



ASX Spotlight Conference

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Singapore & Hong Kong
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“Improving quality of life through innovative cellular therapies”

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Investment Summary



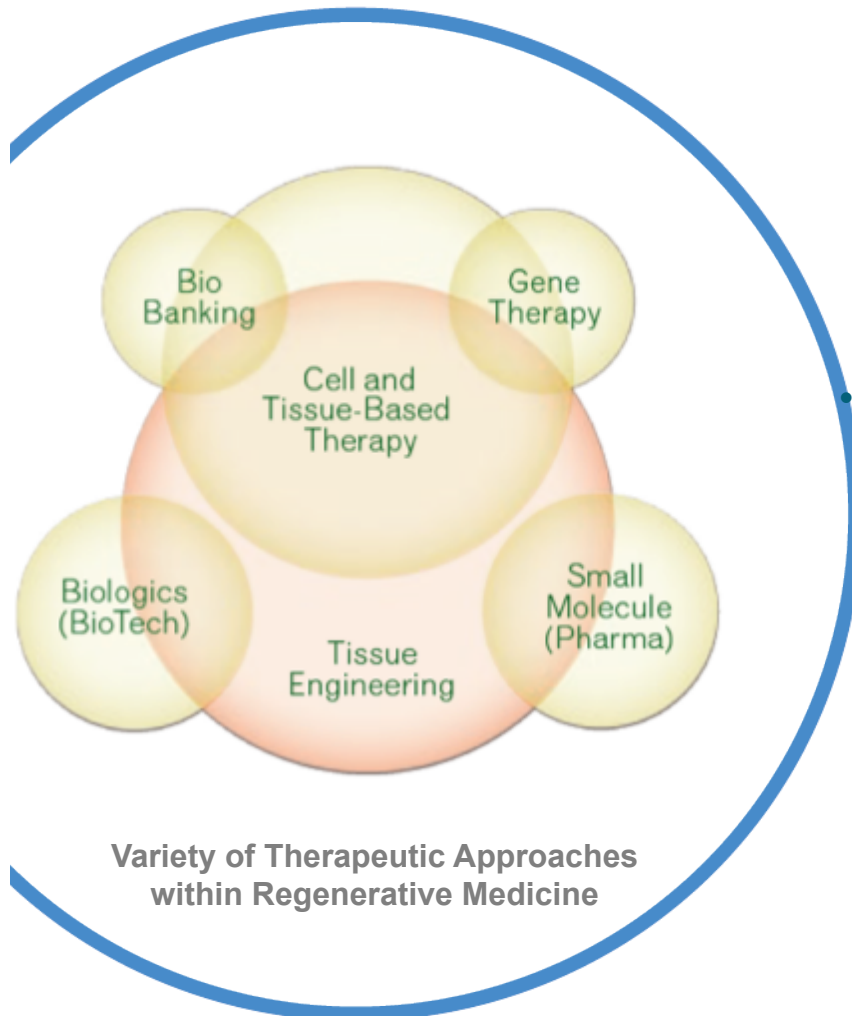
- **Cell therapy is at an inflexion point**
- **Emerging leader in developing new and innovative cell therapies** - 3 product platforms based on proprietary adipose (fat) derived stem cell technologies
- **Generated breakthrough clinical data validating its therapies for osteoarthritis (OA)** – potential 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



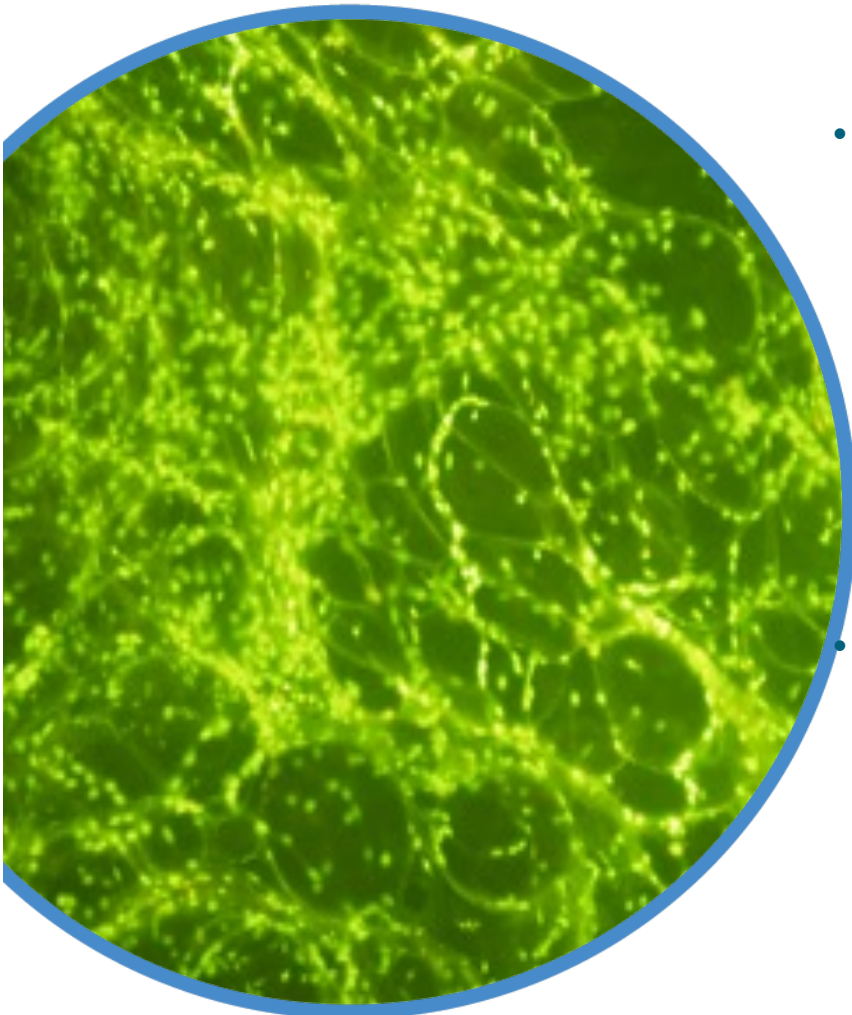
Event	Details
Incorporated	14 August 2007
Pre-IPO funding	A\$12.5m in 4 rounds
ASX Listed	Listing Date - 19 September 2013 - ASX Code: RGS
Shares on Issue	183.8m ordinary shares 14.3m employee options
Shareholders	Top 20 shareholders hold 54% of issued shares 26% of shares subject to escrow
Cash position	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



- 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**

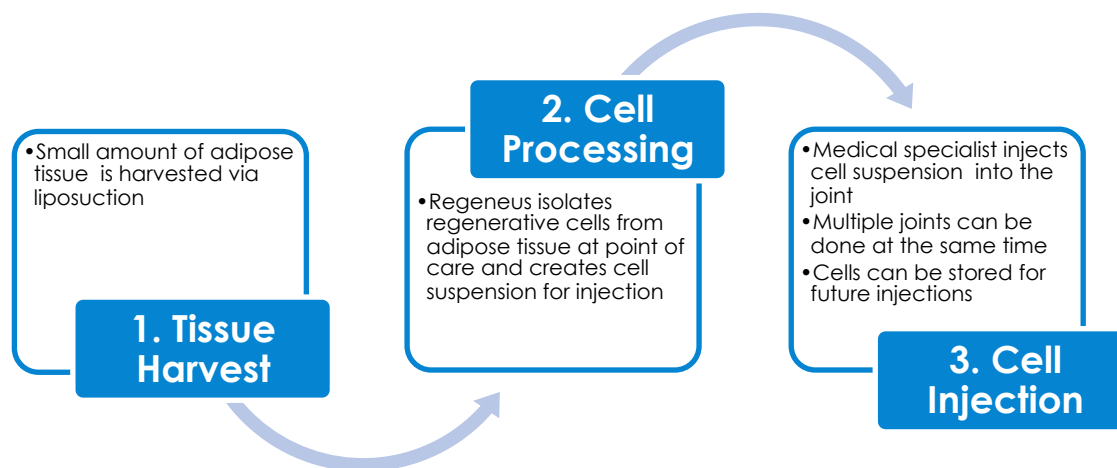
Technology Platforms: Multiple Therapies



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			
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)



- **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



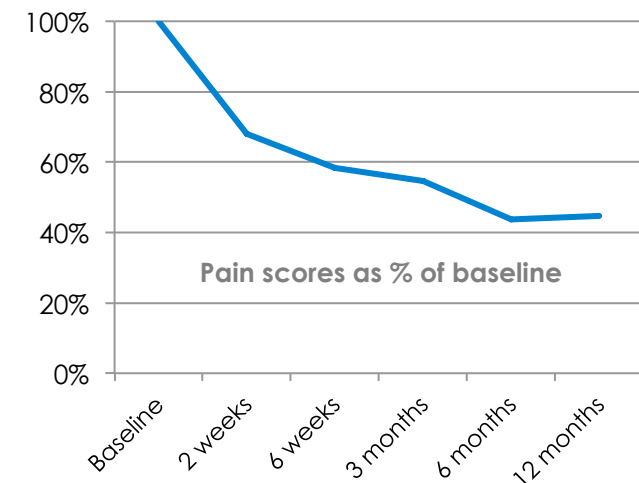
OSCARS

- 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 consistent 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

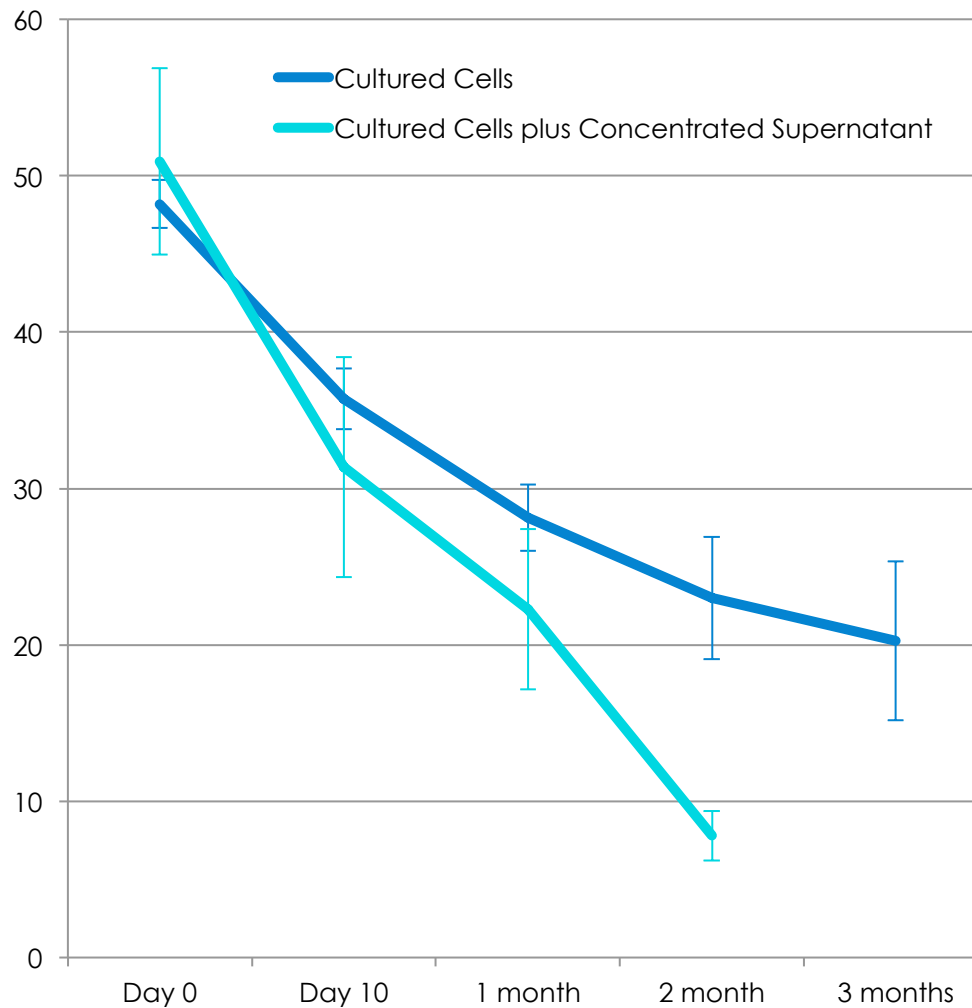


CryoShot – Allogeneic Cell Therapy

- > 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

CryoShot

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



Treatment begun on right leg burn at 1 hour time point

No treatment used on left leg burn

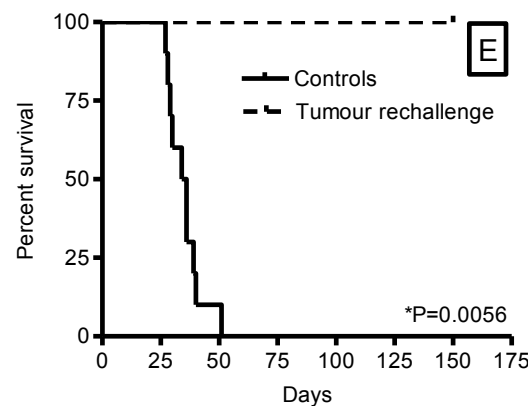
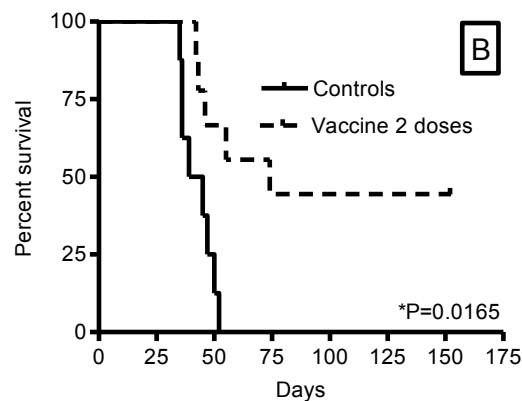
Considerable reduction in pain on the treated burn

Secretions

Autologous Cancer Vaccine



- 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