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# 2019 AGM CEO Presentation

*Developing the next generation of pain management and inflammation therapeutics*

November 2019

Regeneus Ltd (ASX:RGS)

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# Regeneus Overview

Regeneus (ASX:RGS) is a global clinical-stage regenerative medicine company based in Australia



Focus on the growing pain and inflammation market



Significant unmet clinical need for regenerative, non-invasive, pain treatments that do not rely on opioid treatments



Leader in autologous stem-cell transplantation and secretions and moving to the less invasive allogenic development



Two core stem cell platforms:

- Progenza (stem cells and their secretions)
- Sygenus (secretions)



Strong IP across key markets and scientific partnership model allows for licensing of technology



Management with strong track record of bringing medical technologies to market



Clear commercialisation path for Progenza OA in Japan:

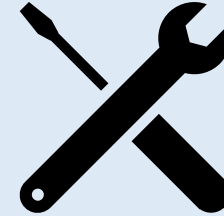
- Licensing deal
- Significant Knee Osteoarthritis (OA) market

# Mesenchymal Stem Cells (MSCs)

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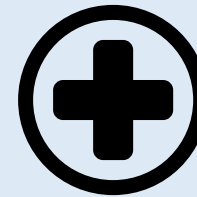
Cells that can differentiate into other cell types, including bone, cartilage, muscle, umbilical cord and fat cells. Originally found in bone marrow.



Can self-renew while maintaining their multipotency.



Ability to differentiate leads to heal and repair tissue.



Application in pain management, anti-inflammation and anti-scarring.

# Regeneus Platform Technologies

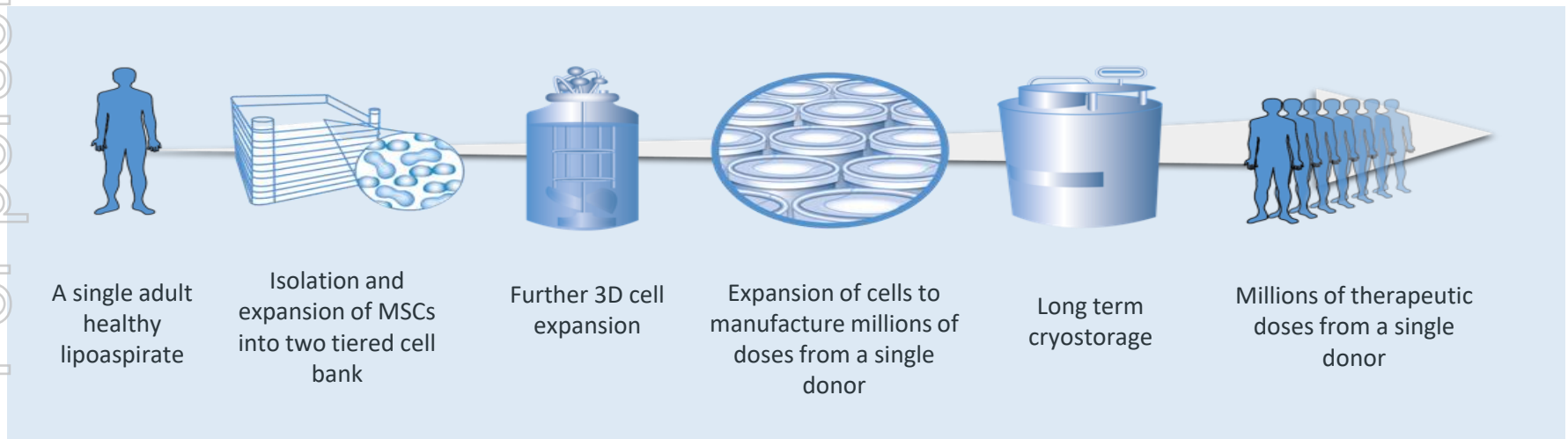
Pain management as key focus area to fill the healing and repair void in the pain treatment market and a solution to opioids.

## Progenza

- Uses MSCs to reduce inflammation and heal/repair damage/diseased tissue
- Targets OA and neuropathic pain
- Moving towards Phase 2 trials for OA after a successful Phase 1 trial

## Sygenus

- Uses bioactive molecules secreted by MSCs to reduce pain and inflammation, and to heal and repair
- Heals and skin non-stimulated skin pain and conditions, neuropathic pain, nociceptive pain and oral conditions
- Pre-clinical stage



# R&D Pipeline – Human Health

Program	Technology	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Filing	Approval
Progenza™	Allogeneic Adipose MSC plus MSC Secretions* (Secretome with Bioactive Molecules & Exosomes)	Osteoarthritis	[Preclinical]	[Phase 1]	[Phase 2]			
		Neuropathic Pain						
		Other Indications						
Sygenus™	Allogeneic Adipose MSC Secretions* (Secretome with Bioactive Molecules & Exosomes)	Burns, Wounds, Radiodermatitis	[Preclinical]					
		Neuropathic Pain						
		Psoriasis, Atopic Dermatitis						
		Rare/Orphan Skin Diseases						

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# Progenza Opportunity in Osteoarthritis (OA)

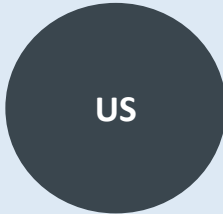
\$9.5B addressable opportunity in knee OA across Japan, US and EU alone<sup>1</sup>

OA is pain and inflammation around the joint from 'wear and tear' on the tissue



Japan

30M+ patients



US

~35M patients



Top 5  
European  
Markets

50M+ patients  
combined

Italy, Spain, Germany,  
France and the UK

Japan is a proven RA market

- Takeda acquired TiGenix for \$630m
- Astellas bought a universal donor cell technology for \$102.5m
- TEMCELL is Japan's first allogeneic cell therapy product
- Helios and Sunbio

Astellas pledges \$102.5M for universal donor cell company

by Phil Taylor | Feb 14, 2018 8:05am



Astellas is building its cell therapy capabilities through acquisition. (Source: Astellas)

REUTERS World Business Markets Politics TV  
Pyongyang 2018 The Trump Effect Politics North Korea Earnings Myanmar

HEALTHCARE JANUARY 8, 2018 / 8:28 PM / A MONTH AGO

Japan's Takeda to acquire  
TiGenix for \$630 mln

Reuters Staff

1 MIN READ



1. GlobalData – Opportunity Analyser Osteoarthritis, <https://www.prnewswire.com/news-releases/major-orthopedic-joint-replacement-implants-global-market-opportunities-and-strategies-to-2022-300696797.html>  
2. Source: GlobalData, Osteoarthritis – Opportunity and Analysis Forecasts to 2026, September 2017.

# Progenza OA & Current Treatment Market

Progenza fills a gap the current treatment market by providing disease modification and pain relief to address patient symptoms - before surgery is required

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50% of diagnosed and prevalent Knee OA is moderate-severe  
~5% cartilage loss per year as disease progresses

Less severe disease  
Less invasive therapies

More severe disease  
More invasive therapies

## PROGENZA

Treats the symptoms  
not the cause

A safe, potent treatment  
BEFORE Invasive Surgical  
intervention is needed

### Lifestyle changes

Weight management,  
exercise and self-  
management



### Pain relief

Paracetamol, non-steroidal  
anti-inflammatory drugs  
Hyaluronic Acid or  
Corticosteroid Injections



### Disease modification

No existing therapy



### Surgery & Invasive procedures

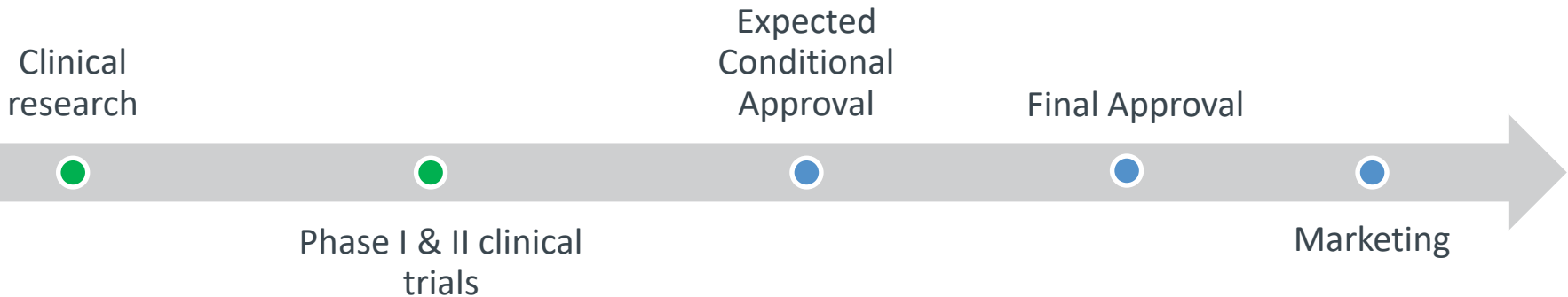
Knee Replacement  
Bone Marrow Stimulation  
Bone Realignment





# Progenza OA Commercialisation Strategy

Japan: An accelerated commercialisation pathway and strategic market for Knee OA



## Progenza Knee OA

Manufacturing  
licensing deal



Progenza  
STEP  
Phase I  
Safety  
Trial



2<sup>nd</sup> clinical  
licensing  
deal  
expected

Phase II  
clinical trial

Ongoing efficacy assessments during  
Conditional Approval Phase

# Competitors for Knee OA

Symptomatic pain relief prior to invasive surgical options

	Pain relief		Side effects	Non-invasive	Disease modifying
	Short term	Long term			
Progenza	✓	✓	✓	✓	✓
Acetaminophen / paracetamol	✗	✗	✗	✓	✗
NSAIDs	✓	✓	✗	✓	✗
Corticosteroids	✓	✗	✗	✓	✗
Hyaluronic Acid	✓	✗	✓	✓	✗
Surgery	✗	✓	✗	✗	✗

- A recent systemic review and meta-analysis for long term pain (>1 year) found that of 31 pharmacological interventions studied, there was no improvement in pain for 29 of the 31 interventions (93%)
- Low treatment satisfaction amongst Japanese patients with OA and chronic knee pain. >90% of patients being managed by an orthopaedic specialist, with many patients visiting their specialist monthly
- Low satisfactory rates for knee replacement options

# Competitive Allogeneic Clinical Landscape in Knee OA

Progenza's advantages: pain and cartilage improvement

Allogeneic Competition						
Company (location)	Product	Cell Source (IA dose)	Phase (location)	KL Grade	Pain Relief	Cartilage Improvement
Regeneus (Aus)	Progenza	Adipose (5m)	Ph 1 (Australia)	1-3	✓	✓
Kolon TissueGene (Korea)	Invossa	Transgenic chondrocytes (18m)	Ph 3 (USA) MA (Korea)	3	✓	○ Trend only
Cellular Biomedicine Group (China)	Allojoin	Adipose (10/20m)	Ph 1 (China)	unknown	Not yet published	
Medipost (Korea)	Cartistem	Cord Blood (7.5m)	MA (Korea)	Cartilage defect (not approved for OA)	Surgery required	
Cells for Cells (Chile)	Cellistem	Cord Blood (20m)	Ph 1/ 2 (Chile)	1-3	✓	✗
Stempeutics (India)	Stempeucel - OA	Bone Marrow (25m)	Ph 2 (India)	2-3	○ Trend only	✗

# Sygenus Overview

Emerging, patented and scalable stem cell technology using MSC secretions

## Sygenus Platform Technology

- **First indication in skin repair**
- **Pre-clinical stage**
- **Safe and tolerable in humans**
  - Positive data in human pilot studies
- **Strong IP**
  - In manufacturing and use
- **Next steps**
  - Partner with potential R&D partners and commercial license partners

## MSC Secretions

- Uses bioactive molecules secreted by MSCs to reduce pain and inflammation, and to heal and repair cells
- MSC secretions alter the balance from a pro-inflammatory destructive environment to an anti-inflammatory constructive environment
- Heals non-stimulated skin pain and conditions, neuropathic pain, nociceptive pain and oral conditions

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# Experienced Board

## Leo Lee

### CEO & Executive Director

- Former President of Allergan Japan and President of Merck Japan
- 20+ years in pharmaceutical innovation, commercialisation, regulatory and policy
- North America and Asian experience, and has lived and based in Japan for last 12 years.



## Prof Graham Vesey

### Chief Scientific Officer & Executive Director

- Regeneus co-founder and founding CEO
- Responsible for product origination and development and IP
- Successful biotech entrepreneur, tech innovator, inventor and a highly regarded scientist
- Co-founder and Executive Director of BTF, which was successfully sold to bioMerieux in 2007
- Adjunct Professor at Macquarie University



## Barry Sechos

### Independent Chairman

- 20+ years experience as a director, business executive and corporate lawyer
- Investment and asset management expertise
- Executive Director of the Sherman Group
- Board member of many Sherman Group companies and investee companies



## Dr Alan Dunton

### Non-Executive Director

- 35+ years experience in pharmaceutical and biotech
- Experienced director of more than 18 companies, including for Palatin Technologies, Oragenics and CorMedix
- Founder and principal of Danerius, a pharmaceutical and biotech advisory services firm



## Dr Glen Richards

### Non-Executive Director

- NED of Greencross Ltd (ASX:GXL), as former MD created Australia's largest veterinary healthcare group
- Established Greencross Vets in 1994, after practising companion animal medicine and surgery in Australia and London
- Director of biotech Smartvet and 1300smiles (ASX:ONT)



## Dr John Chiplin

### Non-Executive Director

- MD of Newstar Ventures
- Currently on boards of Adalta (ASX:1AD), Batu Biologics, Cynata Therapeutics (ASX:CYP), Scancell Holdings plc (LSE: SCLP), Chairman) and ScienceMedia
- Former CEO of three listed biotechnology, cancer immunotherapy and software companies

# Company Strategy - Progress

Revised strategic direction targeting global pain market announced in Q1 FY20

Area of focus	Progress
Japan commercialisation deal for Progenza OA	<ul style="list-style-type: none"><li>• Number one priority and focus</li><li>• Negotiations ongoing, positive outcomes expected in near term</li></ul>
Revised company strategy	<ul style="list-style-type: none"><li>• New strategic direction in global pain market – focus on Progenza</li><li>• New board appointments in FY19 to accelerate global growth strategy in FY20</li></ul>
Scientific partnership model	<ul style="list-style-type: none"><li>• Supports funding and ongoing R&amp;D for Progenza and Sygenus</li><li>• Reduce ongoing costs</li></ul>
Long-term shareholder value creation	<ul style="list-style-type: none"><li>• Alignment of executive remuneration structure – CEO, CSO &amp; CFO</li><li>• Strengthened cash position with \$5.5M capital raise</li></ul>
Cost containment initiatives	<ul style="list-style-type: none"><li>• 50% reduction in recurring operating costs to \$250k per month</li><li>• Restructured operational footprint</li><li>• Reduced headcount to focus on Progenza</li><li>• Smaller office location</li></ul>

# Upcoming Milestones

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Japan commercialisation deal for Progenza OA



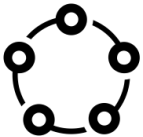
Continue to execute revised company strategy and streamline operations



Target Progenza OA product launch in Japan in 2023



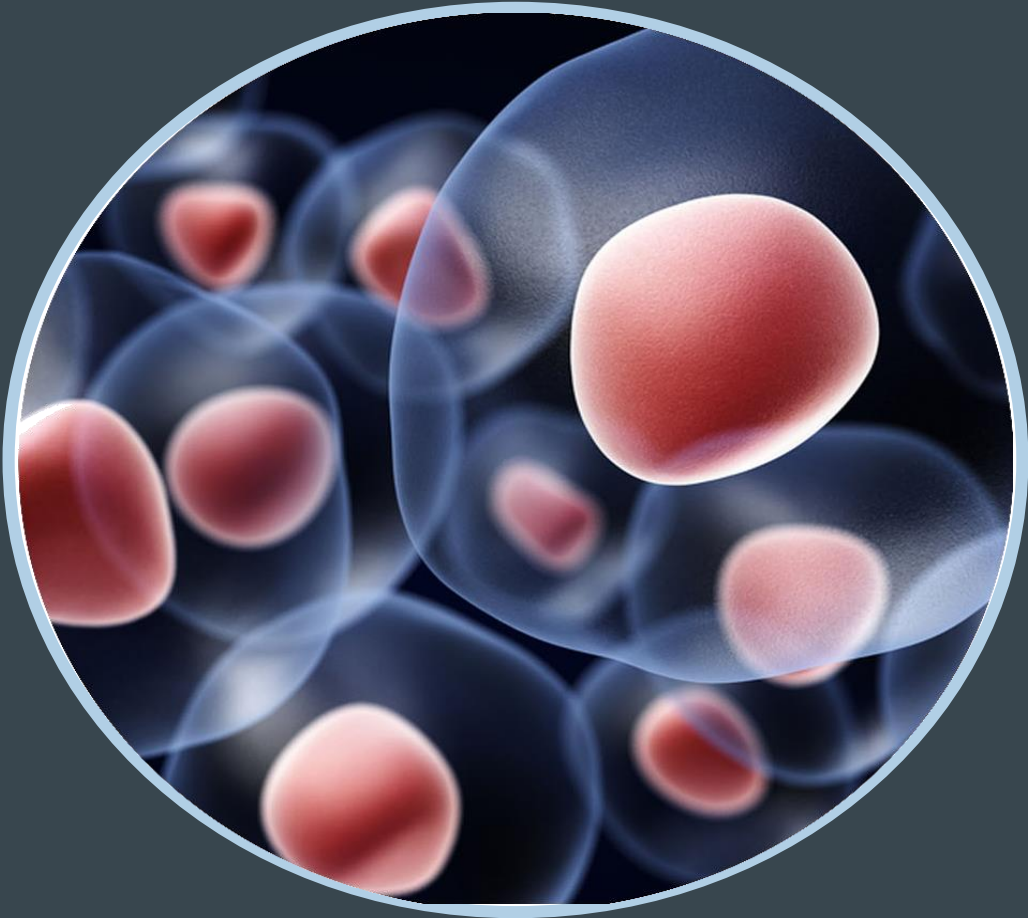
New scientific partnership model allows for technology licensing



Continued synergies from cost-containment initiatives

Thank you

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Investor Relations

[WE-AURegeneus@we-worldwide.com](mailto:WE-AURegeneus@we-worldwide.com)