Biotech Daily
Marc Sinatra's Bioguide

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BIOGUIDE: VENTRACOR - A HEART BEAT AWAY

Overview: Back in mid-2003, Ventracor found blue sky and its share price rocketed to more than three dollars.

Then in a strange move, two US-based ventricular assist device (VAD) companies, Sunshine Heart and Heartware, listed on the ASX. The signal to me was clear, Australia was significantly over-valuing VAD companies.

While avoiding these companies has proved prudent, Ventracor's share price has fallen as low as 8.0 cents. Is it finally a good buy?

Financials: Market cap: $24 million; cash: $18 million; last half burn: $10 million.

Directors: Non-executive chairman, John Ward; CEO, Peter Crosby; non-executive directors, Ross Harricks; Elizabeth Nosworthy; Jeffrey Goodman; William E Curran. Ventracor's board has a solid and balanced mix of individuals focusing on medical devices. In particular, CEO Peter Crosby has an exceptional knowledge of the industry.

Products on market or in development:
Ventrassist is a VAD designed to provide circulatory support for patients with severe or class IV systolic heart failure. It consists of an internal pump attached to the left ventricle and aorta via cannulae. An external controller and battery pack attaches to the pump via a percutaneous lead.

Ventrassist gained Conformitée Européenne (CE) Mark approval in December 2006. It is in two US registration directed trials; one a bridge-to-heart transplant (BTT) and the other a long-term destination therapy (DT) for transplant ineligible patients. Ventracor expects US Food and Drug Administration approval for the BTT indication in mid-late 2010 and for the DT indication in mid 2013. In 2010, Ventracor expects to modify the Ventrassist system such that the controller and battery pack are also implanted.

Last year, Ventrassist generated revenue of $17.3 million via the sale of 189 devices. Ventrassist's US Medicare classification means Ventracor is reimbursed for the device despite its investigational status.

Significant Product Markets: Five to seven million Americans have heart failure, approximately half with systolic heart failure. Five to 15 percent or 150,000 to 450,000 patients have symptoms of class IV heart failure. Five thousand heart transplants were performed in 2007, 1,692 in the US.

About 2,700 Americans are awaiting a transplant at any one time. The BTT market is about 1000 devices a year and Millennium research estimated the 2007 BTT market to be worth approximately $US75 million.

Six VADs have CE Marking, while only two have US FDA approval for BTT. A further three devices are in the early stages of, or close to, commencing US BTT trials. Two of these are third generation devices. Many more are in development.

About 25,000 - 75,000 US patients with class IV heart failure are suitable for destination therapy. One review indicated VAD sales were likely to be at the lower end of this range. All CE Marked VADs can be used in Europe for DT. No VADs are approved for DT in the US and only two, Ventrassist and Thoratec's Heartmate II, are in US trials for DT.

The idea of using VADs as a destination therapy is not new, but the reliability of available devices has been an issue. To increase reliability, newer devices have been greatly simplified. It is thought that when VADs can perform well for two years, DT will be viable.

Opinion: When analyzing Ventracor, two major questions arise; how big will the DT market be and how big a slice of it can they grab?

I favor market size estimates at the lower end of the range above. The reasons for this are primarily the invasiveness and the high cost of the procedure. Nonetheless, the low end still equates to a US market size of $US2.5 billion alone.

Ventracor has, and should garner further, significant revenues from Ventrassist. The company is two years ahead of its third generation rivals and is likely to be the second entrant into the US BTT market, behind Thoratec's second generation Heartmate II.

Other than Thoratec, competitors may find it hard to recruit patients given Ventracor has tied up many US trial sites and the small number of patients suitable for BTT trials. BTT patients also have the option of using an approved device rather than having to put up with the demands of a clinical trial. The same situation may arise in the DT space as well.

One disadvantage of Ventrassist is that, unlike VADs such as Heartmate II and Heartware's HVAD, the pump is placed in the abdomen, so the cannulae must go though the diaphragm making the surgery more difficult. But this disadvantage should vanish in the near future when implantable systems come into play and are likely to only be viable in the abdomen.

Ventracor's only real problem is it needs cash to ensure its strong position. When blue sky vanishes, as it does, share prices are left worse off than if it had never been found and it is happening to Ventracor in terrible market conditions. I have calculated a discount cash flow analysis valuation for Ventracor of 38 cents a share, contingent on a successful capital raising.

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