



## Banking on an artificial heart

Ottawa's 14-month-old WorldHeart Corporation is confident that its product — HeartSaver VAD (ventricular assist device), the first totally implantable artificial heart — will be ready for market early in the next century. Shareholders attending WorldHeart's first annual meeting in May were told that even though the share price has fallen by more than \$1.50, to \$3.37, since the company went public last December, development of the device is on track and it should dominate an emerging industry that has huge growth potential.

"Our product represents an absolutely dramatic and generational breakthrough," said company chair Rod Bryden. "The market for this device is huge. It is potentially at least \$3 billion annually in Canada and the US, and at least \$10 billion world wide."

Dr. Tofy Mussivand (see *Can Med Assoc J* 1997;156:553-5), the company president, said WorldHeart plans to manufacture the first HeartSaver VAD before 1998, and several hundred more devices will be made over the following 2 years to allow for laboratory and animal testing. "In 1999 we will seek regulatory approval to begin clinical testing in humans" and "commercialization will begin in the year 2001."

The company has appointed a clinical advisory board chaired by Dr. Wilbert Keon, chief of cardiac surgery and founder and director general of the University of Ottawa Heart Institute (OHI), which includes members from Yale University, the Texas Heart Institute and the University of Pittsburgh. "No

competitor has been able to put [a board like this] together," said Mussivand.

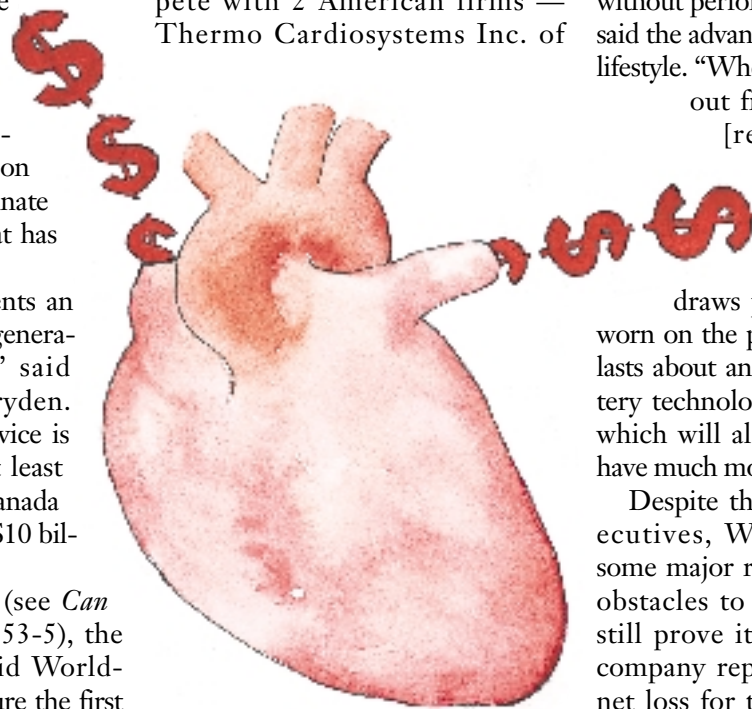
WorldHeart hopes the new board will raise its profile. It currently does virtually all its research and development at the OHI's Cardiovascular Devices Division. A higher profile might help it compete with 2 American firms — Thermo Cardiosystems Inc. of

the patient's chest, which provides both a psychological advantage for the patient and shorter connections between the VAD and the heart, thus reducing the risk of complications.

The most innovative features are the wireless remote power transfer and monitoring, which can be done without perforating the skin. Bryden said the advances add up to a normal lifestyle. "Whether going to work or out fishing on a boat, the [recipient] looks and feels almost totally normal." He added that the implanted battery, which draws power from a battery worn on the patient's belt, currently lasts about an hour. "However, battery technology itself is advancing, which will allow the individual to have much more freedom."

Despite the optimism of its executives, WorldHeart still has some major regulatory and clinical obstacles to overcome and must still prove itself financially. The company reported a \$2.5 million net loss for the year ending Mar. 31; it is not expected to generate revenue for several years.

But Bryden, part owner of the Ottawa Senators of the NHL, isn't worried. There is still money left from the initial share offering made last December, which raised \$18.7 million, and he believes the company will be able to raise an additional \$50 million or more through other public offerings, possibly beginning next year. By the time HeartSaver gets to market, it will have cost more than \$110 million to develop, including \$30 million in government grants made before 1996. — *Lynne Cohen*



Woburn, Mass., and the Chicago-based Novacor Division of Baxter Healthcare Corporation, which are already supplying VADs.

However, observers say the American devices fall short because they require wires through the skin to transfer power, air and electronic data, and are inserted in the abdomen. WorldHeart's product, designed primarily to provide left-ventricular support, weighs about 500 gm and is probably the smallest and lightest artificial heart yet developed. It is also the only one designed for permanent placement in