Medical Xpress

New class of implantable monitoring devices for heart patients

February 4 2011

Atlanta-based CardioMEMS is pioneering a new class of monitoring devices for heart patients. The company is based on Georgia Tech technology, and is located in Technology Enterprise Park. (Click image for high-resolution version)

CardioMEMS, a graduate of Georgia Tech's ATDC startup accelerator, is a rising star in the medical device industry. Pioneering a new class of monitoring devices for heart patients, the company completed a successful clinical trial in May 2010 for its second product, which resulted in a $60 million equity investment and purchase option from St. Jude Medical Inc., a large medical device company based in St. Paul, Minn.

That investment earned the company a 2011 "Deal of the Year" award from Georgia Bio, a nonprofit association that represents Georgia's

pharmaceutical, biotech and medical device community.

CardioMEMS, which has more than 65 employees, grew out of Georgia Tech research. The company's products combine wireless communications technology with microelectromechanical systems (MEMS) fabrication, providing doctors with more information while making monitoring less invasive for patients.

MEMS uses micro-machining fabrication to build electrical and mechanical systems at the micron scale — one-millionth of a meter. Using technology originally developed for the integrated circuit industry, MEMS is an attractive platform for medical devices because mechanical, sensing and computational functions can be placed on a single chip.

CardioMEMS began marketing its first product in 2006: the EndoSure sensor, which measures blood pressure inside a repaired abdominal aortic aneurysm. Implanted along with a stent graft during endovascular repair, this tiny sensor may allow doctors to monitor post-surgery patients more effectively than the CT scans that had previously been used. The EndoSure sensor is also less expensive and more convenient.

Now the company's second product, a sensor that measures intracardiac pressure in people who suffer from congestive heart failure, is moving closer to FDA approval.

Implanted in the pulmonary artery, CardioMEMS' new heart sensor enables Class III heart-failure patients (considered to be in the moderate stage of heart failure) to take daily intracardiac pressure readings at home. This information is transmitted to a website, which enables physicians to monitor patients more effectively and alter medications when necessary. In fact, results from the recent clinical study showed a 40 percent reduction in hospitalizations when doctors used data from

CardioMEMS' system to treat patients.

Launched in 2001, CardioMEMS was co-founded by Dr. Jay Yadav, a cardiologist and director at the Cleveland Clinic Foundation at the time, and Mark Allen, a professor in Georgia Tech's School of Electrical and Computer Engineering and director of the school's MEMS research group.

Due to the unique nature of its technology, CardioMEMS elected to locate in Atlanta to be close to Allen and his students. ATDC accepted CardioMEMS into its incubator program shortly after the startup's formation. The Georgia Research Alliance assisted with an industry partnership grant early in the company's development.

"ATDC has played an important role in CardioMEMS' success, especially during our early years," said David Stern, CardioMEMS' senior vice president for scientific affairs and one of the company's first full-time employees.

Bioscience companies face unique challenges, Stern explained: They have greater needs for capital, face higher technical risks and typically need FDA or other regulatory approval before they can market their products or services. And unlike many entrepreneurs that can start their companies in a garage or home office, bioscience companies require special facilities.

CardioMEMS was among the first tenants in ATDC's Biosciences Center, located within Georgia Tech's Environmental Science & Technology (ES&T) research center, which enabled the company to access wet labs equipped with special ventilation and purified water systems. CardioMEMS was also able to use Georgia Tech clean rooms for micromachining.

If CardioMEMS had been required to build its own clean room, it would have cost millions of dollars and delayed R&D for months, Stern said. In addition, Georgia Tech's clean rooms have a broad array of specialized equipment, which enabled CardioMEMS to execute its prototyping faster — and try different equipment to see what it would ultimately need to invest in.

The physical proximity to other entrepreneurs and researchers in ES&T was also a plus. "At one point we were next to another medical-device company, so it was easy for our staffs to have impromptu discussions walking down the hallways," Stern said. Being on Georgia Tech's campus gave CardioMEMS access to a deep talent pool, and enabled the company to hire professors as consultants, graduate students as permanent employees and current students as interns.

An important aspect of being able to use Georgia Tech facilities and hire talent was the lack of red tape. "With most institutions, that becomes very complicated and you can spend a lot of time negotiating contracts rather than getting work done," Stern explained. "Yet ATDC was able to make it all really easy."

"This may sound like a minor point, but it's not," said Stern, noting that startup is a crucial time for any company, but especially for a biotech firm. "It's during those early years that you have the least amount of money — and the most to accomplish. You don't want to waste time or money on anything that doesn't involve progressing R&D or acquiring talent."

Today CardioMEMS is located in Technology Enterprise Park, a biobusiness complex located south of the Georgia Tech campus, and FDA approval of its heart sensor would position the company for considerable growth. The heart sensor has faced a longer road to commercialization than the company's first product, however, its market

potential is dramatically larger, said Stern, citing a patient population of more than 1.5 million compared to about 30,000 for the EndoSure sensor.

Although CardioMEMS is already contributing to Georgia's economy by generating new high-tech jobs, the company's success has broader implications, observed Nina Sawczuk, ATDC general manager.

The $100 billion U.S. medical device industry is made up of thousands of small and medium-sized enterprises and a few large players. "Medical device companies are located throughout the country, but concentrated in specific regions known for other high-technology industries, such as microelectronics and biotechnology," Sawczuk explained. "Georgia is among the top 10 states with the highest number of medical device companies and our focus is on supporting the small, innovative companies."

To this end Georgia Tech has partnered with Saint Joseph's Translational Research Institute, Piedmont Healthcare and the Georgia Research Alliance to launch the Global Center for Medical Innovation (GCMI), an initiative aimed at accelerating the development of next-generation medical devices and technology in the Southeast.

"CardioMEMS is a catalyst for developing a next generation medical-device industry hub in Georgia," Sawczuk continued. "CardioMEMS marries MEMS technology with more traditional medical device technology. This is particularly exciting because the company is creating a new type of wireless product that is the future of the medical device industry. It is success stories such as CardioMEMS that the GCMI plans to replicate in the Southeast."

Provided by Georgia Institute of Technology