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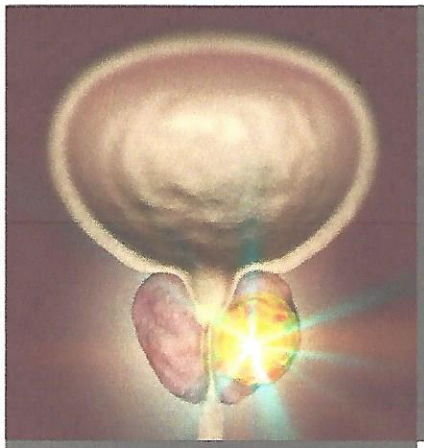

Francis Medical debuts with $18M series A funding for vapor ablation technology

By Liz Hollis, Staff Writer

Minneapolis-based Francis Medical Inc., which is developing a vapor ablation therapy to treat endourology cancers, has wrapped up an $18 million round of series A financing, with an eye toward additional development activities.

The round was led by Arboretum Ventures, with co-investments from H2Oey Ventures, an affiliate of Solas Bioventures Fund, Tonkawa and Boston Scientific Corp., of Marlborough, Mass. The company's initial focus will be prostate cancer.

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Inside

US FDA uses lighter touch in final classification rule

By Mark McCarty, Regulatory Editor

The FDA has finalized the March 2014 draft medical device classification rule, a document that drew only modest attention, but which proposed that clinical trials could be required as special controls for class II devices. The final rule does little more than conform to the requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA), thus backing away from that and other provisions found in the draft, at least one of which could have forced the

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Researchers harness AI to sequence human genome, diagnose PTSD

By Tamra Sami, Staff Writer

BRISBANE, Australia – Australian researchers are using artificial intelligence to diagnose medical conditions ranging from breast cancer to post traumatic stress disorder (PTSD) much more quickly than ever before.

Brisbane's Translational Research Institute (TRI) is working with Siemens Healthineers at Draper Laboratories using magnetic resonance

See Australia AI, page 7

China AF device maker secures series A funding

By Chermaine Lee, Staff Writer

HONG KONG – Artech Medical Ltd., a company specializing in producing minimally invasive devices for treating atrial fibrillation (AF), raised more than ¥10 million (US$1.45 million) in a series A round of financing led by Beijing Dingxin Capital Co. Ltd.

"The funds raised in the A round financing will be used in R&D of new products. . . . We are currently conducting R&D of cryo technology and related

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No escaping Brexit: Industry leaders talk impact, preparation

By Nuala Moran, Staff Writer

LONDON – Don't mention the B word: On a day when anxiety levels over Brexit ratcheted further upward, the if, how and when of the U.K.'s leaving the EU suffused the atmosphere at the 18th annual Genesis conference in London on Thursday.

"The dreaded B word is missing from the agenda," said Jon Green, president of the industry body One Nucleus and vice president at Astrazeneca

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Patent Highlights

BioWorld MedTech presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

BioWorld MedTech's Neurology Extra

Production Editor Andrea Applegate on one of med-tech's key sectors

Read this week's edition

Francis Medical

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Michael Hoey, founder of Francis Medical, also co-founded Nxthera in 2008 to develop and commercialize the urology applications of the vapor platform technology that he invented. Earlier this year, Boston Scientific scooped up Nxthera for $306 million upfront plus up to $100 million in additional maximum milestones. (See *BioWorld MedTech*, March 22, 2018.)

Specifically, Nxthera pioneered its convective water vapor energy technology to treat a variety of endourological conditions, starting with benign prostatic hyperplasia (BPH). It won FDA clearance in August 2015 with the Rezūm system. That system is used in a clinic or out-patient setting using the stored thermal energy steam to treat the extra prostate tissue.

Hoey now has teamed up with Mike Kujak, who was named CEO of Francis Medical last month, on this new venture. Kujak served as chief marketing officer and VP of international sales at Nxthera. Before Nxthera was picked up by Boston Scientific, this company was spun out.

Setting the stage

Francis Medical noted that early feasibility studies in the Dominican Republic, Paraguay and Panama helped set the stage for this initial funding.

"The series A funding will primarily be used to further develop the transurethral treatment of prostate cancer through the completion of a OUS trial and the completion of a U.S. IDE pilot study," Kujak told *BioWorld MedTech*. "The company will also further the development of the bladder and kidney cancer applications through early bench and animal data."

Hoey provided an overview of how using water vapor is different from other techniques, noting that it is quickly applied convectively vs. other thermotherapies, which are slowly applied conductively. "The thermal energy physically moves through the tissue, and when it reaches a physical barrier, such as the prostate capsule, the vapor stops."

As a result, the vapor can fill the prostrate with treatment, but cannot go outside the gland and produce extracapsular side effects. Such side effects include urinary incontinence and erectile dysfunction.

"In addition, water vapor is 'wet' and does not dry out the tissue; this cues the immune system to almost completely resorb the treated tissue. No other technology does that," Hoey added.

How does the process work?

Hoey also went into great detail into how the whole process works. "The application of RF power to sterile water creates water vapor (steam) thermal energy," he told *BioWorld MedTech*. "During the phase change of liquid water to water vapor, a vast amount of energy, 540cal/ml, is absorbed and stored within water vapor molecules. This energy is released upon condensation when the water vapor molecules change back to the liquid state, releasing the energy [and] causing coagulative necrosis. A transurethral device is inserted, and drops of sterile water are vaporized and delivered through a plastic needle into the prostate."

> *"[W]ater vapor is 'wet' and does not dry out the tissue; this cues the immune system to almost completely resorb the treated tissue. No other technology does that.*
>
> Michael Hoey
> Founder, Francis Medical Inc.

He noted that the procedure is done under direct visualization, accompanied by ultrasound. "The vapor treatment is echoic and can be observed real-time," he explained.

Others in the BPH game

For its part, Redwood Shores, Calif.-based Procept Biorobotics Corp., which focuses on BPH, scored $118 million in equity financing to commercialize globally its minimally invasive Aquablation technology. (See *BioWorld MedTech*, Feb. 22, 2018.)

Procept was granted approval of its de novo request with the U.S. FDA for its Aquablation technology and Aquabeam system in December 2017. It is intended to resect and remove prostate tissue as treatment for lower urinary tract symptoms resulting from BPH. The system combines imaging, robotics and a water jet ablation system to remove prostate tissue in a controlled manner.

The company reported in October that the U.K.'s National Institute for Health and Clinical Excellence issued an interventional procedure guidance recommendation approving the use of Aquablation therapy as an alternative to other surgical techniques for the treatment of BPH.

In addition, Teleflex Inc., acquired Neotract Inc. last year. Neotract made the FDA-approved Urolift minimally invasive technology for BPH related lower urinary tract symptoms. (See *BioWorld MedTech*, Sept. 6, 2017.) ♦

Regulatory front

The U.S. **FDA** finalized the draft guidance for manufacturing site change supplemental filings for PMA and humanitarian use devices as well as devices regulated under product development protocols. The guidance said that a site change supplement will be required when the new site was not listed under the original or a previous supplemental filing, or any circumstances in which the site was not previously the location of the manufacture of the device. Such a change would require a 180-day supplement when such a change potentially affects device safety or effectiveness. Some changes in manufacturing sites may be handled via a 30-day notice if that site is already listed in a supplemental filing and if those changes are "for performance of the same or similar manufacturing activities" for the same or a similar device. The scope of the guidance does not include the manufacture of device components, although the agency recommended that the manufacturer of such components employ the appropriate portions of Part 820 in the handling of such changes.