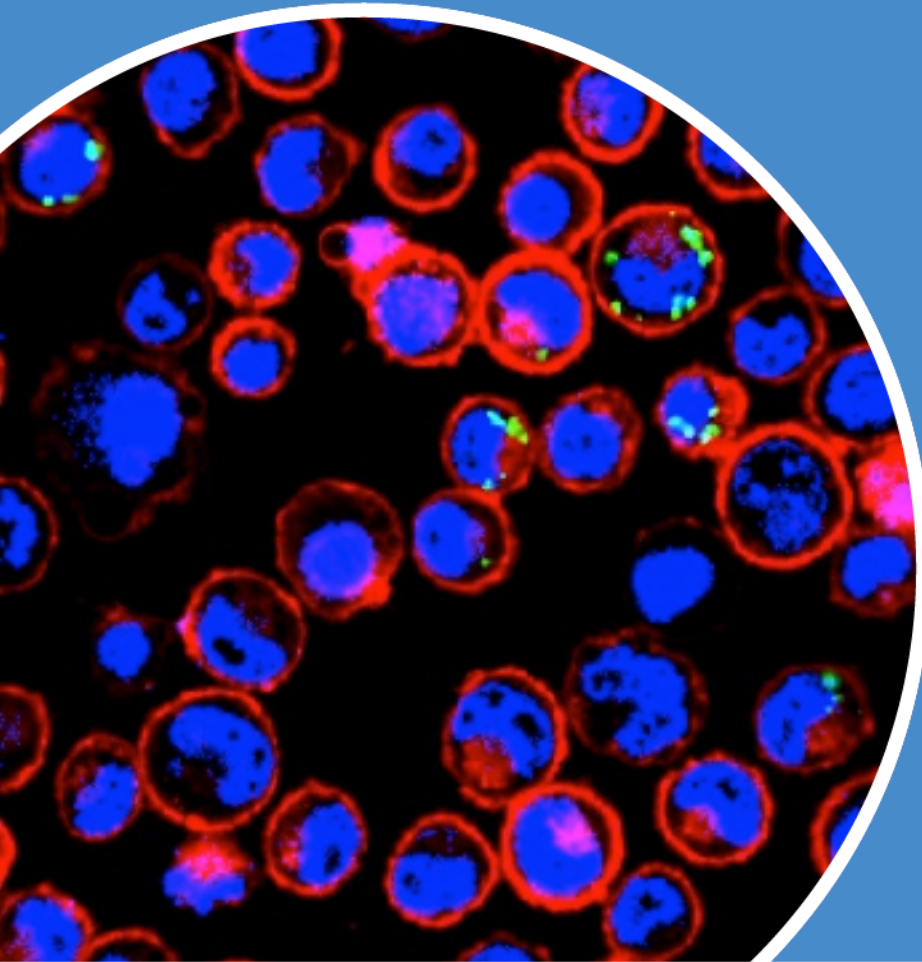


 **regeneus**  
living regenerative medicine



**International**  
**BioFest** 2016



John Martin  
CEO

24-27<sup>th</sup> October 2016  
Melbourne Convention Centre, Melbourne

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# Executive Summary

Developing a portfolio of clinical-stage products for human and animal health markets – focus on musculoskeletal, oncology and dermatology

Disruptive proprietary technology product platforms - allogeneic “off-the-shelf” stem cells; stem cell secretions; and immuno-oncology

Scalable technology and cost-efficient manufacturing

Focus on Japanese market to take advantage of leading regenerative medicine developments

Strategic and growing IP portfolio covering methods of manufacture, composition and broad range of uses

Successful collaborations across technology R&D, product and clinical development and commercial partnering

# Development Pipeline – Human & Animal

Product Technology Platform	Indication	Manufacturing & Process Development	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Market Size	
<b>Progenza</b>	1. Osteoarthritis 2. Other	Allogeneic adipose MSCs							US\$12b
<b>RGSH4K</b>	Solid Tumours	Autologous tumour vaccine							US\$33b
<b>Secretions</b>	Dermatology Wound Healing	Allogeneic adipose MSC secretions							US\$3b (Acne)

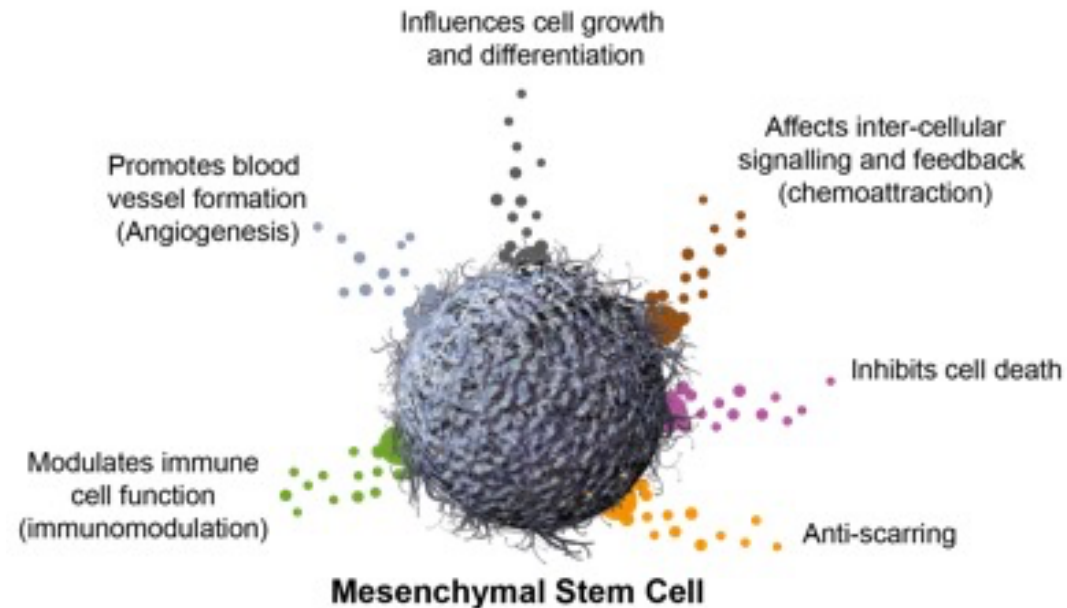
Product	Indication	Discovery	Manufacturing and Process Development	Safety and Efficacy Studies	Pivotal Study	Market Approval	Market Size	
<b>Cryoshot Canine</b>	Osteoarthritis	Allogeneic adipose MSCs						US\$500m
<b>Cryoshot Equine</b>	Osteoarthritis	Allogeneic adipose MSCs						US\$500m
<b>Kvax</b>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

Allogeneic cells - cells from a donor

Autologous cells - patient's own cells

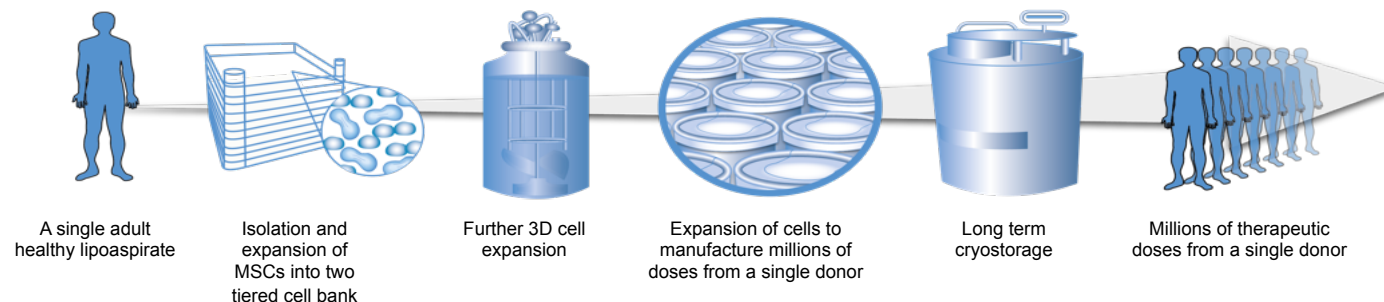
# Secretions – drivers of MSC effect

- MSCs are immune evasive, and can be used in an allogeneic (non-self) setting
- Secretions are the drivers of MSCs therapeutic effect
- 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



# Progenza – allogeneic stem cell technology platform

- Allogeneic mesenchymal stem cells (MSCs) are sourced from a healthy adult donor
  - no reprogramming of cells = **safety benefits**
- 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)
- Addition of secretions with cells (Progenza):
  - **Improve functionality of cells & therapeutic effect**
    - In a rheumatoid arthritis model (CAIA), Average Clinical Arthritis scores were significantly lower with MSCs frozen in cell supernatant compared to MSCs alone



# Progenza OA Update

Do you have **KNEE PAIN**  
from osteoarthritis?

Are you between 40 and 65 years old?

Are you experiencing moderate to severe pain in your knees?

Would you consider being a participant in a research study using a new treatment option?

If so, and if you haven't had surgery on your knees in the past 3 years, you may be eligible to participate in a research study being conducted by some of the doctors at this practice.



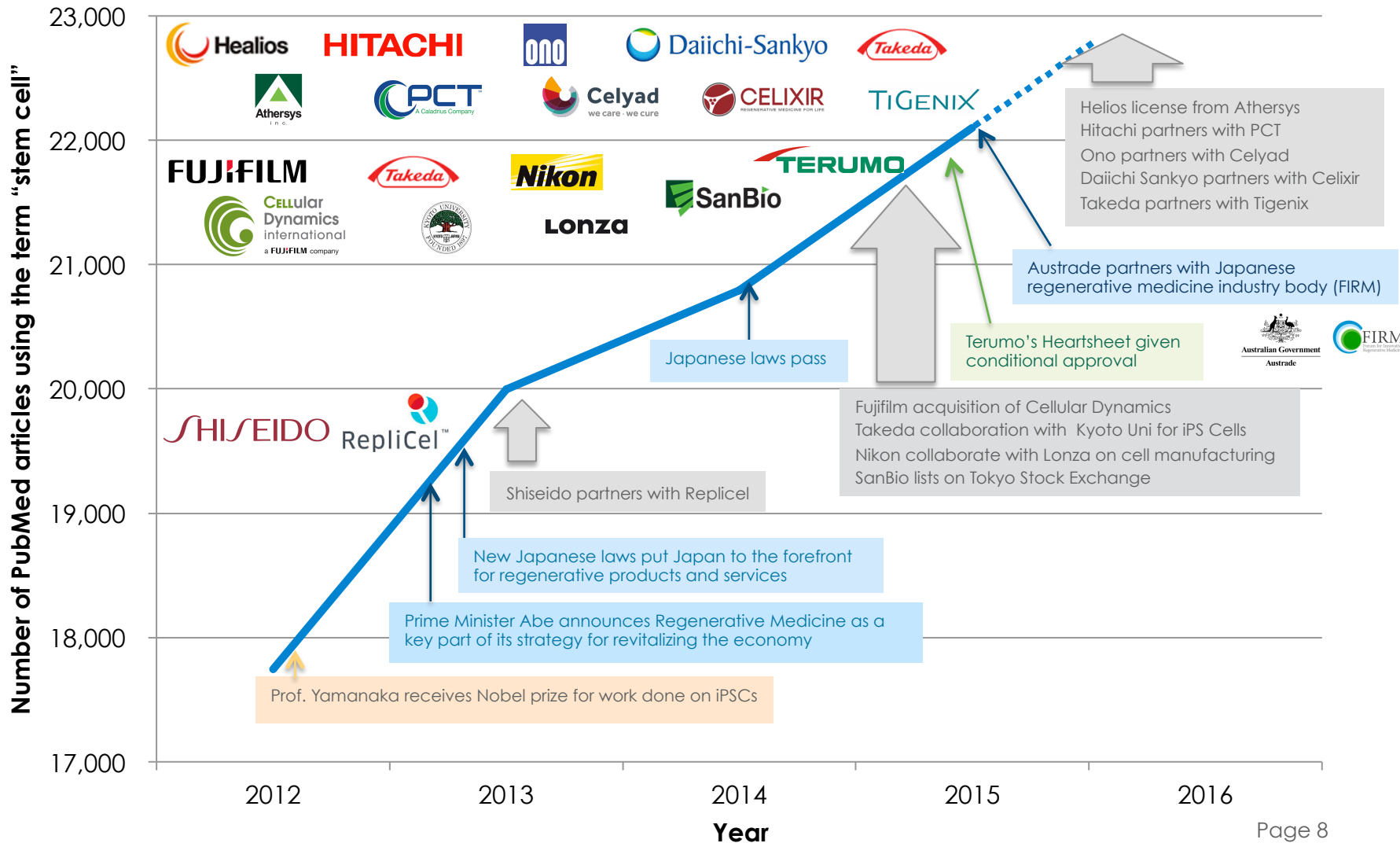
- Progenza Phase 1 Study for OA (STEP Trial) commenced enrolment in Q3 '15
  - Single IA injection with a 12 month follow-up
  - 2 treatment cohorts vs placebo

Activity / Milestone	
STEP trial open for recruitment	<input checked="" type="checkbox"/>
Complete enrolment of Cohort 1	<input checked="" type="checkbox"/>
Complete enrolment of Cohort 2	<input checked="" type="checkbox"/>
Interim safety results	<input checked="" type="checkbox"/>
Last patient last visit – May '17	<input type="checkbox"/>
Analysis and final report	<input type="checkbox"/>

- Procure donor adipose tissue for Phase 2 and manufacture master seed bank H1'17
- Advanced partnering discussions for Progenza manufacture clinical development and commercialisation in Japan
- Targeting Phase 2 Progenza trial for OA in Japan under new cell therapy early access regulations



# Japan – leading market for Regenerative Medicine





# CryoShot – allogeneic stem cell platform

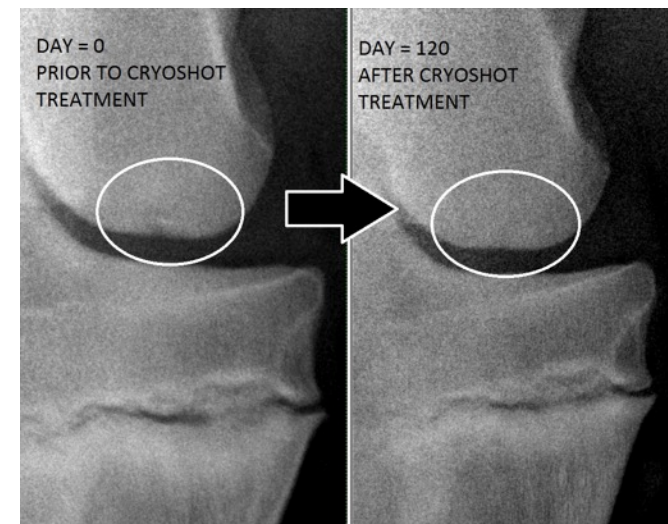
- Leading in-field, practical experience with allogeneic MSCs in the veterinary field globally with >90 vet practices involved and 3,000+ field trial treatments
- Better pain relief than NSAIDs in uncontrolled studies for osteoarthritis in dogs
- Improved interim clinical results on early orthopaedic developmental disease in yearling thoroughbreds
- Commenced study in assessing CryoShot for strengthening equine tendons



## CryoShot

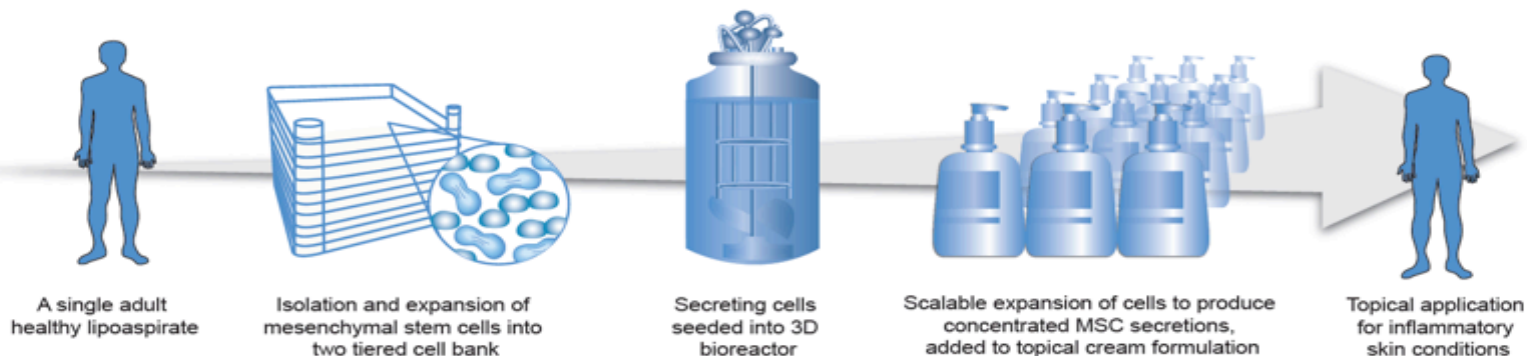


Activity / Milestone	
Signed collaboration with top vet Pharma to partner development and commercialisation of CryoShot Canine	<input checked="" type="checkbox"/>
Commenced pre pivotal dog trial at U.Penn for osteoarthritis (>40% complete)	<input checked="" type="checkbox"/>
Last patient last visit	<input type="checkbox"/>
Analysis and final report	<input type="checkbox"/>



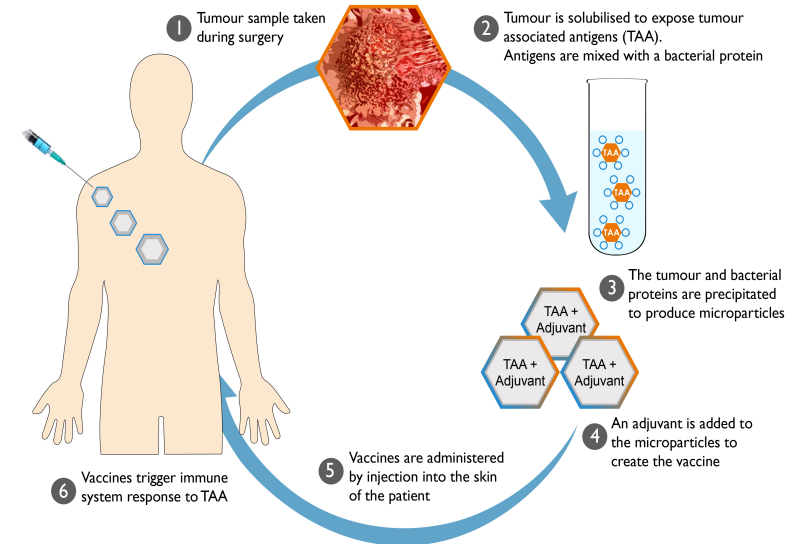
# Secretions Technology – emerging platform

- Developed IP for the manufacture and use of bioactive secretions from MSCs for therapeutic purposes
- Secretions used in Progenza to optimise viability and functionality
- Demonstrated safety and efficacy in preclinical inflammatory disease model
- Secretions can be used as a standalone application
- Secretions have shown promise in topical application for the management of acne, other inflammatory skin conditions and wound care
- Optimised formulation
- Collaborating with CSIRO on manufacturing scale-up



# Cancer Immunotherapy Platform – 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 and become potential targets of the immune system
- 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	Low COGS
Autologous therapies					
RGSH4K tumour cell vaccine	✓	✓	✓	✓	✓
Dendritic cell vaccine	✗	✓	✗	✓	✗
Peptide vaccine	✗	✗	✓	✓	✗
Allogeneic therapies					
Peptide / HSP vaccine	✗	✗	✗	✓	✗
Gene transfer	✗	✓	✓	✗	✗

# RGSH4K Update



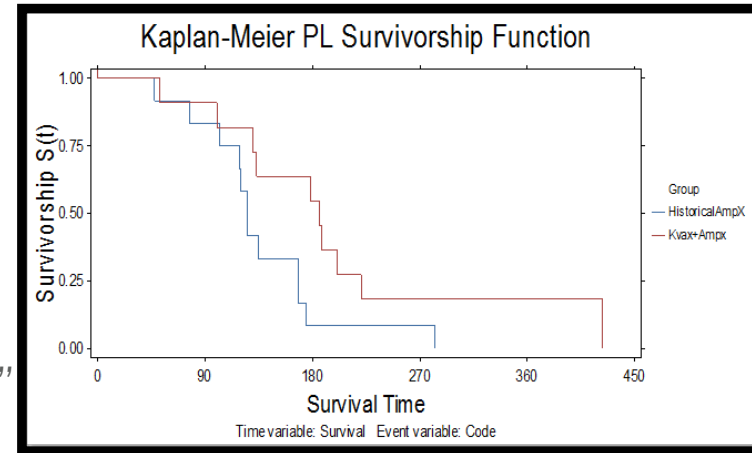
- Phase 1 Study for solid cancers (ACTIVATE Trial) commenced enrolment in Q3 '15
  - Multiple solid tumour types accepted
  - Open to patients with terminal cancer for which no other therapy exists
  - Varying levels of streptavidin to identify biologically active dose

Activity / Milestone	
ACTIVATE trial open for recruitment	<input checked="" type="checkbox"/>
HREC approved tumour bank	<input checked="" type="checkbox"/>
Patients in all cohorts safely treated	<input checked="" type="checkbox"/>
Patent granted	<input checked="" type="checkbox"/>
Last patient last visit	<input type="checkbox"/>
Analysis and final report	<input type="checkbox"/>

- Targeting Phase 2 RGSH4K trial for combination therapy with checkpoint inhibitors
- Pursue RGSH4K early partnering opportunities in US, EU and Japan

# Kvax – Canine Cancer Vaccine

- Clinical trial for osteosarcoma (bone cancer) with Dr Bergman of VCA, largest US vet services group
  - Single arm: post-amputation, Kvax only
  - *“Kvax is well tolerated and appears to confer increased progression free interval and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only.”*



- Initiated canine lymphoma trial in Sydney at the Small Animal Specialist Hospital
  - Lymphoma is most commonly treated cancer in dogs
  - Placebo controlled, conjunction with standard of care chemotherapy



– hyperlink →





# Summary of competitive strengths

- ☑ **Multiple proprietary technology platforms**
  - allogeneic stem cells from adipose tissue for OA and other inflammatory conditions
  - immunotherapy for oncology
  - secretions from adipose MSCs for inflammatory skin conditions and wound healing
  - next generation high secreting cells technology
  
- ☑ **Diversified portfolio of clinical stage products – human and animal health markets**
  - lower technical, clinical and commercial risk
  - product platforms in clinical development
  - scalable manufacturing for allogeneic stem cells
  - IP has application for OA and a broad range of inflammatory clinical indications
  
- ☑ **Catalysts – unlocking near term value**
  - near term licensing and partnering in fast growth market of Japan
  - clinical trial results readouts in FY17
  
- ☑ **Innovation and collaboration – commercially focused and strategic**
  - rapid product development and manufacture capability
  - successful technology and clinical collaborations
  - ability to translate products into the clinic
  - strategic and growing IP portfolio to underpin technologies and products

# Further Information

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