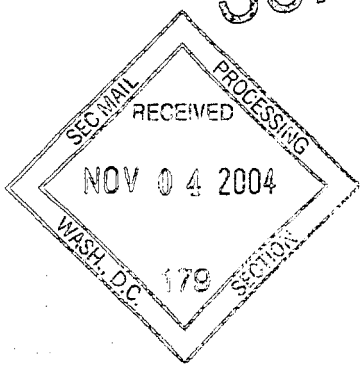
ventracor

Ventracor Limited
ABN 46 003 180 372
126 Greville Street
Chatswood NSW 2067
Australia
T +61 2 9406 3100
F +61 2 9406 3101
W www.ventracor.com

22 October 2004

Securities and Exchange Commission
Division of Corporate Finance
Office of International Corporation Finance
450 Fifth Street, NW
WASHINGTON DC 20549
USA

SUPPL



Dear Ladies and Gentleman

Re: Ventracor Limited
File # 82-4630

Ventracor Limited (the "Company") is furnishing herewith information pursuant to Rule 12g3-2(b)(1)(i) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The attached documents are being furnished with the understanding that they will not be deemed "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter nor the furnishing of such documents shall constitute an admission for any purpose that the Company is subject to the Exchange Act.

If you have any questions or comments please call the undersigned at (61) 02 9406 3100.

Very truly yours

pp
K. Callaghan

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FINANCIAL

Andrew Geddes
Corporate Communications

encls

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ventracor

The ALFRED — Service and Care

asx announcement

First VentrAssist™ Bridge-to-Transplant

Sydney 22 October 2004: Medical investigators today announced a patient implanted in June with its 'artificial heart' for temporary heart support had received a heart transplant at The Alfred hospital.

Chief Medical investigators, Professor Don Esmore and Professor David Kaye, said the patient, who was near death at the time of the VentrAssist™ implant, had been supported out of hospital and had had a greatly improved quality of life while waiting for a transplant. "The VentrAssist™ allowed us to rehabilitate the patient, get him out of hospital and gave us time to find the right heart for him," said Professor Esmore.

Earlier this year, the Pilot Trial criteria were widened to include patients requiring the VentrAssist™ as a temporary assist as 'bridge-to-transplant' until a donor heart became available.

Chief Executive Officer, Colin Sutton PhD, said broadening the Pilot Trial to include heart failure patients on heart transplant waiting lists had been a positive step in the clinical trial process for the VentrAssist™ left ventricular assist system (LVAS) and would accelerate the regulatory approval process.

Dr. Sutton emphasised the primary market for VentrAssist™ remained as a permanent alternative to a heart transplant, but that "bridge" cases such as this added valuable clinical data.

The cumulative time on support by Pilot Trial patients has reached over 3.5 years with the first patient who received the system as a permanent implant marking 17 months of support.

During the pilot trial, nine patients have been implanted with the Ventrassist. Of those patients five continue to do well and four others have passed away. The pilot trial is now complete and no further announcements will be made about the trial.

"We will continue to monitor all implanted patients according to the follow-up schedule and protocol but we believe the encouraging results reinforce the decision to open other clinical centres both here and overseas," Dr. Sutton concluded.

For more information, please contact:

Andrew Geddes
Ventracor Limited
Manager, Investor Relations
02 9406 3086

Trisha Lee
The Alfred
Manager, Public Affairs
03 9276 2266

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25 October 2004

Securities and Exchange Commission
Division of Corporate Finance
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450 Fifth Street, NW
WASHINGTON DC 20549
USA

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Very truly yours

per K. Callaghan

Andrew Geddes
Corporate Communications

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ventracor

asx announcement

Ventracor to Appoint New Director

Sydney 25 October 2004: Ventracor Limited (ASX: VCR) today announced that it intends to appoint Mr. Ross Harricks, who has extensive international medical device experience, as a Non-Executive Director when it next meets on the 12th November 2004 subject to completion of necessary formalities.

Mr Harricks is founder/CEO of AtCor Medical Pty Ltd, an Australian medical device company that is actively expanding its penetration of the US cardiovascular market for its leading SphygmoCor Px diagnostic technology which is already widely distributed in Europe.

Ventracor Chairman John Massey said Mr. Harricks clearly understood the international expansion process Ventracor was undertaking and his experience, particularly in the cardiovascular medical device area, would add value to both the Board and the company.

Mr. Harricks was a Director of ResMed for five years until 1995. Prior to this he was with the Nucleus Group having joined in 1983 as Group Marketing Executive responsible for international markets and was based in the US from 1985. Previously he was general manager of EMI Medical Pty Limited.

Mr. Harricks has extensive experience building a successful medical equipment distribution business in the USA as President of one of the Nucleus Group medical equipment subsidiaries.

He holds a Bachelor of Science, a Bachelor of Mechanical Engineering and a MBA from the European Institute of Business Administration (INSEAD) in France.

For further information, please contact:

John Massey
Chairman
Ventracor Limited
07 3868 4958

ventracor
the heart company

Annual General Meeting

Brisbane, 25 October 2004

Address to shareholders by Chairman John Massey

Ventracor is a company in rapid transition and the past year is no exception. Ventracor has passed a number of critical milestones and the focus on commercialising our leading VentrAssist™ cardiac assist device has continued apace.

I find it frustratingly difficult to explain in written or spoken words just how much progress has been made as Ventracor evolves into our vision of becoming a world competitive medical device company.

The progress we have made this past year is again testimony to an excellent team effort involving many talented and committed people, both within and outside the company. You will readily see on page 10 of the Annual Report that we are attracting outstanding and well experienced people to join the Ventracor team. I will return to this important topic later.

The more significant milestones this year were the completion of the Pilot Trial designed to determine the safety of the device in humans, and the commencement of the Pivotal Trial to support our CE marking application to obtain approval to sell throughout the European Union.

I publicly recognise the contribution being made by the gravely ill patients, and their families, as part of the process of being able to offer the VentrAssist™ to the hundreds of thousands of people worldwide who, like them, are suffering advanced heart failure.

I also acknowledge the many highly skilled professionals involved in the Pilot Trial and in particular, Professors Don Esmore and David Kaye, the medical investigators at The Alfred Hospital who led the successful Pilot Trial.

As we move into the four centres in Australia, the one in New Zealand and the initial one in Europe, it is gratifying that we are receiving the support and commitment from well recognised experts to participate with us in the Pivotal Trial programme.

This year has seen a rapid expansion of our facilities in Chatswood and the opening of a new facility at Kirrawee, south of Sydney, which typifies the pace of our progress. The upgrading and expansion of our manufacturing facilities including new clean rooms and assembly areas, the installation and commissioning of our own sterilisation capability and the redevelopment of all the other research and development and working environments represent the practical implications of Ventracor's move to bring all critical processes in-house.

Ventracor has also entered into an agreement for the supply and implementation of a sophisticated carbon coating chamber and we have also contracted the International Centre for Health Outcomes and Innovation Research of Columbia University in New York to design and conduct the US clinical trials programme.

Ventracor has already engaged or is in the process of engaging the best international advisers available to work with us in attracting maximum reimbursement for VentrAssist™ both during the clinical trials and beyond, as well as experts in the US and Europe to become involved in clinical engineering support and clinical training.

The Board and Management have concentrated considerable energy on identifying and minimising the potential risks to Ventracor's business.

Internal compliance and control systems for the operational and compliance activities, and associated management systems have been thoroughly reviewed and a comprehensive risk management process implemented.

A critically important element in being able to focus on the speedy commercialisation of VentrAssist™ was the decision to undertake the two tranches of fundraising during the second half of calendar year 2003.

The placement and rights issue raised approximately $67 million gross which has placed Ventracor in a significantly better financial position than many other similar companies both here and internationally, including most of our potential competitors worldwide.

At the end of the financial year Ventracor had cash in the bank of $60 million which has allowed, and will continue to allow, the process of commercialisation to be accelerated in an optimal manner without the inhibition of a lack of financial resources.

Total expenditure increased in line with expectations from $14.9 to $18.8 million during the financial year. $7.2 million of this was incurred on manufacturing, production, clinical affairs, regulatory affairs, quality assurance and clinical training to support current and anticipated clinical trial activity, and a further $3.6 million was expensed for research and development expenditure. The loss for the year was $15.9 million.

In my opinion based on internal and external assessments, the Board has led Ventracor successfully over the year and set the standards for the company generally. We are committed to sound

Corporate Governance standards which need to evolve and keep pace as Ventracor develops. Current details of our Corporate Governance regime are included in the Annual Report and changes are incorporated on the website when they occur.

The Board has again undertaken an independently facilitated Board Performances Review which assesses both collective and individual contributions.

As I foreshadowed in the Annual Report, the Board has decided to add an additional independent Non-Executive Director with broad commercial skills and experience gained in the international medical device industry. As a result of a broadly based search, I am pleased to announce that, subject to completion of the necessary formalities, the Board intends to appoint Mr Ross Harricks as a Director at its next meeting on 12 November 2004.

Ross' qualifications include having a Bachelor of Science (in Maths and Physics), a Bachelor of Mechanical Engineering with Honours and a Masters of Business Administration from the European Institute of Business Administration (INSEAD) in France. His work experience includes being General Manager of EMI Medical before

joining the Nucleus Group in 1983 which was then the leading international medical technology group, including both Telectronics and Cochlear, as the Group Marketing Executive responsible for international markets.

Based in the United States from 1985, Ross was, for some years, President of Nucleus subsidiaries which included building a successful USA medical equipment distribution business.

Ross has also been involved with "start-ups" and was a Director of ResMed Limited for 5 years until 1995. At present he is the Founder / CEO of AtCor Medical which has completed FDA approvals for a new cardiovascular device and is expanding its penetration of the US market.

Ross understands the process that Ventracor is undertaking and his experience, particularly in the cardio vascular medical device area, will add value to both the Board and the Company generally. As a matter of course, shareholders will have the opportunity to endorse Ross' appointment at next year's AGM.

It is our Managing Director and Chief Executive Officer, Dr. Colin Sutton and the professional and dedicated team which has made this a successful year.

Last year at the AGM you will recall that I introduced the original six scientists who worked on the VentrAssist™. So that you have a direct opportunity to meet some of the new people working at Ventracor, as part of Colin's presentation to you, he will introduce five of the new important senior people who have joined Ventracor over the year as well as one of the inventors, Dr John Woodard. I am sure you will again be impressed by these people.

The ongoing successful performance of Ventracor is heavily dependent on the commitment and dedication of the highly skilled members of staff. That is why the Board is recommending that Ventracor introduce long-term incentive plans to reward staff at various levels, to ensure their continuing loyalty and to allow them to participate in the long-term increase in shareholder value from the input of their considerable expertise and experience.

On behalf of the Board, I express our appreciation of the ongoing support, commitment and indeed, passion of our shareholders.

Another chapter has been written in Ventracor's history as we rapidly evolve into a worldwide medical device company. We have the product, the skills and the will to succeed and deliver real value for our shareholders.

I formally present the Financial Statements for the year ended 30 June 2004, together with the Reports of Directors and Auditors thereon for your consideration.

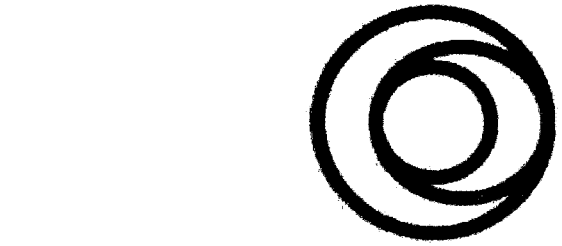
It is now my pleasure to introduce Dr. Colin Sutton to support my presentation.

John Massey

Chairman

25 October 2004

(ends)



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Ventracor Limited

2004 Annual General Meeting

Hilton Hotel
190 Elizabeth Street
Brisbane QLD

Monday 25 October 2004

04

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Proceedings

Chairman's address

CEO's Address

Formal Resolutions

04

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Ventracor Limited

Chairman's Address

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CEO 's Address

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summary of financials

- FY04 loss $15.9 million
- Cash at bank $53.9 million (30 September 2004)
- Monthly cash burn $2million (includes interest revenue)
- Capital equipment expenditure - $3.2m (FY04).
  (Budgeted to spend a further $7.3m in FY05 mostly on diamond coating, fabrication, milling machinery and Kirrawee facility)
- IP protection expenditure approx $200,000
- R&D expenditure of $3.6m (up 16% on FY03)
- Production and QA $4.9m (up 58% on FY03)
- Regulatory submissions and clinical trials $1.7m
  (up 207% on FY03)

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established CEO's objectives

- accelerate product registration/approval
- formalise internal systems
- strengthen organisational structures
- strengthen management team
- increase manufacturing capacity to ensure product supply throughout the clinical trial
- substantially lower product costs without compromising quality and service
- establish clear milestones and manage to them

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accelerated product approval

- regulatory approval in Europe and then USA
- ensure achievement of milestones is top priority
- time based management
- seeing over the horizon
- insightful project planning and management
- matrix product development structure with cross functional teams

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formalised internal systems

- Compliance with worldwide medical devices legislation a pre-requisite
- Upgraded quality system
- Streamlined work instructions
- Audit by Benchmark – ISO9001 accreditation
- Established design control function
- Demonstrated management control

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increased manufacturing

- currently 200 units per year
- not full capacity but sufficient for clinical trials
- new manufacturing capacity
- reducing manufacture time from months to weeks
- COGS reduction next
- commissioning of in-house sterilisation facility
- diamond coating contract
- in-house fabrication
- future consolidation / co-location

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strengthened management team

- new Regulatory Affairs Manager
- new head of Manufacturing and Engineering
- new Quality Assurance Manager
- additional Clinical Studies Associates
- intellectual Property and Information Technology departments are strong
- risk management formalised

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management team

- Roman Greifeneder, Manager, Manufacturing and Engineering
- Victor Windeyer, Program Manager
- Dr Jeffrey Lee, Manager, Quality Assurance
- Valentina Theisz, Manager, Regulatory Affairs
- Dr Monica Hope, Head of Quality, Regulatory and Clinical Affairs

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Roman Greifeneder

Industrial & QA engineer, originally a tool maker

specialist in new product introductions

engineering management of medical devices Class II & Class III

Work experieince in USA, Japan, Belgium, Germany and China

Manufacturing Engineering Manager with ResMed

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Roman Greifeneder

Manage and coordinate teams responsible for transferring manufacturing processes into manufacturing.

Ensure manufacturing processes compliant with all regulatory requirements (GMP) and operate at an acceptable level of performance.

Maintain site equipment standards for purchasing, installation commissioning and handover.

Ensure manufacturing equipment is procured and installed, commissioned and validated to established site standards, suitable for purpose expected.

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Victor Windeyer

Ove Arup – Mechanical Engineer

Cochlear Limited – Mechanical Engineer

ADI Limited – Manufacturing Manager

Clyrcom Limited – Engineering Manager

Invetech Pty Ltd – Program Manager

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Victor Windeyer

Manage company resources to develop and deliver products, processes and projects in line with the corporate goals

Manage teams responsible for R&D, clinical and regulatory, manufacturing, marketing, strategy and administration to

Help deliver VentrAssist to market as soon as possible.

Minimise and manage risks that could threaten goals and strategy
Contribute to the development of corporate goals and strategy.

Dr Jeffrey Lee

More than 16 years experience in development and maintenance of US FDA, TGA and EU standard quality assurance systems.

Head of Quality Assurance and regulatory management with several global health care equipment manufacturers including ResMed.

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Dr Jeffrey Lee

Ensure implementation, maintenance and compliance of the quality system to meet strategic marketing objectives

Implement quality system processes capable and compliant with Australian, European and American regulatory requirements for active implantable medical devices

Manage and coordinate the team responsible for QA and QC to deliver company quality assurance requirements.

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Valentina Theisz

Qualified electrical engineer

Registered ISO 9000 auditor

Quality Assurance Manager for start-up medical company

Former Manager Regulatory Affairs with ResMed

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Valentina Theisz

Prepare successful regulatory submissions and provide regulatory support and advice to departments regarding requirements for regulatory submissions

Prepare regulatory strategy and administer medical device reporting, vigilance, post market surveillance, adverse event reporting post-trial phase

Participate in product development and modification as part of the cross-functional team

Manage resources and budget for regulatory compliance, report to management on regulatory status and issues.

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Dr Monica Hope

Qualified Pharmacist

Research Scientist with Cancer Research Institute

Sirtex Medical (active implantable device for liver cancer)

Head of Quality Assurance, Clinical and Regulatory Affairs

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Dr Monica Hope

Coordinate product clearance to market with production

Ensure regulatory submissions are supported by a compliant quality system and clinical trial trials

Ensure adequate resources for implementing and maintaining internal compliance

Provide CEO and Strategic Planning with data and current status.

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Monica Hope

Implementation of updated quality system

Compliance, training, audit, data review systems functioning

Implement risk management strategy

Risk management strategy established, risk data collated and trended

Regulatory clearance for CE trial and US bridge trial

Plan and initiate trials and sites as required

Plan US bridge trial for implementation early 2005

Manage and report on clinical data as required.

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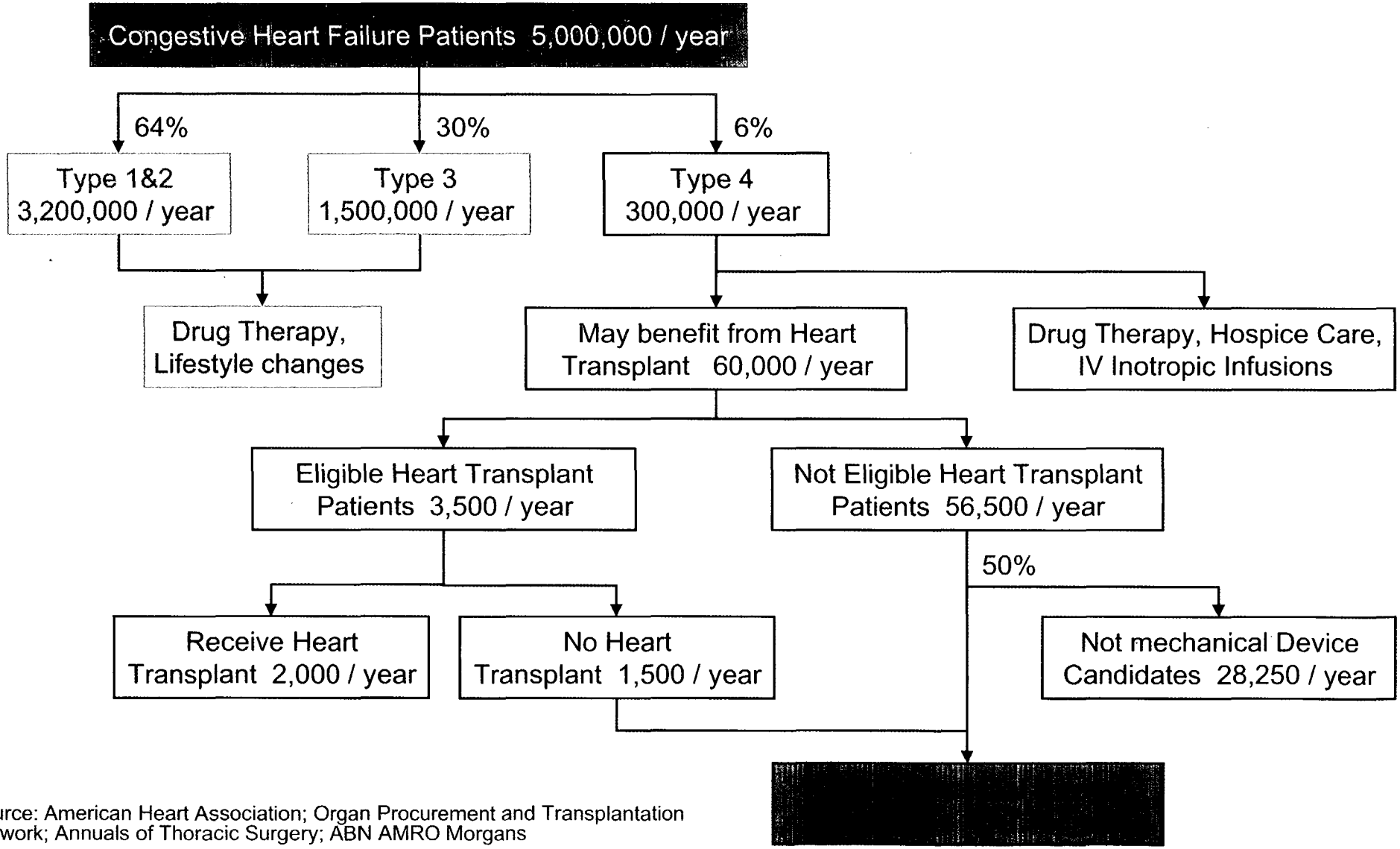
Ventracor Limited

Dr John Woodard

04

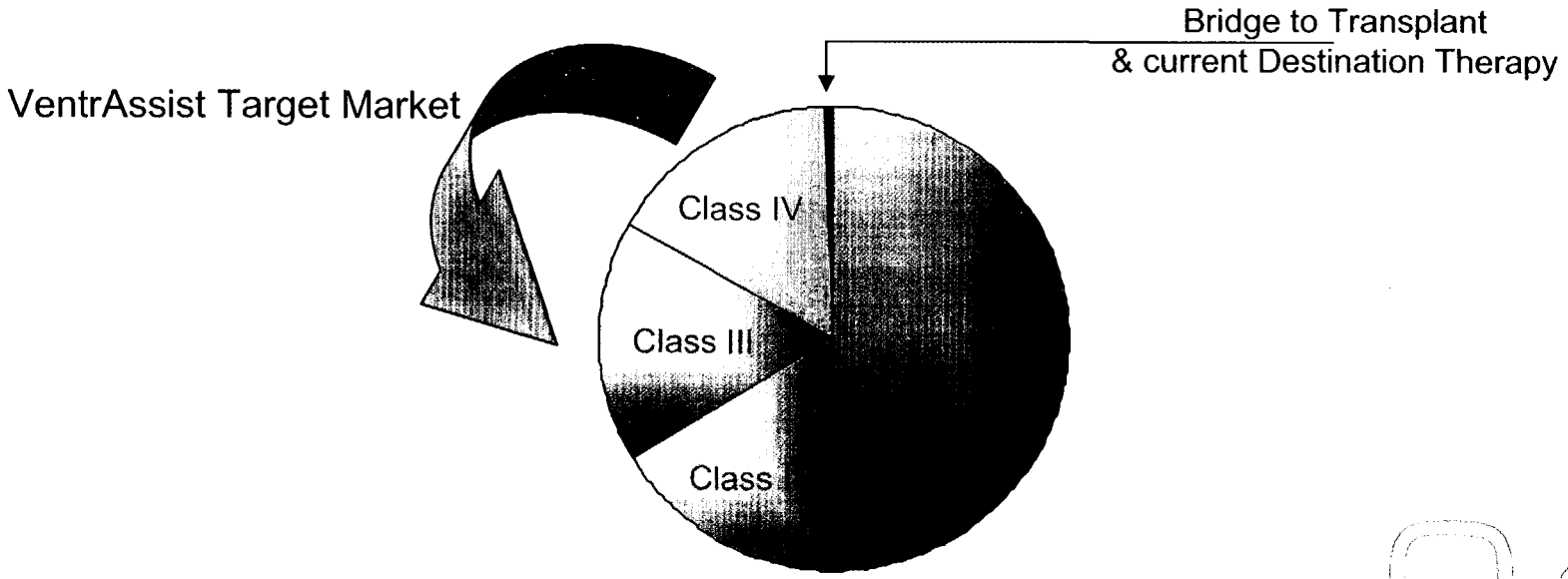
market potential – usa



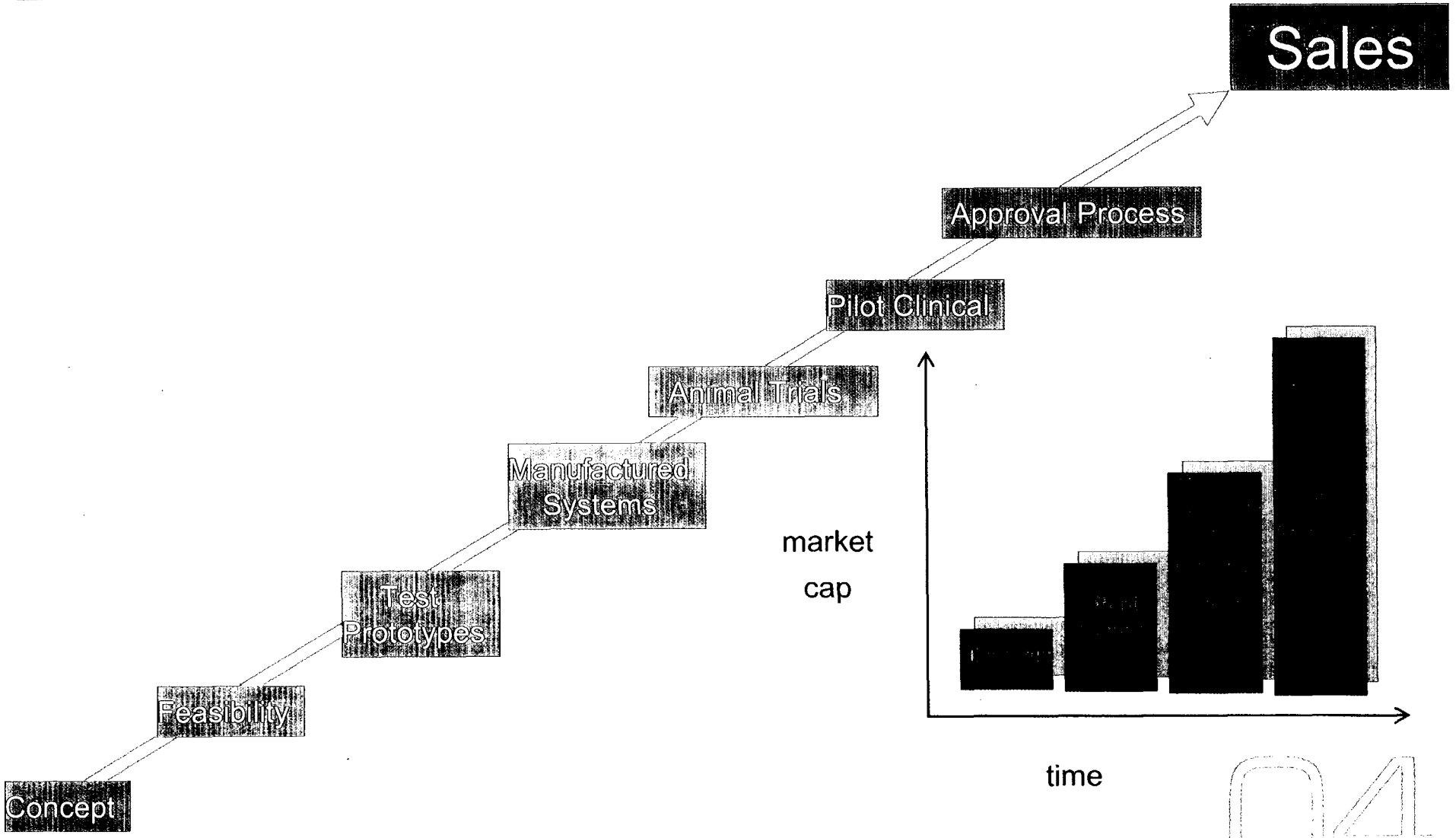
Source: American Heart Association; Organ Procurement and Transplantation Network; Annuals of Thoracic Surgery; ABN AMRO Morgans

increasing markets

- First and Second generation devices target Bridge-to-transplant
- Less sick Class IV and Class III could benefit from more aggressive therapy
- VentrAssist will target Bridge, Alternative as well as Recovery markets
- Marketing focus on selected number of world's best hospitals



we've come a long way



current clinical status - highlights

Pilot trial successfully completed

- first patient now at 17 months
- no serious device issues

European (CE trial) now underway

- 3 implants to date
- many more implants soon
- backup centres also lined up

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third generation devices

Type of LVAS	Company	Product	Implants to date	FDA approval	CE Mark
Magnetic levitation centrifugal	Terumo	DuraHeart	9	No trials planned at this stage	Clinical trials
	Thoratec	HeartMate III	0	No trials planned at this stage	No trials planned at this stage
	MedQuest	HeartQuest	0	No trials planned at this stage	No trials planned at this stage
Magnetic axial levitation	Berlin Heart	Incor	160	No trials planned at this stage	CE Mark
Hydrodynamic centrifugal	Arrow International	CorAide	1	No trials planned at this stage	Clinical trials suspended
	Ventracor	VentrAssist	10	IDE will be submitted 2004	Clinical trials

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marketing and sales

- European subsidiary established
- Executive to be relocated to support additional hospital European arm of trial
- Clinical training programs implemented
- Sales and patient support literature printed
- EACTS (Germany), ISHLT (USA) exhibitions

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product approval update

Europe

- British Standards Institute (BSI) appointed
- CE Mark Trial underway in Australia
- other European centres later
- recruitment to close mid-2005

product approval update

USA

- met with FDA
- bridge-to-transplant
- destination therapy and alternative to transplant
- appointed International Center for Health Outcomes and Innovation Research (InCHOIR) of Columbia University NYC

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reimbursement situation

- Europe
  - re-imbursement consultants appointed
  - health economics data will be collected in the clinical trial
  - then National Institute for Clinical Excellence (NICE) submission
- USA
  - now established by Centers for Medicare & Medicaide Services (CMS)
  - recently increased DRG 525 for bridge & DRG 103 for destination
  - $125k - $130k
- ROW
  - lower priority

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Ventracor Limited

Colin Sutton PhD

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milestones

- Commence CE Mark trial mid-2004 in Australia, New Zealand and Europe
- Complete FDA trial design negotiations 2004
- Submit Investigational Device Exemption to FDA 2004
- CE marking submission 2005

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Thank you

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Ventracor Limited

Formal Resolutions

04

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26 October 2004

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Very truly yours

per K. Callaghan

Andrew Geddes
Corporate Communications

encls

ventracor

asx announcement

Results of 2004 Annual General Meeting

Sydney 26 October 2004: In accordance with Listing Rule 3.13.1 and Section 251AA of the Corporations Act 2001, notice is hereby given that the shareholders of Ventracor Limited approved the following resolutions at the Annual General Meeting of shareholders held on Monday 25th October 2004.

Resolution Number shown on Proxy Form	Resolution 2

Election of Directors;
"That Mr. John Ward be re-elected as a director of the Company"

Approved by show of hands or Poll	**Hands**
Total number of proxy votes in respect of which the appointments specify that:	
• The proxy is to vote for the resolution	12,506,984
• The proxy is to vote against the resolution	389,554
• The proxy is to abstain on the resolution	255,945
• The proxy may vote at the proxy's discretion	6,817,211
• No instructions given	5,236,227

Resolution Number shown on Proxy Form	Resolution 3

Approval of Executive Share Plan;
"That the Executive Share Plan summarized in the Explanatory Memorandum accompanying this Notice of Meeting be approved and adopted for the purpose of ASX Listing Rule 7.2 and for all other purposes, that the Board is authorised to issue up to 5 per cent of the total issued capital of the Company, to executives of the Company pursuant to that Executive Share Plan, in aggregate with any other employee or executive share or option plans currently existing or that may subsequently be approved by shareholders."

Approved by show of hands or Poll	**Hands**
Total number of proxy votes in respect of which the appointments specify that:	
• The proxy is to vote for the resolution	8,770,027
• The proxy is to vote against the resolution	3,974,378
• The proxy is to abstain on the resolution	166,358
• The proxy may vote at the proxy's discretion	6,765,681
• No instructions given	5,236,227

Resolution Number shown on Proxy Form — Resolution 4

Issue of Shares to Dr. Colin Sutton pursuant to the Executive Share Plan;

"For the purpose of ASX Listing Rule 10.14 and for all other purposes, that the Board is authorized to issue up to 400,000 fully paid ordinary shares in the capital of the Company to Dr Colin Sutton pursuant to the Executive Share Plan summarised in the Explanatory Memorandum accompanying this Notice of Meeting."

Approved by show of hands or Poll	**Hands**
Total number of proxy votes in respect of which the appointments specify that:	
• The proxy is to vote for the resolution	9,603,282
• The proxy is to vote against the resolution	2,836,761
• The proxy is to abstain on the resolution	442,470
• The proxy may vote at the proxy's discretion	6,794,681
• No instructions given	5,236,227

Resolution Number shown on Proxy Form — Resolution 5

Approval of Employee Share Plan;

"That the Employee Share Plan summarised in the Explanatory Memorandum accompanying this Notice of Meeting be approved and adopted for the purpose of ASX Listing Rule 7.2 and for all other purposes, that the Board is authorised to issue up to 5 per cent, of the total issued capital of the Company, to employees of the Company pursuant to that Employee Share Plan, in aggregate with any other employee or executive share or option plans currently existing or that may subsequently be approved by shareholders."

Approved by show of hands or Poll	**Hands**
Total number of proxy votes in respect of which the appointments specify that:	
• The proxy is to vote for the resolution	9,354,945
• The proxy is to vote against the resolution	3,039,365
• The proxy is to abstain on the resolution	200,186
• The proxy may vote at the proxy's discretion	6,782,698
• No instructions given	5,536,227

Bernadette Kerrigan
Company Secretary
26th October 2004.

ventracor

Ventracor Limited
ABN 46 003 180 372
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Chatswood NSW 2067
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T +61 2 9406 3100
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W www.ventracor.com

28 October 2004

Securities and Exchange Commission
Division of Corporate Finance
Office of International Corporation Finance
450 Fifth Street, NW
WASHINGTON DC 20549
USA

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File # 82-4630

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Very truly yours

per K. Callaghan

Andrew Geddes
Corporate Communications

encls

fact sheet

ASX: VCR

ventracor
the heart company

October 2004
www.ventracor.com
info@ventracor.com

Ventracor is an international medical device company focussed on commercialising the world's leading artificial heart device known as VentrAssist™. The VentrAssist™ is a latest generation of implantable heart devices known as a left ventricular assist system (LVAS). It is primarily designed as a permanent alternative to heart transplant for people with heart failure as well as a bridge to transplant (BTT) and a bridge to recovery (BTR) cardiac assist device.

A clinical trial to gather data and support a CE Mark application and approval to sell in Europe is underway with first sales expected by the end of 2005. Ventracor's submission to the FDA for permission to conduct a clinical trial in the USA will be made late 2004.

Heart failure

More than eight million people worldwide suffer from congestive heart failure (CHF). Of this figure, approximately 800,000 have a life expectancy of less than one year. At present, a heart transplant is the only effective long-term heart treatment available but an average of only 3,500 people will receive a transplant due to the limited supply of donor hearts.

As other medical advances extend the average length of life, the number of people with CHF continues to grow. The American Heart Association estimates congestive heart failure will compound at a rate of 10 per cent annually.

VentrAssist™

VentrAssist™ is a blood pump connected to the left ventricle of the diseased heart to help its pumping function. The procedure does not require removal of the existing heart, allowing it to rest and possibly recover.

VentrAssist™ has only one moving part – a hydrodynamically suspended impeller. The device has been designed to never wear out or cause blood damage. VentrAssist™ weighs just 298 grams and is made of titanium. It is less than 6cm in diameter and suitable for use in a range of body sizes.

The market

It has been independently estimated the global market for devices such as VentrAssist™ will grow to between US$7.5 billion and US$12 billion annually in the next few years.

Funding

As of 30 September 2004, Ventracor had $53.9 million in cash. This is sufficient funding to complete the CE Mark trial and to start achieving sales in the European Union late 2005.

Intellectual property

Ventracor's strong patent position protects its standing as a leader in the field.

The company holds international patents for each unique aspect of the device's design. Ventracor continues to file patents for potentially lucrative new aspects of the device.

Competitive advantage

There are four significant companies developing third generation left ventricular assist systems – Ventracor, US-based Thoratec (NASD:THOR), Japan's Terumo Heart Inc and privately held German-based Berlin Heart AG. The Thoratec and Berlin Heart devices are axial pumps, which use magnetic levitation. The Terumo Heart Inc device is a centrifugal pump which uses magnetic levitation. Ventracor's LVAS is a rotary centrifugal device which uses hydrodynamic levitation.

Ventracor's competitive advantage is its rotary device using hydrodynamic levitation. The robust simplicity of its design, its outstanding bio-compatibility, a unique patented hydrodynamic impeller, small size and affordability set it apart from other devices. Berlin Heart has completed numerous human implants, Ventracor and Terumo are in clinical trials and a third generation device by Thoratec is also in development. The potential market for these devices is very large and will ultimately sustain a number of players.

The high level of potential profitability of the devices is also likely to attract larger medical device companies as the market grows. Large US-based medical device companies which do not yet have an exposure to the LVAS market but are active in the cardiovascular device market include Medtronic, Guidant, Edwards Lifescience, St Jude, Johnson & Johnson and Boston Scientific.

Profile

Shares on issue:	193.37 million
Shareholders:	20,000+
52-week range:	$1.18 – $3.13
Cash position:	$60 million (July 2004)
Index inclusion:	S&P/ASX 200
Sector:	Life Sciences
Industry Group:	Healthcare Equipment
Sub Industry Group:	Medical Devices
Disease Target:	Heart Failure

Share price performance

Source: IRESS market technology

Milestones

- ✓ Commence CE Mark trial mid-2004 in Australia, New Zealand and Europe
- ✓ Complete FDA trial design negotiations 2004
- • Submit Investigational Device Exemption to FDA 2004
- • CE marking submission 2005
- • First sales in Europe and Australia 2005

Key executives

Chief Executive Officer, Colin Sutton PhD
Dr Colin Sutton has more than 20 years' experience in the successful international commercialisation of implantable medical devices. He was previously Chief Executive Officer of SIRTeX Medical Limited (ASX:SRX) where he directed the successful and rapid global commercialisation of its revolutionary liver cancer treatment.

Business Development & Clinical Director, Dr John Woodard

Dr Woodard has 18 years' cardiovascular device experience, 14 of which involved engineering and clinical aspects of four other earlier generation ventricular assist devices in the USA.

ventracor
the heart company

CE Mark Trial

Ventracor's CE Mark Trial is aimed at gathering data to support an application for permission to apply the CE Mark to the VentrAssist™ so it can be sold in the major market of Europe. It is the last step in product validation to demonstrate that VentrAssist™ is safe and efficacious for Europe as its first intended market. Regulatory approval for Europe will expedite global commercialisation of the VentrAssist™.

The trial has been designed to collect appropriate supporting data as quickly as possible.

USA – steps to market

Implantable medical devices require a Pre-Market Approval (PMA) by the US Food and Drug Administration (FDA) prior to marketing within the USA. To obtain all relevant clinical data to support a PMA application, an investigational device exemption (IDE) is required from the FDA. An IDE allows an unapproved device to be implanted under controlled conditions for the purpose of gathering safety and effectiveness data.

Ventracor will submit its IDE application to conduct a bridge-to-transplant trial to the FDA in late 2004. Ventracor's US clinical trials will be run by the Columbia University Medical Center International Center for Health Outcomes and Innovation Research (InCHOIR) in New York.

Once clinical data has been gathered establishing the safety and effectiveness, Ventracor will submit a PMA for approval to sell the device as an alternative to heart transplant.

The PMA process involves a review of device-related information, including clinical trial data and auditing of quality systems for compliance of the design process and manufacturing within the provisions of Code 21 of the US Code of Federal Regulations, Part 820 – Good Manufacturing Practice (GMP) for Medical Devices.

Following on from the clinical trials conducted under the IDE, Ventracor will seek a PMA to allow the VentrAssist™ LVAS to be used for bridge-to-transplant patients. The company will require a separate IDE to establish the use of the VentrAssist™ LVAS as an alternative to heart transplant.

The review of a PMA is a four-step process consisting of:

1 administrative and limited scientific review by FDA staff to determine completeness (filing review)

2 in-depth scientific (design), regulatory, and Quality System review by appropriate FDA personnel

3 review and recommendation by the appropriate advisory committee and onsite audit for compliance to quality system regulations

4 final deliberations, documentation, and notification of the FDA decision.

USA – reimbursement

The Centres for Medicare and Medicaide Services (CMS) provides healthcare coverage for people over 65 through Medicare and welfare assistance through Medicaide. CMS reimbursement is available for FDA approved LVASs implanted at CMS approved implant centres. CMS reimbursement is also available during clinical trialling for Category B IDE devices.

The VentrAssist™ LVAS is expected to be classified as a Category B IDE device and may be eligible for reimbursement during clinical trials. Ventracor will work with US-based reimbursement specialists to assist in submitting reimbursement requests to insurance providers, including CMS, to ensure timely submission, processing and payment of claims.

From October 2004, LVAS implantation has been shifted to diagnostic related group (DRG) 103, effectively increasing the reimbursement rate by US$30,000 with an average reimbursement anticipated between US$125,000 and US$130,000. This cost covers the entire implant procedure. It applies irrespective of whether the device has been implanted as a bridge-to-transplant or as destination therapy. This further enhances the economics of the LVAS industry with higher reimbursement likely to spur additional usage. Companies developing third generation LVASs, such as Ventracor, are likely to benefit.

Destination therapy – A majority of destination therapy patients are likely to be over 65 and hence to be covered by Medicare.

Bridge-to-transplant – Most bridge-to-transplant patients are likely to be younger than 65 and not covered by Medicare. Most will be covered by private insurers. Ventracor will work with reimbursement consultants to secure coverage for the start of the bridge-to-transplant clinical trial in the USA in 2005.

CE

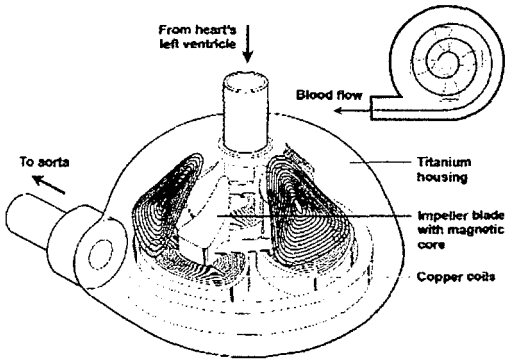
The CE mark

In Europe, the letters 'CE' on a manufactured product are a guarantee it meets the essential requirements of the relevant European Directives. For a medical device manufacturer like Ventracor, this is the *Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC*. CE marking indicates the product can be legally sold within the European Union (EU) and the European Free Trade Area (EFTA).

Notified Body

The assessment procedure for CE marking is carried out by a notified body. Each EU member government appoints several independent companies to conduct conformity assessments on a range of manufactured products. Assessments made by a notified body are recognised by all EU members. Notified bodies assess conformity of a product against the conditions set out in the European Union's *New Approach Directives* in support of CE marking.

Inside the VentrAssist™



More Information

European Commission

www.europa.eu.int/comm/enterprise/newapproach/

www.europa.eu.int/comm/enterprise/medical_devices

Global Harmonisation Task Force: www.ghtf.org

Global Medical Device Nomenclature: www.gmdn.org

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ventracor

asx announcement

Ventracor Presents at UBS Healthcare Conference

Provides Reimbursement Update

Sydney, 28 October 2004: Ventracor Limited (ASX: VCR) has reconfirmed it expects reimbursement for implants conducted as part of its US clinical trials program due to begin in 2005.

Speaking at the UBS 2004 Healthcare Conference in Sydney this week, Dr Sutton said it was important to note reimbursement for new medical devices in US clinical trials covered the entire hospital procedure, not just the provision of the device.

"The current average LVAS reimbursement rate for the entire hospital procedure is between US$125,000 and US$130,000," Dr Sutton said.

"All new implantable medical devices require a Pre-Market Approval (PMA) by the US Food and Drug Administration (FDA) prior to marketing in the USA.

"To obtain relevant clinical data for a PMA application, an investigational device exemption (IDE) is required. An IDE allows an unapproved medical device to be implanted under a clinical trial.

"Ventracor is on track to submit its IDE application to the US FDA before the end of 2004.

"We expect the VentrAssist™ to be classified as a Category B IDE device and Category B devices are generally eligible for reimbursement during clinical trialing," Dr Sutton said.

Dr Sutton added Ventracor was exploring the potential for reimbursement for VentrAssist™ implants conducted at future European implant centers.

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 US$12 billion in coming years.

For more information please contact:

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