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FDA letter causes hurdle in GT's plan for LuViva U.S. approval

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

Disappointment and frustration are perhaps two terms that best describe the tone of **Guided Therapeutics**' (Norcross, Georgia) conference call revealing the news about the company receiving a not approvable letter from the FDA for its LuViva device.

The firm said that it plans to seek an independent panel review of its PMA application for the device.

LuViva scans the cervix with light to identify cancer and pre-cancer painlessly and non-invasively. Unlike Pap or HPV tests, LuViva does not require laboratory analysis or a tissue sample, and is designed to provide results immediately, which eliminates costly, painful and unnecessary testing, the company said.

The firm said it received the letter late Friday – but

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Financings roundup

'Little Engine' AirXpanders raises $10M in 'D' round

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Just like in the classic children's story "*The Little Engine That Could*," it doesn't always take a big engine to make a difference in patients' lives. Even a smaller engine – in this case a company called **AirXpanders** (Palo Alto, California) – can get to the top of the regulatory mountain, but doing so usually requires a lot of determination ("I think I can, I think I can") and support from friends, in this case investors.

This little engine recently secured $10 million in a Series D financing round, enough to help it over the regulatory mountain and to the commercialization door step where it can begin to make a difference in patients' lives. The round includes $7 million from new investor Vivo Ventures and $3 million from existing investors GBS Venture Partners, Prolog

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Report from Europe

FzioMed receives CE mark for Dynavisc adhesion barrier gel

A Medical Device Daily Staff Report

FzioMed (San Luis Obispo, California) reported that it has received CE mark approval to market Dynavisc adhesion barrier gel in Europe for tendon and peripheral nerve surgery.

Dynavis is a clear, absorbable gel supplied ready-to-use in a 1 mL syringe. It is designed to coat tissues during tendon and peripheral nerve surgery. The gel acts as a temporary, protective barrier that separates tissues and reduces fibrosis and the formation of post-surgical adhesions.

Adhesions are internal bands of scar tissue that can develop following surgery as the body attempts to heal. Adhesions tether tissues and surfaces that are normally not connected, later causing pain, nerve compression and

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Washington roundup

New *de novo* process seen as no leaner than current process

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

The saying that a difference that makes no difference is no difference might be applied to the FDA draft guidance on an alternative *de novo* device process, at least where two prominent med-tech associations are concerned. The **Advanced Medical Technology Association** (AdvaMed; Washington) and the **Medical Imaging & Technology Alliance** (MITA; Arlington, Virginia) both inked Jan. 3 responses to the draft guidance published in October 2011, but neither group is convinced that the proposed process is any less cumbersome than the process currently in play. The comments cast doubt on whether the agency can come up with a process that will be a substantial improvement short

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Financings

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Ventures, Heron Capital and WTI.

Scott Dodson, AirXpanders' president/CEO, told *Medical Device Daily* the proceeds from this financing will be used to support the company's efforts to complete its ongoing investigational device exemption (IDE) study of the AeroForm patient controlled tissue expander system in the U.S., obtain a CE mark and to execute market launches in the U.S., Europe and Australia following clearance.

"We're ecstatic about this financing announcement, we know it will take us to the door step of full scale commercialization in some select international markets and in the U.S. as well, based on the timing and our current plans for completing the IDE trial," Dodson told *MDD*.

The results of the IDE study will be used to support the company's 510(k) application in the U.S. later this year, the company noted. AirXpanders enrolled its first patient in the study late last year (*Medical Device Daily*, Dec. 8, 2011) after the FDA granted the IDE (*MDD*, Sept. 1, 2011). The IDE study is a prospective, randomized, controlled, open-label pivotal study of the company's AeroForm breast tissue expansion device in mastectomy patients undergoing breast reconstruction. Participating sites include hospitals in Boston, New York, St. Louis, San Diego, Sacramento, San Jose and Durham, North Carolina.

The AeroForm system consists of a self-contained expander, which is implanted in the same manner as a traditional saline expander following mastectomy, and a small hand-held wireless remote control unit. A small lipstick-sized carbon dioxide reservoir in the expander gradually releases carbon-dioxide through a small internal valve, eliminating the need for invasive weekly saline injections typically associated with current expanders. Following a standard implant procedure, the patient can fully regulate the expansion protocol directed by their surgeon at home.

Tissue expansion is required during breast reconstruction to adequately stretch the skin and underlying muscle in order to create a space to insert the permanent breast implant. Currently, the only commercially available option for patients is insertion of a saline tissue expander under the skin and pectoral muscle at the site of the mastectomy. During subsequent weekly office visits, the surgeon inserts a needle through the skin into the tissue expander's port and injects as much saline into the temporary implant as the woman can tolerate, until full expansion is achieved. Today's expansion process can take up to several months to complete.

Dodson said the company has already seen "great success" in the IDE study, with enrollment about 20% complete and no adverse events reported to date. He said patients are expanding at an "even more rapid pace" than the company had initially seen with its feasibility trial in Australia, and AirXpanders is optimistic about its ability to wrap up enrollment by April.

"We believe that AirXpander's AeroForm tissue expansion system has the potential to provide hundreds of thousands of women who have a mastectomy a more patient-friendly and potentially faster expansion method than what is currently available in order to prepare them for their permanent breast implant," said Albert Cha, MD, managing director at Vivo Ventures. "Given the strong initial clinical data, we believe that AeroForm represents the first major advance in breast reconstruction in decades."

Data from the company's published feasibility trial in Australia suggested that the average expansion time associated with the AeroForm remote-controlled tissue expander may be as short as 15 days.

The results of an earlier pre-clinical animal study appear in the January issue of the *Aesthetic Surgery Journal*, the peer-reviewed journal of the A*merican Society for Aesthetic Plastic Surgery*. Results showed that all 12 paired devices performed to specification and achieved successful expansion with no adverse events.

Given the current financing environment, Dodson told *MDD* that the company's ability to raise these funds speaks well about the technology but also the healthcare space in general, particularly women's healthcare. "I think it's a fantastic story. I think women's healthcare issues, and breast cancer in particular, are a lightning rod for research and development and this speaks to the attractability of the space and the" technology's potential to fulfill an unmet need.

Prior to this financing round, the company had raised $8 million through a $5 million Series C financing led by GBS Ventures in April 2010 and an additional $3 million working capital line from Oxford Finance in February.

In other financing activity:

• **PowerVision** (Belmont, California), a private company developing an accommodating intraocular lens, reported that it has added Johnson & Johnson Development Corporation to its list of investors in a recent closing of its Series C financing. Current investors, Venrock, Advanced Technology Ventures, and Frazier Healthcare Ventures, also participated in the round.

This closing brings PowerVision's Series C financing round to a total of about $37.2 million dollars and now completes the round. The investment will fund the company's ongoing R&D activities as well as its clinical trial targeted at achieving the CE mark in Europe. Other major investors in the round besides those participating in this last closing have also included Panorama Capital and Medtronic.

• **Acusphere** (Lexington, Massachusetts) reported that its stockholders voted to approve a proposed 1-for-10 reverse stock split of its common stock. The company intends to effect the reverse stock split immediately by filing an amendment to its certificate of incorporation, at which

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