ASX Announcement

31 October 2018

Regeneus to present at AusBiotech 2018 - Australia's Life Sciences Conference

Regeneus Ltd (ASX: RGS) (**Regeneus** or **the Company**), a clinical-stage regenerative medicine company, is pleased to announce John Martin, CEO, will present at the AusBiotech 2018 Conference today.

The annual AusBiotech conference brings together Australian and international biotech leaders and stakeholders. For more than three decades, the event has created a forum to reflect on the sector's achievements and exchange ideas to further advance the sector's standing both nationally and globally. AusBiotech is dedicated to consolidating this growth.

John Martin was invited to present as part of the Regenerative Medicine Stream. His session will focus on the successful translation and commercialisation of novel regenerative medicines by Australian companies. MTPConnect, the Australian Government's medtech and pharma growth centre, launched a report entitled 'Regenerative Medicine: Opportunities for Australia' at the beginning of the session. The report was produced in collaboration with AusBiotech's Regenerative Medicine Advisory Group, of which John Martin is a member, as well as other key stakeholders from industry and the research sector.

The following are specific details regarding Regeneus' presentation:

Event: AusBiotech 2018

Date: 31 October 2018

Time: 2.30pm (AEST)

Location: Room 2, Brisbane Convention and Exhibition Centre, Southbank, Brisbane

ENDS

About Regeneus Limited
Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of novel cell-based therapies to address significant unmet medical needs in the human and animal health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology.

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AusBiotech | 2018
Australia's Life Sciences Conference

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Japan First Strategy for Commercialisation of Progenza

John Martin CEO

31 October 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.

Japan – Global Capital for Regenerative Medicine

Japan – Global Capital for Regenerative Medicine

"I will lead the efforts to carve out a new horizon for the latest medical technologies, including regenerative medicine and innovative drug development, through a streamlined system for research to practical application in which the public and private sectors can work together" PM Abe 2013

- PM Abe made Regenerative Medicine a key part of Third Arrow of Abenomics generating and sustaining growth through deregulation
- Alignment of governmental support, academic research, and industry participation
- Critical success factor - new radical accelerated pathway for industry sponsored clinical trials - placing Japan at forefront for attracting the best global RM products
- Success of Japan's strategy in engaging industry and attracting foreign technology has influenced other key regulators to respond with their own version of the regulations: USA, China, Taiwan

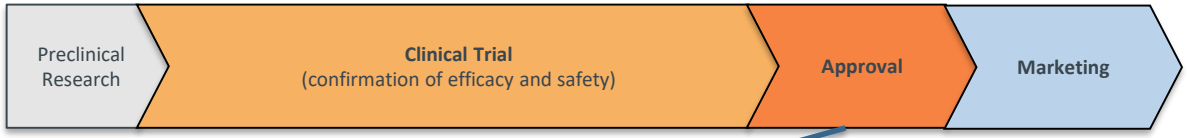
Japan – Fast Track Approval for Regenerative Medicine Products

- In late 2014, new laws came into force in Japan allowing conditional approval of RMPs after confirmation of safety and "probable efficacy" – same level as orphan indications
- Smaller trial numbers
- All cell therapy products have potential to qualify for conditional approval as RMP – open to foreign companies
- Removes need for expensive Phase 3 trials
- 70% Government reimbursement
- 5-7 years to gain clinical data

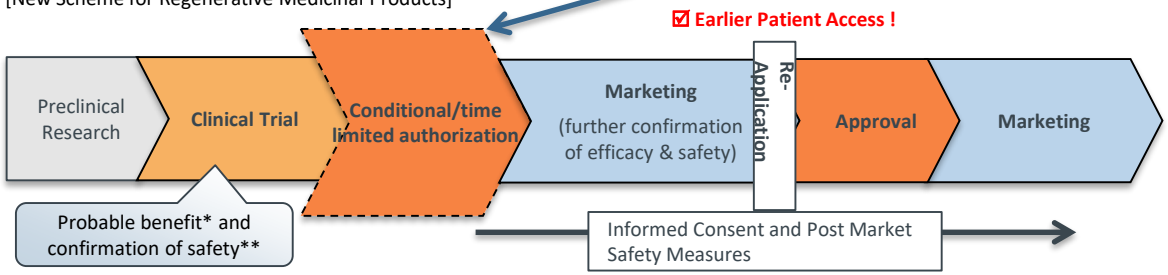
Second largest healthcare market in the world

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

[Traditional Approval Process]



[New Scheme for Regenerative Medicinal Products]



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

Japan – Leading Global RegenMed Corporate Activity

astellas $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

Takeda $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).

Healios $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

FUJIFILM 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.

Progenza – World Class Stem Cell Platform

Progenza

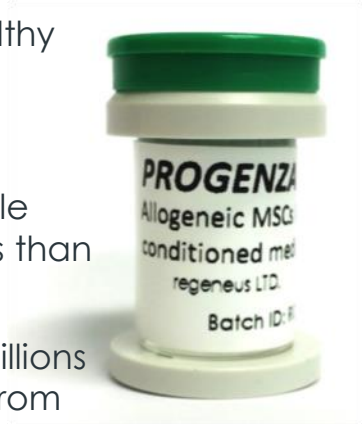
World Class Stem Cell Platform

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



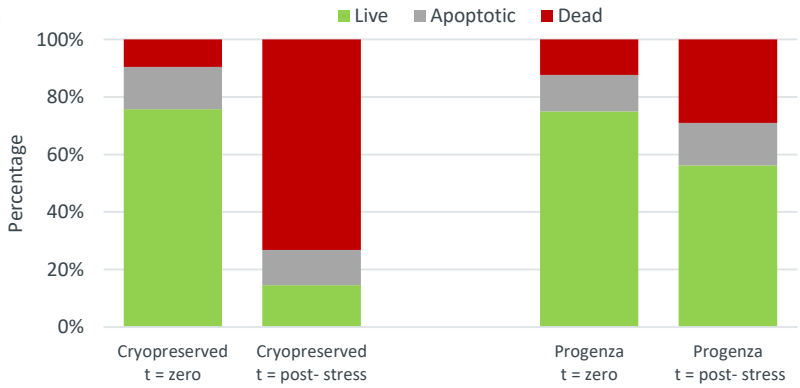
MSCs (aka medicinal signaling cells) secrete a diverse variety of bioactive factors including cytokines, growth factors, extracellular vesicles and exosomes

Secretions respond to the local environment and are the driving force for reducing inflammation, promoting tissue repair and reducing scarring

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



Cryopreserved cells vs Progenza: pre- and post- stress

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Progenza: Phase 1 Knee Osteoarthritis

Primary Endpoints Met - Safe and Tolerable

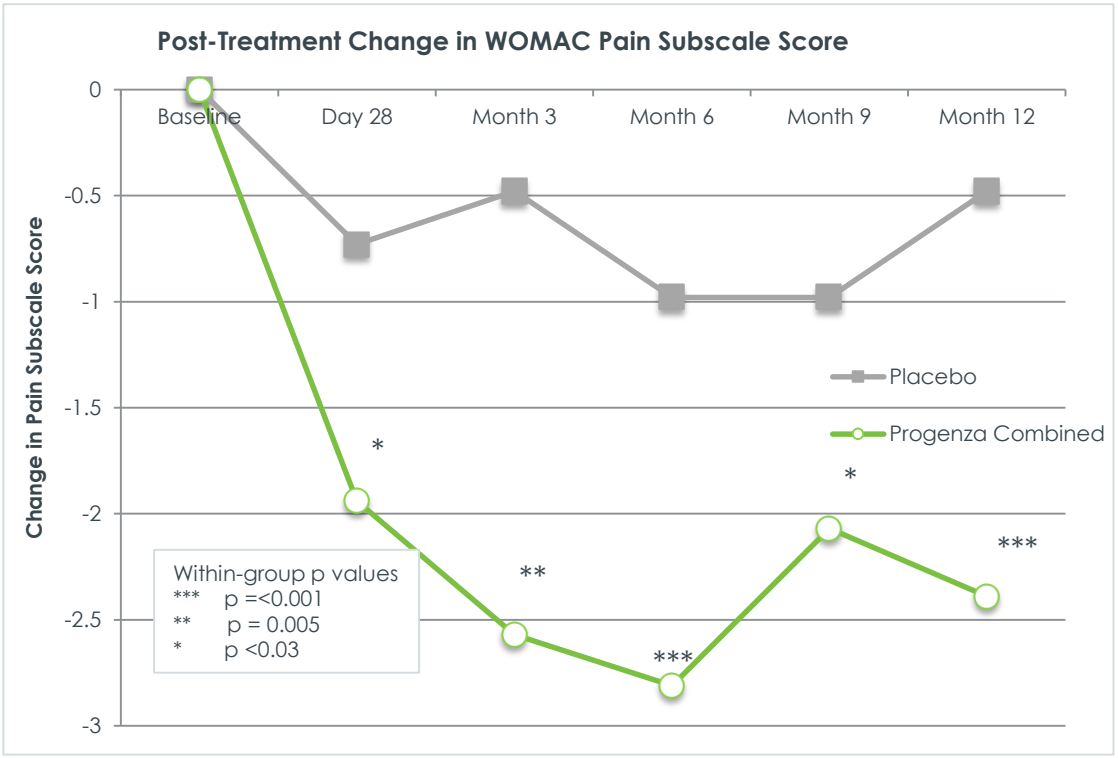
- Progenza at both doses was found to be safe and tolerable
- No serious adverse events occurred
- The majority of adverse events (AEs) were of mild severity
- No meaningful differences between placebo and PRG groups in incidence and nature of adverse events
- No trends or findings of concern were identified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

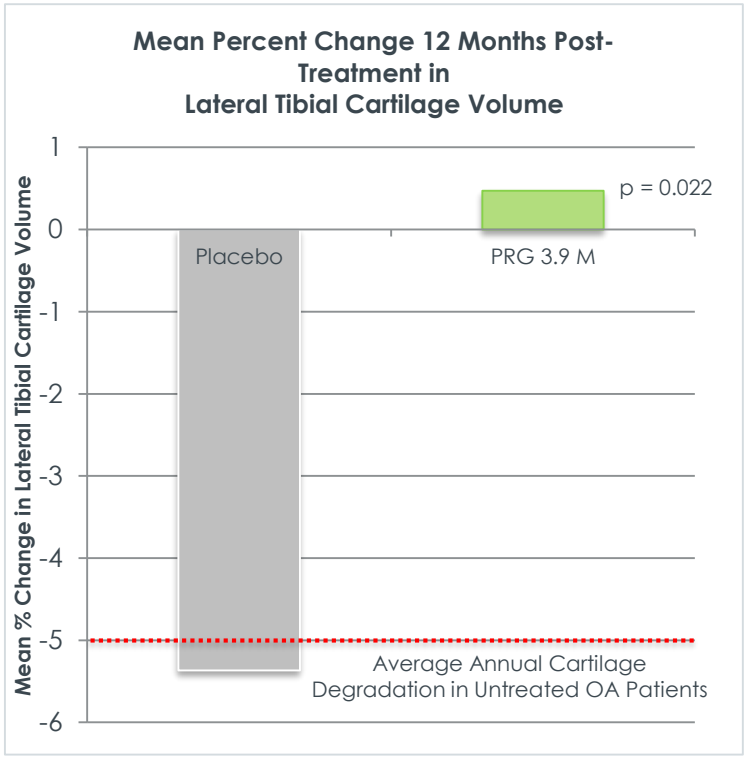
- Double-blind, placebo controlled and randomised 20 patient trial
  - Sydney - late 2015 through April 2017 (reported May'17)
- Single intra-articular injection and monitored for 12 months for safety
  - 2 cohorts, placebo (4:1)
- Mean age 53 years (40-64 years)
- Diagnosed with knee OA
  - mild OA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

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Progenza

STEP Trial Data Consistent with Preclinical Results

Safe and tolerable

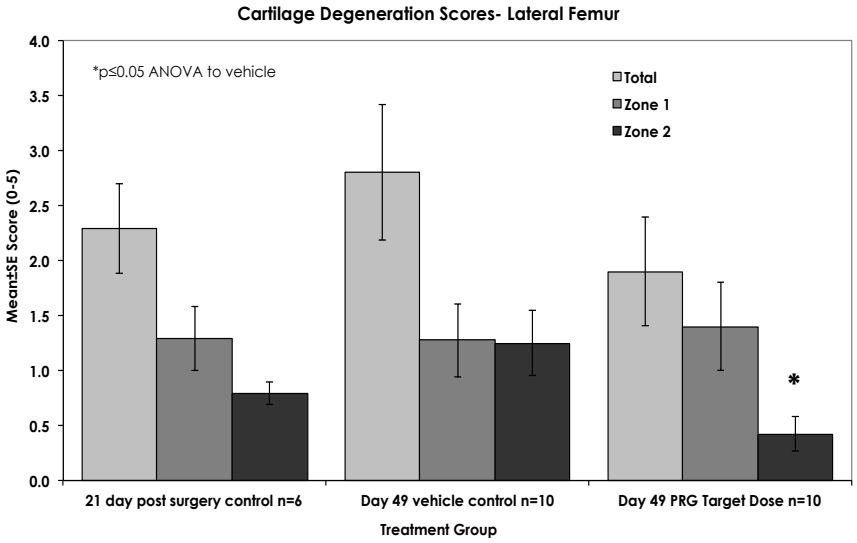
- No Progenza-related systemic or local toxicities or dose related adverse effects

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

MSC Secretions in Pain Model v Morphine

Significantly Greater and Longer Lasting Analgesic Effect

- Topical application of MSC secretions 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 Uni of Adelaide and UNSW on pain
- Translate into clinical neuropathic pain studies

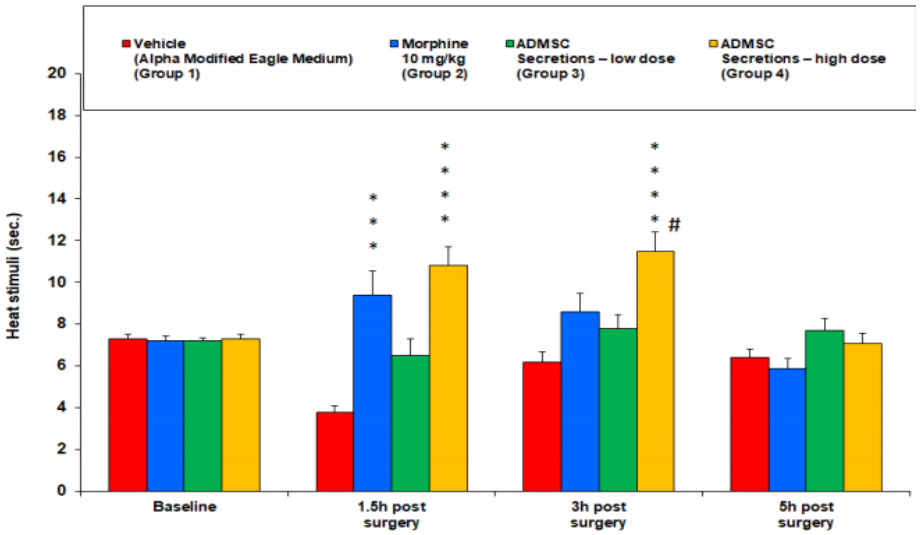


Figure 3: Mean group response to Hot plate test.

*** 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.

Licence and Collaboration of Progenza in Japan

Collaboration with World Leading Biopharma Manufacturer

FY17 - 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

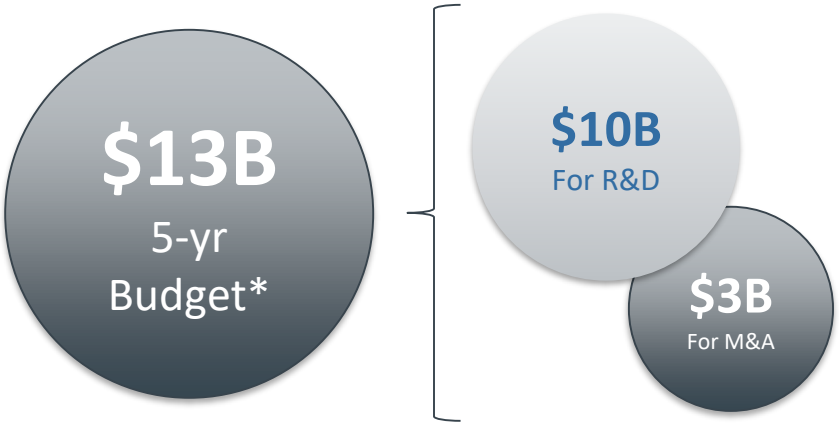
regeneus living regenerative medicine	Received **US$5.5M** Upfront licence fee and US$1m milestone	Entitled to **US$10.0M** In further milestone payments	Established 50/50 JV for licensing clinical development and marketing rights of Progenza for OA and all other indications in Japan	Entitled to 50% of Progenza clinical licensing, milestone payments and sales royalties
AGC	Exclusive manufacturer of Progenza in Japan	Funds product development for GMP manufacture of Progenza for Japan		

AGC – Positioned for RM Led Growth

- **AGC** is Japan's leading biopharmaceutical contract manufacturing organization
  - 2015 Group sales of JPY1,326 billion (US$13 billion)
  - Existing CMO relationships with many major pharmaceutical businesses

- In **AGC**'s "Vision 2025", **Life Sciences** was designated a **strategic business**

Strategic business funding plan:



AGC

AGC Biologics

BIOMEVA MANUFACTURING — Acquired (Sep. 2016)

CMC biologics — Acquired (Dec. 2016)

Outlook for Progenza

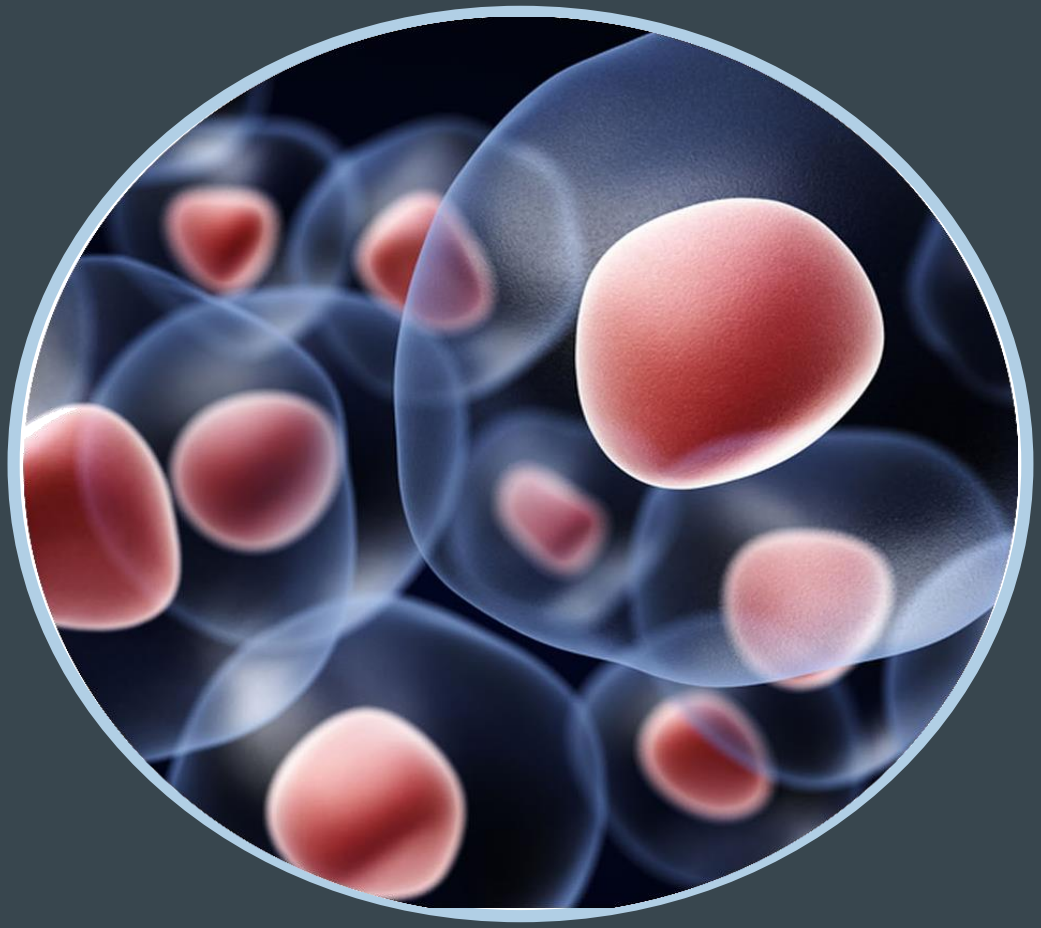
Regeneus remains poised to deliver on significant commercial, clinical and R&D milestones for Progenza for FY19 and into FY20, including:

- Securing its first clinical development and marketing partner for Progenza in Japan
- Progressing the clinical development of Progenza for osteoarthritis and other indications in Japan
- Commencing manufacturing of cGMP Progenza in Japan under the company's existing strategic collaboration and licensing agreement with AGC
- Securing licensing opportunities for Progenza in other key territories, including the USA, China and the European Union
- Progressing the clinical development of Progenza for specific pain indications

Lessons Learned for Japanese Market

- Japan is the most engaged major healthcare market for regenerative medicine aligning government policy, academia and industry
- Japanese government is active in seeking to engage with Australian industry
- Japan industry is active in the technology and clinical licensing space – PMDA rewards pharma companies who invest in new technologies through price reimbursement
- FIRM (Forum for Regenerative Medicine) is the peak industry body with over 250 members
- Austrade is active in Japan in this space hosting events and connecting with FIRM
- AusBiotech has established a RM Advisory Group to help develop vision and strategy for industry development in Australia and engagement with foreign markets –assisted by MTP Connect
- AusBiotech and FIRM have established an MOU for RM industry engagement – first step is a directory on their websites to help identify interested participants in the respective eco systems
- Find a local corporate advisor to help manage language barrier, appreciate business culture and decision making process
- Relationships matter: be prepared to spend the time to build and manage them and get in the "right lane of traffic" – minimum 18 month cycle for completed transactions

Contact



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