



Corporate Presentation for Austrade Mission on Regenerative Medicine Opportunities in Japan



ASX:RGS

Tokyo and Kobe
December 2015

Important Notice



Forward-Looking Statements

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Agenda



- Executive Summary
- Key Facts
- Product Pipeline and Overview
 - Human Health
 - Animal Health
- Emerging Technologies
- Patents
- Upcoming Milestones
- Regeneus Advantages

Executive Summary



- Developing a portfolio of clinical-stage cell-based therapies targeting areas of significant unmet medical needs in human and animal health markets
- Initial focus on osteoarthritis and other musculoskeletal disease and oncology
- Products underpinned by stem cell and immuno-oncology technologies
- Strategic IP portfolio covering products including methods of manufacture, composition and therapeutic uses
- Scalable manufacturing for allogeneic off-the-shelf stem cell products
- Experienced and commercially focused Board and Management

Key Facts



HQ: Sydney

Founded: 2007

ASX Listed:
2013

Employees: 20

Funding: \$30m
of capital,
\$12m in R&D
grants

**Shares on
issue:** 208.89m

Regeneus Ltd (ASX:RGS)

Add to portfolio

0.105 0.000 (0.00%)

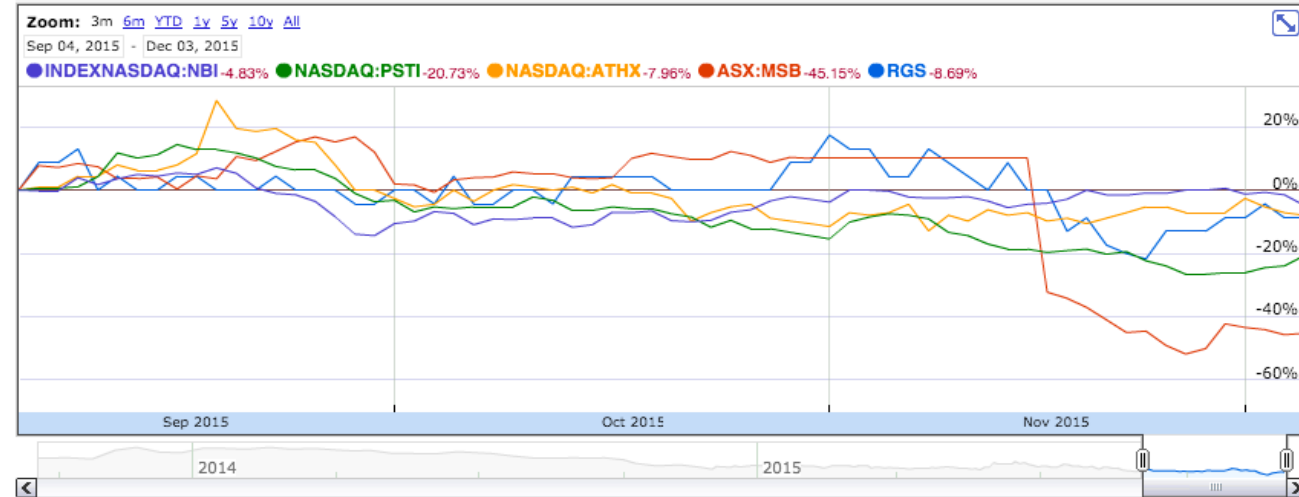
Dec 3 - Close
ASX data delayed by 20 mins - Disclaimer
Currency in AUD

Range	0.10 - 0.10	Div/yield	-
52 week	0.09 - 0.22	EPS	-0.03
Open	0.10	Shares	208.89M
Vol / Avg	251,010.00/254,023.00	Beta	-
Mkt cap	22.98M	Inst. own	-
P/E	-		

G+1 0

Compare: ☐ S&P/ASX 200 ☐ PIQ ☐ GBI ☐ SPL ☐ SBN ☐ PRM ☐ RAP ☐ PAA ☐ PNV
☒ ASX:MSB ☒ NASDAQ:ATHX ☒ NASDAQ:PSTI ☒ INDEXNASDAQ:NBI

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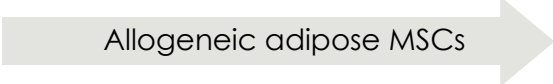
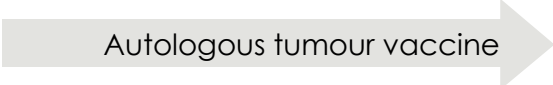
Board and Management: Dr Roger Aston, Chairman; John Martin, CEO; Prof Graham Vesey, co-founder, Director and CSO; Dr Glen Richards and Barry Sechos, NEDs; Janet Wilson, Clinical Research Director; Dr Charlotte Morgan, Head of R&D; Dr Duncan Thomson, Head of Animal Health; John Bird CFO and COO; Sandra McIntosh, Company Secretary and IR

Product Pipeline and Overview



Human Health Pipeline



Product	Indication	Preclinical	Manufacturing	Phase 1	Phase 2	Phase 3	Marketed	Market Size
Progenza	Osteoarthritis	Allogeneic adipose MSCs 						US\$12b
RGSH4K	Solid Tumours	Autologous tumour vaccine 						US\$33b

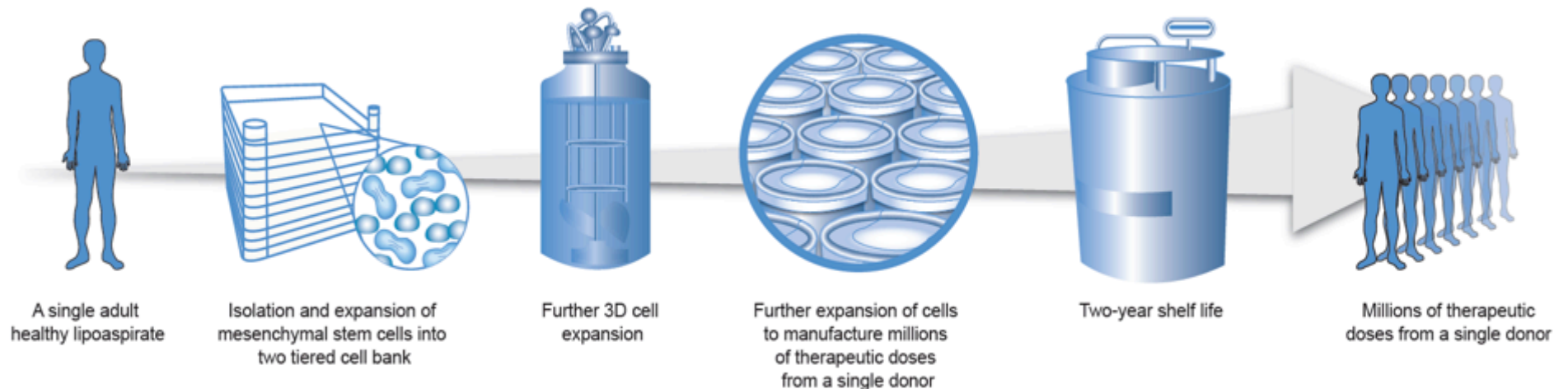
Allogeneic cells - cells from a donor

Autologous cells - patient's own cells

Stem Cell Technology Platform

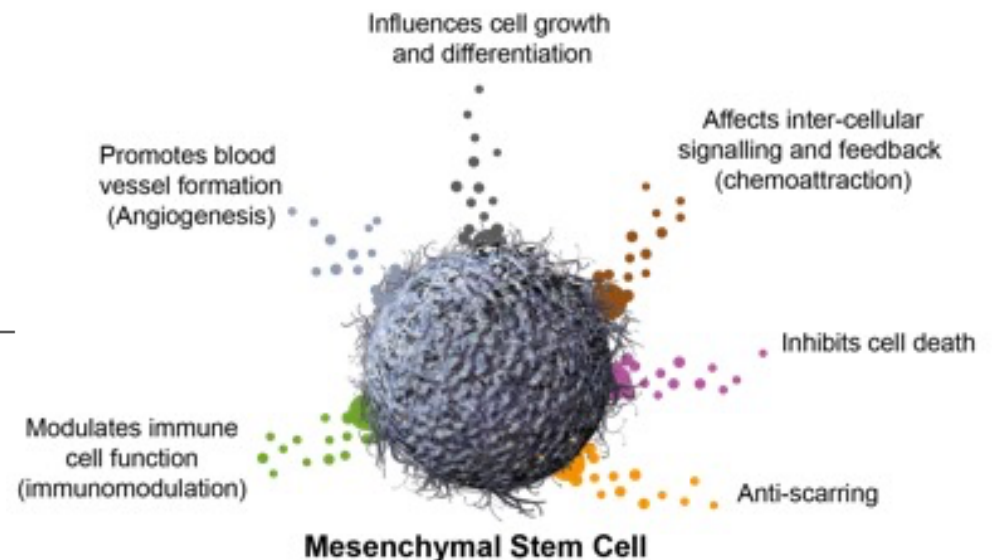


- Stem cell technology platform allows for **scalable production of allogeneic off-the-shelf cell products for a range of therapeutic uses**
- Technology **underpins both the Progenza (Human) and CryoShot (Animal)** product platforms
- Mesenchymal stem cells (MSCs) are **sourced from adipose (fat) tissue of a healthy donor** – no reprogramming of cells
- MSCs are selected and expanded using proprietary IP – **demonstrated capacity to produce millions of doses from single donor**
- Progenza MSCs are **cryopreserved in cell supernatant** to optimise viability and functionality
- **Predictable cell numbers** in each dose



MSC Secretions - drivers of therapeutic effect

- MSCs are found in adipose tissue in much greater numbers than other tissue types e.g. bone marrow, blood
- MSCs can differentiate into other cell types
- MSCs can have immune privileges – suitable for donor product
- MSCs secrete a diverse variety of bioactive factors including cytokines, and growth factors
- Secretions respond to the local environment and responsible for reducing inflammation, promoting tissue repair and reducing scarring



Focus on Osteoarthritis and Japan

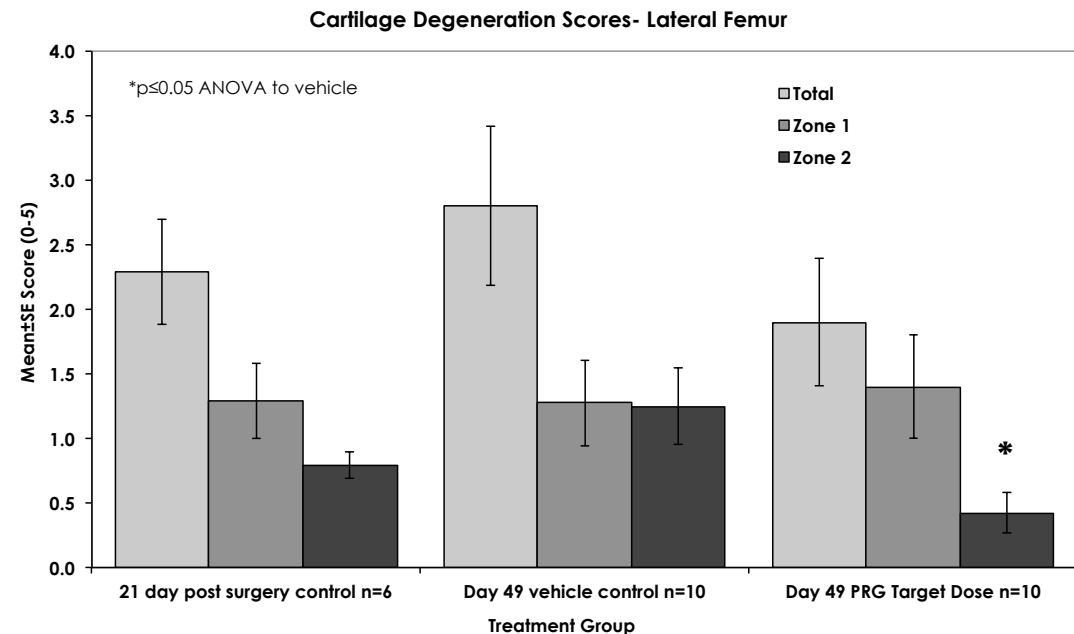


- RGS identified Japan as a key target market for Progenza for OA with the new regenerative medicine regulations
- Japanese market is dominated by NSAIDs and Hyaluronic Acid > JPY 400,000m per year, rapidly ageing population with a preference for non-surgical options – joint replacement as last resort
- > 18 months due diligence on Japanese market opportunity
- RGS has significant experience in the development of technologies and IP for the manufacture and clinical development of MSCs from adipose tissue for OA in humans and animals
- >1000 human joints treated with autologous MSCs - largest joint registry in Australia and > 3000 animal joints (dogs and horses) treated with allogeneic MSCs in field trials
- Transitioned from autologous MSC technologies to allogeneic technologies for scalable and global market solution in human and animal health markets



Progenza – positive preclinical results

- Degenerative OA model (partial menisectomy) in rabbits
- No Progenza-related systemic or local toxicities or dose related adverse effects were noted with intra-articular (IA) administration
- Significant reduction in cartilage degeneration scores with target dose in the middle load bearing femur zone (zone 2)
- Total degeneration scores in Progenza treated knees at 4 weeks showed no further progression of OA compared to 21 day pre-treatment control group



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

Progenza Development Update



Phase 1 Trial Update

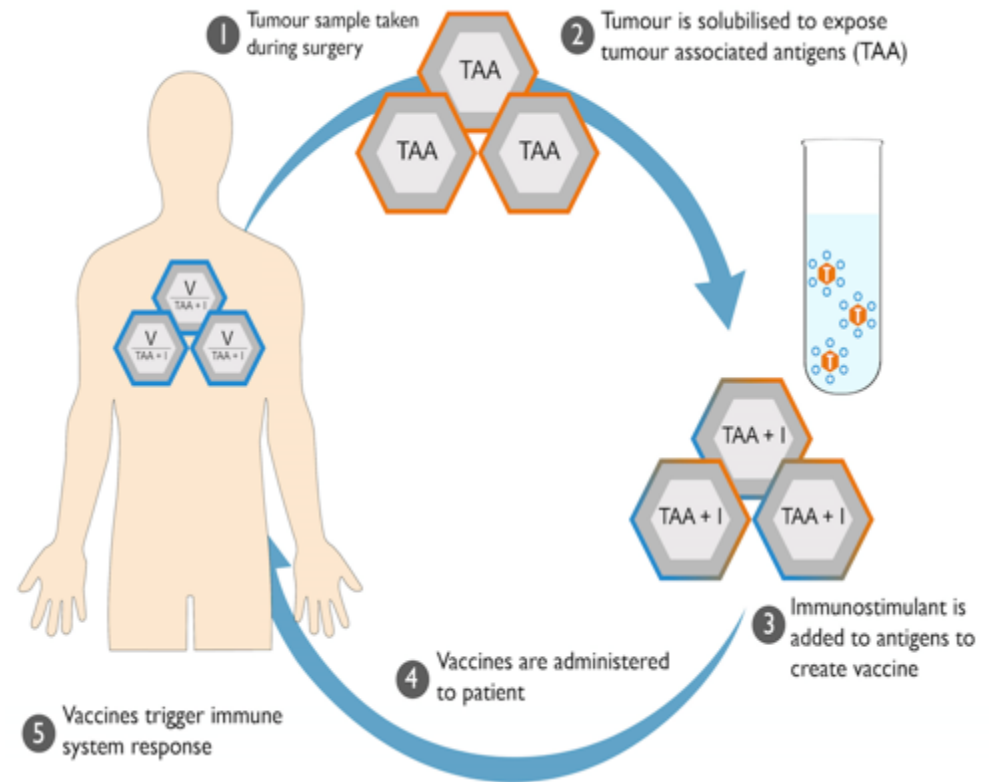
- Progenza Phase 1 Study for OA (STEP Trial) commenced enrolment in Q3 '15 in Sydney
- Review blinded cohort 1 safety data by end of Q4 '15
- Commence recruitment of cohort 2 in Q1 '16
- Complete safety data review of cohort 2 in Q3 '16

Next Steps

- Targeting Phase 2 Progenza trial for OA in Japan
- Exploring potential partners for Progenza manufacture, clinical development and commercialisation in Japan

Cancer Vaccine – RGS4K

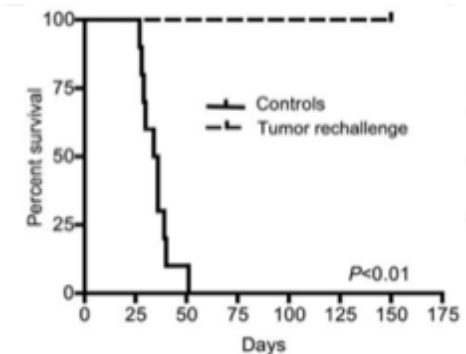
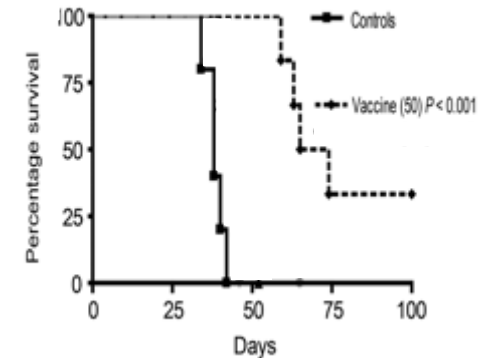
- A clinical-stage, autologous cancer immunotherapy which uses a patient's own tumour as source material for a vaccine, coupled with a bacterial adjuvant for immune recognition
- Addresses tumour heterogeneity as all relevant tumour associated antigens and proteins are included
- Immune memory may be effective in reducing risk of tumour recurrence
- Straightforward and rapid manufacturing process



Phase 1 study commenced



- Technology developed at Bill Walsh Cancer Labs - Kolling Institute of Medical Research
- Exclusive rights to develop and commercialise the technology
- Positive Preclinical data demonstrated efficacy in an aggressive syngeneic tumour rat model
 - Multiple vaccinations conferred significant survival advantage (77 days for optimal dose vs. 38 days for control)
 - Re-challenge with glioma cells in surviving vaccinated rats did not result in tumour formation, suggesting a possible vaccine-induced immune memory (n=4, no control)
 - No tumour formation out to 150 days; all control rats died of disease within 25 days of engraftment. (n=5, control = 6)
- Phase 1 trial open for enrollment at Northern Cancer Institute in Sydney: 21 patients with advanced cancer; 3 dose cohorts of 7
- 1st patient safely dosed; 3 patients recruited



Animal Health



Animal Health Pipeline

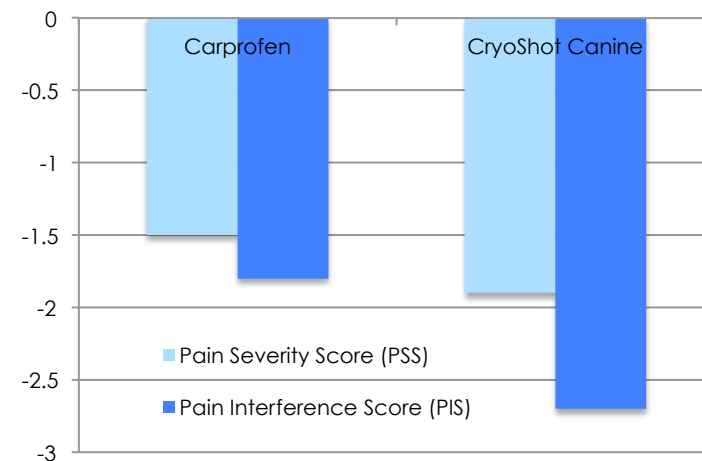


Product	Indication	Discovery	Manufacturing and Process Development	Safety and Efficacy Studies	Pivotal Study	Market Approval	Market Size
Cryoshot Canine	Osteoarthritis	Allogeneic adipose MSCs					US\$500m
Cryoshot Equine	Osteoarthritis	Allogeneic adipose MSCs					US\$500m
Kvax	Solid tumours	Autologous tumour vaccine					US\$550m

Allogeneic cells - cells from a donor Autologous cells - patient's own cells

- Leading in-field, practical experience with allogeneic MSCs in the veterinary field globally - >90 vet practices and >3,000 field trial treatments
- Better pain relief than NSAIDs in uncontrolled studies for osteoarthritis
- Nov '15 commenced pre-pivotal OA efficacy trial at U.Penn - 80 dogs
- Nov '15 signed collaboration and right to licence with top 5 veterinary pharmaceutical company - subject to U Penn results, right to exclusive licence for pivotal study, and global sales and marketing

cBPI (Pain scores) – Day 0 vs Day 10-14
Carprofen (NSAID) vs CryoShot



Kvax – Canine Cancer Vaccine

- >100 dogs treated in Australia without serious adverse events
- Clinical trial for osteosarcoma with Dr Bergman of VCA, largest US vet services group, fully recruited
 - Single arm, Kvax only
 - Reporting in Q1'16
- 1st dog commercially treated outside of the trial in the US
- Initiated canine lymphoma trial in Sydney at the Small Animal Specialist Hospital
 - Placebo controlled - in conjunction with chemotherapy



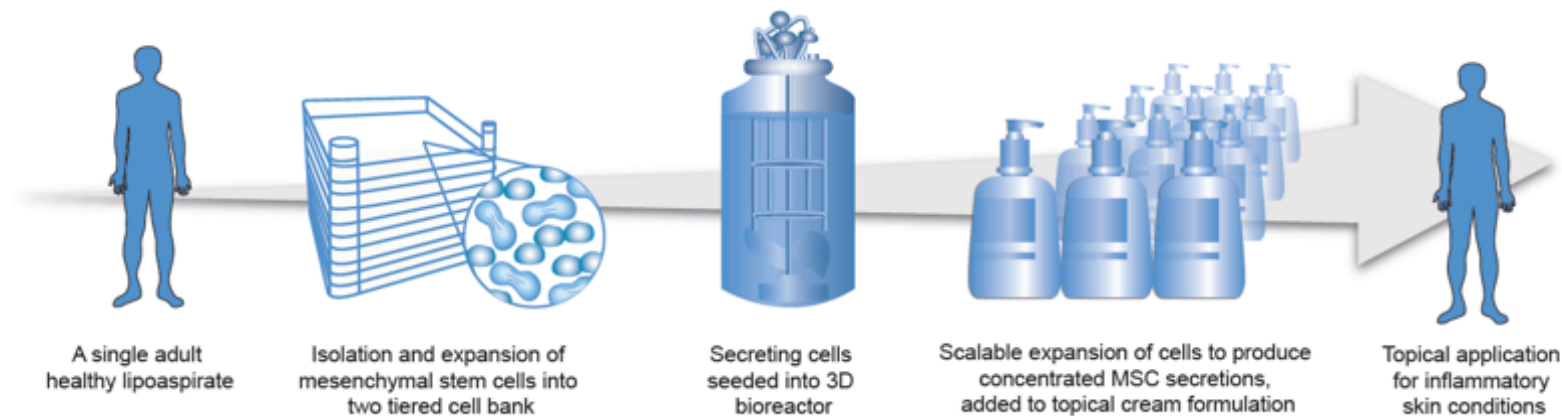
Emerging Technologies



MSC Secretions Technology

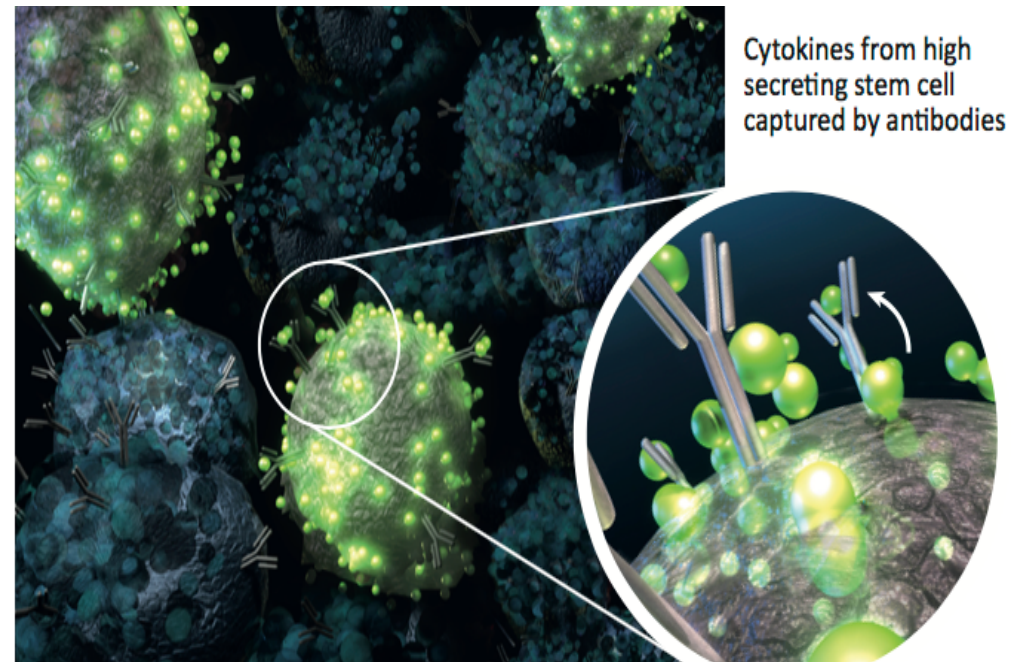


- Developed IP for the manufacture and use of conditioned media for therapeutic purposes
- Technology has broad applications – cell secretions are very stable and do not require freezing like cells
- Initial focus on using secretions for topical application for the management of acne and other inflammatory skin conditions
- Strong IP position
- Collaborating with CSIRO on manufacturing scale-up

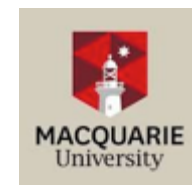


High Secreting Cells – next generation cell therapies

- World first cell identification and selection technology for high secreting MSCs
- MSCs can be selected and sorted based on cytokine profile
- High secreting MSCs maintain secretion profile on expansion
- Enables cell therapies to be designed to match secretion profile with target disease
- Exclusive licence to develop and commercialise technology for R&D and next generation cell therapeutics
 - Research market – US\$5.1bn by 2020
 - Regenerative medicine market - US \$67bn by 2020
- Developed at Australian Research Council's Centre of Excellence for Nanoscale BioPhotonics – Macquarie Uni node

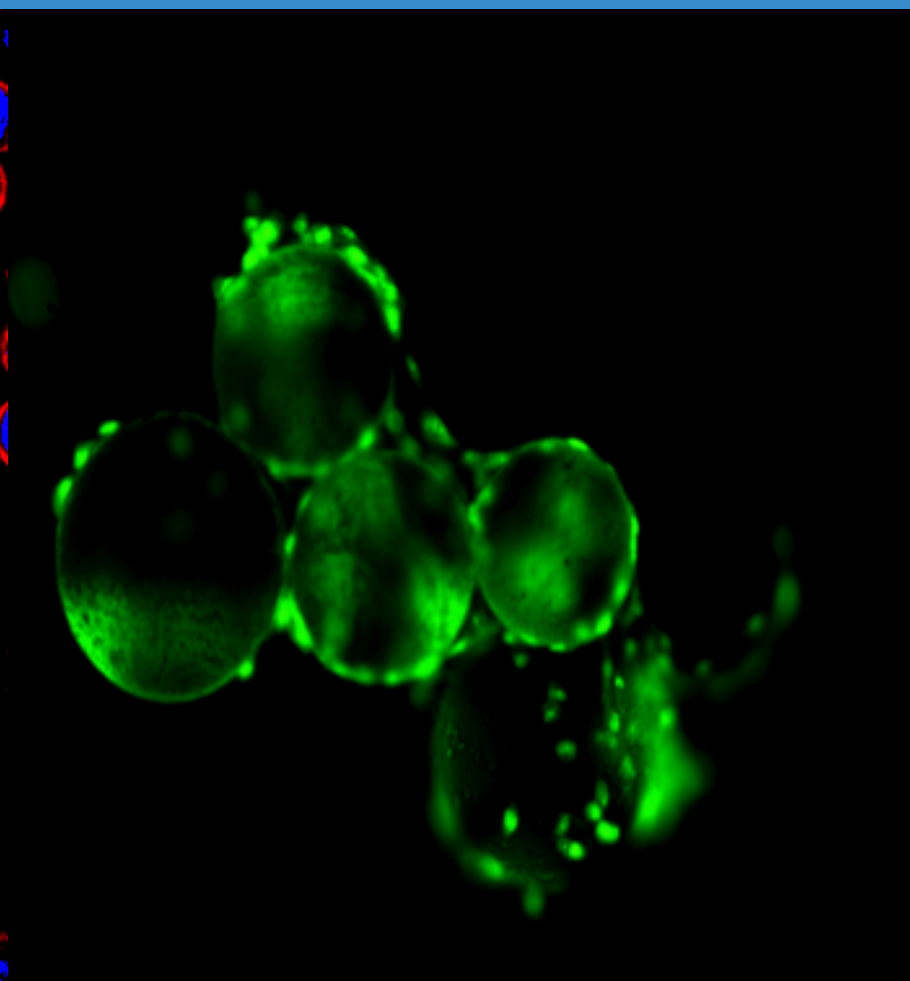
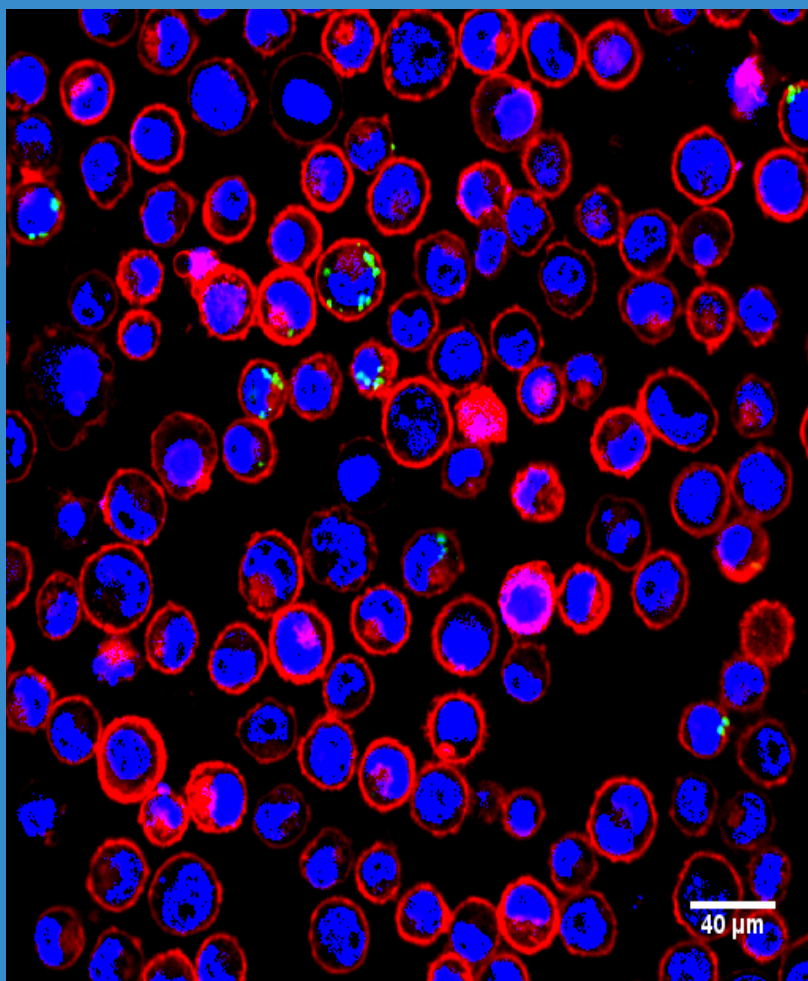


**Centre for
Nanoscale
BioPhotonics**
ARC CENTRE OF EXCELLENCE



Australian Government
Australian Research Council

Patent Portfolio



Growing and Strategic Patent Portfolio



- Track record of generating and licensing valuable IP
- 14 patent families covering products and processes
 - 9 patents granted in Australia
 - 2 patents granted in NZ
 - 1 patent granted in USA
- Pursuing all key territories
- Patents cover:
 - Methods of manufacture
 - Compositions and delivery
 - Use of products for treatment of a broad range of indications
- Key IP covers broad range of clinical indications - opportunities to create value by out-licensing

Upcoming Milestones



Product or Program	Anticipated Milestone	Timing by Calendar Year
Progenza	Review of safety data on cohort 1 of STEP trial	Q4'15
RGS H4K	Cancer Vaccine patent granted	Q4'15
Cell secretions cream	Inflammatory skin conditions patent granted	Q4'15
Progenza	Manufacturing and development partner for Japan	Q1'16
Progenza	Commence enrollment of cohort 2 of STEP trial	Q1'16
Kvax	Data report from canine osteosarcoma trial	Q1'16
Cell secretions cream	Complete stability and clinical testing	H1'16
CryoShot Canine	Complete enrollment in U Penn trial	H1'16
RGSH4K	Complete enrollment in ACTIVATE trial	Q3'16
CryoShot Canine	Data report from U Penn trial	Q3'16

Regeneus Advantages



☑ **Technology - multiple platforms**

- adult stem cells from adipose tissue for OA and other musculoskeletal disorders
- tumour lysate and immuno-stimulant for oncology
- secretions from adipose MSCs for inflammatory skin conditions
- identification and selection of high secreting cells for new cell therapies

☑ **Lower risk - diversified portfolio of clinical stage products for human and animal markets**

- all product candidates in clinical development
- animal products are most advanced clinically and commercially
- scalable manufacturing for allogeneic stem cells
- IP has application to a broad range of clinical indications

☑ **Timing and Catalysts – unlocking value**

- licensing and partnering opportunities including taking advantage of Japan's early market access pathway
- clinical trial data readouts in CY16

☑ **Team and Collaborations – commercially focused and strategic**

- track record of technology and clinical collaborations and generating valuable IP
- pursuing value enhancing licensing with quality partners
- priority for non-dilutive revenue

Further Information

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