



2009 Annual General Meeting Chairman's Address

Sunshine Heart has a business that is relatively straight forward in the health care industry. Our product, the C-Pulse, is a mechanical device that is implantable through a relatively simple operation that takes about an hour. The device just gives a gentle push on the side of the aorta and this gives an additional pulse to move the blood around the body. The device is not in contact with the blood stream, so it does not cause clotting and needs no anti-coagulants. It is not a drug so it doesn't cause side affects or interact with other drugs. The device, being mechanical, either works or it doesn't. All the evidence to date shows it does work. And if, for any reason, the patient turns it off or for any reason it stopped working, the patient is no worse off than they were before the device was implanted. I say this because there are other heart assist devices where the patient dies if the device fails.

We know how to manufacture the C-Pulse, but before we can sell it, we have to convince regulatory authorities that firstly, it is safe and secondly, that the expected patient benefits can be justified by clinical results. The process of getting these approvals is, I am sure you are aware, notoriously challenging and during the year under review, in September last year, we achieved the milestone of FDA approval to begin the clinical tests.

This gave us the green light to start implanting patients and in April this year we achieved the next milestone of our first patients in the USA. Don will take you through the details of all this in his presentation. These first implants also represent our first sales.

You might wonder why arranging implants takes so long. Well, firstly, it is appropriate that any experimental medical device be thoroughly tested and doctors and hospital are understandably cautious and, at the start, tend to select only the patients with the most severe conditions to experiment on. And of course, the patients have to be prepared to be experimented on. The good thing is that, as the first patients are implanted and other potential patients can see that the operation is successful and the benefits of the C-Pulse are real and make a significant difference to a recipient's lifestyle, the rate of acceptance can be expected to increase, we hope quite quickly.

So now all our efforts are concentrated on completing the 20 implants in our first FDA trial. To some extent, this is like pushing on a piece of string. Unfortunately, there is only so much we can do in competing for time with very busy surgeons and to push hospitals to enroll suitable patients. But we are making progress.

Outside this, our main activity, the Company has been active in other areas. We are a developmental company with a huge potential market. We do not have any debt and we cannot sell our product outside the trials at present. Because of these characteristics, the GFC has not had a direct impact on our operations. It has, however, affected the environment in which we have to raise capital. So we have been preserving our cash and paying close attention to our costs. During the past year, we reorganized our structure to consolidate activities and reduce the number of overheads. We also thought it prudent to defer some of our development work until we had the capital to complete it.

Until our operations breakeven, our capital comes from our shareholders. In this regard, we were very heartened at the support for our recent capital raising. In August, we raised \$8.1 million, of which \$1.75m was from placements to new investors and the rest was from existing shareholders.

So that has been the year. For a small company, we have achieved a lot over the past year. We won the FDA approval, implanted our first patients, earned our first revenues and raised additional capital to allow us to continue on the strategic path we have committed to.

I thank Don Rohrbaugh, our CEO, William Peters, the inventor of the C-Pulse and our CMO and all the staff for their notable contributions over the year. I also thank my fellow directors for the close interest they take in the Company and their constant support and assistance.

Nicholas Callinan
Sydney, Australia
29 October, 2009