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**Regeneus Ltd (ASX:RGS)**

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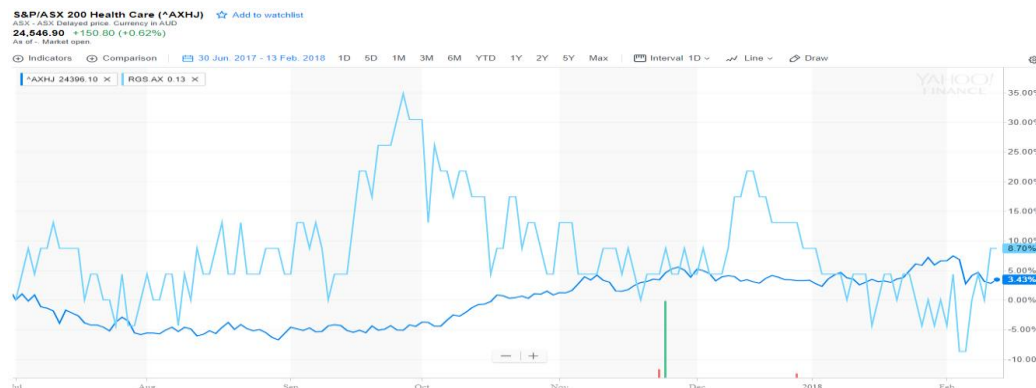
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# Corporate Overview

## Regeneus Ltd (ASX: RGS) - Australian-based clinical-stage **regenerative medicine** company

- Regeneus is developing a **portfolio of novel cell-based therapies**, using stem cell and immuno-oncology technologies
- These therapies will **address unmet medical needs in the human and animal health markets** and focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology
- Technology is validated** by positive preclinical and clinical data; collaboration with AGC, leading biopharma manufacturer in Japan; and substantial IP portfolio >70 patents and patent applications
- Regeneus is only the 17<sup>th</sup> Australian company to have secured a significant technology licensing agreement in Japan over the past 20 years

### Share price Chart



Regeneus → ASX Health Care Index including RGS →

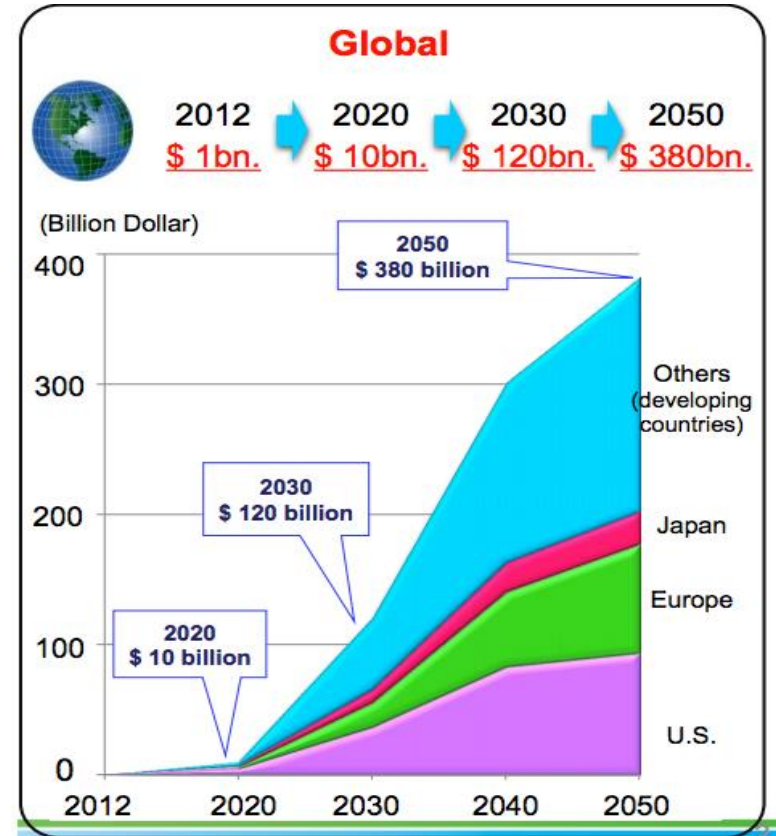
ASX code	RGS
Share price (8 Mar 18)	\$0.11
52 week	\$0.10 - \$0.16
Market Capitalisation	23 million
Shares on issue	209 million
Options <sup>1</sup>	10 million
Board & Executives shares/options	20%
Cash (31 Dec 17)	\$3.4 million
Undrawn loan facility	\$2.0 million
Investment since commencement 2009	
Capital raised	\$31 million
R&D expenditure	\$40 million
R&D tax incentive received	\$18 million
Total cash invested	\$61 million

1. Average Exercise Price \$0.22

# Global Regenerative Medicine Market regeneus

living regenerative medicine

- The global regenerative medicine market is extremely large, high-growth market expected to reach **US\$380 billion by 2050**
- 4<sup>th</sup> therapeutic pillar of global healthcare (alongside pharmaceuticals, biologics and devices)
- Regulatory changes enhancing opportunity
  - US FDA 21<sup>st</sup> Century Cures Act
  - Japan PMD Act
  - Europe ATMP designation



\*Japan's Ministry of Education Trade & Industry

# 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)			

# Osteoarthritis: Significant Unmet Need living regenerative medicine

- Single **most common cause of disability** in adults with no cure
  - Prevalence of >33% in adults aged >65 years

- Major risk factors:

- Advancing age

*“By 2020, for the first time in history, the number of people aged 60 years and older will outnumber children younger than 5 years”*



- Gender (female)

- Increasing BMI

*“Globally 39% of adults are overweight and 13% obese (obesity has tripled since 1975)”*

- With no cure, and **only symptomatic relief**, current market is dominated by pain relief or joint replacement



# Progenza: Proprietary and Scalable Stem Cell Platform

Progenza is a patented, scalable, off-the-shelf stem cell technology platform **to treat a 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
  - no requirement for expensive recombinant growth factors in production process
- Adipose (fat) tissue has competitive advantages as the source for MSCs
  - large starting volume and large number of MSCs in adipose vs. other sources
  - scalable technology – capacity to produce millions of Progenza doses from one donor
  - Better modification of immune response

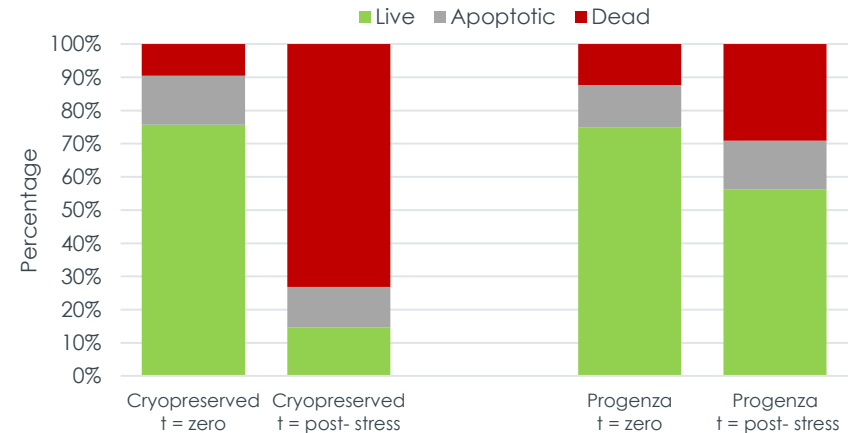
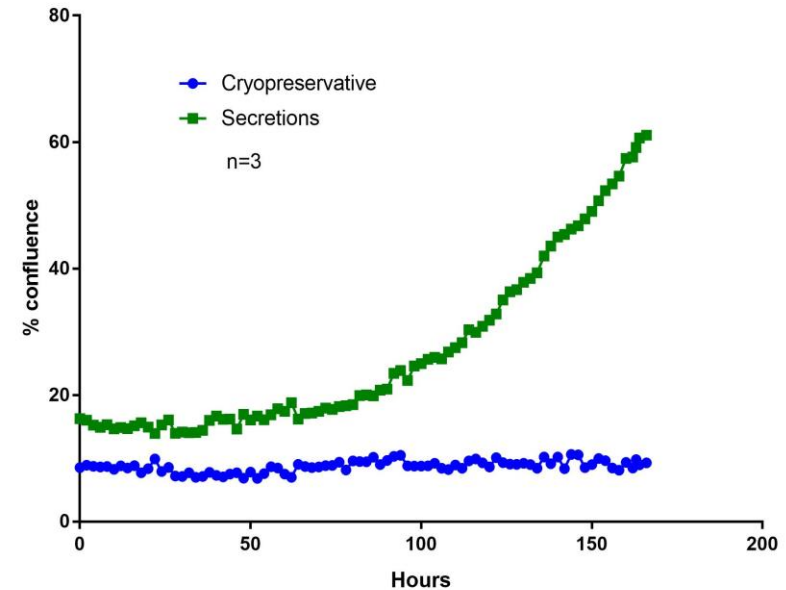
# Progenza: Secretions Create Competitive Advantage

*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
- provide protection for cells to improve proliferation post thawing compared to cryoprotective solutions
- minimises cell loss post thawing and improves cell viability and functionality



Cryopreserved cells vs Progenza: pre- and post- stress



# Progenza: Third-Party Validation



## Positive Phase 1 Trial Results

**Positive results from STEP Phase 1 safety trial** in patients with knee osteoarthritis published in the **Journal of Translational Medicine**



## World-leading Manufacturer

**AGC Asahi Glass** a world-leading leading biopharma manufacturer in Japan **will manufacture Progenza**

Upfront fee received in FY17



## Strong IP

**>70 patents** or patent applications across **14 patent families**

### **STEP Phase 1 Safety Trial of Progenza** in patients with knee osteoarthritis:

- Primary endpoints met - safe and well tolerated
- Secondary endpoints:
  - clinically meaningful and durable pain relief
  - statistically significant improvement in lateral tibial cartilage volume versus placebo

## Targeting second Progenza licence, following successful monetisation of initial Progenza licence in Japan

### Progenza

- STEP trial manuscript published Q3 FY18
- Secure initial commercialisation/clinical partner for Progenza in Japan H2 FY18
- Identify partners for further indications and territories for Progenza ongoing

### 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 FY19/20

### Kvax

- Finalise recruitment for B cell lymphoma trial and report results FY19/20

# Investment Summary

- ✓ Global regenerative medicine market presents a strong and growing market opportunity, estimated to be worth US\$380 billion by 2050
- ✓ Regeneus well positioned with validated, scalable and commercially viable technology combine with a successful licence driven business model
- ✓ Multiple licence opportunities for Regeneus' portfolio of assets across each platform, jurisdiction and clinical application
- ✓ Validated technology through commercial partnership, published results and regulatory approvals
- ✓ Japan presents a growing opportunity with more commercial deals in the pipeline
- ✓ Strong management team with expertise in developing and commercialising regenerative medical technology
- ✓ Significant value creation milestones over the next 6-12 months

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