regeneus
living regenerative medicine

ASX Spotlight Conference

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Singapore & Hong Kong
October 2013

"Improving quality of life through innovative cellular therapies"

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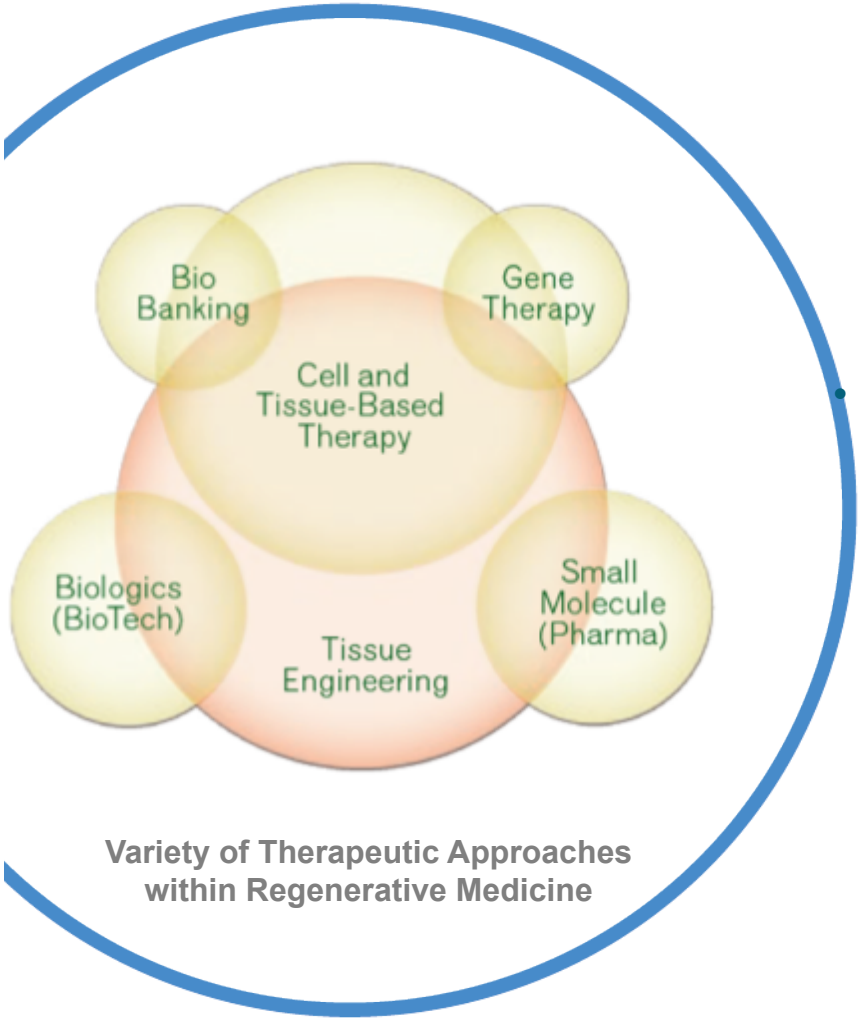
Investment Summary

- **Cell therapy is at an inflexion point**
- **Emerging leader in developing new and innovative cell therapies** - 3 product platforms based on proprietary adipose (fat) derived stem cell technologies
- **Generated breakthrough clinical data validating its therapies for osteoarthritis** (OA) – potential application in multiple inflammatory conditions
- **Adipose tissue provides competitive advantage** as cell source
- New regulatory frameworks can allow for **early access** and **accelerated trial and approval pathways**
- **High value product pipeline**
- **Products underpinned by 9 patent application families**
- Quality Board and Management with **commercial success in biotech**

Corporate and Finance Snapshot

Event	Details
Incorporated	• 14 August 2007
Pre-IPO funding	• A$12.5m in 4 rounds
ASX Listed	• **Listing Date - 19 September 2013** • ASX Code: RGS
Shares on Issue	• 183.8m ordinary shares • 14.3m employee options
Shareholders	• **Top 20 shareholders hold 54% of issued shares** • 26% of shares subject to escrow
Cash position	• **Raised A$10.5m in September** IPO at $0.25c (Mkt cap $45m) • **2 year funding runway** to meet business and R&D milestones
FY13 Financials	• Revenue $1.77m (FY12: $1.25m FY11:$0.785m) • **>40% top line revenue growth pa since start up** • R&D tax $2.37m (FY12: $1.67m FY11: $0.939m) • EBITDA ($5.19m) (FY12: ($3.26m) FY11: ($1.72m))

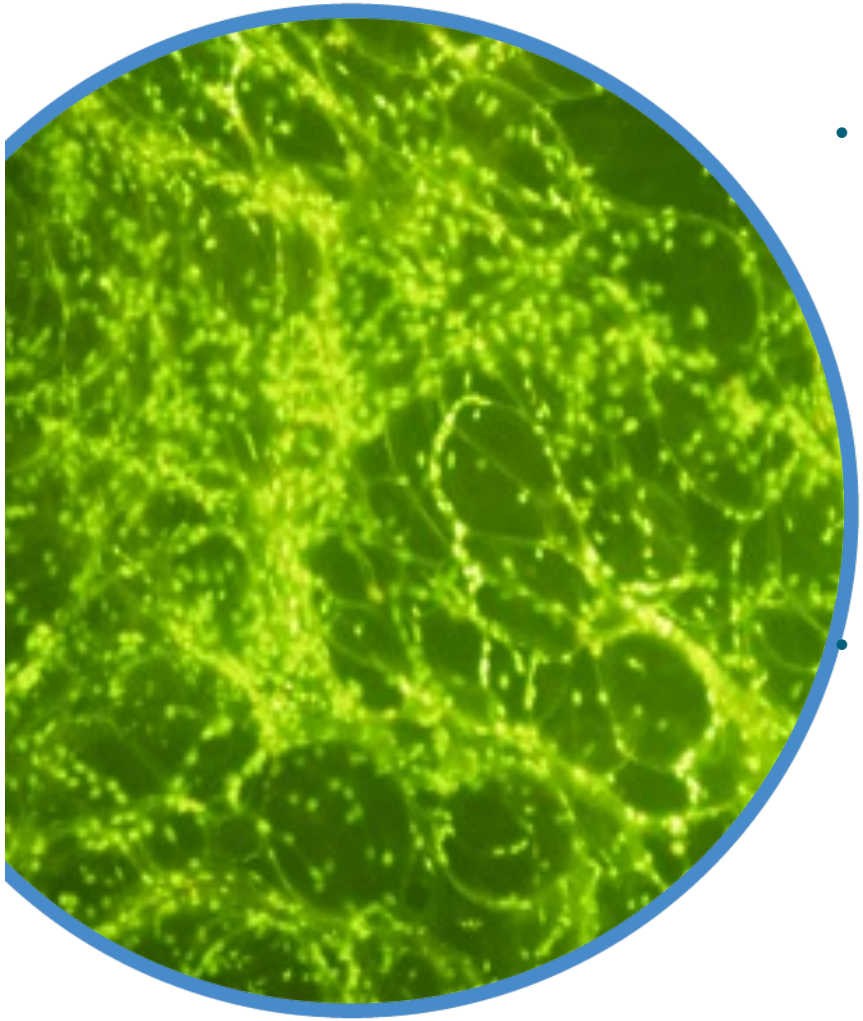
Regenerative Medicine – at an inflexion point



Variety of Therapeutic Approaches within Regenerative Medicine

- Rapidly evolving interdisciplinary field:
  - Potentially transforming healthcare
  - Translating new scientific breakthroughs into a variety of innovative medical technologies
  - Restores function by enabling the body to repair, replace and regenerate damaged ageing or diseased cells, tissues and organs
- Already a medical reality:
  - >60,000 stem cell transplants per year worldwide for oncology and blood based disorders
  - >2,500 ongoing clinical trials for regenerative medicine therapies
  - In 2012, the sector had > $1bn in annual revenue worldwide and attracted >$900m in investment from private investors and public markets worldwide
  - First advanced cell therapy approved in May '12 for GvHD

Benefits of Adipose-Derived Stem Cells



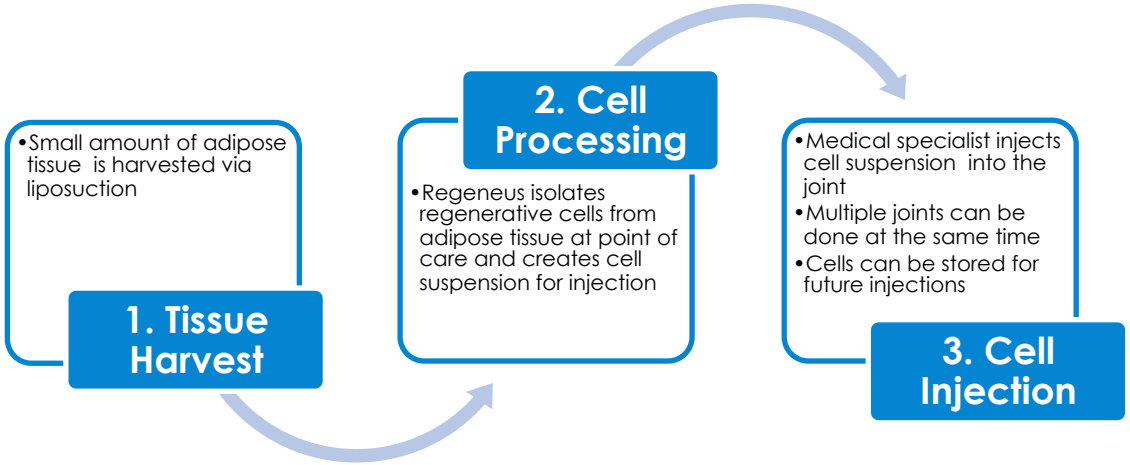
- Various sources of adult stem cells - bone marrow, cord blood, skin and adipose (fat) tissue
- Advantages of adipose tissue
  - **Rich and readily accessible source** of **mesenchymal stem cells** (MSCs)
  - 500-1000 times more MSCs than bone marrow per gram
  - Only source of MSCs to provide a **therapeutic dose without need to culture**
- **MSCs secrete cytokines** and growth factors that **modulate the immune system** to **decrease inflammation** and regulate local environment to **stimulate repair and regeneration**

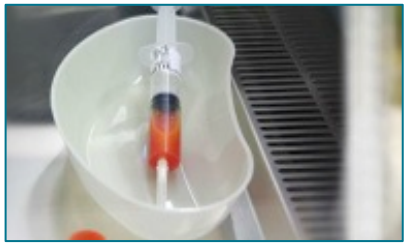
Technology Platforms: Multiple Therapies

Technology Platforms	Autologous Cells (point-of-care)	Allogeneic Cells (off-the-shelf)	Allogeneic Cell Secretions
Cell Source	Adult Adipose Tissue & Other Adult Tissue	Donor Adipose Tissue	Donor Adipose Tissue
Process	Unexpanded Cells	Expanded Cells	Cell Secretions from Expanded Cells
Product	HiQCell	CryoShot	Secretions
Market	Human	Vet and Human	Human
Treatment	Musculoskeletal - OA	Musculoskeletal	Topical inflammatory skin conditions
Other Applications	Pain, Oncology other inflammatory conditions	Pain, Oncology other inflammatory conditions	

HiQCell – leading autologous cell therapy for OA

- Cell-based therapy using autologous unexpanded adipose derived MSCs to treat human osteoarthritis and other musculoskeletal conditions
- Simple, low risk, same day procedure performed by licensed medical specialist (exempt biological under TGA regulatory framework)





HiQCell - Commercial Positioning

- **Best in Class**
  - Proprietary procedure and robust processing protocols supported by patents
  - Optimised for maximum cell yield in 60 minutes
  - Cryostorage option for future injection of cells
  - Proprietary inflammatory biomarkers to measure impact of therapy and timing of reinjection
  - Only available through musculoskeletal specialists
  - Supported by RCT data and joint registry data

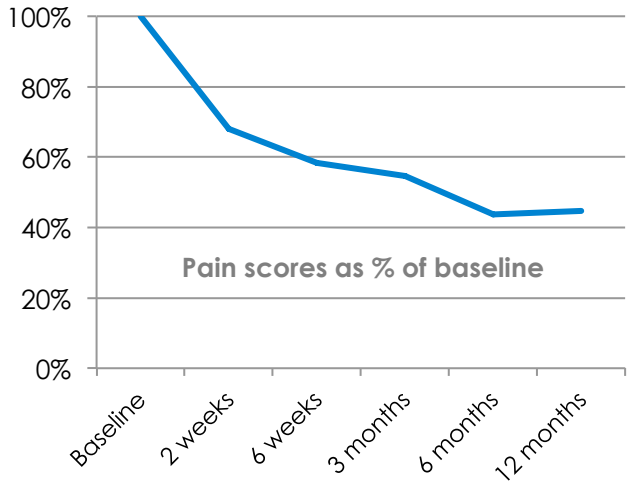
HiQCell – Clinical Validation

OSCARS

- Key findings of pioneering RCT (40 persons) of HiQCell for OA at RNSH:
  - HiQCell **safe with no adverse effects***
  - Large and statistically significant decrease in total pain score from baseline for both groups – high placebo response common in pain scores
  - **MRI shows HiQCell therapy slows cartilage degradation**
    - **Cartilage breakdown marker (CTX-II) stabilises** in HiQCell treatment group and increases significantly in placebo group
  - Inflammation and **osteoarthritis biomarker decreases significantly in HiQCell treatment** group and increases in placebo group (macrophage migration inhibitory factor)

Joint Registry

- Joint Registry data consistant with OSCARs
- > 230 patient's data
  - largest joint registry of its type in Australia



*No serious product related adverse events

HiQCell - Commercial Roll-out Progressing

- Over 350 procedures across 800 joints since commercial launch in FY12
- Initially available in FY12 through Sydney Sportsmed Specialists to treat OA and other musculoskeletal conditions
- Now available through 16 specialists (sports med and orthopaedics) in medical facilities in Sydney, Gold Coast and Melbourne
- **Strategy to create treatment hubs in all major Australian capitals** with musculoskeletal specialist communities (1500 orthopods and 180 sportsmed specialists nationally)
- Looking to launch in Singapore, Germany and UK – identified to have similar regulatory framework to Australia
- Used as adjunct for arthroscopy and for maxillofacial pain with potential for other disorders
- **Plan to seek reimbursement**– some procedures have been funded by private insurers
- Procedure price $9-10k

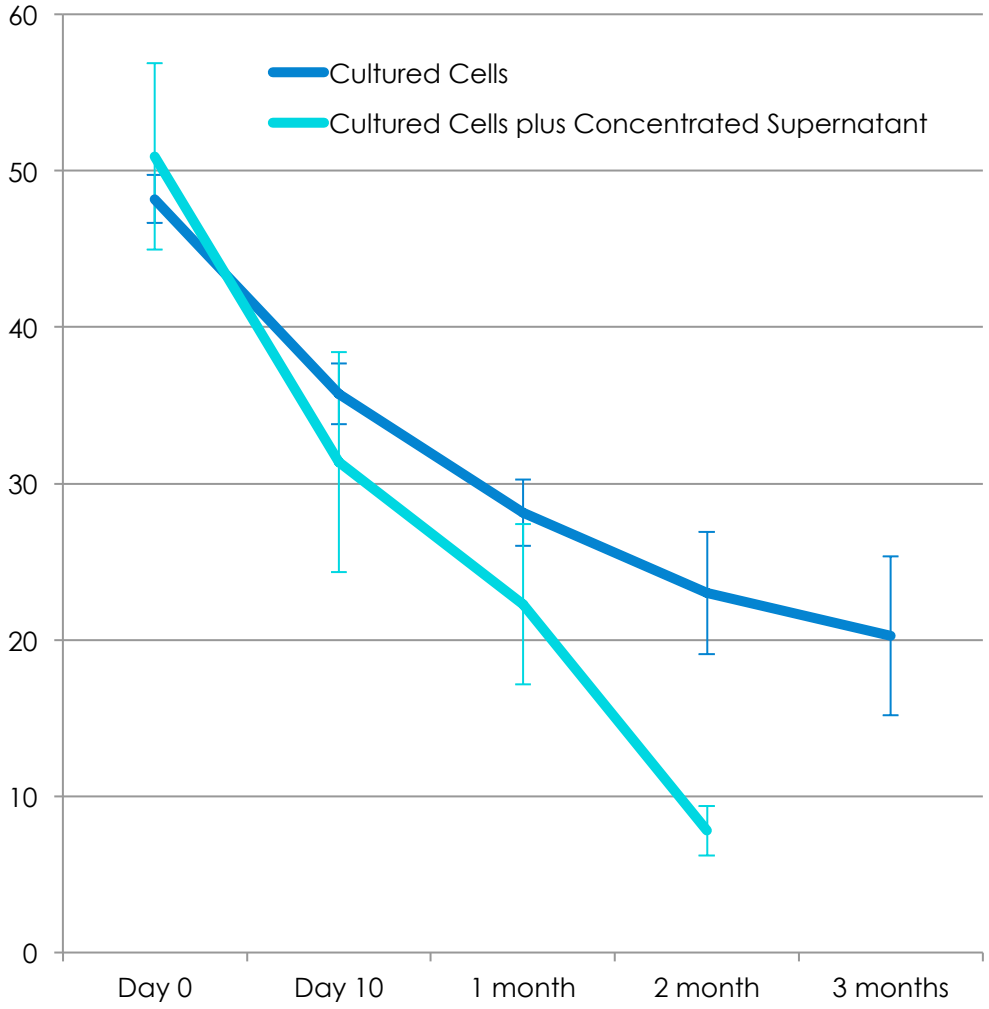
HiQCell – Market Drivers

- **Australian Market**
  - OA is # 1 chronic disease in Australia – no cure
  - OA affects ~4m people and estimated to grow to 7m by 2050
  - Similar rates of disease in major western countries with ageing populations
  - >80k joint replacements (knee and hip) per year and growing
- **Market Drivers**
  - Treatment gap between pain medication and joint replacement procedures
  - Cell based therapies only option to delay or overcome shortcomings of invasive procedure
  - Clinical data now supports benefits of cell therapy
  - HiQCell therapy gives Sports Med Specialists a surgical treatment option they can perform alone
  - Reimbursement will have major impact on procedure rates

CryoShot – Allogeneic Cell Therapy

- > 2000 vials administered for the treatment of canine and equine musculoskeletal conditions since introduction in early 2012 (APVMA permit 7250)
  - > 70 vet practices have taken up the trial product
- Genuine off-the-shelf product
  - Delivered in frozen 2ml vials to maximise the flexibility in terms of use, shelf life and viability
  - In-house manufacturing, distribution and handling capabilities
- Seeking registration in Australia (APVMA), US (FDA), EU (EMA) – opened INADA with FDA on 28 June '13
- Significant reduction in pain and improvement in mobility within 10 days of treatment with no need for ongoing surgery or drugs

CryoShot - Cells plus Secretions Outperform



- Canine Brief Pain Inventory
  - Validated owner questionnaire from University of Pennsylvania
  - Accepted by FDA
- Majority of effect is within the first month
- Cells plus secretions
  - has a greater effect on reducing pain
  - Aligns with stronger Regeneus patent
- Developing human CryoShot for human safety study

Market Sizing for CryoShot

- **Osteoarthritis**
  - ~1 in 5 animals will suffer from OA (incidence rate)
  - →~600,000 - 900,000 animals treated per year in AU
- **Other indications**
  - Tendinopathy
  - 30% incidence of SDFT of horses in training (UK/EU)
- **Market Size ($)**
  - AU Veterinary services (*IBISWorld Veterinary Services)*
  - A$2.55b (+1.4%)
- **Anti-inflammatory agents (ex-wholesaler)**
  - *(APVMA)*~A$30m
    - Companion animal NSAID market (pharmaceutical)
    - **A$16-17m** (estimated)
  - Global companion animal pharmaceutical pain relief market ~US $0.5b *(Vetnosis)* [**OA~80%=US$0.4b**]

Secretions – Stem Cell Cream

- Secretions from MSCs mixed into a cream for application to skin
- Has demonstrated application for:
  - acne
  - psoriasis
  - dermatitis
  - insect stings and bites
  - burns

- Finalising best method of manufacture, applications and commercialisation pathways

- Complete safety study in FY14

Secretions – stem cell cream

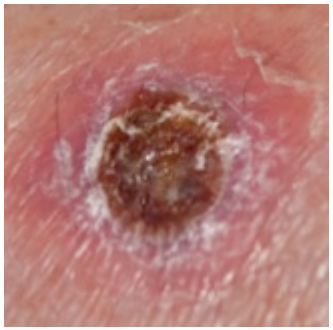
- Liquid nitrogen burns on human

After 1 day blistered

1 week

1 month

Treated Right Leg



28 months

Untreated Left Leg

Treatment begun on right leg burn at 1 hour time point
No treatment used on left leg burn
Considerable reduction in pain on the treated burn

Autologous Cancer Vaccine

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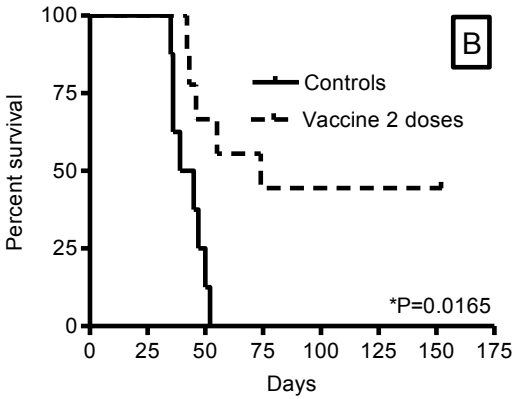
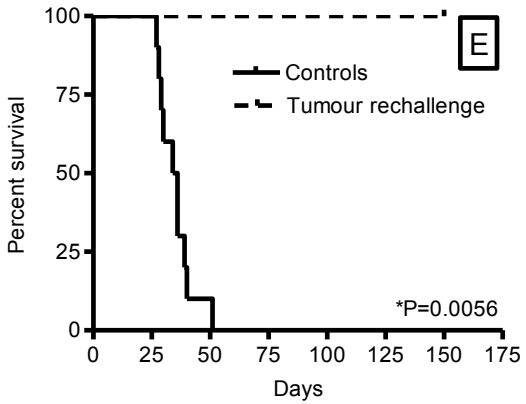
- Autologous cancer vaccine that uses tumour cells as source material for therapy
- Successful pre-clinical studies in Glioma model and successful safety study in dogs with real cancer
  - Massive increase in survival times & re-challenge with tumour unsuccessful
  - No safety issues
  - Planned US efficacy trial in canines
- Potential to accelerate into human safety study
- Developed at Kolling Institute of Medical Research – RNS Hospital/University of Sydney
- Exclusive commercial rights for vet and option over human





Outlook for next 12-24 months

- **HiQCell – Autologous in clinic procedure**
  - Expand treatment footprint and procedure rates in Australia and launch in foreign market
  - Grow registry data
  - Extend to new musculoskeletal applications – pain management

- **CryoShot – Canine OTS**
  - Enter into manufacturing agreement
  - FDA sign off on product for trial and trial design
  - Continue to gather field trial data in Australia

- **CryoShot – Human OTS**
  - Finalise product manufacture
  - Commence phase 1 trial in human OA

- **Cancer Vaccine - autologous in clinic**
  - Commence efficacy trial in canines

- **Secretions -OTS**
  - Safety study for topical applications for inflammatory skin conditions