

# ADMEDUS INVESTOR PRESENTATION

**ASX:AHZ**

**March, 2015**

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## SUMMARY

- Fully integrated Specialist Healthcare Company with growing global footprint
- Leveraging two proprietary and differentiated platform technologies
  - ADAPT® – tissue engineering for regenerative medicine
  - Therapeutic vaccines and immunotherapies for infectious disease and oncology
- Significant value built over the past 12 months
  - Lead ADAPT product, CardioCel®, recently launched in US and EU,
  - Targeting the significant market for cardiovascular repair with CardioCel®
  - Platform for ongoing sales growth and increase use of CardioCel®
  - HSV-2 (genital herpes) vaccine potentially addresses a \$6bn+ market and has begun POC clinical trial; key value inflection point in 2015
- Strong IP position across both platforms underpins broad pipeline
- Experienced management team

# ADMEDUS BUSINESS MODEL

## ADMEDUS ASX: AHZ

Est: 2003

### ADMEDUS Sales & Distribution

- Supporting Admedus with revenue growth
- Infusion, surgery and cardiac hospital markets
- Existing sales and distribution infrastructure
- Commercializing CardioCel® in key markets in 2015

### ADMEDUS Regen

- Product Development based on proprietary tissue treatment (ADAPT®)
- Cleared for sale in the US, Canada, CE mark in Europe and seeking regulatory approvals in other jurisdictions
- Platform to generate portfolio of products

### ADMEDUS Biomanufacturing

- State of the art bio-manufacturing facility
- Focus on scaling up manufacture of CardioCel®
- Infrastructure to manufacture additional products
- Also infrastructure for R&D

### ADMEDUS Vaccines R&D

- Next generation immunotherapies
- Lead by Professor Ian Frazer (Gardasil)
- Positive results from Ph I HSV-2 results progressing into Phase IIa study
- Progressing HPV therapeutic into Ph I study

## ADMEDUS PRESENTATION OVERVIEW

- Regenerative Medicine
- Immunotherapies
- Company Milestones and News flow

# Regenerative Medicine

# REGENERATIVE TISSUE PRODUCT PORTFOLIO

**Congenital Heart Disease (CHD)**

**CardioCel® for CHD**

**Launched in EU & US**

**Cardiovascular Applications**

**CardioCel® vascular and valve reconstruction and repairs**

**On market in US**

**Vascular tissue**

**CABG, vascular repairs**

**File 2017**

**Abdominal surgery**

**Hernia repairs**

**File 2018**

**Stem Cell or stem cell factor delivery**

**CardioCel® or ADAPT I or II with stem cells or factors**

**File 2019**

**Gynecological**

**Pelvic floor repair**

**File 2019**

**Whole Tissue Valves**

**CardioCel® and ADAPT tissue**

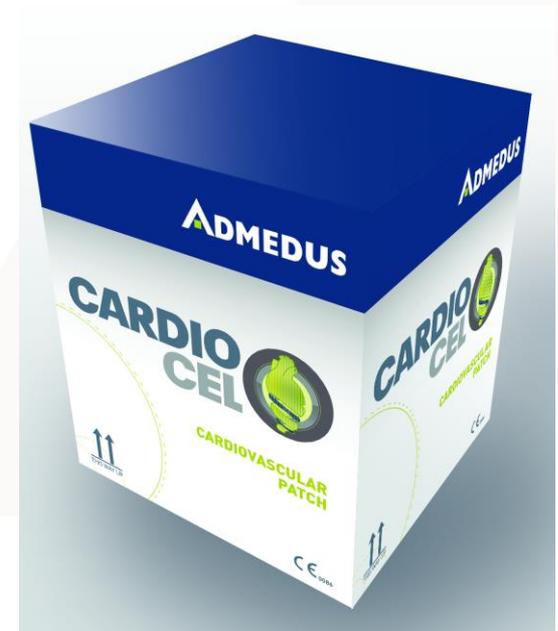
**File 2020**

Indicative pipeline chart

# CARDIOCEL®

## Differentiated regenerative tissue scaffold for cardiovascular repairs

- Targeting the significant cardiovascular market
- Global launch has begun, including approval in:
  - EU – Nov 2013 (CE mark)
  - US – June 2014 (510k)
  - Special Access (named patient) in Asia
  - On market in Hong Kong
- Now in 28 centres in Europe and 28 in the US
- Direct sales teams in North America, EU and Asia
  - Initially targeting use in CHD centres
    - Moving into adult cardiovascular centres



# CARDIOCEL®

## Global launches to continue in 2015

- Europe similar size market to the US
  - Sales in UK, Netherlands, Germany, Italy & France
  - Approved for cardiac repair and reconstruction in adults and paediatrics
- Initial Asian market approvals in 2015
- Continue to grow regional sales teams with experienced sales execs
- Continue ongoing studies to strengthen existing data
  - Further evidence of CardioCel® advantages
  - Broadening applications in cardio and vascular repairs and reconstructions

## CARDIOCEL®

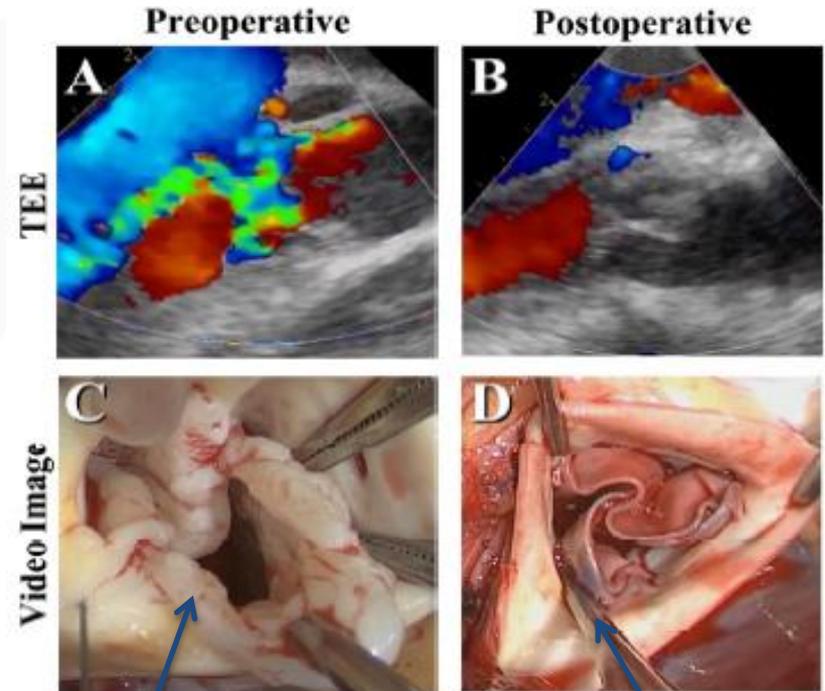
### **Strong clinical data highlights benefits**

- Avoids calcification – a key differentiation
  - No calcification after 48, 60 and 72 month follow up in ongoing extension to clinical study
- Strong regeneration of normal heart tissue around tissue ‘scaffold’
- Allows blood flow through and around facilitating tissue regeneration
- Initial use for congenital heart repairs and building in heart valve repairs
  - Approved for both paediatric and adult use
  - Also on market in US for vascular repairs
- Will expand use into other cardiovascular surgical uses in 2015
- Over 1200 patients implanted

# CARDIOCEL<sup>®</sup> – HEART VALVE REPAIR

Heart valve model data showed:

- After 7 months tissue regeneration around CardioCel<sup>®</sup> after implantation
- No echocardiographic evidence of calcification in the CardioCel<sup>®</sup>
- Study undertaken by Prof. Brizard of University of Melbourne
- Regeneration on CardioCel<sup>®</sup> results showed:
  - Endothelialisation (prerequisite for a normal physiological heart valve-blood interface)
  - New valvular collagen on both sides of CardioCel<sup>®</sup>, typical of native valve tissue and
  - Progression to a repaired heart tissue
  - The trans-differentiation of some of the valvular interstitial cells into functional phenotypes such as new smooth muscle cells



Legend: Echo and video images of a dysplastic unicuspid aortic valve before and after CardioCel reconstruction (Patient #1). TEE = transesophageal echocardiogram.

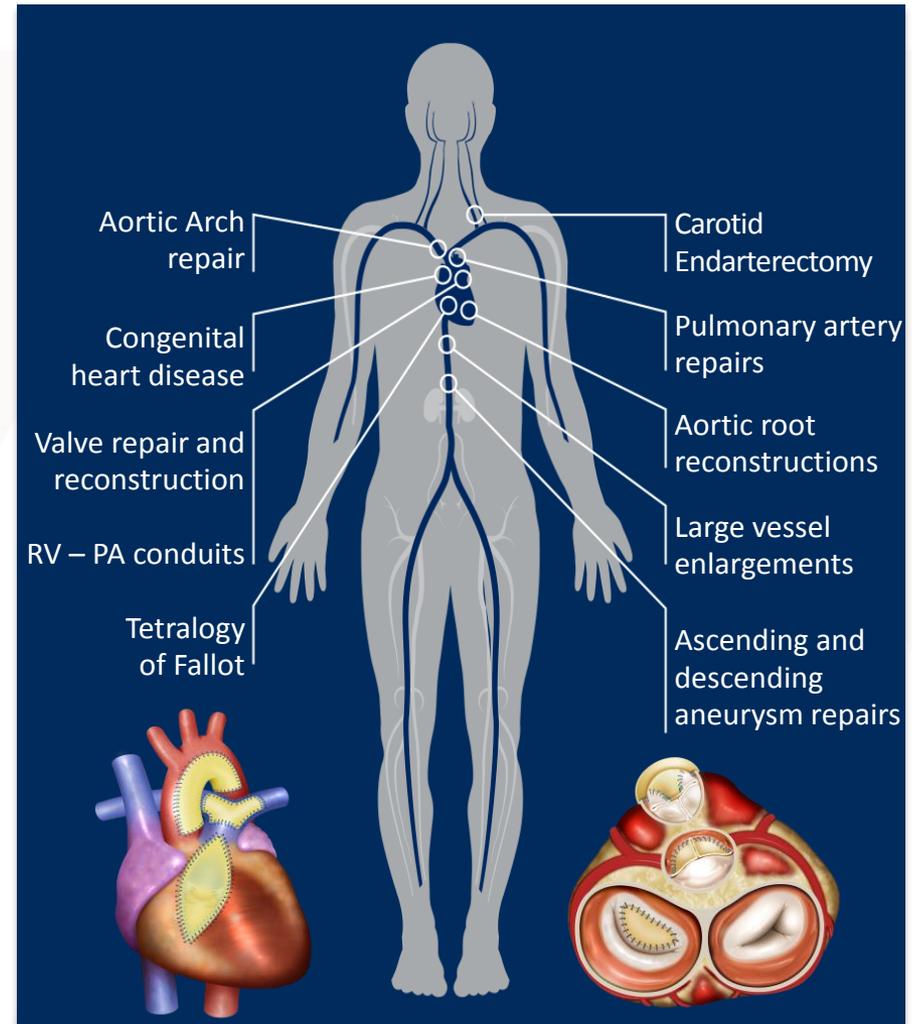
Mazzitelli et al, 2015

Before

After repair with  
CardioCel<sup>®</sup>

## CARDIOCEL® – ADDRESSABLE MARKET

- US – c.2.4 million addressable procedures per annum
- Initial market CHD – 60,000+ case per annum
- Entering heart valve repairs
- 360,000+ procedures per annum including:
  - Surgical Valve Replace Mitral
  - Aorta Replace (Ascending/Arch/Thx)
  - Mitral Repair (leaflet augmentation)
  - Aortic Repair (leaflet)
  - Surgical Valve Replace Aortic
  - Valve Replace TAVR
- Future expansion into vascular repairs
  - Carotid Endarterectomy (CEA) Patch
  - Coronary Revascularisation
  - Endo AAA
  - Open AAA



# ADAPT<sup>®</sup>

## A Platform Technology with broad application in regenerative medicine

- The ADAPT<sup>®</sup> tissue benefits are:

| Safe   | Durable  | Remodels   | Easy to use   |
|--|--|--|---|
| <ul style="list-style-type: none"> <li>• Bio-compatible</li> <li>• Haemocompatible</li> <li>• Maximum haemostasis</li> </ul> | <ul style="list-style-type: none"> <li>• Strong with natural flexibility and elasticity</li> <li>• No calcification</li> </ul> | <ul style="list-style-type: none"> <li>• Promotes site specific tissue regrowth and regeneration</li> <li>• Prevents calcification</li> <li>• Retains tensile strength &amp; elasticity</li> </ul> | <ul style="list-style-type: none"> <li>• Off the shelf</li> <li>• No specific preparation</li> <li>• No special or technical training required for use</li> </ul> |

- CardioCel<sup>®</sup> is the first commercialised product from ADAPT<sup>®</sup>, our proprietary platform technology for tissue engineering
- Use ADAPT<sup>®</sup> to generate additional regenerative tissue products
  - Targeting additional regulatory submissions for product portfolio
- IP strong – core patents out to beyond 2030

# Immunotherapies – Therapeutic Vaccines for Infectious Disease and Oncology

## IMMUNOTHERAPIES – BACKGROUND

### Leveraging a patented DNA platform technology to deliver novel immunotherapies

- Based on technology developed by Professor Ian Frazer
  - Best known for his work in HPV leading to Gardasil® and Cervarix®
- Uses a combination of:
  - Intra-dermal delivery
  - Proprietary codon optimisation
  - Ubiquitin added in the codon to help stimulate the T-cell response
- Targeting therapeutic vaccines for infectious disease and oncology
- Two lead clinical programs – HSV-2 & HPV
- 7 patent families – 6 US granted

# HERPES SIMPLEX VIRUS-2 (HSV-2)

## Tackling an unmet medical need

- HSV-2 commonly causes genital herpes
- 1 in 6 people aged between 14 and 49 in the US estimated to be HSV positive
- No cure available
- Addressable market estimated at \$6bn+
- Preclinical – total HSV-2 viral clearance
  - Prevented establishment of latency reservoirs
- Phase I – consistent with preclinical data
  - Dose ranging study in sera-negative healthy people
  - 3 vaccinations with 3 weeks between
  - Doses 10mcg, 30mcg, 100mcg, 300mcg and 1000mcg
- Results showed:
  - Phase I safe (primary endpoint) – no safety issues
  - 19 of 20 patients showed T-cell response
    - Non-response in lower dose
  - Also strong local (DTH) response

## HSV-2 VACCINE

### Key value inflection point during 2015

- Phase II
  - Currently being initiated
- HSV-2 positive people
  - Two arms – 1000 mcg vs placebo 3:1 ratio
    - 20 patients per arm
  - 45 day pre-vaccination ‘baseline’ period
  - 3 injection regimen with 4 weeks between injections
    - Followed by 6 month booster
  - Looking at safety
  - Also viral load, viral shedding and viral flare frequency
- Anticipating interim results 2015 – key value inflection point

# HUMAN PAPILOMA VIRUS (HPV) VACCINE

## Developing an effective treatment

- HPV infection a direct cause of cervical cancer
- Despite availability of first generation HPV vaccines (Gardasil® and Cervarix®)
  - Low compliance; <35% vaccination completion rate in the US
  - Significant pool of people already HPV infected – vaccine ineffective
  - 14M new infections in the US per annum (CDC)
- Estimated >\$1bn+ market potential for therapeutic vaccine
- Targeting therapeutic use against HPV – E6 & E7
- Strong preclinical data
  - HPV viral clearance
  - 100% survival in TC-1 model (tumour transfer model)
    - 87.5% had no tumour 50 days post treatment
  - Prevents disease progression in multiple HPV tumour models
- Now progressing into Phase I in 2015

# Company Milestones And News flow

## SIGNIFICANT VALUE BUILT OVER PAST 18 MONTHS

### CardioCel®

- Approval for CardioCel® in Europe
- US 510(k) regulatory filing submission
- Marketing clearance for CardioCel® in USA
- Canadian approval for CardioCel®
- Special Access (named patient) approval in Singapore for CardioCel® – first in Asia
- Additional early access approvals for CardioCel®
- Initial revenues from CardioCel®

### Immunotherapies

- Initiation of the HSV immunotherapy Phase I study
- Positive HSV-2 immunotherapy Phase I results
- Strong preclinical data for HPV vaccine program
- Increased ownership stake in Admedus Vaccines to 66%

## EXPECTED NEWS FLOW

### CardioCel®

- Increase number of centres using CardioCel® globally
- Growing sales in the US & Europe
- Asian market approvals for CardioCel®
- Initiation of CardioCel® market expansion studies
  - Tri-leaflet Aortic Heart Valve Repair Study
- Progression of CardioCel® with cellular therapies program
- Expanded regenerative tissue portfolio

### Immunotherapies

- HSV-2 Phase II interim data H2 2015
- Complete and analyse preclinical HPV studies
- Initiation of HPV Phase I

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Thank you

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