

Arizona Daily Star



www.azstarnet.com

Wichner: SynCardia's Ford tackles turnaround of heart-pump maker

December 04, 2013 12:00 AM • By [David Wichner](#)



Local entrepreneur and investor **Rodger Ford** joined artificial-heart maker SynCardia Systems in 2005 and helped the Tucson-based company raise money to develop key components and reach profitability.

Now, Ford is trying to resuscitate a Houston-based company that makes an implantable heart pump.

In late October, Ford launched a new company, ReliantHeart Inc., formed from the bankruptcy assets of Houston-based MicroMed Technology Inc.

It's another turnaround story for Ford, who founded AlphaGraphics in Tucson in 1969 and built it into a quick-printing franchise powerhouse before selling the company in 1986.. He started the private-investment firm Anthem Equity Group in 1989 with partner **David Mackstaller**. Ford and Mackstaller joined SynCardia in 2005, built a management team and helped SynCardia raise \$54 million in private-equity investment to help develop new portable heart drivers.

SynCardia's Total Artificial Heart is the only U.S.-approved artificial bridge to transplant, and the company set records for implants and profits in 2012. The company is awaiting key Food and Drug Administration approvals for its smallest portable heart driver — which is already approved in Europe — and a version for youths and smaller patients.

In 2011, Ford stepped down as SynCardia's CEO to head MicroMed, which had developed a ventricular assist device (VAD) based on a design developed by pioneering heart-transplant surgeons Dr. **Michael DeBakey** and Dr. **George Noon** and NASA engineers.

The DeBakey VAD received European approval in 2001 for both the adult and pediatric versions of the device, and the FDA approved the child version in 2004.

Despite receiving FDA approval for a clinical trial, MicroMed couldn't quite make it to the finish line with its latest adult VAD, the HeartAssist 5, Ford said.

When creditors holding bridge loans wouldn't go along with a new financing plan, MicroMed filed for Chapter 11 bankruptcy reorganization in June 2013 to restructure its debt, Ford said. Chapter 11 protects a debtor from legal action while it works out a plan to repay creditors.

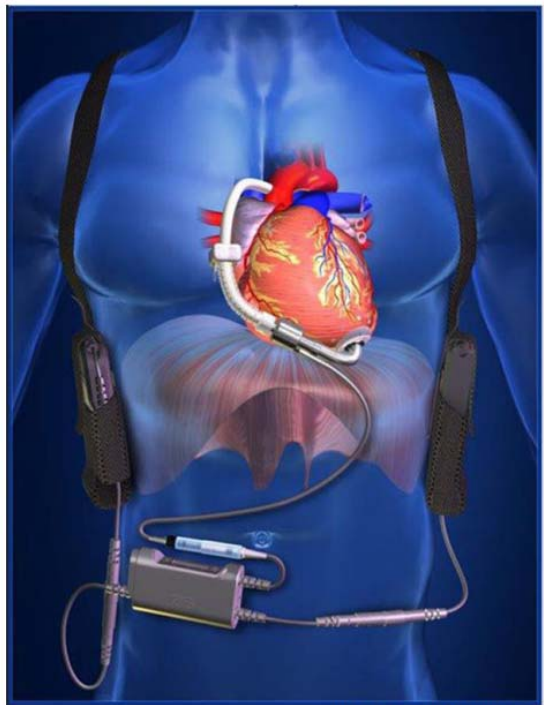
Under a reorganization plan approved in mid-October,

ReliantHeart became the "successor in interest" to MicroMed, assuming its assets and responsibility for paying off debts under the plan. Unsecured creditors are to be paid off fully over five years, according to the reorganization plan, and Ford said the bridge-loan investors were offered equity in ReliantHeart equal to about 30 percent of their debt holdings.

Ford sees a lot of potential in ReliantHeart and the HeartAssist 5 LVAD in a multibillion-dollar market for heart-assist devices.

While SynCardia offers the only FDA-approved complete artificial heart, two makers dominate the market for VADs as an "oligopoly," Ford noted. The biggest VAD maker, California-based Thoratec Corp., has a market capitalization of \$2.3 billion; the next biggest, Massachusetts-based HeartWare International is worth about \$1.6 billion.

And just this past Sunday, Ford noted, HeartWare announced it will buy small VAD company, New Jersey-based CircuLite Inc. in a deal worth up to \$350 million if the company reaches certain regulatory and sales milestones.



Images courtesy of ReliantHeart.com
A rendering shows a ReliantHeart HeartAssist 5 pump as it would look after implantation.

Ford said ReliantHeart is ready to break into the market in a big way, with technology competitors can't match.

The company's HeartAssist 5 is the only VAD that offers constant monitoring of blood flow and heart function, Ford said. The roughly \$100,000 device uses an ultrasonic probe to collect flow and other data and relay it to a wireless controller that can be accessed by health-care providers and patients.

"We have a radio in the controller that constantly sends data regarding the pump's speed, flow and power," Ford said, noting that the system can be set up to send text-message alerts of problems.

“If the patient’s pump has any sign of a challenge, like dehydration or low flow, the remote monitoring signals that to a data-collection center that pushes it off to the transplant center, which further pushes it out to the individual monitoring that patient,” Ford said, noting that patient data is also available via a secure Internet connection.

“So they (health providers) can do something quickly, rather than wait for something more severe to show up.”

The next step is to recruit about 15 transplant centers to enroll 96 patients in the HeartAssist 5 trial, which Ford expects to launch in the second quarter.

The trial will take about 18 months before results are submitted to the FDA for an approval process that will take several more months, said Ford, who was in New York recruiting trial sites this week.

Meanwhile, the company plans to formally launch the HeartAssist 5 in Europe in January, said Ford, who plans to fly to Paris next week to lay groundwork for the launch.

Ford said he’s assembled a top-notch management team including MicroMed veterans and a board that includes **Dr. Charles Richardson**, co-founder of Cleveland Heart, a company developing new heart-assist devices in partnership with the Cleveland Clinic; and **Michael Gerber**, a longtime business coach and author of the E-Myth on entrepreneurship.

While ReliantHeart’s top management is in Tucson, its operations and 18 employees remain in Houston, home to major transplant centers including the Texas Heart Institute. There, ReliantHeart makes the HeartAssist 5 from scratch in a modern factory.

“We make this pump from whole cloth — we start with a piece of titanium and out comes a pump,” Ford said.

Though Ford has no medical background, he is convinced that any company can meet its full potential provided it has a strong foundation of business processes. Among their other ventures, Ford and Mackstaller founded PetsHotel, which was acquired by PetsMart in 2000.

Ford noted that when he joined SynCardia, he replaced the company’s all-paper database system with a computerized system later adopted by the FDA itself.

“To me, the most fundamental thing about running any business is getting everything right before you start selling the product, so that you can correctly manage the chaos,” he said.