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Key stem cell research under way

UM and Bioheart may have breakthroughs

South Florida Business Journal - by [Brian Bandel](#)

How do you mend a broken heart? Many scientists say stem cells are the answer, but they're not sure how best to use them and make money doing it.

Clinical trials by the [University of Miami](#) and Sunrise-based [Bioheart](#) (OTCBB: BHRT) are among a wave of studies searching for ways to repair damaged hearts using stem cells. Numerous animal tests have shown stem cells can transform into new heart muscle to repair tears after a heart attack or partially replace scar tissue from old cardiac episodes.

There are about 1 million heart attacks a year in the U.S., with about two-thirds of the victims surviving, said Dr. Joshua M. Hare, a cardiologist and director of the [Interdisciplinary Stem Cell Institute](#) at UM's [Miller School of Medicine](#). Many survivors have their lives cut short by congestive heart failure.

UM is running four clinical trials that inject stem cells from bone marrow into damaged hearts. One uses a unique catheter designed by BioCardia instead of major surgery. Another compares stem cells taken from patients to donor stem cells.

"If we can get it to work, it would be like doing a heart transplant. Say, a 50 percent recovery," Hare said. "Businesswise, it would have a huge market."

The university has some private companies as partners, but much of the funding comes from the [National Institutes of Health](#). Hare said private investors are hesitant to support stem cell therapies because they don't have any approved treatments in the U.S. and there are concerns over defending intellectual property.

Hare said some investors fear this could become like bone marrow transplants, which aren't patent protected.

"We have a therapy that could save hundreds of thousands of people, but the development is slow because of a lack of investment in the area," Hare said.

As it works on finishing trials during 2010, UM is already looking at the next source of stem cells. It is working on a method to extract stem cells from a patient's heart muscle, multiply them and insert them back into the heart. Hare said these stem cells might convert into heart muscle more easily.

Bioheart has several promising trials ongoing with stem cells. Early-stage data from the company's clinical trial for MyoCell – a process where muscle stem cells are taken from patients' legs and implanted in damaged hearts – showed that patients improved their walking distance. Bioheart needs at least \$5 million to launch a pivotal clinical trial in 2010.

Bioheart recently said it is collaborating on studies in Venezuela where stem cells derived from patients' fat are injected into their hearts shortly after they suffer heart attacks. The TGI 1200 System – a machine that converts fat from liposuction into stem cells – works in about 60 minutes.

Finding a faster way

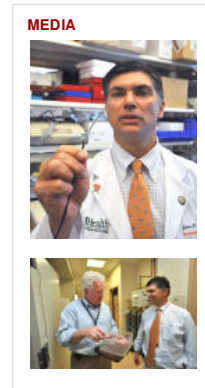
UM's method of getting stem cells from bone marrow takes at about a month, although the university is looking for a faster way. Several of its clinical trials use stem cells from a third party, so the patient has immediate access.

Bioheart Chairman and CEO Karl E. Groth said using TGI 1200, which the company licensed from Tissue Genesis, is one of the fastest ways to treat a patient with their own stem cells. The product is already approved in the European Union, where medical devices must demonstrate safety, but not effectiveness in treatment. Groth said Bioheart is collecting clinical data to promote sales there.

"In America, on the device side, the technology we get in hospitals is usually obsolete in the rest of the world because our regulatory timelines are so protracted," Groth said.

Bioheart has a competitor on its hands in San Diego-based [Cytori](#) (NASDAQ: CYTX). Its Celation System also converts fat from liposuction into stem cells. The company currently has two clinical trials with stem cells in heart patients. If those studies are successful, Cytori would need additional funds to do a pivotal trial in the U.S., company spokesman Tom Baker said.

Both Bioheart and Cytori say their devices deserve a unique patent, although it is not clear whether one of those patents would disallow the competitor's device.



Attorney Greg Mayback, president of Cooper City-based intellectual property law firm **Mayback & Hoffman**, P.A., said a company could patent the process of collecting and injecting stem cells a certain way, but others could try getting around that by changing some steps in the process while achieving the same result.

New York-based Angioblast looks to bypass intellectual property issues by developing its stem cell-based cardiac treatment like a drug. It isolated and purified what it considers the ideal donor stem cell and has mass-produced it for injection into damaged hearts.

Angioblast VP of Operations Michael Schuster said early results from two clinical trials are encouraging. He believes it will prove more consistent than patient stem cells, which could be weak when derived from sick or elderly patients.

“In the next couple of years, there will be a couple different stem cell applications that will be approved,” Schuster said.

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