

## Admedus Limited 2015 Annual General Meeting Friday, 13 November 2015

## **Mr Lee Rodne | Managing Director**



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### **PRESENTATION OVERVIEW**

- Company Overview
- The Year In Review
- ADAPT<sup>®</sup> Regenerative Tissue
- Immunotherapies
- Year Ahead



#### **CORPORATE OVERVIEW**

- Fully integrated Specialist Healthcare Company with 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 and springboard for growth built over the past 2 years
  - Rollout of lead ADAPT product, CardioCel® ongoing-used in 120 centers globally
    - Initially targeting the significant cardiovascular repair market
  - CardioCel launch de-risks underlying ADAPT platform
    - Now Expanding Regenerative pipeline into additional targets
  - Key value inflection points for immunotherapy programs in 2015 / 2016
- Strong IP position across both platforms underpins broad pipeline
- Experienced management team



#### **COMPANY SUMMARY**

- Ticker
- Market cap
- Cash and equivalents
- Revenue ending 30<sup>th</sup> June 2015
- Top 20 shareholders

ASX:AHZ

\$123.8M

\$16M

\$10.2M

28% holding



## The Year In Review



#### SALES HIGHLIGHTS

- Revenue up by 28% on prior year to \$10.2M
- Over 120 centres now using CardioCel
  - 45 centres in Nov 2014
- 2.5M in sales of CardioCel in first full year on market in Europe and initial year of launch in the US
- Strengthened Key Opinion Leader groups in North America, Europe, Singapore and Hong Kong in line with market approvals
- Strategic partnership with Genpharm for sale of CardioCel in the Middle East and North Africa (MENA) regions



#### **REGENERATIVE MEDICINE HIGHLIGHTS**

- Additional CardioCel market approvals in Singapore, Hong Kong and Malaysia
- Approval for Heart Valve repairs and reconstructions in Europe indication expansion
- Expanded ADAPT product line to include initial product for Vascular repairs
- Phase II CardioCel follow-up showing continued positive patient outcomes
  - No signs of Calcification with CardioCel 7 years post implantation
- Positive study in dura mater repair to treat head and brain injuries
- Positive pre-clinical aortic valve reconstruction study showing CardioCel's successful characteristics in heart valve reconstructions
- Continuing to build a portfolio of regenerative products across a broad range of surgical applications



#### **IMMUNOTHERAPIES**

- Clinical advances in immunotherapies programs
- Successful Phase I herpes simplex 2 (HSV-2) study
  - 19 out of 20 participants showed a T-cell response against HSV-2
- HSV-2 Phase II closing results pending
- 100% survival and total tumour removal in over 87% of animals in pre-clinical Human Papillomavirus (HPV) program
  - Progressing Ian Frazer's next HPV product into clinical trials
- Admedus Vaccines rebranded to Admedus Immunotherapies



## ADAPT<sup>®</sup> Regenerative Tissue





## **REGENERATIVE TISSUE PRODUCT PORTFOLIO**

<b>CardioCel</b> ®	Congenital Heart Disease (CHD)	Launched in EU & US
Cardiovascular Applications	Heart valve repairs & reconstructions*	On market in US & Asia
Vascular tissue	Carotid Endarterectomy (CEA)	On market in 2016
Dura mater repair	Spinal and cranial repair	File 2017
Whole vascular tissue	CABG, AV fistula	File 2018
Stem Cell or stem cell factor delivery	ADAPT tissue with stem cells	File/partner 2019
Abdominal surgery	Hernia repairs	File 2020

\* Admedus is currently undertaking a supporting aortic valve reconstruction clinical study with leading global heart centres and surgeons As a platform technology, ADAPT tissue has potential in additional applications and products

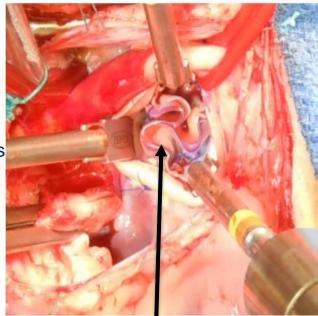




### CARDIOCEL AS A HEART VALVE TREATMENT: ACCESSING A \$2BN OPPORTUNITY

- Large aortic valve market replacement market estimated \$2Bn
- "Repair vs Replacement?" An ongoing debate
  - Growing TAVR valve market competing with established bioprosthetic replacement valves
  - There are known issues with bio- prosthetic, TAVR and mechanical valves
  - Surgeons have been looking for better tissue to repair and reconstruct valves
- CardioCel scaffold uniquely positioned for repairing / reconstructing valves
- Working with KOLs has generated strong preclinical data which highlights
  - Durability and anti-calcification properties; facilitates host tissue remodelling
  - Provides a better functioning valve with better haemodynamics; opportunity to regain "native" valve functionality
  - Ability to repair earlier in the valve disease process with CardioCel
    - Bodes well for longer term better patient outcomes; potentially avoids the need for replacement valves
  - No need for anticoagulants (blood thinners)
- CardioCel aortic valve clinical study initiated with leading heart centres

"The results from this study are some of the best results that we've seen in this model" -Professor Bart Meuris



Aortic tri-leaflet valve reconstruction with CardioCel®

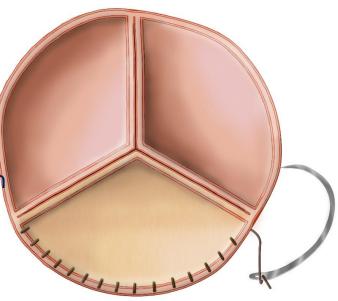
## **CARDIOCEL**®



## AORTIC VALVE CLINICAL STUDY

Currently enrolling aortic valve reconstruction study

- Reconstructing the whole valve instead of replacement with a bio-prosthetic valve
- 4 leading heart centres enrolling 80 adult patients
- Supporting CardioCel use in valve reconstructions instead of bio-prosthetic
- Looking at overall patient valve performance
- To show patient benefits of full valve reconstruction over short-term options of bio-prosthetics
  - Overall benefit of the patient & better haemodynamics
  - Complimented with autologous repair to form 'native' valve
- Further news flow near term with clinical reviews at 6, 12 and 24 months post-surgery





## **ADAPT® FOR VASCULAR REPAIRS**

## LAUNCHING OF NEW PRODUCT RANGE

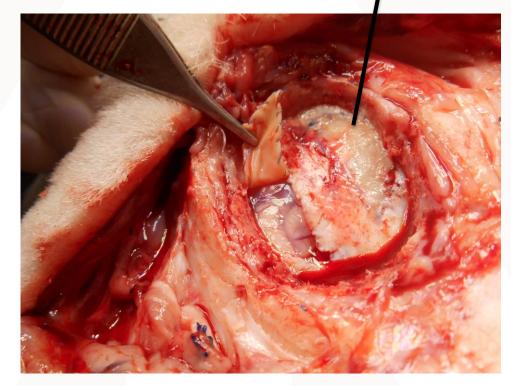
- Admedus looking to launch vascular focused product range
- Vascular tissue being used in pilot clinical programs at key US centres for further data and rollout in 2016
- Leverage off existing regulatory approvals
- 180,000 procedures per annum in the US
- Focused data in 2016 on Carotid Endarterectomy (CEA) procedures
- Broader use across further surgeries
  - Coronary Revascularisation
  - Endo AAA
  - Open AAA



## **ADAPT® TISSUE FOR DURA MATER**

## DEVELOPING A PRODUCT FOR DURA MATER REPAIRS

- US market around 200,000 procedures per annum
- Initial study shows:
  - No post-op leakage
  - No post-op infection
  - Remodelling and endothelialisation within one month
  - No adhesion to brain surface
- Entering a 2<sup>nd</sup> study in 2016
  - Study data intended to aid in US market filing



ADAPT<sup>®</sup> tissue



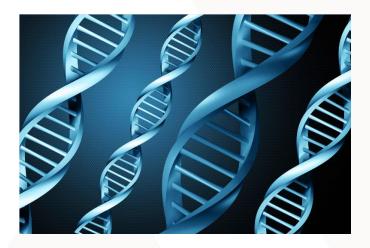
Immunotherapies – Therapeutic Vaccines for Infectious Disease and Oncology



## **IMMUNOTHERAPIES**

#### 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 Coricode<sup>©</sup>
  - Ubiquitin added in the codon to help stimulate the T-cell response Corimmune<sup>©</sup>
- 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 recruiting recruitment nearly complete
  - Initial study participants received vaccine doses with no safety issues
- 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 by year end 2015
  - Additional data expected in 2016





## HUMAN PAPILLOMA 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</li>
  - 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
- Entering Phase Ib in 2016



## The Year Ahead



### **EXPANDING GLOBALLY**

#### ADAPT® & CardioCel®

- Continued growing sales
- Increase number of centres using CardioCel globally
- Continued expansion into Asian market for CardioCel®
- Approvals & sales in the MENA region
- Launch of ADAPT vascular tissue product range
- Post-market clinical study in aortic valve reconstructions underway at leading heart centres
- Initiation of dura mater tissue study for regulatory submission
- Progression of CardioCel® with stem cells program
- Initial CardioCel studies for the Chinese market approval





## **CREATING VALUE – KEY INFLECTION POINTS**

**Immunotherapies** 

- HSV-2 Phase II interim data end 2015
- Additional HSV-2 Phase II data in CY2016
- Complete preclinical HPV studies
- Initiation of Ian Frazer's next HPV product as a treatment against HPV and Cervical Cancer into Phase Ib CY2016





#### **BECOMING A GLOBAL HEALTHCARE LEADER**

- Continued sales growth across Admedus' portfolios
  - Rollout of lead ADAPT ® product, CardioCel® ongoing-used in 120 centers globally
  - Expanding Regenerative pipeline into additional targets
    - Building for next 12 months and beyond with an expanding regenerative tissue pipeline in valve reconstructions, vascular products, dura mater repair and progressing cellular therapies with ADAPT and stem cells
- Key value inflection points for immunotherapy programs in 2015 / 2016
- A strong year ahead with key milestones





## Thank you

# Lee Rodne Managing Director