ASX Announcement
14 October 2020

AGM Chairman's Address and CEO Presentation

Regeneus Ltd (ASX: RGS) (**Regeneus** or **the Company**), a clinical-stage regenerative medicine company, provides its 2020 Annual General Meeting Chairman's Address and CEO Presentation as attached.

-ENDS-

About Regeneus
Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies to address unmet medical needs in human health markets with a focus on neuropathic pain, including osteoarthritis and various skin conditions, with its platform technologies Progenza and Sygenus. Visit www.regeneus.com.au for more information.

Authorisation & Additional information
This announcement was authorised by the Board of Directors of Regeneus Ltd

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Regeneus 2020 Annual General Meeting

Chairman's Address

Good afternoon everyone.

On behalf of the Board, it is a pleasure to have you today at Regeneus' 2020 Annual General Meeting and for us to share the progress and achievements we made in 2020.

First and foremost, I hope everyone is well and safe. Due to the ongoing COVID-19 pandemic, social distancing requirements - and in the interests of health and safety of our shareholders, directors and staff - like many other AGMs this year, we decided to hold this virtually.

2020 was a busy year for Regeneus as we achieved a number of critical milestones. Our conscious focus on the global pain market anchored much of our activities during the financial year, and will continue to do so for years to come.

By focusing on the pain market, we were able to secure a transformative licensing deal with Kyocera Corporation: to collaborate, license and commercialise our lead stem cell technology platform, Progenza, for knee osteoarthritis in Japan. As shareholders will already be aware, Kyocera is a multinational conglomerate and this agreement is not only further validation of our technology, but also a significant milestone for Regeneus and our path to commercialisation.

While this particular announcement was made outside the financial year, our activities during the year paved the way to securing it.

In particular, the Company underwent a major restructure in order to streamline operations and to ensure the preservation and enhancement of shareholder value. This included a reduction in operational expenditure by up to 50 per cent - allowing us to remain focused on the commercialisation of Progenza.

Of course, during the financial year the COVID-19 pandemic affected many businesses across industries and sectors. For Regeneus, disruptions were minimal given our research and development activities were able to continue largely unaffected. This research included our internal studies as well as our external partnerships, with notable groups such as University of Adelaide and Monash University, focusing on Mesenchymal Stem Cells (MSCs) and pain management.

We have started the 2021 financial year positively with the consummation of the Kyocera agreement. This anchors much of our upcoming activities and provides a clear commercialisation pathway for Progenza in Japan, where the osteoarthritis market is expected to be worth US$350 million by 2026.

Globally, the market for osteoarthritis is expected to be worth US$3.5 billion by 2026, and in the new financial year, we will continue to pursue opportunities within the neuropathic pain market, and explore partnerships and studies to drive greater shareholder value.

We look forward to updating the market on our progress in the year ahead and achieving more clinical and regulatory milestones to pave the way for Progenza's commercialisation in Japan.

I'd now like to take this opportunity to thank my fellow directors, the team and our clinical and research partners for their ongoing support and tireless work despite the disruptions the COVID-19 pandemic has brought about.

Of course, we also extend our gratitude to our shareholders for their continued support of Regeneus. We were pleased to share the news of the Kyocera announcement and we look forward to updating you on our progress in the new financial year.

Thank you.

Barry Sechos

Chairman

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2020 AGM CEO Presentation

Developing the next generation of pain management and anti-inflammatory therapeutics

October 2020

Regeneus Ltd (ASX:RGS)

Disclaimer

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.

Company Overview

Summary

Global pain management market is a growing and significant multi billion-dollar opportunity

Progenza™ has a significant opportunity to capture the OA market as it addresses pain management (in a non-invasive manner), disease modification, and inflammatory conditions, along with being secured by strong IP

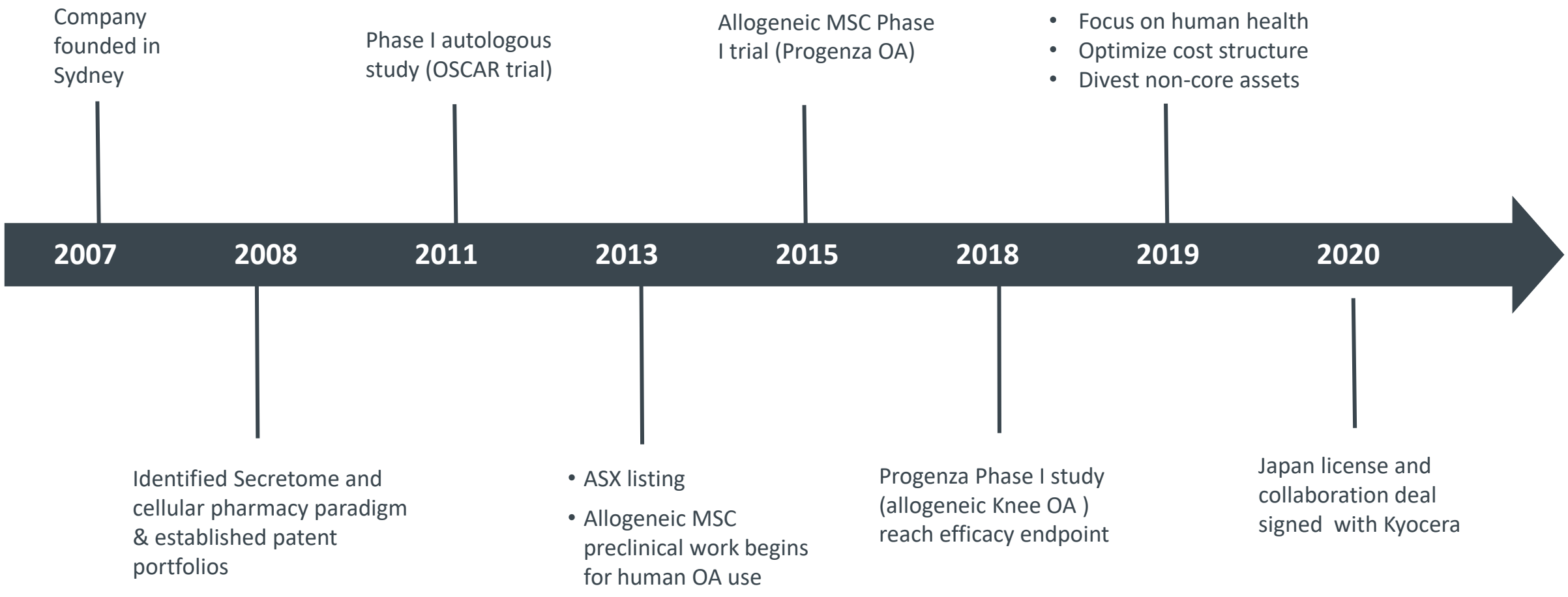
Existing treatments do not address patient needs (pain treatments that do not rely on opioid treatments) or have side effects and limitations

Kyocera licence and commercialisation deal sets out clear commercialisation pathway for Progenza™ OA. Funds from $27m upfront deal help fund other clinical assets – ‘multiple shots on goal’. 25m+ potential OA patients in Japan alone, with 1.25m in clinic

Experienced board and management team with track record of commercialisation

Regeneus – Company History

Regeneus is a global clinical-stage regenerative medicine company based in Australia focusing on mesenchymal stem cells (MSC) technology to treat inflammatory conditions



Company Strategy

Executing revised strategic direction targeting global pain market as announced in Q1 FY20

- ✓ License and Partnership Model for Specialty Disease like Knee OA – Efficiency and Optimal Capital Deployment.
  - ✓ Kyocera to fund product development, manufacturing & regulatory activities in Japan
  - ✓ BD in progress for Europe and US.
- ✓ 2023-2024: Progenza Knee OA launch In Japan

- ✓ 'Hub and Spoke' model to leverage Centre Of Excellence
- ✓ Monash University, University of Adelaide, Agency for Science, Technology and Research Singapore, UTS.
- ✓ Platform development
  - Progenza™
  - Sygenus

- ✓ Industry leading Resource Model – optimized corporate costs
- ✓ Upfront payments from Kyocera deal provides cash runway for RGS through to Progenza OA commercialization in Japan
  - ✓ A$27M in upfront development and regulatory milestone payments
  - ✓ Royalties on future Progenza OA product sales

Board and Company Management

Experienced team with track record of commercialisation

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
- 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

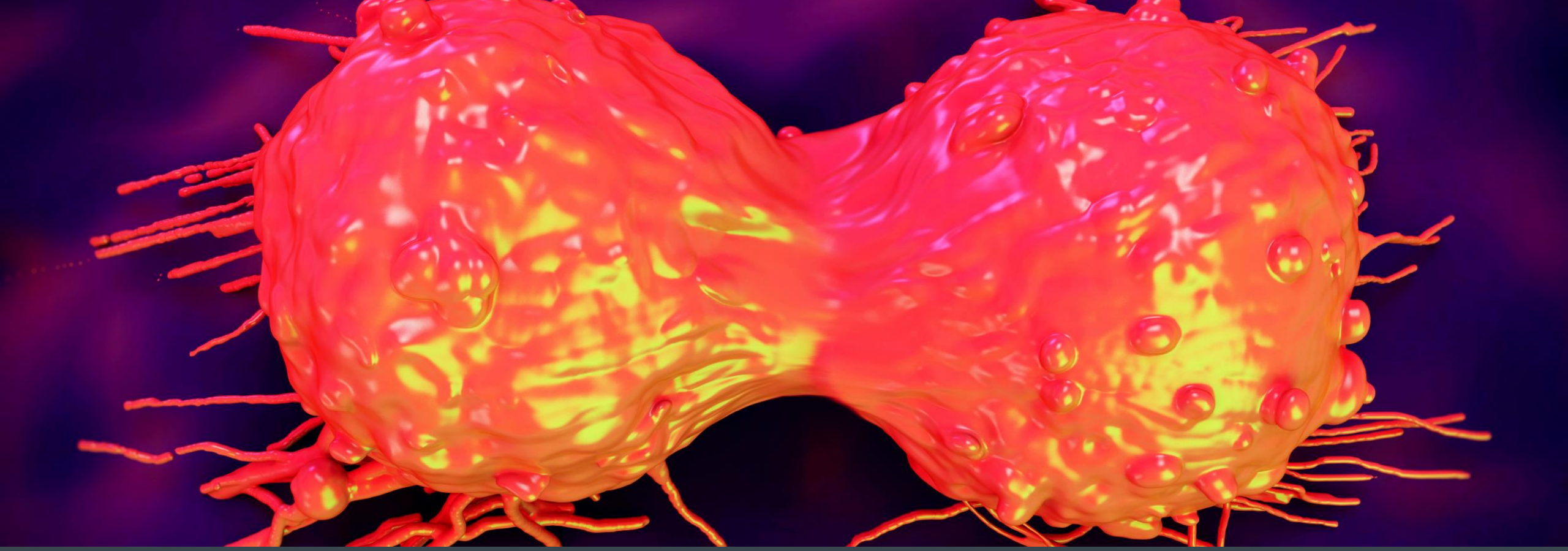
Barry Sechos
Independent Chairman
- 20+ years experience as a director, business executive and corporate lawyer
- Investment and asset management expertise
- Executive Director of the Sherman Group
- Board member of many Sherman Group companies and investee companies

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 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

Dr Charlotte Morgan
Head of R&D
- 20+ years in managing product development and innovation
- PhD in precise microbiological reference materials
- Joined RGS in 2012
- Previous experience in the UK in the water and microbiology industries

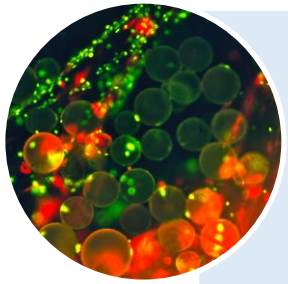
Sandra McIntosh
Company Secretary & Head of Corporate Affairs
- 20+ years management experience
- Joined RGS in 2009
- Previously Global Customer Service Manger at BTF
- Responsible for investor and corporate affairs



Product Portfolio

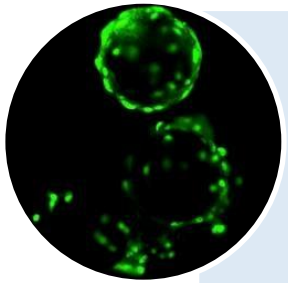
Mesenchymal Stem Cells (MSCs) - Overview

MSCs are Mesenchymal Signaling Cells that target repair of tissue, modulate immune system and pain



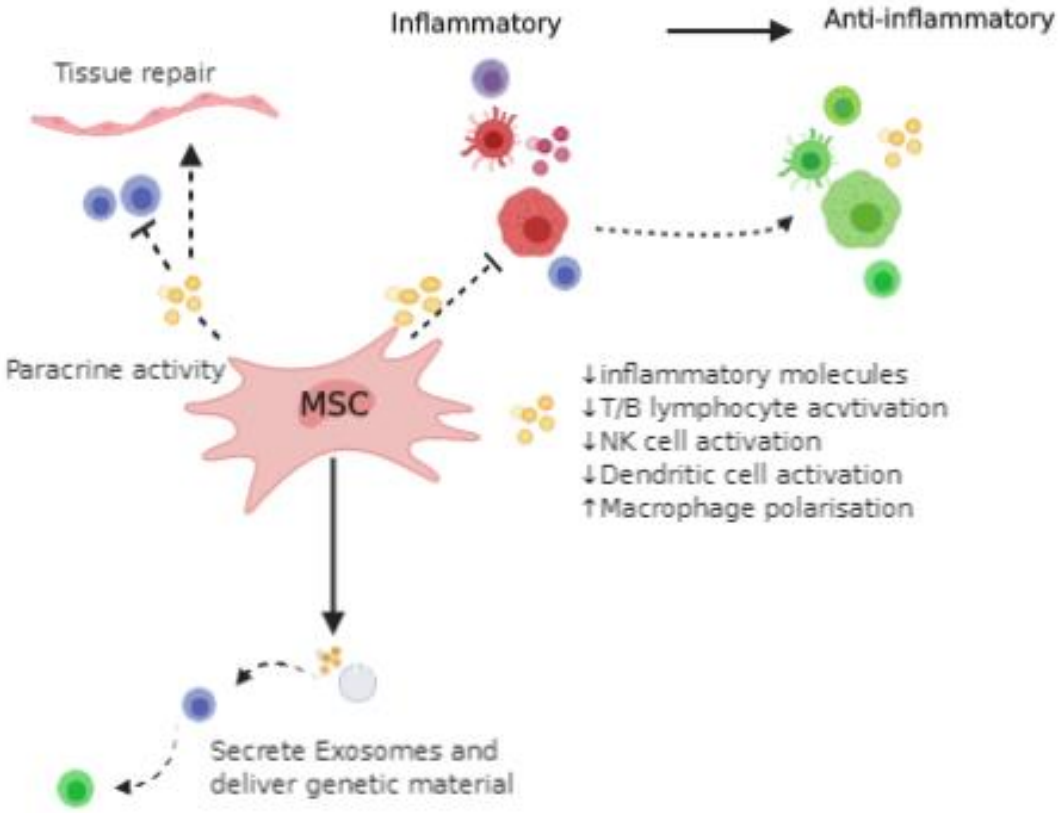
Immunomodulation via secreted factors decreases inflammation

- Exosomes, cytokines, chemokines and growth factors all play a role



Decrease in inflammation halts disease progression and initiates repair

Regeneus filed patents as early as 2008 on the function and use of MSC secretions



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Regeneus - Focus on Pain via Platform Technologies

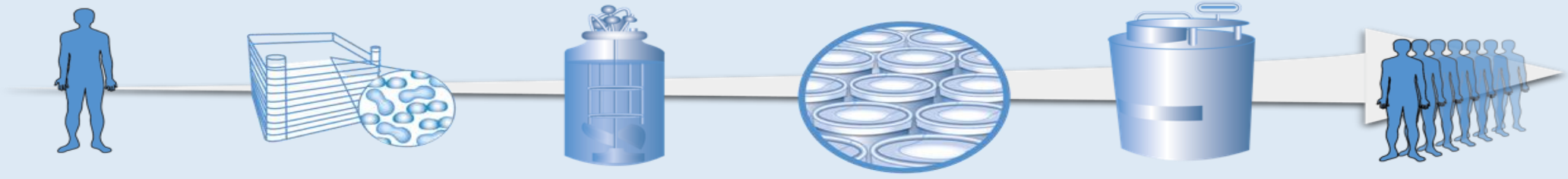
Pain management as key focus area to fill the healing and repair void in the pain treatment market and a solution to opioids

Progenza™

- Uses MSCs and bioactive molecules to reduce inflammation and heal/repair damaged/diseased tissue
- Targets OA and neuropathic pain
- Moving towards Phase II trials for OA after a successful Phase I trial and Kyocera deal

Sygenus

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



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Regeneus – R&D Clinical Pipeline

Two core platform technologies – Progenza™ and Sygenus with multiple potential target indications.

Platform	Technology	Indication	Preclinical	Phase I	Phase II	Phase III	Filing	Approval
Progenza™	Allogeneic Adipose MSC plus MSC Secretions (Secretome with Bioactive Molecules & Exosomes)	Osteoarthritis						
		Neuropathic pain						
		Other indications						
Sygenus	Allogeneic Adipose MSC Secretions (Secretome with Bioactive Molecules & Exosomes)	Burns, Wounds, Radiodermatitis						
		Neuropathic pain						

Regeneus Patent Portfolio – Progenza™ and Sygenus

Regeneus has a strong patent portfolio for its technology platforms, Progenza™ and Sygenus, covering multiple markets and target indications.

Patent family	Technology covered	Patents granted	Patents under review	Total no. of patents	Key markets covered
Cell free preparation and uses thereof	Sygenus	2	-	2	AU
Pharmaceutical compositions and topical use thereof	Sygenus	28	5	33	US/CAN, ASIA, EU, AU
Therapeutic methods and compositions	Progenza™ and Sygenus	19	13	32	US/CAN, ASIA, EU, AU
Biomarkers for cell therapy	Progenza™	-	2	2	ASIA, AU
Enhanced cell therapies	Progenza™	-	4	4	US, ASIA, EU,
Cell expansion methods and therapeutic compositions	Progenza™ and Sygenus	-	9	9	US, ASIA, EU, AU
			Total	**82**	

Knee Osteoarthritis (OA)

Pain - A Growing Problem and Opportunity

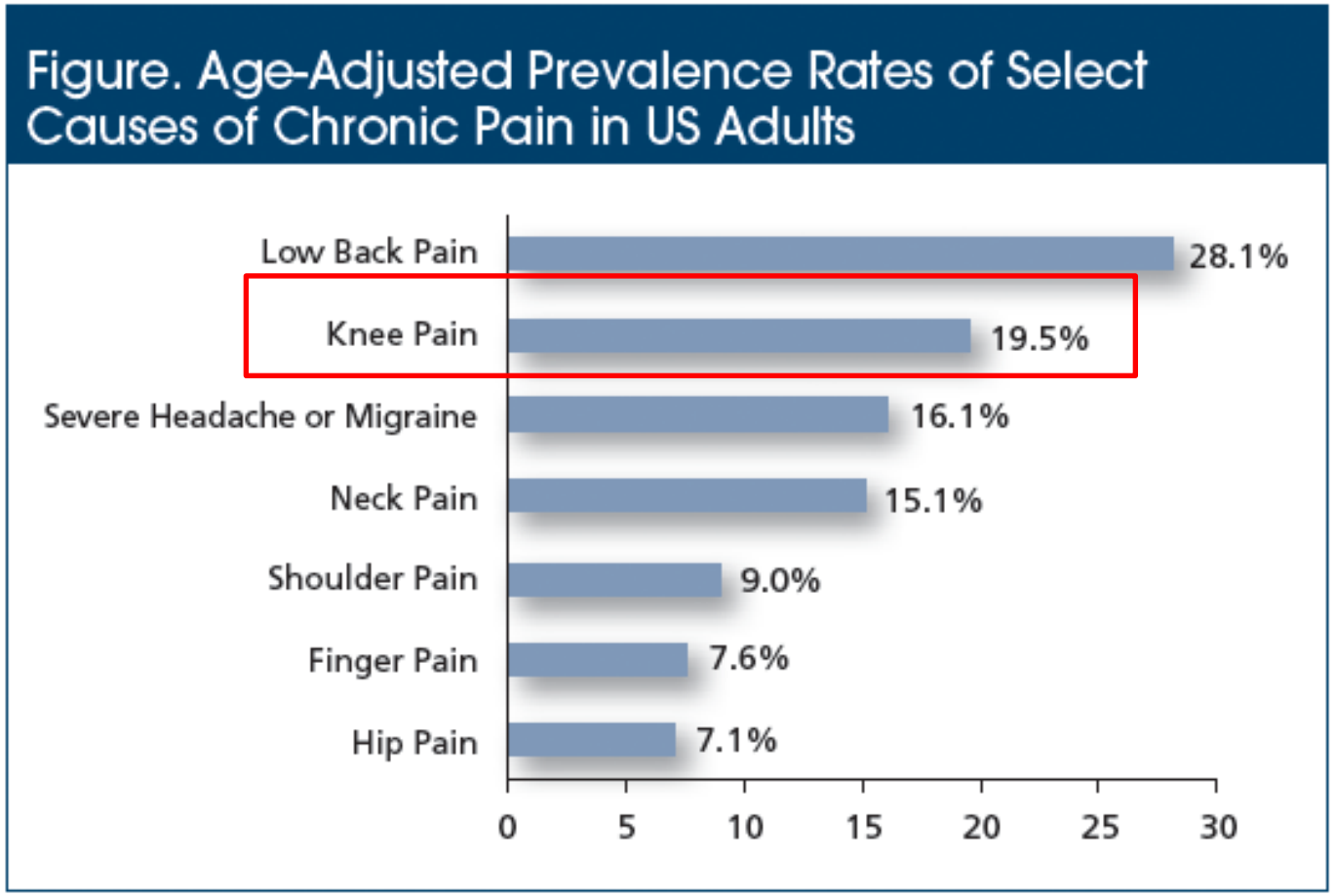
More people are suffering from pain worldwide and report inadequate relief

Pain:

- ~1.5 billion people worldwide[1]
- ~ 50% report inadequate relief[1]

Osteoarthritis (OA):

- 240M worldwide sufferers
- ~15% aged over 60
- US$3.5 billion market by 2026[2]



Source: Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: The National Academies Press; 2011.

Notes:
1. Boston University, *Chronic Pain and the Health of Populations* (2017)
2. *Osteoarthritis market set to be worth $3.5B by 2026 (GlobalData)*

Current Osteoarthritis (OA) treatment market

Current treatments only provide pain relief – not disease modification

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

Lifestyle changes	Pain relief	Disease modification	Surgery & Invasive procedures
Weight management, exercise and self-management	Paracetamol, non-steroidal anti-inflammatory drugs Hyaluronic Acid or Corticosteroid Injections	No existing therapy	Knee Replacement Bone Marrow Stimulation Bone Realignment

Progenza™ - Opportunity in Osteoarthritis (OA)

US$3.5bn global market opportunity in OA by 2026[1]

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

Japan

US$350m OA market[1]

25.6m+ potential OA patients[2]

US

US$2.6bn OA market[1] , including new modalities

54m OA sufferers currently and expected to increase to **78m** by 2040[3]

EU
(France, Germany, UK, Spain and Italy)

US$525m OA market[1]

Notes:
1. *Osteoarthritis market set to be worth $3.5B by 2026 (GlobalData)*
2. *GlobalData, Osteoarthritis – Opportunity and Analysis Forecasts to 2026, September 2017.*
3. *OA Prevalence and Burden, Osteoarthritis Action Alliance https://oaaction.unc.edu/oa-module/oa-prevalence-and-burden/*

Autologous treatment in humans

Regeneus conducted the first human autologous treatment in Australia from 2011

- Treated 600+ patients with OA
- Efficacy and modification benefits shown
- Progressed to a pharmaceutical scale-up model using allogeneic cells (Progenza)

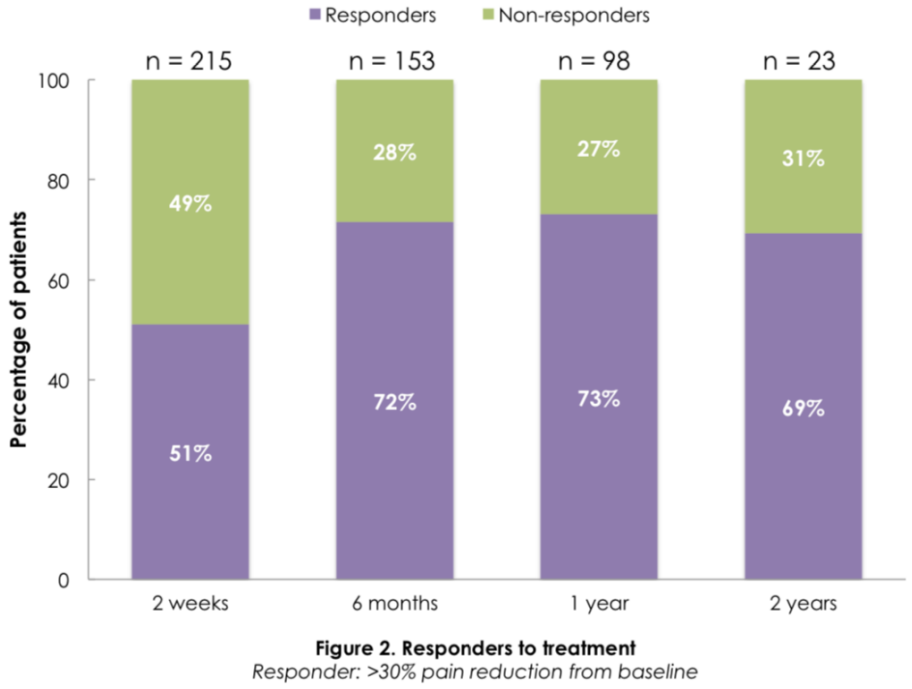


Figure 2. Responders to treatment
Responder: >30% pain reduction from baseline

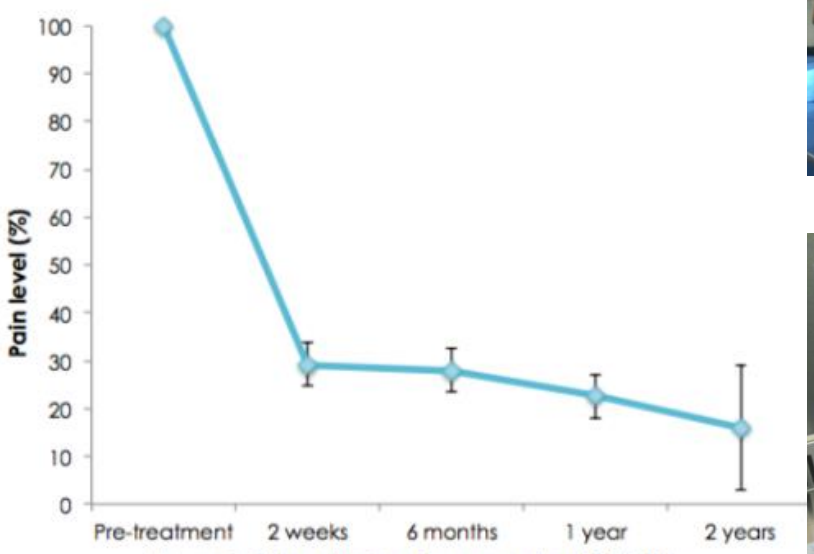
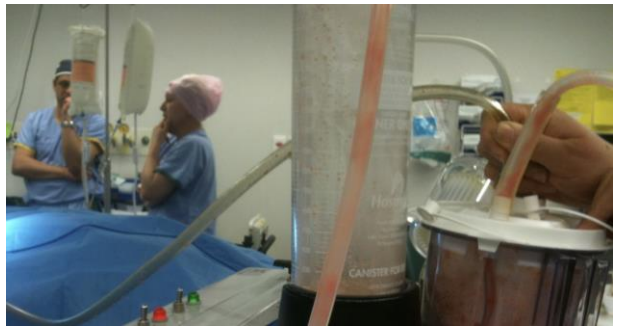


Figure 1: Pain reduction for responders (95% CI)
Responder: ≥30% pain reduction from pre-treatment



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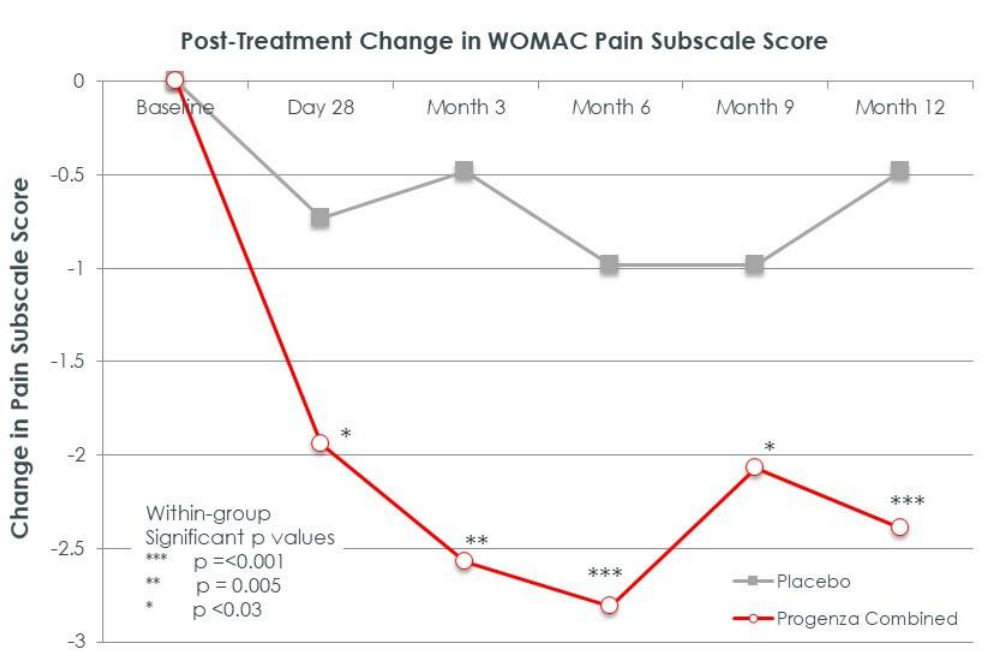
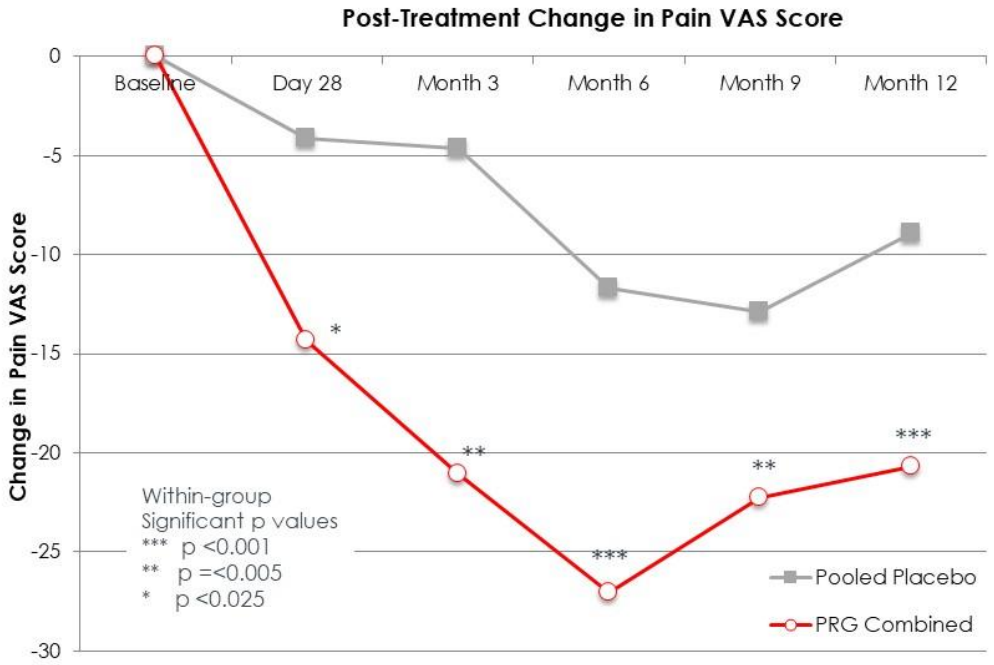
Progenza™ Phase I STEP trial

Secondary Endpoint Results: Efficacy

Progenza™ STEP Trial for knee osteoarthritis confirmed **Secondary Endpoints**:

- Progenza™ STEP Trial for knee osteoarthritis confirmed the **Primary Endpoints** of **safety and tolerability**
- **Progenza™ at both low/high doses was found to be safe and tolerable**
- **Significant, rapid and sustained reduction in knee pain** in the Progenza™ groups
  - Placebo group showed no statistically significant pain reduction during the study period



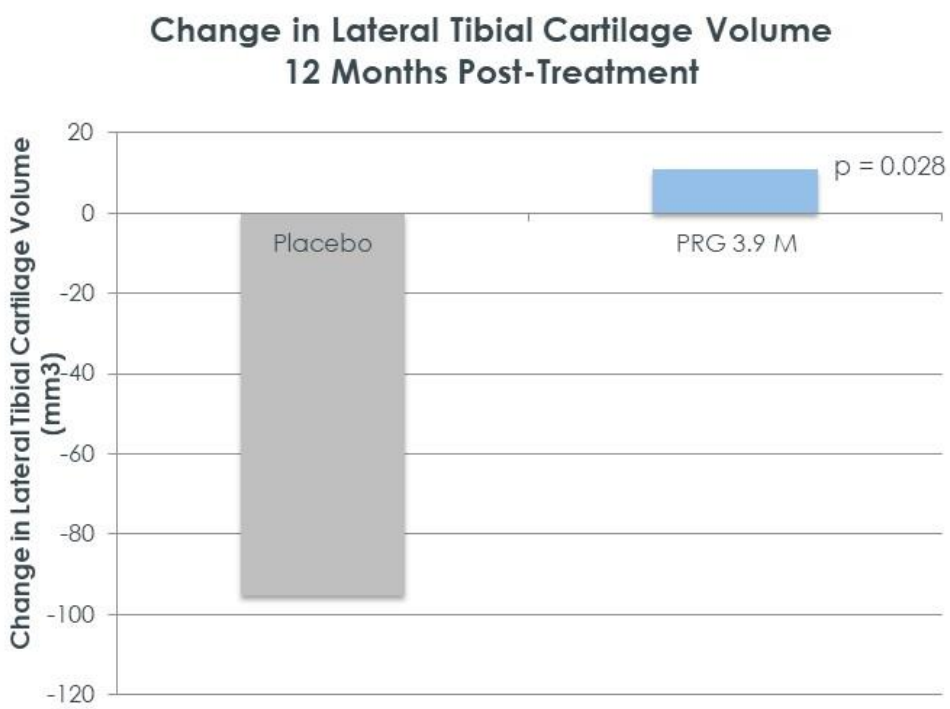


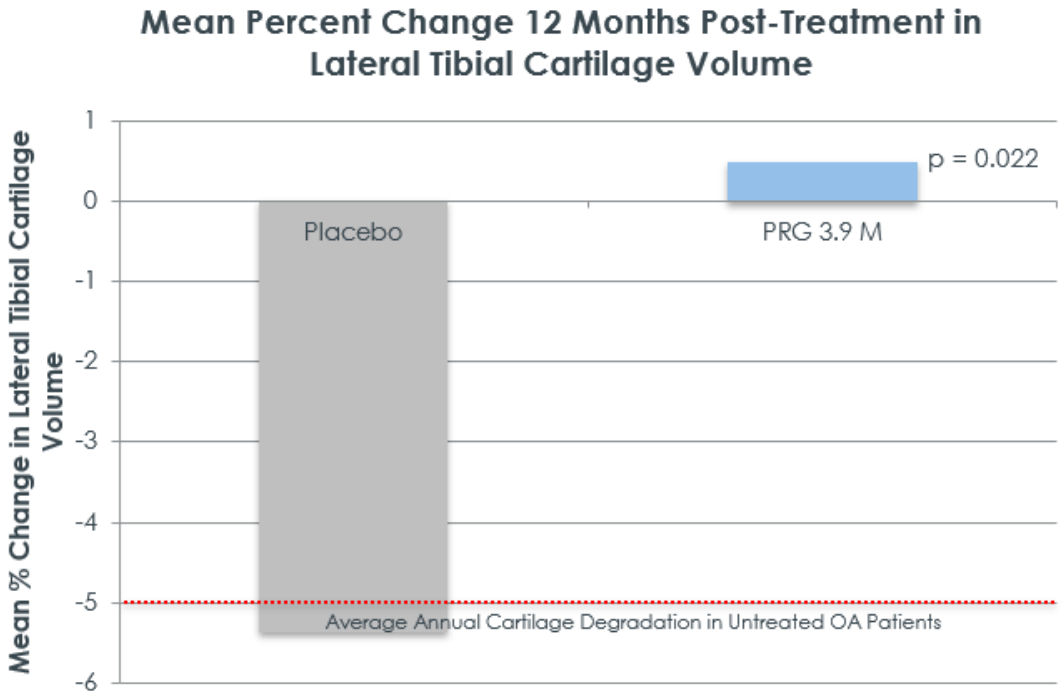
Progenza™ Phase I STEP trial

Secondary Endpoint Results: Efficacy

Progenza™ STEP Trial for knee osteoarthritis confirmed **Secondary Endpoints**:

- **Structural improvement** measured by **MRI** at baseline and 12 months
- **Significant improvement in cartilage volume compared to placebo** in 3.9M dose
  - Placebo group declined in line with average annual cartilage degradation for untreated OA patients (natural decline)
- **Positive signs of disease modification**





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Where Progenza™ fits in Current Osteoarthritis (OA) treatment market

Progenza™ fills a gap in the current treatment market by providing disease modification and pain relief to address patient symptoms without having to undertake surgery and invasive procedures

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™

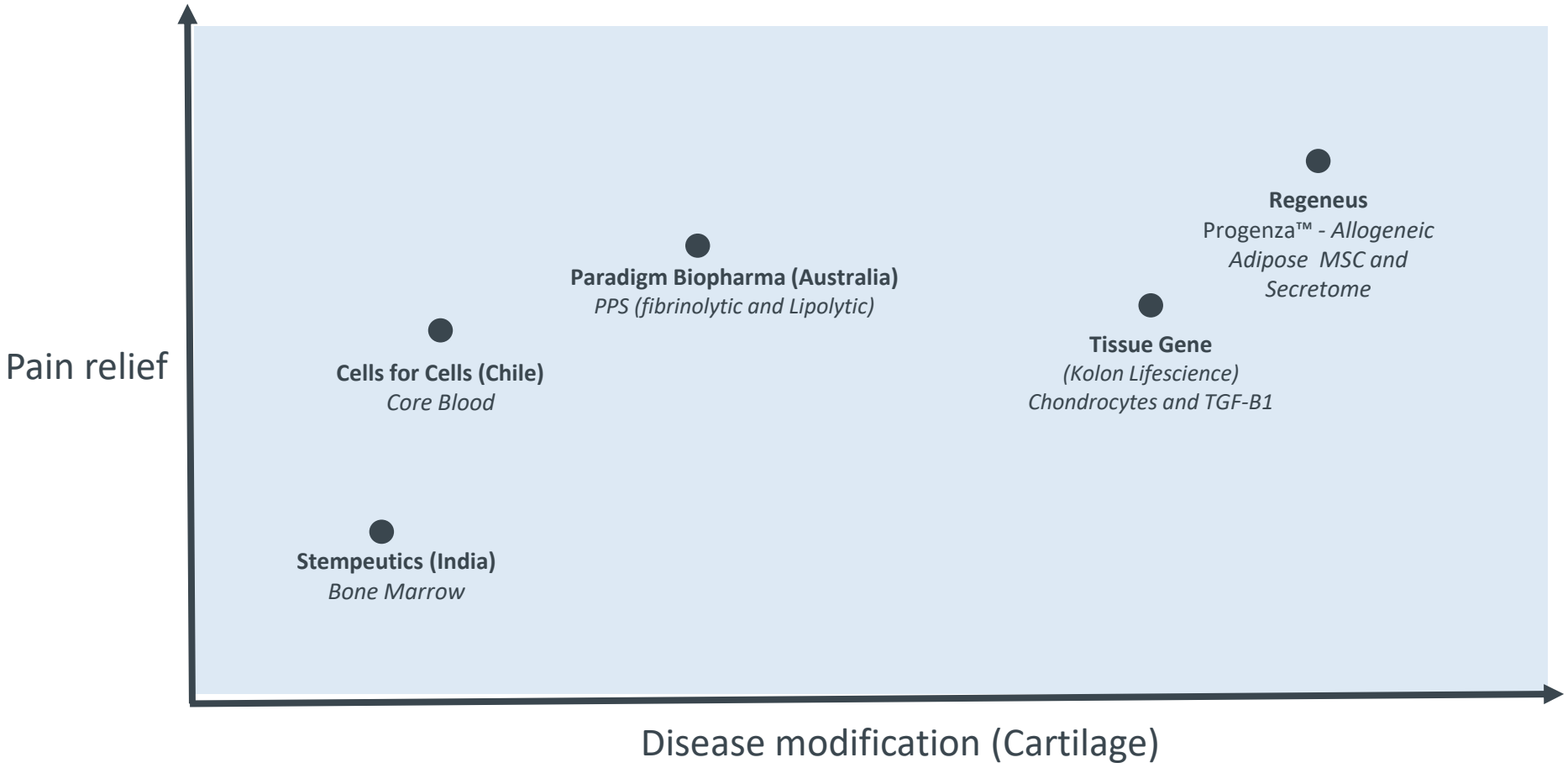
Treats the symptoms not the cause

A **safe, potent** treatment *before* Invasive Surgical intervention is needed

Lifestyle changes	Pain relief	Disease modification	Surgery & Invasive procedures
Weight management, exercise and self-management	Paracetamol, non-steroidal anti-inflammatory drugs Hyaluronic Acid or Corticosteroid Injections	No existing therapy	Knee Replacement Bone Marrow Stimulation Bone Realignment

Competitive Landscape

Knee OA



Unavailable Knee OA Clinical Data to date:

- **Cellular Biomedicine Group (China)**
- **Cynata (Australia) – *IPAC MSC***

Progenza™ OA - Commercialisation Strategy in Japan

An accelerated commercialisation pathway and strategic market for Knee OA

Progenza™ Knee OA

Progress to date

Manufacturing licensing deal	Progenza™ STEP Phase I Safety Trial	Licensing deal signed with Kyocera	Phase II clinical trial	Ongoing efficacy assessments during Conditional Approval Phase
✓	✓	✓	Technology transfer to Kyocera Manufacturing cell bank PMDA consultations	

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Progenza™ OA Collaboration and Licensing Agreement with Kyocera

Major milestone that paves way for commercialisation of Progenza in OA

Payments and royalties:
- A$27M in upfront and milestone payments
- Additional single to high double-digit royalties on product sales

Manufacturing and development:
- Kyocera responsible for product development, manufacturing and regulatory activities in Japan

Other partners:
- Regeneus retains rights to negotiate licensing deals with other parties for Progenza™ outside of Japan, and other indications within Japan

KYOCERA

- Major producer of medical products inc: artificial joints for the knee and hip
- Market cap: 2.5 trillion JPY (Tokyo Stock Exchange)

Neuropathic Pain

About Neuropathic Pain

Neuropathic pain is central in many disease indications

Neuropathic Pain	Biology	Causes	Patient experience
Multimodal disease to the peripheral and central nervous system leading to inflammation and hyperexcitability of the nervous system.	Neuro immune inflammation and hyperexcitability of pain signals leads to an increased trafficking of T-cells and macrophages to the CNS, resulting in increased pain signalling from glial cells.	Damage to a nerve causes initial pain, but Neuropathic pain persists after underlying injury or disease has resolved, so it can be re-triggered as the immune system is still in an excitable state.	Normally non-painful movement/touch is experienced as excruciating pain, as normal sensory signals are being perceived as painful signals.

Indications:

- Trauma and post-surgical neuropathy
- Chronic lower back pain
- Trigeminal neuralgia
- Chemotherapy-related neuropathy

Treatment:
There is **no cure** for the underlying causes of neuropathic pain – only treatment of pain symptoms which have long term side effects

Neuropathic Pain - Market Opportunity

US$4.5bn global market opportunity in neuropathic pain in 2019[1]

Neuropathic pain is a disorder of the sensormotor system – patients feel pain even when its source is removed

US

US$3.2B neuropathic pain sales in 2019[1]

Estimated 16M US patients suffer from neuropathic pain[2]

US sales of Lyrica (Pfizer) was **US$3B+** in 2018[3]

EU
(France, Germany, UK, Spain and Italy)

US$782M neuropathic pain sales in 2019[1]

Japan

US$448M neuropathic pain sales in 2019[1]

Notes: 1. *Global Data Neuropathic Pain Report 2020*
2. *The prevalence of neuropathic pain: Clinical evaluation compared with screening tools in a community population https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2964880/*
3. *Fierce Pharma https://www.fiercepharma.com/special-report/13-lyrica*

Pre-clinical study: Neuropathic pain model (CCI model)

Chronic Constriction Injury (CCI) model using rats and touch stimulator

Rats are assessed for their baseline pain threshold

Touch stimulator applied force though a blunt rod and grams of force recorded at point the paw is withdrawn

Surgery – 3 sutures are added around the sciatic nerve and 1 placed subcutaneously

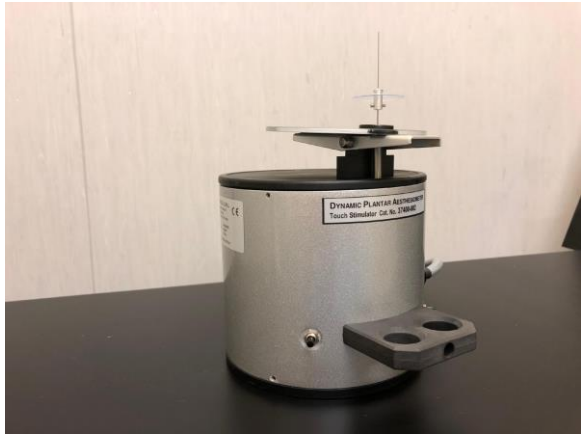
Development of Pain (allodynia) for 14 days

Treatment

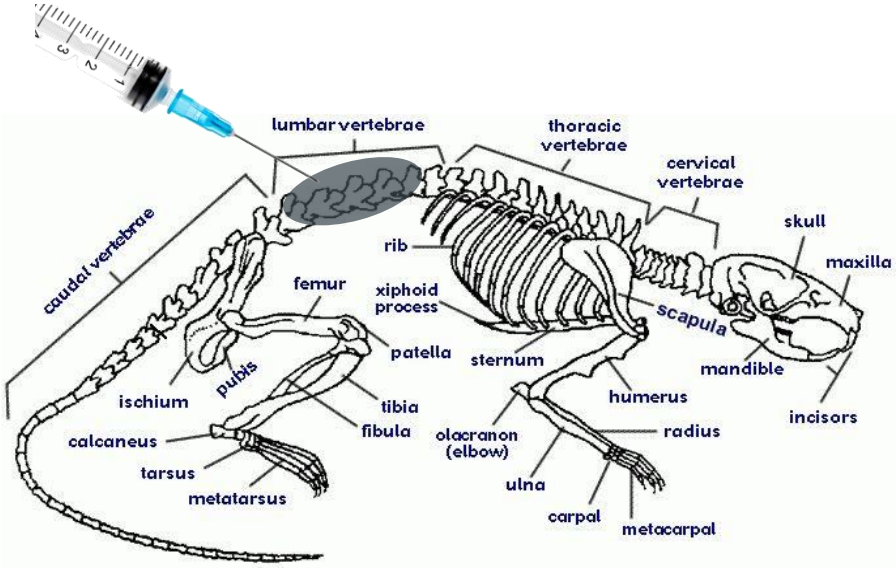
Progenza MSC's administered intrathecally

Assessment of Allodynia and Hyperalgesia

Re-assessment by the touch stimulator to record pain response 24h to 14 days post injection



Touch Stimulator applies measured grams of force to the paw



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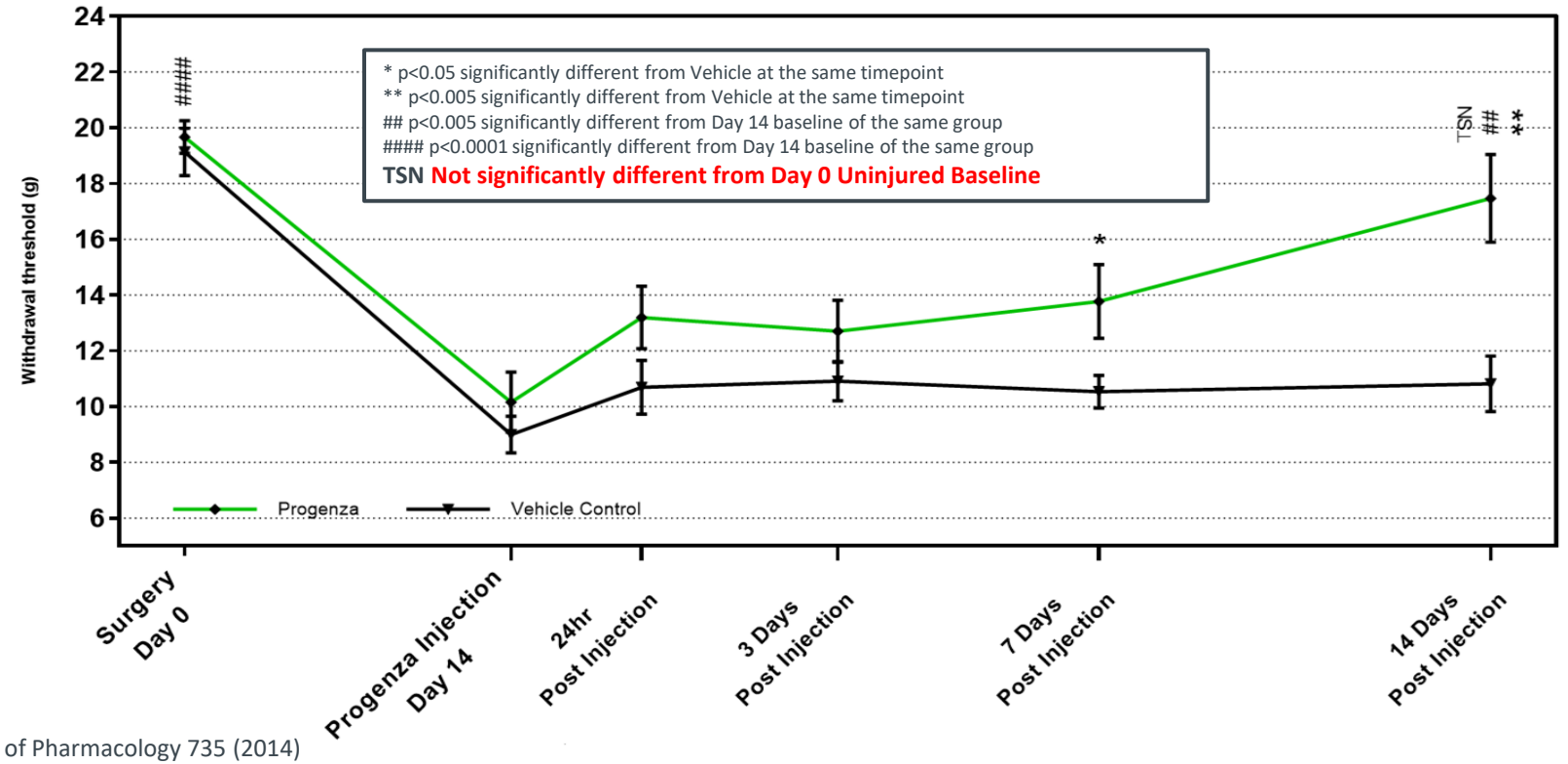
Pre-Clinical Study: Progenza™ MSCs in Chronic Construction Injury (CCI) Study

Disease modification of neuropathic pain

- Standard therapies[1] provide 90-180 mins relief only and require multiple doses per day
- Progenza: single injection and modifies disease and reversal in 14 days

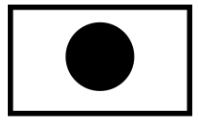
Chronic Constriction Injury (CCI) Study Results



[1] Cudennec *et.al.* European Journal of Pharmacology 735 (2014)

Upcoming Milestones & Outlook

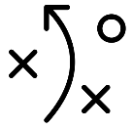
Upcoming milestones



Progress Progenza™ collaboration with Kyocera

Ongoing partnerships to explore Progenza and Sygenus platform technologies

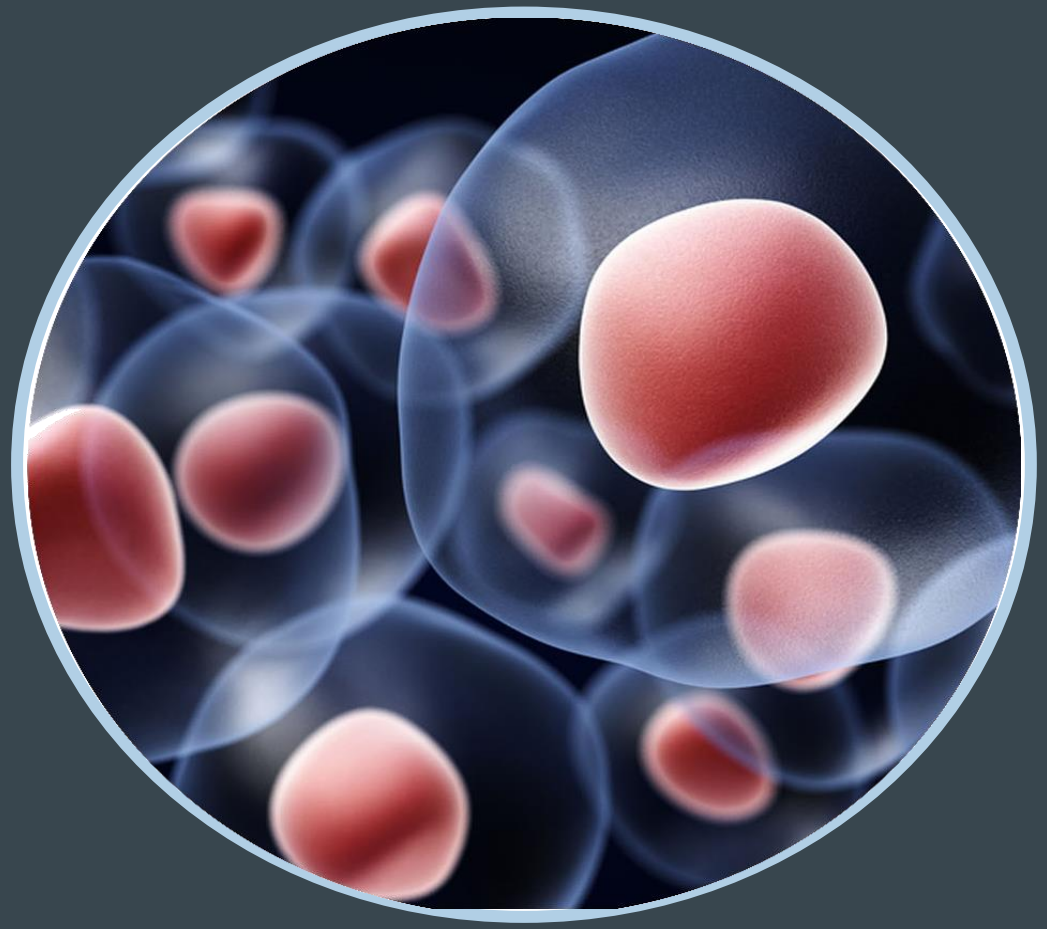
1H 2021: Explore Neuropathic Pain indication



Q4 2021 to Q1 2022: Phase II trial for Japan Progenza™ OA expected

2023-24: Target Progenza™ OA commercialisation in Japan

Thank you



Investor Relations

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