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71st Annual ADA Scientific Sessions

ADA sessions take place in updated regulatory climate

By MARK McCARTY
***Medical Device Daily* Washington Editor**

SAN DIEGO -The 71st annual scientific sessions held by the **American Diabetes Association** (ADA; Alexandria, Virginia) commenced last Friday here in a somewhat different regulatory backdrop than last year thanks to FDA's release of a guidance dealing with a basic type of closed-loop artificial pancreas system. The meeting also followed in short order, however, an appearance on Capitol Hill by adolescent diabetics urging Congress to prod FDAintoallowing more investigational closed-loop devices to move forward into clinical trials.

Industry is also needling FDA on the pace of reviews of investigational device applications, taking the attitude that the slow pace of decisions is the result of a dysfunctional

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FDA sees no need for second sensor in low-glucose devices

By MARK McCARTY
***Medical Device Daily* Washington Editor**

SAN DIEGO - One of the advantages of medical society meetings is that regulator and regulated alike are motivated to conduct a little public outreach. Thus it was that *Medical Device Daily was* able to interview both a representative of FDA and of industry during the 71st annual scientific sessions sponsored by the **American Diabetes Association** (ADA; Alexandria, Virginia) on a long-awaited guidance for a low-glucose suspend (LGS) device, a guidance spanning nearly 60 pages and encompassing a wide array of issues.

The language of the guidance atone point hints that FDA sees the use of a single glucose monitor as offering too little reassurance that such a system will correctly interpret and

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Report from Europe

Sectra to sell mammo modality operations to Philips for €57.5M

A *Medical Device Daily* Staff Report

Sectra (Linkoping, Sweden) and **Royal Philips Electronics** (Amsterdam, the Netherlands) have signed an agreement under which Philips will acquire Sectra's mammography modality operations. The cash purchase consideration amounts to €57.5 million ($82.04 million) on cash and debt-free basis. The agreement also includes an additional possible earn-out €12.5 million ($17.83 million) in accordance with specially agreed terms and conditions.

Through this deal, Sectra's Medical Systems business area gains a distinct approach towards medical imaging IT.

"This is an excellent transaction for all parties. Sectra will free up resources and funds that can be used to develop and expand our operations in medical imaging IT, in

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Hamilton Thorne aims Lykos at clinical, fertility markets

By OMAR FORD
***Medical Device Daily* Staff Writer**

"Wow" and "cool" aren't words that would typically be used to describe a medical device, but those are the terms that are bandied around by clinicians and med-tech companies when they hear about **Hamilton Thome's** (Beverly, Massachusetts) newly-developed Lykos Laser System application.

Hamilton Thome's CEO Meg Spencer told *Medical Device Daily,* that one of the key factors in the excitement surrounding the application, which is aimed at the clinical and fertility markets, is its accuracy and ability to save time and money for clinicians.

"We're not interested in [Lykos] being just a tool, we want to really solve problems in a way that gives greater

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Lykos

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accuracy and saves money and time," Spencer said.

The company is touting Lykos as a significant advance in integrated laser optics, providing additional functionality, improved optics, increased resolution and compatibility with all major microscope models. The device has a design that is engineered to have the laser and RED-i target locator built directly inside the objective. The laser also features enhanced UV transmission/fluorescence, which are compatible with many fluorescing stains. The device also offers additional benefits for cutting-edge clinical processes such as trophectoderm biopsy, blastomere biopsy, pre-implantation genetic diagnosis (PCD), and laser-assisted hatching.

"[Lykos] has aligned inside it, both the laser and the objective and a device we call the RED-I, which allows you to essentially visualize an invisible beam," Spencer said. "It doesn't make the beam visible but it makes the point where it will hit visible. Because all this is aligned and built literally inside an objective [customers] don't lose 45 minutes every morning aligning everything. Most lasers, if you bump the scope -you've got to realign everything."

The company plans to unveil the system during the 27th annual meeting of the **European Society of Human Reproduction and Embryology** (Belgium) taking place in Stockholm, Sweden, July 3-6.

Spencer said that there has been tremendous interest in the device already.

"We've had interest from some of very famous names to mount [Lykos] inside their high content imaging devices," she said. "We expect to see that sooner rather than later. We're in conversations with three of the biggest players in the high content imaging world."

Spencer said that the laser would add a significant dimension to these already existing imaging platforms.

"These devices give you these wonderful images and you've got all this information about cells, but you can't do anything with them. But when you mount [our laser] in there, you have a robotic micro surgeon at your fingertips," Spencer said.

Lykos builds off the success of the Zilos-TK, which is used for laser assisted hatching and embryo biopsy for pre-implantation genetic testing. But Lykos differs a bit because it has a greater safety benefit.

Formed in 2002, Hamilton Thorne is a venture-backed company, and employs an engineering, research, production and professional staff of thirty. In May 2008, the company spun off its molecular diagnostics unit to Thorne Diagnostics.

The firm was formed to meet key needs and problems in cell research. It said that its devices are the first lasers ever mounted directly inside a microscope objective;an innovation which gives the products real advantages in speed, accuracy, ease of use and safety forthe cells. Each member of the laser family serves a different research application.

Since inception the company has raised roughly $22 million and was listed on the Toronto TSXv Exchange in October 2009.

Spencer told *MDD* that the company could possibly go on another funding drive this year to raise money for additional products that it is launching.

Most recently the company reported the advancement of the collaboration with **ISee3D** (Toronto) to market their unique single camera, single lens, single chip 3-D microscope technology currently under development.

The technology partnership was formed to develop a single lens 3-D microscope adapter that will result in the support of 3-D display by research grade microscopes currently only capable of 2-D. Under this agreement, Hamilton Thorne has exclusive rights to sell the ISee3D three-dimensional technology with its lasers within certain cell research and regenerative medical research markets. The product will support both inverted and upright configurations, and is expected to be released in the fall of 2011.

Spencer said that to date it doesn't seem as if there are hardly any limits to the markets the company can enter into.

"Ourcustomer's researchers keep finding new and related markets for us - like elemental biology or gene expression," she told *MDD.* So we're sort of dipping a toe into various markets and seeing what makes the biggest splashes." ■

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