ventracor

asx announcement

Heartware claims on Ventracor's ASX announcement platform

Sydney, 17 March 2005: Yesterday a shareholder update issued by Heartware Limited was posted on Ventracor's ASX announcement platform.

Ventracor Chairman, John Massey said: "We wish to make it very clear this announcement was not authorised by Ventracor Limited.

"As previously reported to the ASX, VentrAssist Pty Ltd (a wholly owned subsidiary of Ventracor Limited) and the University of Technology Sydney (UTS) have commenced legal proceedings against US-based Heartware Inc, a company we believe is infringing two of our US–registered patents.

"In this litigation, our US lawyers recently filed court documents, including sworn declarations, rejecting claims by Heartware Inc that the litigation was not properly commenced.

"This US litigation was initiated after careful consideration of public statements made by Heartware Inc in relation to its heart assist device, its operations and its plans.

"We have commenced this litigation, and will pursue it, to protect our valuable intellectual property portfolio relating to the VentrAssist™ left ventricular assist system (LVAS).

"We firmly reject any assertions by Heartware Limited or Heartware Inc to the contrary.

"Ventracor rejects the claims made yesterday in Heartware's shareholder update that the litigation against Heartware Inc is frivolous.

"Ventracor will keep shareholders updated through ASX announcements and our website.

"For the record we attach our recent shareholder update which clarifies Ventracor's position," Mr Massey said.

About Ventracor
Ventracor (ASX:VCR) is an international medical technology company that has developed a life-saving heart pump, the VentrAssist™ left ventricular assist system (LVAS), for patients in cardiac failure. The company is focused on commercialising the VentrAssist™ and bringing it to global markets in record time. Ventracor is confident of obtaining a significant share of the massive LVAS market, which independent analysts expect to be valued at between $US7.5 billion and $US12 billion per year.

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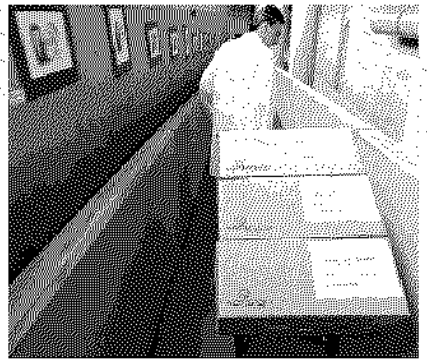
the heart company

ventracor NEWS

February 2005

US trial submission on track – reimbursement a big benefit



Ventracor's IDE submission comprised more than 10,000 pages. This photo shows Ventracor's FDA submission to begin a clinical trial being shipped just before Christmas 2004.

As we begin a new year, Ventracor is in an exceptional position within its market segment.

We recently submitted our investigational device exemption (IDE) application to the FDA to conduct trials of the VentrAssist™ in the USA and are now working closely on preparations with our partners at Columbia University's International Center for Health Outcomes and Innovation Research (InCHOIR).

We are greatly encouraged by evidence that device costs for our US trial will be eligible for reimbursement by government and private insurers.

Reimbursement is available for FDA approved devices during clinical trialling for 'Category B IDE devices'. We expect the VentrAssist™ system to be classified as a Category B, IDE device and be eligible for reimbursement during our US clinical trials.

With the estimated global market for technology like the VentrAssist™ independently estimated to be worth more than US$5 billion in coming years, Ventracor enjoys a considerable early leader advantage in a new and growing global medical device market.

We have strong cash reserves, a very strong intellectual property position and several clear technical advantages we believe will help accelerate the commercialisation of an important solution for the world wide problem of heart failure.

We will soon begin a focused marketing push as we lay the foundations for our future distribution networks in Europe and the USA.

We are enlisting the support of influential clinicians who will ultimately prescribe the product to patients.

We will implement a strong service and support structure for cardiologists who are an important link in the decision making process.

Our trial for European approval is well underway at all major heart transplant centres in Australia.

Clinical trial sites in the UK and New Zealand will come online shortly. Together with participating medical investigators, we are very encouraged by the early clinical results to date.

Everyone here at Ventracor is focused on maintaining the tremendous progress we have made over the past 12 months.

I look forward to being able to report to you on the formal start of our clinical trial in the USA and the finalisation of recruitment in our current CE Mark Trial. Thank you for your continued support. Together we are building another great Australian medical device company.

Colin Sutton PhD Chief Executive Officer

Legal action against Heartware Inc

Ventracor Limited has initiated legal action against the US-based Heartware Inc, a company we believe is infringing two of our US–registered patents.

Ventracor provided Heartware with the opportunity to enter a negotiated settlement to avoid the necessity of legal action. We do not see Heartware as a commercial threat and support the development of solutions for the worldwide medical problem of heart failure.

However, we cannot allow our intellectual property to be wilfully infringed. Ventracor has taken this step based on the very best available legal advice here in Australia and the USA. We will keep shareholders updated through ASX announcements and our website.

Commercialisation milestones

Achieved

- ✓ CE Mark trial commenced in Australia, New Zealand and UK
- ✓ Pilot trial environment completed
- ✓ Completed FDA trial design negotiations
- ✓ Submitted Investigational Device Exemption (IDE) to FDA

Pending

- • Approval to start US clinical trials by Columbia University
- • Complete CE Mark Trial enrolment end 2005
- • Submit CE Mark trial submission by end of 2005
- • First sales in Europe 2006

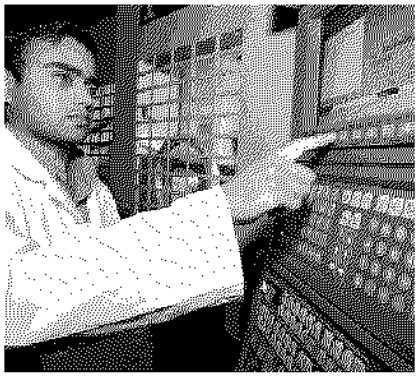
New multi-million dollar global manufacturing facility online

Ventracor has recently commissioned a new 260sqm clean room and manufacturing facility at its Sydney headquarters. Currently, several processes in the manufacture of the VentrAssist™ system are outsourced.

Our new facility gives our engineers and technicians a manufacturing area in a bio-controlled environment (electrostatic discharge, air quality, temperature, humidity and pressure are all controlled) to produce the device to the highest international standards.

As such, a substantial portion of manufacturing can now be brought inhouse. This gives Ventracor control over critical processes and ensures compliance with quality standards required by the relevant regulatory authorities in Europe and the USA.

Our manufacturing investment includes the highly specialised equipment required to produce Class III Active Implantable Medical Devices. The new facility is manufacturing more than 200 devices per annum. This initial production rate is less than full capacity but sufficient to service our clinical trial needs.



A technician operates one of Ventracor's new computer-controlled milling machines.

We have also invested in an additional computer controlled precision milling facility at Kirrawee in Sydney (see picture). This additional hi-tech facility ensures our manufacturing capacity will meet the demand for implantable systems required for European and USA trials and beyond.

A specialist technician at Ventracor's new world-class production facilities with a new VentrAssist™ .

CE

CE Mark Trial designed to get approval data as quickly as possible

Ventracor's CE Mark Trial now underway is aimed at gathering data to support an application for permission for the current notified body to apply the CE Mark to the VentrAssist™ so it can be sold in the major market of Europe. To collect appropriate supporting data as quickly as possible, the trial process has been divided into two sub-groups:

- patients requiring a bridge-to-transplant (BTT)
- patients requiring a permanent implant or 'destination therapy' (DT)

Patient recruitment for the current CE Mark Trial is scheduled to close mid-2005. This trial is the last step in product validation to demonstrate the VentrAssist™ is safe and efficacious for Europe as its first intended market. Regulatory approval for Europe will expedite global commercialisation.

UK office supporting European trials and distribution

Our UK office is now open. Ventracor (UK) Limited is manned by experienced staff who will drive European distribution and play an important support role for European hospitals trialling the VentrAssist™.

Staff in the UK will work closely with Papworth Hospital in Cambridge and other European implant centres.

Our partners at Papworth Hospital established the UK's first transplant program and performed the UK's first successful heart transplant in 1979, followed by Europe's first heart-lung transplant in 1984.

Papworth is a pioneer in the use of mechanical heart assist devices and recently celebrated the 10th anniversary of its left ventricular assist system (LVAS) program.

Papworth Hospital is one of only three designated centres in the UK to perform LVAS surgery for patients with heart failure.

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