermatologic Surgery* in San Diego, held September 30th to October 3rd, 2004, that an independent investigator group presented the results of the first prospective, randomized, controlled, split face clinical study using the Levulan (aminolevulinic acid HCl) Kerastick together with intense pulsed light (IPL) for the treatment of photoaging. DUSA provided Levulan and financial support to the investigator group.

In the 20 patient study, led by renowned laser expert Dr. Jeffrey Dover of SkinCare Physicians of Chestnut Hill, MA, patients received a series of 3 split-face IPL treatments 3 weeks apart, in which half of the face was pretreated with the Levulan Kerastick followed in 45 plus or minus 15 minutes by IPL treatment, while the other half of the face was treated with the same doses of IPL alone. Each patient then received 2 additional full face IPL alone treatments 3 weeks apart, since the standard of care in non-ablative photorejuvenation had been 5 treatments with IPL alone. Patients were assessed by a blinded investigator for global photodamage, fine lines, mottled pigmentation, tactile roughness and sallowness prior to each treatment and 4 weeks after the final treatment. Pre-treatment with Levulan resulted in statistically significant improvement in global scores for photoaging (80% vs. 50%, p less than 0.02), and mottled pigmentation (95% vs. 65%, p less than 0.02). Pre treatment with Levulan also resulted in a significantly greater reduction of mottled pigmentation and fine lines to low or imperceptible levels (p less than 0.001 and p less than 0.01 respectively). Both the

investigator cosmetic evaluations and the subject satisfaction scores were significantly better for the Levulan plus IPL treated sides. The investigators found no difference in the side effect profile with or without Levulan pretreatment, and noted that both treatments were well tolerated. They also noted that no patients dropped out of the study.

The investigators concluded "The adjunctive use of ALA in the treatment of facial photoaging with IPL provides significantly more improvement in global photodamage, mottled pigmentation, and fine lines than treatments with IPL alone, without a significant increase in side effects. This combination treatment allows physicians to provide better results, with higher patient satisfaction."

Facial photoaging or photodamage is a common cosmetic problem seen in light-skinned individuals with years of significant exposure to the sun. Signs of facial photodamage include increasing skin sallowness, roughness, fine wrinkling and mottled pigmentation. Current treatments for this condition include laser resurfacing, nonablative photorejuvenation using laser and non-laser light sources, dermabrasion and chemical peels. Results from earlier published independent investigator studies reported that photodynamic therapy (PDT) carried out using Levulan plus IPL helped to resolve certain signs of facial photodamage. However, no controlled split-face studies versus IPL alone have been previously reported.

Geoffrey Shulman, MD, DUSA's president and CEO, stated "We are very pleased with the positive results of this independent study in the treatment of photodamaged skin, in which 3 treatments with Levulan plus IPL (plus 2 IPL alone) were compared to 5 treatments with IPL alone, which until now has been the standard of care in non-ablative photorejuvenation. DUSA hopes to corroborate and extend these results with DUSA's ongoing Phase II multi-center split-face photodamaged skin study utilizing 3 light sources (IPL, long pulse dye laser and DUSA's BLU-U) with and without Levulan.

The ASDS meeting also included at least 13 other scientific presentations focused on PDT, including a full session called 'Expanding the Uses of Topical Photodynamic Therapy'. DUSA was also well represented at the technical exhibits, with a full complement of sales and marketing staff to answer questions and engage in discussions with the large number of physicians showing interest in our therapy."

- 10/4 **Pharmacyclics, Inc.** announced the presentation of Phase 1 trial results describing the use of Antrin (motexafin lutetium) phototherapy for the treatment of coronary atherosclerosis. The presentation, by Dr. Alan Yeung, included data from intravascular ultrasound (IVUS) imaging studies showing that Antrin prevented plaque build-up following balloon angioplasty and stent placement in patients receiving optimum doses of drug and light therapy. Dr. Yeung's presentation took place at the *Cardiovascular Research Foundation's 16th Annual Scientific Meeting of Transcatheter Cardiovascular Therapeutics (TCT)* held in Washington, DC, at a scientific session entitled, "Vulnerable Plaque: Pathophysiology, Detection and Therapeutic Intervention."

Angiographic data from the Phase 1 study, published in the September 16, 2003 issue of *Circulation*, provided initial evidence of the safety and feasibility of Antrin phototherapy in patients undergoing balloon angioplasty with stent deployment. The current study, reported at TCT, presented quantitative and qualitative results from IVUS imaging studies and represents the first observations detailing the morphological changes of the coronary arterial wall subjected to phototherapy with various doses of Antrin and light.

"Antrin phototherapy is safe and feasible as an adjunctive therapy after coronary stenting in patients with coronary artery disease," stated Dr. Yeung, division head of Cardiovascular Medicine and Professor at Stanford University and one of the investigators on the trial. "One study cohort showed suppression of plaque volume increase using an optimal drug-light regimen. The potential of this dose combination for atraumatic stabilization of vulnerable plaque should be further evaluated in a randomized controlled study to determine clinical efficacy."

During the open label multi-center drug and light dose escalation study, Antrin was administered intravenously to 79 patients 18-24 hours prior to balloon angioplasty and stent insertion for coronary atherosclerosis. Intravascular photoactivation of Antrin was accomplished using an optical fiber inserted into the coronary artery at the time of balloon angioplasty. In a sub-study involving 39 patients, careful qualitative and quantitative IVUS imaging was performed immediately after the procedure and at six months follow-up. Analysis of the IVUS data was based on serial slices through the treated arterial segment and untreated boundaries.

The design of the trial was based on preclinical studies, which suggest that Antrin may localize to plaque, prevent cell proliferation following arterial injury, selectively deplete macrophages (inflammatory cells) from plaque, and cause regression in plaque volume without damaging the vascular wall.

The IVUS analysis provided additional data that suggests Antrin does not have deleterious effects on the vessel wall. In the group of patients (N=7) receiving 2-4 mg/kg of Antrin and 100 Joules of light, no atherosclerotic plaque volume increase was observed at the stented site at six month follow-up (average plaque area 8.01 $\pm$ 4.33mm<sup>2</sup> post stent to 7.86 $\pm$ 3.24mm<sup>2</sup> at six months, not significant, P=0.79). Statistically significant plaque volume increases were observed in the stented arterial segments in the two other patient cohorts receiving lower doses of Antrin (0-1.0 mg/kg, N=9, average plaque area 6.59 $\pm$ 2.28 mm<sup>2</sup> post stent to 7.17 $\pm$ 2.47mm<sup>2</sup> at six months, P=0.028) and higher doses of light (200-600 Joules, N=23, average plaque area 7.76 $\pm$ 3.70mm<sup>2</sup> post stent to 8.91 $\pm$ 3.87mm<sup>2</sup> at six months, P<0.001).

Similar results have been reported in animal models which indicate that Antrin phototherapy with low doses of light produce more favorable effects.

"The detection and treatment of vulnerable plaque represents an emerging area in cardiology," said Richard Miller, MD, president and CEO of Pharmacyclics. "The IVUS data reported here demonstrate that Antrin phototherapy produces a favorable biologic effect in coronary arteries and we intend to pursue the application of our technology to diagnosis and treatment of vulnerable plaque."

10/5 Plastic surgeons around the country are concerned about the message being delivered by some plastic surgery reality shows. According to the *American Society of Plastic Surgeons (ASPS)*, these programs trivialize the process of plastic surgery and can mislead the public. Because of their growing concern, the ASPS is embarking on a public awareness campaign to educate the public on the true nature of plastic surgery.

10/5 **Diomed Holdings, Inc.** acknowledged that, with recently issued health insurance policies, the number of eligible covered lives for the EVLT procedure now exceeds 140 million Americans. "The list of private regional and national insurance providers with positive coverage policies on EVLT has grown significantly over just the last two months driven in large part by the addition of **United Healthcare**," stated John Welch, vice president of Marketing for Diomed. "United Healthcare has joined other organizations such as **Aetna US Healthcare** and **Humana** along with an extensive list of independent **Blue Cross Blue Shield** and Medicare (Part B) carriers now providing our rapidly growing EVLT patient base with access to broad insurance coverage."

It is estimated that at least 25 million Americans suffer from some form of varicose veins due to venous insufficiency. This disorder can have a significant adverse effect upon quality of life, is often unsightly, painful and, if left untreated, may lead to serious complications. EVLT offers patients afflicted with venous insufficiency a relatively pain free and affordable treatment alternative. Unlike traditional varicose vein surgery that can require expensive hospitalization and general anesthesia, EVLT is an outpatient procedure that requires only local anesthesia. Employers recognize an economic benefit because EVLT allows people to return to work within 24 hours or less when compared to traditional surgery, which can require weeks of painful recovery.

James Wylie, president and CEO of Diomed commented, "The rapid expansion of positive coverage policies reinforces the safety and efficacy of the EVLT procedure. Diomed remains committed to continuing its nationwide support of physicians and hospitals through proactive education and advocacy with health insurance carriers to facilitate broader patient access to EVLT."

10/5 **Candela Corporation**, and **Chindex International, Inc.**, a leading independent American provider of western healthcare products and services in the People's Republic of China, jointly announced today an exclusive, multi-year distribution agreement for the People's Republic of China, including Hong Kong. Under the terms of the agreement, Chindex will market and distribute the extensive Candela product line of aesthetic laser systems to dermatologists, plastic surgeons, family practitioners, OB/GYNs, and general and vascular surgeons throughout the healthcare industry in China. The Candela products

offer technologies for hair removal, wrinkle reduction, the treatment of vascular and pigmented lesions, tattoos, acne, and atrophic acne scars.

Chindex president and CEO, Roberta Lipson, said that the emerging market for aesthetic laser treatment in China is very significant. "In the quickly growing economies of the urban cities in China, the business of aesthetic health technologies is growing rapidly. This is a technology which will command a broad and expanding market in China."

"We believe Candela and Chindex will make a great team." Lipson said. "We have already had a Candela Laser Clinic and Training Center at our company's Beijing United Family Hospital for the past year. The Center treats patients of the hospital, as well as trains new and potential customers of Candela in China. Both patient and market reaction have been very impressive. This highlights the synergistic qualities between the products and healthcare services divisions of Chindex, as well as our strong basis for confidence in future laser sales."

Candela president and CEO, Gerard Puorro, said: "Strategically, Chindex is the right partner at the right time. They possess strong distribution skills in China in both capital equipment and cosmetics. Together we look forward to expanding the Chinese market for laser cosmetics and aesthetics."

10/6 Peter Benesh, of *Investor's Business Daily*, wrote about **Palomar Medical Technologies**, in his article entitled: **Maker Of Skin Products Takes Its Pitch To The Masses**

Palomar Medical Technologies built its business by selling doctors on the benefits of light-based devices to rejuvenate skin, treat acne and remove unwanted hair, wrinkles, veins and cellulite. Now the company is taking its products to the masses.

Palomar is partnering with **Gillette** to develop a light-based, home hair-removal device for women. Gillette is responsible for funding development and taking care of marketing, distribution and manufacturing, among other things. Palomar is responsible for getting the device through the Food and Drug Administration.

"We looked at our expertise and where our strength lies. It's in technology and getting a device through FDA approvals," said Palomar Chief Executive Joe Caruso. "Gillette is expert in mass production, distribution, marketing and branding. That's why we passed the ball." He looks for the partnership to give a further lift to his company's financial returns, which already are impressive. Palomar's second-quarter revenue rose 53% from the prior year to \$13.2 million. Earnings quadrupled to 12 cents a share.

First Call analysts see full-year profit more than tripling to 45 cents a share.

Caruso recently spoke with IBD.

IBD: When will the home hair-removal device reach consumers?

Caruso: It should take some time for Gillette to ramp up manufacturing, do their branding and the logistics of distribution. At that point, when they launch the product, they will start to pay us and continue to pay us \$10 million every year for us to remain exclusive to them.

IBD: You also have a deal cooking with **Johnson & Johnson**.

Caruso: For J&J we're working on skin rejuvenation, cellulite and acne treatments. We're at the proof-of-principle phase. Those products may take a little longer. What Palomar's tried to do is align itself with the best partners. In the area of hair management, we think we have the best partner in Gillette. In healthy skin, we think that J&J is the best partner.

We also received a \$2.5 million contract from the U.S. Army to use our hair removal technology to treat a condition called pseudofolliculitis barbae, or PFB. It's a facial condition more common among African-Americans and Hispanics. It's a big problem for military people wearing personal protective gear in the field. It got us some additional funding and helps us in our planning and research.

IBD: You've built your name and reputation in the professional field, selling to doctors. How big is that segment of the market?

Caruso: The equipment side of that market worldwide is about \$650 million. But think about the growth in this industry. It's growing at over 20% a year. Our share has been increasing 35% year over year for the past two years. Only 5% of the population has heard about light-based treatments. And only 1% of the population has been treated. As consumer awareness increases, that will mean increased sales of equipment.

I also see a big increase in the male side of the business. In laser hair removal, 30% of procedures are for men. I also see an increase in treatment for sun-damaged skin, like age spots. In 1997, when the FDA approved the first laser hair removal device, revenue was zero. I expect it to hit \$5 billion in the next few years.

The question for our company is: How do we tap into that? The way to do that is to get into the consumer market with our patented technology.

IBD: Explain that technology.

Caruso: It's really a form of micro-surgery done in a noninvasive way. It's all light based. Light encompasses many different parts. Lasers are a type of light. Flash lamps are a different kind of light. So is halogen. We use photons. By choosing the right wavelength, pulse duration and energy level, we can selectively heat up certain targets in the skin. We change or destroy those targets while the surrounding area remains unharmed.

If we want to selectively treat blood vessels, we use a different wavelength, pulse duration and energy level. At the same time, we leave lipids, melanin and water and all



the parts of the skin intact. This whole aesthetic use of light is really less than 10 years old.

IBD: There are many competitors with similar light-based facial, skin and hair-removal treatments.

Caruso: We have a number of competitors: Candela, Lumenis, Cutera and Syneron Medical. Most of them use laser technology. We started in laser technology but moved into the flash lamp system. Lasers produce a single wavelength. Flash lamps produce multiple wavelengths. By selecting the right filter, we filter out the wavelengths we don't want and use the wavelength of choice for heating specific targets. We combine this technology with hand pieces made for each job.

If a physician wanted to do three procedures, in the past he would have had to buy three lasers with a wavelength for each application. We can offer one system with different hand pieces to do all those jobs.

IBD: Putting this technology in consumer hands might pose a safety risk. How fail-safe is it?

Caruso: These devices have to be extremely safe while still being effective. I can't disclose how we'll take this technology from the professional to the consumer level. Products we will end up with will be safe, effective and at the right price point.

10/6 **Spectranetics Corporation** announced its laser products were used in two more live case sessions at the *Transcatheter Cardiovascular Therapeutics (TCT)* convention bringing to four the total number of Spectranetics live cases performed at this year's TCT.

The two latest live cases were performed at the Cardiovascular Institute of the South by Craig Walker, MD. Both cases treated blockages in the legs and yielded successful results. During one of Dr. Walker's cases, a complication occurred that was associated with a distal embolization (blood clot) dislodged from the blockage as it was being treated with another device. The distal embolization became lodged in an artery in the lower leg and Dr. Walker used Spectranetics' 0.9 millimeter CliRpath Excimer Laser Catheter to ablate the embolized blockage and restored blood flow in the occluded artery. If this blockage could not have been successfully treated, blood flow to the foot would have been compromised and could have progressed to limb ischemia, a debilitating condition that often leads to amputation.

Dr. Walker commented, "The excimer laser is an excellent tool for ablating thrombus and other organic material. The catheters are small and flexible and allow us to remove blockages in the small arteries in the lower leg. We also use the larger catheters to cross and debulk total occlusions in the superficial femoral artery. In the second case, this patient had few options and we were successful in restoring straightline blood flow to the foot without major surgery."

10/7 **BIOLASE Technology, Inc.** announced preliminary results for the third quarter ended September 30, 2004. Total revenue for the third quarter is anticipated to be between \$11.5 and \$12.1 million and a net loss is expected. This compares with revenue of \$13.4 million and revenue of \$10.7 million for the third quarter of 2003. The \$10.7 million excludes \$2.7 million of revenue that was deferred to the third quarter of 2003 as a result of the restatement of revenues. The revenue numbers presented are not in accordance with generally accepted accounting principles but are presented to provide a clearer understanding of the impact on the company's results of changes in revenue recognition. You should not consider this information in isolation or as a substitute for analyzing our results.

"We are disappointed in the level of sales for the quarter," said Jeffrey Jones, CEO and president. "Our initial analysis indicates that sales were adversely impacted by two factors. The first factor was rumors concerning the introduction of the new advanced Waterlase MD. We believe some potential buyers withheld their decision to purchase the Waterlase in anticipation of the company's new product launch at the *American Dental Association (ADA)* Annual Meeting in Orlando, FL. The second factor was the series of devastating hurricanes that struck the Gulf region resulting in the cancellation of the New Orleans Dental Conference 2004 as well as other scheduled sales activities. Historically, these events have been important vehicles for securing sales in the third quarter," continued Jones.

"Our strategy is to introduce new products to speed market adoption of our Waterlase technology with innovative applications for our customers. The recent launch of the advanced Waterlase MD was the most important product introduction undertaken by the company in its history. Unfortunately, however, it is often a risk for a business that derives 80% of its revenue from one product to find itself in this position following a product line extension," Jones concluded.

"Due to the Florida hurricane season, we noted a major decline in attendance at the ADA meeting where we launched our new Waterlase MD system," said Jones. "Industry sources have indicated that the attendance was dramatically down from last year. Although we are confident in our business model; as a cautionary measure, we are revising our revenue guidance."

At this time, management expects revenue for the fourth quarter of 2004 to be in the range of \$17 million to \$20 million as compared to previously reported revenue guidance of \$23 million to \$25 million for the quarter. Due to the disappointing ADA attendance and product transition challenges as well as a possible lull in demand for capital equipment, management has taken a cautionary step to reduce guidance for the upcoming quarter.

The third quarter outlook announced today is preliminary and subject to change as a result of final review by management and closing adjustments for the quarter. BIOLASE expects to report final third quarter results on October 27, 2004.

The company also reported a very successful product launch of the new Waterlase MD at the annual meeting of the *American Dental Association (ADA)* held on October 1-3 in Orlando, FL. Despite a major decline in ADA attendance due to the scare of Florida's hurricane season, BIOLASE recorded more than \$2.6 million in orders during the conference. According to various industry sources, the company estimates that less than 8,000 dentists attended the annual meeting in Orlando, FL, which represents a significant decline from last year with more than 17,000 dentists at the ADA annual meeting in San Francisco, CA.

The Waterlase MD is the most advanced laser system available in the dental market, featuring HydroBeam Illuminated Laser Handpiece -- "first in the industry", SensaTouch Laser Control System and state-of-the-art styling and design. BIOLASE's new, proprietary MD platform provides several new clinical advantages including: (i) fast and smooth cutting of hard tissue in short pulse mode -- with more power and more pulses per second (up to 50 Hz for hard tissue), (ii) great homeostasis and smooth cutting of soft tissue -- with long pulse mode and more pulses per second (up to 50 Hz for soft tissue), and (iii) less pain sensitivity -- more gentle, (lower pressure, more dispersed) continuous spray.

BIOLASE is pleased to report that the product launch of the new Waterlase MD was very well-received both from the dental community and trade media. Over the three day event, the company's VIP viewing sessions, press conferences and other media engagements were well attended. Additionally, as part of the formal program of the ADA, Dr. Stewart Rosenberg's lectures on "Lasers in Dentistry" were also very well attended.

At the ADA, the company also unveiled its new two-story exhibit named the "BIOLASE Experience," which was filled with numerous individual work stations, a large lecture theater with state-of-the-art video and sound equipment for detailed clinical presentations and several plasma video screens showcasing the several FDA cleared procedures performed by Waterlase technology.

Dentists at the BIOLASE exhibits participated in short lectures by experienced Waterlase owners, received hands-on demonstrations using the Waterlase technology on extracted teeth and soft tissue and met with BIOLASE laser specialists to answer detailed questions regarding the company's products.

Jeffrey Jones, CEO and president, stated, "Although the ADA attendance was low, BIOLASE was one of the main attractions at the meeting. It is evident that more and more dentists are becoming aware of Waterlase technology and its compelling financial and clinical benefits. In particular, the Waterlase MD out sold the Waterlase YSGG, notwithstanding a \$20,000 increase in average selling price, by more than 4 to 1. And more importantly, our existing Waterlase owners, who we met with at the ADA, have enthusiastically embraced the new product and look forward to incorporating it into their practices. Given this warm reception from the MD launch, we believe this new product will propel our market leadership into the future."

Dr. Dan Jenkins, practicing dentist in Chino, California said, "Today, the MD is the right decision for my office and that's why I bought one. I love the sleek styling, small footprint, illuminated handpiece and smooth cutting action on both hard and soft tissue."

Finally, the company announced that its Board of Directors declared to pay a regular cash dividend of \$0.01 per share. The dividend will be payable October 27, 2004 to shareholders of record on October 13, 2004.

- 10/7 As reported by Mark Martinez of *TheStreet.com*, in his **Health Stocks in Motion** column, two of the medical laser companies went in the opposite direction. **IntraLase**, off of its IPO went up, while **BioLase**, warning that third and fourth quarter results would be short of analyst's expectations, fell sharply.

Shares of **IntraLase** were among the best-performing health and pharmaceutical stocks Thursday, rising 25% on the company's first day of trading. The medical-device maker priced 6.6 million shares at the high end of its proposed \$11 to \$13 range, raising about \$82 million. About 336,000 shares were offered by selling shareholders. IntraLase designs and markets an ultrafast laser that's used in creating the corneal flap, which is the first step in Lasik eye surgery. The company plans to use the proceeds for general corporate purposes. Shares traded up \$3.25 to \$16.25.

**Biolase Technology** fell 14.8% after the company warned that third- and fourth-quarter results would fall short of expectations. The medical technology company is now expected to post a loss during the third quarter on sales of \$11.5 million to \$12.1 million. Analysts polled by **Thomson First Call** had been expecting a profit of 2 cents a share on sales of \$15.8 million. For the fourth quarter, Biolase expects to post sales of \$17 million to \$20 million, down from previous guidance of \$23 million to \$25 million. Analysts had been expecting sales of \$24 million. The company blamed the weak outlook on disappointing *American Dental Association* attendance, product transition challenges and a lull in demand for capital equipment. Shares traded down \$1.26 to \$7.23.

- 10/7 **IRIDEX Corporation** announced that it had received 510(k) clearance from the FDA for its new VariLite dual wavelength laser. The VariLite was cleared for 19 specific dermatology indications including the treatment of vascular lesions, leg veins, benign pigmented lesions, cutaneous lesions, hair removal, and moderate inflammatory acne vulgaris, making it one of the most versatile semiconductor-based laser systems on the market. The VariLite offers 532 nm and 940 nm wavelengths in a small, reliable, affordable and convenient platform.

Theodore Boutacoff, president and CEO commented, "The VariLite laser increases IRIDEX' product offerings and indications amenable to treatment for dermatologists and plastic surgeons. It combines the benefits of our popular 532 nm DioLite laser system and a high power 940 nm laser system into a single platform. The VariLite satisfies physician demands for versatility and affordability, and we believe it will set a new standard for performance and value in the dermatology and plastic surgery markets."

The VariLite system features ergonomic dual wavelength handpieces that allow immediate switching between the two wavelengths for added convenience when treating a wide variety of dermatological indications. The 532 nm wavelength is the standard of care for purpura-free treatment of facial vessels and pigmented lesions and complements the 940 nm wavelength which penetrates more deeply into tissue allowing treatment of larger vessels, such as leg veins. Treatment usually takes just a few minutes and normally yields immediate outcomes without bruising, allowing patients to quickly resume normal activities with little risk of side effects.

"We believe the VariLite is well positioned for adoption by physicians looking for versatility in a first laser purchase, for those considering purchasing multiple competitive laser systems, and for those with existing IRIDEX products who are looking to upgrade to this new technology system to expand indications," Mr. Boutacoff continued.

IRIDEX will introduce the VariLite at the upcoming *American Society of Plastic Surgery (ASPS)* annual meeting being held October 9-12, 2004 in Philadelphia, PA, and internationally at the 13th Congress of the *European Academy of Dermatology and Venereology (EADV)* being held November 17-21, 2004 in Florence, Italy.

10/7 **CardioGenesis Corporation** announced the launch of **www.HeartOfNewLife.com**, a website designed to meet the increasing demand of patients and physicians searching for timely, accurate medical information regarding Transmyocardial Revascularization, an option for certain patients suffering from severe, debilitating chest pain, or angina. Consistent with the company's branded slogan "At the Heart of New Life," the company anticipates this site will help to meet the informational needs of patients and the medical community regarding heart disease and the application of TMR therapy.

Michael Quinn, chairman and CEO of CardioGenesis stated, "The internet is a prevalent source of healthcare information for patients and doctors alike. We consider this new educational website to be an important tool that patients and the medical community can use in their search for information about the potential risks as well as the dramatic patient benefits of TMR therapy."

Quinn explained that the company is working closely with cardiothoracic surgeons and cardiologists in developing the content and format of this innovative healthcare website. "Surgeons performing TMR today have repeatedly emphasized the need for the company to aid in the process of educating and informing the medical community and potential patients about the latest information regarding TMR," Quinn said. "This website, for the first time, provides that information in an easily understandable and accessible way to anyone with a link to the internet."

When asked what the difference is between this site and the company's existing website, Quinn stated "Our goal with HeartOfNewLife.com is to make sure that every patient suffering from severe angina has access to current information to help them determine if they may be a suitable candidate for this life changing therapy called TMR.

"This site is not a CardioGenesis advertisement, but rather an educational site dedicated to TMR therapy and those patients and their caregivers who desire to get the most out of their doctor visits."

10/8 **Millennium Dental Technologies, Inc.** announced it had received the first FDA clearance ever for a laser-based periodontal (gum) disease treatment protocol while using the first ever digital dental laser -- the PerioLase MVP-7.

50 people out of 100 have moderate to severe gum disease, 40 out of the 50 don't know it, and only 3 people out of 100 will ever get treated before it's too late. Gum disease is a silent, painless, chronic, communicable, bacterial infection that often goes undetected or ignored until severe gum and bone destruction catch the individual's attention. Traditional treatments for gum disease have, until Laser-ANAP, been perceived as painful with a long and uncomfortable recovery, scaring patients away and causing the epidemic numbers suffering with this preventable and now attractively treatable disease.

The FDA cleared Laser-ANAP (Laser Assisted New Attachment Procedure) with a unique and specific claim for, "cementum-mediated new periodontal ligament attachment to the root surface in the absence of long junctional epithelium."

FDA clearance for Laser-ANAP using the PerioLase MVP-7 variable pulsed Nd:YAG dental laser follows three years of research at Louisiana State University, School of Dentistry, New Orleans, by principal investigator, Professor Raymond Yukna, DMD, and coordinator of post-graduate periodontics at LSU. Professor Yukna led a controlled, blinded, clinical and human histology study that evidenced new root surface coating (cementum) and new connective tissue (periodontal ligament) formation (collagen) on tooth roots by stimulating existing stem cells to grow following the use of the PerioLase MVP-7 & Laser-ANAP protocol.

"These results are very positive, very consistent, and very encouraging related to the treatment of deep gum pockets," said Yukna. "Dentists have been looking for ways to regenerate some of the tissues lost to gum infections and Laser-ANAP is an exciting and revolutionary treatment protocol showing microscopically that we can form a new root coating (cementum) and new connective tissue attachment (collagen). Our consistent results (all LANAP treated teeth showed a positive result) suggest that the best possible type of healing can be obtained using the specific Laser-ANAP protocol. This presents a wonderful alternative to traditional surgery."

The preliminary phase of Yukna's study was published in the *International Association of Dental Research*, January, 2004. On March 12, 2004, Dr. Yukna and co-workers presented their complete findings at the *International Association of Dental Research* Meeting in Hawaii in a paper titled, "Human Periodontal Regeneration Following the Laser Assisted New Attachment Procedure."

10/11 **Spectranetics Corporation** announced that it had entered into a series of agreements with **ELANA BV**, a private company based in The Netherlands. The agreements provide for Spectranetics to supply laser systems and to develop and supply catheters. A cross-licensing arrangement of the respective companies' selected intellectual property rights is also a part of the agreements. The products subject to these agreements will be marketed by ELANA for use in bypass surgery, initially focused on neurovascular applications.

ELANA (Excimer Laser-Assisted Non-occlusive Anastomosis) is the only known surgical technique that enables surgeons to create a bypass without occluding the recipient vessel, ensuring continued blood supply during an operation. To make the anastomosis (connection for the bypass graft), a platinum implant is attached onto the outside wall of the recipient vessel. The end of the bypass graft is stitched to the wall of the recipient vessel, using the implant as a guide. A specialized laser catheter is inserted through the bypass graft to the wall of the recipient vessel. Laser ablation is used to create a hole in the artery wall and the laser catheter removes the disc, enabling blood flow to the recipient vessel.

The ELANA clinical research is currently being performed at five European sites accumulating more than 250 cases. Additional clinics are expected to be added soon, including sites in the United States. The ELANA technique will be commercialized by ELANA BV ([www.elana.com](http://www.elana.com)) and is currently used for patients with a giant aneurysm or a skull base tumor and insufficient collateral circulation. The technique has been used to successfully treat patients at risk of hemodynamic stroke, and if pilot studies corroborate these results, further research could result in a considerable expansion in the number of ELANA operations. Future results using the technique suture-less with an anastomosis device developed by ELANA could increase the safety and simplicity of the traditional bypass operation and may expand use of the ELANA technique beyond neurovascular applications.

Revenue to Spectranetics associated with these agreements will consist of laser sales and rental revenue, service revenue, and catheter revenue. Revenue during the first twelve months of the agreements is estimated to be in the range of \$150,000 -- \$200,000 and increases from this level will be dependent on clinical results from the ELANA technique and the success of ELANA's commercialization efforts.

"We are proud to announce our partnership with ELANA today and look forward to their commercialization of the ELANA technique that has been pioneered by the tireless effort of Dr. Cornelius Tulleken. The ELANA technique has the potential to assist many patients at risk for stroke," said John Schulte, Spectranetics' president and CEO.

Rutger Tulleken, CEO of ELANA BV, stated, "The cooperation with Spectranetics with their long experience and excellent technology opens up many opportunities for the spread of the ELANA technique, enabling surgeons around the globe to assist patients in need for whom few or no alternatives exist. We are proud to be able to jointly assist

in these efforts. The ELANA technique is already successfully used for neurovascular applications. The combination with the newly developed suture-less technique could be a major breakthrough for bypass technique in general."

- 10/11 **Syneron Medical Ltd.** announced that it had submitted its defense against the recent frivolous lawsuit by **Shladot Metal Works**, and has countersued the company and specific executives. Syneron submitted its defense on October 8, 2004 against the lawsuit brought against Syneron and its chairman, Dr. Shimon Eckhouse, in a Haifa District Court, in Israel, on July 29, 2004. Syneron also submitted a counter lawsuit for damages of NIS 10M against Shladot, its chairman, Arie Friedeson, and Dr. Rachel Lubart.

**Lawsuit intent was to interfere with IPO:** In its counter law suit against Shladot and in its defense documents submitted to the court, Syneron demonstrates that the only purpose of Shladot's lawsuit against Syneron and Dr. Shimon Eckhouse was an attempt to interfere with Syneron's initial public offering (IPO) in the US by bringing false claims against Syneron and Dr. Eckhouse. Syneron's IPO was finalized five days after the submission of Shladot's frivolous lawsuit.

"The sole reason for Shladot's hasty submission was an attempt to blackmail Syneron and our chairman by trying to unlawfully get money out of Syneron at an extremely sensitive time for the company," said Moshe Mizrahy, CEO of Syneron Medical. "In our countersuit, we further claim that this frivolous lawsuit forced us to reduce the offering price from the original range of \$14 - \$16 per share to \$12 per share, resulting in significant monetary damage to Syneron." (The claim relates only to the damages to Syneron.)

**No basis for patent infringement claim:** Syneron shows that there is no basis for Shladot's lawsuit, as Syneron is not infringing any of the claims of an Israeli patent that is supposedly owned by Shladot. Syneron also shows that the Israeli patent that is the basis for Shladot's claim is actually under review by the Israeli patent office based on a request submitted by a third party. The request submitted to the Israel Patent Office strongly suggests that all the claims of the patent are invalid due to the existence of a large amount of prior art, lack of any novelty, and no improvement over existing art in the field in the claims of the Lubart patent that Shladot used as the basis for its lawsuit.

In the documents submitted to the court, Syneron also shows that the claims of the patent are invalid and lack all the elements necessary for patentability. Moreover, Syneron clearly demonstrates to the court that even if the patent was in fact valid, no Syneron device infringes any of the claims of the patent.

- 10/11 **Trimeddyne Inc.** announced that a clinical study published in the *Journal of Minimally Invasive Spinal Technology* demonstrates the ability of Trimeddyne's Holmium Laser to treat osteoarthritis in lumbar (lower back) facet joints in the spine, a common cause of low back pain. Twenty patients with arthritis of the facet joint were treated on an outpatient basis by Sri Kantha, MD, of the Metropolitan Neurology and Spine Institute,



Fort Lee, NJ All of the patients were discharged the same day, with pain medication, muscle relaxants and no restrictions on physical activity. Fifteen or 75 percent of the patients reported significant or partial relief of their lower back pain. In the remaining five patients (25 percent), their back pain was the same as before the procedure. Older patients did not respond as well as younger patients.

According to Dr. Kantha: "At least one million people in the United States who suffer from lower back facet joint pain could be successfully treated with the new laser procedure, technically called Laser Lumbar Facet Rhizotomy. The 1-year results of Laser Lumbar Facet Rhizotomy reported in the above paper are superior to procedures using radio frequency (RF) energy, as the laser is more precise, and its pain-relieving effect lasts for years."

Trimedyn plans to submit this clinical study to the FDA, along with an application for clearance to market its Holmium Laser and disposable Laser Needles for this use. These devices will not be available for sale for the treatment of arthritis in lumbar facet joints in the United States until and unless they are cleared for sale by the FDA for the treatment of this condition.

10/13 **DUSA Pharmaceuticals, Inc.** announced third quarter Kerastick end-user sales, along with Q3 BLU-U placements. For Q3 2004, end-user Levulan Kerastick sales to physicians totaled 20,196, consisting of 18,870 sold in the United States (US), and 1,326 sold by **Coherent-AMT**, our Canadian marketing and distribution partner. During Q2 2004, US sales totaled 16,002 Kerastick units, while Coherent's initial launch sales totaled 1,908, representing built up demand following the marketing approval in Canada. During Q3 2003, US Kerastick sales totaled 1,938, with no Canadian sales at that time.

The net number of BLU-U units placed in doctors' offices during the quarter was 95, consisting of 70 in the US and 25 in Canada. Q2 2004 placements had totaled 183 units in the US and 58 in Canada, for a total of 241, while net placements during Q3 2003 were 37 units. At the end of Q3 2004, there were 870 units in doctor's offices, consisting of 784 in the US and 86 in Canada, versus 775 at the end of Q2 2004, and 360 at the end of Q3 2003. As announced previously, BLU-U sales during Q3 were expected to decrease as compared with Q2 2004 due to a planned price increase that became effective at the start of Q3, and a decreased emphasis on BLU-U placements by our sales-force, in light of our shrinking BLU-U inventory levels. We have now ordered additional BLU-Us, and expect to be re-supplied starting in Q1, 2005.

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "Due to expected seasonal influences, we had previously stated that our expectations for growth in Q3 US sales were uncertain. Therefore, we are very pleased with the 18% increase in US Kerastick sales during the summer quarter as compared to the prior quarter, and expect strong sales going forward."

10/14 **Diomed, Inc.**, a subsidiary of **Diomed Holdings, Inc.**, announced that it had commenced legal action in the United States Federal District Court for the District of Massachusetts against **New Star Lasers, Inc.**, d/b/a **Cooltouch, Inc.**, seeking injunctive relief and damages for infringement of Diomed's United States Patent Number 6,398,777 covering the endovascular laser treatment of varicose veins.

Diomed, a leading developer and marketer of minimally invasive medical technologies, including EVLT for the laser treatment of varicose veins, acquired exclusive rights to the patent from the five inventors of the procedure in September 2003. Diomed filed similar legal actions against **AngioDynamics, Inc.**, **Vascular Solutions, Inc.**, and **Total Vein Solutions** earlier in the year.

It is estimated that between 25-40 million Americans suffer from venous insufficiency. EVLT represents the next generation of minimally invasive treatment of varicose veins. The procedure takes less than 45 minutes without the need for general anesthesia or hospitalization, and patients experience only minimal discomfort with no scarring. Published clinical studies indicate that EVLT has a 93.4% long-term success rate and is superior to surgery and alternative technologies used for the treatment of varicose veins.

At this time the company is unable to provide further comment on the pending action.

10/14 **Spectranetics Corporation** announced it had initiated U.S. patient enrollment in their Extended FAMILI (Flow in Acute Myocardial Infarction after Laser Intervention) feasibility clinical trial. The feasibility trial will enroll 80 patients at up to 20 multi-national sites. To date, a total of 40 patients have been enrolled, with 39 being enrolled at seven European sites.

The first U.S. patient was enrolled at Pinnacle Health Systems, Harrisburg, Pennsylvania, with the procedure being conducted by Rajesh Dave, MD.

The patient was a 72 year-old male who presented with an acute myocardial infarction due to a complete blockage in the left coronary artery. Dr. Rajesh Dave commented, "I've always believed that ablating thrombus and ruptured plaque with excimer laser technology improves the likelihood of attaining TIMI 3 flow (complete reperfusion or restitution of blood flow), as well as reduces the potential for complications such as 'no reflow' (impairment of blood flow) after stent implantation. In my first case within Extended FAMILI, we attained TIMI 3 flow after only a single pass with a 0.9 millimeter laser catheter. We followed this with a larger 1.4 millimeter laser catheter to further open the vessel and provide a higher chance of attaining a superior outcome with stent implantation. I am very pleased to see excimer laser now being examined in acute myocardial infarction patients." Dr. Dave reported there were no complications.

"Conducting this feasibility trial is an important part of our multi-faceted strategic plan and I am encouraged with the progress we are making with the enrollment of Extended FAMILI patients. Our team is aggressively working with numerous U.S. sites to begin

patient enrollment. We anticipate enrollment will continue to increase as more U.S. hospitals come online, and we expect to complete the trial sometime during the first half of 2005. If the results of Extended FAMILI are promising, we expect to initiate a multi-center randomized trial in 2005," stated John Schulte, Spectranetics' president and CEO.

10/18 **Syneron Medical Ltd.** announced the Health Canada approval for the VelaSmooth, its new aesthetic device for body contouring and the treatment of cellulite. An innovator in combined-energy medical aesthetic devices, Syneron Medical began trading on NASDAQ under the symbol ELOS on August 6, 2004.

The VelaSmooth is a medical device that reduces the appearance of cellulite and safely and effectively re-contours the skin's surface and body shape. Its launch marks a new era in the medical treatment of cellulite.

This VelaSmooth uses the revolutionary elos technology -- the first and only combined-energy medical aesthetic technology. VelaSmooth, like all of Syneron's devices, uses Bi-Polar Radio Frequency and Light with the added feature of tissue mobilization using a deep tissue massage. The synergy of the three components makes VelaSmooth an effective treatment and the only medical cellulite solution on the market. Conducted RF increases oxygen intracellular diffusion by heating the adipose tissue to a depth of 5-15mm. Infrared light increases elasticity of skin and heats subcutaneous fat to a depth of up to 5 mm, while safeguarding the skin from damage. Vacuum manipulates and smoothes out the skin to facilitate safe and efficient energy delivery. Tissue mobilization is facilitated by rotating, self-cleaning electrodes to ensure excellent coupling with the skin.

Physicians who conducted clinical trials in Canada and the U.S. have effectively reduced the appearance of cellulite, and noted reduction in the circumferential measurements of patients in the treated hip, waist and thigh regions of the body.

The VelaSmooth is a breakthrough device according to Dr. Tina Alster, Director of the Washington Institute of Dermatologic Laser Surgery and Clinical Professor of Dermatology at Georgetown University Medical Center. "There has never been a viable treatment for cellulite, disappointing, given the fact that 80% of women are affected by it, and the other 20% think they have it. I am now convinced that we have a viable treatment for this condition," concluded Dr. Alster.

According to the president of **Syneron North America**, Domenic Serafino, the VelaSmooth is one more example of Syneron's commitment to provide innovative technology to the medical community. "The VelaSmooth is unlike any other device ever created for the treatment of cellulite and body contouring. The combination of elos technology with tissue mobilization finally gives the medical community an effective, safe treatment option for their patients with cellulite and skin laxity problems," said Serafino.

10/19 **Spectranetics Corporation** reported revenue for the third quarter ended September 30, 2004 of \$8.9 million, a 29% increase compared with \$6.9 million during the third quarter of 2003. Net income for the 2004 third quarter was \$479,000 (2 cents per share, compared with \$357,000 (1 cent per share) last year.

Revenue of \$8.9 million was comprised of \$1.0 million in equipment sales and rental fees, which was up 36% from the third quarter last year, and \$6.6 million in disposable product revenue, which was up 28% compared with the third quarter last year. The worldwide installed base of laser systems increased to 404 at September 30, 2004 (301 in the United States), a net increase of 10 units, representing the highest number of placements per quarter this year and in line with stated quarterly volume targets. Service and other revenue rose 32% to \$1.3 million, owing to a larger installed base of laser systems.

The increase in net income was primarily attributable to an improved gross margin during the third quarter of 2004 to 76% from 72% in the prior-year quarter, partially offset by a planned increase in operating expenses related to the expansion of the company's sales force, an increase in research and development expenses due to increased new product development and clinical studies activities, costs associated with a promotional campaign to support the recently launched CLiRpath product and administrative costs incurred to support compliance with Sarbanes-Oxley legislation.

Commenting on the quarter, John Schulte, president and CEO, said, "The launch of our new CLiRpath laser catheters is off to a good start and will be a key growth driver going forward. We also received great exposure of our technology at two key cardiology meetings -- TCT and New Cardiovascular Horizons -- raising the level of awareness for our technology's strengths in treating critical limb ischemia and chronic total occlusions."

**Year-to-Date Financial Results:** Net income for the nine months ended September 30, 2004 nearly doubled to \$1.0 million (4 cents per share), compared with \$551,000 (2 cents per share), during the first nine months of 2003. Comparing revenue for the first nine months of 2004 with the first nine months of 2003, total revenue rose 24% to \$25.4 million, equipment sales and rental fees rose 11% to \$2.5 million and disposable products revenue rose 23% to \$18.9 million. Service and other revenue rose 42% to \$4.0 million.

The gross margin for the first nine months of 2004 was 75% compared with 71% in the first nine months of 2003. Gross margin expansion was primarily attributable to disposable products manufacturing efficiencies resulting from higher production volumes and improved average selling prices on laser system sales.

Cash, cash equivalents and current and long-term investment securities totaled \$16.2 million at September 30, 2004, an increase from \$16.0 million at June 30, 2004, and \$13.3 million at December 31, 2003.

**2004 Fourth Quarter and Full Year Financial Guidance:** Spectranetics anticipates revenue for the fourth quarter of 2004 to be \$9.0 million to \$9.3 million, reflecting anticipated sequential-quarter revenue growth from the third quarter to the typically stronger fourth quarter, as well as continued penetration of the newly entered peripheral market. Fourth quarter net income is expected to be \$300,000 to \$500,000, or \$0.01 to \$0.02 per diluted share.

In light of third quarter financial results and revised fourth quarter guidance, the company now is projecting full-year 2004 total revenue to be \$34.4 million to \$34.7 million and net income to be \$1.3 million to \$1.5 million, or \$0.05 to \$0.06 per diluted share.

10/21 **Encore Medical Corporation** announced that the Orthopedic Rehabilitation Division of its subsidiary, **Encore Medical, LP**, plans to introduce several clinical physical therapy laser devices under the Chattanooga Group brands beginning early in 2005. These devices are the culmination of in-house research and development efforts that have been ongoing for over a year. The new laser devices will be marketed as a part of Chattanooga's Clinical Electrotherapy and Therapeutic Ultrasound product lines.

The FDA recently granted pre-market clearance through the 510(k) process. Indications for use include topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, temporary relief of muscle spasm, temporary relief of minor arthritic pain and stiffness and for muscle relaxation.

"This has been an outstanding achievement for our research and development team," commented Paul Chapman, president and CEO. "We are excited to be at the forefront of this up-and-coming market. Our technology is more advanced than other first generation devices and includes multiple applicators with various frequency and power specifications, and also offers true focused lasers or clusters containing lasers and LED's that are less concentrated. These products are consistent with Chattanooga's strategy of maintaining a healthy pipeline of technologically superior products."

Various configurations of the technology will be introduced under the brand names Vectra Genisys Laser System and the Intellect Laser System. The devices will be available as stand-alone units or as a module to be purchased as part of a clinical electrotherapy system. There will be units designed specifically for the U.S. market and units targeted for international markets.

"The Chattanooga brands of clinical electrotherapy devices already have a leading market share in the United States and world wide," remarked Scott Klosterman, president of the Orthopedic Rehabilitation Division of Encore. "Our extension of this product segment to include physical therapy lasers will further solidify our market position. We expect these new devices, over a period of time, to gain acceptance with many practitioners of orthopedic rehabilitation including physical therapists, athletic trainers and chiropractors."

Encore Medical Corporation is a diversified orthopedic device company that develops, manufactures and distributes a comprehensive range of high quality orthopedic devices, including surgical implants, sports medicine equipment and products for orthopedic rehabilitation, pain management and physical therapy. Based in Austin, Texas, Encore's products are used by orthopedic surgeons, physicians, therapists, athletic trainers and other healthcare professionals to treat patients with musculoskeletal conditions resulting from degenerative diseases, deformities, traumatic events and sports-related injuries, and our non-invasive medical devices and related accessories are primarily used by patients for at-home physical therapy. Encore's Surgical Implant Division offers a comprehensive suite of reconstructive joint products, trauma products and spinal implants. Through its Orthopedic Rehabilitation Division, Encore is a leading manufacturer and distributor of orthopedic rehabilitation equipment in the United States.

10/22 **PLC Systems Inc.** reported that it had entered into an agreement to lease a clean room manufacturing facility in Billerica, MA. PLC intends to use the facility for the commercial manufacturing of the disposable components for the Optiwave 980 Cardiac Laser Ablation System. The Optiwave 980 laser is manufactured in PLC's Franklin, MA facility. "This is an extraordinary opportunity for PLC to lease a world-class facility, which includes a clean room for manufacturing processes and product assembly of the Optiwave 980 disposable handpieces," stated Mark Tauscher, president and CEO of PLC Systems. "I expect that this facility will be tested and validated in the fourth quarter. We anticipate to be fully operational and in production during the first quarter of 2005."

Tauscher continued, "Leasing this facility, which complements our stated growth objective of expanding our product portfolio, is an important step for PLC. This decision is a result of the continued progress we are making in the commercialization of the Optiwave 980. After considering several options, we concluded that the Billerica site meets our manufacturing expansion requirements."

During the first quarter of this year, PLC Systems and **Edwards Lifesciences Corporation** announced that the two companies entered into an exclusive, multi-year agreement to develop and manufacture Edwards' Optiwave 980 surgical ablation system. Prior to the PLC and Edwards agreement, the Optiwave 980 project was an ongoing program within Edwards. During 2004, the research and development of the Optiwave 980 system was transitioned to PLC.

Tauscher concluded, "We are excited about the opportunities for the Optiwave 980 project. Combined with our strategic alliance, current development programs and our existing Franklin, MA site, this facility will play an integral role in providing PLC with a strong foundation for growth. This expansion will create a number of technically-skilled jobs in the Commonwealth of Massachusetts."

10/22 **DUSA Pharmaceuticals, Inc.** reported the initiation of a new multicenter Phase II clinical study using the company's Levulan Kerastick (aminolevulinic acid HCL, ALA) and BLU-U photodynamic therapy (PDT) for the treatment of moderate to severe acne

vulgaris of the face. Independent investigator studies have reported that a single topical ALA PDT treatment can help to improve moderate and refractory acne vulgaris, and that several treatments resulted in significant improvement, by both reducing the bacteria at the site of lesions and by acting to reduce activity of sebaceous glands. However, some of the early studies used ALA applied under occlusion for several hours, which was associated with significant side effects such as pain during treatment, a strong inflammatory reaction, and hyperpigmentation. More recently, an independent investigator study used the Levulan Kerastick applied for 15 minutes over the face without occlusion, followed by light treatment with DUSA's BLU-U for 6 minutes. Using this short drug incubation time, the investigator reported improvement in acne, but without pain, inflammation, or hyperpigmentation.

Based on information from these anecdotal and independent investigator studies, DUSA has decided to initiate a study examining the safety and efficacy of short contact Levulan Kerastick combined with the BLU-U for the treatment of patients with moderate to severe facial acne vulgaris. The new study, with up to 80 patients, including a control group, will be carried out at 3 clinical trial sites in the United States. It will examine the effect of varying drug incubation times, followed by a standardized light dose using the BLU-U. There will be up to four Levulan PDT treatments given at 2-week intervals. The primary efficacy parameters will be acne lesion count and acne severity score, assessed 8 weeks following the final Levulan PDT treatment. Safety and tolerability will also be assessed throughout the study.

Dr. Diane Berson, a renowned dermatologist at New York-Presbyterian-Weill Cornell Medical Center in New York, states "It has been a long time since we have seen a novel therapy for the treatment of acne vulgaris. A new and effective treatment would be welcomed by the medical community. I am excited to be a part of the clinical trials that will evaluate the potential of Levulan PDT for the treatment of acne."

Approximately 8 of every 10 persons worldwide have acne at some point during their lives, and acne is the most common reason patients visit dermatologists in the United States. Acne is also known to have a potentially profound impact on a patient's outlook on life. Current standard-of-care for moderate inflammatory acne includes topical or systemic antibiotics, retinoids, cleansers, and blue light such as that provided by DUSA's BLU-U therapy. However, oral antibiotics for acne have been associated with increased bacterial drug resistance, and a recent article in the Journal of the American Medical Association showed an increased risk of breast cancer.

Severe recalcitrant cystic acne is generally treated by orally administered isotretinoin (Accutane, Isotrex). Although highly effective, isotretinoin continues to become more and more regulated by the federal government because of its potentially serious side effects, including a high risk of birth defects in the fetus if taken during pregnancy, and, in a small percentage of patients, depression. While taking isotretinoin, patients must undergo regular blood testing.

10/25 **Trimeddyne Inc.** announced that the U.S. Patent Office had allowed its Patent Application on a new laser angioplasty device. The Patent will issue in a few months. The Patent covers unique optical fiber devices designed to make smooth channels through plaque deposits in arteries, without radiating heat sideways, which could harm the vessel walls. The device is designed for use with small, portable, relatively inexpensive, solid-state diode or Holmium lasers. While lasers used in angioplasty typically sell for \$200,000 or more and usually necessitate costly maintenance, Trimeddyne's small Holmium or diode lasers would sell for about \$50,000, are simple to operate and require minimal maintenance.

Glenn Yeik, president of Trimeddyne, said: "The new device can be made as small as 0.7 millimeters in diameter, allowing it to be used in arteries too small to admit current balloon angioplasty or stent delivery catheters. In addition, the device is designed to create a channel through fully blocked vessels, allowing balloon angioplasty or stent delivery catheters to be used."

Yeik added: "More than one million balloon angioplasty procedures, many accompanied with stent implantations, are performed each year in the United States. Angiograms enable many persons with blockages in very small vessels to be diagnosed, but current balloon angioplasty catheters cannot be employed to treat them. Also, if a major coronary artery is fully blocked, balloon angioplasty cannot be performed, and the patient must undergo bypass surgery. We hope these new devices will be an alternative for these patients."

Clinical trials of the new device in each of the above-described applications will be required before an application to market the new devices and lasers can be submitted to the FDA. Such trials are costly, can take several years and their outcome cannot be predicted. Trimeddyne hopes to secure a marketing arrangement with an established company in the cardiology field to conduct the clinical studies and, if FDA approval is received, market the new devices. There is no assurance any marketing agreement with an established company can be obtained.

10/25 **BioLok International Inc.** announced that the FDA had approved Laser-Lok, a revolutionary Laser Micro-Machined surface on the collar of its Silhouette Tapered Implant System. The new surface induces soft tissue attachment that inhibits epithelial down-growth, has been shown to attach and retain bone adjacent to the implant while not reducing the plaque and inflammation related safety performance of Silhouette implants. BioLok's president and CEO, Bruce Hollander believes this new technology, that induces true "tissue engineering," is the first advancement in implant dentistry since Dr. Branemark's work in the 1970's.

"Laser-Lok allows the doctor to decide in advance where on the implant tissue should attach and where bone should attach. It is now possible to pre-engineer the biological width. Greatly superior restorative results can thus be attained. Our successful R&D team is now also applying this same technology to a new class of transcutaneous implants. We



are extremely excited about these revolutionary developments." Silhouette Laser-Lok Implant will be available for sale on December 1, 2004.

Hollander said, "BioLok and **Orthogen Corp.**, its wholly owned R&D division headed up by Harold Alexander, PhD, have been developing this surface for 13 years, with Clinical Studies completed in Rome, Italy by The Group For Implant Research, headed by Professor Gabriele Pecora." Additional Laser-Lok research has been contracted with the NYU School Of Dentistry where John Ricci, PhD, one of the inventors of the technology is now on faculty. These studies will have side by side comparisons of Silhouette Laser-Lok Implants to a number of competitor products.

#### **MEDICAL/SURGICAL LASER UPDATE -- November 2004**

10/25 **Syneron Medical Ltd.**, and its North American subsidiary **Syneron Inc.**, announced that the FDA had granted 510(k) marketing clearance to Syneron's Aurora and its derivative systems for "removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction". This new clearance expands on the previous clearance for hair reduction granted in July 2002, reflecting the excellent long-term results documented in more than 24 months of clinical studies.

Aurora and its derivative systems, Galaxy and Pitanga, are based on the same platform, utilizing the same form of Syneron's proprietary ELOS (Electro-Optical Synergy) technology. The three systems combine electrical energy (Bi-Polar Radio Frequency) and optical energy (light) to enable highly efficient, safe, long-lasting treatment of unwanted hair from all skin types and all parts of the body.

"Once again Syneron is demonstrating to the aesthetic industry that its products are safe, predictable and extremely efficacious," said Domenic Serafino, president of Syneron Medical Inc. "With more than two years of clinical success, the benefits of Syneron's technology and approach are now well-proven over the long-term."

Added Moshe Mizrahy, CEO of Syneron Medical: "This latest, broad approval from the FDA further strengthens Syneron's position in the market as a leading provider of aesthetic medical treatment solutions. We will hold our leadership position by continuing to offer the most complete range of solutions for all non-invasive medical aesthetic indications."

10/26 **Diomed Holdings, Inc.** announced that it had completed its recently announced \$10.6 million private placement financing. "The completion of this financing provides additional critical resources to continue our aggressive growth strategy," commented James Wylie, Diomed's president and CEO. "With the increasing level of investment in this highly attractive market space, Diomed is well positioned to defend its position as the global market leader in endovenous laser treatment of varicose veins and its solid intellectual property investment."

The private placement financing consists of \$7 million in senior convertible debt and \$3.6 million in common stock. The debt is convertible at \$2.29 per share and bears interest at the six month LIBOR rate plus 400 basis points. The convertible debt has a four-year term and is payable at maturity in cash or stock, at the company's option, subject to certain restrictions. The \$3.6 million in common stock was purchased at \$1.53 per share. The terms of the transaction include 50% warrant coverage with a 5-year term and an exercise price of \$2.10 per share for both equity and debt components.

"We are particularly pleased with the participation by a number of top medically-oriented institutional investors, as well as follow-on investment by a number of existing investors," stated David Swank, the company's CFO. "This provides further confirmation of the market's belief in the company's solid growth potential."

The company has agreed to register the underlying shares with the Securities and Exchange Commission.

10/26 **Cynosure, Inc.** announced that it now includes the "Laser Advantage Practice Success Program" free with the purchase of every new Cynosure laser and light-based system. This exclusive value-added service is being made available through a special arrangement with California-based **Laser Advantage**, a leading consultancy firm that focuses exclusively on helping physicians successfully launch and operate aesthetic clinics.

"We are very pleased to be able to provide this level of support to our customers in a way that helps ensure the success of their aesthetic clinics," said Marina Kamenakis, Cynosure vice president of marketing. "Laser Advantage's principals have a proven track record not only of assisting more than 100 physicians and entrepreneurs in establishing successful clinics, but in the creation and management of their own clinics as well. Laser Advantage's proven business formula eliminates the pitfalls often encountered during the first-year of clinic operation."

The standard "Laser Advantage Practice Success Program" provides customers with a detailed roadmap and all the materials required to launch -- and run -- an aesthetic clinic. The program includes a full array of forms, standardized procedures, office and technical protocols, consent forms, phone scripts, and marketing materials in a manual and on a simple-to-use CD. Thirty days of phone consultation is also included.

A Premier version of the "Laser Advantage Practice Success Program" is also available for an additional fee. With this expanded version, on-site consultants will personally guide Cynosure customers in three key areas: establishing, marketing, and managing the business. The program elements are customized for the practice, including demographic analysis and marketing materials. This version includes 90 days of phone consultation after completion of training.

"We are very pleased to be partnering with Cynosure," said Neil Blanchard, president, of Laser Advantage. "What sets Cynosure apart is that they provide not only the best technology, but also comprehensive training and support. Adding the Laser Advantage Practice Success Program will further help physicians build their aesthetic practices."

"Cynosure continues to provide its customers with extensive marketing materials to support its products," said Kamenakis, "but today's highly competitive environment has raised the stakes for physicians entering the aesthetic clinic business. Laser Advantage's program brings together all the essential elements of an aesthetics business including business strategy, database and referral base development, patient care and education, paperwork, protocols, internet presence, and advertising."

10/27 **Reliant Technologies, Inc.**, the pioneer of the breakthrough FRAXEL SR Laser to treat periorbital (around the eyes) wrinkles and pigmented lesions (e.g., age spots), announced that its strong presence at recent national medical meetings had raised the level of physicians' interest in the technology. Since consumers are increasingly demanding the dramatic results of an ablative laser procedure for wrinkles and sun damaged skin with the quick healing time and gentleness of a non-invasive laser treatment, physicians are turning to the FRAXEL SR Laser for its ability to accomplish both.

"We have had tremendous positive response from physicians attending our scientific presentations at the recent *American Academy of Facial Plastic and Reconstructive Surgery* meeting in September and the *American Society for Dermatologic Surgery* and *American Society of Plastic Surgeons* meetings this month," said Maynard Howe, CEO of Reliant. "The traffic at our exhibit booth during these meetings was overwhelming, and we could not be more pleased with the way physicians embraced the benefits of our Fraxel Laser Treatment for aging skin."

This professional excitement expands the buzz generated by the introduction of Fraxel Laser Treatment at the American Society for Laser Medicine and Surgery meeting in April 2004, where this new technology won the award for the best overall clinical science paper.

As of July 1, 2004, the Fraxel Laser has FDA 510(k) clearance for dermatologic conditions requiring the coagulation of soft tissue, treatment of periorbital wrinkles, and treatment of pigmented lesions (including age spots, sun spots and skin discoloration) at any location on the body. Unlike other lasers, the Fraxel Laser uses light to heat and remove microscopic pinpoints of skin, promoting a more effective result and faster recovery without the downtime or significant side effects associated with more aggressive laser approaches.

The company plans to build on its success this fall by maintaining a strong podium and industry presence at national and international medical meetings in 2005.

"Our goal is to educate more physicians in the coming year so as to provide a new standard of care to patients everywhere looking for a safe and effective treatment for aging and sun damaged skin," said Howe.

Reliant Technologies is positioned for growth and poised to become a new market leader in aesthetic laser medicine, surgery and biomedical technologies. Reliant is dedicated to fulfilling the promise of laser medicine by creating breakthrough systems focused on FRAXEL Laser Treatment. Reliant employs 50 professionals in two primary locations, Palo Alto and San Diego, California. For more information, please visit [www.reliant-tech.com](http://www.reliant-tech.com).

10/27 **Laserscope** reported record revenues of \$24.2 million for its third quarter ended September 30, 2004, a 69% increase from \$14.3 million in the year-ago quarter. Revenues increased 13% from \$21.4 million for the quarter ended June 30, 2004. Third quarter 2004 net income was a record \$4.4 million (19 cents per share) a significant increase from net income of \$533,000 (2 cents per share) in the same quarter last year, and net income of \$3.0 million, or \$0.13 per share, for the second quarter of 2004.

"We had an excellent quarter both domestically and internationally," said Eric Reuter, president and CEO of Laserscope. "Our strong and improving financial performance is being driven by significant success in our urology business and continued solid performance in our aesthetics business. Based on recently published industry reports, we believe the current size of the market for Trans-Urethral Resection of the Prostate (TURP), the current 'standard of care' for Benign Prostatic Hyperplasia (BPH), or enlarged prostate, is more than 1 million procedures per year. This, coupled with an aging world population, is creating a growing worldwide market for more efficacious and cost-effective treatments for enlarged prostate and is providing significant future growth opportunities for the company."

Gross margin in the third quarter of 2004 was approximately 59%, compared with approximately 52% in the third quarter of 2003, and approximately 57% for the second quarter of 2004. Gross margin improvements were driven primarily by a recent U.S. fiber price increase that became effective on July 1, 2004, product mix and manufacturing efficiencies.

Selling, general and administrative expenses were \$8.7 million, or 36% of revenues, in the third quarter of 2004, compared with \$8.2 million, or 38% of revenues in the second quarter of 2004, and \$5.8 million, or 40% of revenues, in the year-ago quarter. Increased SG&A spending on an absolute basis resulted primarily from higher sales and marketing expenses relating to the company's GreenLight PVP and aesthetic products, as well as higher expenses relating to Sarbanes-Oxley compliance.

The company's financial position remains strong. At September 30, 2004, Laserscope had no short-term bank borrowings and a cash position of \$12.7 million, up from \$7.2 million at the end of 2003 and \$10.4 million at the end of June 2004.

For the nine months ended September 30, 2004, Laserscope reported revenues of \$64.3 million and net income of \$9.6 million (42 cents per share) compared with revenues of \$39.6 million and net income of \$1.0 million (5 cents per share) for the same period in 2003.

**Urology Business Update:** "We had an active and productive third quarter in our worldwide urology business, selling a record 63 GreenLight laser systems and nearly 10,000 fibers," said Reuter. "Our international business team had an especially outstanding quarter, selling 22 GreenLight systems and nearly 3,000 fibers. We reached record levels in U.S. system and fiber shipments as well. These results are extremely encouraging given a delay in PVP procedures in the Southeast as a result of the hurricanes that occurred there during most of September, as well as the previously announced fiber pre-buying that some U.S. customers initiated in advance of our July 1st price increase. Absent this pre-buying, fiber sales would have likely been 600-700 units higher in the third quarter. We expect continued strong growth in U.S. fiber shipments during the fourth quarter and beyond.

"Our number one goal is to ensure that Laserscope's GreenLight PVP, or Photo-Selective Vaporization of the Prostate, is recognized as the new worldwide standard of care for treating BPH. We believe our treatment for BPH will increasingly become the definitive procedure of choice for men who must have surgery, as well as a viable option for men who are contemplating drug therapy or other less efficacious surgical procedures. Our continued strong growth in GreenLight systems and recurring fiber sales domestically and internationally is indicative of our continued progress toward reaching this goal.

"Peer reviewed and published results from world-renowned academic medical centers continue to show PVP as a less invasive and safer alternative to TURP, as well as substantially more efficacious than any other known therapy for BPH. Additionally, recent data presented at the American Urological Association (AUA) meeting has indicated that PVP may have substantial cost savings benefits for the health care system as well."

**Aesthetics Business Update:** "Our aesthetic business continues to be solid, with new Gemini platform sales increasing over 50% over the second quarter 2004 and accounting for over 40% of our total worldwide aesthetic revenues in only the second full quarter after its launch," continued Reuter. "We are positioning the Gemini as the premier multi-application, high-end aesthetic laser system and the feedback we have received from our physician users has been very positive thus far. We currently have a number of clinical evaluations underway, which we believe will demonstrate the Gemini's advantages in clinical efficacy and speed for a number of cosmetic treatments. As with our urology business, we believe that demonstrating clinical excellence, customer service, and cost-effective business solutions to our customers are the primary keys to our success.

"We also plan to launch a significant new aesthetic product at the upcoming American Academy of Dermatology meeting in February 2005. This treatment system, called the Solis, will address a growing need in the aesthetic treatment market by substantially improving end-user productivity and patient comfort over existing systems. The Solis will be positioned to strongly complement our existing aesthetic product lines and will help provide Laserscope with one of the widest ranges of clinical solutions for aesthetic applications in the industry.

"Our momentum continues to accelerate across our business, and our worldwide team is executing well on our major strategic initiatives," said Reuter. "We expect a strong finish this year, and as we move into the new year, we're very excited about our future prospects for substantial growth on the top and bottom line."

**Guidance:** As the result of its continued strong performance, Laserscope has raised guidance for the full year 2004 in both revenues and earnings as follows:

- \* 2004 full year revenues are expected to be in the range of \$90 million to \$92 million, with reported pre-tax earnings to be in the range of \$15 million to \$16 million. Net income is expected to be between \$0.62 and \$0.65 per share, assuming a tax rate of 6% which reflects a full tax valuation allowance.

- \* The timing of the release of the tax valuation allowance depends on the company's historical earnings and expectations for the future. When management determines that it is "more likely than not" that the loss carry forward will be utilized, the tax valuation allowance will be released.

Additionally, Laserscope has provided initial guidance for 2005 as follows:

- \* Revenues for 2005 are expected to be between \$125 million and \$130 million.

- \* Gross margin, as a percentage of 2005 revenues, is expected to be in the range of 64% to 68% for the full year.

- \* Reported pre-tax earnings are expected to be in the range of \$28 million to \$31 million.

- \* Net income for the full year 2005 is expected to be between \$0.75 and \$0.80 per share, on a fully taxed basis of 38%. If the company releases its tax valuation allowance in 2004, then the tax rate for 2005 is expected to be 37% to 39%.

10/27 **PLC Systems Inc.** announced financial results for the three and nine months ended September 30, 2004. The company also reported that it delivered the initial shipments of Optiwave 980 lasers to **Edwards Lifesciences Corporation** in October. Earlier this year, PLC and Edwards announced that the two companies entered into an exclusive, multi-year agreement to develop and manufacture the Optiwave 980 Cardiac Laser

Ablation System. Edwards will market and distribute the Optiwave 980 system worldwide.

"Throughout the year we have made substantial investments in research and development programs," stated Mark Tauscher, president and CEO of PLC Systems. "We are very encouraged with the initiatives to re-shape PLC. We entered 2004 with a growth strategy to pursue opportunities that would provide revenue growth and product diversification for the company. I am pleased to say that this quarter's progress on the Optiwave 980 project is a strong step forward in the fulfillment of this vision."

Third quarter total revenues were \$1.6 million compared with \$2.3 million in the third quarter of 2003. The net loss for the third quarter of 2004 was \$436,000 (1 cent per share) compared to net income of \$225,000 (1 cent per share) in the third quarter of 2003.

Total revenues for the nine months ended September 30, 2004 were \$5.3 million compared to total revenues of \$6.0 million for the nine months ended September 30, 2003. The net loss for the nine months ended September 30, 2004 was \$1,037,000 (3 cents per share) compared to net income of \$443,000 (1 cent per share) for the nine months ended September 30, 2003.

Tauscher continued, "Both of PLC's product lines are contributing to the company's overall growth strategy. Optiwave 980 lasers are being built and shipped. We are taking the necessary steps to be able to manufacture the disposable components of the Optiwave 980 system in the first quarter of 2005. With respect to TMR, it is the first time that quarterly domestic TMR kit shipments to hospitals have exceeded 500 kits in consecutive quarters. We are very pleased with the progress that we made during the third quarter."

A leading indicator for the adoption rate of the CO2 TMR therapy is disposable kit shipments to hospitals. During the third quarter of 2004, a total of 592 disposable kits were shipped worldwide, which is an increase of 18% from the 503 worldwide kit shipments in the third quarter of 2003. Edwards delivered 539 disposable kits to United States hospitals and PLC shipped an additional 53 disposable kits to international hospitals. The 539 domestic kits delivered by Edwards Lifesciences represents a growth of 10% over the comparable third quarter a year ago.

Tauscher concluded, "With respect to disposable kit shipments, we are extremely pleased to see the positive trend from the second quarter continue through the third quarter. This continued increased adoption is very encouraging because the third quarter is historically one of the slower quarters for cardiac procedures due to the summer months."

During the third quarter of 2004, six next-generation CO2 Heart Lasers (HL2) were shipped to United States hospitals through Edwards, PLC's exclusive U.S. sales and marketing partner. Two of the six HL2 shipments were new lasers and four were redeployed lasers. In addition to these shipments, PLC shipped 2 HL1 lasers to international hospitals.

PLC ended the third quarter of 2004 with 170 CO2 Heart Lasers located at heart centers throughout the U.S., comprised of 123 HL2 customers and 47 HL1 customers. As of September 30, 2004, PLC's U.S. laser base (HL1 and HL2) had increased by 12% during the preceding twelve months. More significantly, PLC's U.S. HL2 installed base grew to 123 lasers as of September 30, 2004, up 24% from September 30, 2003.

10/27 **BIOLASE Technology, Inc.** announced financial results for the three month and nine month periods ended September 30, 2004. Net sales for the third quarter of 2004 were \$12.0 million as compared to net sales of \$13.5 million for the same period in 2003.

Sales of the company's principal product, the Waterlase system comprised 82% of sales for the third quarter of 2004, compared to approximately 80% of sales in the third quarter of 2003.

Net sales for the first nine months of 2004 were \$41.4 million compared to net sales of \$33.0 million for the first nine months of 2003, representing a year-over-year growth rate of 25%. Gross profit for the third quarter of 2004 was \$7.1 million as compared to \$8.4 million for the same period in 2003. Gross margin was 59% for the third quarter of 2004 compared to 63% for the third quarter of 2003. This decline in gross margin is a result of higher fixed manufacturing overhead costs allocated over a smaller increase in sales volume for the quarter.

Operating expenses were \$9.4 million for the third quarter of 2004 as compared to \$5.9 million for the third quarter of 2003. Sales and marketing expenses were \$5.9 million for the third quarter of 2004 as compared to \$3.7 million for the same period last year. The increase in sales and marketing is related to the expansion of our sales force as well as increased marketing expenses related to consumer awareness initiatives. General and administrative costs were \$2.4 million for the third quarter of 2004 as compared to \$1.5 million for the third quarter of 2003. Increases in general and administrative expenses are due mostly to increased costs associated with professional fees and costs relating to Sarbanes-Oxley implementation, the **Diodem** patent litigation and the shareholder class action litigation. Engineering and development costs were \$1.0 million for the third quarter of 2004 as compared to \$0.6 million for the same period in 2003. Increases in engineering and development costs are due mostly to increased expenses associated with the development of the Waterlase MD product platform.

Loss before income taxes was \$2.0 million for the third quarter of 2004 compared with income before income taxes of \$2.6 million for the third quarter of 2003.

Net loss for the third quarter of 2004 was \$1.2 million (5 cents per share). For the third quarter of 2003, net income was \$2.6 million (11 cents per share).

When comparing the third quarter of 2004 to the prior year same quarter, the results are not directly comparable. Through August 2003, we recognized revenue essentially on a



cash basis for domestic sales whereas we currently recognize revenue on an accrual basis at the time of shipment.

Additionally, no income tax expense was recognized in the third quarter of 2003 because the company had not determined at that time that the realization of its deferred tax assets were more likely than not realizable.

Robert Grant, president and CEO, stated, "We are disappointed that our revenue results did not reach our original expectations. We understood the roll-out of a major new product would be challenging going into the third quarter; however, the shortfall was not anticipated. The setbacks we have experienced during the past two quarters have strengthened our resolve to improve the operating performance of the company going forward."

Grant further commented regarding the recent launch of the Waterlase MD, "Initial feedback regarding the Waterlase MD introduction has been extremely positive both from current and prospective customers around the globe. We believe that the Waterlase MD's technological advancements and clinical benefits will lead to greater adoption of our innovative platform technology."

10/28 **Diomed Holdings, Inc.** announced results for the third quarter ended September 30, 2004. Diomed delivered revenue of \$3.3 million, an increase of nearly \$1.0 million, or 38%, over the third quarter of fiscal year 2003. Revenue from the EVLT product line increased by 45%, including a 96% increase in revenue from EVLT disposable procedure products during the period. "Our strong third quarter performance reflects significant progress towards the global commercialization of our EVLT product line", commented James Wylie, president and CEO. "Diomed's installed EVLT base now exceeds 500 systems worldwide."

Revenue for the nine-months-ended September 30, 2004 of \$9.4 million increased \$2.8 million, or 42%, over the first nine-months of 2003, while EVLT sales increased 54%. Revenue from EVLT disposable procedure products increased 96% during the nine month period over the comparable 2003 period.

"We have delivered seven quarters of consecutive revenue growth since reorganizing the executive management team during the first quarter of 2003," added Wylie. "Third quarter EVLT revenue increased 11% sequentially, reflecting expanded insurance reimbursement for EVLT by major US insurance companies, and the enthusiastic acceptance of EVLT as the minimally invasive procedure of choice by physicians and patients alike. Despite this solid performance, management believes the overall pace of sales can and should be higher and will continue to take steps to further accelerate growth."

"In October, we completed a \$10.6 million private placement of senior convertible debentures and common stock," stated David Swank, CFO. "This financing further

strengthens our financial position and provides additional flexibility in funding the company's programs to protect our intellectual property and take advantage of a rapidly growing market."

10/28 **CardioGenesis Corporation** announced that it has closed a \$6.0 million convertible financing facility from **Laurus Master Fund, Ltd.** The convertible note, which bears a three-year term at an interest rate equal to prime plus 2% per annum, is convertible into shares of CardioGenesis common stock at a premium to current market price, subject to certain conditions and customary anti-dilution adjustments. In connection with the financing, CardioGenesis issued Laurus Funds a common stock purchase warrant to purchase up to 2.64 million shares of CardioGenesis common stock. The net proceeds of approximately \$5.8 million will be primarily used to support the company's introduction and launch of a number of new products for its TMR business and to fund a variety of research and development opportunities. Additional details about the financing are disclosed in the company's Form 8-K filing.

Chairman, president and CEO Michael Quinn said, "We are on the threshold of extending our market leadership with the introduction of a number of innovative new products for the cardiothoracic surgeon, several of which will enable minimally invasive techniques for TMR. These product initiatives, each of which was designed and developed in concert with leading surgeons, represent forward thinking in the application of patient-centered therapies."

Quinn explained that the results replicated in multiple randomized trials demonstrate that TMR provides significant and sustained angina relief and improved quality of life. Over 30,000 patients suffering from severe angina have been treated with TMR to date. In an effort to build upon both the controlled and real world experience, the company has listened to key cardiothoracic surgeons, cardiologists, and their patients to systematically develop tools essential for the minimally invasive application of this important therapy. Experience demonstrates that minimally invasive techniques provide the opportunity to extend treatment to more patients and the potential to reduce the operative morbidity of a standard surgical procedure.

Quinn added, "The completion of this financing from Laurus Funds has provided us with the additional balance sheet strength to enable the timely and effective launch of these important new products, which we believe can dramatically increase the number of TMR procedures being performed worldwide. In addition, we expect to also drive our revenue growth by bringing additional cardiac operating room products to market that will leverage our existing strong surgeon and hospital relationships. The financing provides the company with the capital resources to develop the TMR and PMC business outside the United States while pursuing PMC approval from the FDA. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval for PMC in the United States. Once that is clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. While we are committed to

seeing PMC through to approval, our entire organization is focused on rapidly growing our TMR cardiac surgery business, including more targeted activity outside the United States."

- 11/28 **Palomar Medical Technologies Inc.** announced financial results for the third quarter ended September 30, 2004. The company's third quarter total revenues increased by 52%, product revenues increased by 40%, and gross profit from product sales improved by 59% as compared to the same quarter in 2003. The company realized a significant increase in income from operations of \$1.8 million, or 300%, and a net income improvement of \$1.2 million, or 130%, as compared to the third quarter of 2003.

Revenues for the quarter were \$13.9 million, up from \$9.2 million in the third quarter of 2003. Gross profit from product sales increased to \$7.6 million (66% of product revenues), up from \$4.8 million (58% of product revenues) in the year-earlier quarter. The company reported income from operations of \$2.4 million for the third quarter of this year, as compared to income from operations of \$613,000 for the third quarter of last year. The company reported net income of \$2.1 million (12 cents per share) which includes a non-recurring expense of \$380,000 from settlement of a previously owned subsidiary's facility lease, for the third quarter of this year, versus net income of \$904,000 (5 cents per share) which includes a benefit from income taxes of \$275,000, for the third quarter of last year.

Revenues for the nine months ended September 30, 2004, were \$38.0 million, up from \$24.7 million for the same period in 2003. Gross profit from product sales increased to \$20.7 million (65% of revenues), up from \$12.8 million (58% of revenues) in the year-earlier period. The company reported net income of \$5.3 million (30 cents per share) for the nine months ended September 30, 2004, versus net income of \$2.3 million (15 cents per share) for the same period in 2003.

CEO Joseph Caruso commented, "We are pleased to report another strong quarter with a substantial increase in revenues and profitability, even during what historically has been a seasonally slow quarter for this industry due to the summer vacation months. The newly introduced Palomar StarLux light and laser based system as well as all of our family of Lux products have been well received by our customers, which continues to strengthen our reputation as the technology leader."

Caruso continued, "We have increased market share over the past few quarters and believe our balanced strategy between short term core business growth in the professional market and partnerships with large consumer product companies for the long term will lead to increased shareholder value."

During the third quarter of 2004, the company announced the following event:

\* The company and **Johnson & Johnson Consumer Companies, Inc.**, a **Johnson & Johnson Company**, signed an agreement to develop, clinically test and potentially

commercialize home-use, light-based devices for (i) reducing or reshaping body fat including cellulite; (ii) reducing appearance of skin aging; and (iii) reducing or preventing acne.

10/28 **PhotoMedex, Inc.** announced the results of its operations for the quarter and nine months ended September 30, 2004. Revenues for the third quarter were \$4.5 million, an increase of 35% over the same period last year. Revenues for the third quarter 2003 were \$3.3 million. A component of the increased revenues for the three months ended September 30, 2004 was \$945,755 from the domestic XTRAC procedures, an increase of 76.8% from the \$535,003 reported for the same period in 2003.

The net loss for the quarter was \$1.2 million (3 cents per share) representing an improvement of 39.6% over the loss of \$1.9 million (5 cents per share) for the third quarter ended September 30, 2003.

The revenues for the nine months ended September 30, 2004 were \$12.8 million representing a 20.6% increase over the same period last year. Revenues for the nine months ended September 30, 2003 were \$10.6 million. The net loss for the nine months was \$3.7 million (10 cents per share) representing an improvement of 29.3% over the loss of \$5.3 million (15 cents per share) for the nine months ended September 30, 2003. As of September 30, 2004, the company had cash and cash equivalents of \$5.3 million, including restricted cash of \$110,062, representing a decrease in cash and cash equivalents of \$365,932 from June 30, 2004.

Jeffrey O'Donnell, PhotoMedex CEO and president, commented, "We are pleased with the record revenues for both of our core business units. PhotoMedex dermatology has achieved solid procedure growth for seven consecutive quarters and I am particularly pleased to note that we continue to see positive payment policies adopted for the XTRAC therapy by large health plans in major metropolitan markets."

The following were among the more notable recent achievements:

**Reimbursement:**

- \* Anthem Blue Cross and Blue Shield, the fourth largest health plan with 12.6 million members, adopts XTRAC reimbursement.

**Financial:**

- \* Domestic XTRAC procedures increased 9.1% over the second quarter 2004, constituting seven consecutive quarters of growth in procedures;
- \* Surgical Services yields 6.5% growth over second quarter 2004;
- \* Stock warrants exercised, amounting to \$1,367,875 incremental cash.

**Operations:**

- \* Successfully completed FDA inspection;
- \* Successfully completed ISO 9001 inspection.

#### **New Product Development:**

- \* FDA market clearance for XTRAC 2, a smaller-size excimer laser.

#### **Business Development:**

- \* Acquired dermatology technology from **Stern Laser srl** of Italy.

10/29 **AngioDynamics, Inc.** announced its plans to present the company's new VenaCure laser vein treatment procedure kit at the *American College of Phlebology's* 18th Annual Congress at Marco Island, Fla., November 4-7, 2004. The company expects to ship kits within the United States mid-November.

VenaCure laser vein treatment is a minimally invasive alternative for the treatment of severe varicose veins. The procedure lasts about 45 minutes and offers patients an effective out-patient alternative to surgical ligation and vein stripping.

AngioDynamics' new VenaCure procedure kit is designed to be used with its Precision 980 laser as well as other diode lasers with an SMA 905 connector. The kit was developed to help improve patient safety while providing ease of use for physicians.

Highlights of the kit include, but are not limited to:

- separately packaged sterile micro access kit - designed for less waste;
- double-ended, straight and J-tipped .035" guidewire - allows for physician preference;
- quality manufactured fiber with our patent pending Sheath-Lok system - designed for precise placement and accurate performance

A brand new addition to the kit is the patent pending 4F Tre-Sheath Introducer, one of the lowest profile sheaths on the market for this procedure. The Tre-Sheath features a translucent, super-echogenic braided shaft, with centimeter markers throughout the length of the sheath and at the tip. These features are intended to heighten visibility at different stages during the procedure. This product is also offered in a variety of lengths. These specific features and patent pending design were developed to provide the physician with a more user-friendly approach to this minimally invasive procedure.

Commenting for AngioDynamics, Product Manager David Doster said, "AngioDynamics' design team has been working with leading physicians in the industry on this newly designed sheath and kit. It is very rewarding to see our commitment to the constant improvement of the laser vein treatment, both for patients and physicians, come to

fruition. We believe this new procedure kit -- featuring the Tre-Sheath Introducer -- is a prime example of AngioDynamics' leadership commitment to this new procedure."

- 11/2 **Candela Corporation** reported that earnings from continuing operations for the quarter ended October 2, 2004 were \$2.8 million versus \$1.8 million for the same period a year earlier. Earnings per share from continuing operations were \$0.12 versus \$0.08 - an increase of 50% over the prior period. Revenues for the quarter were \$22.4 million versus \$18.7 million in the previous year -- an increase of 20%, but down 36% from the \$34.2 million reported in the previous quarter.

Gerard Puorro, Candela's president and CEO, commented: "The July to September period is seasonally our slowest. We are pleased with our growth in earnings and revenues. We believe this is a good start to what we expect will be a solid fiscal year for Candela."

- 11/3 **Laserscope** announced that based on the use of its GreenLight PVP procedure for the treatment of Benign Prostatic Hyperplasia (BPH), Kings College Hospital NHS Trust, a leading London-based healthcare facility, won a prestigious clinical excellence innovation award from the Modernisation Agency of the United Kingdom's socialized medicine body, or National Health Service (NHS).

Kings College Hospital demonstrated that by performing Laserscope's PVP procedure on an outpatient basis, versus conducting the more invasive trans-urethral resection of the prostate, or TURP, procedure, the hospital was able to reduce costs and waiting times while increasing patient satisfaction and experience. In the UK, TURP generally involves long hospital stays, long waiting lists and high morbidity.

"We are very excited and encouraged by the work being done by Dr. Gordon Muir and his staff and colleagues at Kings College Hospital," said Eric Reuter, president and CEO of Laserscope. "By utilizing our innovative PVP procedure to treat BPH, the hospital has clearly demonstrated the clinical efficacy and many other important benefits of PVP versus other more invasive, more costly and less effective treatment options.

"We have had considerable success in the UK's private healthcare sector since launching our GreenLight system in 2002, but penetrating the two-tiered health-care system in the UK, as in many other countries, remains a challenge in that not only must clinical efficacy be demonstrated, but also the cost-effectiveness of the procedure as well," said Reuter.

"We believe that the recognition and visibility Laserscope is receiving from this NHS award being granted to a world-renowned medical center such as Kings College, will help us gain a higher level of visibility and credibility for the many positive attributes of PVP, not only within the UK's public healthcare system, but in other two-tiered health-care systems around the globe. This brings us even closer to our top priority -- ensuring that Laserscope's GreenLight PVP, or Photo-Selective Vaporization of the Prostate, is recognized as the new worldwide standard of care for treating BPH."

- 11/3 **Cutera, Inc.** reported financial results for the third quarter and nine-month period ending September 30, 2004. Third quarter revenue was \$12.7 million, compared to \$11.0 million recorded in the same period last year. Net income for the third quarter was \$877,000 (7 cents per share) compared to a net income of \$1.1 million reported in the third quarter of 2003. Included in the third quarter 2004 results is \$356,000 of pre-tax, non-cash, stock-based compensation charges, compared to charges of \$538,000 in the third quarter of 2003.

The company's revenue for the nine-month period ended September 30, 2004 was \$36.5 million, a 37% increase from \$26.6 million recorded in the same period last year. Net income for the nine-month period was \$1.7 million (14 cents per share) compared to net income of \$1.7 million reported in the same period last year. Included in the results for the nine-month period ended September 30, 2004 was \$1.1 million of pre-tax, non-cash, stock-based compensation charges, compared to charges of \$1.0 million in the same period last year.

"Our third quarter results exceeded our expectations, and demonstrate Cutera's continued strong operational performance," said Kevin Connors, president and CEO. "Revenue reached record levels as we continued to expand our global sales channels and develop innovative aesthetic products. We maintained our strong gross margin and continued to invest in research and development and marketing as we position our company to become the leader in light-based aesthetic systems."

Management believes fourth quarter revenue will be approximately \$14.5 million with corresponding earnings per share of \$0.08. This implies full year 2004 revenue of \$51.0 million and earnings per share of \$0.22, an increase from last quarter's guidance of \$0.16 to \$0.19.

- 11/4 **Cell Robotics International Inc.** announced that it anticipated significant sales of its proprietary Lasette product to the blood banking community based on the product's reception at the 2004 annual meeting of the *American Association of Blood Banks* in Baltimore last week. The Lasette instrument provides specific and significant advantages for blood donor screening resulting in greater availability of donors as described in a paper presented to the AABB membership.

"We are overwhelmed by the tremendous response from the worldwide blood banking community," said Gary Oppedahl, "During the AABB trade exposition we conducted product demonstrations almost every 60 seconds for the entire three days. You wouldn't think that people would wait in line for 20 minutes just to have their fingers lanced."

"The Lasette is definitely the most exciting new technology exhibited at this meeting in a long while," said Sheri Goertzen of Children's Hospital of Central California.

The company's Lasette is a small device that uses a tiny laser beam for collection of capillary blood samples. **United Blood Systems (UBS)**, the second largest blood collection

agency in the U.S., has studied application of the Lasette in blood donor screening over the last 13 months. The results of these studies indicate that the Lasette can provide more accurate anemia screening results that are required from volunteer donors prior to blood donation.

"What [the Lasette] does is it provides a better sample for us to determine whether or not someone has enough blood cells to give a pint away," says Elizabeth Waltman, executive director of the UBS' Albuquerque operations. Twelve percent of volunteer donors are turned away, or deferred, due to screening tests. According to study data, the Lasette practically eliminates erroneous deferrals from poor capillary blood samples, increasing the availability of donated blood supply.

Conventional steel lancets leave injured tissue in the skin when creating the wound for blood collection. In contrast, the Lasette removes injured tissue from the skin by laser ablation, similar to the effect of cosmetic laser surgery. The Lasette produces cleaner, better blood samples over longer periods of time, and without coagulation that can lead to errors in screening test results. In addition, the fingers are not sore as they often are after the procedure and the absence of disposable needles eliminates the danger of health care workers or patients accidentally being stuck by a contaminated device.

These results on donor refusal rates and donor satisfaction are a windfall for blood banks and plasma centers. The addition of more qualified donors based on the Lasette blood screening results creates a significant return on investment for blood banks without significantly changing the current costs. This impact on deferral rates has far-reaching implications for blood banks around the world providing preferred and rapid access to a tens of million dollar market with substantial potential for recurring revenues. About 25 million pre-donation blood tests are performed each year in the U.S. alone. The company expects the enthusiasm of the blood banking community to spread to other blood banks and clinical institutions in the United States and abroad.

The Lasette uses a pulse of infrared laser light to ablate a small wound in the patient's fingertip to establish capillary blood access. The procedure requires no physical penetration of the skin and completely eliminates the use of medical sharps for blood collection. After months of product development the company released the newly designed Lasette model P200 in July. The P200 is designed specifically for fast and easy collection of capillary samples for blood chemistry screening and clinical applications. The company will now aggressively introduce the P200 to the clinical market, and expects that introduction of the technology through hospital-based blood banks will stimulate consideration by other clinical departments. The P200 is ideal for all clinical applications with equally good value propositions for prison infirmaries, where the absence of sharps is of primary importance and nursing homes, where the reduction of pain and absence of soreness is very important to seniors and their health care providers. The successful launch into Blood Banks represents a well-executed first step.



In the past year, despite having very limited resources to conduct its operations, the company was able to implement manufacturing improvements and reductions in overall company expenditures, along with design changes and successful negotiations with our vendors which have lowered the costs of the Lasette to the company by 35% with expected further reductions as volumes increase.

11/4 **Syneron Medical Ltd.** announced its 2004 third quarter results, for the period ended September 30, 2004. Revenues for the third quarter of 2004 were \$15.1 million, an 80% increase over the \$8.4 million recorded in the third quarter of 2003. Net income for the third quarter was \$7.3 million (29 cents per share) compared to net income of \$2.3 million (11 cents per share) reported in the third quarter of 2003.

The company's revenues for the nine months ended September 30, 2004 were \$41.2 million, a 78% increase compared to \$23.1 million recorded in the same period last year. Net income for the first nine months was \$19.2 million, a 159% increase compared to net income of \$7.4 million reported in the same period last year.

Management raised its guidance for 2004 full year revenues to approximately \$57.5 million, including \$16.2 million in the fourth quarter.

Key company developments during the third quarter and first month of the fourth quarter of 2004 included:

- \* Successful closing, on August 11, 2004, of Syneron's Initial Public Offering of 5,000,000 of its ordinary shares at \$12.00 per share
- \* Health Canada approval for the VelaSmooth, Syneron's new aesthetic device for body contouring and the treatment of cellulite
- \* US Food and Drug Administration (FDA) marketing clearance of the Aurora and its derivative systems, Galaxy and Pitanga for permanent hair reduction
- \* Opening of the company's Asia-Pacific subsidiary in Hong Kong
- \* Expansion of Syneron's distribution network to include five countries in South America, bringing the total number of Syneron distributors to 33 worldwide

"We are continuing to see strong market acceptance of our ELOS technology and Syneron platforms," said Moshe Mizrahy, Syneron's CEO. "Our third quarter results reflect the growing awareness of our technology and enthusiasm for the benefits our products provide to medical professionals and patients."

Following the release of financial results, John Calcagnini of **CIBC World Markets** provided his take on **Syneron: ELOS: Beats Revenue and EPS Estimates; Raises Revenue Guidance**

Syneron reported an upside revenue and earnings surprise this morning with revenues of \$15 mm versus \$8.4 mm a year ago, above our \$14 mm estimate. The company raised

full-year revenue guidance to \$57.5 mm from \$55 mm. EPS came in at \$0.29 versus \$0.11 a year ago and above our \$0.25 estimate.

We would note that 4Q04 is expected to be a strong quarter as the company is expected to get FDA approval for Vela Smooth (for treating cellulite) and to launch the Comet large surface area hair removal laser.

John Calcagnini of **CIBC World Markets** provided his report on **Syneron's** release of its quarterly results: **ELOS: Beats 3Q04 Revenue and EPS Estmts.; Raises Rev Guidance. Raising Our Price Target**

We are raising our price target on ELOS to \$35 from \$21 following an upside revenue and earnings surprise this morning with revenues of \$15M versus \$8.4M a year ago, above our \$14M est. We are raising our 2004 and 2005 rev. ests. to \$58.7M and \$82.7M, from \$55.1M and \$80M, respectively.

The upside in the revenue was driven by strong sales of Aurora (\$6.5M), the Galaxy (\$3M), and the Polaris (\$4.5M). The Vela product for cellulite, which is not yet sold in the U.S., did approximately \$300K for the quarter. We have modeled Vela at \$1.7M in 4Q04 as FDA approval is expected.

EPS was \$0.29 versus \$0.13 a year ago and above our \$0.25 estimate. Our new EPS estimates for 2004 and 2005 are \$1.18 and \$1.31, respectively, up from \$1.06 and \$1.13 previously.

Syneron has one of the broadest and most dynamic new product pipelines in the industry. The company also has the highest profitability in the laser industry with gross margins of 87% through outsourcing mfg, lower COGS by combining RF and optical energy and tax benefits in Israel.

- 11/4 **Lumenis Ltd.** announced preliminary and unaudited financial results for the third quarter and nine months ended September 30, 2004. Avner Raz, Lumenis' president and CEO, said, "We are pleased that our shareholders ratified the appointment of **BDO Ziv Haft** as our independent auditors. BDO has recently commenced its audit work, which will focus first on prior years and, as a result, we anticipate that the audit review will become current during the second half of next year."

**Third Quarter Results:** Revenues in the third quarter were \$62.5 million compared with \$70.3 million in the previous quarter and \$66.2 million in the third quarter of 2003. Gross profit was \$30.3 million in the third quarter of 2004 compared with \$35.8 million in the previous quarter and \$26.6 million in the third quarter of 2003. Operating income in the third quarter of 2004 was \$1.8 million compared with \$4.4 million in the second quarter of 2004 and an operating loss of \$10.5 million in the third quarter of 2003.

Net loss in the third quarter was \$2.3 million (6 cents per share) compared with net earnings in the second quarter of 2004 of \$1.1 million (3 cents per share) which included Other Income of \$1.8 million as a result of the company's new sales and marketing agreements with **WaveLight Laser Technologie AG**. The company reported a net loss of \$15.3 million (41 cents per share) in the third quarter of 2003.

Commenting on the results, Raz said, "Q3 comparisons reflected some softness in Asia and the fact that we are just now beginning to supply the LumenisOne aesthetic system with the Lightsheer module. "I am pleased by the improvements we have made in operational efficiencies, margins and expenses which resulted in a second consecutive quarter of solid operating profits and continued positive cash flow. These results demonstrate the benefits of our new organization and operating model. Demand for our products is strong. In particular, we have a growing backlog of orders for LumenisOne. We are also encouraged by the excellent reception of our new Novus3000, a high-power 532nm photocoagulator with dual fiber output, specifically designed for use in the operating theater, unveiled at the *American Academy of Ophthalmologists* convention held in October. Our goal is to continue to deliver the most advanced technologies and products to our customers and leverage our global infrastructure to drive growth and profitability in each of our markets," he added.

Net cash flow from operating activities was a positive \$3.3 million in the third quarter of 2004 compared with a negative net cash flow from operating activities of \$1.0 million in the third quarter of 2003. At September 30, 2004, the company had \$19.1 million of cash and cash equivalents and unused borrowing capacity under its committed lines of credit of an additional \$19.7 million. Total debt was \$200.0 million. Based on the preliminary and unaudited results for the first three quarters of 2004, the company is in compliance with its covenants under its bank agreements.

The company had approximately \$19 million in backlog at September 30, 2004 compared with approximately \$15 million at June 30, 2004 and approximately \$20 million at March 31, 2004.

**Revenue Breakdown:** Third quarter 2004 sales by geographic region were as follows:

\* Sales in the Americas were \$30.7 million, compared with \$34.1 million in the previous quarter and \$30.5 million in the third quarter of 2003.

\* Sales in Europe were \$11.8 million, compared with \$15.0 million in the second quarter of 2004 and \$12.7 million in the third quarter of 2003.

\* Sales in Asia Pacific, including China and Japan, were \$20.1 million, compared with \$21.2 million in the previous quarter and \$23.0 million in the third quarter of 2003.

**Third quarter sales by product line were as follows:**

\* Aesthetic products sales were \$19.2 million, compared with \$24.8 million in the previous quarter and \$23.9 million in the third quarter of 2003.

\* Surgical product sales were \$13.6 million, compared with \$11.2 million in the previous quarter and \$10.7 million in the third quarter of 2003.

\* Ophthalmic product sales were \$13.2 million, compared with \$16.3 million in the previous quarter and \$16.6 million in the third quarter of 2003.

\* Dental product sales were \$1.1 million, compared with \$2.4 million in the previous quarter and \$2.7 million in the third quarter of 2003.

\* Service revenues were \$15.4 million, compared with \$15.4 million in the previous quarter and \$12.4 million in the third quarter of 2003.

**Nine Months Results:** Revenues for the first nine months of 2004 were \$198.0 million compared with \$211.7 million in the same period last year. Gross profit for the first nine months of 2004 rose to \$96.8 million from \$80.4 million for the first nine months of 2003. Operating income for the first nine months of 2004 reached \$4.8 million compared with an operating loss of \$37.3 million for the same period last year.

Net loss for the first nine months of 2004 was \$5.4 million (14 cents per share) compared with a net loss of \$55.4 million, including a \$3.6 million loss on the sale of discontinued operations (\$1.49 per share) for the same period in 2003. Net cash flow from operating activities for the first nine months of 2004 rose to \$12.7 million compared with a negative net cash flow from operations of \$3.2 million for the same period last year.

As previously reported, a report prepared for the Audit Committee with respect to the company's internal investigation had concluded that the timing of the company's revenue recognition was inappropriate with respect to certain identified transactions. The aggregate effect of the company's accounting for the transactions identified in the report, as described more fully in the company's press release of May 3, 2004, was to cause revenues in 2001 and 2002 to be overstated, and revenues in 2003 to be understated. The effect of the foregoing on the results of operations for the three and nine-month periods ended September 30, 2003 was to cause revenues to be understated by approximately \$1.0 million or 1.5% and \$2.5 million or 1.2%, respectively. The effect of such understatement of revenues on previously reported earnings (loss), while not included in the report, is estimated, on a preliminary basis and subject to further adjustment, to decrease the net loss as reported in such periods by approximately \$0.6 million and \$1.5 million, respectively. Such adjustments, as well as any other adjustments which may arise from any further investigative activities, are not reflected in the attached financial statements.

As previously reported, the Audit Committee anticipates that a restatement of previously reported financial results may be appropriate, but intends to defer making a final decision

pending completion of the audit by the company's recently appointed independent accountants, BDO Ziv Haft.

- 11/4 **Diomed Holdings, Inc.** announced that the Center for Medicare and Medicaid Services (CMS) has established reimbursement codes for laser ablation as a mode of treatment for superficial vein disorders, including its patented EndoVenous Laser Treatment (EVLT) for varicose veins. The new codes, which are established by the American Medical Association and the CMS, form the basis for Medicare and Medicaid reimbursement across the US and are expected to become effective January 1, 2005.

Under the new codes, doctors performing the EVLT procedure in an office or clinic setting, will be reimbursed an unadjusted base rate of \$2,041 for the first vein treated under code #36478; second and additional veins will have a base rate of \$437 under code #36479. When performed in a hospital setting, the new codes allow for professional (Part B) payments of \$364 for the first vein treated and \$178 for the second and additional veins, along with applicable hospital facility fees. These base rates are adjusted for regional cost differences.

"The new codes represent a significant milestone toward the goal of insurance coverage for all Americans afflicted with painful varicose veins," stated James Wylie, president and CEO of Diomed Holdings, Inc. "We would especially like to recognize our customers and professional medical organizations like the *Society of Interventional Radiology*, the *Society of Vascular Surgery*, and the *American College of Phlebology*, among others, whose hard work and tireless efforts helped make this possible. With existing insurance carrier policies representing over 160 million covered lives and the creation of these new CPT codes, Diomed continues to advance EVLT as the gold standard of care for varicose veins."

- 11/5 **AngioDynamics, Inc.** announced that the Center for Medicare Services (CMS) had established new procedural codes and reimbursement rates for its VenaCure endovenous laser ablation therapy for varicose veins. The codes and payment rates are contained in The Medicare Program Final Rule for the Calendar Year 2005 announced on November 3rd and will become effective on January 1, 2005.

The new codes, established by the *American Medical Association*, are 36478 for endovenous laser ablation therapy of incompetent vein, first vein treated, and 36479, endovenous laser ablation therapy of incompetent vein, second and subsequent veins treated in a single extremity. The physician payment for first vein treated is an average of approximately \$2,011 when performed in the office setting. Actual payments will be adjusted for geographic cost differences.

While these payment rates are applicable to Medicare, the Medicare payment has a strong influence on the establishment of the payment rate for private insurers.

"We have anticipated and worked toward this moment for a long time," stated Brian Kunst, vice president of Regulatory Affairs and Quality Assurance for AngioDynamics. "The establishment of dedicated procedural codes and reimbursement rates for our endovenous laser procedure removes the primary obstacle to commercial acceptance of this innovative therapy. Difficulties encountered by physicians and hospitals in billing and obtaining adequate reimbursement will be eliminated as the new codes and reimbursement rates are incorporated into the payment systems of Medicare carriers and private insurers. Difficulties encountered by insurance companies in processing claims that lacked a dedicated code, and the resulting inconsistencies in reimbursement payment, will also be eliminated, allowing our customers to receive predictable and consistent payment. It is expected that the creation of these codes will also act as a catalyst in achieving additional positive coverage decisions by more insurance companies, allowing more people to take advantage of this less invasive and less costly alternative to traditional vein stripping."

In another important reimbursement announcement, the new endovascular ablation procedural codes were included in the 2005 payment rates established by CMS under the Hospital Outpatient Prospective Payment System published on November 2, 2004. This system governs payments to hospitals for supply, equipment, and overhead expenses incurred during an outpatient procedure. A single average payment rate of approximately \$1,538 applies to the new endovenous ablation codes for both laser and radiofrequency methods.

Commenting on the announcement, Eamonn Hobbs, president and CEO of AngioDynamics, said, "AngioDynamics commends all the professional organizations and affiliations that worked together to accomplish this important goal. It represents a turning point in establishing the economic feasibility of VenaCure laser therapy and will assure continued growth of this market and delivery of the best available treatment to more patients throughout the nation."

11/8 **BriteSmile, Inc.** released results for the quarter ended September 25, 2004. Total revenues increased by \$0.5 million, or 4%, to \$11.9 million for the third quarter ended September 25, 2004, from \$11.4 million in the third quarter of 2003. The net loss was \$2.5 million (24 cents per share) in the third quarter compared with \$4.8 million (70 cents per share) in 2003 (both per share numbers reflect the 5:2 stock split which was effective January 30, 2004).

Earnings before interest, tax, depreciation, and amortization (EBITDA) was \$0.2 million in the third quarter 2004, excluding a \$0.75 million non-cash charge to BriteSmile's income statement required under accounting rules for certain consulting work initiated and paid for by a principal stockholder, a related party. This compares to an EBITDA of \$(2.8) million in the third quarter of last year. EBITDA is a Non-GAAP financial measure. More information regarding this Non-GAAP financial measure, and a reconciliation of EBITDA to net loss, the most directly comparable GAAP measure, is provided below.

**Other key financial highlights for the third quarter were:**

\* Center whitening fees of \$4.3 million were 6% lower than last year, primarily because of recent consumer market conditions.

\* Associated Center whitening fees of \$5.6 million were 5% higher than 2003.

\* Product sales of \$1.9 million were 31% higher than last year, primarily due to sales of the BriteSmile-to-Go(TM) (BTG) take-home whitening pen which was launched in the third quarter of 2003.

"We continue to be pleased by our positive cash earnings in the third quarter, and in the achievement of our revenue guidance for the quarter," said Anthony Pilaro, chairman and acting CEO. "We also look forward to opening our new spas, starting in the fourth quarter of this year. The Woodfield, Illinois spa outside Chicago is planned to open by the end of November, while the previously announced Shorthills, New Jersey project has been canceled due to zoning issues. Additionally, we are pleased to announce that we have recently signed leases to open 2 more spas by the beginning of the second quarter of 2005: on Madison Avenue in New York City, and on Union Square in San Francisco."

"However," continued Pilaro, "we experienced a decline in revenues in October which we believe is attributable to a temporary softening in overall retail consumer demand."

With respect to forward guidance, fourth quarter revenues are anticipated to decline both on a sequential and year-over-year basis, due to the demand softness experienced in the first part of the quarter, as well as significant initial shipments of BriteSmile-To-Go in the fourth quarter of last year.

11/8 **Candela Corporation** reported that its present internal forecast range for the current quarter ending January 1, 2005 is approximately \$28 to \$30 million in net revenues, and its current estimated range of second quarter earnings per share is approximately \$0.12 to \$0.14. The company undertakes no responsibility to update these forecasts at any time, and the forecasts are subject inherently to risks and uncertainties that could cause actual results to differ materially and adversely from those expressed here, including those mentioned below in the Safe Harbor Statement and in Candela's periodic reports filed with the SEC.

Gerard Puorro, Candela's president and CEO, commented: "We and other public companies witness from time to time positive or negative price movements in our stock that can seem excessive when compared to actual financial performance announced. We think it relevant to report that we are not aware at this time of any undisclosed conditions in our markets or any other undisclosed material negative trends or factors impacting our business. Under current law, the company may not and does not selectively provide guidance to financial analysts in the construction of their financial models or share internal company forecasts on a selective basis with them or others. While we have

generally preferred in the past not to publicly provide our internal forecast information because it is by its nature forward-looking and subject to various risks and uncertainties, we are doing so at this time and will continue to review this practice going forward. Of course the fact that the forecasts are internal company forecasts does not necessarily make them any more predictive or reliable than estimates furnished by third parties."

- 11/9 **DUSA Pharmaceuticals, Inc.** announced the signing of a second clinical trial agreement with the National Cancer Institute (NCI), Division of Cancer Prevention (DCP). The new agreement covers the clinical development of Levulan photodynamic therapy (PDT) for the treatment of oral cavity dysplasia. It follows a similar agreement dated September 27, 2004, covering the treatment of high-grade dysplasia (HGD) within Barrett's Esophagus (BE). Levulan is DUSA's brand of aminolevulinic acid, or ALA.

DUSA and the NCI DCP will be working together to prepare an overall clinical development plan for Levulan PDT in oral cavity dysplasia, starting with a Phase I/II study and continuing through Phase III studies if appropriate. The immediate plan is for the NCI DCP to solicit clinical protocols from its extramural expert clinical investigator consortium, after which time DUSA and the NCI DCP will finalize the clinical trial design. The NCI DCP will use its resources to file its own IND. DUSA will provide Levulan, device(s) and the necessary training for the investigators involved in the studies. DUSA will maintain full ownership of its existing intellectual property and, subject to successful Phase II and III clinical trial results, intends to seek FDA approval in due course.

**Oral Cancer and Dysplasia:** Approximately 30,000 Americans will be diagnosed with oral cancer this year, and another 12,500 will be diagnosed with cancer of the larynx, or voice box. Risk factors include tobacco use and alcohol consumption. Some types of pre-malignancy, such as leukoplakia (visible as white patches seen on the lining of the oral cavity and larynx), are relatively common and affect approximately 2.1 million Americans. As many as 25% of leukoplakias are dysplastic at the first visit, and dysplasia currently appears to be the best predictor that a lesion will progress to cancer; There is currently no effective treatment for preventing progression of leukoplakia to cancer.

Independent investigator studies have reported that ALA may be used to both identify and to remove dysplasia within the oral cavity and larynx. DUSA and the NCI DCP will be carrying out clinical testing of Levulan PDT to determine its potential to provide an entirely new approach to the prevention of oral cavity cancer.

Dr. Ramon Franco, Director of the Division of Laryngology at the Massachusetts Eye and Ear Infirmary, uses ALA-PDT to treat his patients with laryngeal keratosis. Dr. Franco states "Based on my experience with this experimental therapy to date, I believe that ALA-PDT holds great promise for the treatment of all oral precancers. There is currently no widely accepted treatment for oral precancers and the current standard of care is 'watchful waiting' for the development of cancer."



Stuart Marcus, MD, DUSA's vice president Scientific Affairs and CMO, stated "We are very pleased that the NCI DCP is bringing its resources to bear on this collaborative clinical development effort. The treatment of oral cavity dysplasia is an example of a significant unmet medical need. Publications of the results of independent investigator studies in this area have reported positive results for ALA PDT in the treatment of oral cavity pre-cancers, using ALA given by both topical and systemic dosing. The goal of the new DUSA/NCI collaboration is the development of a simple, safe and effective treatment for this precancerous condition."

- 11/9 **HaloLaser Biotherapy, LLC** announced the signing of a letter of intent to acquire the assets of **FHJ Scientific, Inc.**, for \$1.2 million in stock, to be included in the merger agreement with **Corbel Holdings Inc.** The purchase includes five Letters of Patent, together with several foreign patents and/or patents pending and other assets of FHJ.

FHJ is a privately held Texas corporation, which was formed in 1985. FHJ has the proprietary SHBAN Solution. In vitro and other testing have demonstrated the capabilities and superiority of SHBAN over known commercial products in applications covering contact dermatitis, dermal wounds and burns, ophthalmic and oral care. An example of the efficacy of the SHBAN Solution is its ability to quickly heal gingivitis.

HaloLaser Biotherapy LLC, and **Charles R. Crane MD and Associates Inc.**, announced earlier that they were to enter an agreement to facilitate a reverse merger of HaloLaser Biotherapy LLC and Charles R. Crane MD and Associates into Corbel Holdings, Inc. for purposes of taking control and functioning on its own merits and being identified as a legal trading company. Corbel Holdings, Inc., HaloLaser Biotherapy LLC, and Charles R. Crane MD and Associates Inc. have remaining a 20-day due diligence period before the closing of the transaction.

HaloLaser Biotherapy LLC in Dallas, Texas is in the biotech medical healthcare business of treating patients with acute pain and arthritis with the new FDA approved Neurolase 150 Medical laser device.

Delton Carrall, president and CEO of FHJ stated: "I believe once the SHBAN product or a derivative thereof is in the marketplace, it will sell itself due to the products superiority. We of FHJ are excited that the potential merger of HaloLaser with Corbel and the asset acquisition of FHJ will help get SHBAN to market more quickly."

Keith Houser, president and CEO of HaloLaser stated, "I have used the SHBAN oral and skin solution and was amazed as to its healing ability. It's exciting providing an opportunity to bring a new technology to improve one's quality of life." Additional information on HaloLaser can be found on the Internet at **[www.halolaser.com](http://www.halolaser.com)**.

Bruce Harlan, president and CEO of Corbel Holdings, Inc., stated, "We are very excited to have the assets of FHJ Scientific, Inc., Halo Laser and Charles R. Crane MD and

Associates Inc., merge into Corbel Holdings and expect to have the transaction closed before the end of this month."

- 11/10 **CardioGenesis Corporation** announced results for its third quarter and first nine months ended September 30, 2004. The company reported that revenues for the 2004 third quarter and first nine months decreased 21 percent and rose 1 percent, respectively, compared to revenues in the same periods last year.

The company recently announced that it closed a \$6.0 million convertible financing facility from **Laurus Master Fund, Ltd.** Chairman and CEO Michael Quinn commented, "The completion of this financing from Laurus Funds provides us with the capital resources to enable the timely and effective launch of our important new minimally-invasive TMR products. We expect the new products to drive utilization of TMR procedures and have a positive impact on our revenue growth. The company is advancing the field of TMR and expanding the potential patient population by providing the cardiothoracic surgeon with tools to treat patients with minimally invasive techniques that have the potential to reduce the operative morbidity and risk of a standard surgical procedure."

"Armed with important new long term data and innovative new products, for the first time in several years the company is now targeting select international markets for our laser revascularization platforms, both TMR and PMC," Quinn explained. "We will also utilize the funding to support our efforts to add to our product base. We expect that new product introductions will enable us to increase our revenue in the TMR franchise and to expand our overall revenue growth. We are also working with the FDA to finalize the next steps regarding our PMA supplement for PMC. We will then determine the resources required to get to approval, and whether we will pursue approval independently or with a corporate partner."

Quinn noted that confusion raised in the marketplace about the July review of laser myocardial revascularization by the Medicare Coverage Advisory Committee (MCAC) clearly impacted sales in the third quarter. "Many of our prospective new customers waited for the outcome of the Medicare advisory panel review before making a final decision about moving forward with TMR or purchasing a laser, which caused a fall off in revenue from this year's first and second quarters and negatively impacted our bottom line in the third quarter. However, we believe this is only temporary," Quinn said.

In September 2004, the minutes from the July MCAC meeting were posted on the Centers for Medicare & Medicaid Services (CMS) website. The company announced that after speaking with CMS at the time of the posting of the minutes, CardioGenesis does not expect any action regarding the current TMR coverage by CMS at this time. Quinn commented, "The silver lining to the whole Medicare review process was the direct involvement of the leadership of the *Society of Thoracic Surgeons (STS)* in the open public forum. As the physicians most familiar with the medical condition and needs of the Medicare patients in question, the STS was committed and persuasive in their assertion

of the importance of TMR as a therapy available to treat severe angina. Additionally, the American College of Cardiology confirmed its endorsement of TMR as a part of the public process."

Revenues in this year's third quarter decreased to \$2.8 million from \$3.6 million in the prior year period. The net loss in the 2004 third quarter increased to \$924,000 (2 cents per share) from a net loss of \$129,000 (0 cents per share) in the 2003 third quarter. For the first nine months of 2004, revenues increased to \$10.3 million, from revenues of \$10.1 million in the same period last year. The net loss for the first nine months of 2004 was \$921,000 (2 cents per share) compared to a net loss of \$886,000 (2 cents per share) in the prior year period.

Gross profit margins as a percentage of sales were 82% for this year's third quarter and 85% for the first nine months of 2004, as compared to 83% for both of the prior year's respective periods.

The company's September 30, 2004 balance sheet, which does not reflect the recently completed convertible financing transaction with Laurus Master Funds, Ltd., showed cash and cash equivalents of \$2.9 million, total assets of \$8.5 million, shareholders' equity of \$5.5 million with no long term debt.

During the year's third quarter, the company shipped one laser and had worldwide disposable sales of 731 units, compared to the shipment of three lasers and worldwide disposable sales of 778 units in the third quarter of 2003. At the end of the third quarter there were 442 sites with CardioGenesis lasers for myocardial revascularization compared to 433 sites at the end of the third quarter of 2003.

- 11/10 **Cutera, Inc.** introduced a new platform design for aesthetic systems. The first application available in this tabletop platform is the new and exciting Titan procedure. Titan, Cutera's latest product offering, is a light-based system that targets the dermis and provides sustained heating to the deep layers of the skin while simultaneously protecting the epidermis.

Commenting on the announcement, Cutera president and CEO Kevin Connors said, "We are very excited about the interest that Titan has generated. Titan had been available only on our Xeo platform, Cutera's multipurpose device for skin rejuvenation, hair removal and vascular treatments. The new Titan platform offers another choice to physicians who want to expand their practice with an exciting new application."

The FDA has cleared the Titan to be marketed to aesthetic professionals in the new tabletop platform and is now available for sale. The Titan on the Xeo platform received Canadian approval in June, 2004 and received the CE Mark in Europe in April, 2004.

- 11/11 **DUSA Pharmaceuticals, Inc.** reported its corporate highlights and financial results for the third quarter ended September 30th, 2004. As reported earlier, Q3 2004 end-user

Levulan Kerastick net sales to physicians totaled 20,196, including 1,326 sold by **Coherent-AMT**, our Canadian marketing and distribution partner. During Q3 2003, only 1,938 Kerastick units were sold, all in the U.S. Quarter over quarter, U.S. Kerastick sales grew 18% to 18,870, versus 16,002 during Q2 2004.

The net number of BLU-U units placed in doctors' offices during the quarter was 95, consisting of 70 in the U.S. and 25 in Canada, versus 37 units placed during Q3 2003. At the end of Q3 2004, there were 870 units in doctor's offices, consisting of 784 in the U.S. and 86 in Canada, versus 360 at the end of Q3 2003.

This past quarter, DUSA continued with Part A of its Phase II clinical trial on Levulan PDT in the treatment of photodamaged skin. In October, following FDA review, we also announced the initiation of a Phase II study on Levulan PDT for the treatment of acne vulgaris.

There were a number of peer-reviewed scientific articles related to the use of Levulan published in the dermatology literature during the quarter, as well as numerous lectures and presentations at scientific meetings and CME events. One important study combined Levulan with intense pulsed light (IPL) versus IPL alone for the treatment of photodamaged skin. The study, led by Dr. Jeffrey Dover of SkinCare Physicians of Chestnut Hill, MA, showed that Levulan combined with IPL resulted in statistically significant improvement (vs. IPL alone) in global photoaging, mottled pigmentation, and fine lines. DUSA provided Levulan and financial support to the investigator group.

Late in the quarter, we also announced the signing of a clinical trial agreement with the National Cancer Institute (NCI) Division of Cancer Prevention (DCP), for the clinical development of Levulan photodynamic therapy (PDT) for the treatment of high-grade dysplasia (HGD) within Barrett's Esophagus (BE). The NCI DCP will pay for the clinical trial costs, while DUSA will provide Levulan, device(s) and the necessary training for the investigators involved in the studies. Subject to successful Phase II and III clinical trial results, DUSA intends to seek FDA approval in due course. During the quarter, we also continued with our Phase II pilot study using Levulan PDT for the treatment of HGD within BE. The data from this pilot trial will contribute to the design of the NCI study, which is not expected to commence for a number of months.

Other developments during the quarter included an announcement of a mediation agreement with Photocure and Galderma related to our potential U.S. and other patent disputes; our inclusion in the 2004 UBS Global Life Sciences Conference in New York; and the announcement that our CFO would be leaving the company after the end of the year for personal reasons (a search for a replacement is underway).

Dr. Geoffrey Shulman, DUSA's president and CEO, stated "We are very pleased with our Q3 performance. U.S. Kerastick sales continued to increase despite seasonal factors, our net loss decreased versus the prior quarter, our therapy continued to get increasing recognition among dermatologists, our clinical trials continued to progress, and we

announced an important agreement with the NCI. We believe that we are now well positioned to become a significant competitor in the field of dermatology and beyond."

**Financial Highlights:** For the three months ended September 30, 2004, DUSA's net loss was \$3.0 million (18 cents per share), compared to a net loss of \$3.7 million (26 cents per share) in 2003. This lower net loss was primarily due to higher net Kerastick and BLU-U product sales, and lower legal costs, offset, in part, by an increase in marketing & sales expenses.

Revenues for the three months ended September 30, 2004 were \$2.0 million, compared to \$163,000 in 2003. During the current quarter, Kerastick and BLU-U sales to physicians were \$1.5 million and \$512,000 respectively, including sales in Canada by Coherent-AMT, versus 2003 revenues of \$163,000 that were totally comprised of U.S. Kerastick sales. This significant increase in revenues compared to the prior year was directly related to the efforts of our sales force since its launch in October 2003. In addition, the increase in BLU-U sales was caused, in part, by our ability to sell the BLU-U to physicians as a stand alone device for the treatment of moderate inflammatory acne vulgaris. Although the level of Kerastick sales to end-users for 2004 is much higher than for 2003, Kerastick sales must continue to increase significantly in order for DUSA to become a profitable operating company.

- 11/12 **HaloLaser Biotherapy, LLC** announced the signing of a letter of intent to acquire the ongoing customer base, inventory, patents and patents pending of **MEDICARDIUM, Inc.**, which is expected to be included in the merger agreement between HaloLaser and **Corbel Holdings Inc.**

MEDICARDIUM, Inc. is a privately held Panamanian corporation, which was formed in 2000. MEDICARDIUM is an over-the-counter chelation therapy product. Medicardium Chelation is a proprietary patented product used by a person to remove metal toxicity, aid circulatory disorders, diabetes and aging. The FDA has not made any evaluation of the Medicardium product. Medicardium has had 4 prior years of increased annual revenues and is estimated to have \$500,000 in Gross Sales for 2005.

Additionally, a new patent pending physical therapy table called the Vibraboard will be an integral part of the assets in the merger. The Vibraboard provides Biomechanical Stimulation (BMS) as a therapeutic modality. The Vibraboard is primarily used by medical practitioners to help increase the strength and coordination of the musculoskeletal and nervous systems and to increase the rate at which an injured person heals.

HaloLaser Biotherapy LLC, and **Charles R. Crane MD and Associates Inc.**, announced earlier that they were to enter an agreement to facilitate a reverse merger of HaloLaser Biotherapy LLC and Charles R. Crane MD and Associates into Corbel Holdings, Inc. for purposes of taking control and functioning on its own merits and being identified as a legal trading company. Corbel Holdings, Inc., HaloLaser Biotherapy LLC, and Charles

R. Crane MD and Associates Inc. are in a due diligence period before the closing of the transaction.

HaloLaser Biotherapy LLC in Dallas, Texas is in the biotech medical healthcare alternative pain management business of treating patients with acute pain and arthritis with the new FDA approved Neurolase 150 Medical laser device.

Keith Houser, president and CEO of HaloLaser stated, "The products incorporated with the Medicardium merger bring proven proprietary alternative pain management products to our growing company that will demonstrably improve one's quality of life. This will give us a competitive edge in the field of pain management." Additional information on HaloLaser can be found on the Internet at **www.halolaser.com**. Additional information on Medicardium can be found at **www.medicardium.com**.

Bruce Harlan, president and CEO of Corbel Holdings, Inc., stated, "We are elated to have the Medicardium assets and ongoing business of Medicardium incorporated in the Halo Laser and Charles R. Crane MD and Associates Inc., merger into Corbel Holdings."

11/12 **CoolTouch Inc.** announced new reimbursement codes for its CTEV 1320 nm Endovenous Laser for varicose vein therapy during the 18th *Annual Congress of the American College of Phlebology (ACP)*.

The Center for Medicare and Medicaid Services (CMS) has established payment rates for two new dedicated Level 1 CPT reimbursement codes established by the *American Medical Association* for endovenous laser ablation to become effective January 1, 2005.

The two new codes, which apply to the newly introduced CoolTouch CTEV 1320 nm endovenous laser ablation procedure, are:

-- 36478 Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated, with a national average reimbursement of \$2,041.16 and \$364.57 for procedures performed in the office setting and in the hospital setting, respectively, and

-- 36479 Second and subsequent veins treated in a single extremity, each through separate access sites, with an average national reimbursement of \$437.72 and \$178.12 for the office and hospital setting, respectively.

Regionally adjusted payments rates are available from CoolTouch Inc.

Commenting on the announcement, Dave Hennings, CEO of CoolTouch Inc., said, "The tremendous attention drawn to our booth at the American College of Phlebology Congress last week was enhanced by the announcement of the new reimbursement. Without the difficulties of processing claims without a dedicated code, CTEV 1320 nm

endovenous laser will now have assured growth as the preferred endovenous treatment of varicose veins."

Laser endovascular ablation procedural codes 36478 and 36479 are also included in the 2005 payment rates established by CMS under the Hospital Outpatient Prospective Payment System and assigned under APC (Ambulatory Payment Classification) group 0092. This coverage applies to hospitals for expenses incurred during an outpatient endovenous procedure. A national average payment rate of approximately \$1,538,27 applies to ablation for both laser and radiofrequency endovenous ablation methods.

- 11/12 The Board of Director of **El.En. SpA** approved the quarterly report on the financials closed on September 30, 2004, which shows revenues of 21 Euro millions for the quarter, up 18% with respect to the same quarter of the previous year.

Revenues show a positive trend in all segments, markedly in the medical segment and on the American market, with a 38% growth in the first nine months, up to 66 millions of Euro with respect to the 48 millions of Euro of the first nine months of year 2003.

The Group is closing the third quarter showing a pre tax income of 826 euro thousands, and the first nine months of 2004 with a pre tax income of 6 Euro millions, an outcome that, though enhanced by the gains on asset sales which are accounted for as other income, shows the fulfillment of the target set by the management.

During the quarter El.En. SpA increased its interest in **Cynosure Inc.** from 57,5% to 78,2% with an expense of roughly 5 millions of dollars. At the end of the quarter the Net financial position is still positive for more than 6,4 millions of Euro.

- 11/15 **Candela Corporation** announced that Jeffrey Dover, MD will be the keynote speaker at the *6th Annual Candela Users Meeting* in conjunction with the *13th Congress of the European Academy of Dermatology and Venereology (EADV)* in Florence, Italy.

Dover will kick-off this gala event with an overview of how lasers have changed the landscape of the aesthetic laser industry, and the role that Candela lasers have played throughout the years. Dover said, "I have been using lasers in my practice for more than 18 years, and have found Candela lasers to be the cornerstone of the aesthetic laser industry." He added, "Efficiency, effectiveness and versatility combined with their advanced technology are the key attributes that have made Candela lasers the 'workhorses' in my practice year after year."

Well-respected physicians throughout Europe will join Dr. Dover once again at this year's meeting. This elite group of laser experts will present new clinical data and expertise on the following topics:

Dr. Christine Dierickx (Belgium): Treatment of acne and other sebaceous conditions with Smoothbeam.

Dr. Jean-Michel Mazer (France): New clinical data with long-term follow up in the treatment of acne with Smoothbeam.

Dr. Dick van Gerwen (Netherlands): Nd:YAG treatment of leg veins (GentleYAG) comparison with sclerotherapy.

Dr. Giuseppe Scarcella (Italy): Q-switched Alexandrite for treatment of tattoos (AlexLazr).

The Candela Users meeting has grown over the past 6 years to be a pinnacle event at the EADV meeting each year. The meeting features an interactive discussion where leading physicians share their best practices, lessons learned, and discuss future trends and emerging technologies. Robert Wilber, vice president of Candela European Operations stated, "We're honored to bring together this group of prestigious leaders year after year, and we expect a record turnout of some of the most widely known and advanced users of cosmetic lasers in all of Europe." Wilber added, "At the event, Candela users are able to share their ideas and personal clinical experiences. It is this exchange that makes our meeting so popular."

- 11/15 **Syneron Medical Ltd.**, and its European subsidiary **Syneron GmbH**, announced that Syneron had been granted Medical CE Mark 0344 approval of its Vela system for non-invasive cellulite treatment.

The Vela system is based on Syneron's proprietary ELOS (Electro-Optical Synergy) combined energy technology, which uses Bi-Polar Radio Frequency and light energies to treat a wide range of medical aesthetic conditions. Utilizing a unique combination of RF energy, infrared light, tissue mobilization and suction, Vela safely and effectively re-contours the skin surface.

"This unique medical CE Mark further proves that Syneron products meet the exacting quality and efficacy standards of the international medical community," said Hans Edel, Managing Director of Syneron GmbH. "With this latest regulatory approval, Syneron is able to market the widest offering of products in Europe of any medical aesthetic company."

The Vela system will be launched at the *EADV (European Academy of Dermatology & Venereology)* conference in Florence, Italy, November 17-21, 2004.

- 11/18 **Lumenis Ltd.** announced the introduction of the Lumenis One system in Europe on November 17 at the *European Academy of Dermatology and Venereology (EADV)* congress taking place this year in Florence, Italy. At the symposium, leading dermatologists Professor Palombo from Italy, Dr. Mitchel Goldman, USA and Dr. Maurice Adatto, Switzerland, will provide an overview of their experiences with the Lumenis One system and with Lumenis' proprietary, market leading IPL systems.



Avner Raz, Lumenis president and CEO said: "Lumenis One was designed specifically to answer physicians' requests for a state-of-the art aesthetic system and is the world's most sophisticated platform for aesthetic treatment technologies. Offering industry gold standards, Lumenis One brings together three technologies essential to today's aesthetic practices: Intense Pulsed Light (IPL) for skin treatments using photorejuvenation, the treatment of vascular and pigmented lesions; the LightSheer diode laser for hair removal; and the Nd:YAG for treatment of leg veins and deeper vascular lesions."

Both multi-application and multi-technology, Lumenis One is equipped with three technologies, seven applications and presets for more than 35 conditions, enabling users to treat the widest range of patients. The logical, friendly user interface software was also planned for ultimate learning and interface ease. Lumenis One's smart software is the only package on the market to include a database, and treatment head, filter and light guide recognition. Increased patient comfort is a top priority for aesthetic physicians, and all Lumenis One treatment heads have continuous contact cooling and sapphire light guides. The versatile Lumenis One platform secures physicians' investments and expands with the needs of their practices. It offers the widest range of aesthetic treatments in the most cost-effective way.

Lumenis will also be introducing the 1064 nm Q-switched Nd:YAG Upgrade for the popular IPL Quantum system at this year's EADV. This upgrade will be the fourth in a line of technology upgrades that are available as add-ons to the IPL Quantum platform. This means that physicians have been able to continually expand their treatment capabilities with the Quantum system since its introduction in 2000, a further demonstration of Lumenis' commitment to providing value to our customers. The Q-switched Nd:YAG Upgrade is pending FDA approval.

11/18 *Reuters Health* reported on how laser skin resurfacing has become a popular way to wage war on wrinkles, and now a new study details how one type of laser may help turn back the clock. The study was reported in *Archives of Dermatology*, November 2004.

The carbon dioxide (CO<sub>2</sub>) laser is one of the systems used in laser skin resurfacing. The laser beam is passed over the skin to vaporize problem areas at the surface, while the heat that hits the underlying tissue is believed to spur the growth of new collagen -- the fibrous protein that helps keep skin taut. Revved up collagen production has been thought to be one reason laser resurfacing works. Still, the details of the process have not been clear.

Getting a measurement of how the CO<sub>2</sub> laser affects the biochemistry of the skin should allow for better comparisons among the different types of lasers used in cosmetic procedures, according to the authors of the new study. To do this, the researchers analyzed genetic material in tissue samples taken from adult volunteers who underwent CO<sub>2</sub> resurfacing of sun-damaged skin on their forearms. They found that one week after the procedure, levels of an enzyme involved in breaking down collagen -- known as MMP-1 -- were nearly 40,000 times higher than they were before surgery.

It's likely that the enzyme was "induced" by the laser to break down the patients' sun-damaged collagen, according to the researchers, led by Dr. Jeffrey Orringer of the University of Michigan Medical School in Ann Arbor. This "clearance" of old collagen may make room for a new generation, the researchers report in the November issue of the Archives of Dermatology. Indeed, their analysis found a "marked elevation" in procollagen proteins that occurred after levels of MMP-1 and related enzymes declined. The procollagen, which is turned into collagen, increased to seven to nine times its original levels and stayed elevated for at least six months after the laser treatment, Orringer and his colleagues report.

The findings, they say, may serve as a "measuring stick" against which other lasers can be compared. The challenge now, the researchers add, is to create a device that creates the same biochemical changes in the skin, but with fewer side effects. The risks of laser skin resurfacing include long-term skin discoloration, sun sensitivity, and in a small number of cases, scarring.

- 11/24 **Syneron Medical Ltd.** and its North American subsidiary **Syneron Inc.**, announced that the FDA had granted 510K marketing clearance to Syneron's Comet and Polaris DS systems for permanent hair reduction on all skin types (I-VI), including tanned skin. This new approval expands on the FDA's earlier clearance for hair reduction for these systems, granted last year.

Comet and Polaris DS are based on the same form of Syneron's proprietary ELOS (Electro-Optical Synergy) technology. Both systems combine electrical energy (Bi-Polar Radio Frequency) and diode laser energy to enable highly efficient, safe, long-lasting treatment of unwanted hair from all skin types and all parts of the body.

"This expanded clearance reflects the excellent long-term results of clinical studies summarizing more than two years of patient follow-up," said Dr. Amir Waldman, VP Regulatory and Clinical Affairs at Syneron Medical. "It reinforces our message to the medical community that Syneron products deliver outstanding medical aesthetic safety and efficacy."

Domenic Serafino, president of Syneron North America, noted: "The momentum of our market penetration has been steadily gaining speed with every additional regulatory approval. Coming just a month after similar clearance for permanent hair reduction for Syneron's Aurora, Pitanga and Galaxy systems, this latest approval will further strengthen Syneron's leading position in the aesthetic medical market."

- 11/24 **Lumenis Ltd.** announced that its distributor for aesthetic products in four states in the southern United States, **Eclipse Medical**, had advised Lumenis that it is terminating its distribution agreement with the company. Lumenis will be assuming direct sales and service operations in Eclipse's former region, which comprises Texas, Louisiana, Oklahoma and Arkansas, as early as the beginning of 2005. Lumenis and Eclipse expect a smooth operational transition. In sending its termination notice, Eclipse appears to be

seeking to preserve any rights that it may have to require Lumenis to purchase from Eclipse the related distribution business assets of Eclipse and to make payments therefore in accordance with the terms of the distribution agreement.

Based upon prior conversations with Eclipse, Lumenis believes that Eclipse may seek, in connection with the termination, aggregate payments of up to \$7 million, less any amounts then owed by Eclipse to Lumenis (including the amount of an outstanding loan with principal and interest aggregating more than \$1.2 million). Both Lumenis and Eclipse have alleged cross-defaults under the distribution agreement which could affect the amount of the purchase price by, among other things, either increasing it by 25% or eliminating Lumenis' obligation to purchase Eclipse's business assets altogether. The parties are in discussions regarding the termination, which may move to arbitration if no agreement is reached.

Avner Raz, president and CEO said, "We have plans in place to assume direct responsibility for the region with a sales and service organization that will be ready to continue uninterrupted sales and support to our customers. We do not expect any material impact on our revenue from the region going forward. We already have an organization in the region that sells and services our other product lines."

- 11/24 According to a report by *Reuters Health*, if brushing and mouthwash don't improve bad breath, an Israeli scientist may have the solution -- a laser treatment. "Now there's a laser treatment for one of the worst forms of halitosis, a rarely diagnosed version wafting relentlessly from the tonsils," *New Scientist* magazine reported. Yehuda Finkelstein of Meir Hospital at the Sapir Medical Center in Kfar Saba, Israel has successfully treated 53 patients suffering from bad breath, or halitosis, with a new, 15-minute technique.

Bad breath is usually caused by the build-up of bacteria around the gums and teeth which release foul-smelling gases but in more serious cases bacteria breed in grooves in the tonsils. "It's the ideal place for them," Finkelstein told the weekly science magazine. The laser treatment hits the infected tissue in the tonsils and creates scar tissue that seals the grooves so bacteria cannot grow in them. More than half of the patients were cured after one treatment, while the others required two or three more sessions, according to the magazine.

- 11/24 **AngioDynamics, Inc.** announced that **Anthem, Inc.**, one of the largest health benefits companies in the United States, has expanded their coverage of treatments for varicose veins to include the VenaCure endovenous laser ablation procedure. Anthem serves more than 11.9 million customers, primarily in Indiana, Kentucky, Ohio, Connecticut, New Hampshire, Maine, Colorado, Nevada, and Virginia. The total number of eligible covered lives for the VenaCure procedure now exceeds 150 million Americans.

"This is part of a trend we expect to see continue," stated Brian Kunst, vice president of Regulatory Affairs and Quality Assurance for AngioDynamics. "An increasing number of insurance companies have been issuing positive coverage policies for endovenous laser

treatment over the past 12 months. This coverage decision, combined with the recent establishment of dedicated procedural codes and reimbursement rates for our endovenous laser procedure, gives us significant momentum toward widespread commercial acceptance of this innovative therapy."

- 11/26 Alison McCook of *Reuters Health* wrote about a new laser therapy that can easily remove acne scars. A few sessions of a new type of laser treatment appears to smooth out acne scarring with a relatively short recovery time, according to the results of a new study.

"Improvement is long-lasting, and (patients) may continue to improve for up to a year following the last treatment," lead author Dr. Paul Friedman of the DermSurgery Laser Center in Houston told Reuters Health. Friedman noted that acne scars are typically the result of damage to the protein collagen of the skin. During the treatment, a series of "nonablative" lasers "work beneath the surface skin layer to stimulate collagen growth," Friedman explained, which helps improve scarring as well as minimize fine lines. "By stimulating collagen production, nonablative lasers also give the skin a healthy glow and smoother texture," he added.

Ablative lasers, in contrast, work by heating and removing the skin. After this treatment, patients typically take longer to recover, and are at risk of pigmentary changes and post-operative redness, Friedman and his team report on the laser therapy in the November issue of the *Archives of Dermatology*.

People are able to go right to work after nonablative laser treatment, he said, making it a "lunchtime procedure." In contrast, people need 7 to 10 days of "downtime" to recover after treatment with ablative lasers, he said. Each nonablative laser treatment costs approximately \$400-\$600 per session, Friedman noted. To test how well nonablative lasers work, Friedman and his colleagues administered multiple sessions of the laser treatment to 11 people with mild-to-moderate acne scars. After three sessions, participants' skin improved by an average of nearly 10 percent. However, one month after the fifth treatment, improvement rates rose to 23 percent. And at six months, the researchers recorded a nearly 40-percent decrease in skin roughness.

Friedman explained that skin likely continues to improve following treatment because the skin collagen continues to remodel. "The use of nonablative laser systems is a good treatment alternative for patients with acne scarring who are unable or unwilling to endure the prolonged postoperative recovery process associated with ablative laser skin resurfacing procedures," Friedman said. He added that some nonablative laser treatments also appear to work by shrinking oil-producing glands in the skin.

#### **MEDICAL/SURGICAL LASER UPDATE -- December 2004**

- 11/30 **OmniGuide Communications Inc.**, a company developing the OmniGuide Fiber, a hollow-core cylindrical photonic bandgap optical fiber, announced the successful completion of the first minimally-invasive procedure in a patient using a prototype

OmniGuide Fiber to deliver CO2 laser energy. The procedure was performed by Dr. Jamie Koufman, the director of the Center for Voice and Swallowing Disorders of Wake Forest University at the Voice Center in Winston-Salem, North Carolina.

The patient, who was diagnosed with recurrent respiratory papillomas (RRP), suffered from near-total obstruction of the larynx (voice box) and trachea (the breathing tube that joins the throat and the lung). The patient's growths in the larynx and trachea were cleared using a CO2 laser delivered endoscopically with an OmniGuide Fiber. The patient was awake during the procedure. Other than spraying a numbing spray in the throat and trachea, the patient required no anesthesia.

CO2 lasers have been used to treat RRP for many years. In the past, these procedures could only be performed in the operating room, with the patient under general anesthesia. The OmniGuide Fiber allows use of the same CO2 laser technology, but in a clinic setting instead of in the operating room. With the OmniGuide Fiber used to deliver the laser energy through a flexible Pentax endoscope, the patient treated by Dr. Koufman was able to go home immediately following the procedure. FDA clearance for the OmniGuide Fiber is expected in early 2005.

Dr. Koufman pioneered work in laryngeal laser surgery, laryngopharyngeal reflux, laryngeal electromyography, laryngioplasmic phonosurgery, and other forms of laryngeal (voice) rehabilitation surgery. Dr. Koufman said, "Unsedated, laryngeal laser surgery with the OmniGuide Fiber and the new Pentax optical scopes is a dream come true for me as an endoscopic surgeon, and the patient who had this surgery loved it because it was easy for her." She added, "OmniGuide has introduced a cutting-edge technology that will push out-patient laryngeal surgery to a new level; and, by moving most of laryngeal surgery out of the operating room and into the clinic, the cost savings per procedure will be measured in the tens of thousands of dollars, and the national cost savings will be huge."

Dr. Steve Sheng, OmniGuide's president and CEO said: "The ability to deliver a CO2 laser beam through a flexible fiber into a patient's body has been the dream of many surgeons for a long time. We are extremely pleased to see that the breakthrough hollow-core OmniGuide Fiber can indeed turn such a dream into reality. This pioneering work has opened the door for more effective treatments for many diseases."

The Center for Voice and Swallowing Disorders at the Wake Forest University Baptist Medical Center, a leader in the field of laryngology and the voice, is nationally and internationally renowned ([www.thevoicecenter.org](http://www.thevoicecenter.org)). To learn more about RRP visit [www.rpf.org](http://www.rpf.org).

Yoel Fink, John Joannopoulos and Edwin Thomas, all faculty members at MIT, and Uri Kolodny, OmniGuide's vice president of Marketing and Business Development, founded OmniGuide in May 2000, in order to commercialize patented research conducted at MIT on omnidirectional reflectors (Temelkuran et al. Nature 420, pp. 650-653 (2002)).

Based in Cambridge MA, where its corporate offices and labs are located, OmniGuide has an exclusive license from MIT on omnidirectional reflectors. The company has raised \$29.5M from Ray Stata, Mukesh Chatter, **Alliance Technology Ventures, 3i US, Westbury Partners, and Gainesborough Investments**. OmniGuide's progress to date has captured broad attention in both scientific and popular venues.

11/29 **Syneron Medical Ltd.**, and its North American subsidiary **Syneron Inc.**, announced that the FDA had notified the company that it will not be able to market the VelaSmooth system in the U.S. with a 510K pre-market notification and asked the company to resubmit the device with a PMA application.

The VelaSmooth, which was cleared for non-invasive treatment of cellulite in Europe under the Medical CE mark and in Canada under Health Canada clearance, is sold outside of the U.S. on the basis of these clinical clearances. Syneron intends to submit to the FDA a request for an IDE for the VelaSmooth in order to enable its clearance by the FDA via the alternative PMA route.

"We will be working expeditiously, thoroughly and cooperatively to provide the FDA all of the information they require. The delay in the clearance of VelaSmooth is disappointing but we believe that it demonstrates the unique clinical potential of the device and will enhance its competitive advantage in the body shaping market place," commented Dr. Amir Waldman, vice president, Clinical and Regulatory Affairs, Syneron Medical Ltd.

Following the announcement, John Calcagnini of **CIBC World Markets** issued an update report on **Syneron: ELOS: Will Need PMA on Vela Smooth Product; Downgrading to Sector Underperformer**

Effective 11/30, we are downgrading Syneron to Sector Underperformer from Sector Outperformer. The stock has crossed our \$35 price target, which we are dropping, and Syneron said last night that the FDA has requested that it re-submit the Vela Smooth application as a PMA.

Vela Smooth, its device for treating cellulite, had been submitted to the FDA as a 510 (K) filing with limited clinical data. The premarket approval requirement has the potential to delay the U.S. approval timing by a year, give or take. The device has already been approved in Europe and Canada.

We must wait and see how much incremental human clinical data will be required by the FDA before getting a keener sense of the PMA submission and approval dates. Vela Smooth remains a promising product; we believe the company's business is likely to continue to post healthy growth.

Growth in the next year is expected to be driven by this quarter's launch of the Comet for large surface area hair removal, the Galaxy 5-mode laser, the Polaris laser, and the

company's Flagship Aurora device that combines RF with intense pulsed light for photofacials and small-area hair removal.

- 12/1 **PhotoMedex, Inc. and ProCyte Corporation** announced that the companies had entered into a definitive merger agreement pursuant to which PhotoMedex will acquire ProCyte in a stock-for-stock transaction valued at approximately \$24.4 million. Under the terms of the agreement, PhotoMedex will issue 0.6622 shares of its common stock in exchange for each outstanding share of ProCyte common stock. PhotoMedex expects to issue approximately 10.5 million shares of common stock. In addition, certain options to purchase ProCyte common stock will be assumed in the transaction. On a pro forma basis, assuming that all ProCyte shareholders exchange their ProCyte shares for PhotoMedex shares, and giving effect to the shares underlying the ProCyte stock options to be assumed by PhotoMedex, ProCyte's stockholders would own approximately 21% of the combined company's common stock on a fully diluted basis. Based on the closing prices of the companies' common stock on November 30, 2004, the offer represents a purchase price of \$1.49 per share and a premium of 33%.

ProCyte develops and markets therapeutic and daily use skin care and procedure-based products to dermatologists. Many of ProCyte's products incorporate the company's patented GHK Copper Peptide technology. ProCyte sells its products directly to physicians through its 25-person sales organization. Physicians use the company's products to improve healing following aesthetic procedures such as laser resurfacing, laser hair removal and microdermabrasion, and for daily use to promote healthy skin and reduce hyperpigmentation, fine lines and wrinkles. ProCyte also reaches the broader consumer markets through license and supply agreements with strategic partners. For the twelve months ended September 30, 2004, ProCyte reported total revenues of \$13.0 million. In addition, ProCyte currently has over \$6 million in cash.

Jeff O'Donnell, president and CEO of PhotoMedex, commented, "PhotoMedex is pleased to expand its presence in the dermatology community by acquiring a company that is highly regarded by our customers and our scientific advisory board. We immediately increase our dermatology sales force five-fold, which will enable us to accelerate the roll out of our XTRAC laser therapy. ProCyte also will provide us with a line of quality skin care products supported by accepted science for our existing customers. This increase in our sales resources is particularly timely to take advantage of an improving reimbursement environment for laser therapy for psoriasis. The combined company will be able to offer significant value to our dermatology customers by providing a proven treatment option for psoriasis and provide effective pre- and post-procedure treatment products that generate recurring revenue and an opportunity to improve practice profitability. Financially, we are extremely pleased that this acquisition will accelerate our profitability and is accretive to our shareholders."

Jack Clifford, ProCyte's president and CEO, stated, "We are very pleased to be joining forces with PhotoMedex and are excited about the additional opportunities that the combination offers our shareholders in terms of revenue growth and improved liquidity.

The companies share a vision for the future and believe that, with our collective product offerings, we are well positioned to further expand our presence in the marketplace. For the past several years, ProCyt's management and board have focused their efforts to maximize stockholder value. We believe this combination best positions ProCyt's stockholders to capitalize on those efforts."

The merger is subject to customary terms and conditions including the approval by the stockholders of ProCyt and PhotoMedex. The directors and officers of ProCyt, who collectively own approximately 3.9% of the outstanding ProCyt common stock, have agreed to vote all of their shares in favor of the proposed transaction. The merger is expected to close in the first quarter of 2005.

In this transaction, **CIBC World Markets** and **Wells Fargo Securities, LLC** acted as the financial advisors to PhotoMedex and ProCyt, respectively.

- 12/1 **Lumenis Ltd.** announced that it had entered into a three-year dual-source agreement with **Novation**, the supply company for **VHA Inc.** and the **University HealthSystem Consortium (UHC)**. The agreement takes effect December 1, 2004, and runs through November 30, 2007. Novation managed more than \$20 billion in annual purchases for VHA and UHC on behalf of their 2,300-plus health care organizations. Novation represents 27% of the staffed beds in the United States, 31% of the nation's hospital admissions, and 29% of total surgeries. Lumenis has manufactured lasers for ophthalmology, urology, ENT, gynecology, and orthopedic procedures for over 35 years. The cutting-edge technology of Lumenis lasers will now be made available to the thousands of facilities served by Novation.

The agreement with Novation will provide Lumenis greater access to member institutions through a variety of marketing and sales opportunities. As a leading medical laser manufacturer, Lumenis offers VHA and UHC members the opportunity to work with the best laser technology available. Lumenis has a history of medical milestones in a variety of product areas. For example, Lumenis holmium lasers were the first to be approved for Benign Prostatic Hyperplasia (BPH), and the Selective Laser Trabeculoplasty (SLT) lasers are the first and only approved light devices for the treatment of open angle glaucoma to reduce intraocular pressure.

"This contract is an example of Novation's efforts to enhance the purchasing options available to members," said Keith Johnson, product manager for Novation. "Lumenis was awarded the contract based on input from the member-based Novation Perioperative Council and an analysis that considered both financial and non-financial criteria, such as product performance, product acceptance and conversion capability."

Lumenis is committed to working together with physicians and health care facilities in providing them the equipment necessary to improve the quality of life of their patients, according to Avner Raz, president and CEO of Lumenis. "By responding to the needs of the medical community through highly focused laser solutions, patient-driven



enhancements, and a tradition of strong customer service, Lumenis continues to help transform the clinical management of many diseases," said Raz. "The agreement awarded Lumenis by Novation is a testament to our focus on providing effective medical solutions."

**About Novation:** Based in Irving, Texas, Novation was established in January 1998 through a combination of the supply programs of VHA and UHC, two national health care alliances. Novation serves the purchasing needs of more than 2,300 members and affiliates of VHA and UHC. Novation managed more than \$20 billion in annual purchases for VHA and UHC members in 2003. For more information, go to [www.novationco.com](http://www.novationco.com).

- 12/2 **Diomed Holdings, Inc.** announced that the FDA had granted 510k clearance for the expanded use of its patented EVLT procedure. Since initial FDA clearance in January of 2002, the company has been marketing EVLT for the treatment of venous reflux in the Great Saphenous Vein (GSV) associated with varicose veins. The new FDA clearance authorizes the use of Diomed's 810nm D15 Plus and D30 Plus laser systems and associated procedure kits for treatment of venous incompetence and reflux of other superficial veins in the lower extremity. Lower extremity venous insufficiency is a common medical condition afflicting 20% to 25% of women and 10% to 15% of men. Although GSV reflux is the most common underlying cause of significant varicose veins, the impact of other "truncal" veins such as the small saphenous vein system (SSV) is also very significant.

According to Robert Min MD, vice chairman of Radiology and Director at Cornell Vascular and one of the developers of the EVLT procedure, "It has been a challenge handling non-GSV sources of reflux without surgery, but advances in duplex ultrasound imaging and the versatility of the EVLT procedure have made safe and effective minimally invasive treatment possible. In our experience, more than 95% of small saphenous veins, accessory saphenous veins and posterior thigh circumflex veins have remained closed after initial EVLT treatment."

According to an independent study published in the November 2000 issue of *Journal of Vascular Surgery*, "Isolated SSV system incompetence can cause the entire range of signs and symptoms of chronic venous disease." Of the 2,254 limbs with chronic venous disease in the study, 10% had SSV incompetence as the primary cause of reflux, with another 5.6% having combined GSV and SSV reflux.

Diomed's president and CEO James Wylie concluded, "Our FDA clearance represents another first for Diomed. Once again, we have reinforced our position as the leader in the field of endovenous laser treatment of varicose veins. We view this as a further growth opportunity and we plan to actively promote use of EVLT treatment in this market segment."

- 12/2 **Candela Corporation** announced that it had received clearance from the FDA to market its Smoothbeam diode laser for the treatment of sebaceous hyperplasia, adding to the previously cleared treatments of facial acne, back acne, acne scars and wrinkles. Sebaceous hyperplasia is a very common skin condition most often seen in middle-aged to older adults. This benign proliferation of the sebaceous gland appears on the skin as small, soft, yellowish papules. Most often, these lesions are located near the nose, cheeks, forehead, and also on the chest.

Suzanne Kilmer, MD, Director of the Laser & Skin Surgery Center of Northern California, stated, "The FDA clearance is great news for Candela. Existing therapies for sebaceous hyperplasia are invasive and the treatment creates social downtime for patients. I have used the Smoothbeam for this application in many patients with great success. Smoothbeam represents an effective solution for sebaceous hyperplasia with little or no downtime for my patients."

Gerard Puorro, Candela's president and CEO, said, "The additional clearance for sebaceous hyperplasia represents an important additional indication for Smoothbeam. Adding clinical indications adds incremental value to a laser from a customer's perspective. This FDA clearance is the fifth FDA clearance for Smoothbeam."

- 12/3 John Calcagnini of **CIBC World Markets** upgraded **Syneron: ELOS: Upgrading to Sector Performer Following Pullback**

We are upgrading ELOS to Sector Performer from Sector Underperformer effective 12/3, as we think that the recent sell-off is overdone and the stock now trades at 19x our 2005 earnings estimate.

ELOS has dropped from ~\$37 since late Nov. after the FDA's decision to require a PMA submission for the VelaSmooth device for the treatment of cellulite. We downgraded ELOS 11/30 from SO. ELOS hopes to meet with the FDA shortly to clarify the steps that will be required to get approval.

ELOS believes that Vela Smooth should be approved under the 510(k) regulatory path and that there are several predicate devices to justify doing so, including existing laser devices, Thermage for RF energy, LPG for the vacuum/massager for cellulite, and dermatology devices for NIR.

The company plans to provide data on 500-1000 additional Vela Smooth patients from 35 of their 71 IRB approved sites that have the device to support a PMA submission. The timeline could get pushed out if FDA requires them to open an IDE and enroll new patients per a new protocol.

- 12/7 **Cell Robotics International Inc.** announced that in cooperation with major shareholders it had developed a capitalization plan to address the first significant stages of market entry for its recently redesigned products and continuation of new product development

efforts. The plan includes a working capital credit facility, the private placement of up to 3.4 million shares of restricted common stock, the private placement of up to 25,000 shares of a newly created class of preferred shares and debt to equity conversion.

The company has executed an agreement with its existing lender, **F.A. Voight & Associates**, to extend the maturity date of its working capital facility from December 2004 to July 2005 and to increase the facility from \$1 million to \$2 million. The new funding from the working capital facility will be provided in increments of \$250,000 approximately every 30 days beginning on December 15, 2004 and ending on March 15, 2005.

As a further vote of confidence in the company, Voight & Associates have also agreed to convert \$1 million of the facility into equity after matching equity has been raised by the company in the private placement. Other lenders have indicated their intent to convert approximately \$500,000 of current debt into equity as part of the funding plan. If and when consummated, these actions could reduce the company's debt by approximately \$1.5 million.

To further strengthen the long tenured relationship between the company and Voight & Associates the company has asked, and Voight has accepted, an appointment to its Board of Directors. Voight will be leading our renewed efforts and will focus on shareholder and investor communications.

The funding plan is intended to simultaneously infuse capital while strengthening the company's balance sheet. If the plan is fully consummated, it will make available \$1 million in working capital included in new funding of up to approximately \$2.5 million from a combination of new common and preferred equity placement and conversion of the facility expansion into equity.

The company intends to apply this capital to marketing and sales initiatives, such as the recently announced entry into the blood bank market, as well as to continue to pursue other activities such as hospitals, prisons and assisted living facilities, which have been inhibited strictly by lack of funding.

The company will also extend the range of application of its laser microscopy products, including the emerging field of nanotechnology. The company's LaserTweezers microscopy system has already proven useful for nanotechnology applications by at least one leading semiconductor manufacturer. Further product improvements and designs for this field, resulting from ongoing discussions with prominent research scientists, are under development.

In addition, the company intends to pursue remaining tasks in the development of its Lasette product for infant heelsticks. These tasks include market validation of current product designs and finalization of regulatory approvals. Significant fundamental FDA approvals for the new product design have already been received.

The company's "Lasette" is a laser lancing device which is the only FDA cleared needle-free instrument available for collection of capillary blood samples by fingerstick procedure. The Lasette now includes design features specifically directed to clinical applications; including screening tests and point-of-care blood analysis. The P200 is now designed for fast and easy collection of capillary samples of up to 200 microliters (previously 75 microliters). Other improvements include doubling the maximum frequency of use, simplifying its operation and maintenance. These and other improvements make the Lasette P200 especially well suited for applications at all clinical environments.

- 12/8 **BriteSmile, Inc.** released an updated revenue guidance for the fourth quarter ending December 25, 2004. As previously announced, revenues for the fourth quarter are expected to decline both on a sequential and year-over-year basis, due to the softness in demand experienced in the first part of the quarter, as well as significant initial shipments of BriteSmile-To-Go in the fourth quarter of last year. Based on quarter to date results, and with three weeks remaining in the quarter, including the Holiday Season, fourth quarter revenue is projected to be in the range of \$9.5 to \$10.1 million compared with \$12.4 million last year.

"This revenue performance reflects factors specific to the 2004 marketing strategy that we have already taken steps to address" said Anthony Pilaro, chairman and Acting CEO. "We have initiated a multi-faceted 2005 marketing platform that addresses issues and opportunities highlighted in a recent marketing report prepared for us by **McKinsey & Company**. We believe that recent successes including our on-line booking and our Smile Forever program, both implemented in November, indicate that we are on the right path to re- establishing revenue momentum. In addition, we plan to introduce a new advertising campaign in the first quarter of next year".

- 12/10 **Syneron Medical Ltd.** issued a statement to clarify the recent news from **Thermage** that they have added more patents to their lawsuit against Syneron. On December 3, 2004, after losing its motion for a preliminary injunction, Thermage amended its complaint in its patent infringement action against Syneron Medical Ltd. and **Syneron Inc.** Thermage had sought a preliminary injunction against the sale of Syneron's Polaris WR device in the United States. The court denied Thermage's preliminary injunction motion, finding that Thermage had failed to establish a likelihood of success on the merits and therefore was not entitled to a preliminary injunction. The court held that Syneron had raised substantial questions regarding the validity of the claim at issue, based on the patent law defenses of lack of written description, lack of enablement and anticipation.

Following this defeat with respect to the patent asserted in its original complaint, Thermage filed its amended complaint, which added five other patents to the case. Each of these patents was issued in 2002 or earlier and could have been asserted in the initial complaint. Thermage had every incentive to include its strongest infringement claims in its original complaint and to bring its preliminary injunction motion based on these claims.

"Syneron regrets that Thermage has chosen to compete in court rather than in the marketplace, and that Thermage has attempted to use the lawsuit to cast aspersions on Syneron's products. Thermage's claim that Syneron's elos technology is damaging their reputation is unfounded and baseless. In fact, on a daily basis more than 2,000 elos-based devices are used worldwide, providing patients with safe and efficacious outcomes. Our technology also continues to be widely accepted by key luminary physicians in North America and the rest of the world," said Domenic Serafino, president of Syneron Inc. Moshe Mizrahy, CEO of Syneron Medical Ltd. added that "Syneron will continue to compete strongly in the marketplace by supplying doctors with its high quality devices and will continue to defend itself vigorously against Thermage's lawsuit."

- 12/13 **BIOLASE Technology, Inc.** announced that it had been granted a new U.S. patent protecting key areas related to its laser pulse technology. U.S. Patent No. 6,821,272, granted by the U.S. Patent and Trademark Office, has broad claims related to the laser pulse technology utilized in the Waterlase and Waterlase MD hard and soft tissue lasers. The patent is a continuation of previously granted U.S. Patent 6,288,499, and has 111 claims, of which seven are independent. Method and apparatus claims cover the use of laser pulse technology, which allows the laser system to effectively interact with the water spray, to produce a fast, clean and precise cutting action. The scope of the patent's claims is very extensive, and not limited to only dental and medical applications.

The patented laser pulse technology is responsible for the physical shape of the laser energy pulses emitted from the laser active medium, which for BIOLASE's product is the Er,Cr:YSGG crystal. The combination of specialized laser pulses, laser wavelength and water spray technology is the critical driving factor behind the company's proprietary Waterlase technology.

"As this advancement in our core technology demonstrates, we remain committed to the development of new innovations that will further strengthen our industry-leading position in the field of laser dentistry," said Jeffrey Jones, CTO. "This patent has method and apparatus claims covering a unique laser pulse circuitry that drives HydroPhotonic technology. Additionally, this patent is part of the company's strategic plan to expand its intellectual property portfolio and protect its market leading Waterlase technology," continued Jones.

This patented technology has been incorporated into the company's new Waterlase MD system, which offers variable pulse rate functionality of 10 - 50 Hz, or pulses emitted per second. Pulse rate variability provides dentists with greater functionality and flexibility to adjust the speed and quality of hard and soft tissue cutting in a broad range of dental procedures.

- 12/13 On November 9, 2004, The People's Hospital of Beijing University performed a combined revascularization procedure utilizing beating heart bypass surgery, along with transmyocardial revascularization and stem cell implantation. This is believed to be the first of such combination procedure. The patient is a 61 year old male suffering from

chest pain related to an acute myocardial infarction. Angiography, as confirmed by SPECT, confirmed severe three vessel disease, with only the left internal mammary artery bypass from a previous surgical procedure still patent and perfusing the left anterior descending artery.

In preparation for the procedure, 5 ml of stem cells were derived from the patient's own bone marrow. Following the beating heart bypass through a left thoracotomy, TMR channeling (utilizing the Holmium: YAG laser system by **CardioGenesis**, Foothill Ranch, California, USA) was completed in all ischemic regions and the infarct zone. This was followed by injection of the stem cells in the same regions of the TMR channeling.

The attending cardiac surgeon, Dr. Wan Feng, Chairman of the Department of Cardiac Surgery at The People's Hospital of Beijing University, stated, "The objective of this procedure is to optimize the long term outcome of the patient. The bypass of the native coronary's will provide immediately improved perfusion to the ischemic areas. The TMR channels combined with autologous stem cells are intended to augment the bypass of the native coronary's with additional revascularization in the treated areas, including the infarct zone."

Dr. Wan has performed over 200 adjunctive TMR procedures to date. His belief that TMR promotes angiogenesis motivated him to apply the laser therapy with stem cells in the infarct area as well as the ischemic areas of the heart. "TMR by itself has been proven to promote angiogenesis in viable, ischemic heart muscle. By combining the laser with stem cells in the infarct zone, we are hopeful to contribute to the optimal outcome for this patient. Ultimately, we hope to see improved function in all areas of his heart, including the infarct area."

This procedure includes the application of several innovative technologies in the treatment of a challenging revascularization. The early outcome was favorable, with the patient in recovery with no arrhythmia. We look forward to further follow up of this innovative new combined treatment of advanced coronary artery disease. This combined procedure represents a first in China, and is worthy of a controlled, comparison study to identify the specific benefit of each of the techniques, and in combination.

- 12/13 The 2004 edition of *Dental Applications of Advanced Lasers (DAAL)* is now available from **JGM Associates, Inc.** *DAAL* describes in detail laser products intended for dental applications, and includes descriptions of product performance, features, and accessories. Laser list price information is also included.

*DAAL* also provides tutorial sections for the non-laser-technical reader, so readers can better appreciate recent advancements in dental laser technology and applications. *DAAL* is recommended reading by the Academy of Laser Dentistry.

*DAAL-2004* sells for \$100, plus shipping. This price includes a searchable PDF version of *DAAL* on CD-ROM (with color photos of commercially available products), and a one-

year subscription to *DAAL Update* on-line newsletter. A table of contents, sample passages, and ordering details are provided at its new web site at [www.jgma-daal.com](http://www.jgma-daal.com).

The **News and Articles** page provides free dental laser-related news and brief articles written by JGM Associates. The **DAAL Info** page provides a detailed table of contents and sample passages from *DAAL-2004*. The web site's **Ordering** page allows visitors to buy *DAAL-2004* on-line and immediately download a searchable PDF version of the publication. The print version, which also includes *DAAL-2004* on CD-ROM, is then mailed to purchasers.

The **DAAL Update** page of the web site is an on-line newsletter that provides new information on dental laser products and applications, and new tutorials, in the interim between updates of the print version. Purchasers of *DAAL-2004* get a one-year subscription to the *DAAL Update* web page, which is password-protected.

12/14 **Lumenis Ltd.** announced that recently presented clinical study results indicate photorejuvenation skin treatments using the IPL Quantum SR system can be enhanced by combining the light treatment with Levulan (aminolevulinic acid HCl) Kerastick. Lumenis also offers IPL in its Lumenis One system.

IPL provides gentle, non-ablative treatments that remove sun-induced freckles, most benign brown pigments, and redness caused by broken capillaries. Lumenis is conducting a series of joint studies with **DUSA Pharmaceuticals, Inc.** to demonstrate the extent to which IPL treatment results can be enhanced by combining them with Levulan.

Avner Raz, president and CEO, said, "At Lumenis we are absolutely committed to providing the best possible technology and treatments for our customers and their patients. IPL-PDT is an exciting technique and takes photorejuvenation to the next level."

Dr. Jeffrey S. Dover (Chestnut Hill, MA), lead investigator on the study, stated, "I've used the IPL Quantum for several years as a standalone treatment to treat photoaging, and my patients have been very pleased with the great results achieved. By combining Levulan and the Quantum, however, the outcomes are even more impressive. Patients in the study have had a very high degree of satisfaction."

**Clinical Study Results:** In results recently presented by Dr. Dover, 20 patients in a prospective, randomized, controlled and split-faced clinical study received a series of treatments for photoaged skin using the IPL Quantum and Levulan. The first three treatments were three weeks apart, in which half of the face was pretreated with Levulan followed in 45 minutes (+/- 15 minutes) by a full- faced IPL treatment. Each patient then received two additional full-faced, IPL-alone treatments three weeks apart, since the standard of care in non- ablative treatments is five treatments with IPL alone.

Before each treatment and four weeks after the final treatment, patients were assessed by a blinded investigator for global photodamage, fine lines, mottled pigmentation, tactile

roughness and sallowness. Combination treatment with Levulan resulted in a statistically significant improvement in global scores for photoaging (80% vs. 50%,  $p>0.02$ ), and mottled pigmentation (95% vs. 65%,  $p>0.02$ ). Combination treatment with Levulan also resulted in a significantly greater reduction of mottled pigmentation and fine lines to low or imperceptible levels ( $p>0.001$  and  $p>0.01$ , respectively). Investigator evaluations and subject satisfaction scores were both significantly better for the combination treatment sides. The investigators found no difference in the side effect profile with or without combination treatment, and noted that both treatments were well tolerated. No patients dropped out of the study.

- 12/14 **Cutera, Inc.** announced the addition of **ConBio China** to its family of distribution partners. ConBio China, based in Shanghai with multiple offices throughout China, is one of the leading sales organizations for medical lasers in China. Conbio China will be responsible for the marketing, sales and technical service of Cutera's full line of aesthetic systems to dermatologists, plastic surgeons, Ob/GYNs and family practitioners throughout China. Commenting on the announcement, Cutera president and CEO Kevin Connors said, "Broadening our distribution network is a key initiative to drive our future growth. ConBio China will allow us to enter this large, emerging market with an advanced level of expertise. Cutera's skin tightening, skin rejuvenation, hair removal and vascular systems will reach the Chinese market at a time of growing consumer demand in cosmetic procedures. Conbio China is a partner that brings experience handling regulatory issues with highly trained technical service, sales and marketing staff located in major cities throughout China to ensure full support for Cutera's customers."

Cutera estimates that the vast China market is one of the fastest growing international markets, with continued strong growth anticipated for many years. The partnership with ConBio China compliments Cutera's direct operation in Japan and Australia as well as a network of distributor relationships in the region. Expansion of our distribution positions the company to increase market share and accelerate its growth in Asia.

- 12/14 Adding to the company's light-based skin therapy product portfolio, **Radiancy, Inc.** recently announced the signing of an exclusive worldwide marketing and distribution agreement with **BioCell, L.P.** of Austin, TX for a unique handheld Erbium YAG laser technology. According to Fabian Tenenbaum, vice president Sales and Marketing for Radiancy, "This innovative technology represents the cutting edge in aesthetic lasers; providing an ultra-fast true laser peel with outstanding results. What's more, there's no anesthesia, and no downtime. In great part, we chose to add this technology to our product portfolio because of its unique combination of therapeutic efficacy and patient satisfaction. We feel confident this new technology will complement the treatments provided by our SkinStation and other Radiancy systems powered by LHE currently in use worldwide."

"It's exciting to be associated with a company like Radiancy," said David Shockley, president of BioCell. "From our vantage point, the new agreement marries the strengths of our patented handheld laser technology with the worldwide marketing and sales



strengths of Radiancy." Added Shockley, "We completely re-engineered the erbium laser into a digital handheld technology that is highly reliable, requires virtually no maintenance, and is more economical than previous lasers."

According to Dr Alan Rosenbach, MD, a private practitioner in Los Angeles, CA, "The handheld laser is used for superficial or moderately deep peels. The superficial peel is a state-of-the-art alternative to glycolic peels or microdermabrasion. Several treatments spaced a few weeks apart will smooth the skin, soften pores and improve discoloration. There is no down time and the side effects are limited to a few days of light peeling.

"The moderately deep peel is inexpensive yet highly effective. This office-based procedure allows for improvement of fine wrinkles, smoother skin, a reduction in the appearance of pores, and improvement in color. There is minimal postoperative discomfort and peeling occurs for 5-6 days after the procedure."

"The hand-held laser represents the next level of skin renewal," stated Dr. Neil Sadick, of Sadick Aesthetic Surgery and Dermatology in New York City. "I have been using the technology for over a year and it appears to provide a greater therapeutic effect with enhanced safety than available alternatives. The system is simple, fast, and effective in the treatment of fine lines and wrinkles, while improving overall skin texture without the downtime associated with a traditional chemical peel."

12/15 **Syneron Medical Ltd.** announced that it had raised its revenue guidance for Q4/2004 from \$16.2M to \$16.7M. This reflects a higher guidance for the full year 2004 of \$58M. Syneron set its guidance for FY2005 at \$75M, a 30% increase over 2004. Syneron said that the recent FDA decision to ask for marketing clearance of the VelaSmooth under a PMA will not adversely affect company revenues in Q4, 2004 or in 2005. The VelaSmooth is already approved and being sold in other markets around the world and Syneron believes that it will receive US market clearance for the VelaSmooth by the middle of next year.

"We are working closely with the FDA to resolve any issue raised by the agency regarding market clearance for the VelaSmooth," noted Moshe Mizrahy, CEO of Syneron. "We are well-structured to absorb any delays in the clearance of the VelaSmooth because Syneron is a multi-platform company, selling in a global marketplace. Our US and worldwide sales of Aurora, Polaris, Galaxy, Pitanga and Comet machines, and of the VelaSmooth outside the US, continue at a strong pace."

"We are very pleased with our ongoing results and anticipated growth," said Dr. Shimon Eckhouse, chairman of the Board. "The already widespread market acceptance of our ELOS technology is steadily growing all over the world, and we are confident that this will continue through the coming years."

John Calcagnini of **CIBC World Markets** issued an update on Syneron following the above announcement: **ELOS: Revising Revenue and EPS Ests. for 4Q04 and CY2005**

We reiterate our SP rating on Syneron following its announcement this morning that it is raising 4Q04 revenue guidance to \$16.7M from \$16.2M and establishing CY05 revenue guidance of \$75M.

Our new 4Q04 revenue and EPS estimates are \$17M and \$0.31, respectively, from \$17.5M and \$0.32. Our new CY05 revenue and EPS ests. are \$75M and \$1.20, respectively, from \$82M and \$1.31. EPS for CY05 is essentially flat due to a full year weighted avg of shares from the IPO.

Syneron now expects to receive FDA approval for Vela by the middle of next year. We previously had taken Vela out of our revenue numbers in the U.S. in CY05 following the company's announcement in November that the FDA required the company to submit a PMA.

If the company gets approval in mid CY05, there is potential for upside to our numbers. Growth in CY05 is expected to be driven by sales of the Comet for hair removal, Galaxy, Polaris and the Aurora for photofacials and small area hair removal.

12/17 **BriteSmile, Inc.** announced today that it had entered into a definitive agreement for the private placement of up to \$16 million in Senior Convertible Notes (the "Notes"). The company has agreed to sell \$12 million of the Notes to seven investors who have the option within 180 days to purchase up to an additional \$4 million under the same terms. The investors include qualified institutional buyers and LCO Investments Limited, the company's largest shareholder. The proceeds from the sale of the Notes will be used to fund the continuation of the company's spa roll-out strategy, expansion of the International Associated Center footprint, the establishment of International spas and for working capital purposes.

The Notes accrue interest at 5% per annum or 6 month LIBOR plus 300bp, whichever is greater (capped at 8%), payable in cash or registered stock. The Notes are convertible into shares of the company's common stock at a per share conversion price of \$7.61, which is 115% of the volume-weighted average price of the common stock during the ten day period immediately prior to signing of the transaction documents. The Notes will be repaid in monthly installments over 36 months beginning in June 2006 in cash or registered stock. The company also issued to the investors five year warrants for 544,253 shares of common stock at an exercise price of \$7.61 per share.

**Merriman Curhan Ford & Co.** acted as the sole placement agent in this transaction. The company will file a registration statement covering the shares purchased in the transaction.

12/17 **CardioGenesis Corporation** announced the launch of the CelleratOR system for the point of care preparation of autologous platelet rich plasma. Chairman and CEO, Michael Quinn, stated, "Our focus is to add new exciting technology to our market basket. We were attracted to the CelleratOR technology because of its potential for contributing to

improved patient outcomes. The benefits of this technology are known and embraced in several surgical specialties, and we are eager to provide the CelleratOR offering to our customers. CelleratOR is our first new product beyond laser myocardial revascularization devices, and we expect it to be a useful addition to patient-centered cardiovascular medicine."

Quinn explained that the company is bringing new tools to help address the advanced cardiovascular disease, and related co-morbidities of patients being referred today to cardiovascular surgery. "Today, patients, and the physicians who care for them, are expecting improved outcomes along with reduced risk following surgery ... despite the more advanced disease conditions with which they present. This mandate requires innovative new tools to help improve patient outcomes."

Quinn added that, "The CardioGenesis CelleratOR system is simple to use, and provides the advantage of scalability over competitive systems. The concentration level can be determined by the physician at the time of preparation. The end result is a concentration of the patient's own platelets from a small blood sample. The system consists of a small centrifuge system, and proprietary disposables to prepare the platelet concentrate from the patient's blood sample. We are excited to bring this technology to our customers."

"We will formally launch our CelleratOR System in January in conjunction with the *Society of Thoracic Surgeons* annual meeting," Quinn explained. "The CelleratOR system is an exciting new technology. While we are committed to growing the TMR business with the innovative new minimally invasive products we have developed with key clinical champions to expand that market, we are also committed to adding additional tools and innovative new products going forward."

The company intends to highlight the CelleratOR technology, along with its minimally invasive TMR tools that are currently in the regulatory process, at an educational symposium in conjunction with the STS meeting in January. This will include physician experience in the cardiac surgical suite using autologous platelet concentrate. Quinn stated, "This technology is just gaining awareness in cardiovascular medicine. We intend to lead the way in developing the application of autologous platelet rich plasma by working closely with our technical and clinical advisors in identifying potential new applications in the cardiovascular arena."

12/20 **BIOLASE Technology, Inc.** announced the acquisition of the intellectual property portfolio of **Diodem LLC**. As a result of the acquisition, Diodem will immediately withdraw its patent infringement claims against the Company. Under the terms of the transaction, BIOLASE will acquire all of the intellectual property portfolio of Diodem LLC, consisting of eight U.S. and international patents of which four were asserted against the Company, for a consideration of \$3.0 million in cash, \$4.5 million in common stock, valued at \$11.06 per share as of the closing price on December 17, 2004, and 81,037 five-year warrants at a strike price of \$11.06 per share. The companies have also entered into other terms and details as related to the Binding Letter of Intent.

"The Diodem transaction is very positive for the long-term strength of the Company. We believe the combination of the Diodem patent portfolio along with the large intellectual property portfolio developed by BIOLASE, offers great synergies both from a product development and licensing vantage point. In short, this transaction protects and solidifies our core technology and clears the way for strategic licensing opportunities for BIOLASE both in the U.S. and internationally," commented Robert Grant, president and CEO.

The transaction will become effective upon the execution of a definitive agreement, which is expected to be completed in early January 2005. Under the terms of the Binding Letter of Intent, the Company will not incur any royalty obligations on past or future sales of BIOLASE products. All other terms and conditions of the transaction are confidential.

12/22 **Spectranetics Corporation** announced the Company's CLiRpath Excimer Laser Catheters were featured in the *"Health Headlines"* segment on **WFXT Fox television** evening news in Boston, Mass. at 5:00 p.m. and 10:00 p.m. on December 9, 2004. The segment featured the treatment of peripheral vascular disease with Spectranetics' CLiRpath excimer laser catheter at Brigham and Women's Hospital by Dr. Andrew Eisenhauer, and included favorable testimonial by a patient approximately one month post-procedure. "Television news health segments such as our recent coverage in Boston are potentially powerful additions to our marketing communication strategy, which is focused on physician training, podiatry outreach, public relations aimed at assisting hospitals in their local markets, and economic outcomes study results," said John Schulte, president and CEO of Spectranetics. "I'm delighted with the clinical outcomes by physicians treating peripheral vascular disease with our CLiRpath excimer laser catheters and the progress of the CLiRpath product launch, which is focused on the 120 hospitals with identified potential users that already have an excimer laser system."

Commenting on his experience with CLiRpath excimer laser catheters, Dr. Eisenhauer said, "The addition of the excimer laser to other innovative techniques in our practice allows us to treat peripheral vascular disease and critical limb ischemia more successfully and has improved patient quality of life and procedure success rates."

Dr. Andrew Eisenhauer is Director of the Interventional Cardiovascular Medicine Service at the Brigham and Women's Hospital and Assistant Professor of Medicine at The Harvard Medical School. He and his colleagues have pioneered a systematic approach to the diagnosis and treatment of vascular disease in a variety of patient situations.

12/26 **Lumenis Ltd.** announced the shipment of its 150th Lumenis One system, a significant milestone for the company. The Lumenis One is a sophisticated platform for aesthetic light and laser treatments designed to meet physician needs. Lumenis began shipping Lumenis One in May 2004 and has provided thousands of IPL systems since it first introduced IPL technology to the market in 1995. Lumenis One represents the fourth generation of IPL technology and reinforces Lumenis' place at the forefront of innovation. Optimizing and building upon a firm foundation, Lumenis One unites three

gold standard technologies on one multi-technology and multi-application platform: Intense Pulsed Light for skin photorejuvenation and treating vascular and pigmented lesions, the LightSheer diode laser for hair removal and the Multi-Spot Nd:YAG for treating leg veins and deeper vascular lesions. The system's key features include Optimal Pulse Technology (OPT), numerous presets, easy custom settings, and an intuitive touch-screen software interface. These enable Lumenis One to provide increased patient comfort, faster treatments and easily tracked patient information.

Avner Raz, president and CEO, said, "Shipping the 150th Lumenis One clearly illustrates our firm commitment to product excellence. As the market leader, Lumenis invests heavily in research and development for all our products -- more than \$10 million in the first nine months of 2004 alone. We design products to satisfy the specific needs of our customers and provide direct benefit to their patients. As a result, customer demand for Lumenis One is strong, as evidenced by the large number of systems sold."

Physicians who have purchased Lumenis One during the last year are quick to praise its benefits citing patient satisfaction, speed and cost effectiveness among the key advantages. Dr. Dore Gilbert of Newport Beach, California said, "When my patients look in the mirror, they are so happy -- they see that the treatments have removed years from their appearance." "Lumenis One's greatest advantage is speed. Doing hair removal, we used to shy away from large areas, like backs, but now that's no problem," said Dr. Jeffrey Hunt of Tampa, Florida.

"The (special feature) Patient Database has saved me significant time and money. It's great to be able to get all treatment parameters, as well as medical records that help the operator go to advanced settings quickly. The Database should be on every system," stated Dr. Corey Maas of San Francisco, California.