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Sales near for Delphinus ultrasonic breast cancer detector

By TOM HENDERSON |

Barbara Ann Karmanos Cancer Institute Health Care More +



Photo by Delphinus

The SoftVue System uses technology that was spun out of the Barbara Ann Karmanos Cancer Institute in 2009 after a decade of research. There's a prototype in use at the institute.

Delphinus Medical Technologies Inc. is about to graduate. And, after 17 years of research and development and three rounds of venture capital totaling \$58.5 million, it will start selling its first devices for ultrasonic detection of breast cancer.

Delphinus has been a tenant since 2010 in the Plymouth Township-based **Michigan Life Science and Innovation Center**, a tech incubator in a former **Pfizer Inc.** facility that is owned by the **Michigan Economic Development Corp.**

According to Mark Forchette, the company's president and CEO, within two weeks Delphinus will move into 21,000 square feet in the former **Lee Steel Corp.** building in Novi, on Grand River Avenue just east of the **Suburban Collection Showplace**. He hopes to start selling devices by the end of the year.

"This will triple our space, which is fantastic. It gives us an opportunity to expand our lab and our R&D facilities and to expand our head count. We've been busting at the seams. This will give us a much better recruiting environment," Forchette said. He said the company employs about 45 now, and he

hopes to hire 10-15 by year's end.

"It's good news," said Fredrick Molnar, the MEDC's vice president of entrepreneurship and innovation. "That's the way it's supposed to work. Companies aren't supposed to stay here forever. They get incubated here and then they move on. That's the way it was for Esperion, too."

Esperion Therapeutics Inc. and **Lycera Corp.**, two drug discovery companies, were original tenants of the innovation center when it opened in 2009. Both have subsequently moved into their own headquarters in Ann Arbor.

Forchette said the new facility will have about 7,000 square feet of lab and R&D space. And the new building will allow Delphinus to build a demonstration and training room to teach physicians how to use its devices.



Mark Forchette: "Investors are very supportive."

Delphinus will be reaching out to physicians at the **Radiological Society of North America's** 102nd annual meeting. Nov. 27-Dec. 2 at the **McCormick Place** in Chicago, where it has rented space.

"That's a big meeting, and it's key," he said.

Delphinus' device, marketed as the SoftVue System, looks like a bed with a hole near the top. Patients lie down, with a breast through the hole.

The breast is immersed in water and surrounded by a ring containing 2,048 ultrasound sensors, which generate data that are converted to 3-D images.

The technology was spun out from the Detroit-based **Barbara Ann Karmanos Cancer Institute** in 2009 after 10 years of research. In 2010, the company raised a VC round of \$8 million, and in 2013, it raised an additional \$11 million.

In September, the company raised a third round of \$39.5 million, the largest in state history for a medical device company. Before being spun off, more than \$19 million in grant funding had gone into the technology.

In January 2014, Delphinus got approval from the **U.S. Food and Drug Administration** for the

devices to be used as a follow-up diagnosis for women who have already been screened by traditional mammography, and cancer is suspected. So far, the only device in use, a prototype, is at the Karmanos Cancer Institute.

When he closed on the VC round last September, Forchette said the money would be used to fund trials on women with dense breast tissue and to continue refining the software and hardware components of the system. Those trials, if successful, would ultimately allow the SoftVue System to be used as a screening tool to detect breast cancer. That is a much bigger market than its current FDA approval as a secondary screening tool.

Forchette said one major problem with mammography when used on women with dense breast tissue is the high number of false positives, which leads to further testing that eventually proves to be unnecessary and expensive. He said ultrasonic imaging will sharply lower the incidence of false positives.

Mammography also uses radiation, which has risks. Ultrasound is benign.

Forchette said he is firming up details on trials and expects them to start in the third quarter this year. They will involve 10,000 women at eight sites, one of them in Michigan, none of which he said he can disclose yet.

He said he hoped to have positive results by mid-2017 and approval from the FDA to start selling devices as a primary screening tool in 2018. He declined to disclose a sale price until the company starts selling them later this year or early next year.

The last funding round was led by Madison, Wis.-based **Venture Investors LLC**. It was joined by previous investors — Ann Arbor-based **Arboretum Ventures LLC**, Ann Arbor-based **North CoastTechnology Investors LP** and Farmington Hills-based **Beringea LLC**, and by Grand Rapids-based **Hopen Life Science Ventures** and **Waycross Ventures** of Menlo Park, Calif.

When asked if the last funding round was enough to get Delphinus through FDA trials and full commercialization, Forchette said: "Our investors are very supportive, and they have a very robust ability to see us through. But I'm thinking about clinical trials, and not about fundraising. Delphinus is going to be a spectacular story for this industry, and for Michigan."