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NEWCO ON THE GO

Sequent gets FDA nod to include next generation device in IDE trial

By Omar Ford, Staff Writer

Sequent Medical (Aliso Viejo, California) said that the FDA has approved the inclusion of the SL ("Single Layer") family of WEB Aneurysm Embolization Device devices for use in its U.S. Investigational Device Exemption clinical study called WEB-IT. The firm originally gained FDA approval to go ahead with the trial in August of last year.

The WEB-IT study is a prospective, multi-center, single-arm study evaluating the WEB in 150 patients with ruptured or unruptured wide neck intracranial bifurcation aneurysms. The study will be conducted at 25 investigational sites, including

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ISRAEL IN THE NEWS

Israeli imaging companies often must reach maturity to find a proper suitor

Jonathan Goldstein, Israel Editor

Innovation in different fields of medical technology inspires different types of investors and entrepreneurs. From a technical perspective, the Israeli entrepreneur has shown significant prowess in fields of advanced software, hardware, mechanical and electrical engineering. These skills may derive from advanced military research – compulsory military service offers many a technical background and experience; from expertise derived in the former Soviet Union – approximately one million immigrants since 1985 transferred immense skillsets in algorithms, software and materials to Israel; or from Israel's

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SPOTLIGHT ON ASIA

Export tax rebate to boost China's high-end exports

By Kristine Yang, Staff Writer

HONG KONG — A recent adjustment in China's export tax rebate scheme is likely to benefit foreign-funded medical device makers in China.

But in the long-term, as domestic manufacturers take advantage of growth opportunities, this adjustment will assist Chinese companies grow their high-end exports as well.

China's Ministry of Finance recently adjusted its export tax rebate rate for several products, including 55 Western medicines, four traditional Chinese medicines (TCM) and eight medical devices. The adjustments will benefit about 6,100

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REGULATORY ROUNDUP

Patent reform sequel could be an investment killer, VC group says

By Mari Serebrov, Regulatory Editor

Some investors in start-up drug and device companies are concerned that a patent reform bill beginning its way through the House could discourage venture capitalists (VCs) from backing entrepreneurial companies whose only value at the time is in their intellectual property.

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Holiday notice

The offices of *Medical Device Daily* were closed Monday, Feb. 16, due to the President's Day holiday in the U.S., and no issue was published that day.

INSIDE

CARDIOLOGY EXTRA

Senior Staff Writer Amanda Pedersen on one of med-tech's key sectors

Read this week's Tuesday Special

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world-class academia, often focused on applied sciences for hi-tech or medical applications.

But different fields of medical technology innovation have their own characteristic styles. Certain fields – particularly cardiology and certain other implanted technologies – often find suitors at an early stage in their lifecycle. Israeli imaging technology companies have not, however, experienced that good fortune. Consider the purchase of **Given Imaging** by **Covidien** (now **Medtronic**) or the divesting of **Elscint** in the 1990s to what is now **Philips** (Eindhoven, Netherlands) and **GE Healthcare** (Chalfont, UK), where both Israeli companies had annual sales of hundreds of millions of dollars before acquisition. Comparing these exits to early-stage Israeli device success stories – such as J&J's Biosense pre-FDA purchase or Medtronic's early grab of Ventor's transcatheter valve – raises questions for companies, analysts and VCs alike.

The reason for earlier exit routes in certain sectors might be due to the rapid uptake of certain technologies into the market, or the relatively more cautious penetration of others, particularly those products/fields that involve a heavy capital expense. The 'wait and see' approach played by the largest imaging players is often a safe bet: the fittest technology startups will survive, and will then be ready for purchase after significant market validation.

The medical imaging startup may have additional hurdles to reach maturity when compared to her siblings in other device sectors, and there may exist a difference between the software and hardware modalities. Below, we highlight a few privately-funded Israeli imaging-related startups that may offer significant novelty and value to the industry. **MedicVision** (Tirat Hacarmel) and **UltraSPECT** (Raanana, Israel, and Auburndale, Massachusetts) add value to existing imaging modalities, while **Real Imaging** (Airport City) has developed a new system that has the potential to significantly change the world of diagnostic breast imaging.

MedicVision has developed proprietary algorithms and technology to provide fast and precise image enhancement for CT and other modalities. Its FDA-cleared SafeCT is a turn-key solution that enables a dramatic dose reduction in CT scans without compromising image quality.

Eyal Aharon, MedicVision's CEO, explained to *Medical Device Daily* that SafeCT empowers existing CTs without the need to purchase top-end next-generation hardware products. "Approximately 50% of the current CT installed base in the U.S. is unsuitable for the OEM upgrades" Aharon shared, "and we can offer great benefit to the operators of these high-value assets."

"The core of the technology is from our proprietary algorithms", he explained to *Medical Device Daily*. The company's ability to recruit Jonathan Adereth, previously Elscint's president/CEO, and Bar Meir, the erstwhile Head of Radiology at **Bnei Zion Hospital** (Haifa), as company advisers, is testimony to the quality of the solution.

Today, SafeCT serves more than 70 sites across the U.S., including **Massachusets General Hospital** (Boston), **Cedars-Sinai Medical Center** (Los Angeles), and **Montefiore Medical Center** (New York). SafeCT supports CT scanners of all vendors and models, at any number of satellite sites, using a single server system that provides robust centralized low-dose imaging functionality. This is of increasing importance in today's distributed medicine approach: Aharon shared that "many of our customers are operating between 5-15 satellite radiology clinics," where issues of data consolidation and uniformity are of increasing importance.

Based on its initial value-added developments, MedicVision is advancing its product line towards new CT image enhancement applications, and is currently expanding its marketing towards the Far East.

Another software company – also working closely with Elscint's Adereth – is UltraSPECT, a leading provider of reduced-dose image reconstruction products. By using the company's proprietary workstation, a Gamma Camera (used for Nuclear Medicine (NM)) can be used in the identical fashion, with only 25% of the standard dose of contrast agent (radioisotope) required.

The UltraSPECT Gate product is placed between the Gamma Camera and the camera workstation. The system receives DICOM data from the camera, deploys the relevant algorithm for the new mode of reconstruction, and presents the physician with the new improved set of clinical images. The Gate product occupies a minimal lab footprint and requires no technician involvement.

"Our software iterative reconstruction software solutions can be used for both nuclear oncology and cardiology application to reduce the amount of injected dose, shorten scan time and improve image quality," Yossi Srour, UltraSPECT's president/CEO, told *MDD*. "Our advanced software enables the reduction of either injected isotope or shortened scan time by up to 75%, while the common use is decrease of dose by 50% combined with a 50% shortened scan time," he added. "In some cases, the users maintain the current dosage, and take our technology advantage towards increased image resolution for better detection."

The need to achieve major dose-reduction goals in Nuclear Medicine (NM) has been specified by papers published by the **American Society of Nuclear Cardiology** (ASNC, Bethesda, Maryland) in early 2014, as well as CMS and other's directives. "These market trends towards lower dosage imaging have been a helpful catalyst in ensuring more rapid market uptake in recent quarters," added Srur, who has now 450 sites worldwide, with the majority in the U.S., and the Far East growing rapidly.

As a result of this ASNC requirement, UltraSPECT received a further boost in the U.S. market, Srur shared. Radiopharmaceutical Suppliers, he explained, "are reimbursed per unit dose, irrespective of the amount of isotope required, so a lower dose of agent offers a win-win

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AGREEMENTS/CONTRACTS

AHA/ASA, Medtronic collaborate on stroke management, awareness

Staff Report

The **American Heart Association/American Stroke Association** (AHA/ASA; Dallas) and **Medtronic** (Dublin) reported a collaboration to reduce the rate of recurrent strokes in the U.S. The two organizations will work together over several years to educate, raise awareness and support effective management of patients who have strokes, one of the most devastating diseases affecting Americans.

The initiative, announced at the American Stroke Association's annual International Stroke Conference in Nashville, Tennessee, will focus on reducing strokes of unknown cause, called "cryptogenic stroke."

Recent studies have shown that many stroke patients have a common heart condition called atrial fibrillation (or AF), when the heart beats irregularly or rapidly. Patients with AF are five times more likely to have strokes, but their condition often goes undiagnosed because their AF episodes occur only sporadically and may not have any symptoms. Studies have shown that continuous, long-term cardiac monitoring of cryptogenic stroke patients helps physicians detect and diagnose AF and provide treatment to prevent a recurrent stroke. //

WORLD IN REVIEW

Varian Medical Systems to service new national proton therapy center

Staff Report

Varian Medical Systems (Palo Alto, California) has been selected to equip and service a new national proton therapy center in Aarhus, Denmark, with the Varian ProBeam proton therapy system. Under a completed public tender, Varian was selected to provide equipment, software and service to operate a four-room center for up to an estimated $70 million. Varian expects to conclude and sign the contract and book the equipment and software portion of the order in March.

In addition to the ProBeam system, Varian will provide its ARIA information management software. Equipment installation is expected to take place in mid-2017, with patient treatments expected to begin in the second half of 2018.

Varian's ProBeam system with Dynamic Peak Scanning is uniquely capable of high-speed intensity modulated proton therapy (IMPT) which is the most precise form of proton therapy available.

Proton therapy makes it possible to treat certain types of cancer more precisely and with potentially fewer side effects than is possible with conventional radiation therapy. With proton therapy, the risk of damage to healthy tissues and potential side effects is reduced because the beam stops and deposits dose within the tumor site rather than passing all the way through the patient. Proton therapy can be used for many of the most common types of cancer. In pediatric patients the risk of developing a new, radiation-induced cancer later in life may be reduced. //

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situation while delivering safer imaging and better care to patients." Additionally, UltraSPECT's low-dose solution enables radiopharmaceutical suppliers to assure customers that they can maintain quality patient care regardless of global radioisotope shortages.

Another promising, though earlier-stage company, is Israel's Real Imaging addressing the challenging but needy field of breast cancer diagnostics, with technology that has emerged from research on structured-light and infrared optics.

"About 50% of U.S. women undergoing mammography have dense breast tissue, for whom mammography might not be sufficient enough, and additional imaging modality may be recommended." explained Maiki Yoeli, CEO of Real Imaging. "We plan to be a key player in this multi-modality breast cancer screening market, adjunctive to mammography, and especially for women with dense-breast tissue."

The company uses its contact-less Infra-Red imaging techniques to assess a variety of parameters that might suggest the presence of tumor tissue. Rather than adding another set of images, MIRA offers a set of metabolic-related parameters to create a 'likelihood score,' to advise the clinician whether the patient should be sent to biopsy. "Our output is not based on thermography," explained David Izhaky, VP R&D of Real Imaging "but rather that we use a variety of imaging biomarkers that are associated with physiological changes in the breast, in order to establish the risk profile of the individual."

In addition to the needs in the Western world as an adjunctive tool, this approach may be very appealing for Far Eastern markets, which do not necessarily have access to suitable personnel (or funds) for extensive screening technologies, even using standard mammography. MIRA's solution – not requiring an experienced radiologist to extract a result – may offer a mechanism to prioritize higher-risk sub-populations. This aspect may also explain the investment of Hong-Kong based financial enterprise, China Everbright Ltd, in the latest fundraising at Real Imaging.

Beyond to its multi-center studies to date, Real Imaging is currently conducting a study at **Karolinska Institute** (Stockholm, Sweden) which will include 2000 women with dense breast tissue. "Data from the first 450 patients has been most promising," the company told *MDD*. //