

ASX Announcement
25 August 2020

Regeneus to present at FNN Virtual Investor Event

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today announced that its CEO Leo Lee, will present at the Finance News Network (FNN) CEO Showcase virtual event on Tuesday 25 August 2020 at 12:55pm (AEST). The event is primarily attended by Australian-based retail investors and advisors.

Details of the virtual event can be found [here](#). The presentation will feature an overview of Regeneus' business for new investors, including the Company's platform technologies and recent highlights, including the Kyocera collaboration and licensing agreement for Progenza OA for Japan.

The slide presentation is attached

-ENDS-

About Regeneus

Regeneus Ltd (ASX:RGS) is a Sydney-based regenerative medicine company using stem cell technologies to develop a portfolio of novel cell-based therapies. The regenerative therapies seek to address unmet medical needs in human health markets, focusing 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 Investor Presentation

Developing the next generation of pain management and inflammation therapeutics

August 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

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Regeneus – company snapshot

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

Innovative platform technology

- Two platform technologies:
 - Progenza™ (stem cells and their secretions) – Phase I study complete
 - Sygenus (secretions) – pre-clinical stage
- Backed by high quality R&D partners – scientific partnership model
- Comprehensive IP portfolio across key markets

Transformative commercialisation deal

- Executed a exclusive licensing & collaboration agreement for Progenza™ OA in Japan with Kyocera
- Significant upfront and milestone payment (A\$27M)
- Kyocera to invest in Japan Manufacturing, Clinical Study, Registration and Commercialization.
- Future royalties against product sales
- Regeneus fully funded to Japan commercialisation (expected in 2023-24)

Significant market opportunity

- Targeting growing pain and inflammation market
- Significant unmet clinical need for regenerative, non-invasive, pain treatments
- US\$3.5B market in OA alone; Japan market to be worth \$350M in 2026¹

¹ Osteoarthritis market set to be worth \$3.5B by 2026 <https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026/>

Transformative Progenza™ OA deal with Kyocera



Exclusive licensing agreement for Japanese market:

- Develop & commercialise Regeneus' lead platform technology Progenza™ OA
- Kyocera to fund all development, manufacture & commercialization costs
- RGS retains rights to negotiate other licensing agreements (ex Japan)



Significant payments & future value for Regeneus:

- Upfront and milestone payments of A\$27M
- Royalties on future product sales
- 25M+ potential OA patients in Japan alone, with 1.25M in clinic¹



Pathway to commercialisation:

- Upfront payment to provide cash runway until commercial launch of Progenza™ OA, expected in 2023-2024
- Phase II trials to commence 2021-2022

¹Japanese Government statistics and patient surveys 2017



Company Overview and Market Opportunity

What is neuropathic pain?

Neuropathic pain is pain caused by damage or disease affecting the somatosensory nervous system.

Spontaneous pain, or pain that occurs without a trigger

Pain caused by something that does not usually cause pain

Peripheral

- Diabetes mellitus and Chemotherapy
- Infectious diseases (mainly HIV infection and leprosy)
- Inflammatory disorders and Inherited neuropathies
- Trauma and post surgical neuropathy
- Complex regional pain syndrome
- Trigeminal neuralgia and Post Herpetic Neuralgia

Central

- Stroke pain
- Neurodegenerative diseases (notably Parkinson disease)
- Spinal cord lesions or diseases:
- spinal cord injury
- Demyelinating diseases (multiple sclerosis)

Treatment: There is **no cure** for the underlying causes of neuropathic pain – only treatment of pain symptoms

Pain: A Growing Problem and Opportunity

More people are suffering from pain worldwide

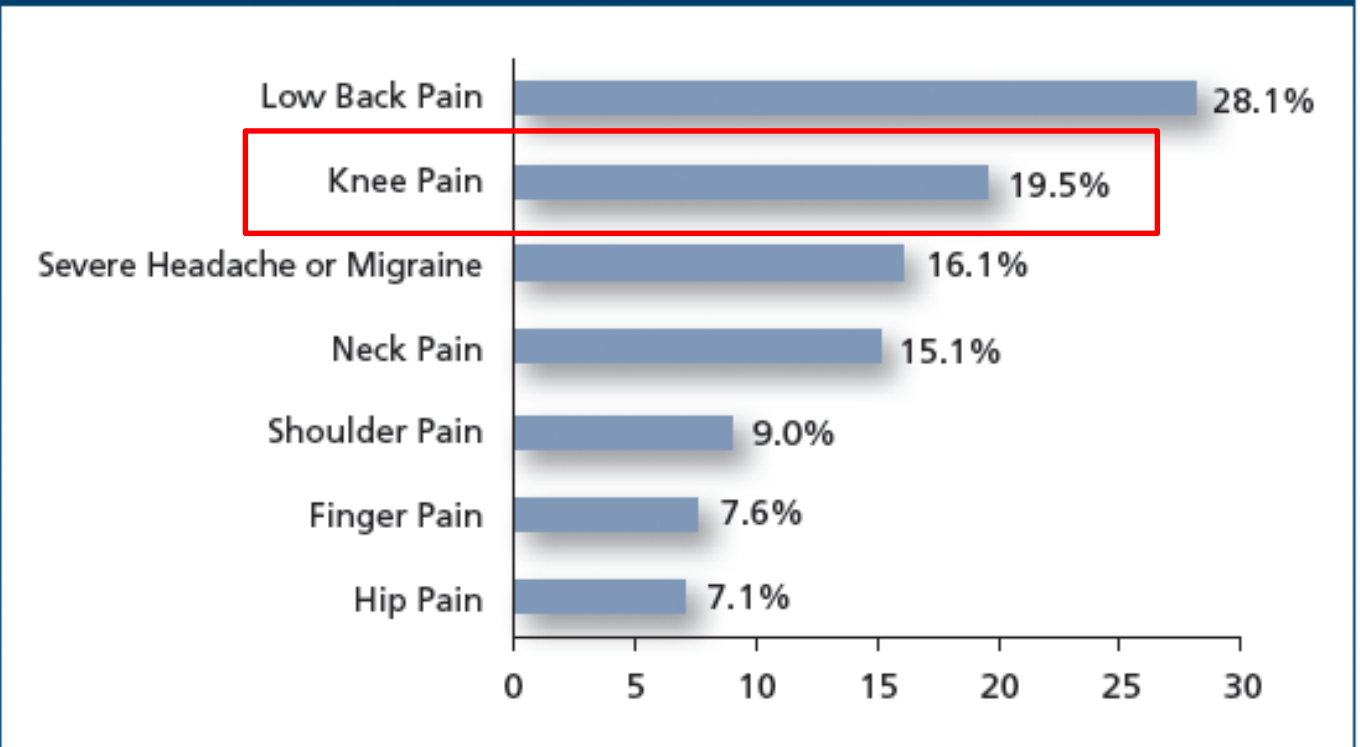
Pain:

- ~1.5 billion people worldwide
- ~ 50% report inadequate relief

Osteoarthritis:

- 240M worldwide sufferers
- ~15% aged over 60
- US\$3.5 billion market by 2026¹

Figure. Age-Adjusted Prevalence Rates of Select Causes of Chronic Pain in US Adults



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

¹ Osteoarthritis market set to be worth \$3.5B by 2026 <https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026/>

Mesenchymal Stem Cells (MSCs)



Cells that can differentiate into other cells 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: Focus on Pain via Platform Technologies

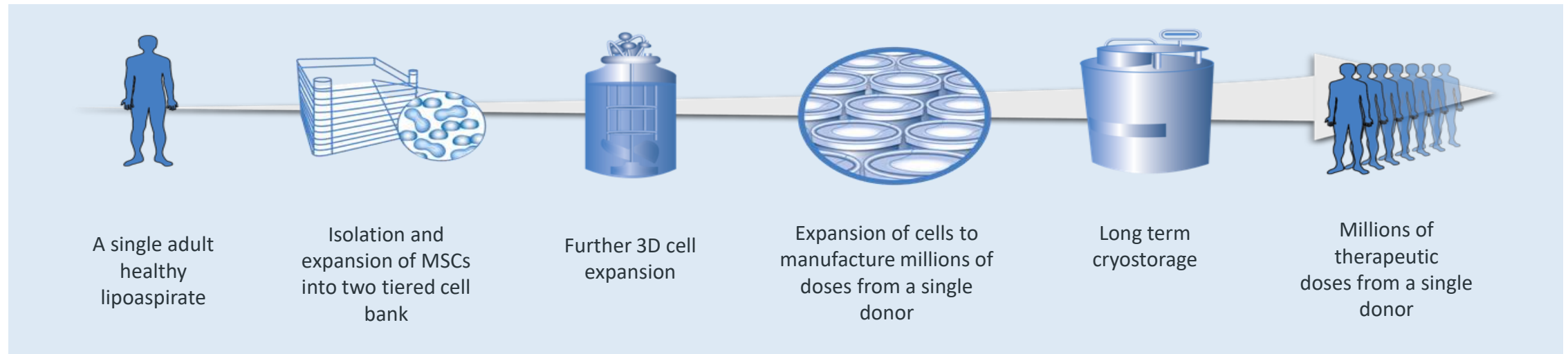
Pain management as key focus area to fill the healing and repair void in the pain treatment market and a solution to opioids.

Progenza™

- Uses MSCs 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 and Kyocera deal

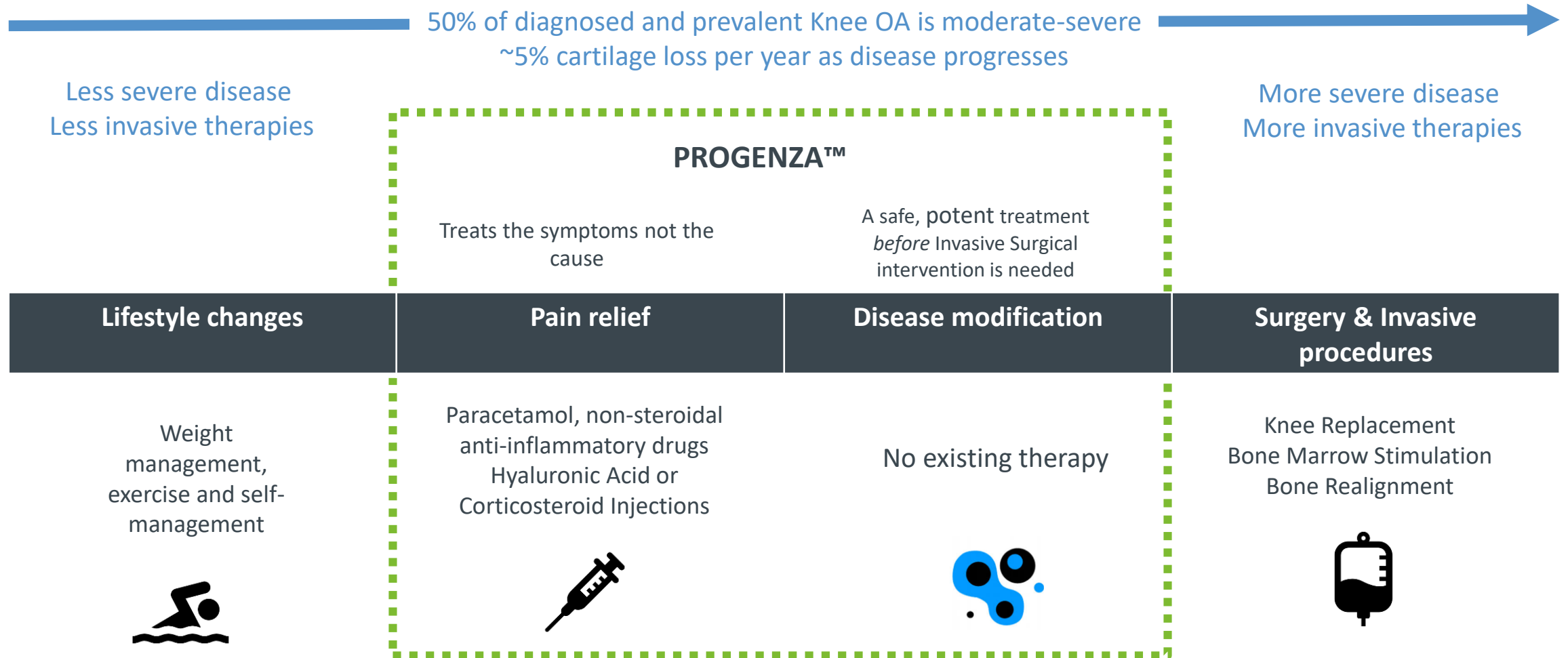
Sygenus

- 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



Progenza™ OA & Current Treatment Market

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



Regeneus' Clinical Pipeline

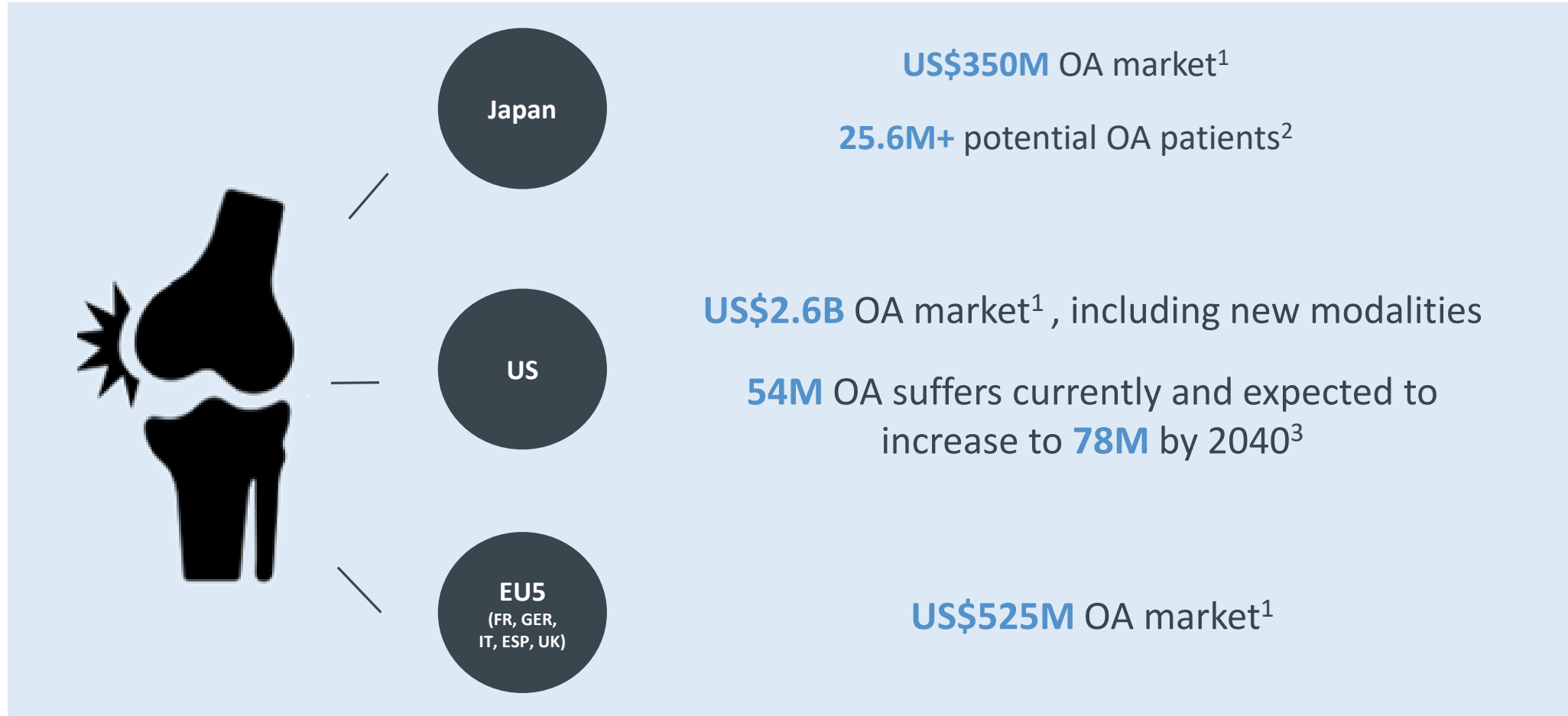
Two core platform technologies – Progenza™ and Sygenus - with multiple potential target indications

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						
		Neuropathic pain						
		Other indications						
Sygenus	Allogeneic Adipose MSC Secretion (Secretome with Bioactive Molecules & Exosomes)	Burns, Wounds, Radiodermatitis						
		Neuropathic pain						
		Psoriasis, Atopic Dermatitis						
		Rare/Orphan Skin Diseases						

Progenza™ Opportunity in Osteoarthritis (OA)

US\$3.5B global market opportunity in OA by 2026¹

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



¹ Osteoarthritis market set to be worth \$3.5B by 2026 <https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026/>

² Source: 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/>

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	✗

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



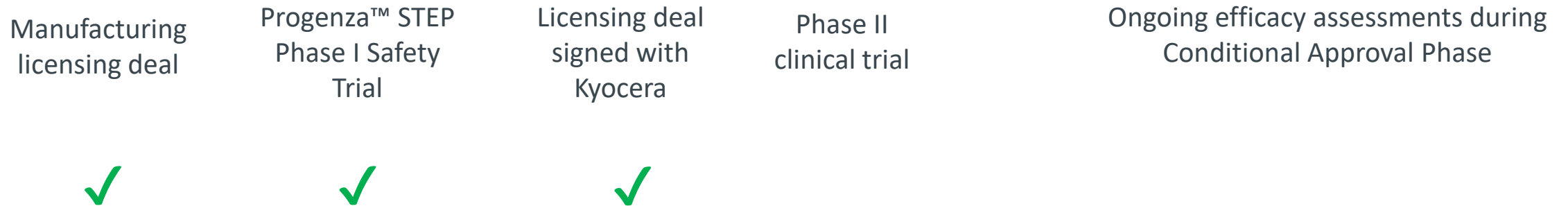
Commercialisation Pathway & Outlook

Progenza™ OA Commercialisation Strategy

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



Progenza™ Knee OA



Collaboration and Licensing agreement with Kyocera

- US\$19M (A\$27M) in upfront and milestone payments + single to high double-digit royalties on Progenza OA product sales
- Kyocera will be responsible for product development, manufacturing and regulatory activities in Japan
- Regeneus retains rights to negotiate licensing deals with other parties for Progenza outside of Japan, and other indications within Japan

Next steps in collaboration:

- 2020 and ongoing - Collaboration with Kyocera on Progenza OA development process
- 2021 - Manufacturing facility to scale up technology
- 2021-22 - Phase II trial for Progenza OA

About Kyocera

- Diversified, multinational Japanese manufacturer
- Major producer of medical products including artificial joints for the knee and hip
- Market cap: 2.5 trillion JPY (Tokyo Stock Exchange)
- FY2018 revenue: 1.6 trillion JPY
- Headquartered in Kyoto, Japan



Company Strategy Progress

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



- ✓ Priority focus
- ✓ Licensing agreement secured with Kyocera
- ✓ Kyocera to fund product development, manufacturing & regulatory activities in Japan
- Targeting commercialisation in 2023-24

- ✓ Platform development
 - Progenza™
 - Sygenus
- ✓ Reduced funding requirement via partnerships

- ✓ Operating cost base reduced by 50% since FY19
- ✓ Upfront payments from Kyocera deal provides cash runway for RGS through to Progenza OA commercialisation

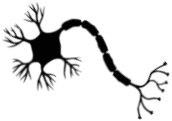
Upcoming Milestones



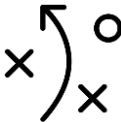
Phase II trial for Progenza™ OA – expected 2021-22



Target Progenza OA commercialisation in Japan in 2023-24



Expansion of clinical pipeline into other indications in neuropathic pain



Continue to execute revised company strategy and streamline operations



New scientific partnership model allows for technology licensing



Invest in manufacturing capabilities to facilitate technology scale up

Investment Highlights



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, disease modification, and inflammatory conditions, along with being secured by IP



Existing treatments do not address patient needs or have side effects and limitations

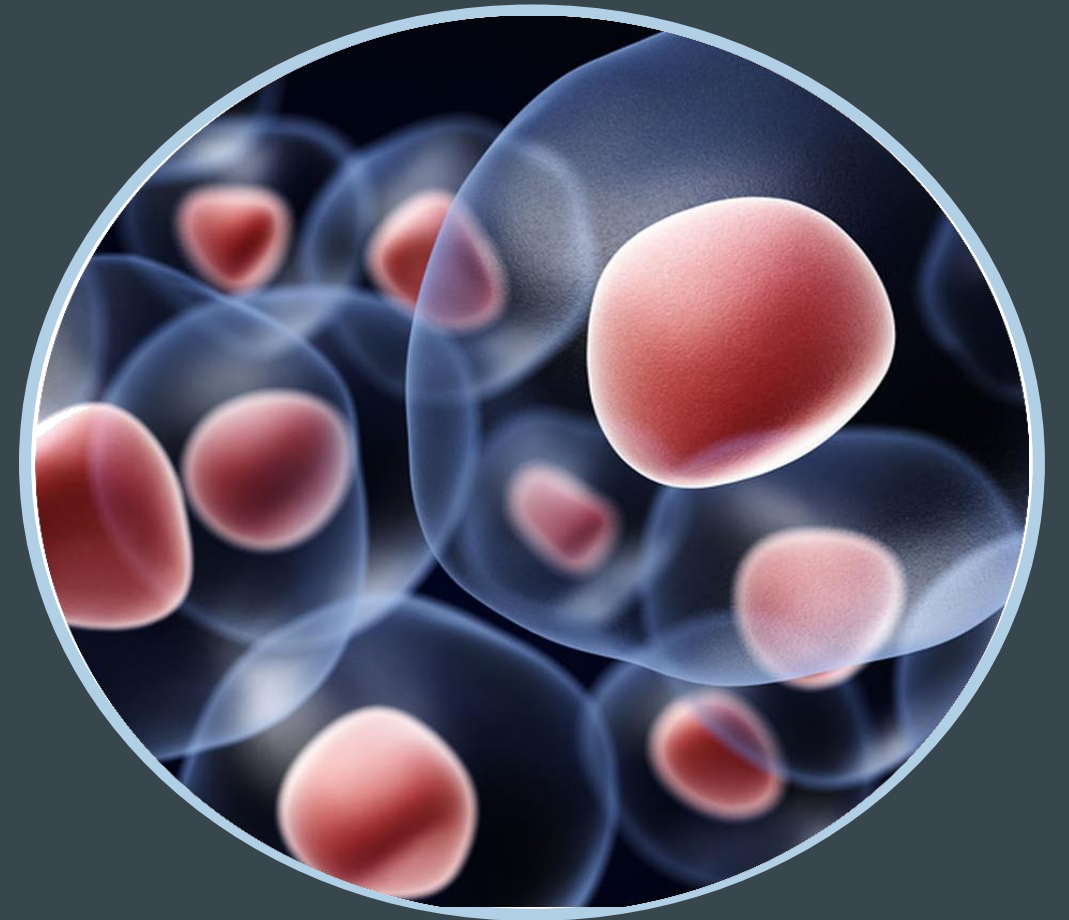


Kyocera licence and commercialisation deal sets out clear commercialisation pathway for Progenza OA. Funds from upfront deal help fund other clinical assets – ‘multiple shots on goal’



Experienced board and management team with track record of commercialisation

Thank you



Investor Relations

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