

Austrade Business Mission to Japan

John Martin CEO



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Tokyo
(ASX: RGS)

Important Notice

Forward-Looking Statements

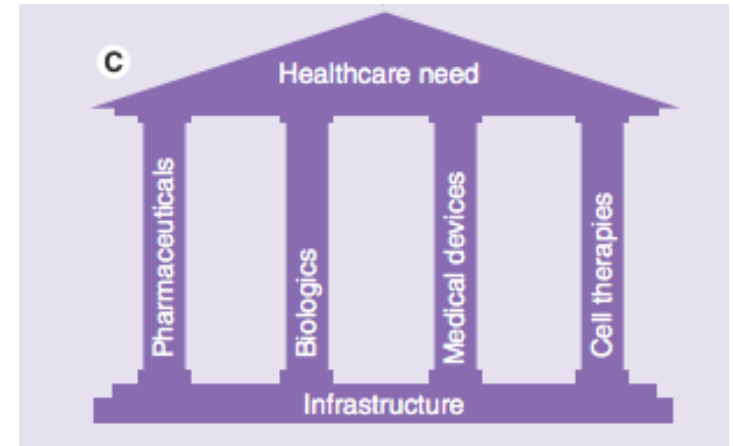
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The 4th Therapeutic Pillar of Healthcare

- Regenerative Medicine represents a paradigm shift in future healthcare therapies and treatment
- We are writing the pre-history of the regenerative medicine revolution
- Rapid developments are taking place in:
 - our understanding at the cellular level of the workings of the body's built-in repair and regenerative capabilities; and
 - new technologies that allow for optimized and scalable manufacturing platforms for cellular therapeutic products
- These new generation regenerative medicines address the underlying causes of disease and have the potential to cure or significantly reduce the disease burden for some of the most common chronic and acute conditions

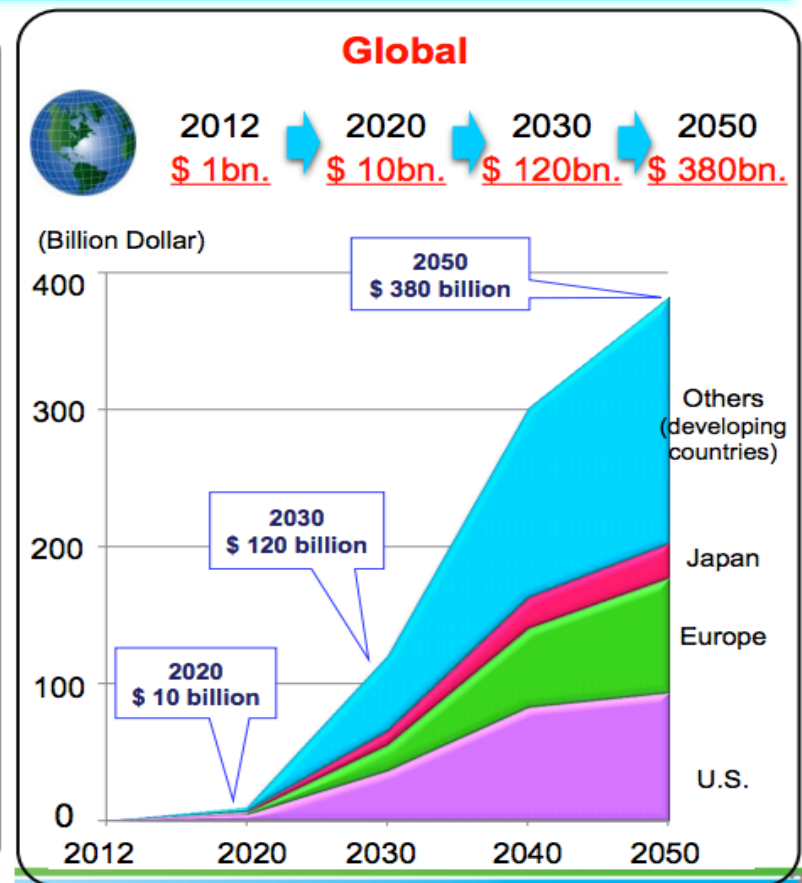
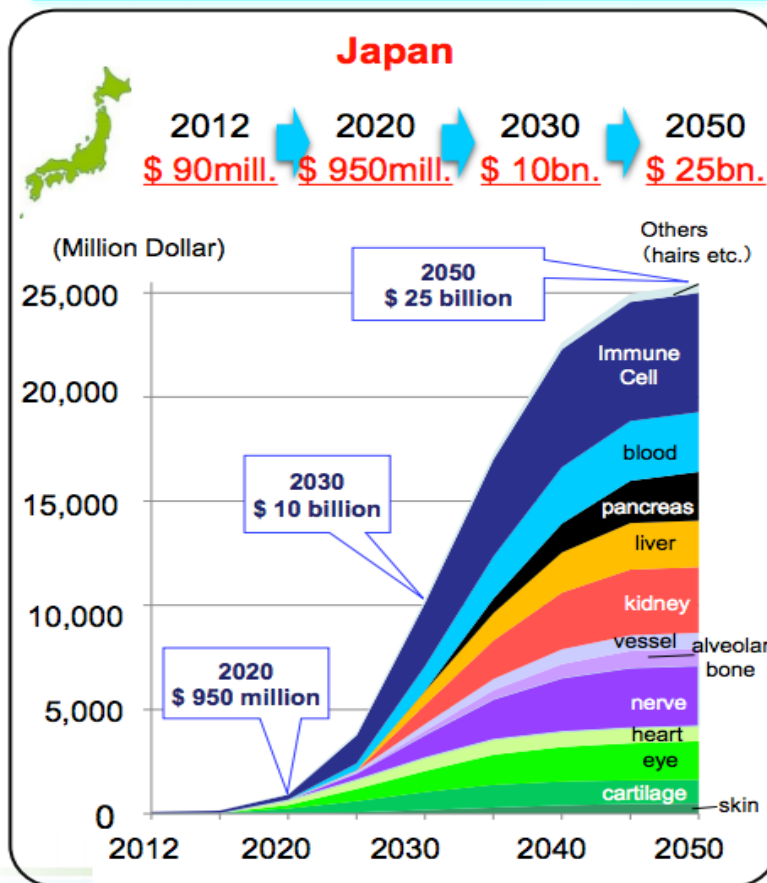


Japan, EU and USA have enacted new regulatory frameworks to enable the accelerated development and early access to new regenerative medicines

Regenerative Medicine markets are large and growing rapidly

Market Forecasts for Regenerative Medicine

○ METI estimates the market size for regenerative medicine at about **\$ 25 billion** in 2050 (Japan), and **\$ 380 billion** (global), which promises enormous economic benefits.



Our Competitive Strengths

Disruptive proprietary technology platforms

- Allogeneic adult stem cells (MSCs) from adipose tissue for 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



Development Pipeline Summary

Human Health Development Pipeline

PROGRAM	TECHNOLOGY PLATFORM	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	FILING	APPROVAL
Progenza	Allogeneic Adipose MSCs & Secretions	Osteoarthritis					
RGSH4K	Immunotherapy for oncology	Solid Tumours					
Secretions	Allogeneic Adipose MSC Secretions	Inflammatory skin conditions/ wound care					

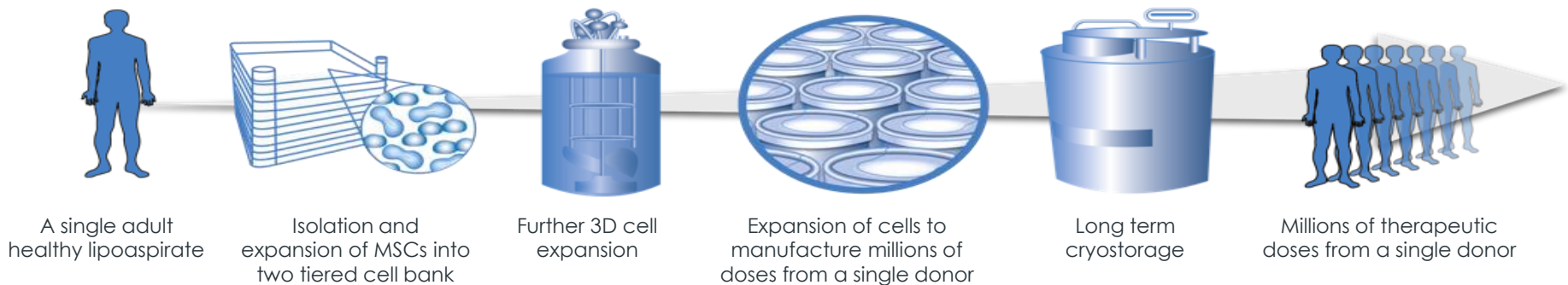
Animal Health Development Pipeline

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

- 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)



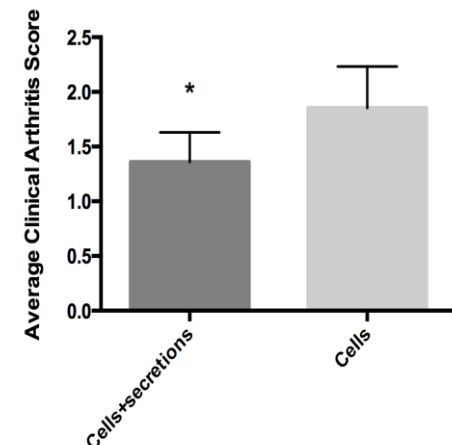
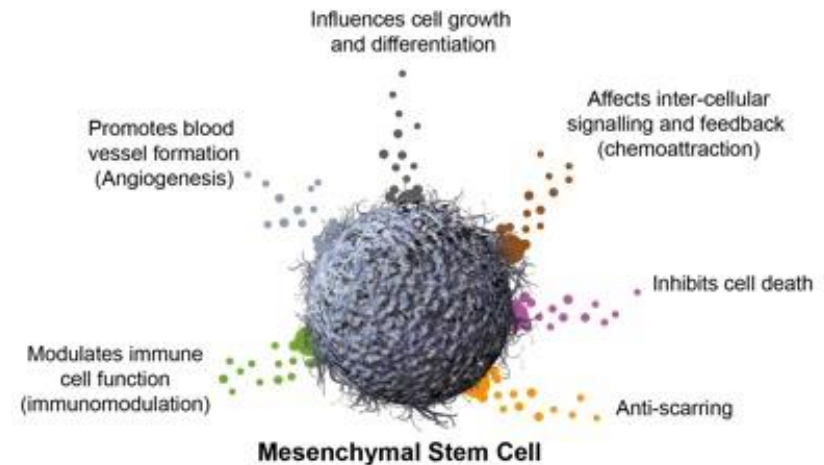
Progenza

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 with AGC in Japan



Regeneus and AGC, a leading Japanese manufacturer of biopharmaceutical products, have entered into a collaboration and licence agreement for the manufacture and clinical development through partnering of its off-the-shelf stem cell therapy platform, Progenza, for all indications in Japan

	Received US\$5.5M Upfront licence fee	Entitled to US\$11.0M Specific milestone payments	Established 50/50 JV for licensing through partners the 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
	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

Progenza

Benefits of Collaboration with AGC



AGC

+

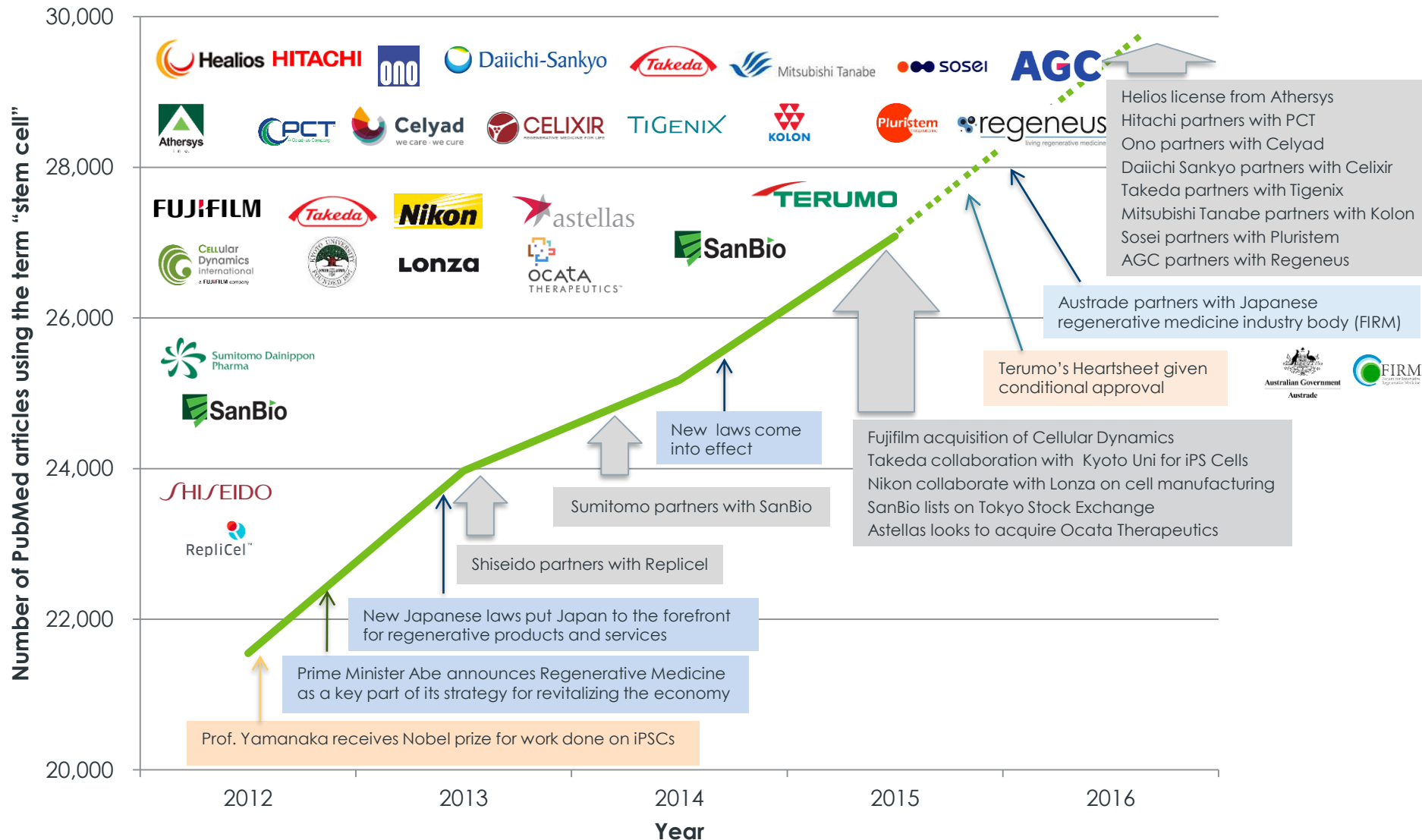
regeneus

living regenerative medicine

- **Leading Japanese biopharma manufacturer with global capability and aligned goals**
 - Leading biopharmaceutical contract manufacturer in Japan – expanded global capability with recent acquisitions of Biomeva in Germany and CMC Biologics in EU and USA
 - Strategic commitment to grow life sciences business
 - Targeting accelerated entry into cell-based therapeutics manufacture
 - Ambition and resources dedicated to supply global market
- **Existing and ongoing relationships with**
 - Regulators in biopharmaceuticals manufacturing
 - Major pharmaceutical businesses
- **Increased impetus of Progenza development**
 - Takes advantage of new Japanese regenerative medicine laws
 - Initial osteoarthritis development
 - Other inflammatory indication areas



Increasing Japanese Corporate Activity living regenerative medicine



Progenza

Update First Indication - Osteoarthritis

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)
 - Single IA injection with a 12 month follow-up
 - 2 treatment cohorts vs placebo

Activity / Milestone

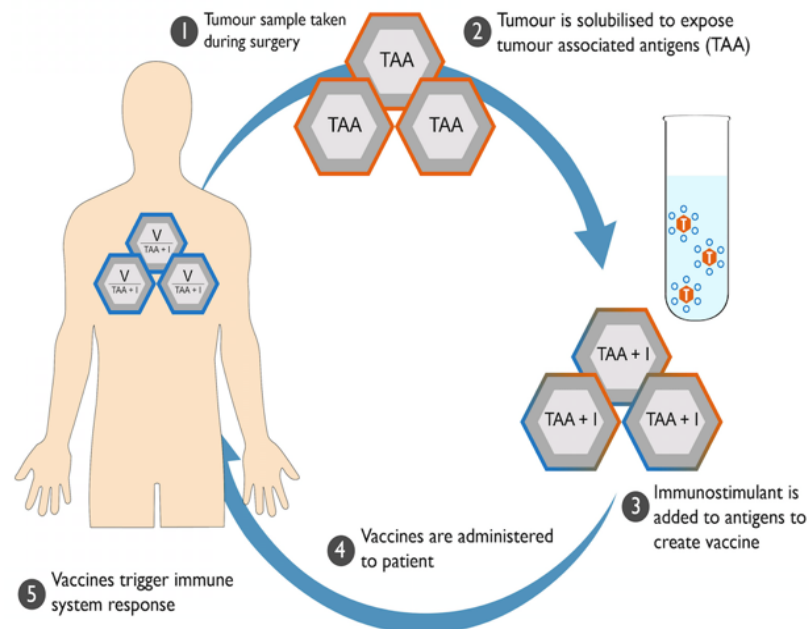
STEP trial open for recruitment	<input checked="" type="checkbox"/>
Complete enrolment of Cohort 1	<input checked="" type="checkbox"/>
Complete enrolment of Cohort 2	<input checked="" type="checkbox"/>
Interim safety results	<input checked="" type="checkbox"/>
Last patient last visit	<input checked="" type="checkbox"/>
Analysis and final report (due Q2'17)	<input type="checkbox"/>

- 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
- In discussions with potential partners in Japan for other indications

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

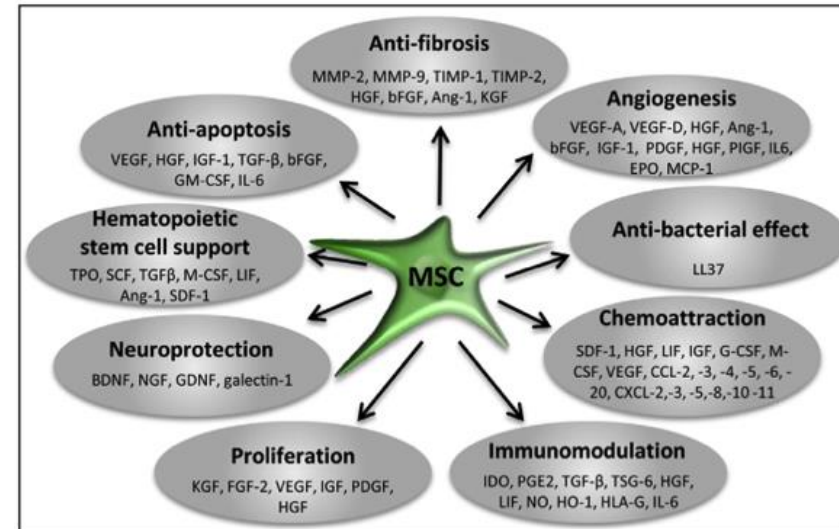
Activity / Milestone	
ACTIVATE trial open for recruitment	<input checked="" type="checkbox"/>
HREC approved tumour bank	<input checked="" type="checkbox"/>
Patients in all cohorts safely treated	<input checked="" type="checkbox"/>
Patent granted	<input checked="" type="checkbox"/>
Last patient last visit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

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

MSC Secretions

Emerging Technology Platform

- MSC Secretions show great promise as a stand alone scalable technology suitable for a wide range of inflammatory conditions
- 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 and injectable
- Initial focus on topical applications for the management of acne and other inflammatory skin conditions
- Scalable technology – product is stable at room temperature and easy to prepare and handle for off-the-shelf use
- Strong IP position - methods of manufacture, composition and therapeutic use
- Patents pre-date rising interest in stem cell conditioned media supernatant and publications



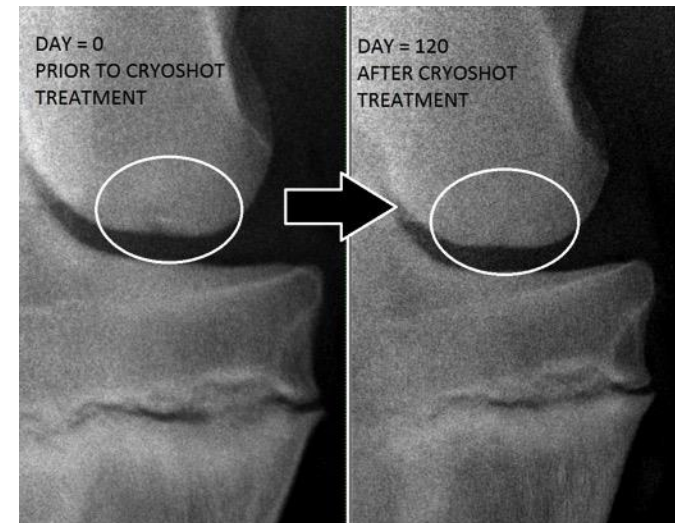
Animal Health



CryoShot Veterinary Allogeneic Stem Cell Platform



- 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



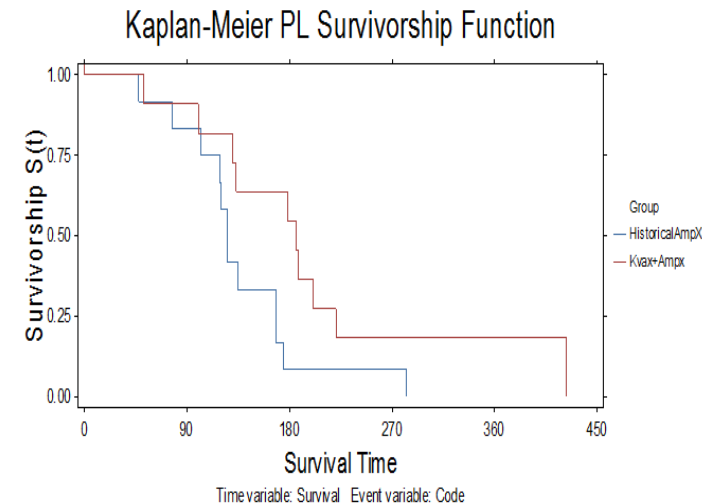
Activity / Milestone	
Signed collaboration with top Animal Health Pharma to partner development and commercialisation of CryoShot Canine	<input checked="" type="checkbox"/>
Commenced pre pivotal dog trial at University of Pennsylvania for osteoarthritis (currently >50% complete)	<input checked="" type="checkbox"/>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

Kvax Canine Cancer Vaccine

- 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



Patent Portfolio



Patent Portfolio Update

Overview

- >50 patents or patent applications across 14 patent families
- 11 patents granted in Australia; 2 in NZ; 1 in US, EU, China and Singapore
- Patents cover:
 - Methods of manufacture
 - Compositions and delivery
 - Use of products for treatment of a broad range of indications
- Patent granted in Australia covering:
 - Progenza technology – allogeneic stem cells and secretions for the treatment of osteoarthritis and other inflammatory conditions in humans and animals
 - cancer vaccine technology for the treatment of cancers in humans (RGSH4K) and animals (Kvax)
- Pursuing all key territories

Anticipated Milestones for next 18 months

Progenza

- Advance clinical partnering discussions for Progenza in Japan Ongoing
- Commence donor procurement and process development for manufacturing for Phase 2 trial in Japan Q2 '17
- Report on osteoarthritis STEP trial Q2'17
- Commence 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