

*Financings roundup***AxioMed raises \$6.4M, seeks to raise \$18.5M in Series C round****A Medical Device Daily Staff Report**

AxioMed Spine (Garfield Heights, Ohio) said it has completed the first part of its third financing round, raising \$6.4 million from venture capital firms, which were not named.

The company, which is developing next-generation spinal disc replacements, said it is working toward a Series

C round of \$18.5 million.

AxioMed said it would use the funds to continue developing its Freedom lumbar and cervical disc replacements. The company also said it plans to use the money to expand its operations by adding to a headquarters workforce of 15 people, once the fundraising round is complete.

In May the company won CE-mark approval for its Freedom Lumbar Disc, an elastomeric total spinal disc replacement device (*Medical Device Daily*, May 21, 2009).

The disc replacement device is designed to restore function of the spine and reduce pain and disability. ■

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force supports those decisions," Petitti said, adding, "the task force's communication was poor" in terms of making clear this part of the recommendations.

"In making its final recommendation," Petitti said, the task force used data from a variety of sources. "The systematic review identified almost 3,000 studies" most of which were used, she said.

Petitti tackled a seemingly obscure element of the debate in her discussion. "The benefits of breast cancer screening have been easy to communicate, but the harms have been difficult to communicate," she said, remarking that the psychological impact of a false positive is difficult to overstate. "The psychological harms have been

ridiculed," she said, but asserted, "a positive screening tests means cancer until cancer" is eliminated by further tests. The amount of time between initial diagnosis and the clarifying follow-up "is not always short," she remarked, and "carries special emotional weight."

Petitti also made the case that "anxiety and psychological distress . . . [are] amply documented in the evidence" and that "false positive tests are more frequent in younger women than older women." She concluded her remarks by reiterating the task force's conclusion: "Mammography starting at 40 should not be automatic," but should hinge on discussions between patient and doctor. ■

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gate the sensitivity to changes in heart failure status of PhD, a unique diagnostic feature using the dual sensor technology of minute ventilation and accelerometer to monitor patient's breathing and activity levels every day.

The algorithm aims to provide physicians with both trends and indicators in order to highlight sustained changes in overall health status that could relate to heart failure (HF) evolution.

PhD is available in the Paradym family of ICDs in Europe and under clinical evaluation in Implantable Cardiac Resynchronization Therapy Defibrillators (CRT-D) in Europe and U.S.

As the severity of HF can fluctuate and drug therapies adjusted to improve the patient's condition, it is important to monitor recognized indicators of disease progression to prevent the patient being hospitalized. PhD measures activity workload and ventilation at rest and exercise, which are two key measurements to indicate that a patient's heart failure condition is progressing. The Clepsydra study will test the PhD algorithm that is designed to give advance notice of sustained deterioration. Advanced warning at follow-up could give physicians time to intervene in the patient's treatment to avoid the costs and

patient burden associated with hospitalization.

The Clepsydra study, will evaluate PhD in 550 patients to be enrolled in the U.S. and Europe. Patients will be closely monitored over a minimum of 13 months by hospital visits and by telephone checks.

The first implant was performed by Andrew Kaplan, MD, cardiac electrophysiologist with CVAM, CardioVascular Associates of Mesa, at **Mountain Vista Medical Center** (Mesa, Arizona).

"Tracking and managing heart failure progression in our patients is complex and time consuming. The Clepsydra study should help us better predict and intervene earlier in the heart failure process through evaluation of the data collected by the PhD sensor-based function. The implantation in our first patient was smooth and the device performed well," said Kaplan. ■

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