

AGM Presentation

Highlights and Business Update for FY17

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Agenda

- Overview
- Business Highlights and Update for FY17
- Financial Highlights for FY17
- Outlook for FY18



Overview

Overview

3 world-class technology platforms

- Allogeneic adult stem cells (MSCs) from adipose tissue for osteoarthritis and other inflammatory conditions (Progenza, CryoShot)
- Allogeneic cell-free secretions from adipose MSCs focused on dermatology, inflammatory skin conditions and pain (Sygenus)
- Immuno-therapy for oncology (RGSH4K, Kvax)

Diversified portfolio of clinical-stage products

- Human and animal health markets
- Multiple product opportunities addressing multiple significant unmet medical needs – many shots on goal
- Technology supported by emerging positive clinical data
- Scalable manufacturing for allogeneic stem cells
- Significant IP portfolio underpins technology and product pipeline for wide range of inflammatory indications
- Licence driven business model

Driven by innovation and collaboration

- Track record of technology innovation and rapid translation to the clinic
- Successful technology and clinical collaborations
- Landmark collaboration with AGC for Progenza in Japan
- Experienced and commercially focused management team and Board
- Well positioned to unlock significant value over next 12 months

Development Pipeline

Human Health Development Pipeline

PROGRAM	TECHNOLOGY PLATFORM	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVAL
Progenza	Allogeneic Adipose MSCs & Secretions	Osteoarthritis				
		Pain				
RGSH4K	Immunotherapy for oncology	Solid Tumours				
Sygenus	Allogeneic Adipose MSC Secretions	Dermatology				
		Pain				

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)			



Business Highlights and Update for FY17





Landmark Collaboration with AGC on Progenza in Japan

Landmark Collaboration with AGC for Progenza in Japan



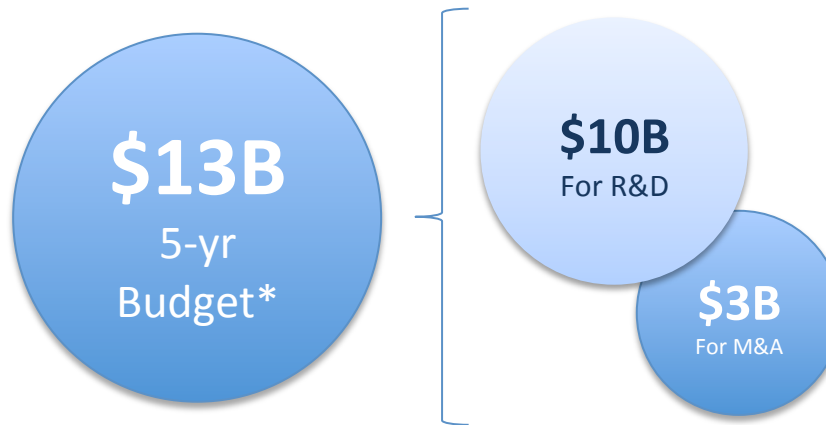
In December '16, Regeneus and AGC, a leading Japanese manufacturer of biopharmaceutical products, entered into collaboration and licence agreement for the manufacture and licensing of the clinical development of its off-the-shelf stem cell therapy platform, Progenza, in Japan

	Received US\$5.5m upfront licence fee in January 17 and US\$1m in June 17 for successful STEP trial results	Entitled to further 2x US\$5m payments on meeting specific milestones	AGC acquires 50% of RGS Japan which has exclusive rights 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
	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

AGC - Japan's leading bio-CMO

- **AGC** is Japan's leading biopharmaceutical contract manufacturing organization
 - 2016 net sales of JPY1,283 billion (US\$12.8 billion)
 - Existing CMO relationships with many major pharmaceutical businesses
- In **AGC's** recent "Vision 2025", **Life Sciences** was designated a **strategic business**

Strategic
business
funding
plan:



AGC
AGC plus



Acquired (Sep. 2016)



Acquired (Dec. 2016)



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

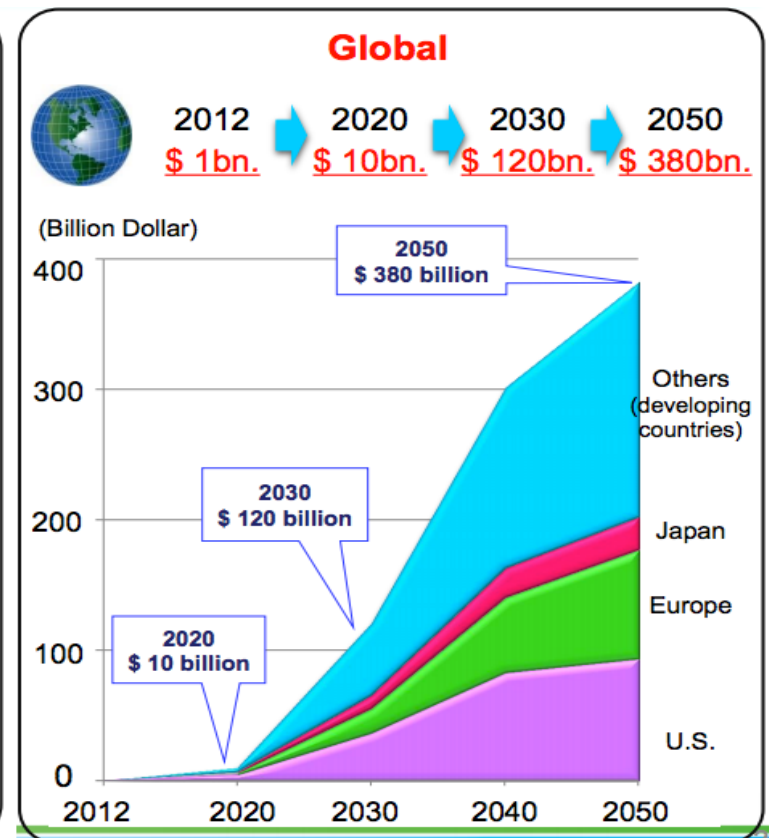
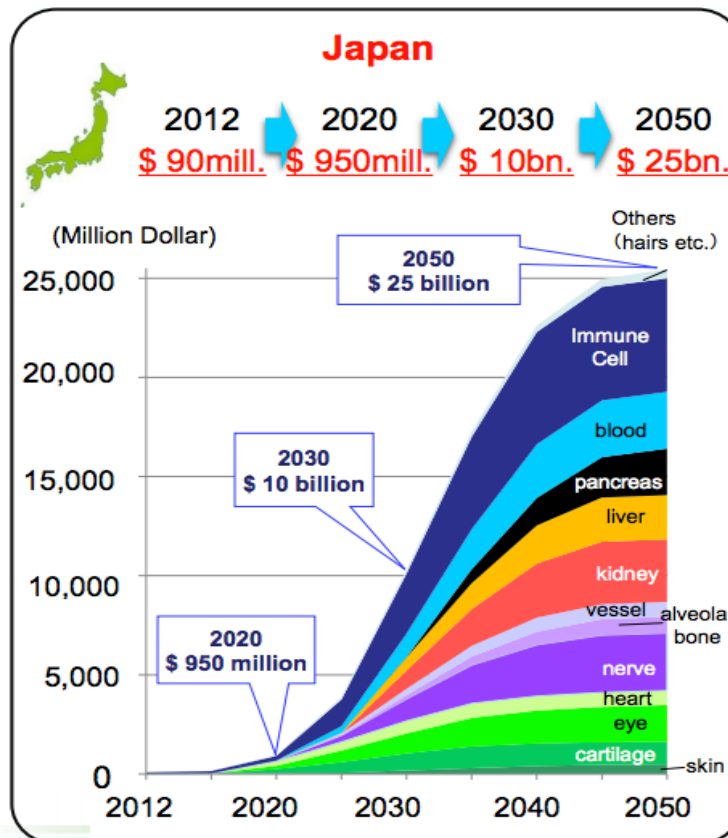


Japan First Strategy for Progenza

- Japan First Strategy for Progenza takes advantage of Japan as global capital of regenerative medicine
 - fast-track regulatory environment for RM products
 - shorter phase 2 trial – “probable efficacy”
 - Conditional Approval 5-7 years - no requirement for phase 3 trial
 - 70% government reimbursement includes CA phase
 - supportive regulator – PMDA and government departments
 - high level of industry engagement for market sector – FIRM >230 members
- Focus on product manufacturing and standardization allowing for separation of manufacturing and clinical licensing transactions
- Licensees willing to do Japan only transactions – benchmarks value and leaves other territories available
- Japan can validate opportunity for other markets
- Other jurisdictions influenced by new regulatory framework
eg South Korea and USA

Regenerative Medicine Markets are Large and Growing Rapidly

- Japan is 2nd largest healthcare market in the world
- Forefront of Accelerated Approval for Regenerative Medicines
- Leading market for Regenerative Medicine licensing activities





Successful Progenza STEP Trial Results for Knee Osteoarthritis

Progenza - Ph 1 Trial for Knee OA - Primary Endpoints Met

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 trends or findings of concern were identified

Trial Design

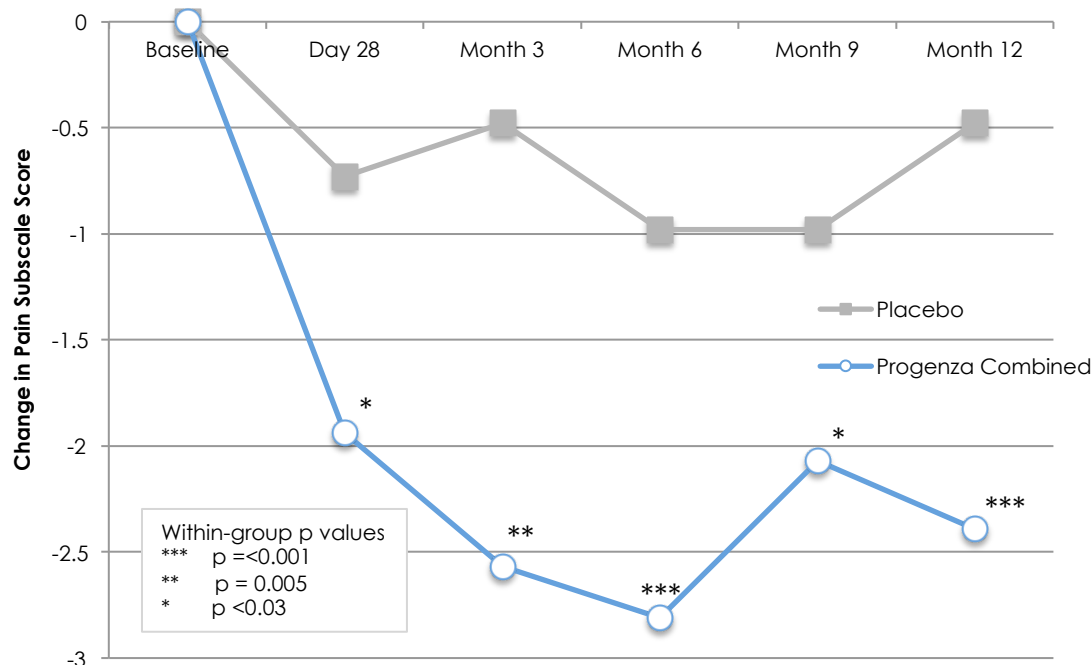
- Double-blind, placebo controlled and randomised 20 patient trial
 - Sydney - late 2015 through April 2017 (reported May'17)
- Single intra-articular injection and monitored for 12 months for safety
 - 2 cohorts, placebo (4:1)
- Mean age 53 years (40-64 years)
- Diagnosed with knee OA
 - mild OA 25%,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

Progenza - Ph 1 Trial for Knee OA - Significant Secondary Endpoints

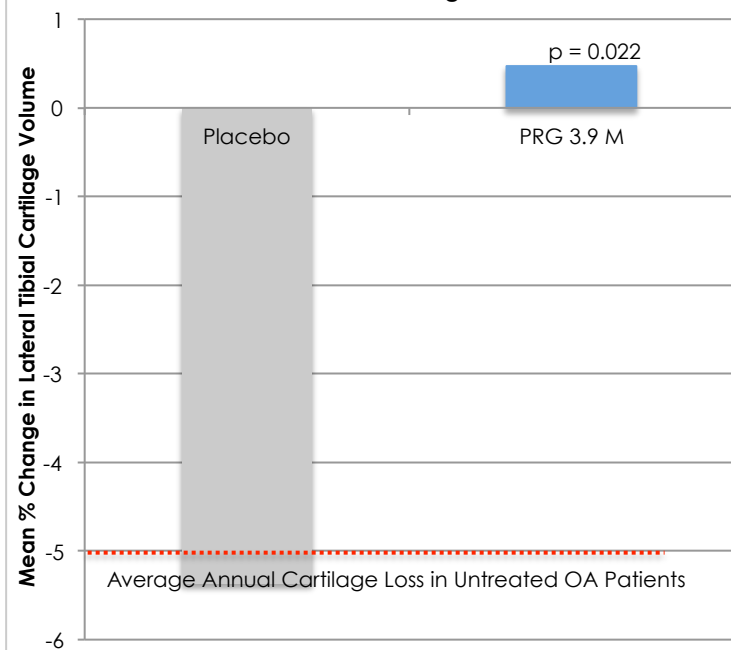
Significant Secondary Endpoints

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

Post-Treatment Change in WOMAC Pain Subscale Score



Mean Percent Change 12 Months Post-Treatment in Lateral Tibial Cartilage Volume



Progenza STEP Data Aligns with Preclinical Results

Safe and tolerable

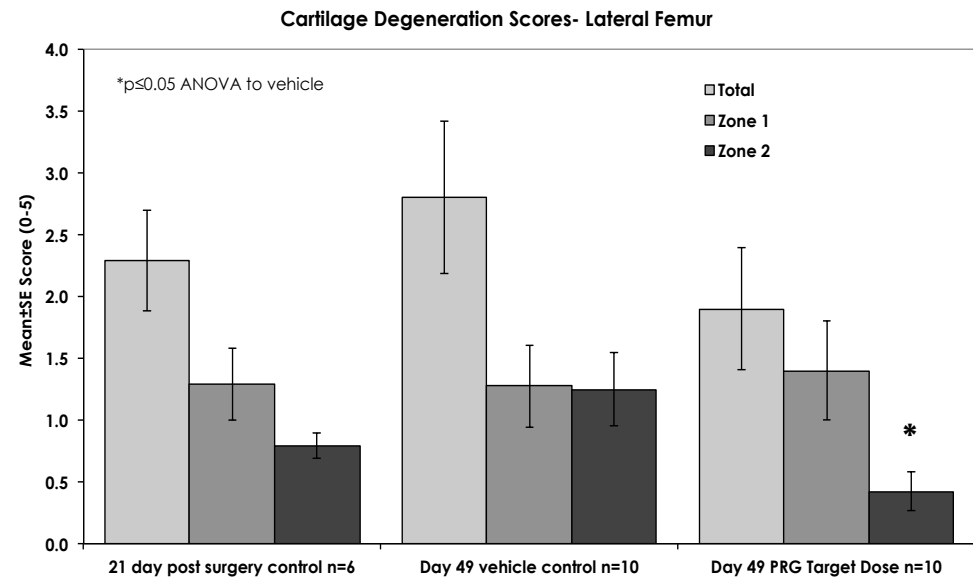
- No Progenza-related systemic or local toxicities or dose related adverse effects

Significant Secondary Endpoints

- Significant reduction in cartilage degeneration scores with target dose in middle load bearing femur zone (zone 2)
- Progenza-treated knees showed no deterioration from the time of injection, in contrast to the vehicle control group, which continued to deteriorate over the 7-week study. These study results support the role of Progenza in preventing disease progression

Rabbit Osteoarthritis Model - partial meniscectomy

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

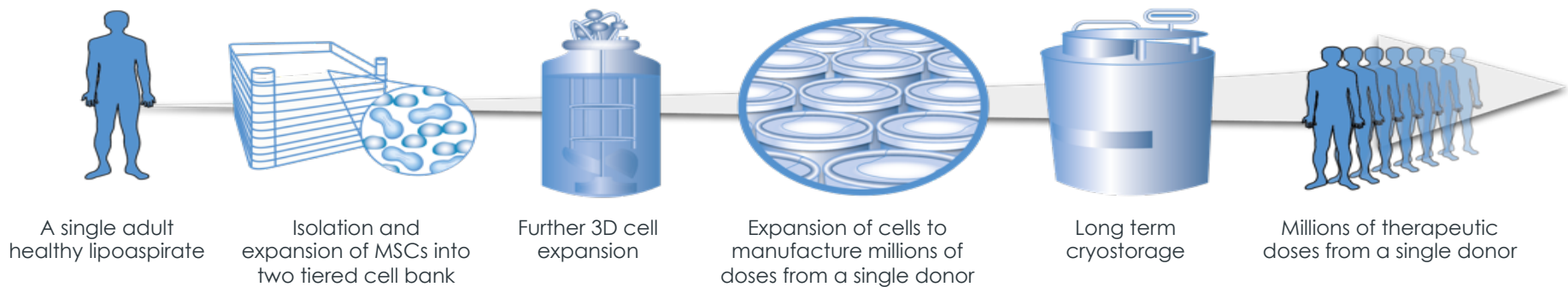


Conducted by US-based Pre-clinical Research Services, a degenerative OA model (partial meniscectomy) in rabbits (n=46; 23M, 23F)

Progenza – MSCs + Secretions Creates Competitive Advantage

Progenza – Patented and Scalable Allogeneic Stem Cell Platform

- Progenza - patented, scalable, off-the-shelf stem cell technology platform to treat a wide range of inflammatory conditions
- Progenza mesenchymal stem cells (MSCs) are sourced from a healthy adult donor
 - high safety and tolerability profile - no reprogramming or genetic modification of cells with lower clinical and regulatory risk
- Adipose (fat) tissue has competitive advantages as the source for MSCs
 - large starting volume, and large number of MSCs in adipose vs. other tissue sources
 - scalable technology: capacity to produce millions of Progenza doses from single donor – reduce risks and costs of pooled and multiple
 - immuno-modulatory benefits of adipose derived cells (vs other sources)



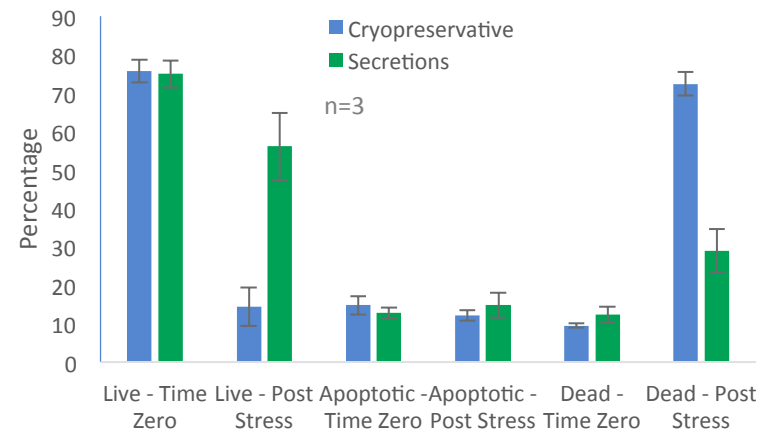
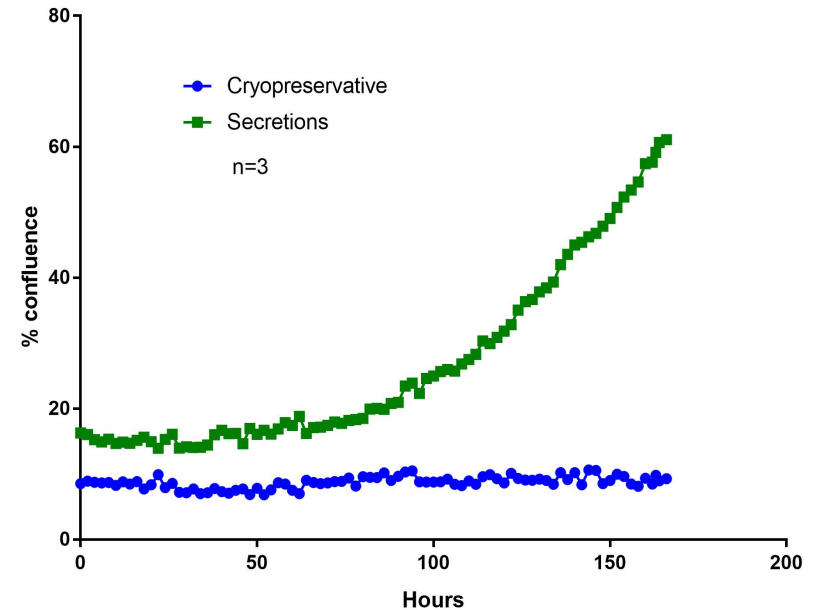
Progenza – Secretions Create Competitive Advantage

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 has a competitive advantage over other MSC products as it includes secretions with cells which:

- improves viability, stress resistance and functionality of cells
- secretions provide protection for cells to improve proliferation post thawing compared to cryoprotective solutions
- minimises cell loss post thawing and improves cell viability and functionality



Secretions Show Promise in Pain Model v Morphine

- Secretions administered in a post-operative pain model show significantly greater and longer lasting analgesic effect than a standardised dose of morphine
- Initial pain reduction in OA from Progenza is believed to be due to the fast acting secretions component
- Powerful dose dependent response seen

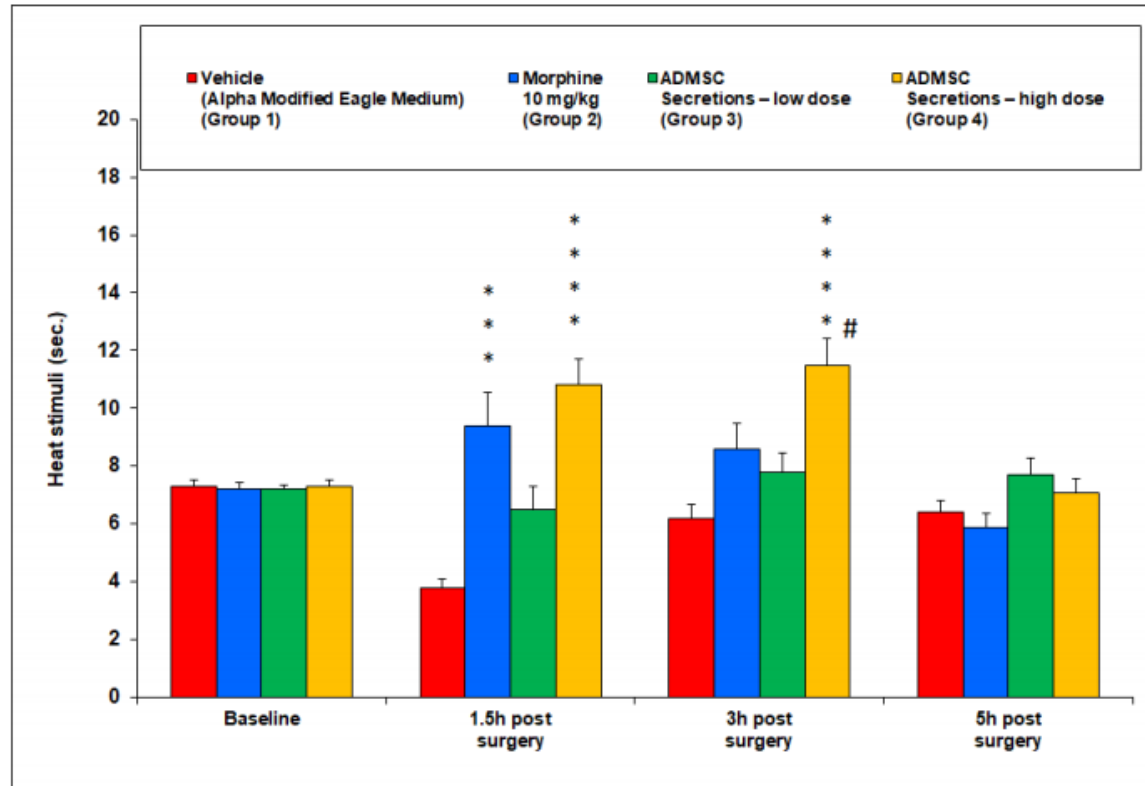


Figure 3: Mean group response to Hot plate test.

*** $p < 0.001$ vs. Vehicle using one-way ANOVA followed by Tukey test.

**** $p < 0.0001$ vs. Vehicle using one-way ANOVA followed by Tukey test.

$p < 0.05$ vs. Morphine using one-way ANOVA followed by Tukey test.

Positive Outlook for Progenza in Japan



- Tech transfer of Progenza to AGC on track
- AGC well positioned to establish global cGMP manufacturing hub for Progenza
 - industrialisation of product manufacturing with world class biopharma manufacturer
 - confidence in product manufacturer assists with regulatory engagement and clinical partnering
- JV in Japan with AGC
 - validation of company and technology
 - local market knowledge
 - supports clinical partnering and
- Good interest and engagement from local Japanese pharma for Progenza licensing opportunities for OA and other indications

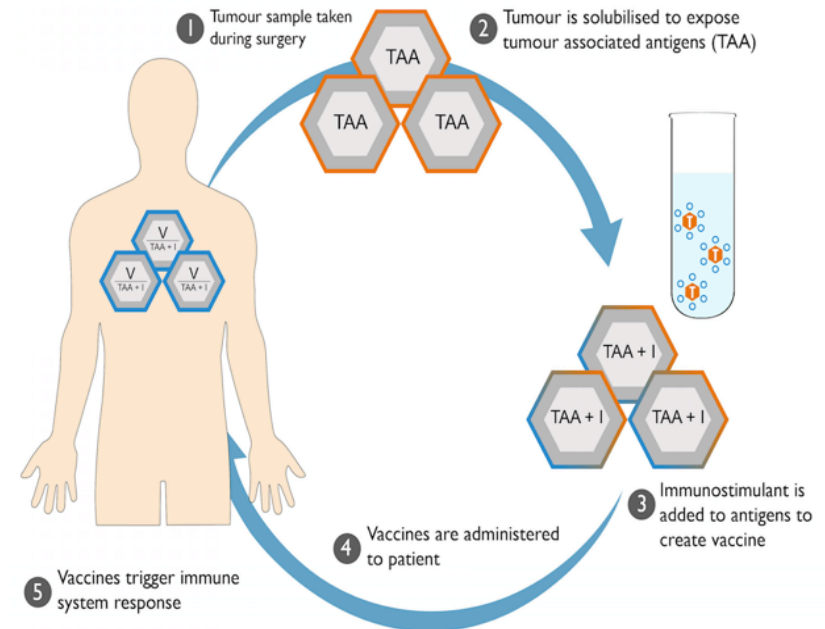


Progress on ACTIVATE Cancer Vaccine Trial

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"/>

- Exploring RGSH4K effect in combination therapy with checkpoint inhibitors
- Pursuing early partnering opportunities
- Targeting completion of recruitment in FY18



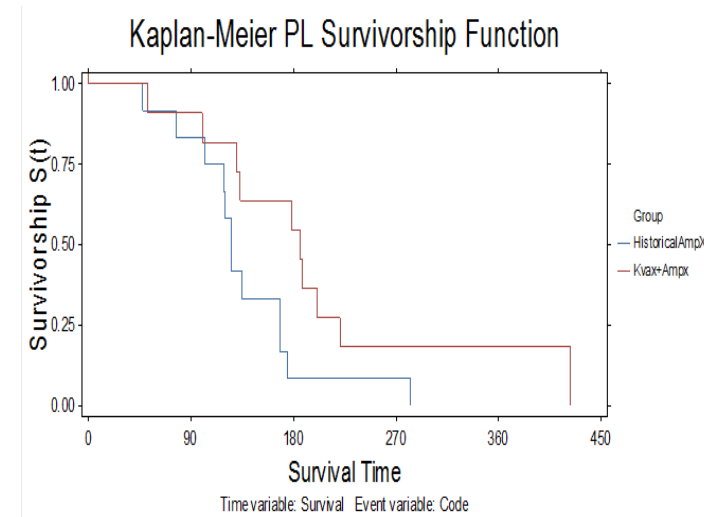
Progress on Animal Health Trials

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

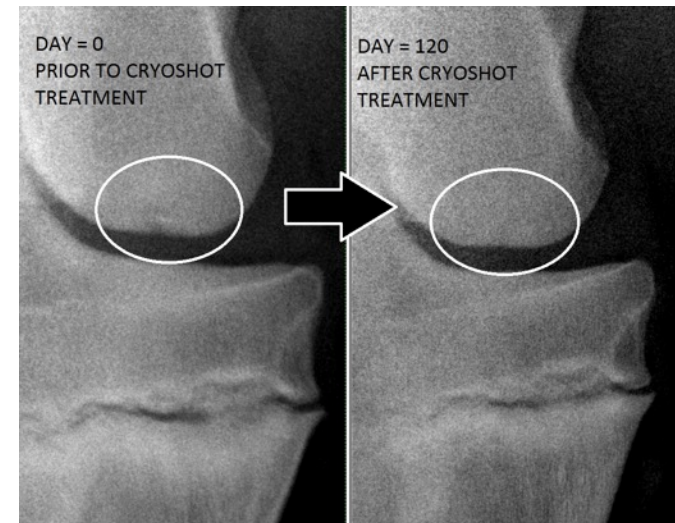
“Kvax after amputation is well tolerated and appears to confer increased PFI and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only”

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



CryoShot - Allogeneic Stem Cell Platform living regenerative medicine

- 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"/>



Key Patents Granted

Patent Portfolio Update

Overview

- 58 patents or patent applications across 14 patent families
- 12 patents granted in Australia; 3 in NZ; 2 in Japan
- Patents cover: methods of manufacture; compositions and delivery; use of products for treatment of a broad range of indications

Key patents granted in FY17

- Patent granted in Japan covering Progenza technology – allogeneic stem cells and secretions from any tissue for the treatment of osteoarthritis and other inflammatory conditions in humans and animals
- Patent allowed in EU, USA, JP and HK covering Sygenus stem cell secretions for topical treatment of acne
- Patent granted in Australia and NZ covering cancer vaccine technology for the treatment of cancers in humans (RGSH4K) and animals (Kvax)



Financial Highlights for FY17

FY17 Financial Results Overview

	\$'000's	2017	2016	Change
Revenue		10,169	1,878	8,291
Cost of Sales		(55)	(292)	237
Gross Profit		10,114	1,586	8,528
Other income		2,608	2,747	(139)
R & D expenses		(4,456)	(4,309)	(147)
Selling expenses		(238)	(375)	137
Occupancy expenses		(420)	(473)	53
Corporate expenses		(2,912)	(2,730)	(182)
Finance Costs		(16)	(20)	4
Other expenses		(1,300)	-	(1,300)
Share of loss on investment		(9)	-	(9)
Net Expenses		(6,743)	(5,160)	(1,583)
Profit / (Loss) for half year		3,371	(3,574)	6,945

- Revenue includes \$8.9m from AGC licence fees
- R&D tax incentive of \$2.6m included in other income, consistent with 2016: \$2.7m
- Other expenses are individually significant expenses associated with securing licence to AGC including; withholding tax, legal fees and other professional fees

Forecast Operating Cashflows

	\$'000's
Cash at 30/06/2017	4,135
Material cash inflows	
• R&D incentive receipt October '17	2,608
• Shareholder loan repayment June '18	1,251
Cash available FY18	7,994
monthly cash burn (estimate)	650
Cash available	12+ months

- Prior year quarterly cash outflow from operations was maintained at \$1.7 million up from 2016 \$1.5 million
- Future quarterly cash burn to progressively increase to up to \$2 million per quarter
- Incremental cash receipts not in forecast include:
 - AGC milestone payments – potential US\$5m
 - Share of licence fees from licensing clinical development and marketing rights of Progenza for OA and other indications in Japan
 - Licensing of other clinical assets
- Sustainable 12 month cashflow

Outlook for FY18

Progenza

- Convert clinical partnering discussions for Progenza for OA and other indications in Japan and other territories

Sygenus

- Report on studies for topical application of MSC secretions technology

RGSH4K

- Complete recruitment of ACTIVATE Phase 1 clinical trial

CryoShot

- Report on results of CryoShot Canine pre-pivotal OA trial

Further Information

ASX: RGS

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