

Half-Year Results

FY18

Sydney
20 February 2018

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Agenda

- Business Overview
- Financial Highlights for H1 FY18
- IP Update
- Milestones & Emerging Catalysts





Business Overview

Investment Overview

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 industrial production of Progenza in Japan
- Experienced & commercially focused management team and Board
- Well positioned to unlock significant value over next 12 months
- Monetisation of licences has commenced

Licensing Driven Business Model

Multiple business opportunities:

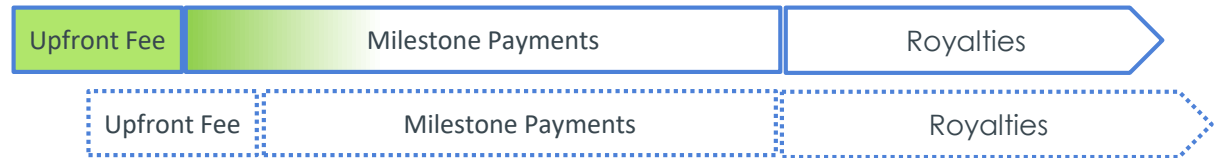
- Licensing opportunities
- 3 technology platforms
- Additional jurisdictions

Product map



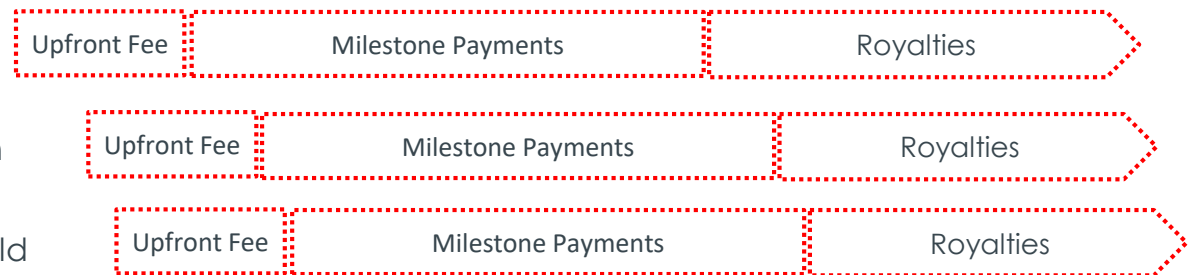
Manufacture licences

- AGC licence for Japan
- US, Europe etc



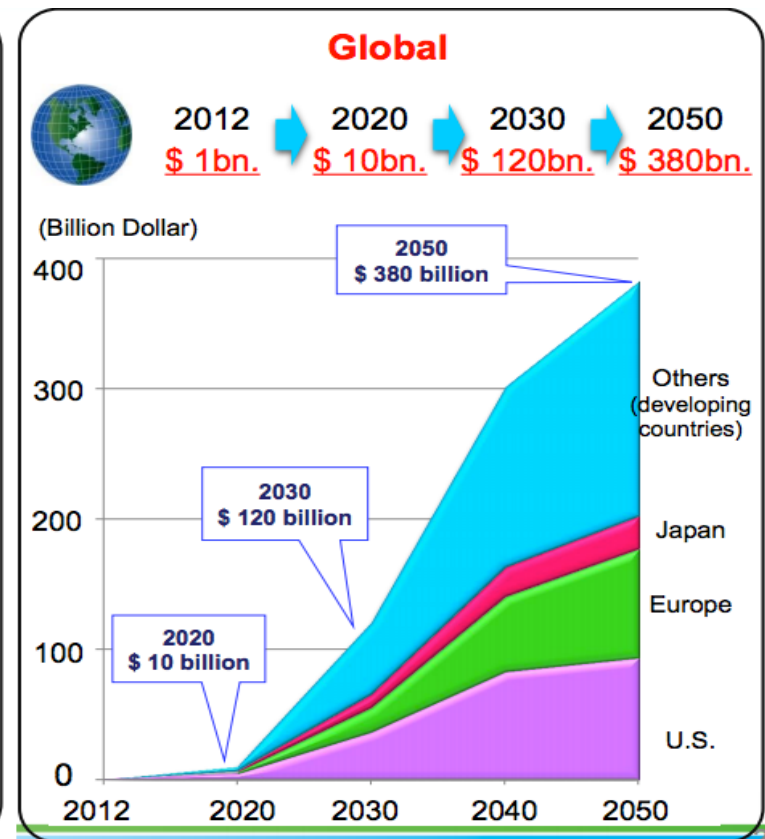
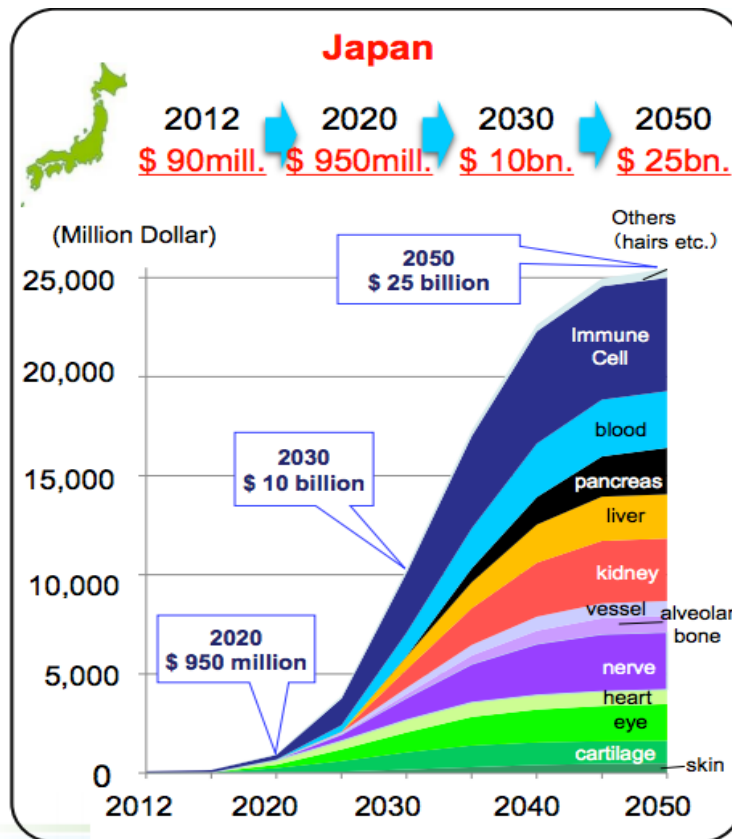
Clinical development and manufacture licences

- Osteoarthritis - Japan
- Further indication - Japan
- Osteoarthritis – rest of world




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




Japan is at the Forefront of Regenerative Medicine

- 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



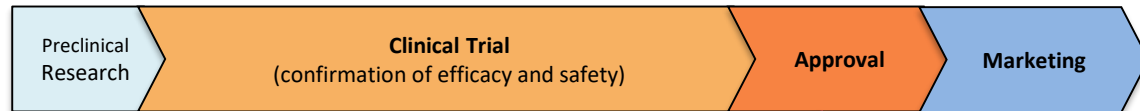
Second largest healthcare market in the world



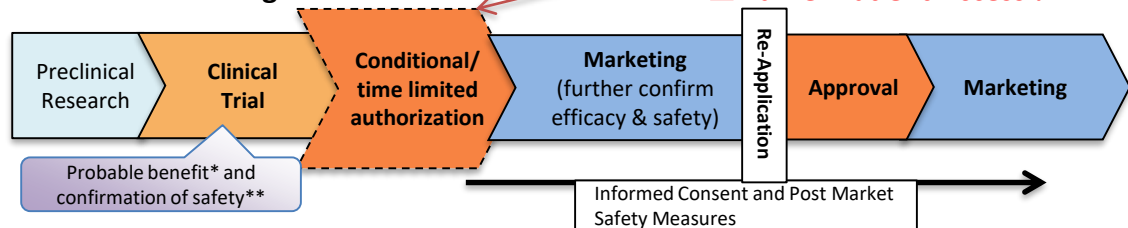
Regen Med sector projected to grow to US\$5.5b by 2030

- 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**

Traditional Approval Process



New Scheme for Regenerative Medicinal Products ☑ Earlier Patient Access !



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

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 standardisation allowing for separation of manufacturing and clinical licensing transactions
- Licensees willing to do Japan only transactions – benchmarks value and leaves other territories available
- Japan provides validation for other markets
- Other jurisdictions influenced by new regulatory framework eg USA and South Korea

Progenza in Japan – Status Update

- AGC initiate manufacturing licence (Dec '16)
 - Tech transfer of Progenza to AGC on track
 - AGC establishing global cGMP manufacturing capability for cell therapies
- Partnering in Japan with AGC provides
 - validation of Regeneus and its technology
 - local market knowledge
 - support in clinical partnering
- Regeneus Japan (JV with AGC) has progressed discussions and due diligence with potential clinical development partners for Progenza in Japan



Financial Highlights for H1 FY18

H1 FY18 Financial Results Overview

	\$'000's	2017	2016	Change
Revenue		354	8,189	7,835
Cost of Sales		-	(54)	54
Gross Profit		354	8,135	7,781
R & D incentive		1,170	-	1,170
R&D expenses		(2,134)	(1,843)	(291)
Occupancy expenses		(238)	(192)	(46)
Corporate expenses		(1,851)	(1,521)	(330)
Other Costs		(15)	(12)	(3)
One-off transaction costs		-	(810)	810
Net Expenses		(3,068)	(4,378)	1,310
Profit/(Loss) for half year		(2,714)	3,757	(6,471)

- Revenue in prior year includes \$7.6m from AGC licence fees
- R&D tax incentive, not recognised in prior half year results. Full year claim is expected to be similar to prior year \$2.5m to \$2.7m
- One-off transaction costs in prior year were costs incurred in securing licence to AGC - including withholding tax, consulting fees and legal costs

Forecast Operating Cash Burn

	\$'000's
Cash at 31/12/2017	3,372
Material cash inflows	
• Shareholder loan repayment June '18	937
• R&D tax incentive receipt Sept '18	2,700
• Next Milestone from Japan	pending
Cash available end FY18	7,009
Monthly cash burn	650 to 700
Cash available	10+ months

- Loan facility forward funding R&D incentive to \$2m or 80% of eligible claim supports R&D activities
- R&D tax incentive in line with prior years
- Quarterly cash burn has been held at \$1.8 million for first half FY'18
- Future quarterly cash burn to progressively increase to ~\$2 million
- Incremental cash receipts not in forecast include:
 - AGC milestone payments
 - Share of licence fees from licensing clinical development & marketing rights of Progenza for osteoarthritis & other indications in Japan
 - Licences of other clinical assets
- Sustainable cashflow until next milestone received



IP Update

Overview

- Over 70 patents or patent applications across 14 patent families with patents granted in Australia, New Zealand, USA, China, Japan & EU
- Patents cover: methods of manufacture; compositions and delivery; use of products for treatment of a broad range of indications

Key patents granted in H1 FY18

- Patent granted in USA covering Sygenus stem cell secretions for topical treatment of acne
- Patent granted in Japan covering cancer vaccine technology for the treatment of cancers in humans (RGSH4K) and animals (Kvax)

Milestones & Emerging Catalysts

Progenza

- Secure initial commercialisation/clinical partner for Progenza in Japan H2 FY18
- STEP trial manuscript to be published Q3 FY18

Sygenus

- Further product development to target specific pain and dermatological indications H2 FY18
- Explore licencing opportunities for pain & dermatology FY19

RGSH4K

- Recruitment for ACTIVATE trial closed and report trial results H2 FY18
- Advance clinical partnering discussions with further trial data ongoing

CryoShot

- Finalise recruitment and report results FY19

Kvax

- Finalise recruitment for B cell lymphoma trial and report results FY19

Further Information

ASX: RGS

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