Corporate Presentation
for
Austrade Mission on
Regenerative Medicine
Opportunities in Japan

Tokyo and Kobe
December 2015
Important Notice

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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

**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
## Human Health Pipeline

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Preclinical</th>
<th>Manufacturing</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Marketed</th>
<th>Market Size</th>
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<tr>
<td>Progenza</td>
<td>Osteoarthritis</td>
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<td>Allogeneic adipose MSCs</td>
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<td>RGSH4K</td>
<td>Solid Tumours</td>
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<td>Autologous tumour vaccine</td>
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*Allogeneic cells - cells from a donor
Autologous cells - patient’s own cells*
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 meniscectomy) 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 meniscectomy) in rabbits (n=46; 23M, 23F)
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 – RGSH4K

- 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
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• 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
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
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
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

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

ASX:RGS

John Martin
CEO
M: +612 408 544 395
P: +612 94998010
E: john.martin@regeneus.com.au

Sandra McIntosh
Investor Relations
M: +612
P: +612 94998010
E: sandra.mcintosh@regeneus.com.au