MEDICAL LASER REPORT
MONTHLY UPDATE ON BUSINESS AND TECHNOLOGY ®

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STOCK REPORT

	Nov. 1	Dec. 2
American Medical	0.12	0.21
BioLase	4.68	5.79
Biolitec	4.22EUR	2.78EUR
BriteSmile	0.65	0.65
Candela	5.87	6.29
Cardiogenesis	0.84	0.81
Carl Zeiss-Meditec	9.40EUR	9.60EUR
Cell Robotics	0.65	0.50
Diomed	0.45	0.52
Dusa Pharm	1.55	1.78
Iridex	3.30	3.10
Laserex (ellex medical)	0.86AU	0.445AU
Laserscope	3.70	4.45
LaserSight	0.24	0.25
Lumenis	2.98	2.30
MediScience	0.045	0.06
Miravant	0.45	0.56
Palomar	1.44	1.38
Paradigm Medical	0.19	0.18
Photogen	0.64	1.66
Photomedex	1.40	1.70
PLC	0.69	0.61
Sight Resource	0.10	0.17
SLT	1.43	1.80
Spectranetics	1.85	2.47
SpectraScience	0.09	0.16
SpectRx	2.30	1.77
SurgiLight	0.15	0.15
Trimedyne	0.15	0.18
VISX	8.36	8.78
Wavelight	6.65EUR	6.25EUR

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Eye-laser firms push customization at AAO

All of the refractive laser companies—Alcon, Bausch & Lomb, Carl Zeiss Meditec, LaserSight, Nidek, Schwind, VISX, and WaveLight—were at this year's American Academy of Ophthalmology (AAO) meeting, held in October in Orlando, FL (see *MLR*, November 2002). Several introduced new or upgraded lasers at the meeting, including a concept for the future from WaveLight.

MARKET UPDATE

WaveLight. This company, which is in the final stages of preparing its FDA submission for treating myopia with and without astigmatism for its Allegretto laser, unveiled what it called a "concept" for the future. Some of the features of the new laser included a 500-Hz repetition rate, which would cut the ablation rate down to 2 s per diopter, and bring a –3 diopter myopic correction treatment time down to 6 s, and a –6 diopter correction to 12 s (about one-fourth of the time for its current 200-Hz Allegretto). The system would have a matching 500-Hz tracker with a delay time of as little as 2–3 ms. In addition, the wavefront diagnostic would have built-in intraoperative adaptic optics that would allow the screening of appropriate corrections prior to them being performed. The laser system would also have built-in optical pachymetry to measure 1–µm changes in the corneal surface while the ablation is being performed. Of course, as the company emphatically stated, these improvements are, for now, only conceptional in nature, but might become a reality some time in the future.

VISX. The Star S4 laser, which was introduced at the meeting, is fully customized ablation ready, with upgraded algorithms and the capability of producing the PreVue lenses that allow patients to "see" what custom solutions to their vision might be like before deciding to go ahead with the actual procedure. The S4 system combines the laser and the WaveScan diagnostic and will be ready for sale to customers as soon as custom ablation approval is forthcoming, anticipated sometime during the first half of 2003.

As for future improvements in the VISX platform, Liz Davilla, CEO, in her presentation at the "Catch the Wave" symposium, talked about some of the changes she anticipated for her company. The company is working on cyclotorsion eye tracking, which uses iris pattern information for automatic axial registration of

Continued on next page

Argon laser offers alternative tissue-bonding method

Researchers from the Wellman Laboratories of Photomedicine (Cambridge, MA) report that using a 514-nm argon-ion laser to attach a skin graft appears to make it adhere better than traditional methods such as stitches, staples, and tissue glues. Robert Redmond and his colleagues say that their approach, dubbed photochemical tissue bonding (PTB), could find many uses in plastic surgery, burn therapy, and ulcer management.

To test this approach, Redmond's team performed an *ex-vivo* study on pig skin. The researchers doped the skin graft with a light-sensitive dye (rose Bengal) before performing the procedure. Delivering the laser light through a fiber, the researchers found that 0.56 W/cm^2 was enough to join the skin graft in 15 minutes without causing peripheral thermal damage to surrounding tissue. However, when they increased the laser energy to 1.68 W/cm^2 to speed up the procedure, thermal damage occurred in the cell.

The team is now working to balance the irradiance and treatment time while investigating ways to cool the skin. They reported their findings in the November 1, 2002 issue of *Journal of Surgical Research*.

VISX Terminates Medjet Deal

VISX (Santa Clara, CA) has terminated its merger and research and development agreements with Medjet. In accordance with the provisions of the merger agreement, VISX will incur a termination charge of $250,000 in the fourth quarter of 2002. According to Liz Davila, chairman, president, and CEO of VISX, "As we moved through the planning process for 2003 and beyond, we carefully evaluated our internal and external research and development projects. We have chosen to focus on a number of areas that we believe align our resources efficiently and maximize our investment in research and development."

Spectranetics Denies Allegations

The Spectranetics Corporation (Colorado Springs, CO) received a notice from the Special Receiver for Interlase claiming Spectranetics is in breach of a patent license agreement entered into in 1993. Interlase, which was placed into receivership as a result of state court proceedings in Virginia that related to a dispute between the inventors of the U.S. patents licensed to Spectranetics, claims that it is owed approximately $1.1 million for royalties related to certain products used in connection with the removal of pacemaker and defibrillator leads, certain services the company provides to its customers, and future royalties on these products and services.

Spectranetics strongly denies any breach of the license agreement. Emile Geisenheimer, chairman of the board and acting president and CEO, said, "We are surprised that a claim of this nature has been raised. Moreover, with more than four years having past since the first lead removal product was introduced to our customers, we are further puzzled by its timing. Nevertheless, we have initiated communications with Interlase and will vigorously defend our position on this matter."

the diagnostic and treatment data, which should be available within a year; multifocal ablation patterns for correcting presbyopia are in clinical trials, both in the United States and internationally; adaptic optics built-in to the WaveScan device for prescreening custom corrections before they are done—and avoiding the need for the PreVue lens—is under development; and the combination of wavefront and topography, as well as the use of ray tracing in combination with wavefront, are both in development.

Carl Zeiss Meditec. Meditec introduced its new upgraded refractive laser system, the MEL 80. As shown in the accompanying table comparing the major refractive laser systems, the new MEL 80 is a small spot fast pulsing scanning laser system, with a matching fast response automated pupil capture active eye tracker. The laser is mounted on wheels and can be easily moved from room to room or out of the way in the surgery, with a rapid, easy, re-set time. The MEL 80 replaces the MEL 70 G-Scan. The laser employs an algorithm to produce aspheric/prolate corneas (remembering that prolate is better than oblate), to help reduce any induced higher-order aberrations, especially spherical aberration. It is used with the WASCA wavefront aberrometer (based on the WaveFront Sciences COAS system) and showed excellent results in a LASIK nomogram validation study performed by a cadre of three European ophthalmologists in Belgium, Poland and the Czech Republic.

The surgeons treated 174 eyes, with one surgeon, F. Goes, showing that higher-order aberrations up to 4th order did not increase significantly with the laser. The cumulative results showed that 84% of the eyes achieved 20/20 or better and 7% were 20/15 after 1 month. Ninety-three percent were within ±0.5 diopters in accuracy of predicted outcome. The laser system links to both the WASCA and TOSCA workstations, for producing wavefront and/or topographic diagnostics, or to the new CRS Master, which combines the outputs of both topography and wavefront in a single device. The latter, still undergoing proof of concept, is expected to be released for sale sometime in 2003.

Nidek. Even though this company is under legal attack in the United States, having just lost a jury trial over patent infringement to Summit Technology, now owned by Alcon, and about to go to battle over patents with VISX next spring, the company unveiled its latest concept for customized ablation, the NAVEX system. NAVEX consists of the new EC-5000CX II NAVScan laser system, the NAVFocus eye tracker, the NAVWave OPD-Scan that combines wavefront analysis with corneal topography to map aberrations of the entire optical system, and the NAVTome MK-2000 microkeratome. The EC-5000CX II, which was officially introduced at this meeting, includes an improved, faster sampling and response four-beam infrared eye-tracker with automatic pupil registration of the undilated eye and a new cyclotorsion error correction algorithm, along with the multispot ablation system (MultiPoint), announced at last year's AAO meeting.

> Katana is a new German company that has developed a diode-pumped Ti:sapphire solidstate laser operating at 210 nm.

A final word about Nidek's legal problems: During the AAO meeting, a Nidek representative provided me with a copy of an appeal filed with the court asking the judge to overturn the jury verdict that awarded Summit/Alcon $14.8 million in damages, in the Summit vs. Nidek trial. After reading the appeal, in which Nidek's attorneys claimed that Summit's expert infringement technical witness, Dr. Michael Feld of MIT, admitted that Nidek's laser did not infringe key claims of either the Summit Azema or Marshall patents during cross examination, Nidek may have a strong case for overturning the verdict. The judge's ruling is expected by year's end. It should be made clear that the outcome of the trial effects only the company, and not its customers or equipment users.

New Lasers

In addition to the above systems, two new solid-state refractive lasers were introduced at the AAO meeting; the CustomVis Pulzar solidstate Custom Laser Corneal Reshaping System and the LaserSoft diode-pumped solidstate laser from Katana Technologies GmbH.

CustomVis. The new CustomVis Custom

Laser Corneal Reshaping System is composed of the Pulzar small spot (0.6 mm), fast pulse (300–400 Khz) CrystalScan solid-state spot scanning, 213-nm (quintupled Nd:YAG) solid-state laser, combined with an analog-based ZTRAK 5-Khz gaze tracker, that locks onto the limbus and monitors both eye movement and gaze direction with a closed-loop 1-Khz response time. The diagnostic system utilizes an Orbscan topography device for measuring surface abnormalities, and will, in the future, possibly use the Tracey VFA (visual function analyzer) wavefront diagnostic for higher-order aberrations, along with a LASEK surgery approach to minimize flap aberrations. By proper registration of the wavefront and topography data, along with minimizing the problems of centration and cyclorotation and intraoperative eye and gaze tracking, along with utilizing LASEK to avoid flap problems, the company hopes to minimize all potential problems and deliver superior results.

Katana Technologies. Katana is a new German company that has developed a diode-pumped Ti:sapphire solidstate laser, operating at 210 nm. The LaserSoft system has a tiny 0.2- to 0.3-mm near Gaussian spot that pulses at about 1 KHz with a fluence of 120 to 200 mJ/cm^2, and is delivered under computer-controlled scanning. The active eye tracker is continuous with a latency of 1 ms. The solidstate laser platform, based on exclusive patented technologies, allows the future introduction of a dual system, wherein two lasers could be combined in one unit, combining the UV refractive wavelength with an IR laser microkeratome. The latter is now under investigation. As far as we were able to determine, the company has no plans to enter the U.S. market at this time.

—IJA

Editor's Note: *Part II of this article will appear in the January 2003 issue of* MLR *and will cover diagnostics, photocoagulators, and femtosecond lasers.*

Scanner eliminates overlap effects on tissue

A simple dial-up procedure that accommodates variations in human treatment topography may provide uniform beam scanning without overlap for lasers performing a variety of medical procedures, according to Todd Lizotte, vice president of research and development at NanoVia (Londonderry, NH).

"Laser-based medical procedures for surgical, dental, and aesthetic applications to precisely remove layers of skin or to laser scalpel targeted tissue are only as good as the technology utilized," Lizotte said.

NanoVia, which develops optical systems and laser process technologies for microelectronics, semiconductor, telecom, and commercial markets, is hoping to use optical advances developed in the semiconductor industry to upgrade the capabilities and the quality of laser-based medical procedures for applications where uneven beam intensities and overlapping scanning zones create undesired and uncomfortable results, such as redness and blotching of skin that can delay healing, according to Lizotte.

NanoVia has announced the patent-pending ScanLinx selective beam shaper and scanner technology for medical-laser surface-treatment procedures. The ScanLinx design can be integrated with user-selectable beam pattern shapes and scanning sequences appropriate for different treatment topography and areas. Clinicians can choose from as many as six beam pattern shapes within a dial indexer. The handheld device will use specialized optics to accommodate for the "nooks and crannies" of the body and optimize the shape of the laser beam to avoid scanning the same surface multiple times, as clinicians currently do in many laser applications, according to Lizotte.

Computer-generated holographic optics etched into the surface of the device shape the

ICN To Divest Photonics Business

ICN Pharmaceuticals (Costa Mesa, CA) has implemented a new strategic focus for the company that includes restructuring several of its business units to refocus the company on its core specialty pharmaceuticals business. As part of this plan, ICN will divest noncore business groups, including its photonics skin-tightening business. ICN currently markets two nonablative lasers, the NLite System and the Cool Touch system, both designed to treat facial wrinkles.

Infrared Laser Influences Neurons

Researchers from the University of Texas (Austin) and the University of Leipzig have shown that using a low-power beam from a Ti:sapphire laser can stimulate and alter nerve-cell growth. Their work suggests that optical techniques may one day be able to perform *in-vivo* repair of the nervous system.

Cells from the leading edge of mouse and rat neurons were placed on a glass slide and illuminated with 800-nm light guided by a confocal scanning microscope. The beam power varied between 20 and 120 mW; the spot size was 2–16 µm. The cell was illuminated by approximately one quarter to one-half of the beam, with the remainder positioned ahead of the cell's leading edge. In 35 out of 44 experiments, the scientists found that this enhanced neuron growth toward the focus of the beam. In 17 out of 20 tests, steering the beam caused the growing neuron to make guided turns.

While they are not sure exactly what the underlying mechanisms are, the researchers believe it involves some kind of interaction between the laser energy and proteins in the cell cytoplasm.

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beam and compensate for power and energy variations. The optical techniques being developed allow for a homogeneous beam profile at the surface, providing far better control of pulse-to-pulse beam fluctuations and mode variations that might occur in the fiber of the fiberoptic device as it bends during the procedures. The company uses several optical technologies within its systems, including traditional refractive optics with specific diffractive/holographic optics to take the beam output of a fiber or articulated arm beam-delivery system and provide beam shaping to create a uniform beam profile and deliver that beam to the target surface.

Dental and surgical applications

The potential application of NanoVia beam shaping and scanning controllers and methodologies might provide enhanced results for applications involving superficial laser treatments involving the skin. The ability to deliver a uniform beam to the surface to be treated could provide more precise exposure and minimize beam overlap issues that could cause adverse effects such as lengthening the healing time for patients. NanoVia has patents pending on the use of holographic/diffractive optics for beam scanning and shaping in dental and surgical applications, as well as for aesthetic surface treatments.

"Beam shaping offers many advantages by allowing the doctor to use a dial to choose a specific beam shape to use at specific junctures of a procedure," Lizotte explained. "The clinician can select a larger or smaller spot size or specific geometric shape to illuminate facial zones and other specific features being treated, making certain to not upset areas where treatment is not necessary. The beam shaping elements can provide other shapes that are procedure-specific, such as for microsurgery, tooth whitening, periodontal procedures, gingivoplasty, and gum recontouring."

Many current laser procedures require the doctors to change a variety of handpieces and fibers, which provide broad spots only defined by the how far the doctor holds the end of the fiber from the patient, Lizotte added. NanoVia anticipates providing greater flexibility for clinicians by offering user selectable shapes and even offering the doctor a programmable procedure sequence. These enhancements would enable the doctor to predetermine the patient's procedure, program the specific shapes that will be used, and have them indexed by means of a thumb/finger button on the handpiece.

NanoVia has produced optics for a variety of infrared, visible, and ultraviolet laser wavelengths. Specific designs have been tested and adapted for pulsed CO_2, Er:YAG, Nd:YAG, and diode lasers used in dental applications. Fast Fourier Transform optics based on diffraction can be designed for specific wavelengths of light for a variety of medical procedures, Lizotte concluded. Custom designs are possible to provide tailored assemblies that fit specific requirements.

—IS

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