regeneus
living regenerative medicine

FY18 Results & Business Highlights Presentation

August 2018

Regeneus Ltd (ASX:RGS)

Forward-Looking Statements

This Presentation contains certain statements which constitute forward-looking statements or information ("forward-looking statements”). These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the general economic and industry conditions in Australia and globally and the operations of the Company. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the Company believes the expectations and assumptions reflected in the forward-looking statements are reasonable, as of the date hereof, undue reliance should not be placed on the forward-looking statements as the Company can give no assurances that they will prove correct and because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risks associated with biotechnology companies, regenerative medicine and associated life science companies; delays or changes in plans; specific risks associated with the regulatory approvals for or applying to the Company’s products; commercialisation of the Company’s products and research and development of the Company’s products; ability to execute production sharing contracts, ability to meet work commitments, ability to meet the capital expenditures; risks associated with stock market volatility and the ability of the Company to continue as a going concern. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by securities laws.

No offer to sell, issue or recommend securities

This document does not constitute an offer, solicitation or recommendation in relation to the subscription, purchase or sale of securities in any jurisdiction. Neither this presentation nor anything in it will form any part of any contract for the acquisition of securities.

Corporate Overview

Regeneus Ltd (ASX: RGS) – Australian-based clinical-stage Regenerative Medicine Company

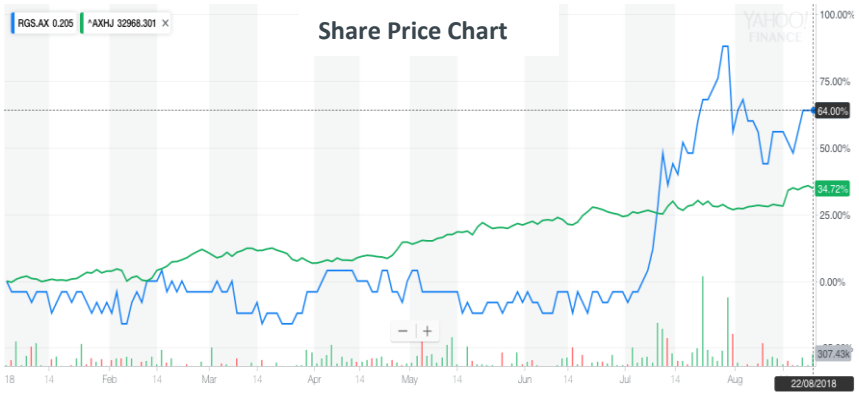
Regeneus is developing a **portfolio of novel cell-based therapies**, using stem cell and immuno-oncology technologies

- 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
  - Substantial IP portfolio >70 patents and patent applications
- Regeneus only the 17th Australian company to **secure a significant technology licensing agreement in Japan** in past 20 years

ASX code	RGS
Share price (29 Aug 18)	$0.215
52 week	$0.10 - $0.27
Market Capitalisation	44.9 million
Shares on issue	209 million
Options (average exercise price $0.22)	9 million
Board & Executives shares/options	>17%
Cash (30 Jun 18)	$1.1 million
Undrawn loan facility	$0.8 million
Investment since commencement 2009	
Capital raised	$31 million
R&D expenditure	$45 million
R&D tax incentive	$20 million
Total cash invested	$70 million

Financial Highlights for FY18

- Operating loss of $5.18m (FY: $2.17m profit). Operating expenses maintained at $7.96m (FY17: $8.05m)
- R&D tax incentive of $2.16m (FY17:$2.61m)
- Quarterly cash used in operations (including R&D incentive and FY17 Japan licence) maintained
- Loan facility secured of $1.9m



regeneus
living regenerative medicine

FY18 Highlights

Progenza

- Significant progress to establish AGC's manufacturing capabilities of Progenza to prepare for commercial-scale production and further clinical trials in Japan
- Second Japanese licence deal on track for Q2 FY19, as management significantly advances discussions to secure a partner for the Phase 2 trial and clinical development and commercialisation of Progenza
- Journal of Translational Medicine[1] publishes positive results from Progenza Phase 1 STEP safety trial, showing disease modification in patients with knee osteoarthritis
- Progenza granted Advanced Therapy Medicinal Therapy (ATMT) classification by Committee of Advanced Therapies of the European Medicines Agency, recognising it as a regenerative therapy within the EU's legal and regulatory framework
- US Patent[2] to be granted for the composition, manufacture and use of Progenza

Sygenus

- Sygenus preclinical trial delivers positive results in post-operative pain study, demonstrating a sustained analgesic affect, which was longer lasting than morphine
- Cosmetic trial delivers positive results from the topical application of Sygenus gel, which was shown to significantly reduce the appearance of non-inflammatory lesions and significantly reduced patients' acne global severity score after a 6-week period
- Cosmetic trial delivers positive results from the topical application of Sygenus gel, which was shown to significantly lighten the colour and size of age spots, increase skin smoothness and was well tolerated by patients
- Broad Australian patent granted for the topical application of Sygenus in the treatment of aging skin and age spots
- Chinese patent for the use of Sygenus in the topical treatment of Acne, providing commercial rights in China to 2023

RGSH4K Cancer Immunotherapy Vaccine

- Primary endpoint of safety and tolerability met with Phase 1 ACTIVATE safety trial showing signs of immune stimulation in patients, as demonstrated in changes in cancer markers, immune cells and cytokines, with some patients showing preliminary indications of anti-tumour activity

1. Kuah et.al. *JTranslMed (2018)* 16:49. 2. US Patent Application Number 14/342479 "Therapeutics using adipose cells and cell secretions."

Product Progress Update

Progenza

World Class Stem Cell Platform

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

Safe and Scalable

Mesenchymal stem cells (MSCs) are sourced from adipose tissue from healthy adult donor

- High safety and tolerability profile
- Adipose tissue is a readily available source of MSCs – 500x more MSCs than bone marrow per gram
- Scalable: capacity to produce millions of standardized Progenza doses from single donor

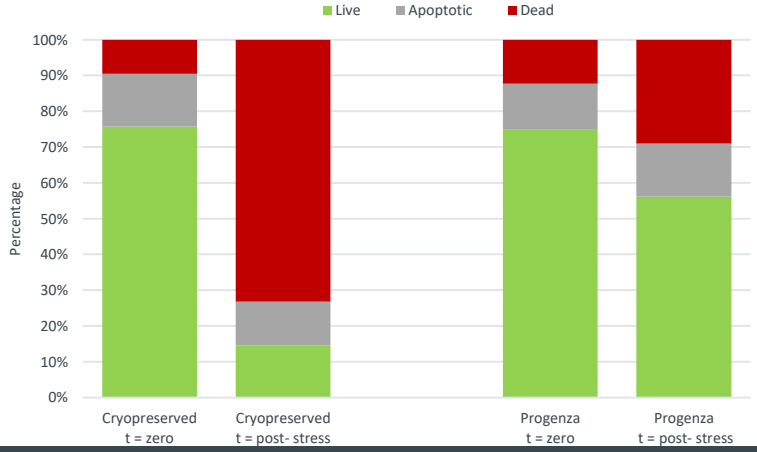
Competitive Advantages

Includes cell secretions with cells:

- Improves the viability, stress resistance and functionality of cells
- Provides protection for cells to improve proliferation post-thawing, compared to cryoprotective solutions
- Minimises cell loss post-thawing and improves cell viability and functionality

MSCs (aka medicinal signaling cells) 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



regeneus
living regenerative medicine

Progenza: Phase 1 Knee Osteoarthritis

Primary Endpoints Met - Safe and Tolerable

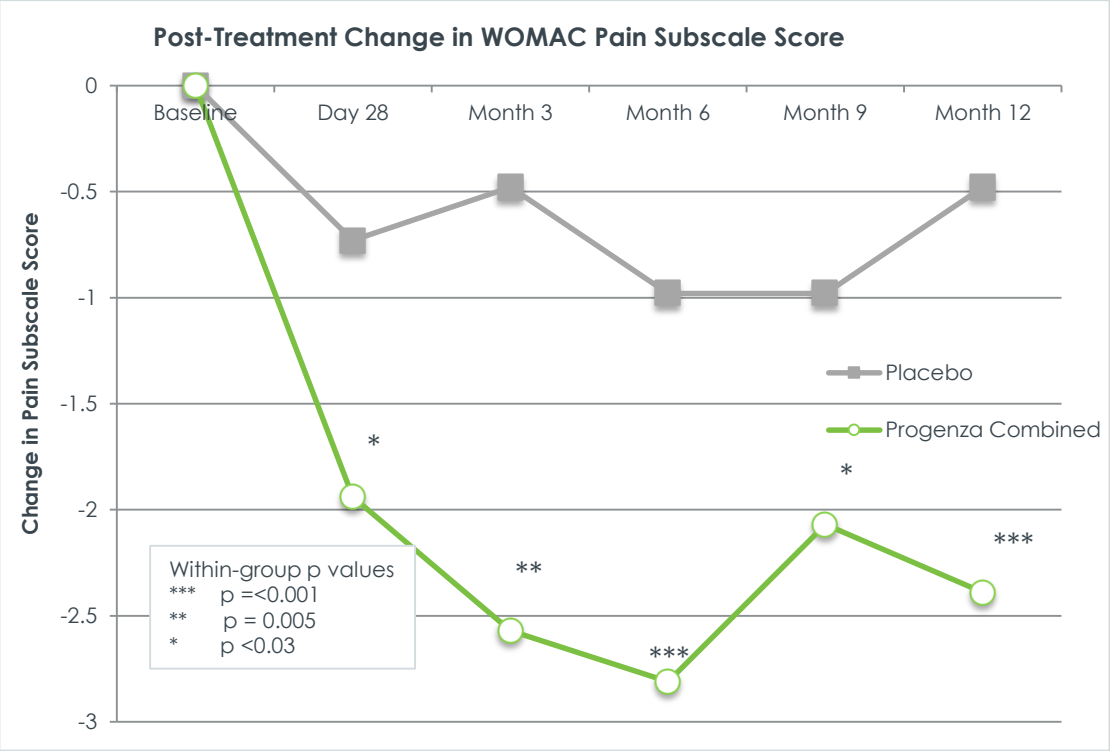
- Progenza at both doses was found to be safe and tolerable
- No serious adverse events occurred
- The majority of adverse events (AEs) were of mild severity
- No meaningful differences between placebo and PRG groups in incidence and nature of adverse events
- No trends or findings of concern were identified
  - from patients' vital signs, laboratory tests, physical examination, ECGs or other safety measurements

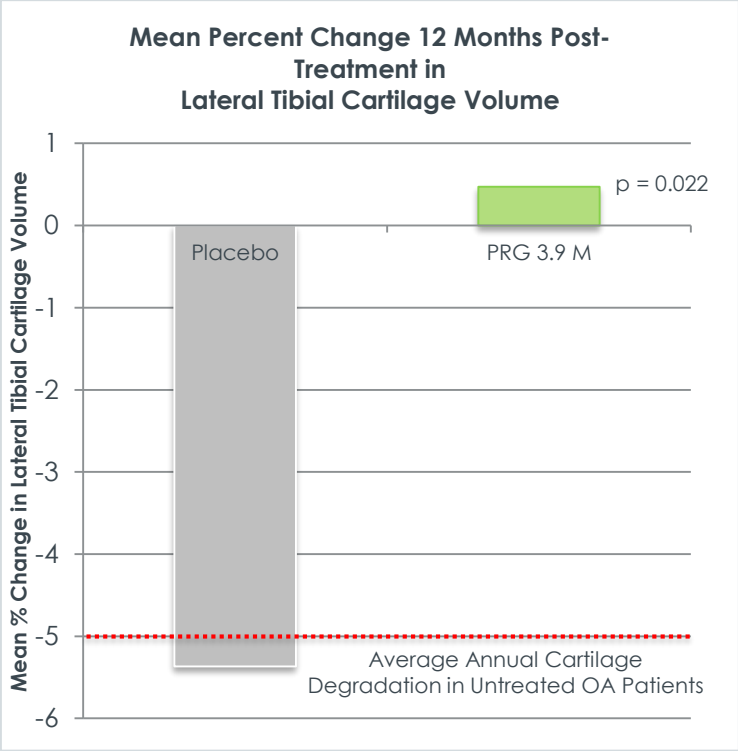
- Double-blind, placebo controlled and randomised 20 patient trial
  - Sydney - late 2015 through April 2017 (reported May'17)
- Single intra-articular injection and monitored for 12 months for safety
  - 2 cohorts, placebo (4:1)
- Mean age 53 years (40-64 years)
- Diagnosed with knee OA
  - mild OA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

Progenza: Phase 1 Knee Osteoarthritis

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

regeneus
living regenerative medicine

Progenza

STEP Trial Data Consistent with Preclinical Results

Safe and tolerable

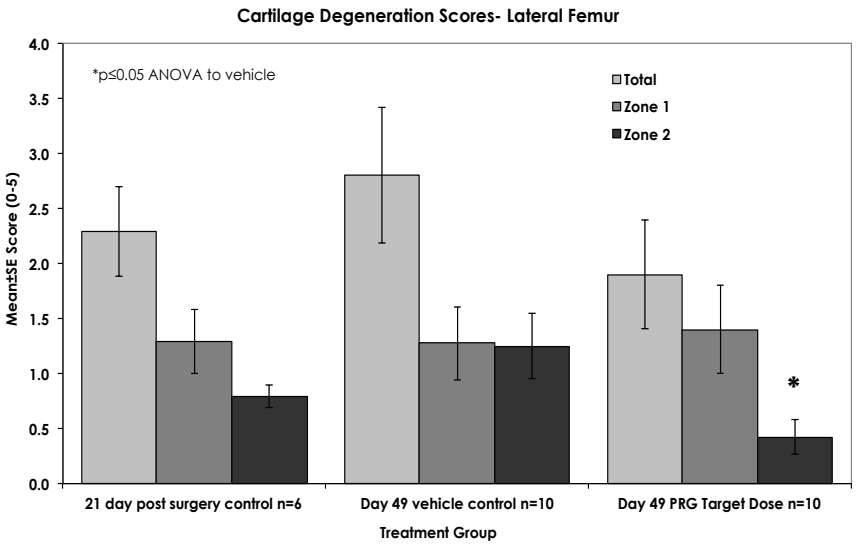
- No Progenza-related systemic or local toxicities or dose related adverse effects

Significant Secondary Endpoints

- Significant reduction in cartilage degeneration scores with target dose
  - Middle load bearing femur zone (zone 2)
- No further progression of OA
  - Total degeneration scores in Progenza treated knees 4 weeks post-treatment showed no further progression of OA compared to the pre-treatment control group (21 days post surgery)

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)

Next steps

- Pursuing licensing of Progenza for clinical development and commercialisation in Japan and ROW
- Targeting Phase 2 Progenza trial for OA in Japan under new cell therapy early access regulations

regeneus
living regenerative medicine

Progenza

Multiple Licensing Opportunities

Progenza = Multiple
→ licensing opportunities
→ technology platforms
→ jurisdictions

Product map

Manufacture licences

Clinical development licences

regeneus
living regenerative medicine

Progenza: Third-Party Validation

Positive Phase 1 Trial Results

Positive results from STEP Phase 1 safety trial

in patients with knee osteoarthritis **showing disease modification**

World-leading Manufacturer

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

Upfront fee received in FY17

Strong IP

>70 patents

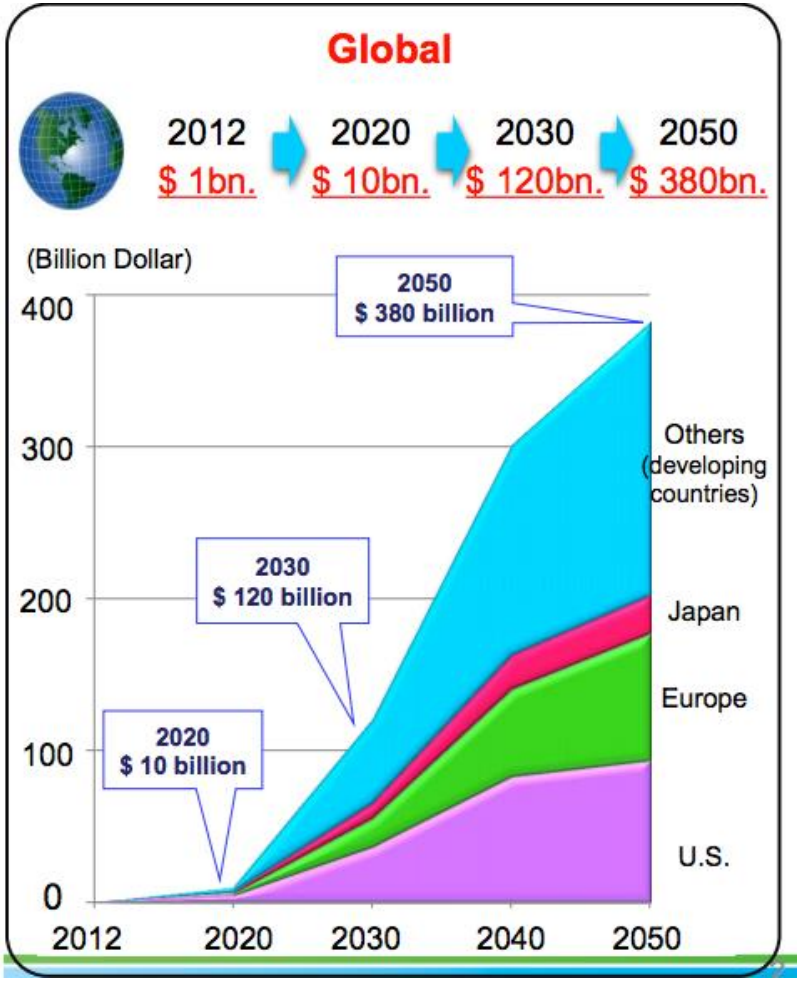
or patent applications across **14**

patent families

Global Regenerative Medicine Market

Large, high-growth market growing from US$10bn in 2020 to US$380 billion by 2050*

- Over 700 companies working on new cell, gene and tissue engineered therapies (>728 clinical trials)
- These therapies have the potential for profound and durable response in patients with a diverse array of serious and costly conditions, many of which lack current treatments
- Mission of RM technologies is to establish or restore healthy functioning of human cells in patients with cellular dysfunction
- Global regulatory changes create fast track for RM products in major markets
  - US 21st Century Cures Act
  - Japan PMD Act
  - Europe ATMP designation
  - China announces new laws in Dec 17



*Japan's Ministry of Education Trade & Industry

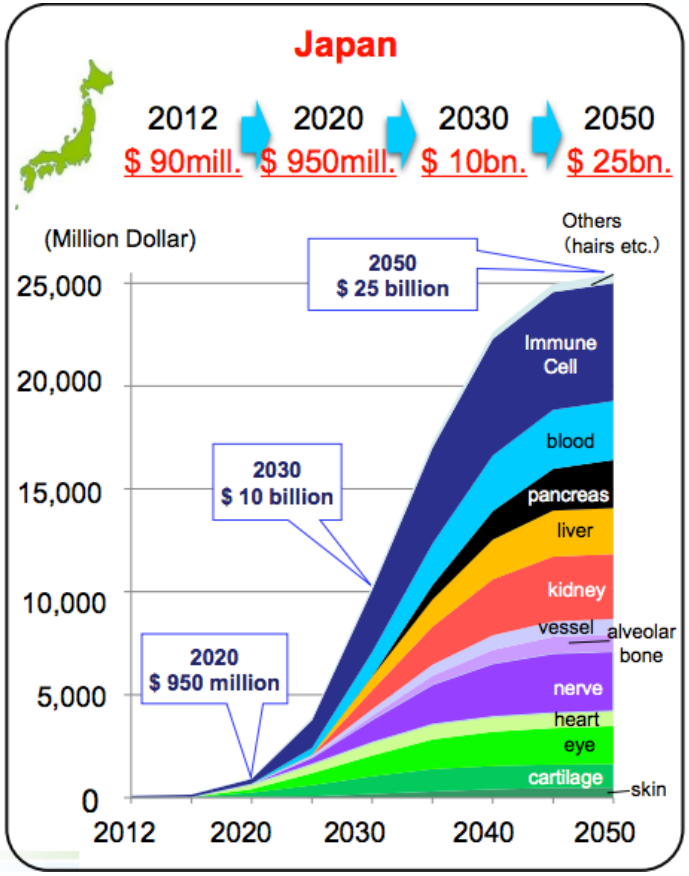
regeneus
living regenerative medicine

Japan: Attractive Market Conditions

Initially targeting Japan, the 2nd largest healthcare market in the world

- Leading market for regenerative medicine manufacturing, clinical development and licensing activities
- Accelerated approval process for regenerative medicines:
  - Shorter Phase 2 trial – "probable efficacy"
  - Conditional approval (CA) in 5-7 years removes requirement for Phase 3
  - Commercialisation possible during CA phase
  - 70% government reimbursement includes CA phase
  - Supportive regulator – PMDA and government departments

Growth in Japan's regenerative market



*Japan's Ministry of Education Trade & Industry estimates

regeneus
living regenerative medicine

Japan – Significant Regen. Med. Corporate Activity

$630 million acquisition

- Belgian BioTech
- Exploiting anti-inflammatory properties of stem cells
- Developing novel therapies for serious medical conditions in areas of high unmet medical need

HEALTHCARE JANUARY 5, 2018 / 5:23 PM / A MONTH AGO

Japan's Takeda to acquire TiGenix for $630 mln

Reuters Staff 1 MIN READ

TOKYO, Jan 5 (Reuters) - Japan's Takeda Pharmaceutical Co said on Friday it has agreed to buy Belgian biotech group TiGenix NV for 520 million euros ($628 million).

$102.5 million acquisition

- Universal Donor Cell technology
- Therapeutic cell therapy products that do not require Human Leukocyte Antigen (HLA) matching
- Developing potential innovative cell therapies for numerous diseases with high unmet medical needs

$56 million license expansion

- US Bone Marrow derived MSC company
- Developing novel therapies for neurological, cardiovascular, inflammatory and immune disease areas.

June 07, 2018 11:33 am UPDATED 6/8/2018

Athersys Inc. and Healios complete deal to expand their MultiStem partnership

By SCOTT SUTTELL

Strategic 9% equity stake

- Australian stem cell and regenerative medicine company
- Stem-cell platform technology (IPSCs) with starting material with unlimited expansion potential

Cynata Therapeutics Lands Japanese Giant Fujifilm

March 28, 2017 By Cade Hildreth (CEO)

*Post also available in: 日本語

It is not every day that an Aussie minnow lands a deal with a Japanese whale. When Fujifilm took a 9% equity stake in Cynata Therapeutics Ltd (ASX: CYP), it was a major lift for the regenerative medicine company, positioning Cynata to benefit not only from Fujifilm's resources but also more broadly from current economic strategy within Japan. Prime Minister of Japan, Shinzō Abe, has committed to building leadership around a new generation of regenerative medicine products involving human cells and tissues and Cynata is now perfectly positioned to take advantage of this in the world's second largest market for healthcare products.

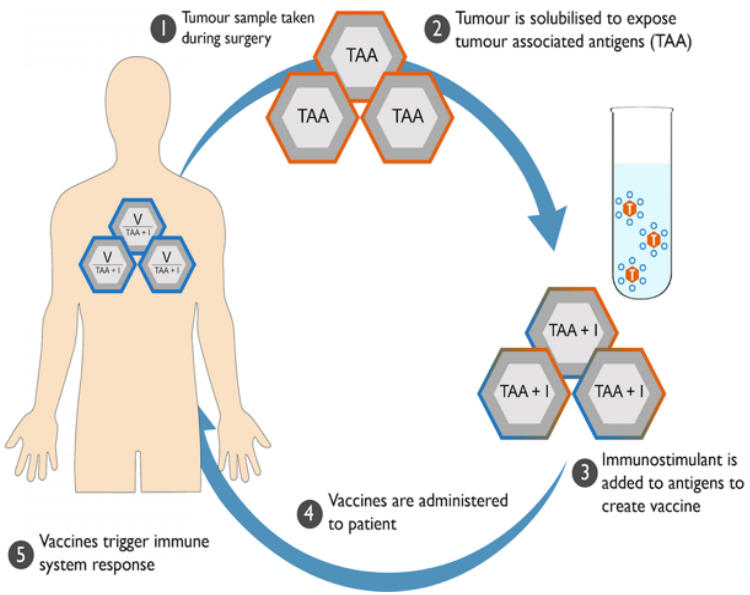
Collaboration with World Leading Bio-pharma Manufacturer

Regeneus and AGC, the leading Japanese manufacturer of biopharmaceutical products, enter into collaboration and licence agreement for the manufacture and joint licensing of the clinical development of its off-the-shelf stem cell therapy platform, Progenza, in Japan

regeneus living regenerative medicine	Received **US$5.5M** Upfront licence fee	Entitled to **US$11.0M** Specific milestone payments	Established 50/50 JV 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
AGC	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture for Phase 2 Progenza trial		

RGSH4K

Cancer Immunotherapy Platform



	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		✓	✓		✓	

- Autologous cancer immunotherapy
  - Uses 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

RGSH4K - Update on Phase 1

Study for solid tumours – **ACTIVATE Trial**

- Single centre, open label, first-in-human Phase 1 study to evaluate the safety and tolerability
- 12 patients, received RGSH4K in 3 dose cohorts
  - Various advanced solid tumours, heavily pre-treated with chemotherapy or radiotherapy
- 3 vaccines were administered at 3-week intervals, and patients had the option to continue dosing in an extension phase

- All dose levels were safe and well tolerated, achieving the safety primary endpoint.
  - There were no dose limiting toxicities and no serious adverse events related to the vaccine
  - Injection site reactions were the most common adverse event related to RGSH4K administration

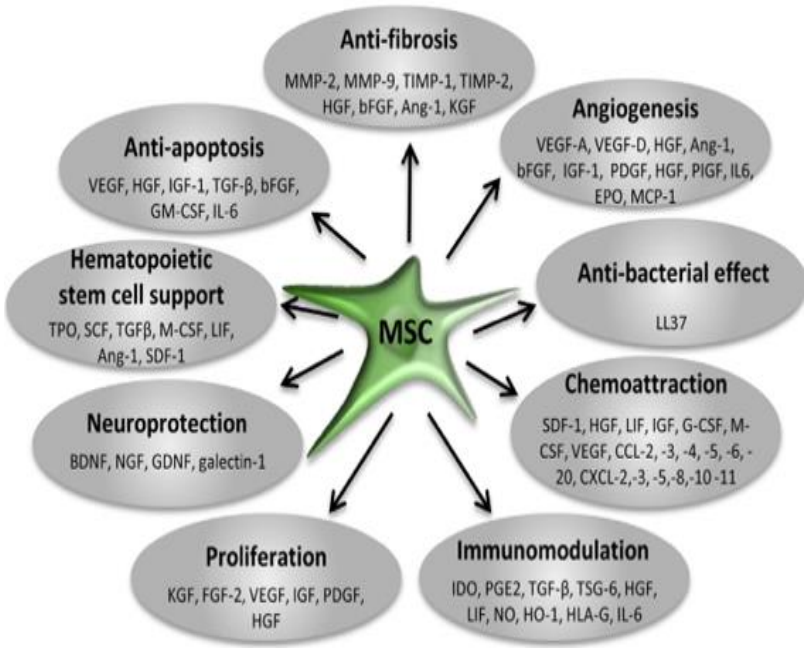
- RGSH4K also showed encouraging signs of immune stimulation in some patients, as demonstrated by changes in cancer markers, immune cells and cytokines
- This immune stimulation was seen in one or more patients at all three dose levels
- Preliminary indications of anti-tumour activity were seen in some patients however long term follow up on 50% of the patients continues

Sygenus: Emerging MSC Secretions Technology Platform

Sygenus is an allogeneic adipose MSC secretions-based technology platform

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

- **3 main therapeutic effects**
  - reduce pain and inflammation;
  - promote tissue repair; and
  - reduce scarring



- Potential to **treat a wide range of inflammatory conditions and pain** where using cells is not an appropriate solution
- **Various forms of administration** such as topical, injection and potentially aerosol
- **Scalable technology:** easy to prepare and handle for off-the-shelf use
- **R&D focus** on topical applications for acne and other inflammatory skin conditions, pain and wound healing

Sygenus Shows Promise in Pain Model v Morphine

Significantly Greater and Longer Lasting Analgesic Effect

- Topical application of Sygenus in post-operative pain model shows significantly greater and longer lasting analgesic effect than a standardised dose of morphine
- Effect is above and beyond the anti-inflammatory effect observed with MSCs and secretions
- Powerful dose dependent response
- Results feed into ARC linkage research program with Adelaide and Macquarie Universities on pain
- Translate into clinical neuropathic pain studi

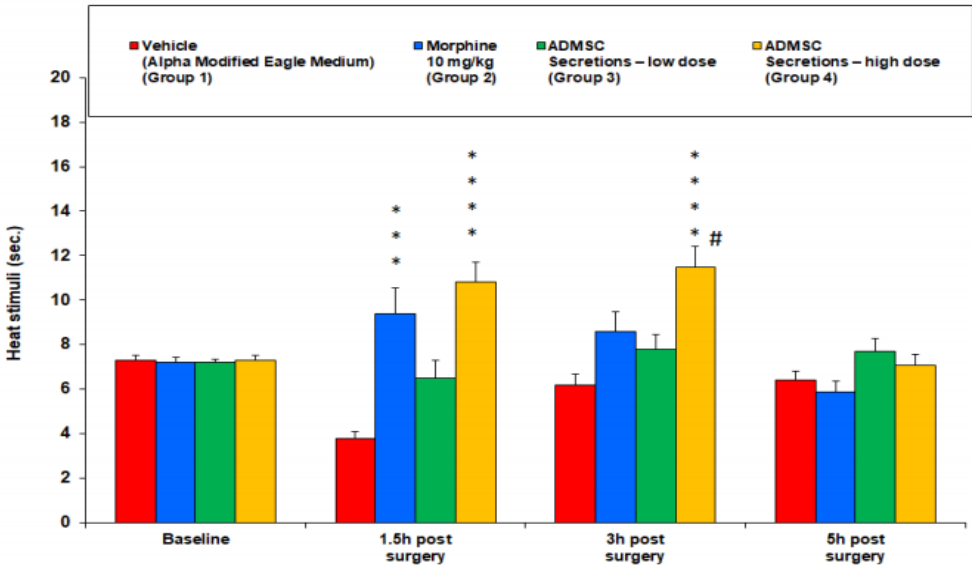


Figure 3: Mean group response to Hot plate test.

*** 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.

Kvax - Canine Cancer Vaccine

Safety Study Results

>100 dogs treated

17 different tumour types

No safety concerns

71% exceeded survival time up to 22 months

(at Census, 25 dogs)

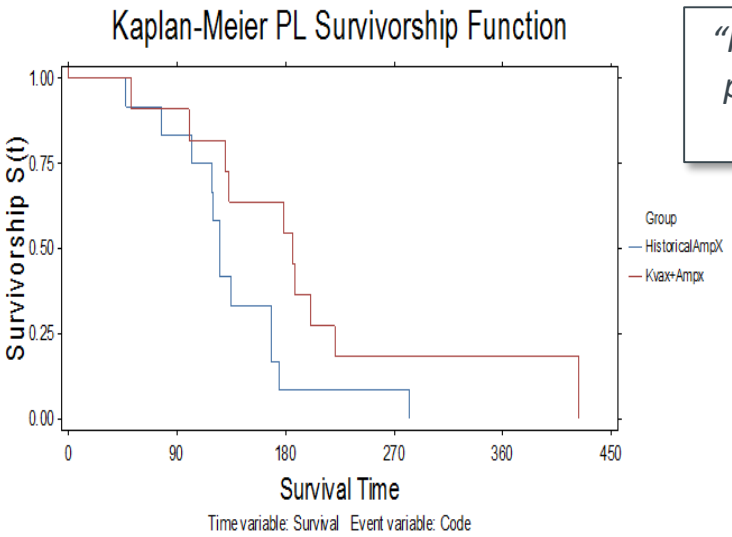
Osteosarcoma Study Results

- Canine clinical trial complete
- Led by Dr Bergman of VCA, the largest US vet services group
- Single arm, Kvax only

B-Cell Lymphoma Study Ongoing

- Study initiated at the Small Animal Specialist Hospital in Sydney
- Placebo controlled with standard of care chemotherapy

sash

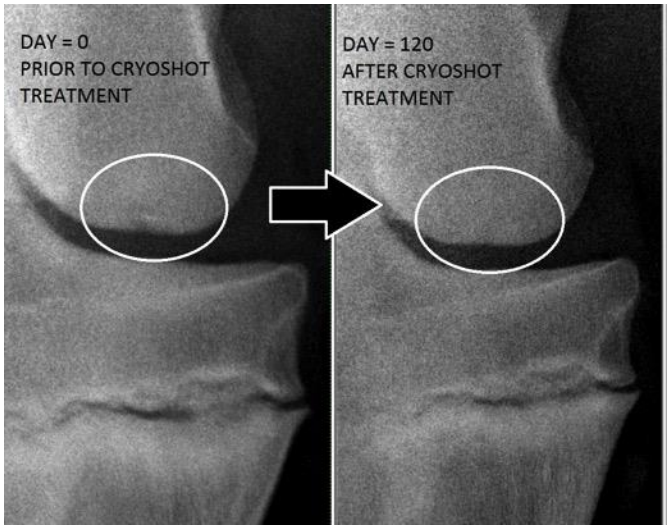


"Kvax after amputation is well tolerated and appears to confer increased progression free interval and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only"

regeneus living regenerative medicine

CryoShot: Allogeneic Stem Cell Platform

- Leading in-field, practical experience with allogeneic MSCs in the veterinary field globally
  - >90 vet practices involved
  - 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

PennVet

regeneus
living regenerative medicine

Patent Portfolio Update

70

patents or patent applications
across 14 patent families

---

11 patents in Australia
2 patents in New Zealand
2 patents in the US
1 patent in the EU, Japan, China & 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 or allowed in US, Australia, NZ and 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)

Value Creation Catalysts

Targeting 2nd Progenza licence following successful monetisation of 1st Progenza licence in Japan

Progenza

- Secure initial clinical and marketing partner for Progenza in Japan
- Identify partners for further indications and territories for Progenza

Sygenus

- Further product development to target specific pain and dermatological indications
- Explore licensing opportunities for pain and dermatology

RGSH4K

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

Animal Health

- Finalise Cryoshot recruitment and report results
- Partner on successful Cryoshot data
- Finalise KVax recruitment for B cell lymphoma trial and report results
- Partner on successful KVax data

FY18 Results Highlights and Outlook

FY18 Financial Results

For the year ended 30 June	2018 $'000	2017 $'000	Movement $'000
Revenue	**611**	**10,069**	**(9,458)**
Cost of sales	-	(55)	55
Gross profit	**611**	**10,014**	**(9,403)**
Other income	2,164	2,608	(444)
Research and development expenses	(3,957)	(4,456)	499
Occupancy expenses	(475)	(420)	(55)
Corporate expenses	(3,462)	(3,150)	(312)
Finance costs	(26)	(16)	(10)
Other expenses	-	(1,300)	1,300
Share of loss on investments accounted for using equity method	(40)	(9)	(31)
Profit/(loss) before income tax	**(5,185)**	**3,271**	**(8,456)**

- FY17 revenue includes $8.9m in AGC licence fees. Appointment of second licensing partner expected to contribute to FY19 licence fee income
- R&D tax incentive of $2.2m is included in other income (FY17: $2.6m)
- The operating result for the year is a loss of $5.2m (FY17: $3.3m profit). The current year loss is reflective of ongoing R&D expenditure, slightly reduced from prior year with the successful completion of the Progenza phase 1 clinical trial in the prior year

Outlook for FY19

The Company remains poised to deliver on a number of important commercial, clinical and R&D milestones FY19 and into FY20, including:

- Securing its first clinical licence for Progenza in Japan
- Progressing the clinical development of Progenza for osteoarthritis in Japan
- Commencing manufacturing of cGMP Progenza in Japan under the Company's existing strategic collaboration and licensing agreement with AGC
- Securing additional licensing opportunities for Progenza in additional key territories, including the USA, China and the European Union
- Progressing the development of Progenza for specific pain indication
- Progressing the development of Sygenus for specific pain and dermatological indications
- Advancing licensing discussions for RGSH4K following positive ACTIVATE trial results
- Reporting on Cryoshot canine pre-pivotal trial and advancing licensing discussions

Investment Summary

- Global regenerative medicine market presents a strong and growing market opportunity, growing from US$10bn in 2020 to US$380 billion by 2050
- Well positioned with novel, validated, scalable and commercially viable stem cell and immuno-therapy technologies combined with a successful licence driven business model
- Multiple licence opportunities for Regeneus' portfolio of assets across each platform: manufacturing rights; clinical indications; and territories
- Validated technology through published clinical data; technology licensing and collaborations, business partnerships and granted patents
- Well positioned for clinical licence of Progenza in Japan following AGC manufacturing licence and collaboration in FY17
- Management team with track record of developing and licensing novel regenerative medical technologies and translating into the clinic
- Profitable in FY17 driven by Japanese partner licence fees – further licence fees in FY19
- Significant value creation milestones over the next 6-12 months

Development Pipeline

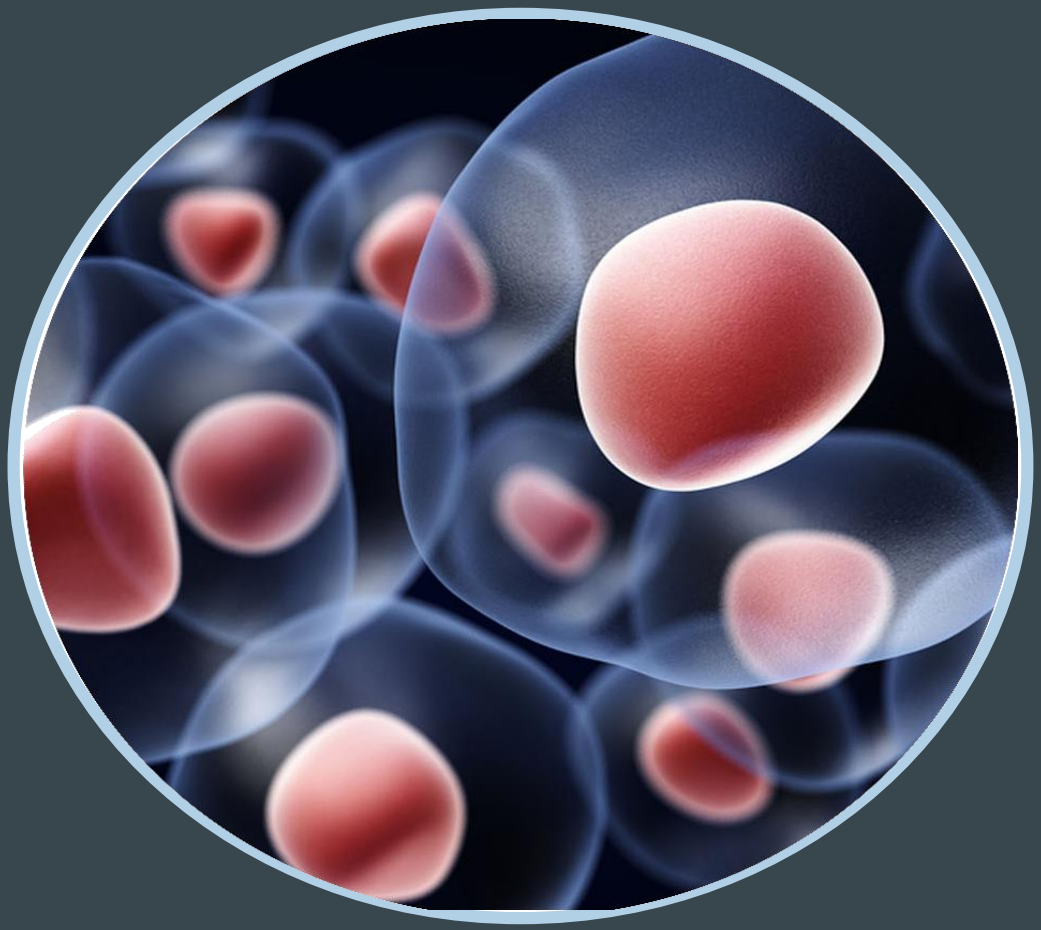
Human Health Development Pipeline

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	Allogeneic Adipose MSCs	Osteoarthritis			
Kvax	Immunotherapy for oncology	Naturally Occurring Advanced Cancers (Conditional Approval))			

Contact



Sandra McIntosh

Company Secretary
& Investor Relations
M: +61 450 253 059
P: +61 2 9499 8010
E: investors@Regeneus.com.au

regeneus
living regenerative medicine