

# Investor Presentation

September, 2013

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# Presentation Overview

- **AHG overview**
- **Sales & Marketing division**
- **Regenerative Medicine division**
- **DNA Vaccine division**
- **Company Summary**
- **Company Milestones**

# Company Overview

**Allied  
Healthcare  
Group  
ASX:AHZ**

## Sales & Marketing

- Profitable & growing business centre
- Infusion, surgery and cardiac hospital markets
- Existing sales and distribution infrastructure
- Launching CardioCel® in key global markets in 2013

## Regenerative Medicine

- Based on proprietary tissue treatment
- Initial product seeking regulatory approval
- Potential for initial revenues 2013
- Platform to generate portfolio of products

## R&D

- Next generation immunotherapies
- Lead by Professor Ian Frazer
- Heading for Phase I studies in 2013
- Strong pipeline of projects

# Company Strategy & Value Proposition

## Building an integrated healthcare company

- Recognised and experienced Board & management
- Extensive corporate development, finance, M&A, medtech, therapeutics, sales and licensing experience

## Growing Revenues

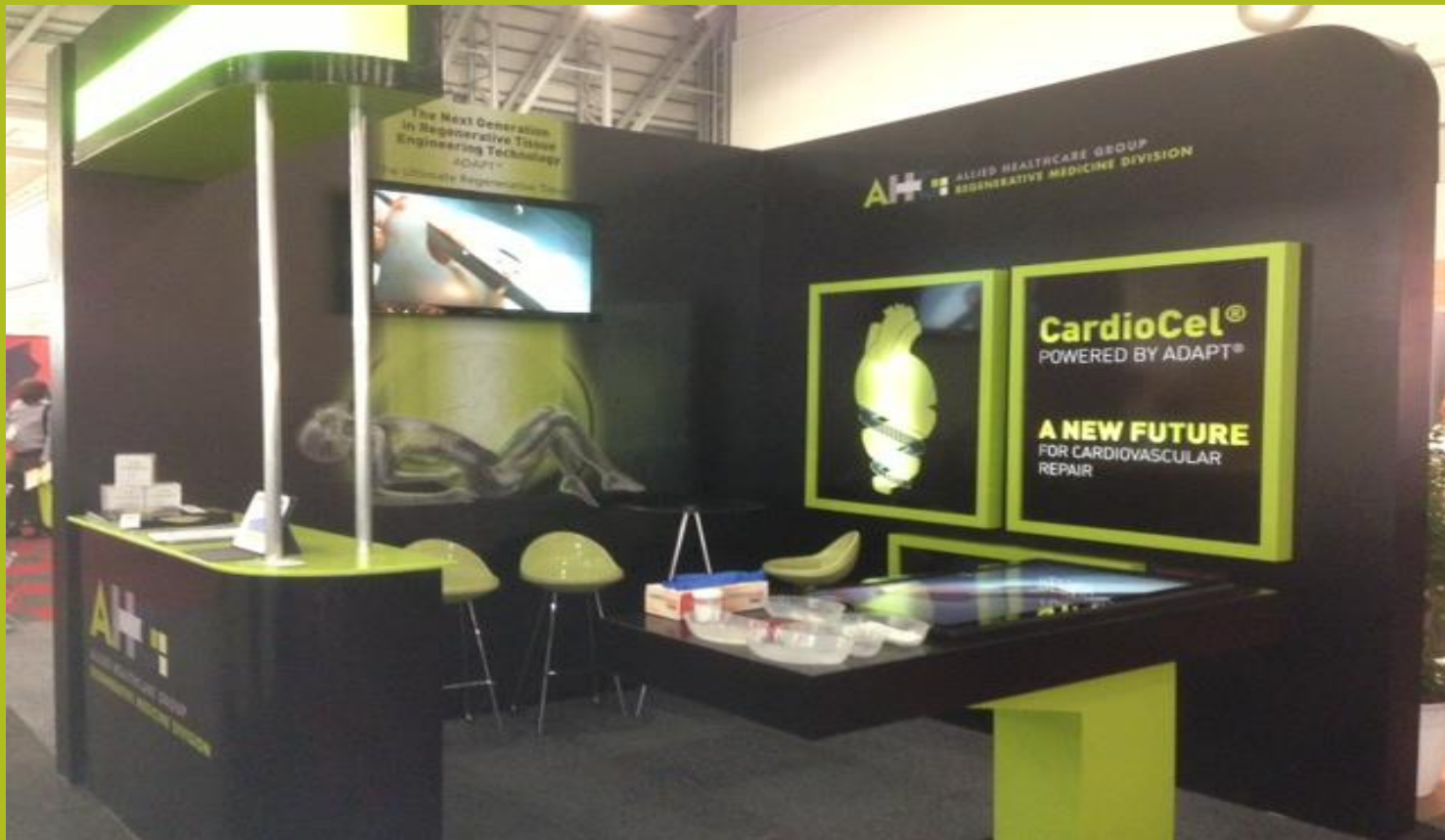
- Expanding organically and via products developed in-house focusing on our regenerative medicine platform
  - Potential for >\$100m in sales

## Commercialising pipeline of next generation immunotherapeutics

- DNA vaccines from Professor Ian Frazer's team
  - Near-term revenue potential via licensing / partnering

**Revenue + Significant value drivers over the next 12 – 36 months**

# Sales & Marketing



## **Sales & Distribution Division**

- **Extensive infusion and cardiology focused product range**
  - **Over 20 products in the range**
  - **8 global suppliers with exclusivity for Australian & NZ**
  - **Providing innovative solutions with clinical benefits**
- **Profitable, growing business**
  - **+50% gross margins on most product lines**
- **Averaged 20+% growth per annum over the past 10 years**
- **Established sales force and growing globally**
  - **Experience in building and running sales teams**
- **Over 800 customers**
  - **Experience in getting customers buying our products**

## **Key points on Sales & Distribution**

- **Provides growing revenue to Allied (\$7.4M FY'13)**
- **Experience in product registration**
  - **Over 20 products registered in Australia/NZ**
- **Experience in successful product launches**
- **Experience in building sales teams**
- **Experience in getting customers buying product**
- **Platform to launch “In-House” regenerative tissue products**
  - **In process of launching our lead regenerative tissue product developed by our platform technology in tissue engineering (“ADAPT<sup>®</sup>”)**



# **ADAPT<sup>®</sup>**

## **Tissue treatment process**

# **ADAPT<sup>®</sup> Tissue Treatment Process**

- **Developed by cardiologists and tissue engineering experts**
- **Developed over the past 10 years**
- **Aimed at addressing issues with existing tissue products**
  - **Prevent calcification**
  - **Facilitate regeneration**
  - **Retain tensile strength**
- **Can be used to treat many types of tissue**
- **Used to develop a strong pipeline of regenerative products for large applications**

# CardioCel®

# Going Global CardioCel®



CE mark  
approved  
August 2013

## **CardioCel®**

- **1<sup>st</sup> product (medical device) developed by our regenerative medicine division**
- **Cardiovascular tissue patch used to treat & repair heart defects caused by Congenital Heart Disease (CHD)**
- **CHD is one of the leading causes of deaths in infants**
  - **Also major issue in children with a high unmet clinical need**
- **Initial stage of global launch**
  - **EU (CE mark) approved**
  - **USA 510 (K) marketing approval application submitted**
  - **Early access approval for initial indications in Australia**
    - **6 surgeons now using CardioCel® in Australia**
- **Sold through Allied Healthcare Sales & Distribution**

## Phase II Clinical study

- **30 patient study into congenital heart disease repair**
  - age range - 2.3 mths to 171 mths
- **Primary Endpoints**
  - **Early (<30 days) morbidity;**
  - **Time-related incidence of device related complications**
    - **i.e. device failure, thromboembolism, structural leak, infections, device-related re-operation and replacement**
  - **Haemodynamic and anti-calcification performance of the device**
    - **Measured by echocardiography**
- **Secondary endpoints**
  - **Handling characteristics**
  - **Shape and sizing characteristics**
  - **Implant complications**

## **Phase II Results**

### **Primary endpoints met**

- **No patch related 30 day mortality**
- **No incidence of patch related complications**
- **Intact Haemodynamics on Echo**
- **No evidence of calcification at 6 or 12 months time points on Echo/MRI**

### **Positive secondary endpoints**

- **No handling or implant issues**

## Phase II Results

### Long term open label follow up

- 18, 24 ,36 & 48 months follow ups

### Open label study results

- No graft related adverse events or calcification

### Publication expected in 2013 in peer review journal

### Early access in Australia

- Approved by Australian regulatory authority for early access
- ~ 50 patients successfully implanted to date
- Expecting further early access sites



## Top down approach to launch

Paediatric congenital heart disease



Adult CHD market

**CHD market**

1<sup>st</sup> Tier - Global paed KOLs & centres

2<sup>nd</sup> Tier - Country KOLs & centres

3<sup>rd</sup> Tier – Paed clinicians

1<sup>st</sup> Tier - Global adult KOL & centres

2<sup>nd</sup> Tier – Country adult KOLs & centres

3<sup>rd</sup> Tier - Adult clinicians

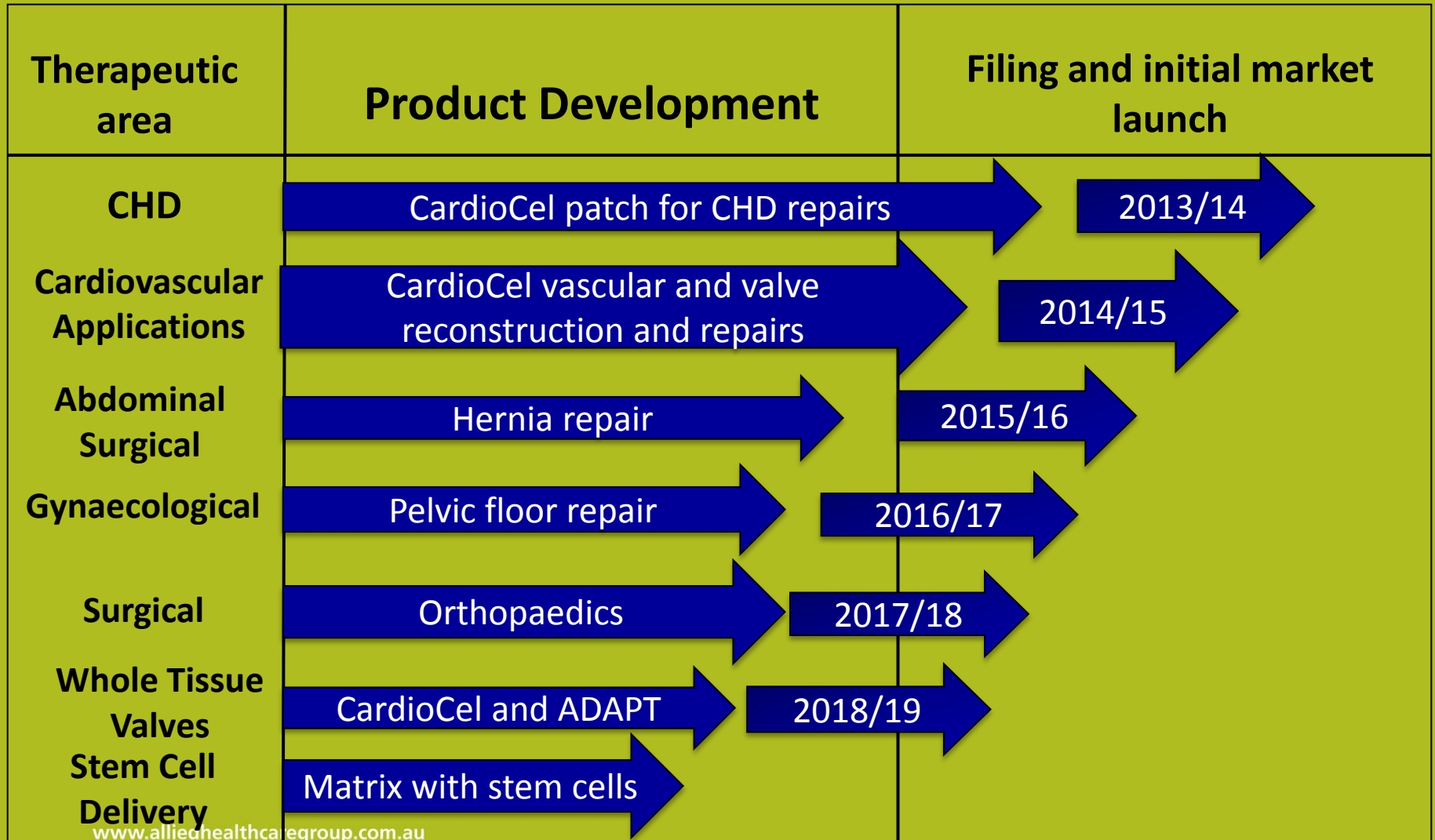
## **Why is CardioCel<sup>®</sup> Important?**

- **Has shown strong regeneration of normal heart tissue around tissue ‘scaffold’**
  - **With no calcification**
- **Expected to remove the need for repeat open heart surgery**
  - **Minimising the impact to patients & their families**
- **Provides a tissue that addresses the requirements of surgeons while addressing problems of existing approved products**
- **Potential in both paediatric and adult heart surgery markets**

# Product Development

**Focused on Regenerative Medicine  
and Soft Tissue Repair products**

# Regenerative Pipeline



# **ADAPT<sup>®</sup> Tissue Advantages**

- **No Calcification**
- **No Cytotoxicity**
- **Bio compatibility / absorbability**
- **Bio durability and strength**
- **Restores natural elasticity**
- **Ready to go - off the shelf**
- **Ease of use and tissue user friendly 'feel'**
- **No technical training required for support staff**
- **Excitement from surgeons about the opportunity to reduce repeat surgeries**

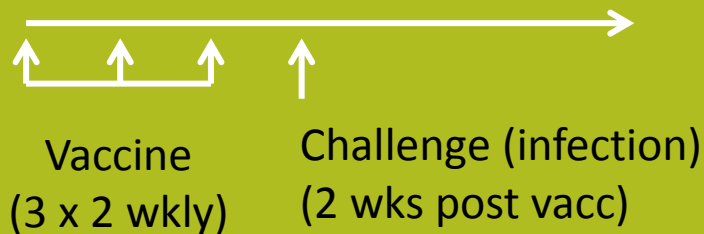
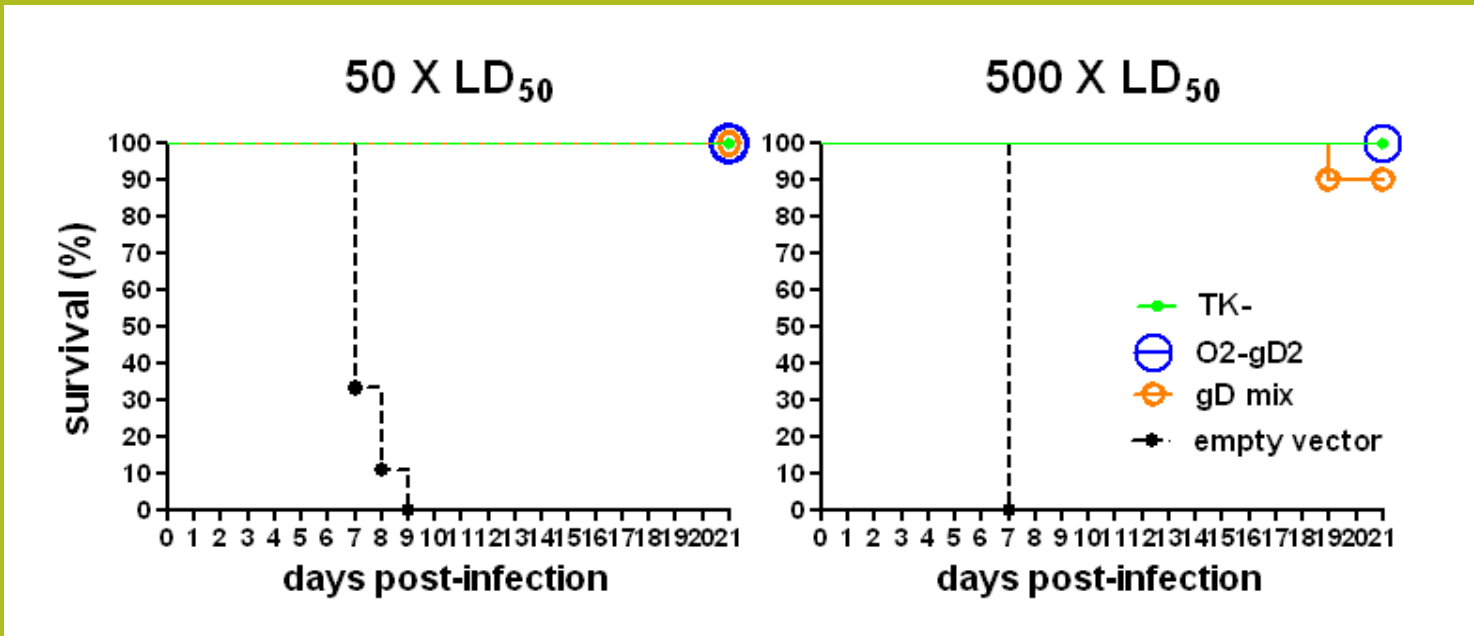
# **Commercialising Vaccines with Ian Frazer**

## **Immunotherapies for infectious diseases and oncology**

# Immunotherapy vaccine Programs

- Core technology developed by Professor Ian Frazer & his team
  - Developing immunotherapeutic vaccines
  - Targeting multi-billion \$\$\$ global markets for vaccines
  - Potential for licensing revenue plus royalties in the next few years
- Initially targeting HSV-2 & HPV
  - Application in infectious diseases & oncology
- HSV-2
  - Pre-clinical data shows total viral clearance with treatment
  - Initiated Phase I human “proof of technology” August 2013
  - Goals = safety, antibody generation & CTL responses
  - Interim results scheduled for end of 2013
- Positive preclinical results in HPV shown late 2012
  - Results showed vaccine stopped HPV related cancer progression
  - Ongoing preclinical studies
  - Additional results scheduled for end of 2013

# HSV-2 vaccine effective in mice





# DNA Vaccine Program Markets

## HSV-2 program

- 1 in 6 people in the US estimated to be HSV positive
- Significant market size
- Estimated growth north of \$6Bn with treatment/vaccine available
- No approved vaccine available

## HPV program

- Still many people not using or completing the HPV vaccine therefore need
- ~<35% vaccination rate for HPV in the US
- Current HPV vaccines do not treat the disease (people already infected)
- Estimated at greater than \$1Bn market potential for therapeutic vaccine

# Company Summary

## Company Summary

- **Ticker** **ASX:AHZ**
- **Employees** **32**
- **Market cap** **\$100M**
- **Cash & equivalents** **\$2.5M (June '13)**
- **Current revenue** **\$7.4M**
- **Top 20 shares** **37% holding**

## Company Key Points

- Existing revenue of \$7.4 million & growing
  - CardioCel® to grow significantly in overseas markets
- Near term regenerative tissue product approval
  - CardioCel® approved in Europe
  - Differentiated via true tissue regeneration and preventing calcification
  - Early access approval already in Australia
  - Significant revenue increase from a high unmet need
- Large potential with Prof Frazer's DNA vaccine technology
  - Multi-billion market potential
  - Revenue potential via licensing / partnering with pharma

## **Milestones for Next 12 months**

- ✓ **Initial preclinical data for HPV vaccine program**
- ✓ **Additional “early access” approvals for CardioCel®**
- ✓ **Initial 510K US regulatory filing**
- ✓ **Initiation of the HSV immunotherapy Phase I study**
- ✓ **Approval for CardioCel® in Europe**
- **Initial revenues from CardioCel®**
- **Initial HSV-2 immunotherapy Phase I results**
- **Preclinical HPV results**
- **Approval for CardioCel® in USA**
- **Expanded regenerative tissue portfolio**

# Thank you

Allied Healthcare Group

*An opportunity to invest in a new diversified  
healthcare company with large growth potential*

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