

## Pumped Up

■ A needle inserted deep into the heart could deliver a promising new treatment to millions of people suffering from heart disease.

Bioheart, a Broward-based biotechnology company, developed the therapy, which involves threading a catheter into the patient's heart and delivering immature muscle cells that take root and replace weak or damaged cells. The technique could one day mitigate the need for pacemakers, drugs or heart transplants, says the company's CEO, Howard J. Leonhardt.

"Those techniques only treat the symptoms as opposed to the underlying cause of the disease, and they have modest effects on limiting the progression of the disease," he says.

An estimated 23 million people worldwide suffer from heart failure, including 5.5 million in the US. For many of them, Bioheart's MyoCell therapy holds the promise of a healthy heart. In one clinical study, the therapy improved the heart's pumping ability by 25 percent — outperforming the more commonplace pacemak-

stopping him from trying to commercialize the therapy.

Armed with more than \$40 million in private and venture capital financing, Bioheart received permission from the US Food and Drug Administration to begin further tests of the treatment next year in 20 centers nationwide, including three in South Florida. Clinical trials in Europe began in 2001.

Bioheart hired Oxford, England-based biomedical consulting firm Health Decisions to manage its European trials to FDA standards. If regulators accept the European

**Lifesaver:** Howard J. Leonhardt hopes to heal hearts with an injection of a patient's own cells.



### A promising new therapy by the Broward-based company could replace pacemakers and make many heart transplants unnecessary. Does Bioheart have the right stuff?

ers that instead depend on mechanical devices implanted on the heart to synchronize its pumping action. The results of the study were published in the December 2003 *Journal of the American College of Cardiology*.

Gaining acceptance for the MyoCell therapy — the company's first product — is critical for Bioheart's survival. The company lost \$5.3

million in 2003, and is expected to lose \$7.5 million this year. As physicians begin administering the therapy, the company forecasts its net income will rise to \$1.6 million for 2005 and approximately \$37 million by 2007. Leonhardt is sanguine about the company's prospects.

"We have a solid patent portfolio and good clinical data from our studies," he says. "We will continue to be a leader in this field."

Still, he is quick to caution that more studies need to be done, but that is not

test results, sales of the treatment in the US could begin as early as 2006.

For those suffering from heart disease, the therapy is a welcome hope.

Patients with congestive heart failure face a 50 percent risk of death within a few years. Current treatments do little to reduce that mortality rate, experts say. The MyoCell therapy involves removing immature muscle cells from a patient's thighs, and injecting those cells into the weakened heart tissue. As the new muscle cells mature, the heart's pumping power improves. Studies so far indicate the new cells may even work better because they require less oxygen than regular heart cells.

Commercial use of Bioheart's new therapy will begin in Australia, Korea, South Africa, the Bahamas and Argentina this year, Leonhardt says. He expects that approximately 115 patients will receive the MyoCell therapy this year.

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By 2007, that number is expected to grow to 5,470 patients.

If he is successful at turning around Bioheart's prospects, it would be the second time he has done so for a company. In 1986, Leonhardt, who holds seven US patents in the cardiovascular sciences, launched World Medical Manufacturing Corp., a Sunrise-based producer of balloon catheters and stent grafts used in heart repair surgery. He sold the company in 1998 to Minneapolis-based medical technology firm Medtronic.

This summer, he plans to move Bioheart's 20 employees into the space formerly occupied by World Medical in order to have room to grow and to meet the expected increase in demand.

David Gury, the retired chairman of Boca Raton-based Nabi Biopharmaceuticals, calls Leonhardt a "serial entrepreneur. He's doing with Bioheart what he's done with his other investments." — Richard Westlund