Emerging-Trends:
Executive Laser Report
September 2013

Volume VIII No. 9 **laser@emerging-trends.com** **September 30, 2013**

We hope that you are enjoying a cool and crisp autumn. Here's the news for September.

General News and Overview

- **Abbott Labs** was named an "industry group leader" in the 2013 Dow Jones Sustainability Index (DJSI).
- **Alcon** global launched its Centurion vision system, a phacoemulsification (phaco) technology platform designed to provide superior cataract removal capabilities.
- The Intrabeam radiotherapy system from **Zeiss** now offers additional options for cancer treatment – in dermatology, gastroenterology, and palliative cancer treatments.
- **Ellex Medical Lasers** launched its Rapide pattern scanning photocoagulator at the 13th EURETINA Congress in Hamburg September 26-29, 2013. In other news, the company said that its SLT glaucoma lasers now qualify for inclusion on its US GSA contract, and, effective October 1, 2013, Ellex's SLT lasers can be sold to US government medical facilities in the US and around the world.
- The FDA told **Guided Therapeutics** that the PMA for its LuViva advanced cervical scan is not approvable in its current form and asked for more information.
- **Lumenis** introduced the AcuPulse Duo CO_2 laser at the American Academy of Otolaryngology – Head and Neck Surgery 2013 annual meeting. In other news, the FDA gave 510(k) clearance to ResurFX, a new fractional non-ablative laser module. The company also launched its new MicroLase fiber and otology kits.
- TauTona Group sold its surgical marker technology to **Novadaq**.
- **Sciton** launched its new hair removal treatment, Forever Bare BBL, designed for a broad range of light to dark skin types.
- **Syneron**'s VelaShape III received FDA clearance and a CE Mark. In other news, the company launched new applicators, with expanded spot sizes for two of its platforms, and ***Allure*** magazine named **Syneron**'s elure Advanced Lightening lotion in its "Best of Beauty Awards."
- **Topcon Medical Systems** began a trade-in program for retinal laser users. The program will allow users of single-spot lasers to trade them in for a new Pascal Synthesis or Streamline green or yellow pattern scanning laser.

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FINANCIAL NEWS

(Note: on September 27, 2013, €1 = US $1.35041, £1 = US $1.60534, A$1 = US $0.93673)

- **AngioDynamics** amended its existing credit facilities and successfully refinanced its long-term debt.
- **Biolase** has a commitment from Camber Capital Management to buy an aggregate of $5 million of its common stock.
- **El.En. SpA**'s half-year financial report showed revenue in line with the first six months of 2012.
- **Ellex** completed a placement to institutional and sophisticated investors, raising gross proceeds of ~A$3.3 million.
- The Securities and Exchange Commission (SEC) charged **Imaging Diagnostic Systems** and two top executives with making material misstatements and omissions in public filings about the timing of its FDA application and its failure to remit payroll taxes to the IRS.

Stock Watch

Company	Symbol	9/27/2013	8/28/2013	% Change
Dow Jones	DJI	15,258.24	14,824.51	2.93%
Abbott Medical Optics	ABT	33.14	33.75	-1.81%
AngioDynamics	ANGO	13.15	10.97	19.87%
Biolase	BIOL	2.01	1.77	13.56%
Biolitec	BIPX.F	21.692	15.106	43.60%
Carl Zeiss Meditec	AFX.DE	21.67	22.48	-3.58%
Coherent	COHR	61.32	55.76	9.97%
Cutera	CUTR	8.97	9.37	-4.27%
Cynosure	CYNO	22.76	23.59	-3.52%
El.En. SpA	ELN.MI	16.15	16.70	-3.29%
Ellex	ELX.AX	0.31	0.33	-6.06%
Guided Therapeutics	GTHP	0.639	0.685	-6.72%
Imaging Diagnostics	IMDS	0.0001	0.0001	0
IPG Photonics	IPGP	57.33	54.86	4.50%
Iridex	IRIX	6.08	6.11	-0.49%
LCA-Vision	LCAV	3.70	3.74	-1.07%
MedX Health	MDX.V	0.06	0.06	9.09%
Novadaq	NDQ.TO	17.05	14.94	14.12%
Novartis	NVS	77.08	73.45	4.94%
PhotoMedex	PHMD	16.07	16.15	-0.50%
Quantel	QUA.PA	1.56	1.48	5.41%
Refocus	RFCS	0.041	0.040	2.50%
Solta Medical	SLTM	2.12	2.14	-0.93%
Spectranetics	SPNC	16.61	16.07	3.36%
Synergetics USA	SURG	4.39	4.11	6.81%
Syneron Medical	ELOS	8.61	8.35	3.11%
TearLab	TEAR	10.77	12.57	-14.32%
Trimedyne	TMED	0.16	0.16	-1.88%
Vascular Solutions	VASC	16.48	16.06	2.62%

FUTURE CONFERENCE CALLS AND CONFERENCES

October 1, 2013

Synergetics USA will release 4Q13 results and hold a conference call at 5 pm EDT. Dial 800-588-4973, code 35678823. For callers outside the US, the number is 847-230-5643. The call will also be at **www.synergeticsusa.com**. A replay will be available for 30 days.

October 10, 2013

AngioDynamics will release its 1Q14 financial results for the period ended August 30, 2013, after the close of the US markets. The company will hold a conference call at 4:40 pm EDT; dial 877-941-8609. The live and archived webcast will be at **http://investors.angiodynamics.com/events.cfm**.

October 16, 2013

Abbott will release 3Q13 financial results before the market opens, followed by a live webcast of the earnings conference call at 9 am EDT, which will be at **www.abbottinvestor.com**. It will be archived.

October 22, 2013

AngioDynamics' annual meeting of shareholders will be held in New York.

November 18, 2013

Novadaq will hold an investor and analyst meeting at 10 am in New York. Advanced registration is required. The live webcast will be at **www.novadaq.com/investors/events**.

May still be available

Iridex presented at the Craig-Hallum 4th Annual Alpha Select Conference on September 26 in New York. The replay audio webcast of the presentation is at **www.iridex.com**.

Novadaq president/CEO Arun Menawat, PhD, presented a corporate overview at the Stifel Healthcare Conference 2013 on September 12 in Boston. The replay webcast is at **www.novadaq.com**.

Vascular Solutions presented at the 2013 Stifel Nicolaus Healthcare Conference on September 11 in Boston. A replay of CFO James Hennen's presentation is at **www.vasc.com**.

PEOPLE IN THE NEWS

Joseph Caruso resigned as both president and a member of the board of directors of **Cynosure**. **Michael Davin** is the new president.

Spectranetics CEO **Scott Drake** is now a director of medical device company AtriCure.

INDIVIDUAL COMPANY NEWS

ABBOTT MEDICAL OPTICS (ABT)

September 25, 2013
Abbott will release 3Q13 financial results on October 16 before the market opens, followed by a live webcast of the earnings conference call at 9 am EDT, which will be at **www.abbottinvestor.com**. It will be archived.

September 12, 2013
Abbott declared a quarterly common dividend of $0.14 per share, marking the 359th consecutive quarterly dividend paid by Abbott since 1924. The cash dividend is payable November 15 to shareholders of record as of October 15. Abbott has increased its dividend payout for 41 consecutive years.

September 12, 2013
Abbott Labs was named an "industry group leader" in the 2013 Dow Jones Sustainability Index (DJSI), one of the most prestigious benchmarks for worldwide corporate sustainability. As the leader in the healthcare equipment and services industry group, Abbott was one of 24 companies selected for leading their respective industries. The DJSI leaders are chosen from among the 3,000 largest companies worldwide, including 800 companies in emerging markets. This is the ninth consecutive year in which Abbott was included on both the Dow Jones sustainability world index and North America index.

Abbott also was the leader in its specific DJSI industry sector – healthcare equipment and supplies. The company's overall score of 82 was significantly higher than the average score of 39 for other companies in the sector. The company had the highest scores across all three main areas of evaluation, including economic, environmental, and social performance. Within the three areas, Abbott had a ranking of 100% in multiple categories, including innovation management, supply chain management, stakeholder engagement, customer relationship management, environmental reporting, human capital development, talent attraction and retention, labor practices and human rights, social reporting, strategy to improve access to drugs or products, corporate citizenship and philanthropy, and health outcome contribution.

Chairman/CEO Miles White said, "Our company was founded to improve lives; we've stayed true to that purpose for 125 years, as a business, as a scientific innovator, and as a citizen of the communities of which we are a part. At Abbott, we are acutely conscious of the world's growing healthcare needs and the opportunities they present. We are equally attuned to the responsibilities that such opportunities confer. Helping to meet them, as we serve all of the people who depend upon our company, is at the heart of our mission for our next 125 years."

ALCON (ACL)

September 5, 2013
Alcon global launched its Centurion vision system, a phacoemulsification (phaco) technology platform designed to provide superior cataract removal capabilities. Alcon said that the device is the only intelligent phaco technology that optimizes every moment of the cataract surgical procedure. It automatically and continuously adapts to changing conditions within the eye, provides greater anterior chamber stability during each step of the surgery, and has enhanced fluidic management and surgical precision. More than 40 surgeons from around the world have tested the system for more than 2,000 cataract surgeries.

The system includes:

- Active fluidics technology, an automated system that optimizes anterior chamber stability by allowing surgeons to pro-actively set and maintain target intraocular pressure (IOP) within the eye during the cataract removal procedure, providing enhanced IOP control during the procedure in comparison to gravity fluidics and fixed pressure irrigation. It reduces surges due to occlusion breaks, increases IOP efficiency at lower, more natural settings, and eliminates the need to manually adjust fluid pressure.
- Balanced energy technology improves phacoemulsification efficiency through proven OZil intelligent phaco and the Intrepid balanced tip probe. Efficiency and control is improved while reducing energy levels, and the fragmented lens material is kept at the shearing plane for emulsification.
- Applied Integration, a design that enables the system to be seamlessly integrated with multiple cataract surgical technologies, like Alcon's LuxOR surgical microscopes with Q-Vue 3-D assistant and the LenSx Laser to create a comprehensive cataract surgery suite designed to minimize variability at every step of the procedure.
- The Centurion vision system also offers an improved ergonomic design, wireless footswitch, and intuitive touch-screen display.

Alcon global head of cataract franchise Stephen Speares said, "As the world leader in eye care, Alcon is on the frontlines of delivering new innovations to help improve cataract care. By combining multiple proprietary technologies and unique innovations as part of the Centurion vision system, we are offering surgeons the next-generation phaco platform that will enable them to optimize every step of the cataract surgery, and ultimately, help deliver exceptional patient outcomes."

The system will be available in 2013 in those countries where the new phacoemulsification system has received the necessary regulatory approvals. Alcon will continue its global rollout throughout 2014. Live surgery demonstrations will take place during the upcoming European Society of Cataract and Refractive Surgeons (ESCRS) and AAO (American Academy of Ophthalmology) Congresses.

ALMA LASERS, LTD.

September 23, 2013
Alma Lasers unveiled "speed technology" for new and existing Soprano hair removal systems. The new technology performs more treatment sessions in less time, allowing quick treatment of large target areas. The Soprano is Alma's flagship hair removal laser system, the first to offer virtually painless hair removal for people of all skin colors as well as tanned skin.

September 12, 2013
Alma Lasers is hitting the road this fall with its "Practice for Success" seminars. This series of seminars will focus on marketing strategies proven to grow aesthetic practices as well as hands-on demonstration of Soprano ICE, ClearLift, and vShape. The seminars will happen during the fall in Chicago, Toronto, Dallas, San Diego, Palo Alto, New York, and Miami.

ANGIODYNAMICS (ANGO)

September 24, 2013
AngioDynamics amended its existing credit facilities and successfully refinanced its long-term debt. The new debt facility will reduce the company's interest rate on its credit facility by up to 75 basis points and improve its cash flow while extending the maturity of the debt. The company has a loan agreement with JPMorgan Chase, the lead bank in the transaction, along with co-arrangers Bank of America and Key Bank. The facility includes two components, a $100 million term loan and a $100 million revolving line of credit. The company will retire all existing loans with the new debt facilities.

September 23, 2013
AngioDynamics modified its licensing agreement with Interface Biologics for AngioDynamics' Endexo technology for peripherally inserted central catheters (PICCs), ports, and dialysis catheters, to include Central Venous Catheters (CVCs). Endexo technology is a permanent, non-eluting integral polymer that imparts devices with a passive character demonstrated to have such benefits as reduced platelet and reduced thrombus accumulation on medical devices based on *in vitro* testing. In contrast to thrombus-resistant coatings or impregnated alternatives, which may be superficial and/or transient, Endexo is incorporated directly into the base polymer to create a material that provides long-term utility and durability without impacting the base underlying mechanical properties of the medical device. The Endexo technology also has significant manufacturing advantages over noted thrombus-resistant alternatives as it can be incorporated directly into existing manufacturing processes.

AngioDynamics' BioFlo PICCs with Endexo technology received FDA clearance in September 2012, and it is also approved in Europe and Canada. In August, the company's BioFlo Port with Endexo technology also received FDA clearance.

September 19, 2013
AngioDynamics will release its 1Q14 financial results for the period ended August 30 on October 10 after the close of the US markets. The company will hold a conference call at 4:40 pm EDT – dial 877-941-8609. The live and archived webcast will be at **http://investors.angiodynamics.com/events.cfm**.

September 18, 2013
AngioDynamics' distribution partner Medcomp has Health Canada approval for the Celerity tip location system. The company plans to start distribution in Canada in October 2013 and will showcase the technology at the Association for Vascular Access (AVA) annual scientific meeting September 20-23, 2013, in Nashville, TN.

The Celerity tip location system is an ECG-based peripherally inserted central catheter (PICC) tip confirmation technology indicated for use as an alternative to chest x-ray and fluoroscopy for PICC tip placement in adult patients. The system has been approved for commercial sale by Health Canada and is currently under regulatory review in the US and in Europe. In January, AngioDynamics entered into a non-exclusive, global distribution agreement with Medcomp for the system.

September 13, 2013
AngioDynamics hosted the inaugural St. Jude Gala on August 29 at the Saratoga National Golf Club and raised $183,763 for St. Jude Children's Research Hospital. The gala supported the pioneering research and exceptional care offered to children through treatment advances cures, as well as the means of prevention for catastrophic pediatric diseases.

September 11, 2013
AngioDynamics' annual meeting of shareholders will be held on October 22 in New York.

BIOLASE, INC. (BIOL)

September 24, 2013
Biolase received a commitment from Camber Capital Management to buy an aggregate of $5 million of its common stock. Camber subscribed for an aggregate of 2,688,172 shares of Biolase's common stock at $1.86 per share, a price equal to the closing price on September 23, 2013. The closing of the offering is expected to take place on September 27. A shelf registration statement was filed with and declared effective by the SEC.

September 10, 2013
Effective September 6, 2013, Biolase amended the terms of its two revolving credit facility agreements with Comerica Bank. Biolase's credit agreements with Comerica provide for borrowings against certain domestic accounts receivable and

inventory and certain export related accounts receivable and inventory. Amendment No. 3 to the loan and security agreement reverted the available maximum borrowings under the domestic revolver to $4 million from $6 million (in addition to up to another $4 million on the Ex-Im revolver). The interest rates on the outstanding principal balance of the credit facilities will continue to bear interest at annual percentage rates equal to the daily prime rate plus 2.00% for the domestic revolver and 1.50% for the Ex-Im revolver. Amendment No. 3 also revised certain financial covenants for the quarters ending September 30, 2013, and December 31, 2013. The maturity date for the credit agreements remains May 1, 2014.

Chairman/CEO Federico Pignatelli said, "We have completed the process of amending our credit agreements with Comerica Bank. Biolase is now entering what has traditionally been its strongest revenue period of the year, September through December, and finalizing the Amendment No. 3 provides us with the flexibility to continue our growth while on the way to generating cash and profitability. Comerica has been a good lending partner. We appreciate their continued support of our long-term strategic business objectives and look forward to building further on our relationship."

In connection with Amendment No. 3, the company also issued warrants to Comerica to purchase up to 100,000 shares of the company's common stock at an exercise price of $2.00 per share. The 2013 Comerica warrants vest in four equal quarterly tranches beginning on December 31, 2013, and will expire if unused on September 6, 2018. The company incurred a fee of $8,000 to process the amendment.

September 5, 2013
President/CEO Alexander Arrow, MD, will present at two upcoming investor conferences:

- Rodman & Renshaw 15th Annual Global Investment Conference on September 10 in New York,
- Stifel Nicolaus 2013 Healthcare Conference on September 11 in Boston.

August 29, 2013
Two more law firms, the Rosen Firm and Brower Piven, filed class action suits against Biolase. The company acknowledged the suits in an SEC filing, and said it is determined to vigorously defend against the claims.

CARL ZEISS MEDITEC AG (AFX.DE [Xetra], CZMWF [NYSE])

September 24, 2013
As a radiation oncology platform, the Intrabeam radiotherapy system from Zeiss now offers additional options for cancer treatment. It can now also be used in dermatology, gastroenterology, and palliative cancer treatments.

Over the past 14 years, Zeiss Intrabeam has been used globally for more than 8,000 patients, predominantly for breast cancer. With more than 200 installed systems, Zeiss is the market and innovation leader in intraoperative radiotherapy for breast cancer. The world's largest study on partial breast irradiation, TARGIT-A, was conducted exclusively with Intrabeam. The study included 3,451 patients in 33 international centers, half of whom received external beam radiotherapy (EBRT) and half targeted intraoperative radiotherapy (TARGIT). The study compared the Zeiss Intrabeam to traditional whole breast irradiation in women 45 years and over with invasive ductal carcinoma. The TARGIT-A trial demonstrated that for a select group of patients, targeted intraoperative radiotherapy with Zeiss Intrabeam spherical applicators at the time of lumpectomy was non-inferior to traditional EBRT. With Intrabeam radiotherapy, either the tumor itself, or the tumor margins, after removal of the tumor, are locally irradiated with a low energy 50 kV x-ray.

Carl Zeiss Meditec president/CEO Ludwin Monz, PhD, said, "While our focus has been on intraoperative radiotherapy for breast cancer, we now also offer patented radiation technology for patients with skin or gastrointestinal tumors, or with metastases in the spine area. Patients who are potential candidates for this type of treatment receive radiation targeted directly to the diseased tissue with the dose and duration of the treatment adapted to the specific needs of each patient."

With Intrabeam, unlike traditional radiotherapy, a low-energy x-ray source is brought into direct contact with the tumor or tumor margin. This means that the affected tissue is irradiated with a high degree of precision, reducing irradiation to healthy tissues and organs. Due to the low x-ray energy, Intrabeam does not require any complex radiation shielding measures and is even suitable for mobile use.

For non-melanoma skin cancers, a new radiotherapy treatment option with the Intrabeam surface applicator is now available for patients, particularly those with high surgical risk or those requiring treatment on cosmetically relevant areas where

surgery is not desired. Together with the new Intrabeam flat applicator and the needle applicator, the benefits of treatment – precise radiation dose targeted directly to the diseased area – can now be utilized for other types of cancer such as spinal cancers.

CYNOSURE (CYNO)

September 6, 2013
Joseph Caruso resigned from the board of directors and as president of Cynosure. Michael Davin is the new president.

September 4, 2013
TheStreet downgraded Cynosure from Buy to Hold.

EL.EN. SPA (ELN.MI)

August 29, 2013
El.En. released its half-year financial report:

- Revenue in line with the first six months of 2012.
- Net income affected by one-time extraordinary charges in the affiliate Cynosure.
- Improvement in 2Q13 aligning trend with yearly guidance.

The main consolidated financial results as of June 30 included:

- Consolidated revenue: €73.8 million (€74.8 million as of June 30, 2012).
- EBITDA: €5.9 million (€6.3 million last year).
- EBIT: €3.7 million (€3.8 million as of last year).
- Net Income for the Group: €1.3 million (€1.6 million last year).
- Net financial position up to €19.2 million from €17.8 million as of December 31, 2012.
- €3.9 million of dividend paid out in the six months.

During the first six months of 2013, the group registered consolidated revenue of €73.8 million, just below the €74.8 million of the first semester of 2012, and net income of €1.3 million also slightly decreased from €1.6 million as of June 2012, affected by the results of the associate Cynosure. The Group booked a €0.6 million loss as share of Cynosure's period loss; that would have been ~€0.8 million profit without the significant one-time costs related to Cynosure's acquisition of Palomar.

The company said the trend in the second quarter showed a marked improvement over the first, with turnover and operating results trending correctly to meet the annual targets, and El.En. was "fairly satisfied with the six-months financial results, though they're not an improvement on 2012."

The circumstances which might have affected turnover and operating profit:

- The devaluation of the Japanese currency, which hit sales and margins in one of the most important markets for the group in the medical field.
- The transition phase of certain functions of production or distribution (China, Brazil, and the US) with lower revenues and certain transition costs.
- The crisis in Italy and in Europe, with the stagnation of the markets exacerbated by the widespread difficulty of customers in raising funds for investments.

For the first semester 2013, the financial results of Cynosure are not fully consolidated in the El.En. consolidated financial report, which continues to include Cynosure in terms of connection due to the 2.1 million shares, representing 9.41%, held by El.En. The Cynosure share price as of August 28, 2013, was $23.59.

For a uniform comparison with 2013, 2012 financial results are shown, excluding Cynosure from the consolidation area. The results of Cynosure are shown under "Net income from discontinued operations."

Gross margin was €36.3 million, up 3.1% vs. €35.2 million in the same period of the previous year, due to improved profitability of sales. The profitability improved in the medical field, in spite of the unfavorable exchange rates, and remains unchanged in the industrial sector. EBITDA was €5.9 million, down from €6.3 million as of June 30, 2012. It was affected by the increase in cost of services and operating expenses and personnel, structured for a level of expected turnover higher than achieved. The costs for depreciation and amortization dropped 10.9% vs. June 30, 2012, maintaining an unchanged 3% impact on sales. EBIT was positive for €3.7 million, essentially unchanged compared to €3.8 million as of June 30, 2012. EBIT margin on sales was 5.1%, which is also unchanged on 2012. The net income of associated companies included the share of the result of Cynosure which, as described above, contributed decisively (€0.6 million) to the negative balance of the entry. Pre-tax income showed a €3.4 million profit, slightly decreasing from €3.6 million as of June 30, 2012.

The first half of 2013 closed with a net profit for the Group of ~€1.3 million vs. €1.6 million as of June 30, 2012. Without the negative impact of the non-recurring transaction of the affiliated Cynosure, net profit would have marked a clear improvement on the previous year. The net financial position of the Group at June 30 remained strong, positive for €19.2 million, up from the €17.8 million on December 31, 2012. In the second quarter El.En. reduced the delay on the roadmap for the achievement of the 2013 sales and operating result guidance: revenue growth of 5% (10% if supported by an improved general economic situation) and improved operating results. Despite the unfavorable conditions in some of the markets and the gap accumulated in the six-month delay, the Group still considers the objectives set for 2013 within its reach.

ELLEX MEDICAL LASERS LTD. (ELX.AX)

September 26, 2013

Ellex Medical Lasers said that its portfolio of SLT glaucoma lasers is now qualified for inclusion on its US GSA contract, and, effective October 1, Ellex's SLT lasers can be sold to US government medical facilities in the US and around the world. Based on the qualification, the Tango SLT/YAG laser and Solo SLT laser will be added to the company's current US GSA contract, which includes its range of cataract and retinal lasers, as well as its diagnostic ultrasound system.

According to CEO Tom Spurling, the company's updated GSA contract status offers a significant competitive advantage. He said, "The GSA contract inclusion demonstrates to a potential US government buyer that, along with our other products, Ellex is a responsible vendor of SLT lasers. We are now one of only two medical device manufacturers which can sell their SLT lasers to US government medical facilities. We are also the first manufacturer to be granted this status for SLT since the July 8, 2013, expiration of the SLT patent, which previously precluded our entry into the US market."

The milestone follows the launch of the company's proprietary SLT technology into the US market in July 2013. Non-invasive and non-thermal, SLT is an advanced laser therapy for glaucoma.

September 25, 2013

Ellex Medical Lasers launched its Rapide Pattern Scanning Photocoagulator at the 13th EURETINA Congress in Hamburg September 26-29. Following the recent CE Mark and FDA clearance for the company's proprietary 2RT (Retinal Rejuvenation Therapy) for the treatment of diabetic eye disease (diabetic macular edema, DME), the Rapide Pattern Scanning Photocoagulator is a continuation of Ellex's efforts in the fight against diabetic eye disease. More than 60 million people suffer from diabetes in Europe, with prevalnce expected to increase. With the burgeoning diabetes epidemic, pattern scanning has become an indispensable tool for the retinal surgeon.

Rapide was developed specifically for the application of pattern scanning laser technology. Ellex said that, unlike other systems, which were adapted from conventional single-shot photocoagulation and provide limited precision, visibility, and patient accessibility due to the use of external adapters, Rapide delivers more reliable and faster system performance.

The company claimed that its device is the fastest pattern scanning photocoagulator, featuring the latest generation of pattern scanning laser technology and equipped with two high-precision, high-speed galvanometers scanning at 4 KHz. The device can deliver 2,000 laser shots during PRP treatment in less than 7 minutes, including the time required to prepare the patient.

September 19, 2013
Ellex completed a placement to institutional and sophisticated investors, raising gross proceeds of approximately A$3.3 million. The placement of ~12.7 million ordinary shares was completed at an issue price of A$0.26 per share, a 13.3% discount to the closing price of the company's shares on the ASX on September 16. CEO Tom Spurling said, "We are delighted with the strong support in the placement from new and existing institutional investors. We look forward to applying these funds to support a range of initiatives related to our proprietary 2RT laser in the treatment of early age-related macular degeneration (AMD). In particular, the funds will enable Ellex to accelerate recruitment for the 300 patient early AMD clinical trials via new sites in the US, Europe, and Australia. The placement will also assist pursuing growth initiatives and debt reduction." The placement raised A$3.3 million and was made within the company's 15% placement capacity and does not require shareholder approval.

September 4, 2013
Ellex announced several key milestones in the company's clinical trial program for its proprietary Retinal Rejuvenation Therapy (2RT) in the treatment of early age-related macular degeneration (AMD). There are no approved treatments for the early form of AMD, a considerable market opportunity for Ellex.
Ellex said that recruitment for the "Laser Intervention in Early Age-Related Macular Degeneration" (LEAD) trial recently surpassed 50 patients at two clinical sites at the Centre for Eye Research Australia (CERA) in Melbourne and at Marsden Eye Clinic in Sydney. Two more sites have been established at Eye Surgery Associates (associate professor Wilson Heriot) in Melbourne and at Lions Eye Institute in Perth. Patient recruitment has begun at Eye Surgery Associates and will soon start at Lions Eye Institute.

The recent FDA 510(k) approval for 2RT in the treatment of diabetic eye disease has cleared the pathway to extend the 2RT clinical trial program to the US. The establishment of additional clinical sites over the coming months is expected to further accelerate patient recruitment efforts.

The LEAD trial is a multicenter, double-blind, randomized clinical trial. About 300 patients with bilateral, high-risk, early AMD (AREDS simplified severity score of 2-4) over 50 years of age will be recruited. Patients in the treatment group will undergo the 2RT procedure in one eye, with treatment to be repeated at six-monthly intervals, as required under the protocol design. Patients in the control group will undergo a sham procedure.

- The primary endpoint of the LEAD trial is progression to advanced AMD in the treated eye, as assessed by ocular examination, color fundus photography, Ocular Coherence Tomography (OCT), and fluorescein angiography at 36 months post initial intervention.
- The secondary endpoint is progression to advanced AMD in the non-treated eye. The LEAD trial was launched in November 2012, to validate the clinical efficacy of 2RT in the treatment of the early stages of AMD and is led by professor Dr. Robyn Guymer, head of Macular Research at CERA.

GUIDED THERAPEUTICS, INC. (GTHB)

September 9, 2013
The FDA sent Guided Therapeutics additional questions about the premarket approval (PMA) application for the LuViva advanced cervical scan. The FDA told the company that the PMA was not yet approvable in its current form and that the company needs to address these questions. The new questions, received in a letter dated September 6, pertain to the cleaning and disinfection of the LuViva device, the optics of the system, and a new analysis on specific subsets of the patient population.

The company said that it can successfully answer the cleaning and optical questions. While the company plans to work with the FDA, it said that it is also focused on its international launch of LuViva, with a meeting later this week with the Ministry of Health in Mexico in conjunction with its current distribution partner, the placement of devices with the Ministry of Health in Turkey, and in servicing of devices in Canada, Africa, and Europe.

President/CEO Mark Faupel, PhD, said, "While we are disappointed with the FDA's latest response, we feel we have made progress by responding to more than 100 questions during the review process. We continue to believe that the US will be a viable market for the product and that we will ultimately receive home country approval. At the same time, we also believe that the international market provides tremendous opportunity for growth. We have received regulatory approval to sell LuViva in Europe with the Edition 3 CE Mark, and marketing approvals from Health Canada and Singapore Health Sciences

Authority and are in the process of filing for approval in Mexico. Additionally, we continue to aggressively expand our markets in the Middle East, Asia, Africa, and Latin America."

IMAGING DIAGNOSTIC SYSTEMS, INC. (IMDS)

September 18, 2013
The Securities and Exchange Commission charged Imaging Diagnostic Systems and two top executives for making material misstatements and omissions in public filings about the timing of its FDA application and its failure to remit payroll taxes to the IRS.

According to the SEC's complaint filed in US District Court for the Southern District of Florida, Imaging Diagnostic Systems repeatedly disclosed in filings and letters to shareholders that it expected to file by specific deadlines a premarket approval application with the FDA to obtain permission to market and sell the CTLM. The company failed to meet its projected deadlines. CEO Linda Grable and CFO Allan Schwartz knew there was no basis for the projections because Imaging Diagnostic Systems did not have enough cancer cases to finish its clinical trials and could not pay for the clinical sites.

The SEC further charged that beginning in early 2010, Imaging Diagnostic Systems stopped remitting payroll taxes to the IRS for its employees. The company's failure to pay payroll taxes constituted an event that should have been disclosed in the Management's Discussion and Analysis sections of the company's periodic filings, which were signed by Grable and Schwartz, but did not disclose it for 16 months. The SEC also charges that Grable and Schwartz failed to file beneficial ownership reports in 2009, 2010, and 2011 despite having received stock or options.

IRIDEX (IRIX)

September 25, 2013
A number of upcoming international conferences and workshops will feature the company's MicroPulse laser therapy for the treatment of diabetes and glaucoma related disorders. The European Society of Retina Specialists (EURETINA) conference in Hamburg, Germany, will feature an official instructional course on the use of Iridex's MicroPulse for retinal disorders such as those caused by complications of diabetes. EURETINA is Europe's largest society of retina specialists. MicroPulse is a vision-preserving laser treatment that does not produce the retinal tissue damage that is often associated with traditional laser therapies. There also will be a company-sponsored satellite training meeting at the upcoming European Society of Cataract and Refractive Surgeons (ESCRS) conference. ESCRS is Europe's leading organization for cataract and refractive surgeons.

The physician-led training will focus on clinical application of Iridex's MicroPulse technology as a single-versatile solution to address the needs of comprehensive ophthalmologists in both glaucoma and retina.

President/CEO Will Moore said, "Independent, physician-sponsored inclusion within these influential conferences further validates our MicroPulse laser therapy, which we believe is well positioned for the current global trend toward value-based healthcare. The durable clinical effect combined with the substantial economic benefits for healthcare systems support the global market opportunity available for our technology. With more than 1,400 global views of Iridex's most recent webinar, we are seeing strong interest from physicians in MicroPulse laser therapy as a durable and economically appealing medical solution for both the glaucoma and retina markets. Recent data regarding MicroPulse laser's effectiveness for patients suffering with glaucoma should prove to be a catalyst for ophthalmologists looking for a versatile solution for their retina, glaucoma, and comprehensive practices."

September 17, 2013
Iridex will present at the Craig-Hallum 4th Annual Alpha Select Conference on September 26 in New York. The live and replay audio webcast of the presentation will be at **www.iridex.com**.

LUMENIS LTD.

September 24, 2013
Lumenis launched its new MicroLase fiber and otology kits, designed to expand use of the AcuPulse 40WG and AcuPulse DUO CO_2 laser systems for ear surgery, and further improve return on investment for hospitals and clinics. Based on physician input, the MicroLase otology kits include two single-use handpieces to give physicians easy access to all parts of the ear. The new smaller handpieces, with a 400µm shaft tapering down to a 250µm spot size, greatly improve visibility as well as reach to the middle ear anatomy.

The MicroLase otology kit significantly reduces the cost per procedure since its multi-use fiber can be used up to 25 times, and it offers disposable tips. The MicroLase fiber is embedded with Lumenis' AcuPulse 40WG and AcuPulse Duo technologies, which deliver unmatched energy transmittance, critical for the low energy levels required in middle ear surgeries. The design of the Lumenis fiber is efficient in transmission of the laser energy, getting as close as possible to parity between the energy displayed on screen and the energy actually delivered to the patient.

Elad Benjamin, vice president/general manager of Lumenis' surgical business unit, said, "The CO_2 laser wavelength is ideal for the delicate anatomy of the middle ear, so we are very pleased to expand our precision capabilities to otology. The ergonomic design of the otology handpieces provides unprecedented visibility and versatility to ENT surgeons. The reusable fibers with disposable tips help busy ENT practices save on sterilization time and cost per procedure."

September 22, 2013
Lumenis introduced the AcuPulse Duo CO_2 laser at the American Academy of Otolaryngology – Head and Neck Surgery 2013 Annual Meeting. It is the only integrated CO_2 laser system that allows surgeons to switch between fiber and free beam modalities electronically. The laser provides a broad range of clinical solutions for ear, nose, and throat; gynecology; otology; and general surgery. It has three power modes, three timed-exposure modes, and a SurgiTouch scanner that gives surgeons the freedom to customize beam delivery and control tissue effect for optimal balance between surgical precision and micro-vascular hemostasis. The AcuPulse Duo CO_2 fiber allows surgeons to cut and ablate around corners and reach tight spaces. The free beam digital AcuBlade scanning micromanipulator enables virtually char-free margins for excellent tissue sample, analysis, preservation of healthy surrounding tissue and superior visibility when surgery requires the highest level of CO_2 laser precision. AcuPulse Duo is backed by a full suite of free beam laser accessories.

September 16, 2013
The FDA gave 510(k) FDA clearance to ResurFX, a new fractional non-ablative laser module. It is the latest application module for Lumenis' M22 platform, expanding its capabilities to perform fractional non-ablative skin resurfacing, one of the fastest growing minimally-invasive procedures in recent years. The module uses a 1565 nm fiber laser and a unique CoolScan scanner, which, unlike other non-ablative fractional technologies, enables a homogeneous and uniform pattern of coagulation columns, and requires only one pass. The feature saves time and helps protect the patient's skin. The scanner allows the user to choose from more than 600 combinations of shape, size, and density for optimal treatment and results. CoolScan uses a proprietary algorithm that places each fractional spot in a controlled, non-sequential manner allowing the tissue to relax between pulses and providing protection from overheating. The platform uses three technologies in one system: Intense Pulsed Light (IPL) with optimal pulse technology, multi-spot Nd:YAG, and the ResurFX for a complete aesthetic workstation.

NOVADAQ TECHNOLOGIES, INC. (NDQ.TO)

September 18, 2013
Novadaq will hold an investor and analyst meeting at 10 am on November 18 in New York. Advanced registration is required. The live webcast will be at **www.novadaq.com/investors/events**.

September 5, 2013
TauTona Group sold its surgical marker technology to Novadaq. The technology is designed to work with select imaging procedures, such as those done with Novadaq's Spy fluorescence imaging system, which is used in reconstructive surgical procedures, and Luna, which is used to assess perfusion in patients with non-healing wounds. The combination of the two technologies will allow surgeons to better capture and review image sequences of blood flow in vessels and micro-vessels during the course of performing a wide variety of surgical procedures.

August 29, 2013
President/CEO Arun Menawat, PhD, will present a corporate overview at the Stifel Healthcare Conference 2013 on September 12 in Boston. The replay webcast will be at **www.novadaq.com**.

PHOTOMEDEX (PHMD)

September 23, 2013
President/CEO Dennis McGrath will present at the 2013 Aegis Capital Healthcare Conference on September 27 in Las Vegas, NV. No plans for a webcast were announced.

September 13, 2013
Gabelli initiated coverage with a Buy rating.

SCITON, INC.

September 4, 2013
Sciton launched its new hair removal treatment, Forever Bare BBL, designed for a broad range of light to dark skin types. While other hair removal treatments apply energy to a given spot all at once, Forever Bare BBL treats with continuous movement and multiple lower fluence pulses at a high repetition rate. Forever Bare BBL uses Sciton's broadband light (BBL) technology. BBL offers a comprehensive range of aesthetic procedures and non-invasive treatments. Its flexible Finesse Adapters enable treatment of hard to reach areas, producing long-lasting results on uniformly treated skin.

SOLTA MEDICAL, INC. (SLTM)

September 3, 2013
Solta Medical hired CTPartners Executive Search to look for a permanent president/CEO.

SPECTRANETICS CORPORATION (SPNC)

September 16, 2013
Paladina Health and Spectranetics are collaborating to offer an innovative medical home option for Spectranetics teammates and dependents in two Colorado Springs locations. One Paladina Health clinic will be on-site at the Spectranetics corporate headquarters; another clinic will be conveniently located for use by Spectranetics employees and their families throughout the Colorado Springs community.

The Paladina Health model components:

- 24/7 access to a personal physician, who is available via mobile phone and is held accountable for each patient's satisfaction, engagement, and health.
- Convenient clinics that provide same-day or next-day appointments.
- A broad range of medical services, including primary and preventive care, personalized chronic condition support, and basic urgent care; and assistance to patients in navigating specialty and hospital-based care.

September 3, 2013
CEO Scott Drake is now a director of medical device company AtriCure.

SYNERGETICS USA, INC. (SURG)

September 16, 2013
Synergetics USA will release 4Q13 results and hold a conference call at 5 pm EDT on October 1. Dial 800-588-4973, code 35678823. For callers outside the US, the number is 847-230-5643. The call will also be at **www.synergeticsusa.com**. A replay will be available for 30 days.

SYNERON MEDICAL (ELOS)

September 17, 2013
Allure magazine named Syneron's elure Advanced Lightening lotion in its Best of Beauty Awards, to be published in the October 2013 issue. elure Advanced Lightening lotion was named in the Best of Beauty: Skin Care category as one of the best anti-agers for skin discoloration. The magazine noted that the lotion contains a mushroom-derived enzyme which it said "diminishes discoloration in four weeks without irritating hydroquinone."

September 11, 2013
The FDA gave clearance to the VelaShape III, and it also received a CE Mark. The non-invasive body shaping platform is effective for temporary reduction in circumference of the abdomen and is also used in a wide range of other body shaping applications such as cellulite treatments.

September 3, 2013
Syneron Medical launched new applicators with expanded spot sizes for two of its best-selling platforms, Gentle Pro Laser Hair Removal and elōs Plus systems. For the Syneron Candela Gentle Pro laser hair removal series, there is a new, proprietary Large Spot Delivery System (LSDS) handpiece featuring 20 mm, 22 mm, and 24 mm spot sizes. The new handpiece pioneers the first and only 24 mm treatment spot with the Dynamic Cooling Device (DCD) cryogen-cooling component that protects the skin's surface for maximum patient comfort.

The delivery system is designed to increase efficiency for both the practitioner and consumer, reducing treatment time by 30% while providing safe, comfortable, and effective hair removal for all skin types. Ideal for larger areas like the legs and back, the LSDS enables trained practitioners to treat a full back in as little as 20 minutes, significantly increasing the patient flow and revenues potential for the doctor.

TEARLAB CORPORATION (TEAR, TLB.TO)

September 19, 2013
TearLab CEO Elias Vamvakas will present at the 4th Annual Craig-Hallum Alpha Select Conference on September 26 in New York. The presentation will not be webcast.

TOPCON MEDICAL LASER SYSTEMS

September 9, 2013
Topcon Medical Systems began a trade-in program for retinal laser users. The program will allow users of single-spot lasers to trade them in for a new Pascal Synthesis or Streamline green or yellow pattern scanning laser. The program, launched in conjunction with the introduction of the Pascal Synthesis, allows current retinal laser users to trade up to a new compact system unit at a new compact price.

The new Pascal Synthesis is Topcon's premiere dual-port pattern scanning retinal laser, available in both 532 nm and 577 nm wavelengths. The compact, portable design of the device allows it to be integrated with Topcon SL-D7 and Haag-Streit style slit lamps, with pricing similar to a premium single-spot laser system. Synthesis will allow fast and effective treatment of retinal disorders using Pascal technology, while offering physicians the option of keeping their current slit lamp set-up. The Pascal or "Pattern Scanning Laser" method applies an innovative pattern scanning technology which allows the practitioner the use of a short duration pulse laser combined with a selection of delivery patterns that are automatically placed on the treatment area in less than a second, minimizing tissue damage and patient discomfort.

Marketing vice president Bob Gibson said, "The retinal laser trade-in program combined with the introduction of the Pascal Synthesis and the reduced pricing of the Pascal Streamline, now places these instruments within the reach of all retina specialists and ophthalmologists practicing medical retina, contributing to the better, safer, and faster treatment of patients with retinal conditions requiring laser procedures."

VASCULAR SOLUTIONS (VASC)

September 16, 2013
Vascular Solutions said that more than 30,000 ClosureFast catheters have been successfully reprocessed by its partner Northeast Scientific since Vascular Solutions launched the reprocessing service for the popular vein ablation catheters in January 2012.

Vascular Solutions also announced the availability of its new VSI 0.025" guidewire for use during ClosureFast procedures. A 0.025" guidewire is commonly used during radiofrequency vein ablation procedures to facilitate placement of the ClosureFast catheter into desired treatment locations.

August 28, 2013
Vascular Solutions will present at the 2013 Stifel Nicolaus Healthcare Conference on September 11 in Boston. The replay of CFO James Hennen's presentation is at **www.vasc.com**.

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