ASX Announcement
29 November 2022

AGM Chairman's Address

Regeneus Ltd (ASX: RGS) (**Regeneus** or **the Company**), a clinical-stage regenerative medicine company, provides its 2022 Annual General Meeting Chairman's Address.

- 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. Regeneus' regenerative platform technologies Progenza™ and Sygenus seek to address unmet medical needs in human health markets, focusing on neuropathic pain, osteoarthritis and various skin conditions. Visit www.regeneus.com.au for more information.

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

Regeneus 2022 Annual General Meeting

Chairman's Address

On behalf of the Board of Directors, I welcome you to Regeneus' 2022 Annual General Meeting. It really is a pleasure to be able to meet in person today, for the first time in three years, and for your Board to share with you the progress we have achieved this year.

As noted previously, our CEO, Karolis Rosickas, will provide you with a more fulsome update today with his shareholder presentation. Over the two years that Karolis has been with the Company, he has worked tirelessly to properly position Regeneus to capitalize on its technology, while continually reviewing all costs of our operations, to ensure the Company is sufficiently funded as we move towards commercialization of our lead stem cell technology platform, Progenza.

I would like to thank Karolis for his huge efforts in this regard.

Throughout 2022, we have continued to work collaboratively with Kyocera, under the terms of our Collaboration and Licence Agreement entered into in August 2020, to:

- establish Progenza manufacturing in Japan,
- launch a pivotal Phase 2 trial, and
- obtain Conditional Approval to commercialise the therapy for knee osteoarthritis patients in Japan.

While the Japanese market remains our core current focus, we continue with our search for strategic partners to co-develop Progenza™ in the United States, South Korea and China. Licensing discussions with a number of parties are advancing well, and we expect to secure at least one new partner in the near future.

The appointment during the year of Dr Scott Bruder to our Board as an Advisor is welcomed. Dr Bruder is assisting the Company on Progenza™ development work in the US following our Pre-IND Consultation with the US Food and Drug Administration in November 2021, and the licensing process for Progenza™ in the US.

We continue to progress the development of our second stem cell technology platform, Sygenus, through the development partnership entered into with the Department of Defence for combat casualty care. The development program is progressing well and multiple animal model studies have been performed over the last 12 months.

Our focus remains on bringing Progenza™ to market in Japan through our partnership with Kyocera, and securing partners in other major markets. Japan represents a significant market opportunity given its accelerated approval pathway for Progenza™. The global market for injectable treatments for knee osteoarthritis is US$6.1 billion, with the Japanese market alone worth US$1.5 billion.

The Company is also exploring various M&A options, including bolt-on acquisitions of other regenerative medicine companies and merging with other listed biotechnology companies.

There is no doubt that the bio-tech sector has been impacted greatly by recent market corrections worldwide and Regeneus is focused on preserving its capital to ensure it can continue to operate and deliver on its goals.

To this end, during the year, Regeneus secured a A$4 million working capital facility, secured against relevant milestone payments to be made by Kyocera under the Collaboration and Licence Agreement.

Regeneus operates under a lean, capital-efficient model, with a disciplined focus on operating costs and a continual focus on reducing cash-burn, to allow it to continue to advance its technologies and come out of the biotechnology industry recession in a strong position.

On behalf of our Board, I would like to thank our hard working and committed staff for their continued resilience during these challenging times and to thank our shareholders for your ongoing support and trust in us as we seek to capitalize on the commercialization of our differentiated stem cell technologies.

Barry Sechos
Chairman

ENDS

2022 Annual General Meeting
CEO Presentation

Developing next generation pain management and inflammation therapeutics

Regeneus Ltd
ASX:RGS

29 November 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 (25 Nov 2022)	A$ 0.045
Shares issued	306.4m
Market capitalisation	**A$ 13.8m**
Net Debt (as of 30 Sep 2022)	A$ 1.37m
Enterprise value	**A$ 15.2m**

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

- CEO, 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

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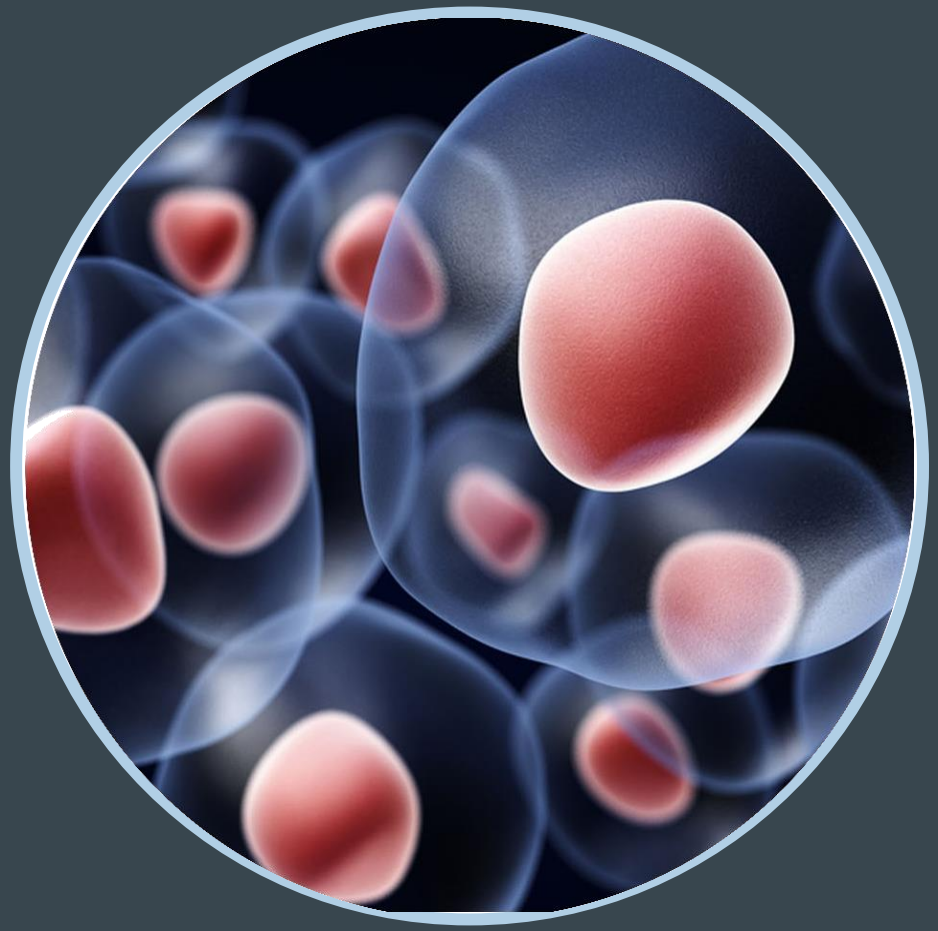
Regeneus investment highlights

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 Japan and the United States (2024) — 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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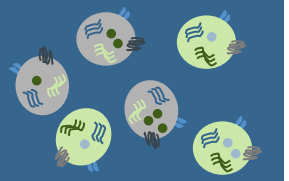
Bioactive Secretome

- 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

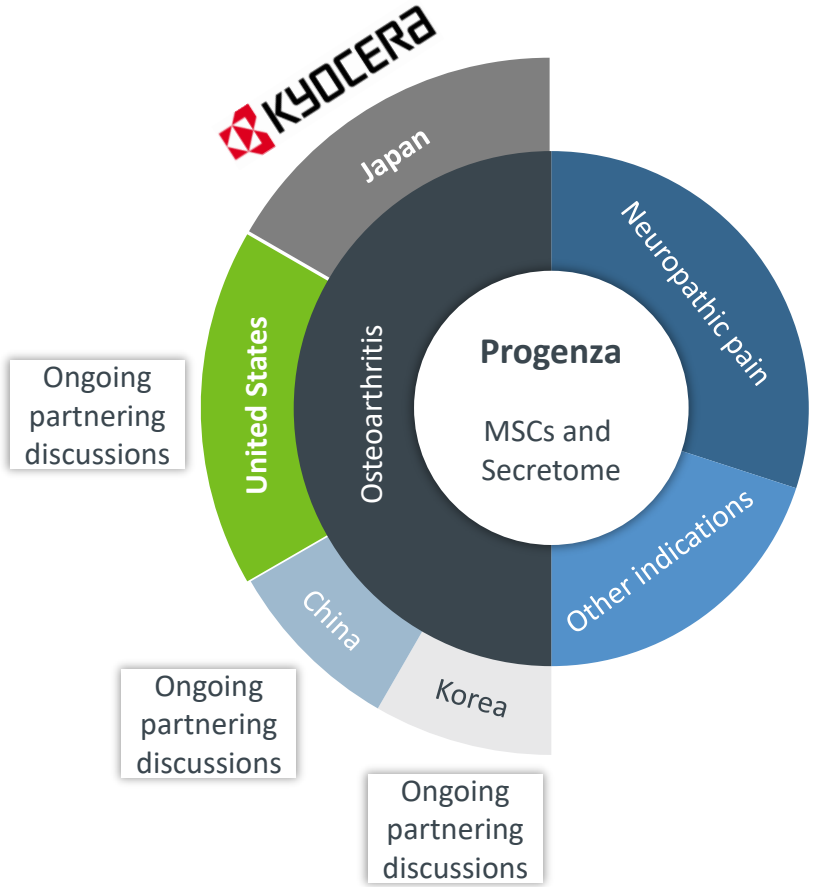
- MSCs are immune-privileged cells, which escape patient's immune system without the risk of rejection
- No genetic modification of cells

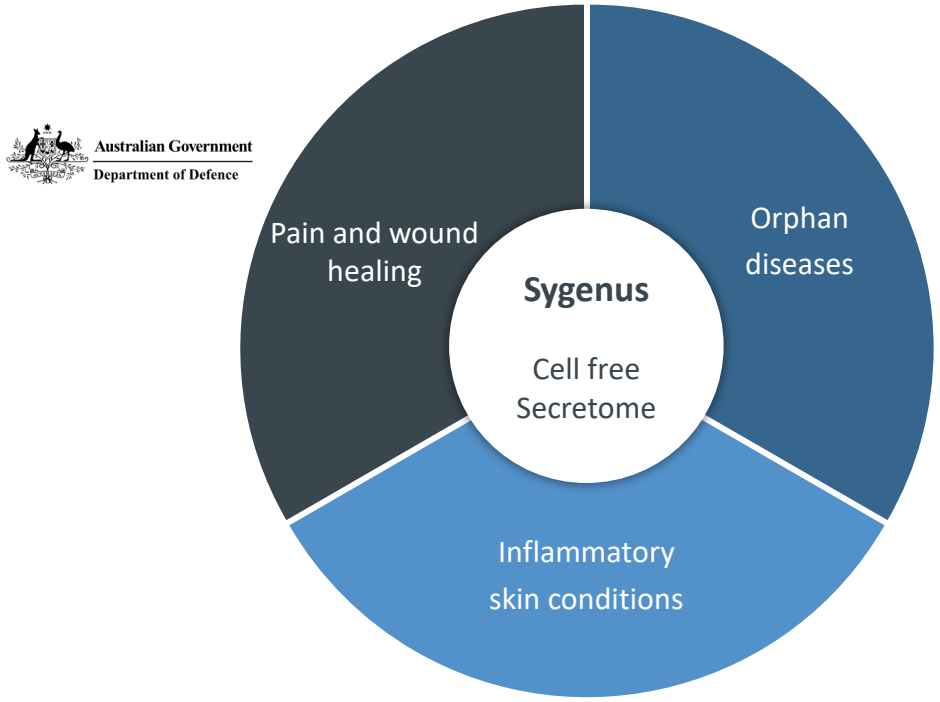
Superior efficacy

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

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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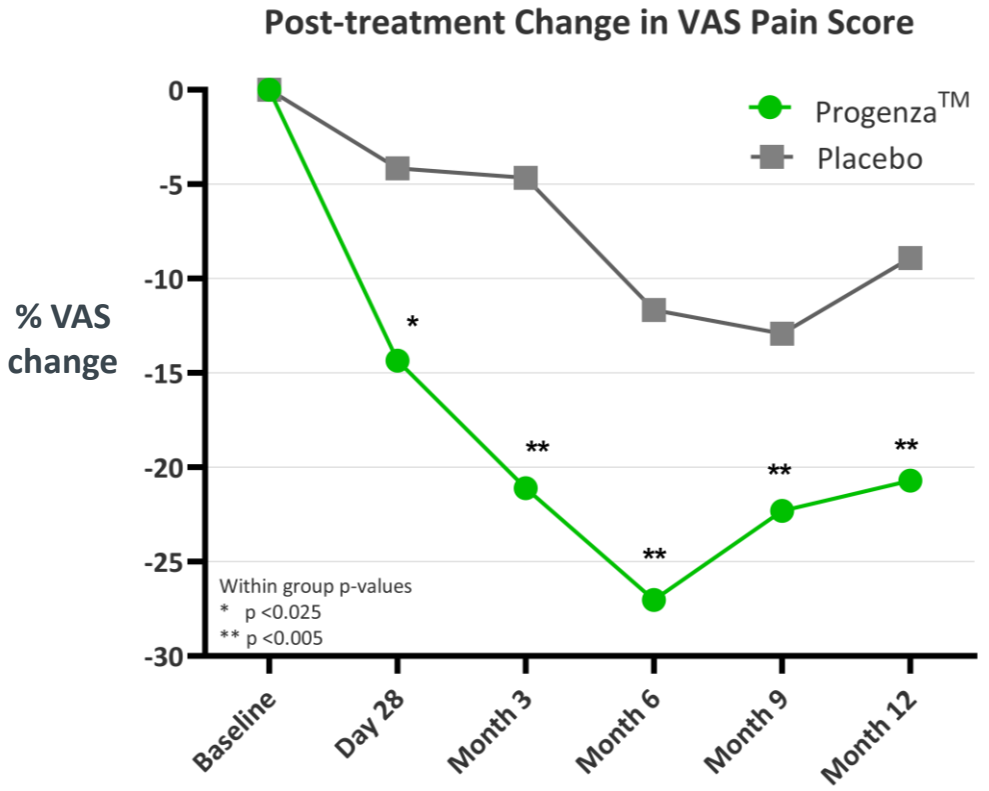
Phase 1 Progenza Results Demonstrate Statistically Significant Pain Reduction

Study Design/Observations

- 20 adults with symptomatic knee OA (KL grade 1, 2 or 3)
- Three treatment groups:
  - Low dose – 3.9M cells (n=8)
  - High dose – 6.7M cells (n=8)
  - Control group – saline (n=4)
- Met primary endpoints of **safety** and **tolerability** at both low and high doses with a **single injection**
- Met the secondary endpoints showing **efficacy**
  - Significant and **durable** pain relief relative to placebo out to 12 months (3.9M dose)
- Observed safety and efficacy profile supports transition to Phase 2 studies

Significant, Rapid and Sustained Pain Reduction



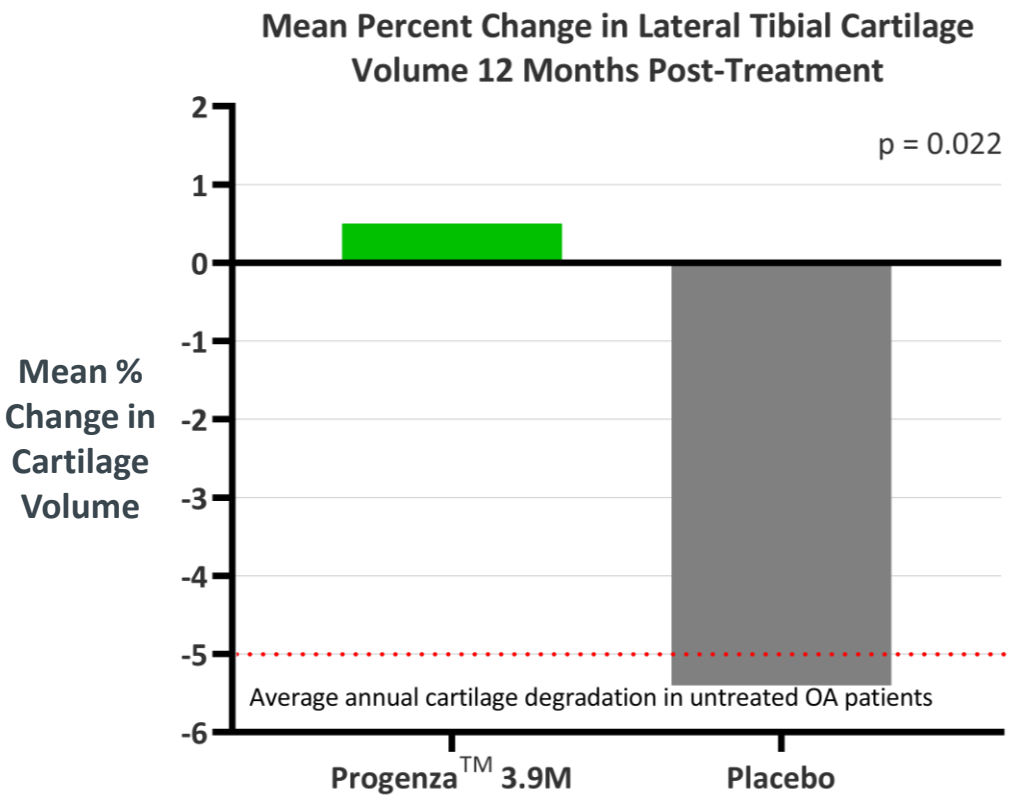
Reference: Kuah (2018)

Phase 1 Progenza Results Demonstrate Stable Cartilage Without Degradation

Preliminary Evidence of Disease Modification

- Cartilage volume was quantitatively assessed in all patients at multiple timepoints
- Patients treated with the 3.9M dose experienced **no decrease in cartilage volume** at 12 months
- Conversely, placebo patients showed statistically significant cartilage loss (~5%) over the same period
- Placebo patient experience mirrored that of untreated patients from the peer-reviewed literature
- Progenza's **concordant** clinical results (pain reduction coupled with halted disease progression) provide encouraging basis for future DMOAD claims

Halted Disease Progression Through 12 Months



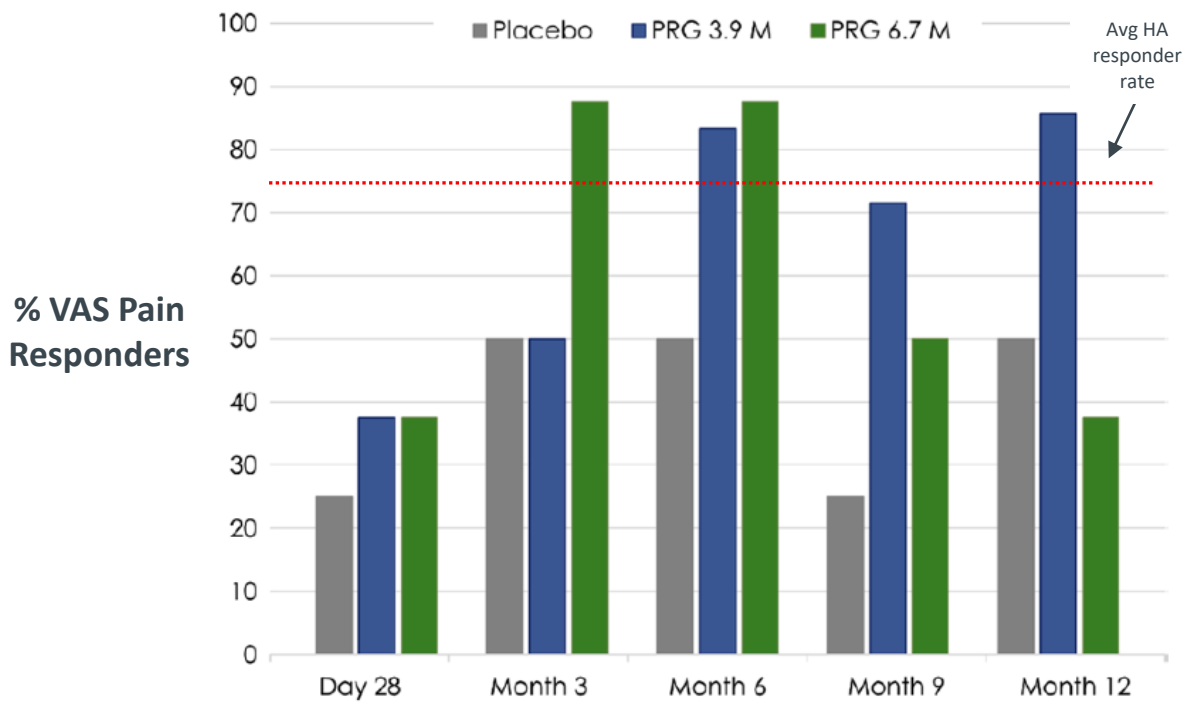
Reference: Kuah (2018)

Phase 1 Progenza Results Demonstrate High Patient Responder Rate

Preliminary Evidence of High Responder Rate

- All patients were evaluated for “VAS response” defined as ≥ 30% pain improvement relative to baseline
- 3.9M dose demonstrated **88% responder rate** at 12 months
- For comparison, a peer-reviewed analysis of RCTs of hyaluronic acid injections estimated a 74% responder rate using a lower threshold for success (i.e. ≥ 20% VAS improvement)
- Favorable clinical responder rate underscores a critically important aspect of Progenza’s potential therapeutic utility

Progenza Showed 88% Responder Rate at 12 Months



Reference: Kuah (2018), Maheu (2019)

Note: Progenza patients categorized as responders if >30% improvement in VAS pain over baseline. HA products per referenced paper evaluated per OMERACT-OARSI criteria, which requires a ≥ 20% improvement in pain, with an absolute change of ≥10mm.

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Established chemistry, manufacturing and controls (CMC) processes

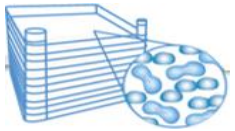
Source material

- 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

Single healthy adult lipoaspirate



Expansion and release of MSCs + secretome

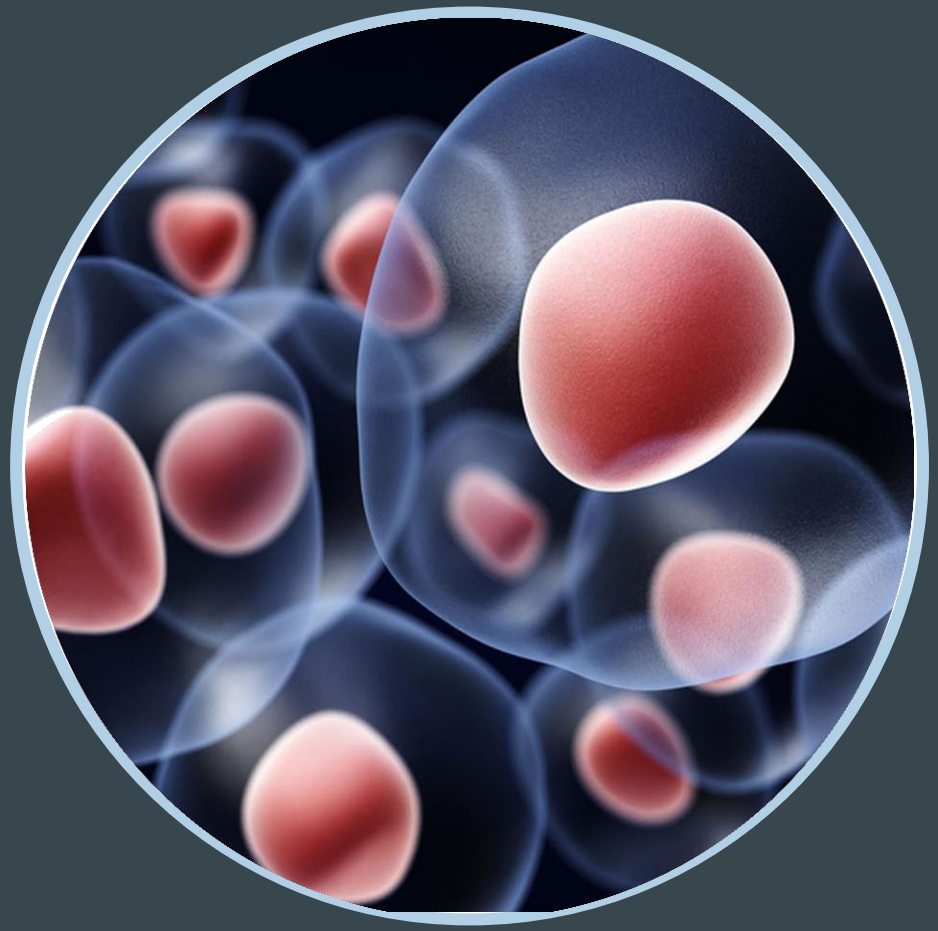
Cryo-storage under GMP conditions

Treat millions of patients from a single donor

Advantages

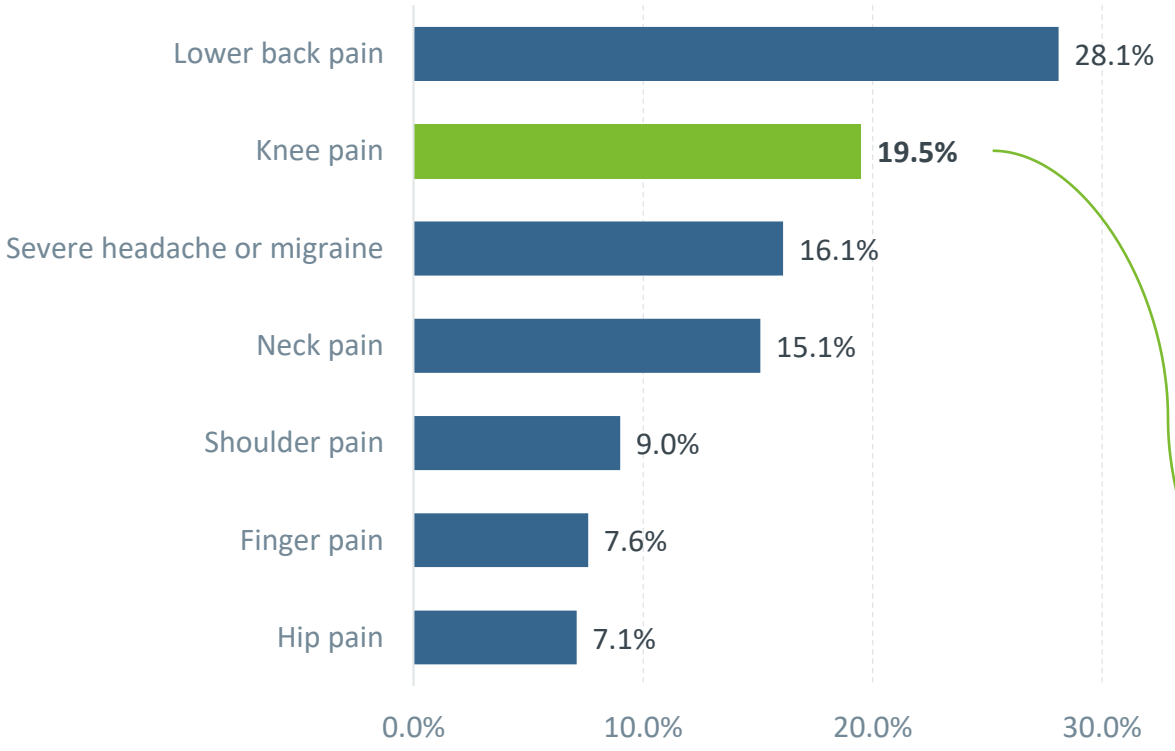
- ✓ **Optimised, highly scalable manufacturing process** of up to a million doses from a single donor
- ✓ **No source material or process variability**, resulting in a homogenous final product
- ✓ **Lower cost of goods (COGS)** compared to autologous therapies, pluripotent stem cell therapies, or EV 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 is highly prevalent and debilitating, driven by an aging population

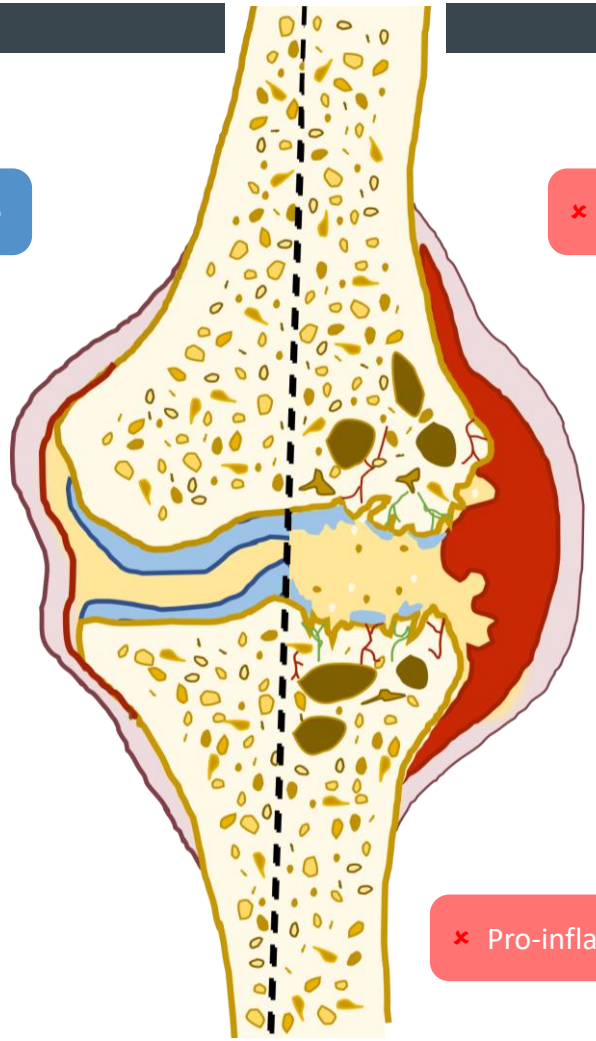
Osteoarthritis is the most common joint abnormality affecting humans

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 clinical 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 – injectable 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

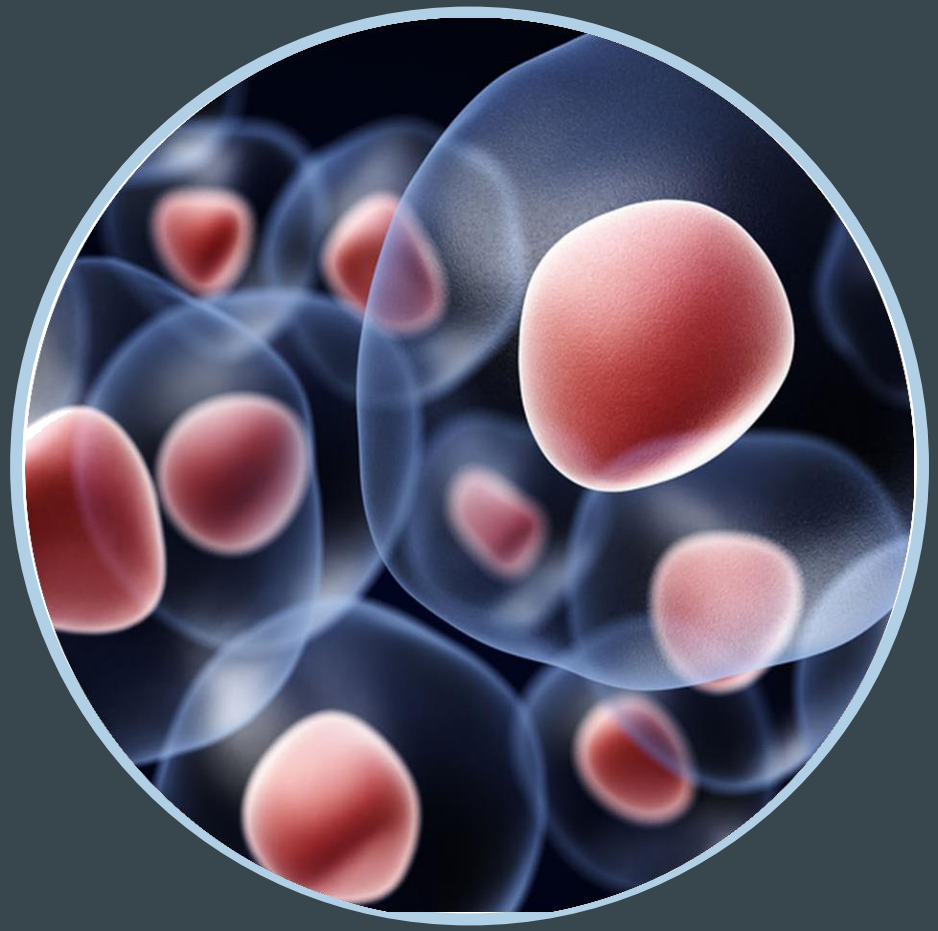
Dissatisfaction with existing treatments

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

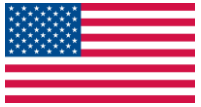
Multiple levers to create shareholder value

- Commercialise Progenza OA in partnership with Kyocera in Japan
- Licensing opportunities for Progenza OA in:
  - United States
  - China
  - South Korea

- Strategic exit to a big pharma or a biotech company with a significant potential for synergies
- Synergistic bolt-on acquisitions in adjacent regenerative medicine modalities

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

Update on Progenza OA licensing discussions

Country	Local advisor	Parties contacted	Due diligence processes
 United States	BRÜDER Consulting & Venture Group	70	5
 China	雅法资本 YAFO Capital	61	3
 South Korea	KDB산업은행	43	3

Update on M&A discussions

Sale of Regeneus

- 30+ exploratory discussions with listed and private biotechs in the US, Japan, Canada, and Australia
- Most companies are open to exploring an all-stock M&A route given challenging market conditions and potential for synergies
- Retaining a US small/mid cap-focused investment bank to run a structured sale process is being considered
- Potential transaction options:
    1) Sale for cash to a pharma co/biotech or other company,
    2) Sale for stock to a listed pharma co/biotech,
    3) Reverse merge into a Nasdaq/NYSE American listed shell (21 companies are currently exploring “strategic options”),
    4) Merge with a SPAC (a wave of SPACs are expiring in early 2023).

Bolt-on acquisitions

- Engaged in advanced due diligence discussions with a private US-based regenerative medicine company
- Phase 3-ready ophthalmology asset with two IND Applications approved by the FDA for the registration-enabling trials
- Significant product development synergies
- All-stock transaction structure is being contemplated by issuing new Regeneus shares to target company shareholders

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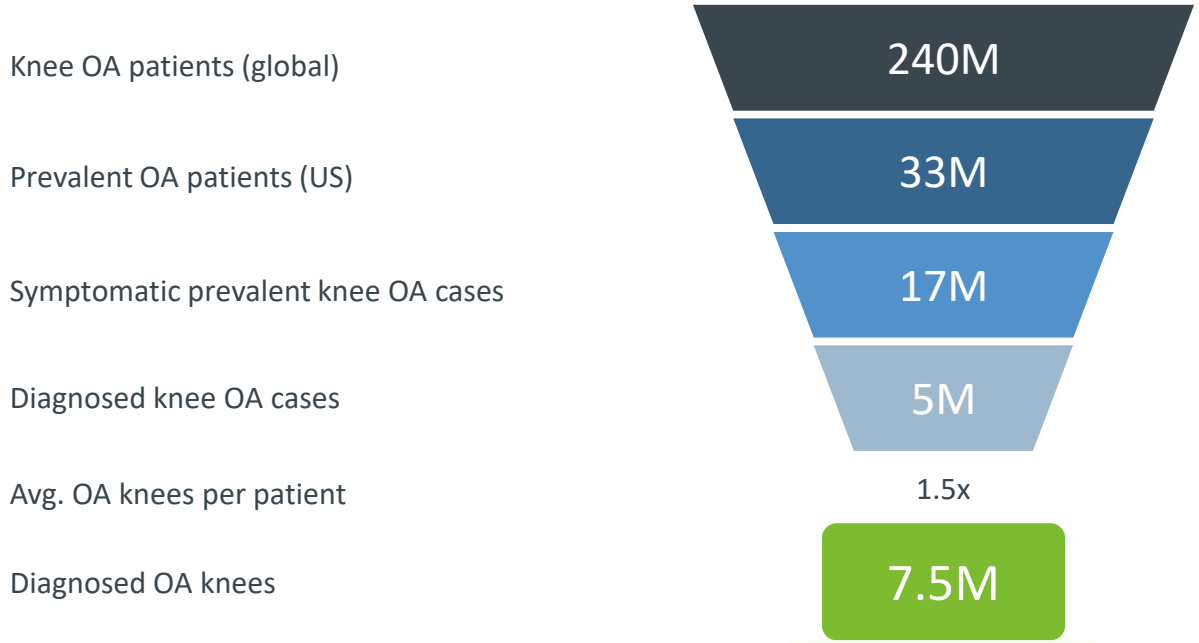
Large unmet need presents significant market opportunity in OA in United States



	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 2029 with strategic partner

2

- FDA Pre-IND Consultation meeting took place in November 2021
- Regeneus developed a detailed plan to submit an IND Application in 2023
- GMP manufacturing with the US-based CDMO
- An indicative Phase 2 clinical trial design includes c.100 patients
- Primary and secondary endpoints – 12 months pain reduction, knee function and stiffness, cartilage volume and thickness (for potential disease modification claims)

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	2023
IND and IRB approvals	2024
Patient recruitment	2024
Follow-up period	2024 – 2025
End of Phase 2 FDA meeting	2025
Phase 3 trials	2026 – 2028
BLA and Approval	2028 – 2029

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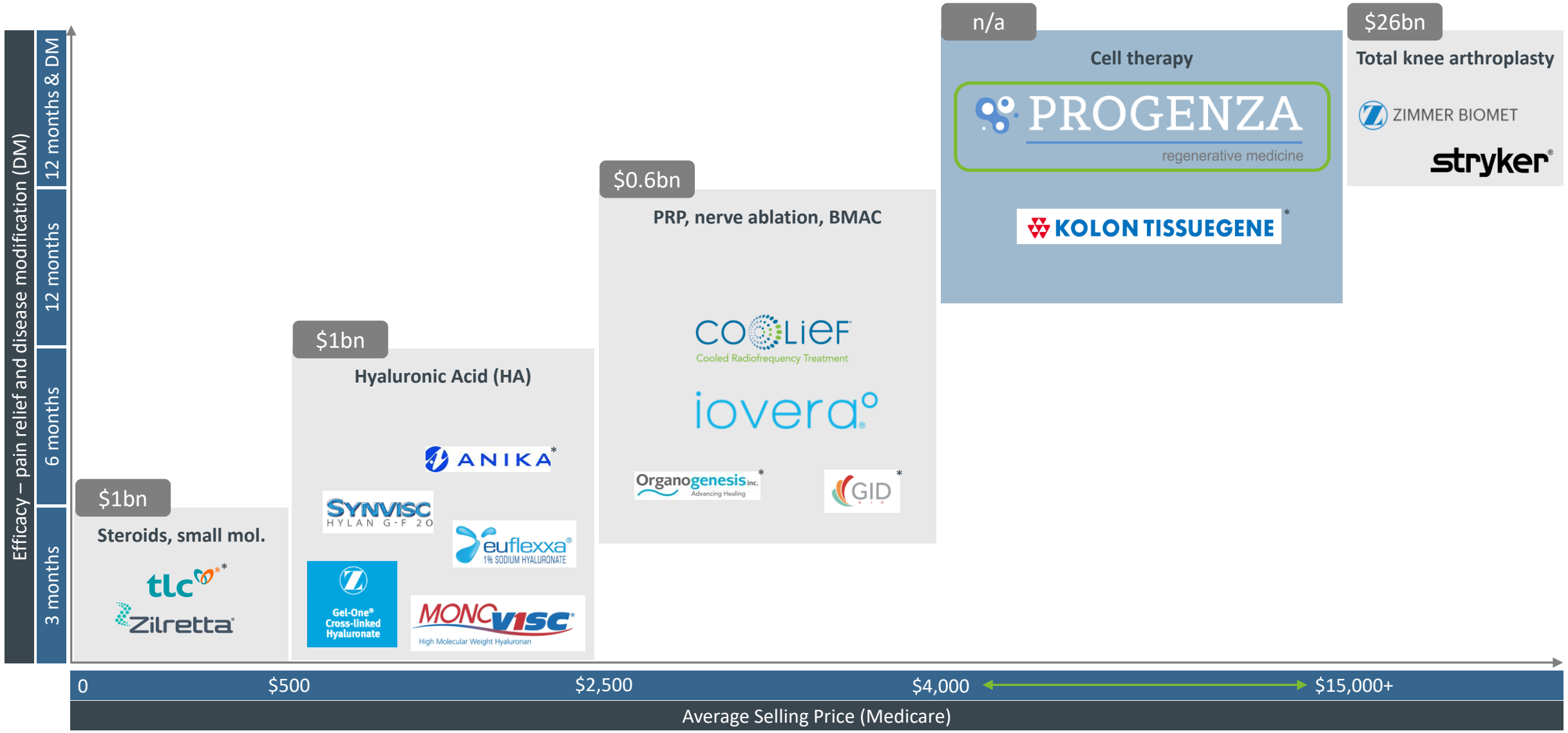
Progenza is well positioned to enter injectable knee osteoarthritis segment in US



Sources: Bruder Consulting, company websites, Medicare, SmarTRAK

Note: * denotes Phase 3 asset

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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 applications in combat situations
- 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

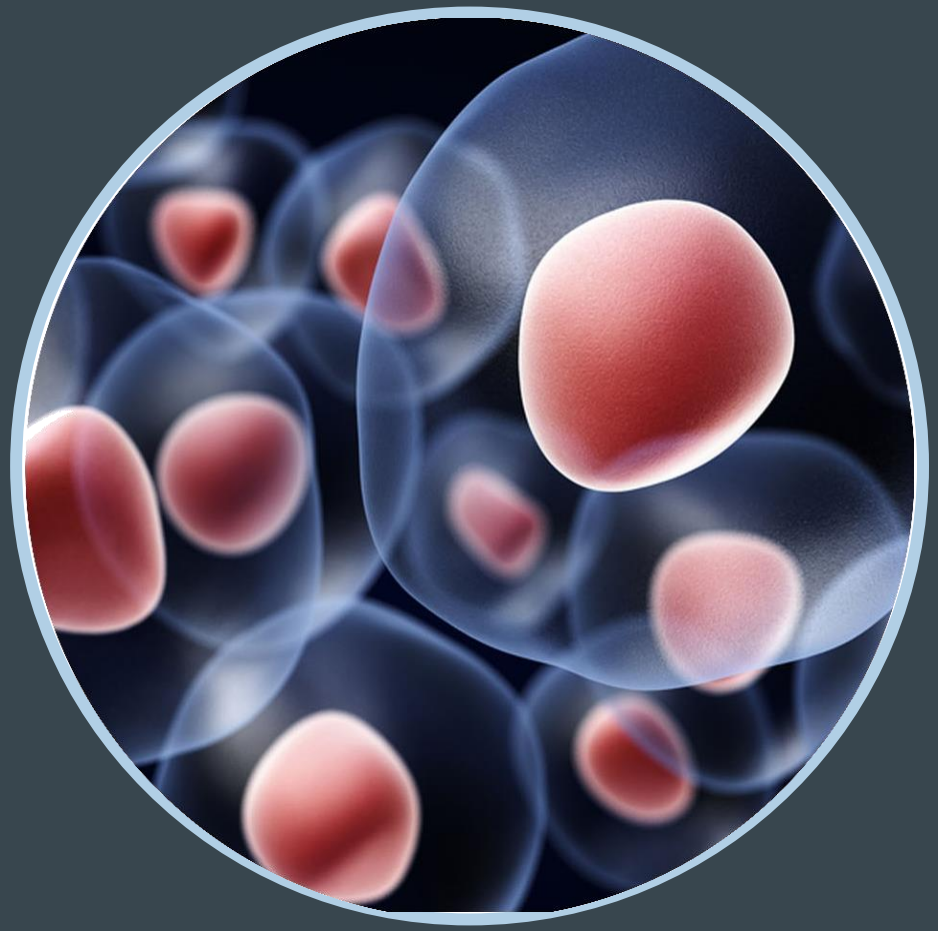
Activity	Timing (CY)
Contract execution	Q2-21
Optimisation of product formulation	Q2-21 – Q3-21
Preclinical study in animal models	Q3-21 – Q2-23
Potential First in Human (FIH) pain trial	2023

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 Japan and the United States (2024) — Potential Sygenus Pain Phase 1 trial in Australia (2023)

Appendix:
Biotech capital markets update

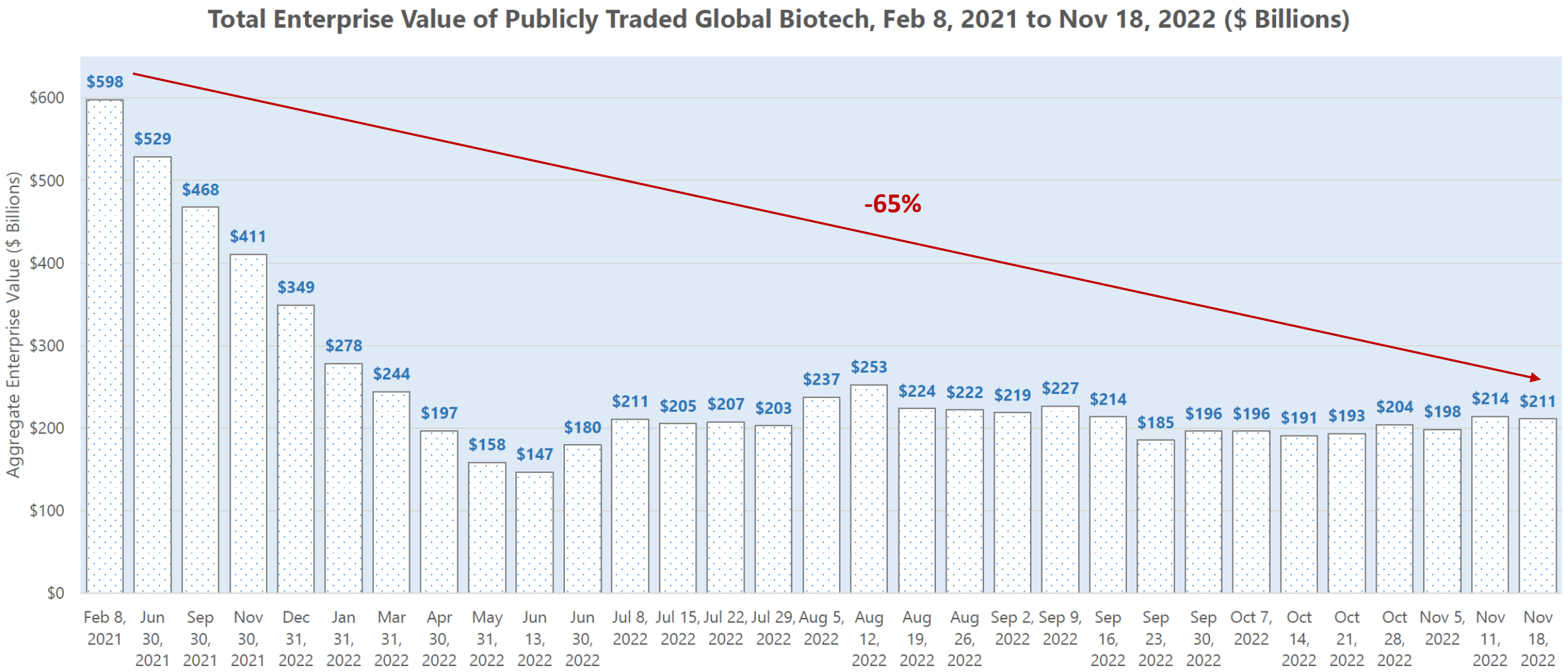


Biotech Index (XBI)

The duration and magnitude of the biotech market correction comparable to the bursting of “the genomics bubble” in 2001

Source: Credit Suisse, S&P 500 Biotech Index (XBI) used for 2008, 2015, 2021 cycles; Nasdaq Biotech Index used for 2001 cycle

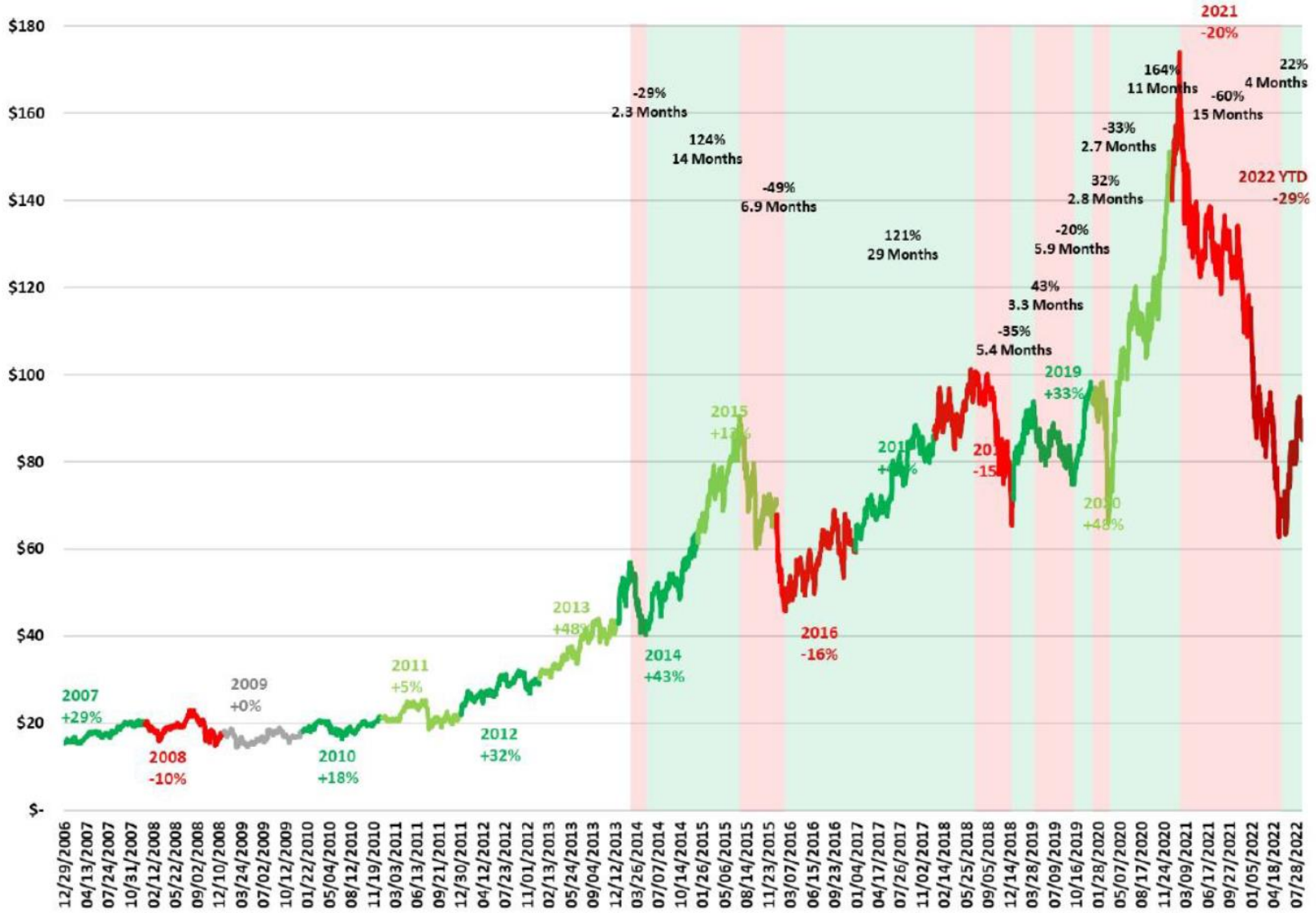
Global biotech enterprise values (EV) are down 65% since peak



- Number of worldwide biotech companies trading at negative EV worldwide – **204**. One third of US-listed biotechs are trading below cash

Source: Torreya Partners, CapitalIQ. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange.

Biotech Index (XBI) is potentially stabilising post-crash



Source: Michael Yee, Jefferies, "Reading the Yee Leaves" Thoughts Post Q3 and Upcoming Events of Focus (November 12, 2022)

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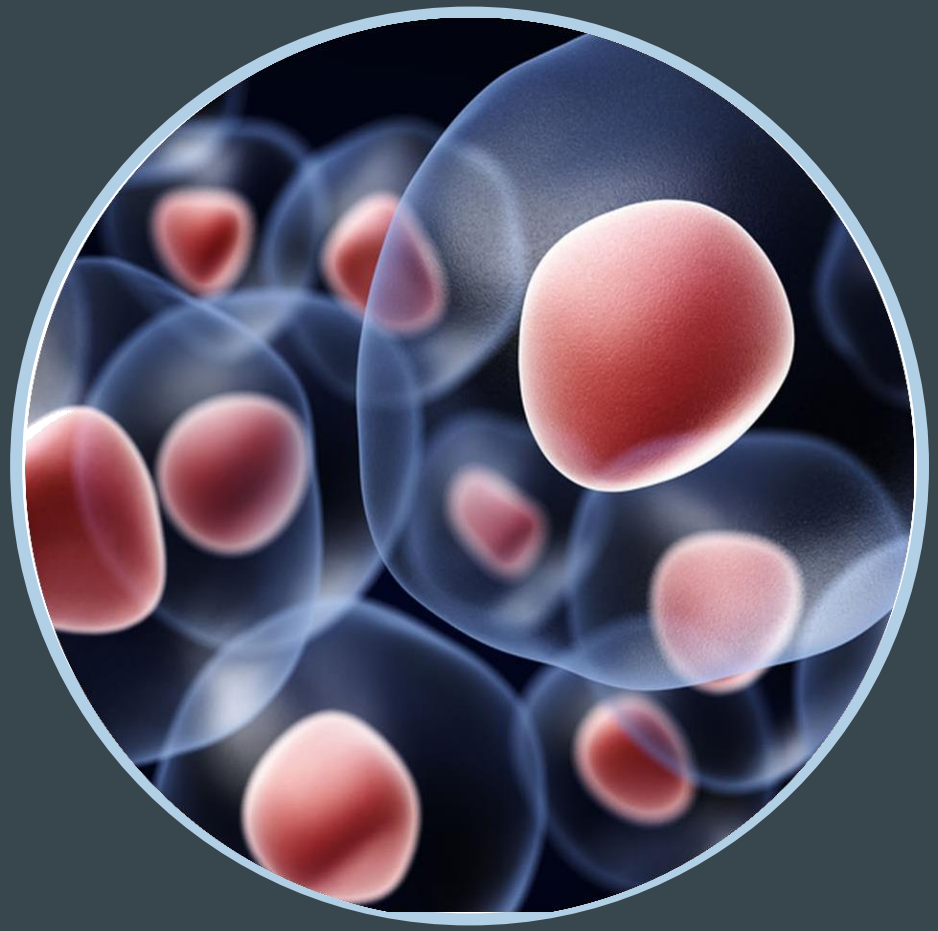

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