

## EXCLUSIVE REPORTS

From the September 1, 2000 Print Edition

### Bioheart licenses cell therapy

Scott Shepard

A Florida medical technology company, Bioheart, Inc., has licensed myoblast cell therapy and is conducting human clinical trials in Europe using myoblast to regenerate damage human hearts. The company plans to apply to the FDA Dec. 1 to conduct human heart regeneration trials in the United States.

Myoblast was developed and is owned by neurological researcher Peter Law, founder of the Cell Therapy Research Foundation in Memphis. Law and his two co-principal investigators advanced mammal cardiac experiments to pigs earlier this year at the Medical Education and Research Institute in Memphis (MBJ, May 19-25, 2000).

Myoblast was first created by Law at the University of Tennessee, Memphis as a treatment for muscular dystrophy; when UT and Law parted a decade ago, Law said the same technology would apply to regeneration of heart tissue and other muscle.

"We are focused on heart muscle regeneration, and Bioheart itself represents a collection," says Howard Leonhardt, founder and CEO of Bioheart. "What we've done is bring together all of the leading scientists in the world who have been researching heart muscle regeneration for the last two decades, and invited them to combine forces to address the No. 1 killer worldwide, which is heart disease. Peter Law is certainly recognized as one of the pioneers."

In cardiac cases, immature myoblast cells are injected into damaged heart tissue, where they take on the characteristics of surrounding cells, and turn into mature heart cells.

Bioheart began by looking at the four different cellular platforms: embryonic stem cells, myoblast, adult stem cells from bone marrow and cardiomyocytes. Researchers concluded that myoblast offered the best potential with the fewest complications. Law has since become the second largest stockholder in Bioheart, a member of the scientific advisory board and on the company's board of directors. The deal promises further cash infusions into Cell Therapy as regulatory hurdles are cleared, but both Law and Leonhardt decline to discuss specifics.

"We've entered into an agreement with a conditional exclusive license to all his technology as the may relate to heart regeneration," Leonhardt says. "He would be given a royalty on every unit which would be sold."

In the world of medical business Leonhardt is best known as the founder of World Medical, Inc., who patented and marketed a number of improvements to angioplasty balloons and cardiac stents. He sold the company to Arterial Vascular Engineering in 1998 for \$62 million in stock options; that immediately became worth \$70 million as AVE was absorbed into Medtronic, Inc., for \$4.3 billion. The stake owned by Leonhardt and his wife was worth about \$30 million.

Within months Leonhardt incorporated Bioheart, which has a subsidiary, Bioheart Microimplants of Cambridge, Mass., myocardial tissue engineering, based primarily on myoblast technology.

"What we concluded is that the other cell types we were looking at have the danger of over proliferation, so we could not control whether they would grow into tumors in the heart," Leonhardt says. Myo-blast cells are also unique in their ability to survive in scar tissue within the heart.

"They not only survive like a cactus in the desert, but they will thrive like a cactus in the desert," he says.

In over 1,000 animal studies, including rats, rabbits and pigs, using 10-20 injections into damaged heart muscle, heart wall thickness of the damaged area more than doubles, and the wall motion of the area improves 540%-90% within eight weeks.

"In a recent sheep study we did, the normal left ventricular wall motion had a value of 71 before inducing a heart attack," Leonhardt says. "It was 40 afterward, but in eight weeks returned to 65."

Pigs were used in the final animal studies because their physiology is so close to humans. Pig studies in Memphis developed the final injection techniques, and Law was in Stockholm, Sweden last week presenting the results before a joint meeting of the American Physiological Society and the Scandinavian Physiological Society. The presentation was reviewed by four Nobel laureates.

"It's a good idea to go after the cardiac problems; people with muscular dystrophy certainly are suffering, but coronary artery disease is the biggest killer in the world," says interventional radiologist Scott Williams. He's medical director at MERI and a co-investigator with Law on the cardiac myoblast studies. "With cardiology, we can have a much bigger impact on the health of the entire world, and what we learn along the way can help in other areas."

The peak of cardiac intervention is technology like stents, which reopen clogged arteries and re-establish blood flow.

"We have good technology for opening up the pipes, but if the downstream tissue is dead, it's no good," he says. "We have the opportunity to open up the pipes and restore the downstream tissue."

Results of the European human trials will be presented at the American Heart Association's Scientific Sessions 2000: Touching Hearts Through Science, Nov. 12-15 in New Orleans, Leonhardt says.

"I'm optimistic it's going to work out, we just have to work out the parameters," Williams says. "The idea makes good clean sense and if it really works, it will change the world."

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