regeneus
living regenerative medicine

CHINABIO® PARTNERING FORUM
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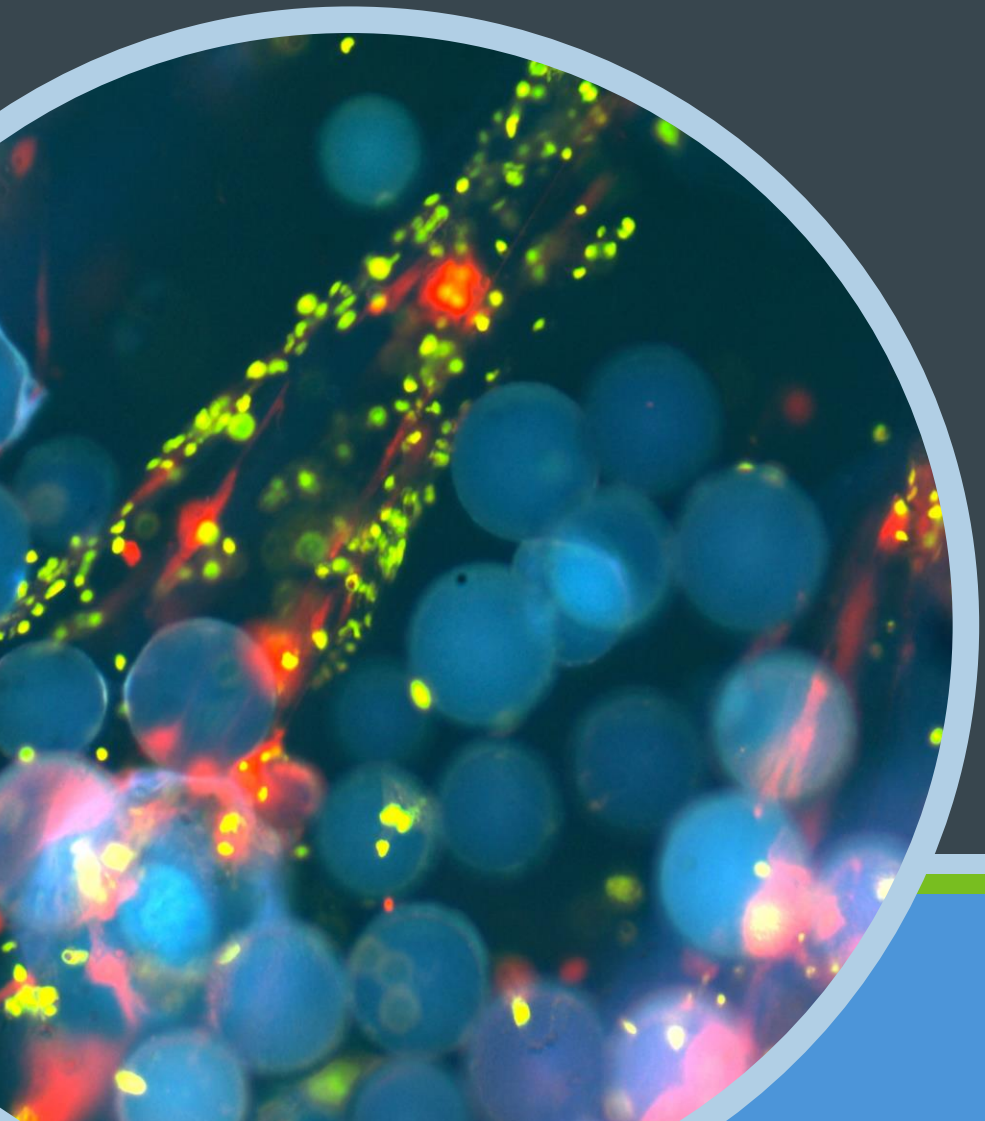

Regeneus Ltd (ASX: RGS)

Duncan Thomson

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Overview of Regeneus

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A Sydney based, Regenerative Medicine company listed on the Australian stock exchange (ASX:RGS)

Disruptive proprietary technology platforms

- Allogeneic adult stem cells (MSCs) from adipose tissue for osteoarthritis and other inflammatory conditions (Progenza, CryoShot)
- Immuno-therapy for oncology (RGSH4K, Kvax)
- Cell secretions from adipose MSCs for inflammatory conditions

Diversified portfolio of clinical stage products

- Human and animal health markets
- All product platforms in clinical development
- Scalable manufacturing for allogeneic stem cells
- Strategic and growing IP portfolio to underpin technologies and products

Innovation and collaboration

- Commercially focused
- Successful technology and clinical collaborative partnerships (AGC Glass, University of Adelaide, Macquarie University, Kolling Institute)
- Strong and proven management team
- Experienced technical resources

Product Pipeline and Overview

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Pipeline Summary

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Human Health Development Pipeline

Program	Technology Platform	Pre-Clinical	Phase 1	Phase 2	Phase 3	Filing	Approval
Progenza	Allogeneic Adipose MSCs & Secretions	Osteoarthritis					
		Pain					
RGSH4K	Immunotherapy for oncology	Solid Tumours					
Secretions	Allogeneic Adipose MSC Secretions	Dermatology					

Animal Health Development Pipeline

Program	Technology Platform	Manufacturing & Process Development	Safety & Efficacy Studies	Pivotal Trial	Market Approval
CryoShot Canine	Allogeneic Adipose MSCs	Osteoarthritis			
CryoShot Equine	Allogeneic Adipose MSCs	Osteoarthritis			
Kvax	Immunotherapy for oncology	Naturally Occurring Advanced Cancers (Conditional Approval))			

Progenza
Allogeneic Stem Cell Platform

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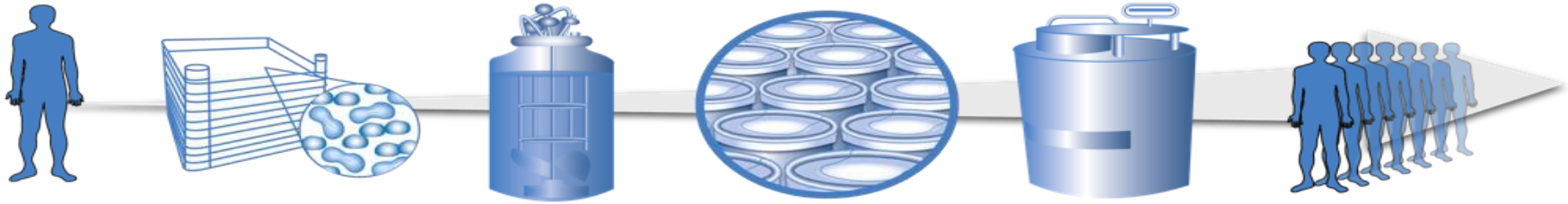
- Progenza is a patented, scalable, off-the-shelf stem cell technology platform **to treat a range of inflammatory conditions**

- Allogeneic mesenchymal stem cells (MSCs) are sourced from a healthy adult donor
  - no reprogramming of cells = **safety benefits → lower regulatory risk**

- Adipose (fat) tissue is the source of cells
  - large starting volume, and large number of MSCs in adipose vs. other tissue sources
    - Optimised production using proprietary IP → production of millions of doses from one donor = **scalable technology**
  - immuno-modulatory benefits of adipose derived cells (vs other sources)



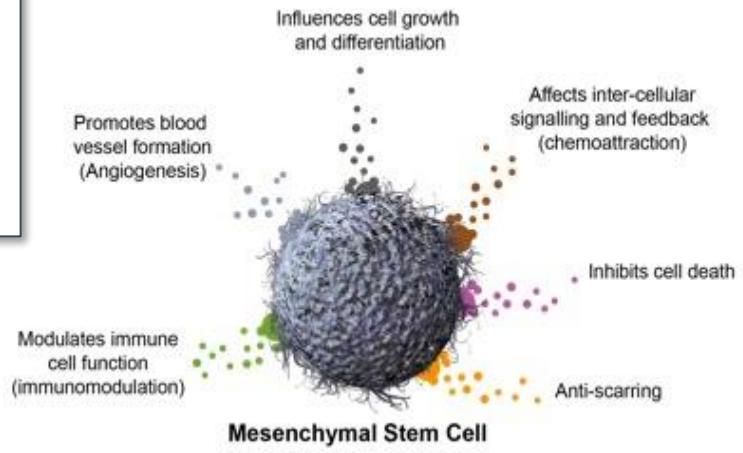
A single adult healthy lipoaspirate | Isolation and expansion of MSCs into two tiered cell bank | Further 3D cell expansion | Expansion of cells to manufacture millions of doses from a single donor | Long term cryostorage | Millions of therapeutic doses from a single donor

Zhu, Y., Liu, T., Song, K., Fan, X., Ma, X., & Cui, Z. (2008). Adipose-derived stem cell: a better stem cell than BMSC. Cell Biochem Funct, 26(6), 664–675.
Melief, S. M., Zwaginga, J. J., Fibbe, W. E., & Roelofs, H. (2013). Adipose tissue-derived multipotent stromal cells have a higher immunomodulatory capacity than their bone marrow-derived counterparts. Stem Cells Translational Medicine, 2(6), 455–463.

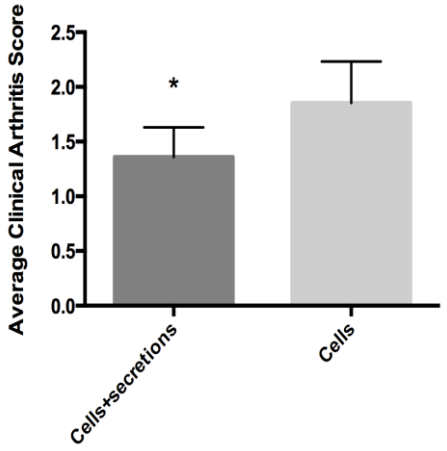
Progenza
Advantages of Secretions

MSCs secrete a diverse variety of bioactive factors including cytokines, growth factors, extracellular vesicles and exosomes

Secretions respond to the local environment and are the driving force for reducing inflammation, promoting tissue repair and reducing scarring



- Progenza is different from other MSC products as it includes secretions with cells which:
  - **improves functionality of cells**
    - ability to secrete and proliferate post thawing
  - **improves therapeutic effect**
    - e.g. rheumatoid arthritis model (CAIA) in mice tested MSC cells alone and MSC cells frozen in cell supernatant
      - Average Clinical Arthritis score were significantly lower with cells frozen in cell supernatant compared to cells alone



Progenza Collaboration in Japan

In December '16, Regeneus and AGC, the leading Japanese manufacturer of biopharmaceutical products, entered into collaboration and licence agreement for the manufacture and joint licensing of the clinical development of its off-the-shelf stem cell therapy platform, Progenza, in Japan

regeneus living regenerative medicine	Received **US$5.5M** Upfront licence fee	Entitled to **US$11.0M** Specific milestone payments	Established 50/50 JV for licensing clinical development and marketing rights of Progenza for OA and all other indications in Japan	Entitled to 50% of Progenza clinical licensing, milestone payments and sales royalties
AGC	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

Progenza
Benefits of Collaboration with AGC

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- **Large Japanese/global partner with aligned goals**
  - Dominant biopharmaceutical contract manufacturer in Japan targeting accelerated entry into cell-based therapeutics manufacture
  - Ambition and resources dedicated to supply global market
- **Increased impetus of Progenza development**
  - Takes advantage of new Japanese regenerative medicine laws
  - Initial osteoarthritis development
  - Other inflammatory indication areas
- **Existing and ongoing relationships with**
  - Regulators in biopharmaceuticals manufacturing
  - Major pharmaceutical businesses

Progenza – Phase 1 Osteoarthritis Safe and Tolerable

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Primary Endpoints Met

- Progenza at both doses was found to be safe and tolerable
- No serious adverse events occurred
- The majority of adverse events (AEs) were of mild severity
- No meaningful differences between placebo and PRG groups in incidence and nature of adverse events
- No trends or findings of concern were identified
  - from patients' vital signs, laboratory tests, physical examination, ECGs or other safety measurements

- Double-blind, placebo controlled and randomised 20 patient trial
  - Sydney - late 2015 through April 2017 (reported May'17)
- Single intra-articular injection and monitored for 12 months for safety
  - 2 cohorts, placebo (4:1)
- Mean age 53 years (40-64 years)
- Diagnosed with knee OA
  - mild OA 25% Moderate OA 75%

Progenza – Phase 1 Osteoarthritis Significant Secondary Endpoints

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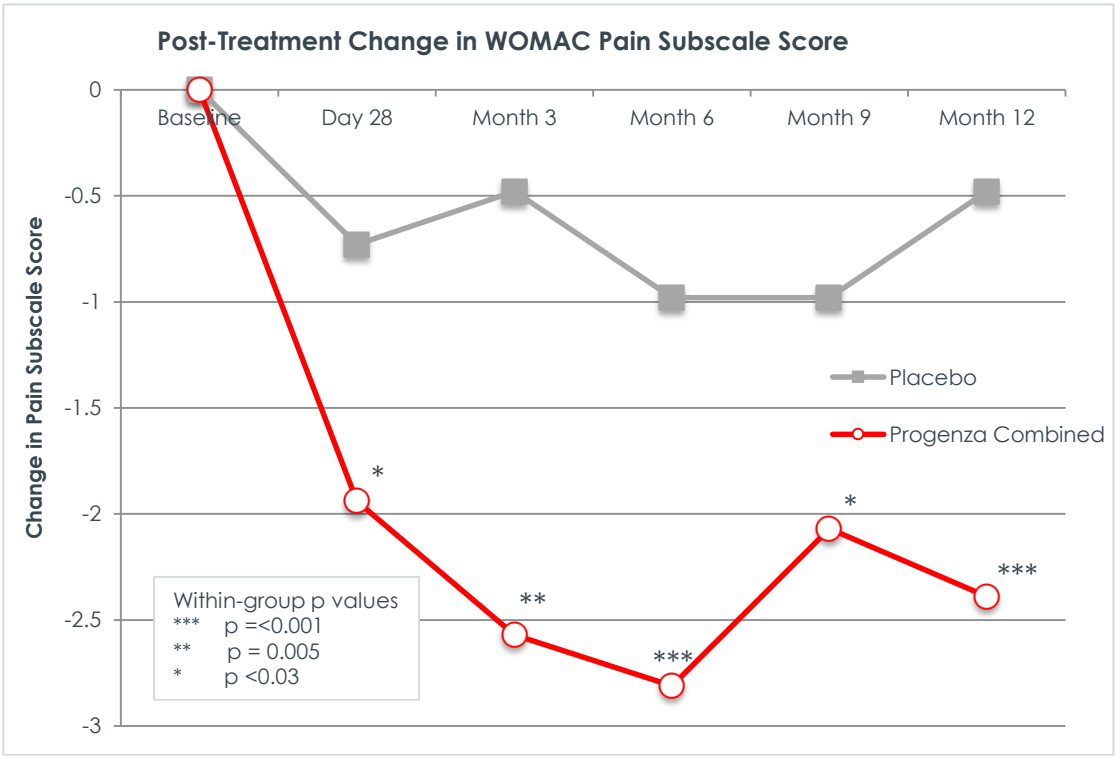
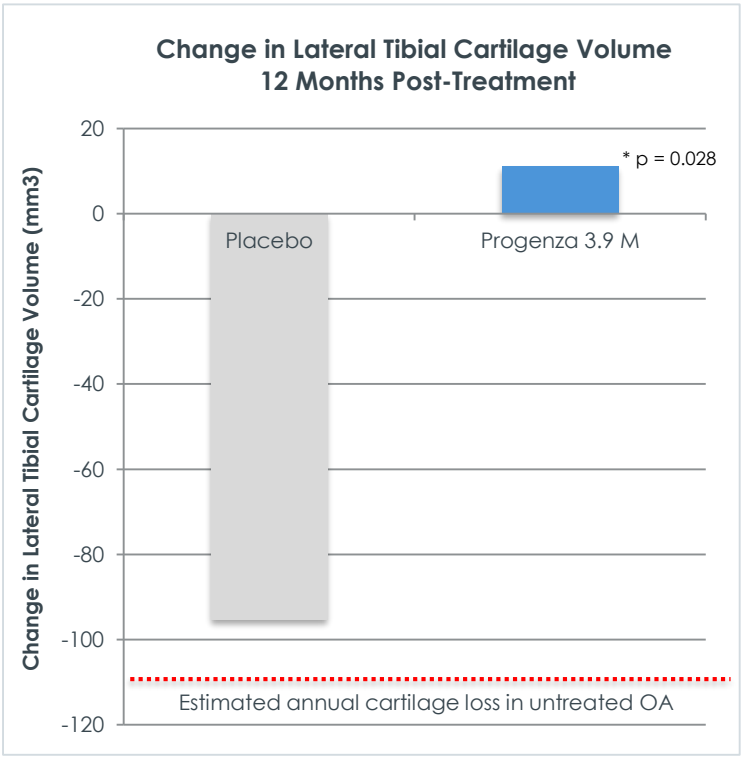
Secondary Endpoints

- Significant reduction in knee pain in Progenza groups - rapid and sustained
- Significant improvement in cartilage volume compared to placebo in 3.9M dose
- Positive signs of disease modification





Untreated OA is estimated to lose 5% of Lateral Tibial Cartilage Volume per year

Progenza – Osteoarthritis
Data consistent with Preclinical Results

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Safe and tolerable

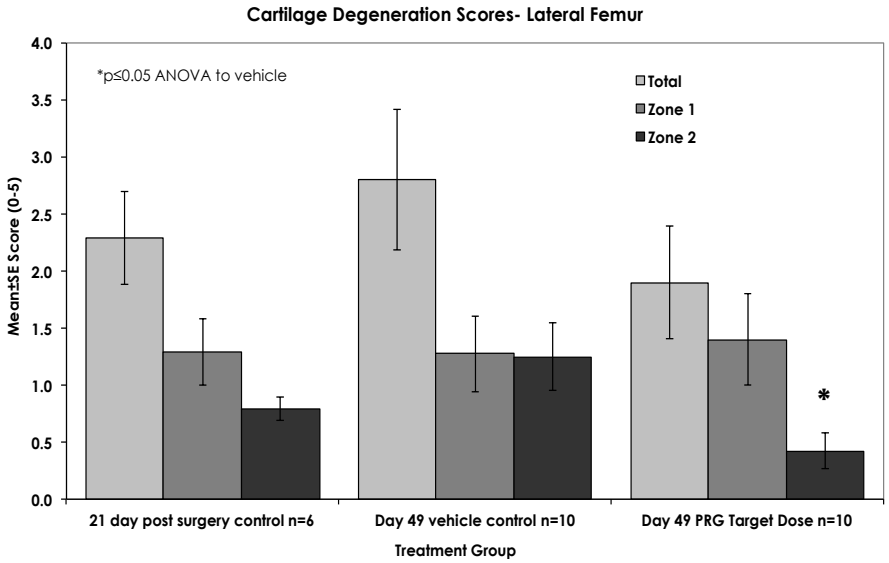
- No Progenza-related systemic or local toxicities or dose related adverse effects

Significant Secondary Endpoints

- Significant reduction in cartilage degeneration scores with target dose
  - Middle load bearing femur zone (zone 2)
- No further progression of OA
  - Total degeneration scores in Progenza treated knees 4 weeks post-treatment showed no further progression of OA compared to the pre-treatment control group (21 days post surgery)

Rabbit Osteoarthritis Model - partial meniscetomy

- Single Progenza intra-articular injection 21 days post-surgery



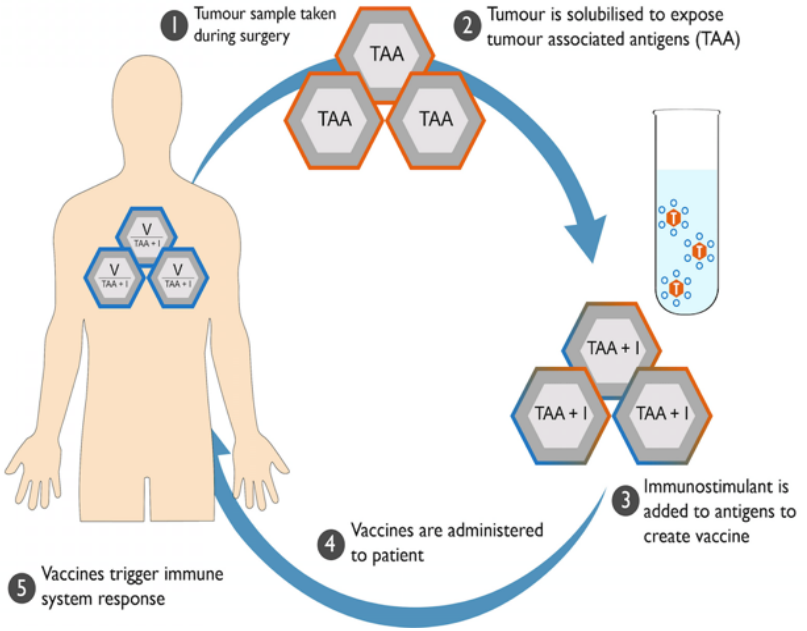
Conducted by US-based Pre-clinical Research Services, a degenerative OA model (partial menisectomy) in rabbits (n=46; 23M, 23F)

Next steps

- Pursuing potential partners for Progenza clinical development and commercialisation
- Targeting Phase 2 Progenza trial for OA in Japan under new cell therapy early access regulations

RGSH4K
Cancer Immunotherapy Platform

- Autologous cancer immunotherapy which uses a patient's own tumour as source coupled with a bacterial adjuvant
- Addresses tumour heterogeneity as all relevant tumour associated antigens are included
- Immune memory may be effective in reducing risk of tumour recurrence
- Straightforward and rapid manufacturing process
- Multi-tumour type potential



	Multiple Relevant Antigens	Potent Immunological Response	Ease of manufacture	Safety Profile	Ease of Use	Low COGS
AUTOLOGOUS THERAPIES						
RGSH4K tumour cell vaccine	✓	✓	✓	✓	✓	✓
Dendritic cell vaccine		✓		✓		
Peptide vaccine			✓	✓	✓	
ALLOGENEIC THERAPIES						
Peptide / HSP vaccine				✓	✓	
Oncolytic virus		✓	✓	✓		
Gene transfer		✓	✓		✓	

RGSH4K
Update on Phase 1

- Phase 1 Study for solid cancers (ACTIVATE Trial)
  - Multiple solid tumour types accepted
  - Patients with terminal cancer for which no other therapy exists
  - Varying levels of streptavidin to identify biologically active dose

Activity / Milestone	
ACTIVATE trial open for recruitment	☑
HREC approved tumour bank	☑
Patients in all cohorts safely treated	☑
Patent granted	☑
Last patient last visit	☐
Analysis and final report	☐

- Targeting Phase 2 RGSH4K trial for combination therapy with checkpoint inhibitors
- Pursuing early partnering opportunities

MSC Secretions
Emerging Technology Platform

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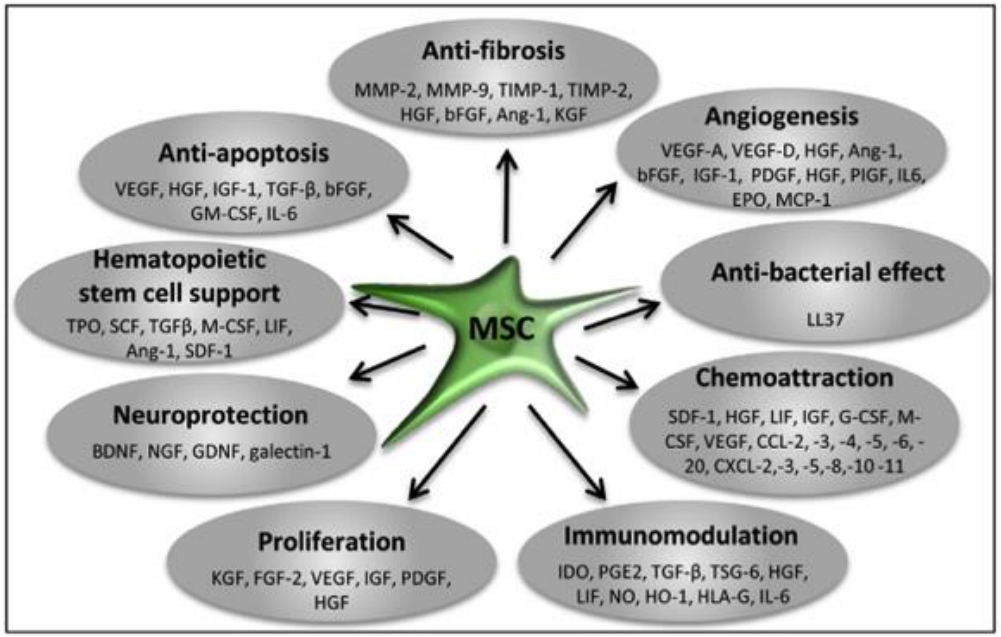
- MSC Secretions show promise as a stand alone therapeutic platform
- MSCs secrete a diverse variety of bioactive factors including cytokines, growth factors, extracellular vesicles and exosomes
- Secretions respond to the local environment reducing inflammation and scarring, and promoting tissue repair
- Secretions can be used for various forms of administration such as topical, injectable
- Initial focus on topical applications for the management of acne and other inflammatory skin conditions
- Scalable technology – produce high volumes from a single donor



Animal Health

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CryoShot
Veterinary Allogeneic Stem Cell Platform

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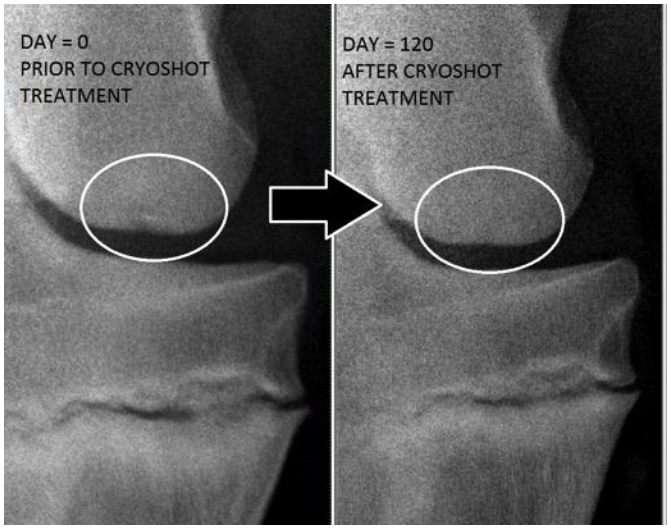
- Leading in-field, practical experience with allogeneic MSCs in the veterinary field globally with >90 vet practices involved and 5,000+ field trial treatments
- Better pain relief than NSAIDs in uncontrolled studies for osteoarthritis in dogs
- Improved interim clinical results on early orthopaedic developmental disease in yearling thoroughbreds



PennVet

Activity / Milestone	
Signed collaboration with top Animal Health Pharma to partner development and commercialisation of CryoShot Canine	☑
Commenced pre pivotal dog trial at University of Pennsylvania for osteoarthritis (currently >50% complete)	☑
Last patient last visit	☐
Analysis and final report	☐

Kvax
Canine Cancer Vaccine

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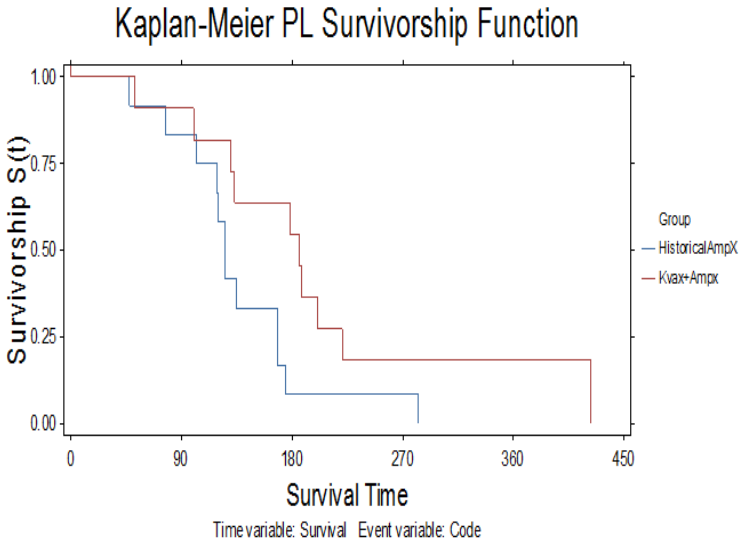
- Safety Study results
  - >100 dogs treated & 17 different tumour types
  - No safety concerns
  - At census (25 dogs) - 71% exceeded survival time up to 22 months

- Osteosarcoma study results
  - Completed canine clinical trial with Dr Bergman of VCA, largest US vet services group
  - Single arm, Kvax only

"Kvax after amputation is well tolerated and appears to confer increased PFI and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only"



- B-cell lymphoma study ongoing
  - Study initiated at the Small Animal Specialist Hospital in Sydney
  - Placebo controlled, conjunction with standard of care chemotherapy

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Patent Portfolio

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Patent Portfolio Update

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Overview

- 56 patents or patent applications across 14 patent families
- 11 patents granted in Australia; 2 in NZ; 1 in US, EU, Japan, China and Singapore
- Pursuing all key territories
- Patents cover:
  - Methods of manufacture
  - Compositions and delivery
  - Use of products for treatment of a broad range of indications

Key patents granted

- Patent granted in Australia, NZ, Japan covering Progenza technology – allogeneic stem cells and secretions for the treatment of osteoarthritis and other inflammatory conditions in humans and animals
- Patent granted in Australia covering cancer vaccine technology for the treatment of cancers in humans (RGSH4K) and animals (Kvax)

Anticipated Milestones for next 18 months

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Progenza	
• Advance clinical partnering discussions for Progenza in Japan	Ongoing
• Progress donor procurement and process development for manufacturing for Phase 2 trial in Japan	Q2 '17
• Complete chronic pain preclinical study	Q2'17
RGSH4K	
• Further recruitment on ACTIVATE clinical trial	Ongoing
• Complete recruitment and report on ACTIVATE trial	H1'18
• Advance partnering discussions	Ongoing
Secretions	
• Undertake preclinical trials for inflammatory skin conditions	Q2'17
CryoShot	
• Complete recruitment and report on canine pre-pivotal osteoarthritis trial	H1'18

Further Information

ASX: RGS

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