

## CEO Update

When I joined Sunshine Heart in late 2009, the focus of the Company was the completion of enrollment in the feasibility trial and rightly so. The Company added new sites and personnel in 2010 to help expedite the process. I am pleased to announce that we completed the 20th implant on March 31. To date, this is the most significant milestone the Company has achieved and many more are expected this year. I believe our Chairman Nick Callinan expressed it quite appropriately when he said that “we have now crossed the starting line.” While we are excited to reach this milestone, we firmly understand a great deal of work remains.



Dave Rosa  
CEO

Shortly after completing the 20th implant, we received additional positive news from the FDA. They approved our request for an expansion protocol to add another twenty patients and two sites. We were pleased with the FDA’s decision and have informed some of our high enrolling sites that they can implant additional patients under this new approval. While I do not expect to implant all 20 patients, we will continue to enroll patients at sites that have targeted additional patients for the therapy. Another notable event that occurred in the first quarter was the addition of Paul Buckman to our Board of Directors. Paul’s cardiovascular background and senior executive roles with both large public and privately held companies is an excellent complement to our existing Board.

Soon you will be hearing more about our plans to list the Company on NASDAQ, a requirement in our U.S. private placement

completed in December 2010. I would also like to inform you that in May, we will be accompanying the co-principal investigator of our feasibility trial, Dr. William Abraham and the trial’s leading enroller, Dr. Sanjeev Aggarwal to Australia to discuss heart failure therapies and where the C-Pulse System fits in the overall heart failure landscape.

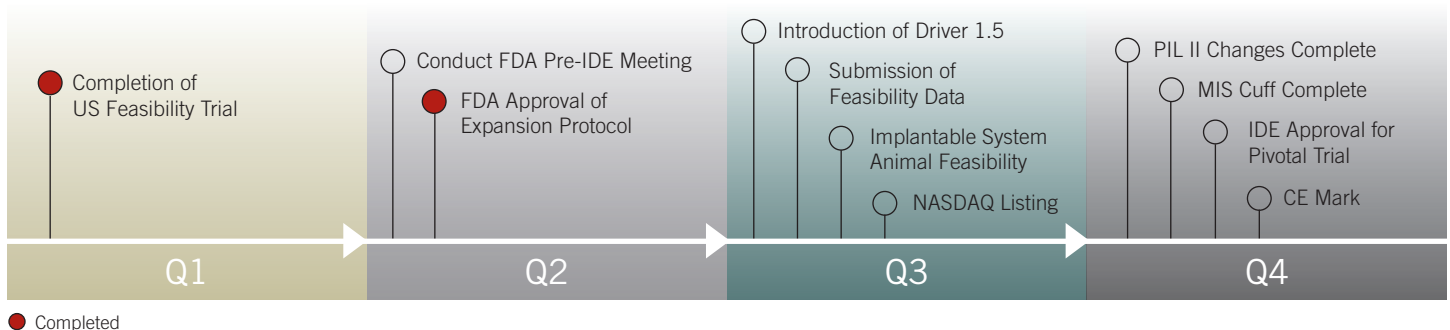
Finally, when I look at what we have recently accomplished and what we expect to accomplish this year, I can’t help but believe Sunshine Heart is one of the most undervalued companies in the medical device sector in the world. When you consider that we have a highly differentiated, minimally invasive technology in a billion dollar plus market opportunity in what many experts consider the fastest growing cardiovascular segment, it certainly suggests a significantly greater market value.

For many of you the ride with Sunshine Heart has been a long, and at times, frustrating journey. While every company goes through challenging times, some finally get to a stage where they get over the hump and garner momentum that leads to success. I believe we are at that point and expect great things in the near future. Also, I can tell you that feedback from the investment community and analysts that cover this space confirms we have a great plan in an exciting space.

Of course, none of this would be possible without dedicated employees and an intense commitment to achieving our milestones. While there will be bumps in the road, I expect that Sunshine Heart will be mentioned as another great Australian public company success story. It is my hope you will continue to support the Company as many of you have in the past so that we can continue to achieve our milestones.

Dave

## 2011 Milestones



# Technology Update

We continue to make great progress on our research and development goals. Our single unit system remains on schedule to be completed in the third quarter of 2011. This device will also be offered to existing implanted patients that meet select criteria. While the patients will have to visit their physician to upgrade to the new system, no surgical or medical procedure is required to upgrade the patients.



Prototype of new Driver.

Early last year we shared that we were targeting the end of the second quarter 2012 to demonstrate feasibility of our completely implantable system. We are very pleased that we expect to accomplish this goal by the end of the second quarter 2011. We have two physicians from our current sites that are confirmed to participate in the feasibility testing of this system. To see a future with a "Sync-Pulse" system that can connect to a pacemaker and be able to transmit the power through the skin with no cables or drive lines is truly exciting. Look for more news on this late second quarter.



Downsized driver is easier for patients to manage and is more comfortable.

# C-Pulse Clinical Trial News

As mentioned previously, we completed the 20th implant in March and received FDA approval for an expansion protocol. In addition, the FDA allowed us to open two new sites in the U.S. Two centers have been identified that we believe would be good targets for future patient enrollment. A previous newsletter mentioned some of our enrollment issues were related to site selection. To demonstrate how critical this is, 45 percent of the first 20 cases were performed by new sites that were on board for no more than six months. We have been asked what we learned from the first 20 patients and what we will do differently in the pivotal trial. Here are the lessons learned:

- Patients and physicians want a minimally invasive procedure
- Patients want a single unit system
- Our protocol made it challenging at times to enroll patients due to the inclusion and exclusion criteria
- Site selection is critical to enrollment

We have taken steps to address items one and two and we have already completed a draft protocol for our pivotal trial which incorporates suggestions from our physician advisory board to address item number three. I believe we know the type of hospital we need to target and the proof is in the enrollment results of our new sites.

After we have collected all the feasibility follow-up data, we will submit the report to the FDA. Once approved, we will submit our pivotal protocol for FDA approval. Also, we recently received feedback from the European regulatory agency we are working with that they will accept the data from our 20 patient feasibility trial to apply for CE mark. The end of this year is still targeted for this approval.

## New Company Hires

The Company added additional infrastructure in the first quarter of 2011. New hires included Sophia Rubalcaba, Director of Regulatory Affairs; Berk Tas, R&D/Director of Development; Sue Raddatz, Director of Supply Chain Management, Jeff Mathiesen, United States CFO and Khamporn Phanthanivong, Principle Engineer. These employees come from large medical device companies such as Boston Scientific and St. Jude Medical and smaller public companies. We are already beginning to build the infrastructure required to execute our pivotal trial plan and expect to continue hiring in the second quarter and beyond.



Khamporn Phanthanivong



From left to right: Sue Raddatz, Berk Tas, Sophia Rubalcaba, Jeff Mathiesen

# Personnel spotlights

*Editor's note: From time to time we will focus on one or two key members of the Sunshine Heart team. In this issue we have William Peters and Rodney Parkin.*

## William Peters, Co-founder

### What led you to co-founding Sunshine Heart?

This concept was based on my experience in developing minimal invasive (“port-access”) heart surgery and from training in transplant and LVAD surgery. I wanted to approach advanced heart failure with a mechanical assist system that avoided both sternotomy and blood contact. In addition, one that was able to be turned on and off electively and safely and that could be placed earlier with the view to inducing recovery in some. Crispin Marsh had written my earlier patents for minimally invasive surgery and on this approach he said ‘lets start a company.’

### What is your current role?

Fundamentally, I orchestrate the device design versus the limits of the human body and of engineering. I seek to find the minimalist of compromises across multiple design constraints from multiple disciplines and ongoing clinical feedback to achieve the best possible device form and function. It's a job that has also brought with it responsibilities I could not have imagined. I could not ask for a better job.

### How have you seen the company progress?

Sunshine Heart started as a virtual company hosted Balmain harbour-side by Crispin Marsh and with clinical support from Mr. Paget Milsom and Dr. Malcolm Leggett (Founding consultants), Auckland City Hospital and from Profs Cliff Hughes (Chairman ANZ DSMB), Geoff White (Founding director) and Colin Sullivan (Founding consultant), all of Royal Prince Alfred Hospital, Sydney University. Today the company is a primed medical device start-up company headquartered in Minneapolis with a US Feasibility IDE study that has completed enrollment of 20 patients worldwide. During the past months, Dave Rosa has worked relentlessly and with passion and vision to set the stage for rapid growth with an international team of physicians, engineers and regulators working toward a common purpose: development of a safe and effective mechanical heart assist device.

### What did the 20th implant mean to you?

Completing enrollment of the 20th implant represents a nodal transition in Sunshine Heart company development and great credit is due to Dave Rosa and Debra Kridner for making it happen. After 11 years, to see the company to this stage, it's a wonder as to the efforts of all involved over the years to have achieved this milestone; my deep thanks to all concerned. I'm looking forward to seeing Sunshine Heart progress in its aims for delivering a novel form of mechanical circulatory support.



William Peters, MD, Medical Director and Chief Technical Officer; Board of Directors; company co-founder (left) Rodney Parkin, Director of Clinical Engineering (right).

## Rodney Parkin, Director of Clinical Engineering

### When did you start with the Company?

My first involvement with Sunshine Heart was in December 2001. I was a consultant helping to facilitate a “QFD program” where we identified the basic customer requirements of what was later to become known as C-Pulse. This meeting was attended by a cross-functional group which included Will Peters, Dr. Peter Ruygrok (one of Will's colleagues from Auckland), Crispin Marsh, and various engineering and regulatory contributors (including Scott Miller and Arthur Brandwood). I formally became a full-time employee in December 2008.

### What is your role at Sunshine Heart?

My current role is as Director of Clinical Engineering. I am responsible for ensuring that C-Pulse is correctly and effectively set-up and used — although in practice this is very much a team effort with Will Peters and Tammy Davis. The role includes providing training to sites in the use of the C-Pulse Driver and Programmer and providing technical support on-site by phone and e-mail. Also, I'm responsible for ensuring that sites are supplied with the C-Pulse product they require to perform and support implants. I act as an interface between Product Development and the sites — passing field experience back to the engineers, and passing new engineering information about the devices back to the sites. I've been part of Sunshine Heart for a long time and as a result I get involved in quite a range of activities in the company such as managing our IT systems and helping to create prototypes of our next generation device.

### What did the 20th implant mean to you?

The 20th implant was a culmination of over 10 years of ups and downs for Sunshine Heart, and it seemed so long in coming. Even in the last few days we weren't sure where and when the 20th implant would occur. But when it did happen, it all went so smoothly, the team was by now so practiced that we all did our bit and it just happened.

## Congratulations to St. Luke's in Kansas City, Missouri

We would also like to express our appreciation to Dr. Sanjeev Aggarwal, implanting surgeon and Dr. Steven Kao, heart failure cardiologist and their entire staff. They completed five implants with our device and were the leading enrollers in the trial. They averaged approximately one implant per month and performed all implants minimally invasively.

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## Website Enhancements

Hopefully by now you have all had the chance to review the new Sunshine Heart website, [www.sunshineheart.com](http://www.sunshineheart.com). The launch of any new website is just the foundation. Continuous changes and enhancements should be expected to keep viewers interested and coming back to your website. We are working on the following enhancements, some of which will be obvious while others are behind the scenes:

**Search Engine Optimization (SEO)** — an audit has been conducted by using key search terms and reviewing competitive search terms. This allowed us to see where Sunshine Heart will appear if a search term is entered into a Google search. “Tags” will be added as well as links to increase the presence of Sunshine Heart when a search is performed.

**Newspaper articles and News Stories** — over the past year there have been several newspaper articles and new stories that include video that positively highlight the company. We are looking to incorporate the actual articles and video into the news section.

Currently if they appear, it is in the news section and it contains no images or video. Having these available in their original state will provide additional credibility from outside sources about the company.

**C-Pulse Live Case** — a minimally invasive case performed by Dr. Aggarwal will soon be available on the site. The case will be broken into sections that will have call outs to easily go to the part of the case that is of interest.

**URL icon** — the C-Pulse logo “C” has been added to the URL address when you go to the website. Previously it contained an icon from



the hosting company. The “C” appears before the URL. Although not a major change, it is an opportunity for continued company branding.

**Animation** — on the main site page, an animation teaser will be added to the “C-Pulse Heart Assist System” section to show how the C-Pulse System works.

Look for these enhancements and changes to the website over the coming weeks. We appreciate the compliments that we have gotten on the site and also the feedback on things that would continue to improve the site. If you have ideas or comments please use the “Contact Us” section on the site.

CORRECTION: This PDF corrects a typographical error. Rodney Parkin was misspelled Rodney Parkins in the Personnel spotlights section of this newsletter.

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### Forward Looking Statement

Statements in this document that are not purely historical are forward looking statements. Various factors could cause actual results to differ materially from any forward looking statement, such as the timing and outcomes of clinical results including the efficacy of products, financing availability, and product sales and marketing. Whilst we believe any forward looking statement made to be reasonable as of the date hereof, we can give no assurance that our expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.

### US Securities Statement

The shares of Sunshine Heart have not been registered under the Securities Act of 1933 (the “US Securities Act”) and may not be offered, sold or delivered in the United States, or to, or for the account or benefit of, any US Person, as such term is defined in Regulation S of the US Securities Act. In addition, hedging transactions with regard to the shares may not be conducted unless in accordance with the US Securities Act.

C-Pulse is a trademark of Sunshine Heart, Inc. AND is registered in the United States Patent and Trademark Office. The C-Pulse System is undergoing clinical evaluation and is not available for commercial sale.  
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