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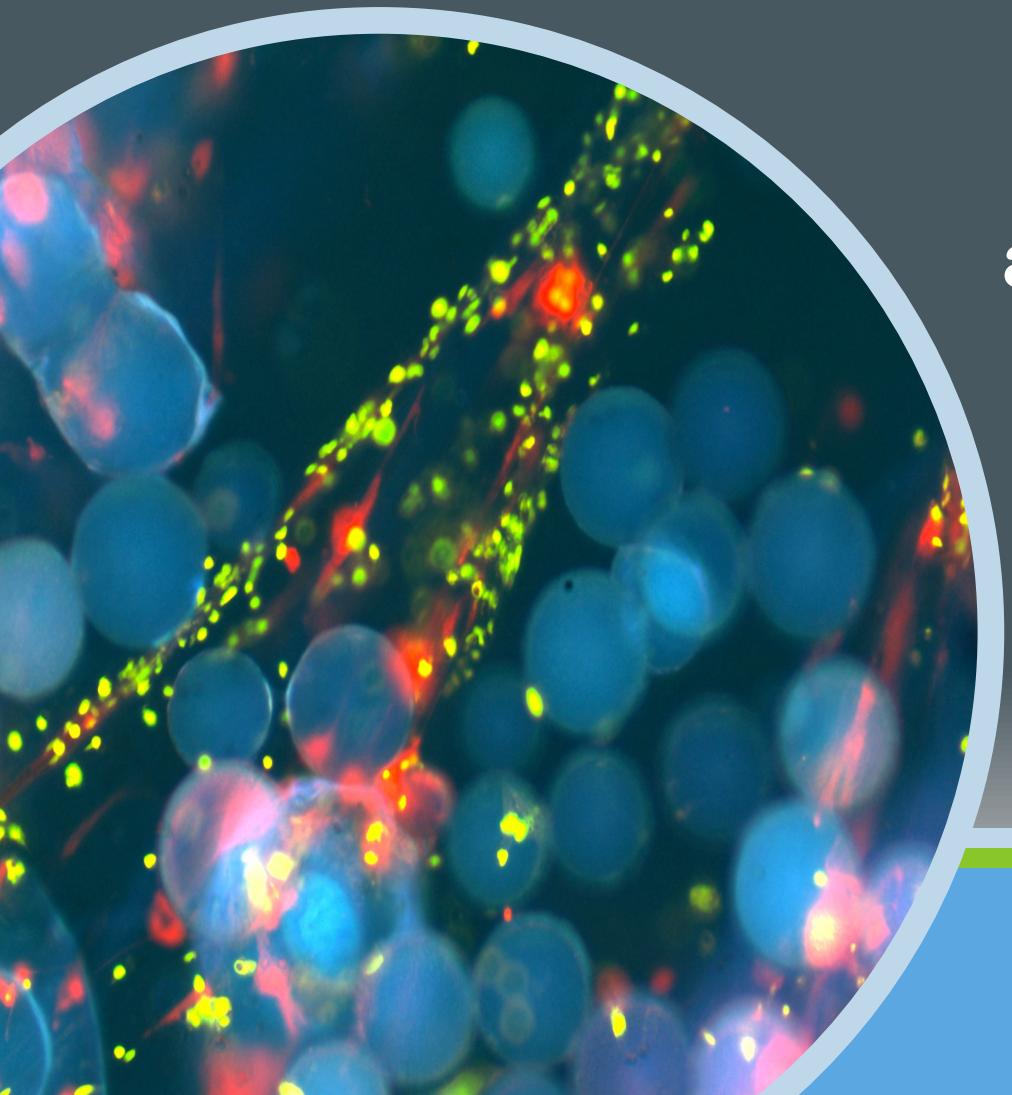

Business Update and Full-Year Results for FY17

Sydney
22 August 2017

Important Notice

Forward-Looking Statements

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Agenda

- Business Overview
- Business Update and Key Achievements for FY17
  - Progenza
    - AGC Collaboration
    - STEP Phase I Trial Results
  - RGSH4K
  - Sygenus
  - CryoShot
  - Kvax
  - IP update
- Financial Highlights for FY17
- Outlook for FY18

Overview

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Overview

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3 world class-technology platforms

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

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
- 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 (AGC, Kolling Institute, Macquarie and Adelaide Unis)
- Experienced and commercially focused management team and Board
- Well positioned to unlock significant value over next 12 months

Development pipeline summary

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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					
Sygenus	Allogeneic adipose MSC secretions	Derm / Wound					

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 update and key achievements for FY17

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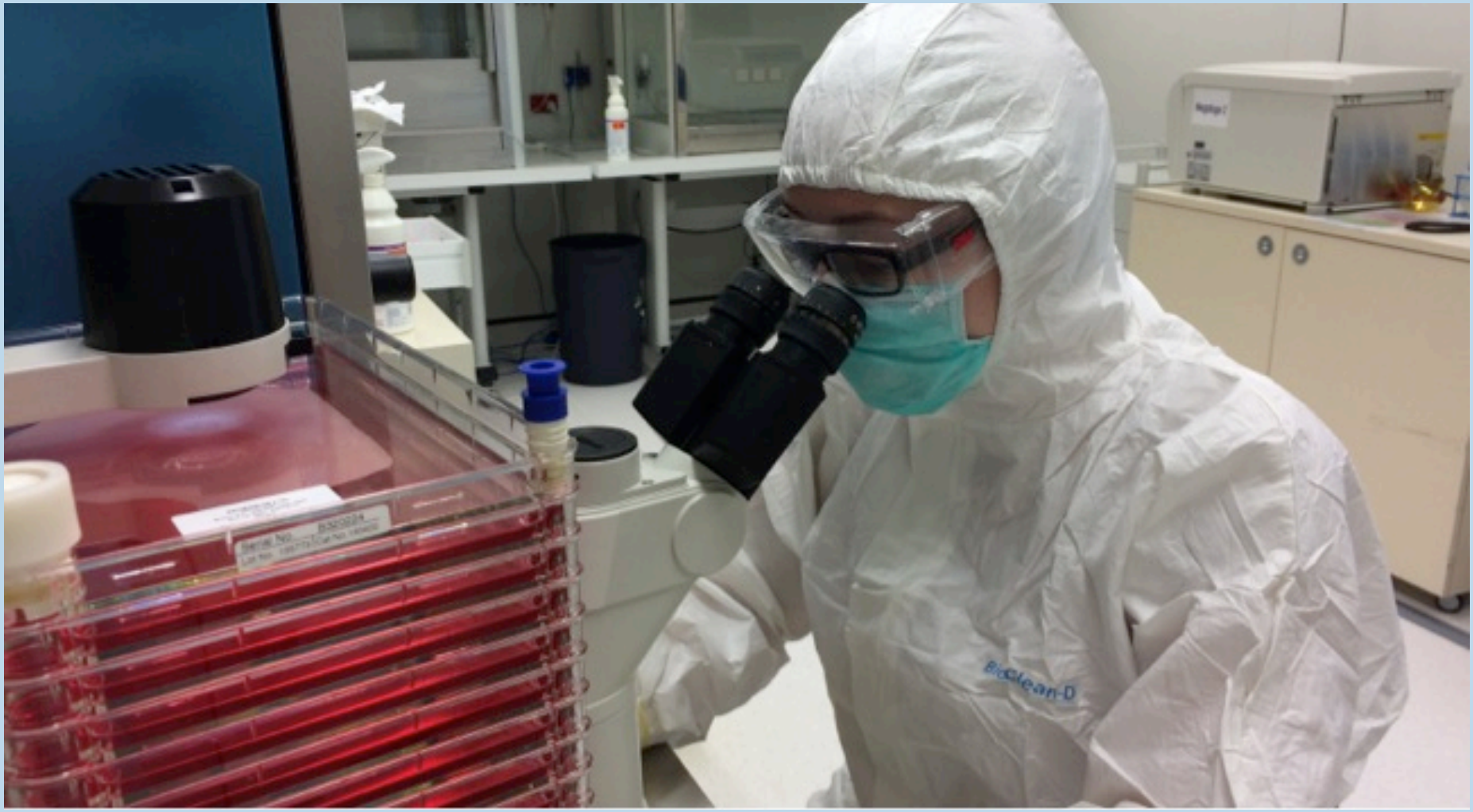

Overview of AGC collaboration for Progenza

Regeneus and AGC, a leading Japanese manufacturer of biopharmaceutical products, enter 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

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AGC	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

Benefits of AGC collaboration

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- **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 is at the forefront of Regenerative Medicine

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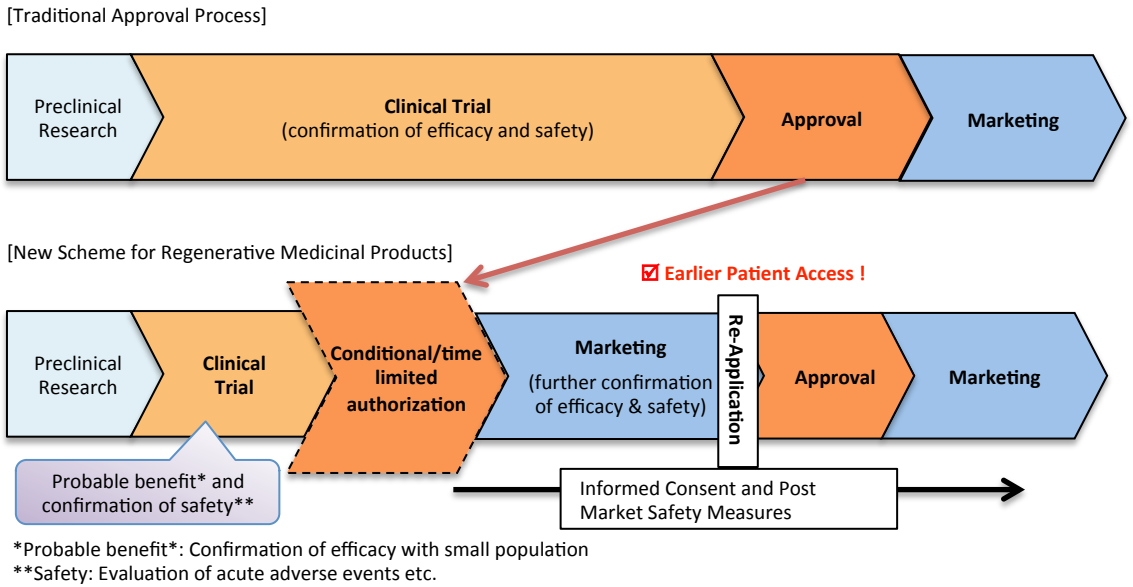
- Prime Minister Abe made Regenerative Medicine a key part of its strategy for revitalising the economy
  - **New laws** passed in Nov 2013 (took effect in Nov '14) positioned Japan at the forefront for regenerative products and services
  - New **accelerated pathway** for industry sponsored clinical trials

Second largest healthcare market in the world

Regen Med sector projected to grow to US$5.5b by 2030

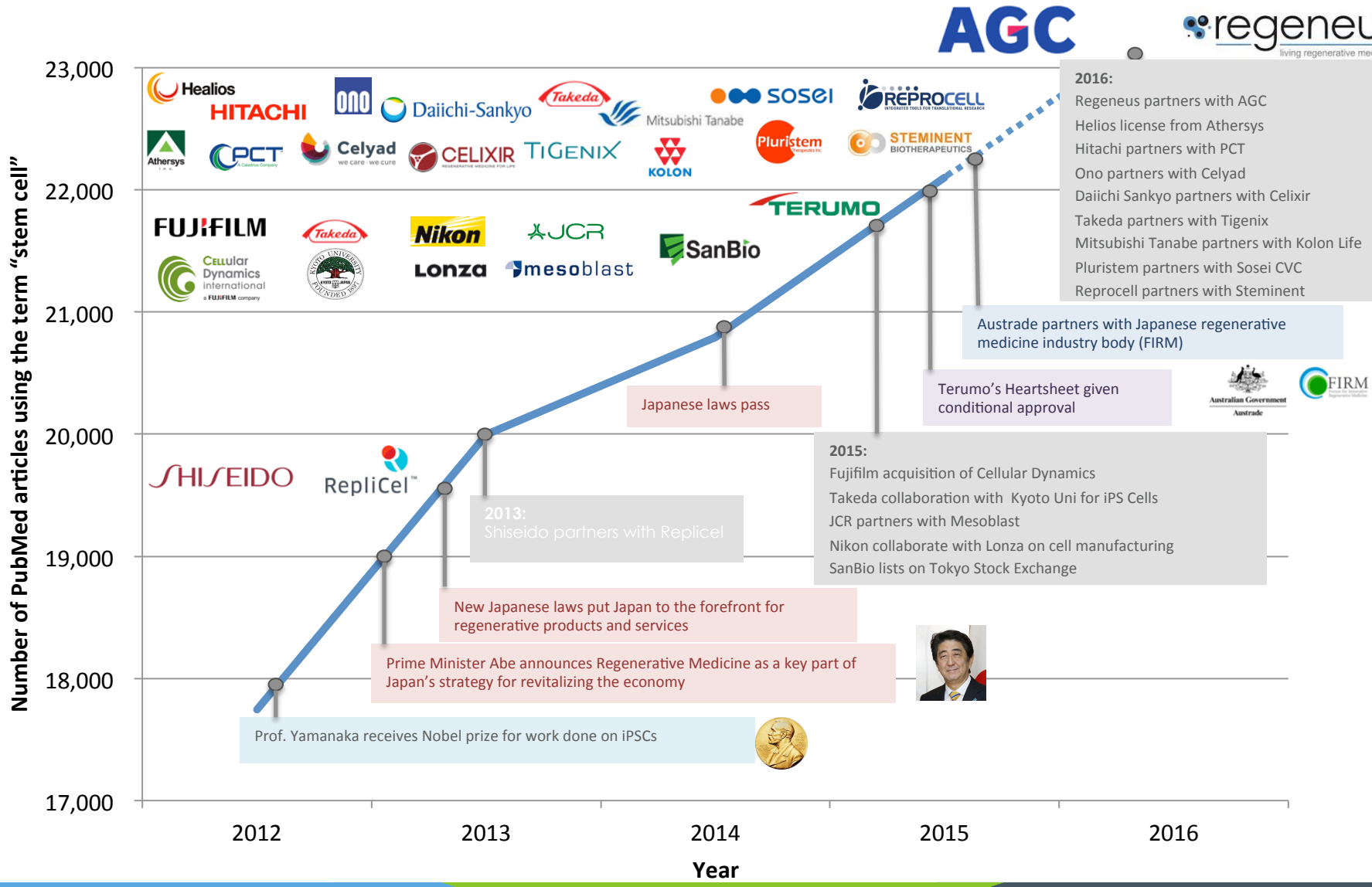
- Allows for **conditional approval** of new cell therapy after confirmation of safety and "predicted efficacy"
- **5-7 years** to gain clinical data
- **70% Government reimbursement**



Probable benefit: Confirmation of efficacy with small population
**Safety: Evaluation of acute adverse events etc.

https://www.jetro.go.jp/ext_images/australia/JVBFPresentations/FIRM.pdf

Increasing Japanese corporate activity



Regenerative Medicine markets are large and growing rapidly

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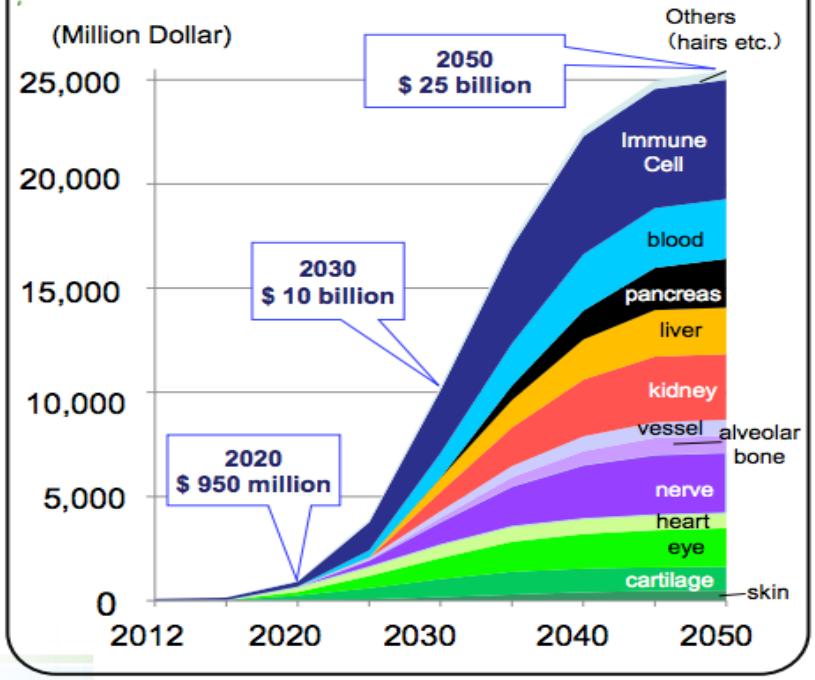
Market Forecasts for Regenerative Medicine

経済産業省

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

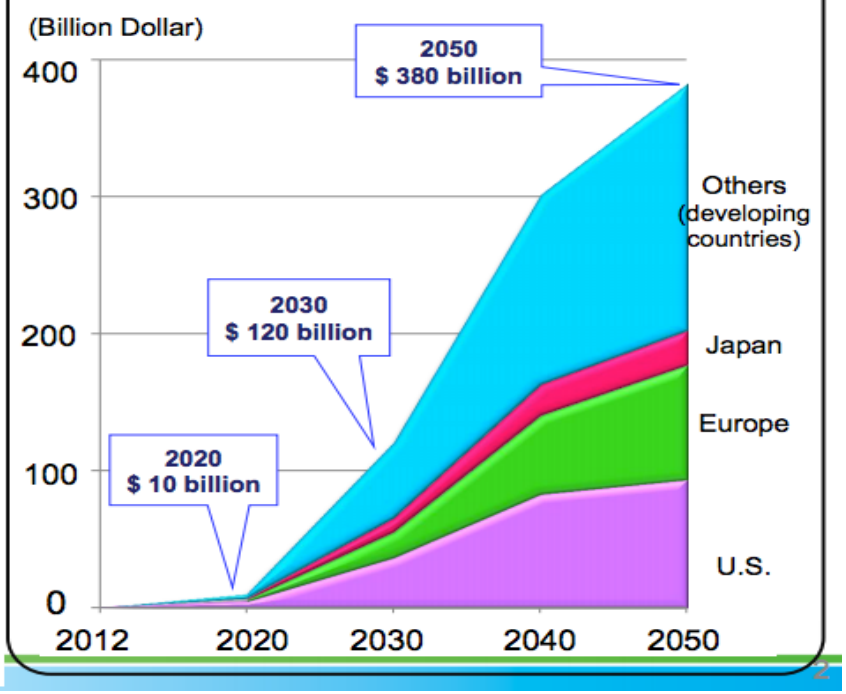
Japan

2012 $ 90mill. → 2020 $ 950mill. → 2030 $ 10bn. → 2050 $ 25bn.



Global

2012 $ 1bn. → 2020 $ 10bn. → 2030 $ 120bn. → 2050 $ 380bn.



Progenza – Phase 1 for OA safe and tolerable

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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 meaningful differences between placebo and PRG groups in incidence and nature of adverse events
- No trends or findings of concern were identified
  - from patients' vital signs, laboratory tests, physical examination, ECGs or other safety measurements

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 – Phase 1 for OA significant secondary endpoints

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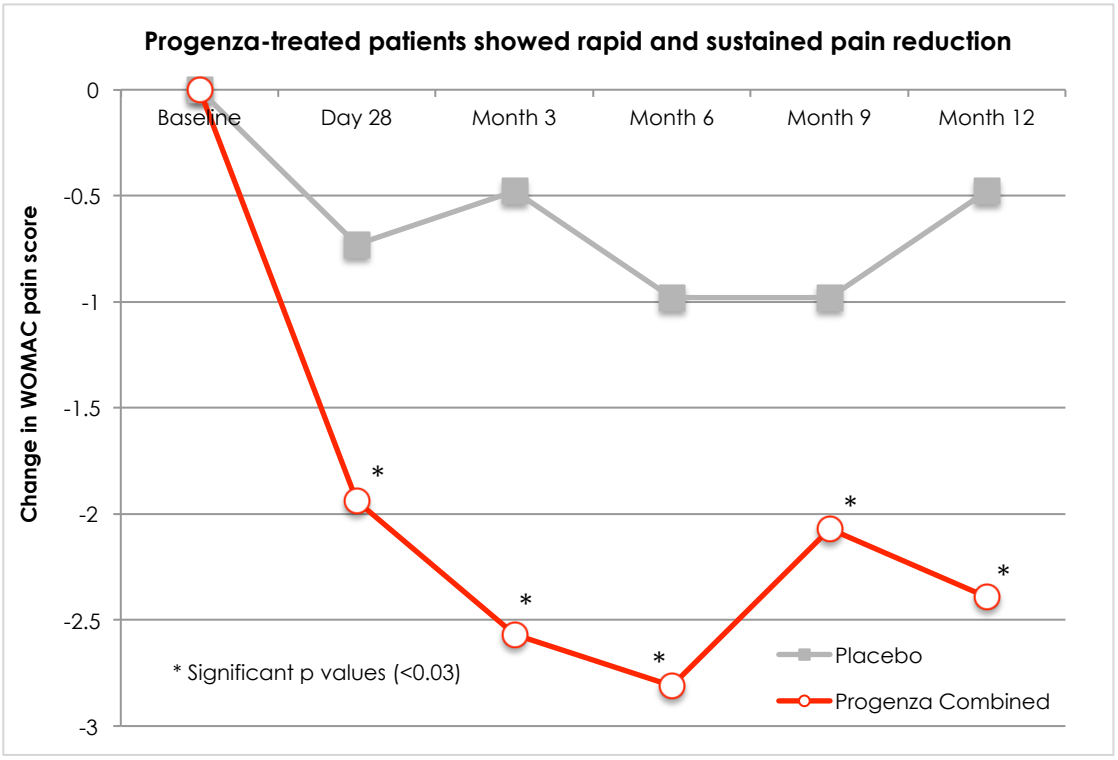
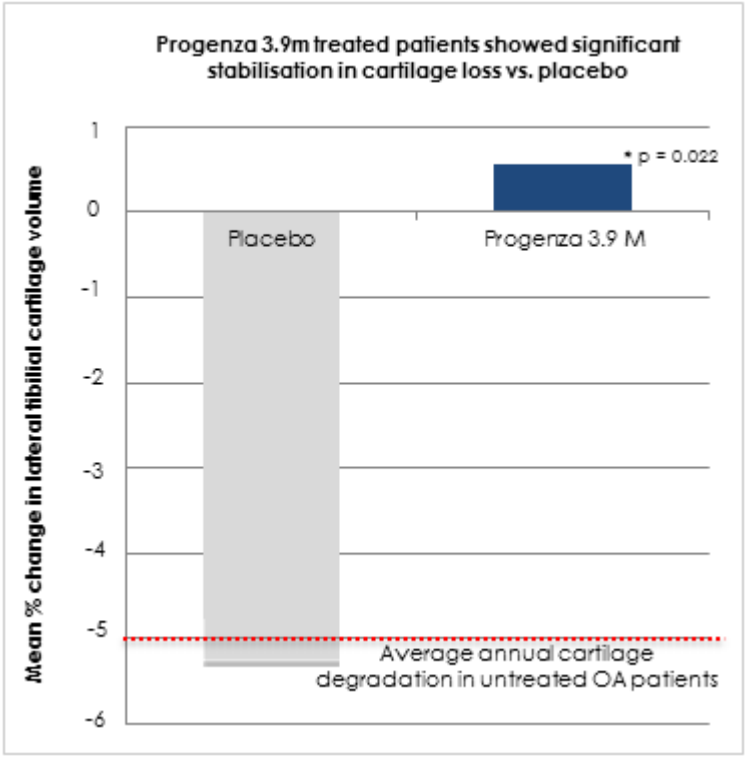
Significant Secondary Endpoints

- 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





Untreated OA is estimated to lose 5% of Lateral Tibial Cartilage Volume per year

Progenza - STEP data aligns with preclinical results

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Safe and tolerable

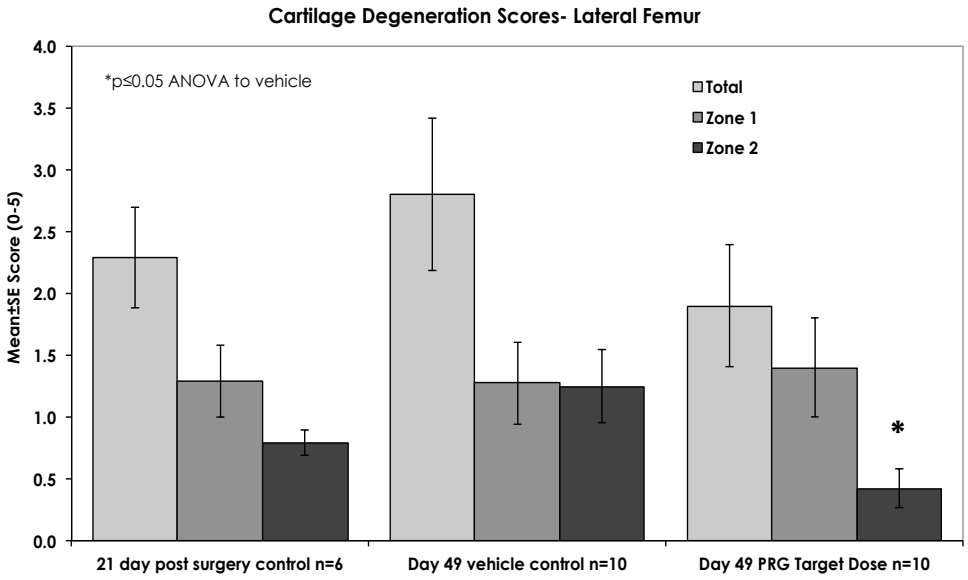
- No Progenza-related systemic or local toxicities or dose related adverse effects

Significant Secondary Endpoints

- Significant reduction in cartilage degeneration scores with target dose in middle load bearing femur zone (zone 2)
- Significant, rapid and sustained reduction in knee pain in both cohorts
- Positive signs of disease modification consistent with preclinical results

Rabbit Osteoarthritis Model - partial meniscetomy

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



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

Progenza – Leading stem cell platform

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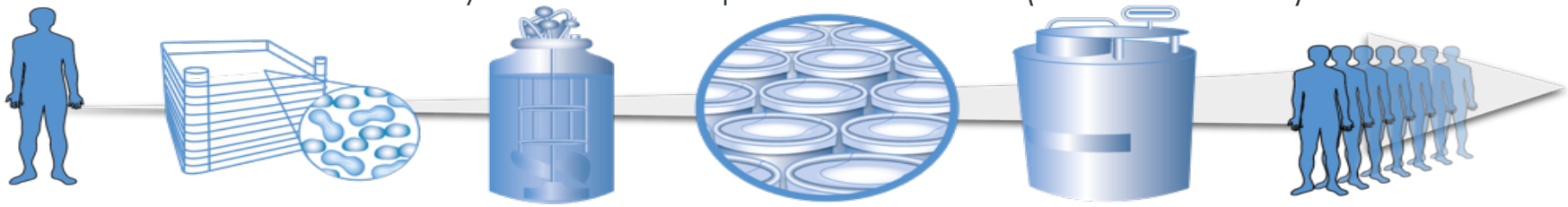
- Progenza is a patented, scalable, off-the-shelf stem cell technology platform **to treat a range of inflammatory conditions**

- Allogeneic mesenchymal stem cells (MSCs) are sourced from a healthy adult donor
  - no reprogramming of cells = **safety benefits → lower regulatory risk**
  - no need for expensive growth factors in production process

- 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)



A single adult healthy lipoaspirate | Isolation and expansion of MSCs into two tiered cell bank | Further 3D cell expansion | Expansion of cells to manufacture millions of doses from a single donor | Long term cryostorage | Millions of therapeutic doses from a single donor

Zhu, Y., Liu, T., Song, K., Fan, X., Ma, X., & Cui, Z. (2008). Adipose-derived stem cell: a better stem cell than BMSC. Cell Biochem Funct, 26(6), 664–675.
Melief, S. M., Zwaginga, J. J., Fibbe, W. E., & Roelofs, H. (2013). Adipose tissue-derived multipotent stromal cells have a higher immunomodulatory capacity than their bone marrow-derived counterparts. Stem Cells Translational Medicine, 2(6), 455–463.

Progenza - Advantages of secretions

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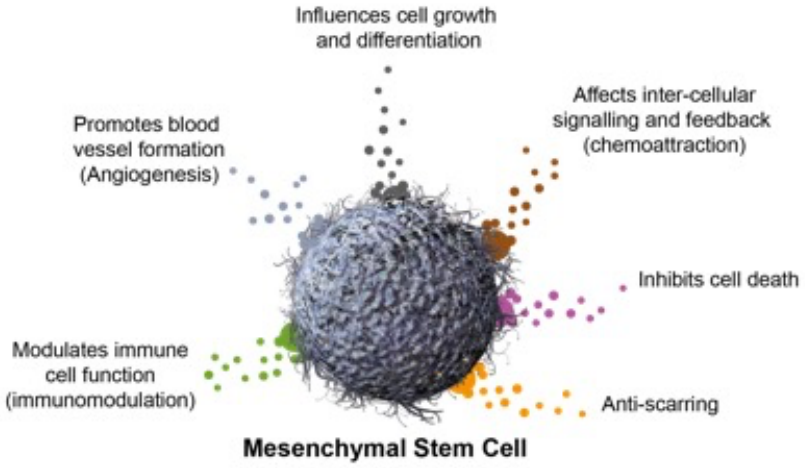
MSCs secrete a diverse variety of bioactive factors including cytokines, growth factors, extracellular vesicles and exosomes

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

RGSH4K - Update on Phase 1 Trial

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- 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	☑
HREC approved tumour bank	☑
Positive safety profile across all dose levels	☑
Patent granted	☑
Last patient last visit	☐
Analysis and final report	☐

Pursuing early partnering opportunities

RGSH4K – Cancer immunotherapy platform

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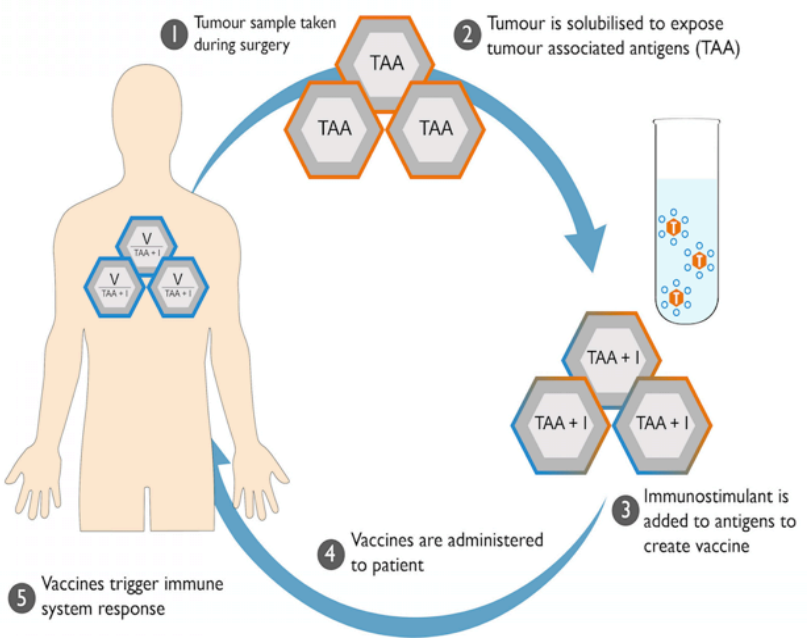
- Autologous cancer immunotherapy which uses a patient's own tumour as source coupled with a bacterial adjuvant
- Addresses tumour heterogeneity as all relevant tumour associated antigens are included
- Immune memory may be effective in reducing risk of tumour recurrence
- Straightforward and rapid manufacturing 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		✓	✓		✓	

Sygenus – MSC secretions technology platform

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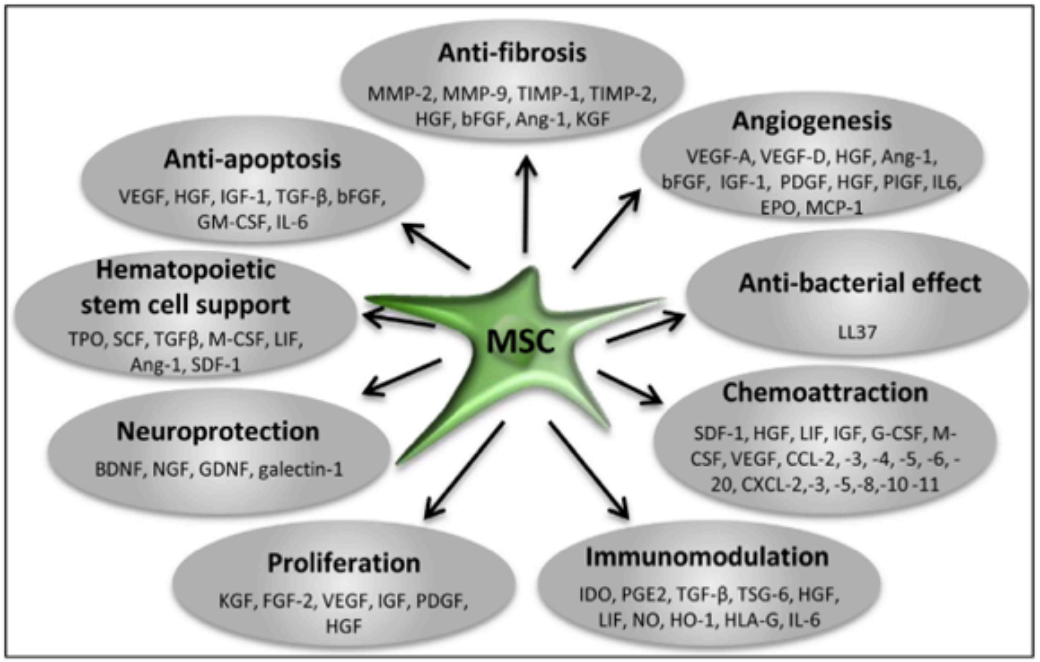
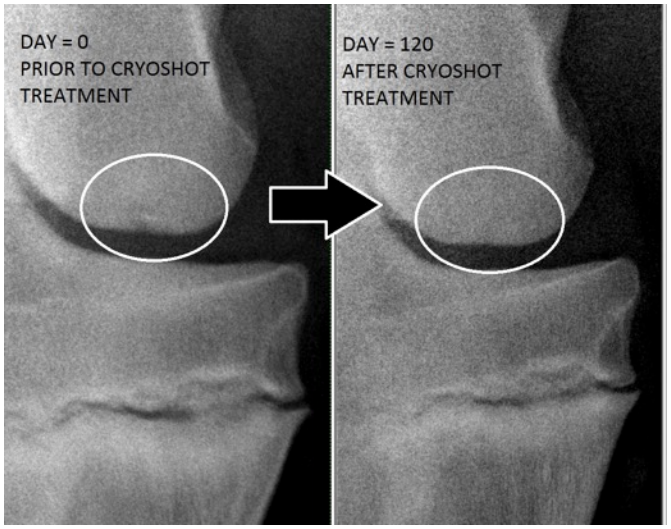
- Sygenus shows great promise as a stand alone allogeneic scalable technology that has potential to treat a wide range of inflammatory conditions
- Secretions can be used for various forms of administration such as topical, and injectable, aerosol
- Initial focus on topical applications for the management of acne and other inflammatory skin conditions
- We are conducting acne safety and tolerability studies with Sygenus in a gel format



- **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**

CryoShot – 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



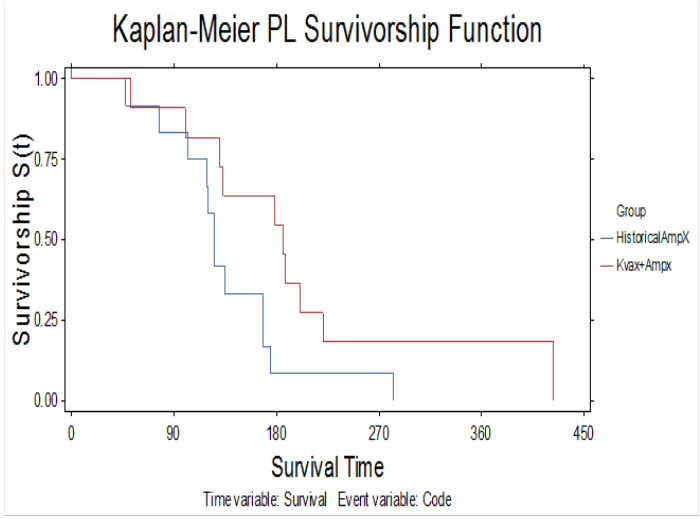
Activity / Milestone	
Signed collaboration with top Animal Health Pharma to partner development and commercialisation of CryoShot Canine	☑
Commenced pre pivotal dog trial at University of Pennsylvania for osteoarthritis (currently >50% complete)	☑
Last patient last visit	☐
Analysis and final report	☐

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 Update

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Overview

- 56 patents or patent applications across 14 patent families
- 11 patents granted in Australia; 2 in NZ; 1 in US, EU, Japan, China and Singapore
- Patents cover: methods of manufacture; compositions and delivery; use of products for treatment of a broad range of indications

Key patents granted

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

Financial Highlights for FY17

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FY17 financial results overview

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$'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
  - Licences of other clinical assets
- Sustainable 12 month cashflow

Outlook for FY18

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

RGSH4K
- Report on results of ACTIVATE Phase 1 clinical trial

Sygenus
- Report on studies for topical application of MSC secretions technology

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

Further information

ASX: RGS

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