

CARDIOVASCULAR DEVICE UPDATE

A Thomson BioWorld monthly publication

Vol. 12, No. 3

March 2006

SynCardia marks profit milestones

Rodger Ford, CEO of **SynCardia** (Tucson, Arizona), maker of the only FDA-approved total artificial heart, last month at an investor meeting promised that the company will move from “life-saving science venture” to profitability this year. The company in late 2004 reached a major milestone in the artificial heart/heart assist sector with FDA approval of its CardioWest temporary Total Artificial Heart (TAH-t) for bridge-to-transplant, thus becoming the first company to win U.S. commercialization for a total artificial heart. Ford told investors that the five-year-old company would see sales of \$14.9 million and profit of about \$6 million this year.

An updated version of the original 1980s-era Jarvik heart, the TAH-t is used to keep the patient alive until a donor heart is available. About 550 patients have received CardioWest hearts or earlier versions since 1985. Crucial to the growth promised by Ford is development of a more portable pneumatic “driver” to power the CardioWest TAH-t devices.

Unlike the AbioCor heart from **Abiomed** (Danvers, Massachusetts), which is totally implanted in the patient’s chest, the TAH-t is a pulsating biventricular device that replaces the patient’s left and right ventricles and is sewn to the patient’s

remaining atria. The device is connected to a driver by means of tubes back through the chest wall, that provides pulsed pressurized air and enables device monitoring.

SynCardia has been hampered, however, by the availability of just 37 drivers inherited from **Symbion**, a predecessor company. These drivers, supplying power and air to the TAH-ts, are called “Big Blues” for their filing-cabinet size and blue exterior finish. “We can sell more hearts than we can drive,” Ford told *Cardiovascular Device Update*. But the lack of additional Big Blues has turned out to have a beneficial effect, forcing the company to focus on “the foundation we’ve laid over the last year to systematize the business,” he said.

He said Syncardia is in the process of adding two smaller drivers, one from **Berlin Heart** – a “recovery driver, not a primary driver” that the patient transfers to after two, three or four weeks on the larger driver” – and another driver that it licensed from **Medos Medizintechnik** (Stolberg, Germany) that will replace a Big Blue. These alternate drivers have been submitted for CE-marking and the company plans to apply for FDA approval of the small primary driver – citing “equivalency” to its large driver – “later this year,” Ford said. ——— 🌐

SPECIAL REPRINT

Reprinted with permission of Thomson American Health Consultants,
P.O. Box 740056, Atlanta, GA 30374. For subscription information: (800) 688-2421.