Corporate Presentation

Developing next generation pain management and inflammation therapeutics

Regeneus Ltd
ASX:RGS

September 2022

Disclaimer

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Company overview

Background

- Regeneus ("RGS") is a pioneer cell therapy company founded in Sydney in 2007
- The company went public (ASX:RGS) on the Australian Securities Exchange in 2013
- Two platform technologies leveraging proprietary IP in allogeneic adipose-derived mesenchymal stem cells ("MSC") and their bioactive secretome (incl. cytokines, extracellular vehicles, miRNA)
- Successful Progenza Phase I trial in knee osteoarthritis demonstrating product efficacy
- Signed Progenza collaboration and licensing partnership with Kyocera in Japan in 2020
- The platform is supported by over 80 granted and pending patents worldwide

Financial information

Share price (31 Aug 2022)	A$ 0.050
Shares issued	306.4m
Market capitalisation	**A$ 15.3m**
Net Debt (as of 30 Jun 2022)	A$ 0.9m
Enterprise value	**A$ 16.2m**

Experienced Board and management team

Barry Sechos
Independent Chairman

- 20+ years experience as a director, business executive, and corporate lawyer
- Executive Director of Sherman Group

Leo Lee
Non-Executive Director

- President, Novartis Japan
- 20+ years in pharma
- Former President of Allergan and Merck Japan

Dr. Scott Bruder
Board Advisor

- WW VP of J&J Regenerative Therapeutics, DePuy
- CSO & CMO of Stryker
- CTO of Becton, Dickenson
- Senior roles at Anika, Osiris

Karolis Rosickas
Chief Executive Officer

- 17 years experience in healthcare and technology
- Co-founder and CEO of SingCell and OME Health
- VP at HSBC M&A in London

Prof Graham Vesey
CSO & Executive Director

- Regeneus co-founder
- Co-founder of BTF, sold to BioMerieux in 2007
- Adjunct Professor at Macquarie University

Dr Charlotte Morgan
Head of R&D

- 20+ years in managing product development and innovation
- PhD in microbiology
- Joined Regeneus in 2012

Dr Sinead Blaber
Clinical Director

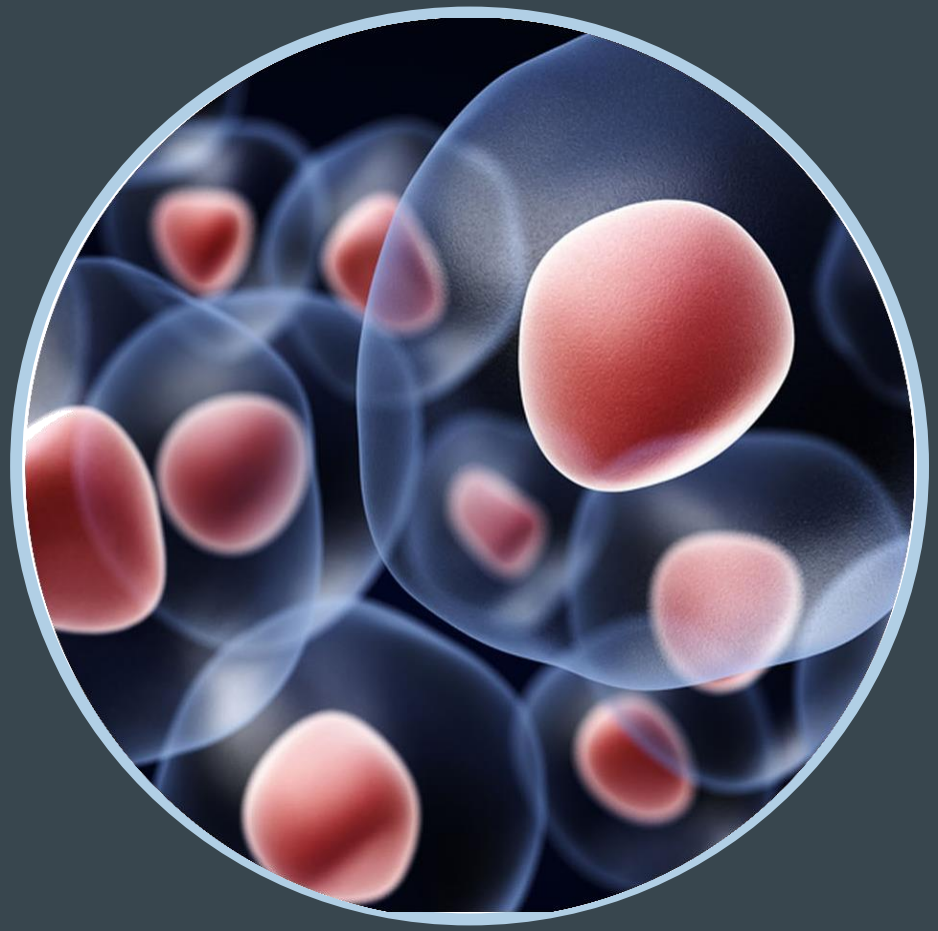
- 10 years experience in biotechnology industry
- Directed Progenza STEP Trial
- PhD in Biotechnology
- Joined Regeneus in 2009

Regeneus investment highlights

Pioneering regenerative medicine company developing next generation cell-based therapies to manage pain and inflammation

Leading, differentiated technology platform	• A unique combination of stem cells and their bioactive secretome exerts superior therapeutic effect • Applicable in a broad range of pain and inflammation indications • A scalable and cost effective manufacturing process • IP has been developed and is fully owned by Regeneus
Attractive market potential	• Global pain management market is a growing and significant multi billion-dollar opportunity • Large unmet market need for disease-modifying therapeutics in osteoarthritis • Secular tailwinds in the osteoarthritis market – ageing population and increasing prevalence of obesity
Progenza OA Phase 2 ready asset	• Progenza OA is a Phase 2 ready asset with strong nonclinical and Phase 1 data — validated by Kyocera during the extensive technology due diligence process • Active pipeline of potential licensing opportunities in the United States, China, and South Korea
Near term value accreting opportunities	• Kyocera partnership to deliver additional US$13m in milestone payments in the next 3 years • Opportunities beyond osteoarthritis in Japan: — Progenza OA Phase 2 trial in the United States (2023) — Potential Sygenus Pain Phase 1 trial in Australia (2023)

Technology and products



Proprietary allogeneic mesenchymal stem cells and secretome platform

Mesenchymal stem cells

- Multipotent stem cells, which perform multiple functions in human body including direct differentiation, activation of resident stem cells and secretion of bioactive molecules (secretome)

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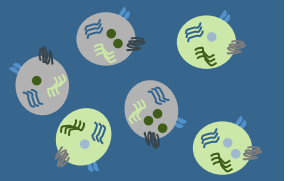
Bioactive Secretome

- Bioactive molecules (cytokines, chemokines, growth factors, extracellular vesicles) secreted by MSCs
- Reduces inflammation and promotes tissue repair
- Improves functionality and viability of MSCs



The combination of MSCs and the bioactive MSC secretome exerts a more powerful therapeutic effect

Allogeneic cells

- Derived from a single donor
- Can be used in millions of patients

Adipose-derived

- Adipose contains 500-1000x more MSCs than bone marrow or other sources

Safe

- MSCs are immune-privileged cells, which escape patient's immune system without the risk of rejection
- No genetic modification of cells

Superior efficacy

- ✓ Sustained pain relief for 3, 6, 12 months
- ✓ Disease modifying cartilage repair
- ✓ **Potentially, first-in-class disease modifying osteoarthritis drug (DMOAD)**

How Regeneus platform technology is different to other regenerative medicine technologies

MSCs / iPSCs only

- Generation 1.0 therapies
- ✗ Now well understood to provide only limited functionality through differentiation and engraftment
- ✗ Have underperformed in clinical trials

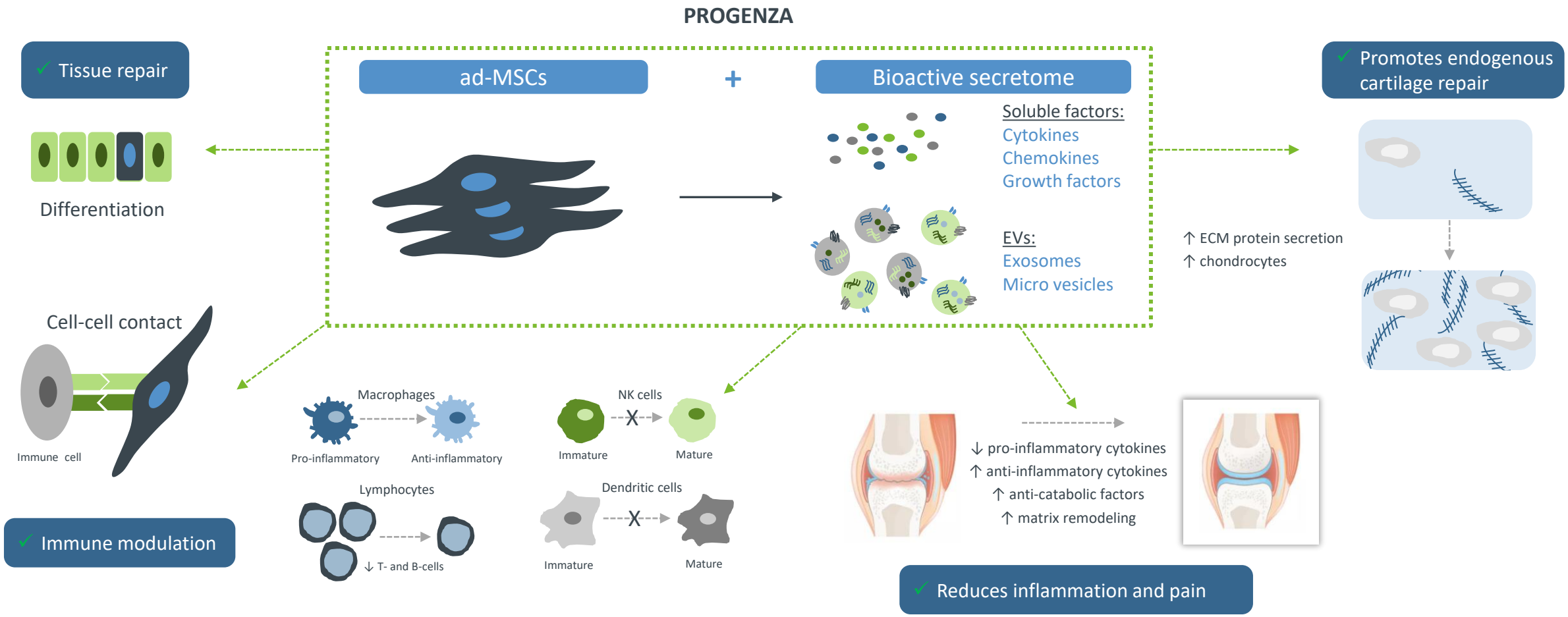
Progenza
MSCs and Bioactive Secretome

- ✓ Secretome enhances viability and functionality of MSCs
- ✓ Secretome has independent immuno-modulatory functions in inflamed environment
- ✓ Scalable and cost-effective manufacturing process

Extracellular vesicles (EVs)

- Emerging novel, early-stage modality
- ✗ Expensive isolation and purification process
- ✗ Manufacturing scalability not proven yet
- ✗ Still unknown mechanism of action of individual EVs
- ✗ Years away from regulatory approvals

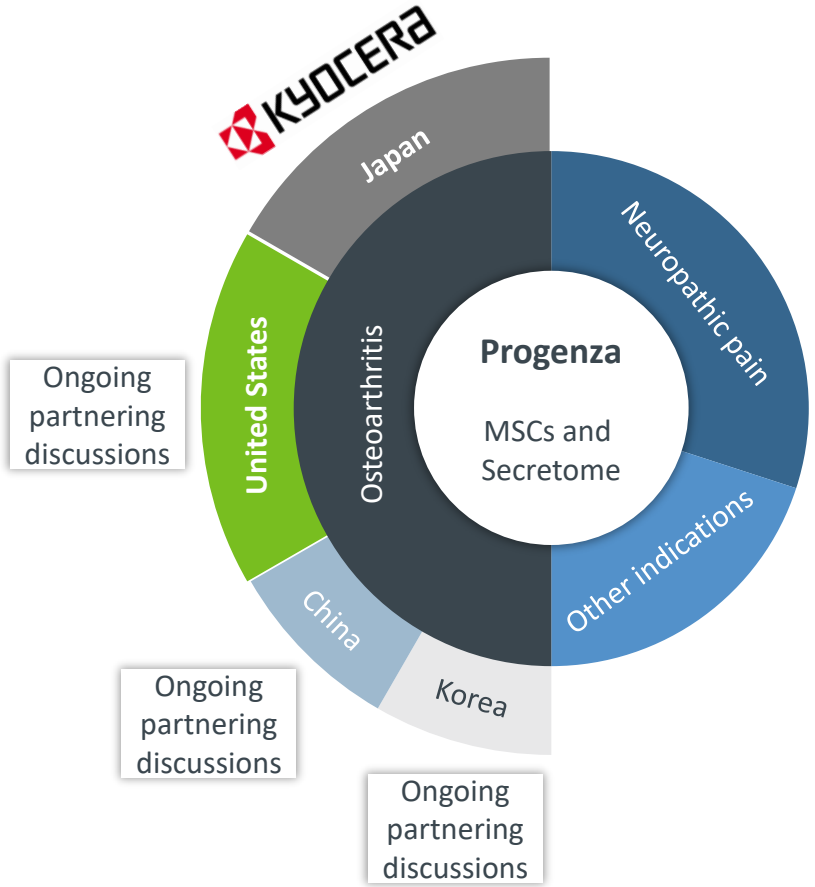
Multi-modal mechanism of action in knee osteoarthritis

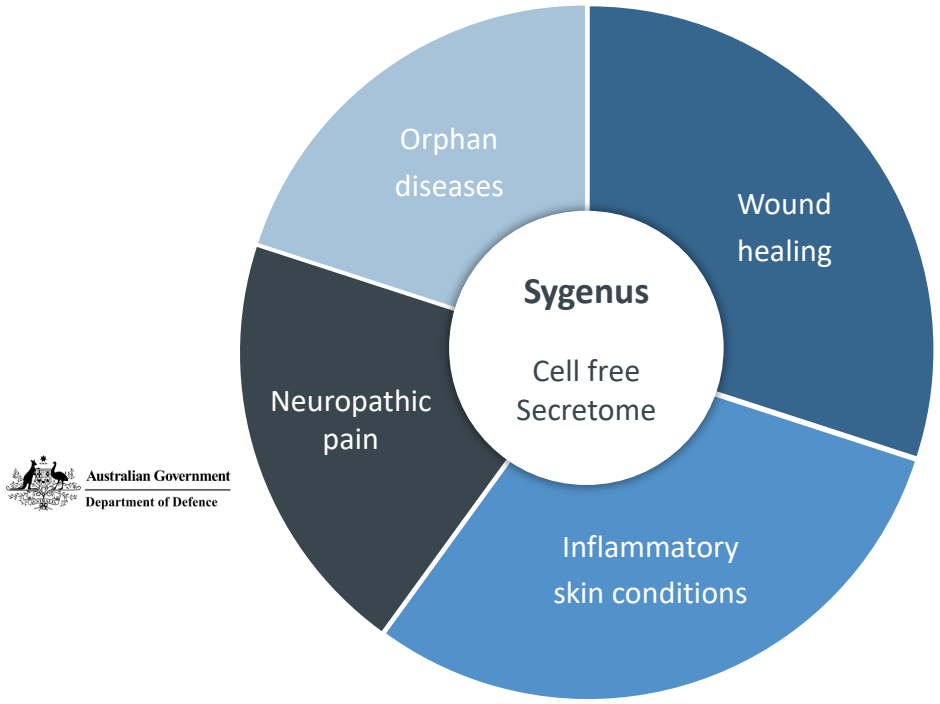


The combination of MSCs and the bioactive MSC secretome in Progenza exerts a powerful therapeutic effect via repair and regeneration of endogenous joint tissues, reducing inflammation, modulation of the immune system and pain relief

Scalable product platforms

Multiple opportunities in pain and inflammation focused indications





The product platforms are protected by a portfolio of 80+ patents covering multiple indications in key markets and expiring in late 2030s

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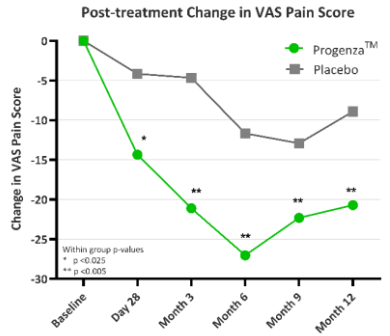
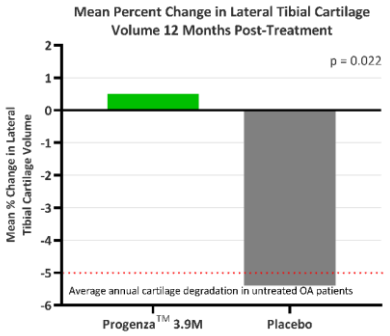
Strong nonclinical & clinical data supports platform development across multiple indications

Progenza Osteoarthritis Phase 1 (STEP) [1]

- Confirmed the Primary Endpoints of **safety** and **tolerability** at both low and high doses with a **single injection**
- Confirmed the Secondary Endpoints of efficacy:
  - **Pain**: significant, rapid and sustained pain relief achieved via VAS and WOMAC Pain scores
  - **Cartilage**: halting of disease progression 12-months post-treatment
- **88% responder rate** at 12 months defined as ≥ 30% pain improvement





Progenza Neuropathic pain Preclinical

- Neuropathic pain is central in many disease indications (chronic lower back pain, trigeminal neuralgia, etc.) with no cure for the underlying causes
- Performed a study on Chronic Constriction Injury (CCI) model using rats and touch stimulator
- Demonstrated that a single injection of Progenza modifies disease in 14 days

Sygenus Various indications Preclinical

Primary indication	Study Type	RoA	End Date	Subject #	Conclusions
Topical safety	Safety & tolerability	Topical	Aug 2017	33 humans	✓ **Safety:** Safe & well tolerated in acne prone patients
Topical safety	Safety – RIPT	Topical	Oct 2017	50 humans	✓ **Safety:** non-sensitizing and non-irritating
Acne	Safety & efficacy	Topical	Jan 2018	30 humans	✓ **Safety:** Safe and well tolerated ✓ **Efficacy:** Significant improvement in acne measurements
Age spots	Safety & efficacy	Topical	Mar 2018	36 humans	✓ **Safety:** Safe and well tolerated ✓ **Efficacy:** Significant reduction in age spot size and pigmentation

Source: (1) Kuah D, Sivell S, Longworth T, et al. Safety, tolerability and efficacy of intra-articular Progenza in knee osteoarthritis: a randomized double-blind placebo-controlled single ascending dose study. J Transl Med 2018;16:49.

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Well established chemistry, manufacturing and controls (CMC) process

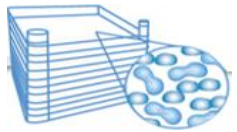
Source material

- Adipose-derived: adipose contains 500-1000 times more MSCs than bone marrow
- Allogeneic: multiple patients from a single donor. Improved product safety, potency, and consistency
- Rigorous donor screening process
- No genetic reprogramming of cells

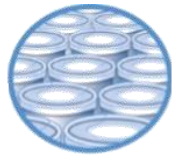
Process overview

Screen healthy donors based on strict cGCP and proprietary criteria

Single healthy adult lipoaspirate



Isolation, MCB and expansion of MSCs into two-tiered cell bank



Expansion of cells to manufacture millions of MSC doses

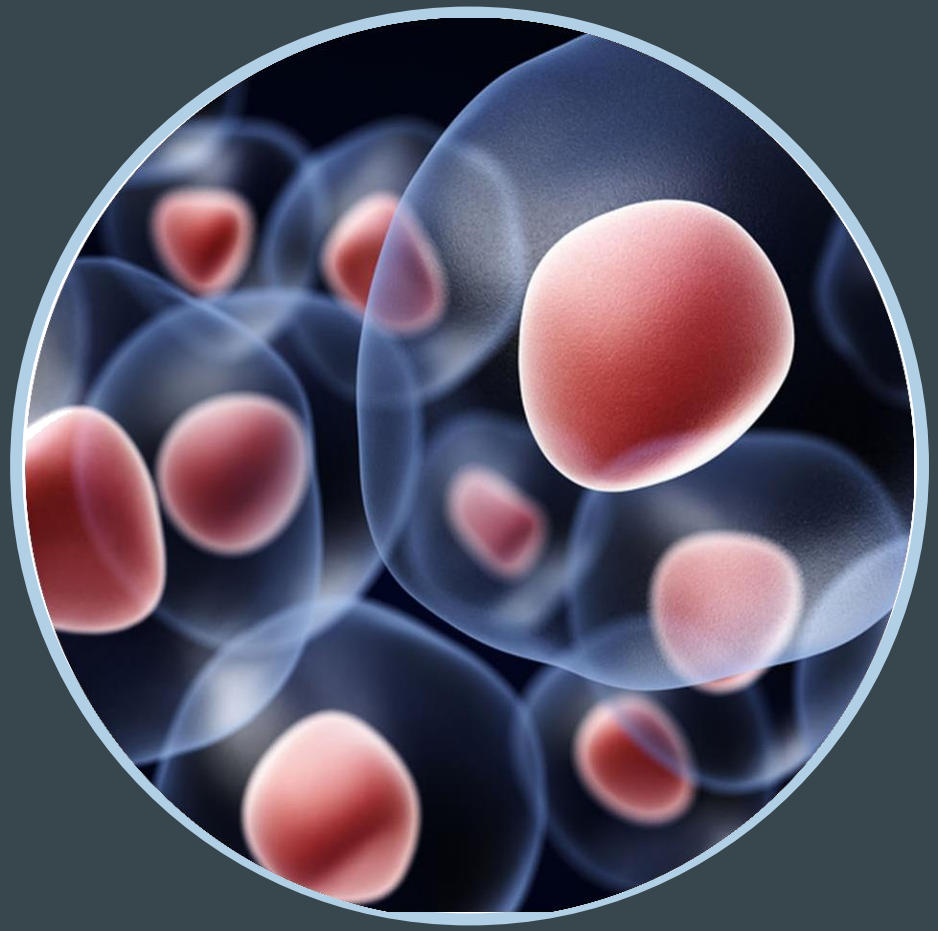
MSC long-term cryo-storage under GMP conditions

Millions of doses from single donor

Advantages

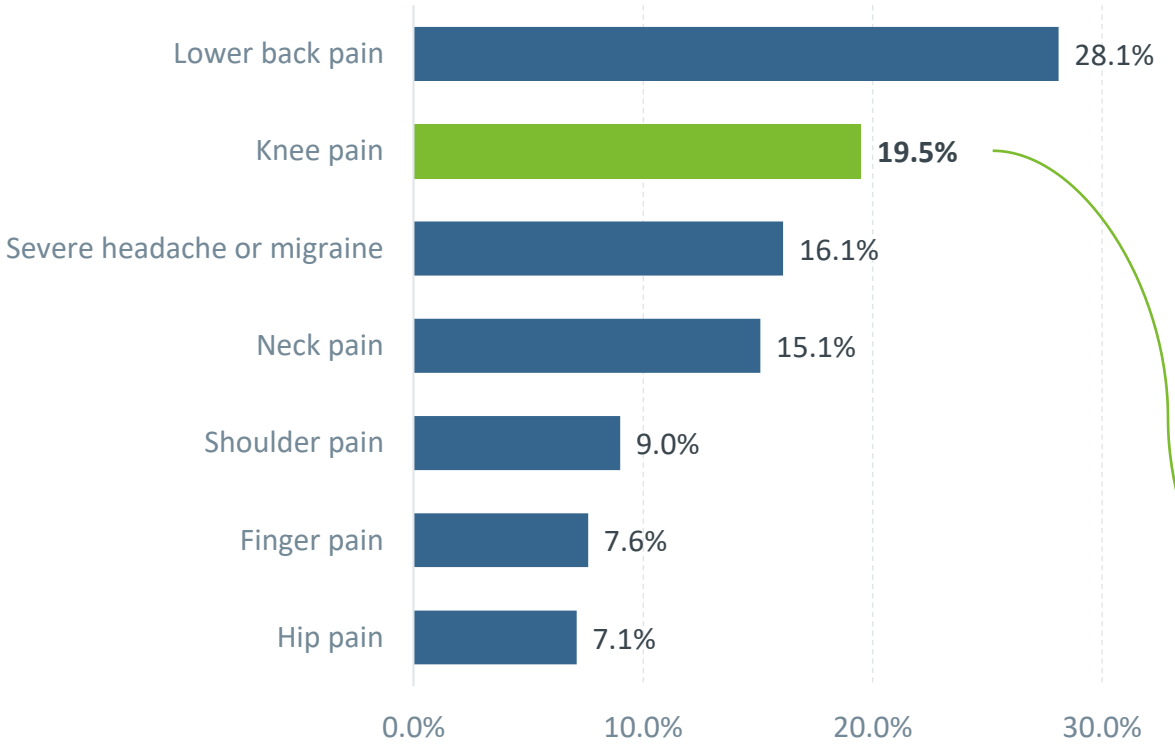
- ✓ **Optimised, highly scalable manufacturing process** of up to 100 million doses from a single donor
- ✓ **No source material or process variability**, resulting in a homogenous final product
- ✓ **Lower cost of goods (COGS)** compared to autologous therapies, pluripotent stem cell therapies, or EV therapies
- ✓ **Potential for further COGS reduction** by transitioning to a 3D bioreactor-based manufacturing process

Pain and osteoarthritis market opportunity



Pain is large, growing problem worldwide, with significant unmet need

Prevalence of chronic pain (1)



Large addressable market

1.5bn

people worldwide suffering from pain (2)

50%

of patients report inadequate relief (2)

Knee Osteoarthritis

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

Figure: Age-adjusted prevalence rates of select causes of chronic pain in US adults

Sources:

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

(2) Chronic Pain and the Health of Populations. Boston University; 2017

Knee osteoarthritis pathophysiology

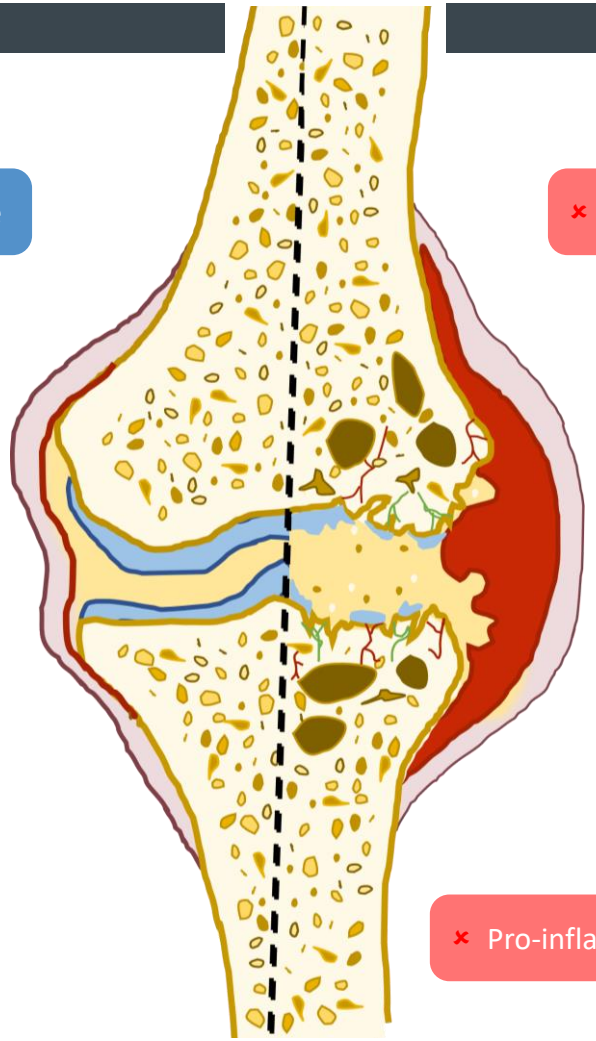
Osteoarthritis is the most common joint abnormality affecting humans

Osteoarthritis is an active dynamic disease of the entire joint involving an imbalance between joint tissue repair and joint destruction.

Complex pathogenesis involving mechanical, inflammatory and metabolic factors leading to joint destruction.

Pain is central clinical issue for patients

Healthy joint	Osteoarthritic joint
✓ Healthy articular cartilage	× Synovial fibrosis and inflammation
✓ Non-inflamed synovium	× Subchondral bone remodelling
✓ Intact subchondral bone	× Cartilage degradation
✓ Stable environment	× New nerve growth
	× Osteophyte formation
	× New blood vessel formation
	× Pro-inflammatory and degradative environment



Continuum of treatment options for knee osteoarthritis

Low — Severity of pain — High

Lifestyle modification

- Weight loss
- Exercise
- Physical therapy

- ✖ Patient adherence
- ✖ Insufficient in severe disease

Analgesics & Opioids

- Paracetamol
- Oral and topical NSAIDs
- Opioids

- ✖ Short-term pain relief
- ✖ Limited efficacy
- ✖ Poor tolerance
- ✖ Addiction risk (opioids)
- ✖ CV/bleeding (NSAIDs)

Injection treatments

- Corticosteroids
- Hyaluronic acid
- Platelet rich plasma (PRP)

- ✖ Short-term pain relief
- ✖ Inconsistent patient response
- ✖ Chondrotoxicity (steroids)
- ✖ Equivocal clin data (HA)
- ✖ Not reimbursed (PRP)
- ✖ Non-regenerative

Surgery

- Knee replacement

- ✖ Invasive surgery
- ✖ Long rehab time
- ✖ Limited lifespan/need for revision
- ✖ Not suitable for young patients
- ✖ High cost (US$30-50k)

Opportunity for disease-modifying therapeutics

Large addressable market with strong growth fundamentals

Large addressable market – interventional knee osteoarthritis treatments to manage advanced pain (steroids, hyaluronic acid, other therapies)

	Worldwide	United States	Japan	5EU: DE, FR, GB, IT, ES
Patients	240m[1]	33m[2]	25m [3]	52m [4]
Market size[4]	$6.1bn	$2.6bn	$1.5bn	$2.0bn

Attractive market characteristics

Ageing population

Increasing prevalence of obesity

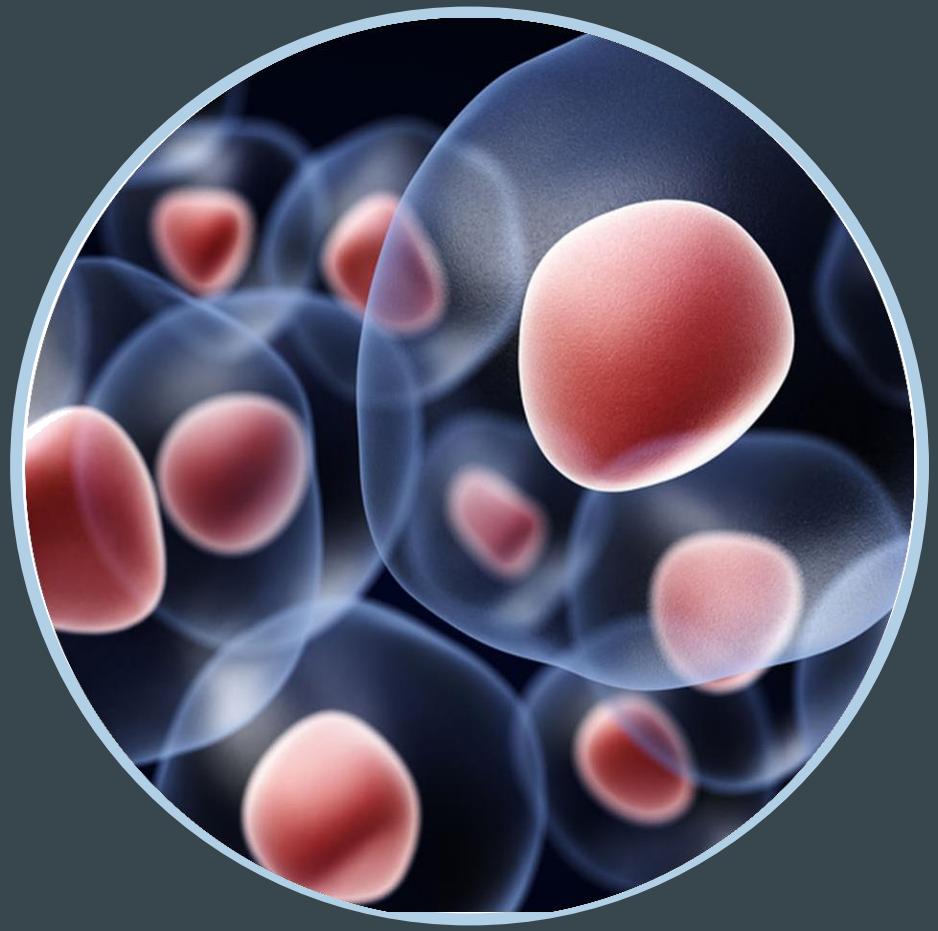
Dissatisfaction with existing treatments

No disease-modifying treatments

Sources:

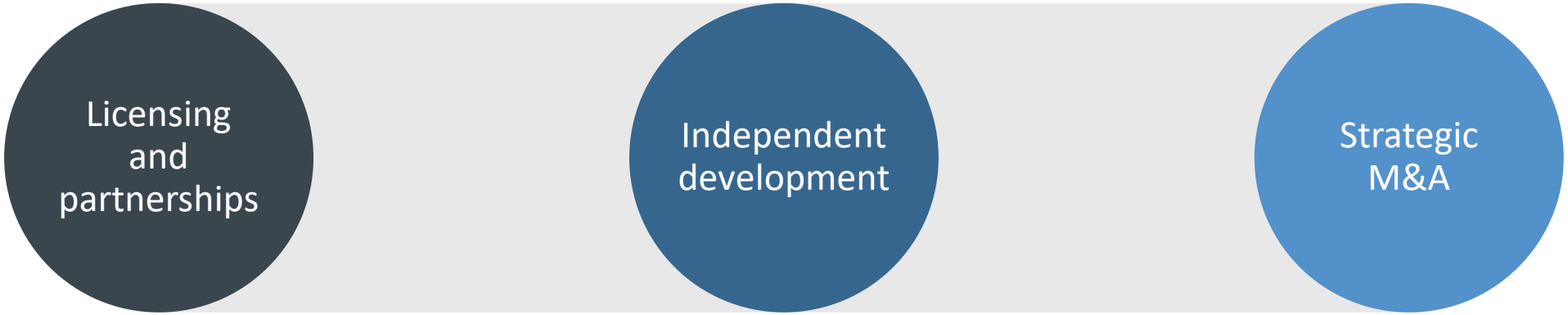
1) Osteoarthritis Action Alliance, https://oaaction.unc.edu/oa-module/oa-prevalence-and-burden/
2) Centers for Disease Control and Prevention (CDC)
3) Knee osteoarthritis only. *Epidemiology of osteoarthritis in Japan : the ROAD study*. 2011
4) GlobalData, Bruder Consulting, SmarTRAK, internal estimates

Value creation plan



Value drivers for Regeneus

Multiple levers to create shareholder value



- Launch Progenza OA in partnership with Kyocera in Japan
- **Licensing opportunities for Progenza OA in the United States, China, and South Korea**
- Progenza licensing opportunities in other indications (e.g. neuropathic pain)
- Licensing of Sygenus

- Progenza OA Phase 2 trial in the US
- Grant opportunities in the US and Australia
- Sygenus co-development with medical dermatology, cosmetics companies, and Government agencies
- Research partnerships with Monash University, University of Adelaide, UTS, and A*STAR Singapore

- **Strategic exit to a large pharma or a biotech company with significant potential for synergies**
- Synergistic bolt-on acquisitions to increase scale

Advanced clinical development pipeline

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Collaboration and licensing agreement with Kyocera for osteoarthritis in Japan

1

Regeneus is well on track to fulfil its obligations under agreement and earn future milestone payments and royalties

KYOCERA

- Kyocera is Japan headquartered global diversified conglomerate
- Revenue $15bn, market capitalisation $21bn
- Medical & Healthcare division manufactures medical products, including orthopaedic joint implants
- With no. 4 position in prosthetic knee market, Kyocera has an established network of orthopaedic physicians to distribute Progenza knee OA cell therapy
- Entering into the agreement with Regeneus demonstrates Kyocera's belief in the Progenza technology
- Kyocera responsible for product development, manufacturing, regulatory, and commercialisation processes in Japan
- Regeneus retains the right to negotiate licenses with parties within Japan for indications other than knee OA and outside of Japan for all indications

Milestone	Payment	Timing (CY)
Execution of Agreement	JPY 100m	Q3-20
Data transfer	USD 4.0m	Q3-20 – Q4-20
Establishment of manufacturing process	USD 3.0m	Q4-20 – 2023
50% of patients recruited for Phase 2 trial	USD 1.5m	2024
100% of patients recruited for Phase 2 trial	USD 1.5m	2024
Submission of New Drug Application (NDA)	USD 3.0m	2025
National Health Insurance (NHI) price listing	USD 4.0m	2026
Total	**USD 17.7m**	
Royalties from product sale	Single to double digit %	2026

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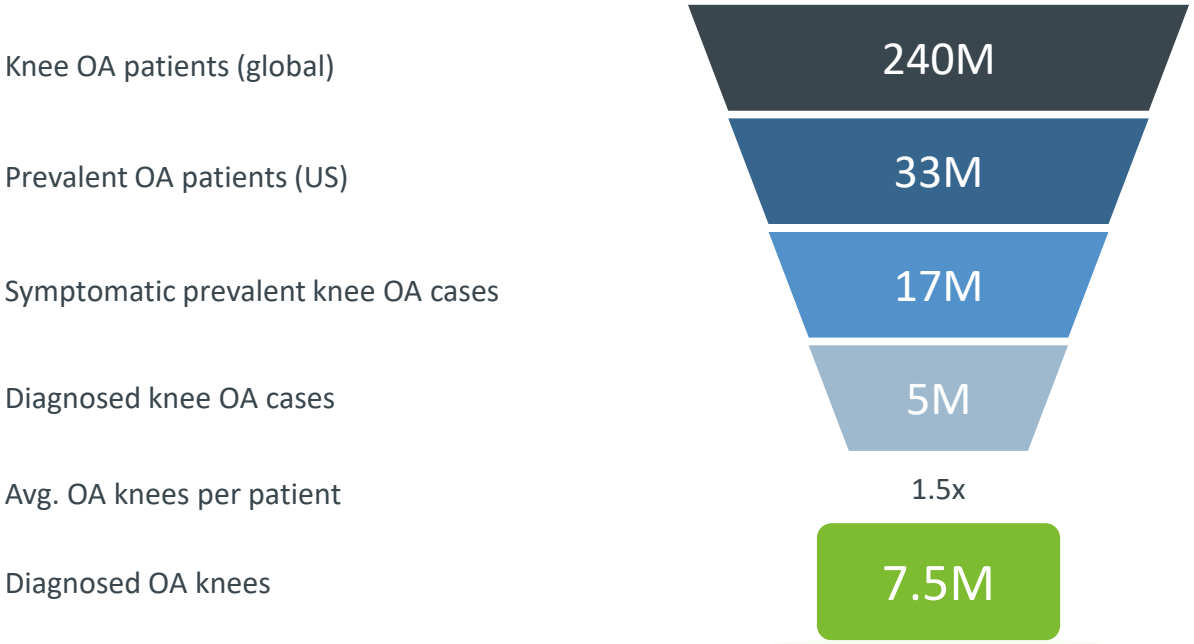
Large unmet need presents significant market opportunity in OA in United States



	Steroid injections	Hyaluronic Acid injections	Opioids & other therapies	Total knee arthroplasty
Annual procedures	4M	2M	900k	750k
Market size	$1bn	$1bn	$0.6bn	$26bn

Sources:
Osteoarthritis Action Alliance, https://oaaction.unc.edu/oa-module/oa-prevalence-and-burden/; Centers for Disease Control and Prevention (CDC); "*Osteoarthritis – Opportunity Analysis and Forecasts to 2026*" GlobalData, Bruder Consulting

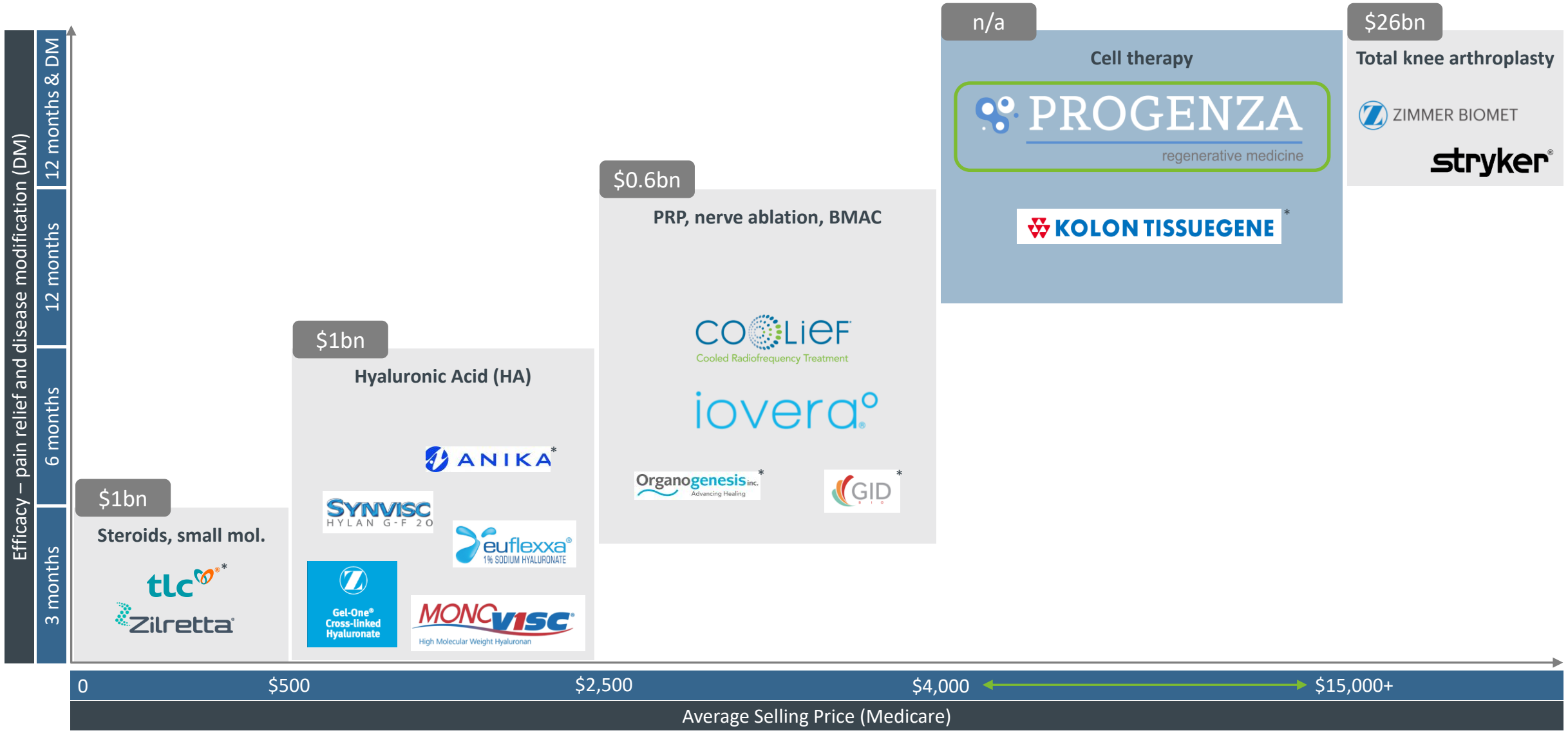
Pathway to FDA BLA approval by 2028 with strategic partner

2

- FDA Pre-IND Consultation meeting took place in November 2021
- Clear plan for the IND submission in 2023
- GMP manufacturing with the US based CDMO
- Indicative Phase 2 clinical trial design includes 100 patients
- Primary and secondary endpoints – 12 months pain reduction, knee function and stiffness, cartilage volume and thickness (disease modification)

Activity	Timing (CY)
Master Cell Bank manufacturing	Q4-20 – Q3-21
FDA Pre-IND Consultation	Q4-21
IND enabling studies	Q3-21 – 2023
GMP Investigational Drug manufacturing	Q3-21 – 2023
IND and IRB approvals	2023
Patient recruitment	2023
Follow-up period	2023 – 2024
End of Phase 2 FDA meeting	2025
Phase 3 trial	2025 – 2027
BLA and Approval	2028

Progenza is well positioned to enter interventional knee osteoarthritis care in US



Sources: Bruder Consulting, company websites, Medicare, SmarTRAK

Note: * denotes Phase 3 asset

Sygenus collaboration with Department of Defence in Australia

Opportunity to commercialise Sygenus cell free platform in clinical applications

- $300k provided by the Australian Department of Defence (DoD) to develop Sygenus for combat casualty care
- Competitive funding program through the Next Generation Technologies Fund focused on the R&D of emerging and future technologies
- Sygenus is a morphine alternative without the addiction and non-ambulatory considerations associated with morphine use
- Continues a successful 5-year research partnership with pain specialist, Mark Hutchinson, and his group at the University of Adelaide
- Regeneus retains the rights to Sygenus IP and has freedom to license the technology

Activity	Timing (CY)
Contract execution	Q2-21
Optimisation of product formulation	Q2-21 – Q3-21
Preclinical study in animal models	Q3-21 – Q4-22
Potential First in Human (FIH) pain trial	2023

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Attractive market potential	• Global pain management market is a growing and significant multi billion-dollar opportunity • Large unmet market need for disease-modifying therapeutics in osteoarthritis • Secular tailwinds in the osteoarthritis market – ageing population and increasing prevalence of obesity
Progenza OA Phase 2 ready asset	• Progenza OA is a Phase 2 ready asset with strong nonclinical and Phase 1 data — validated by Kyocera during the extensive technology due diligence process • Active pipeline of potential licensing opportunities in the United States, China, and South Korea
Near term value accreting opportunities	• Kyocera partnership to deliver additional US$13m in milestone payments in the next 3 years • Opportunities beyond osteoarthritis in Japan: — Progenza OA Phase 2 trial in the United States (2023) — Potential Sygenus Pain Phase 1 trial in Australia (2023)

Appendix: Glossary

- **Stem cells** are special human cells that are able to develop into many different cell types. Typical sources of stem cells are adipose (fat), bone marrow, placenta, and umbilical cord.
- **Mesenchymal stem cells (MSCs)** - multipotent adult stem cells present in tissues including bone marrow, fat tissue. MSC's can differentiate into multiple tissue including bone, cartilage, muscle and fat cells, and connective tissue.
- **Secretome** - proteins secreted by cells into extra-cellular space (outside of cells), and includes bioactive molecules like enzymes, growth factors and signaling proteins such as cytokines and chemokines which regulate immune response.
- **Adipose tissue** – fat tissue
- **Allogeneic cells** – single donor cells used with multiple patients
- **Pluripotent cells** – cells that can develop into any cell type in the body
- **Multi-potent cells** – cells that can develop into more than one cell type, but differentiation is more limited compared to pluripotent cells
- **iPSC** – induced pluripotent stem cells, a type of pluripotent stem cell derived from adult cells that have been genetically reprogramed to an embryonic stem cell-like state
- **FDA** – Food and Drug Administration, the regulatory body in the United States
- **PMDA** – Pharmaceuticals and Medical Devices Agency, the regulatory body in Japan
- **cGMP** – Current good manufacturing practice regulations enforced by the FDA. Provide for systems that assure proper design, monitoring and control of manufacturing processes and facilities. All drug manufacturers have to comply with cGMP regulations
- **PRP** – Platelet Rich Plasma, treatment for knee osteoarthritis
- **BMAC** – Bone Marrow Aspirate Concentrate (bone marrow stem cell treatment) for knee osteoarthritis
- **EV** – extracellular vesicles

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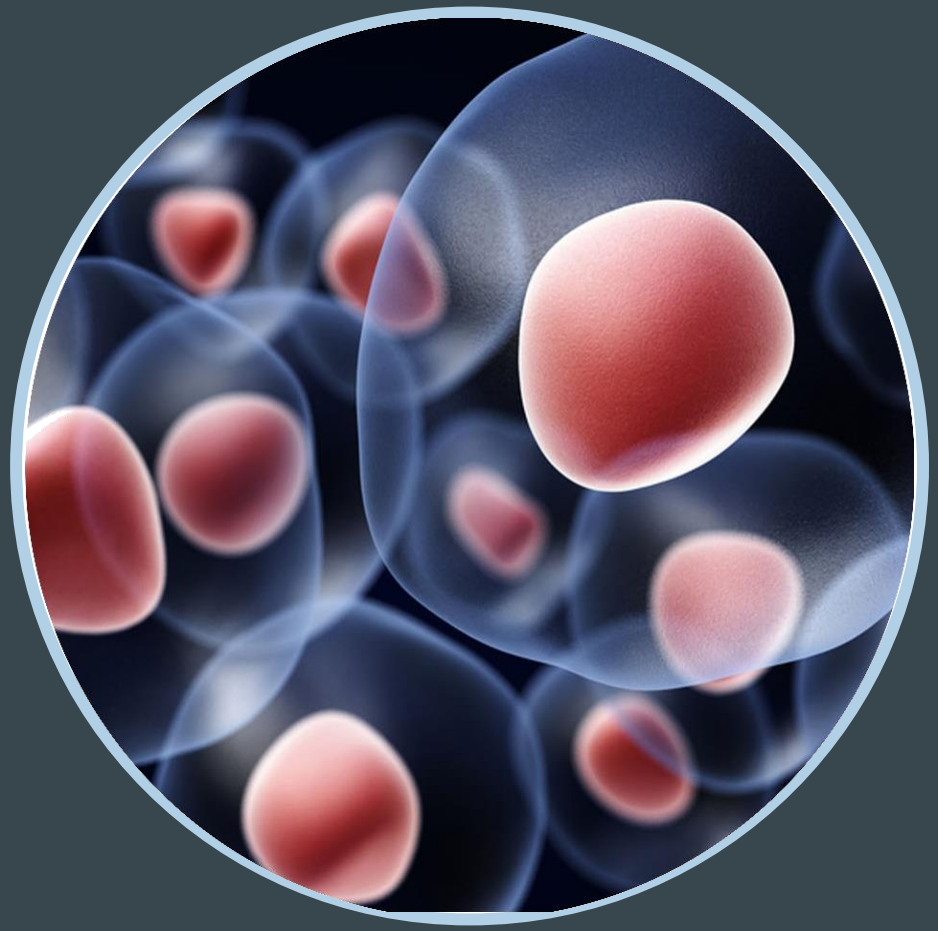

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