

ASX RELEASE

9 November 2022

Paradigm Presentation to the Bell Potter Virtual Healthcare Conference

Paradigm Biopharmaceuticals Ltd (ASX:PAR, “Paradigm” or “the Company”), a late-stage drug development company focused on delivering new therapies to address unmet medical needs, is pleased to share the attached presentation materials to all shareholders, that is being presented at the Bell Potter Healthcare conference. The conference will take place virtually over three days on 8, 9, and 10 of November 2022.

Paradigm CEO, Mr Marco Polizzi presented to the Bell Potter Healthcare Conference at 4:50pm on 8 November 2022. Mr Polizzi's session discussed recent Company milestones and progress of our lead clinical programs in osteoarthritis and mucopolysaccharidosis. This virtual conference will showcase Australia's best small to mid-cap healthcare and biotech companies.

A copy of the presentation is available on the paradigm website via the link:

<https://paradigmbiopharma.com/performance-progress/#presentations>

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About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing injectable (subcutaneous) pentosan polysulfate sodium (**iPPS**) for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

Authorised for release by the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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PARADIGM

B I O P H A R M A

Bell Potter Healthcare Conference 2022



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The Information is based upon management forecasts and reflects prevailing conditions, which are accordingly subject to change. In preparing the Information, the Company has relied upon and assumed, without independent verification, the accuracy and completeness of all information available from public sources, or which was otherwise reviewed by it. In addition, the analyses are not and do not purport to be appraisals of the assets, stock or business of the Company. Even when the Information contains a kind of appraisal, it should be considered preliminary, suitable only for the purpose described herein and should not be disclosed or otherwise used without the prior written consent of Paradigm. The Information is provided on the understanding that unanticipated events and circumstances may occur which may have significant valuation and other effects.

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About Paradigm

Paradigm Biopharmaceuticals Ltd is an Australian public company founded in 2014 that listed on the Australian Stock Exchange (PAR.ASX) in 2015.

SAS – Special Access Scheme
EAP – Expanded Access Program
ADL – Activities of Daily Living
PGIC – Patient Global Impression of Change

Proven Molecule

Lead Programs

Established Safety & Efficacy

Pentosan polysulfate sodium for subcutaneous use (PPS, iPPS)

- PPS is a **non-opioid** with a 60-year track record treating pain, inflammation and thrombosis in humans.

Osteoarthritis (OA) ZILOSUL®

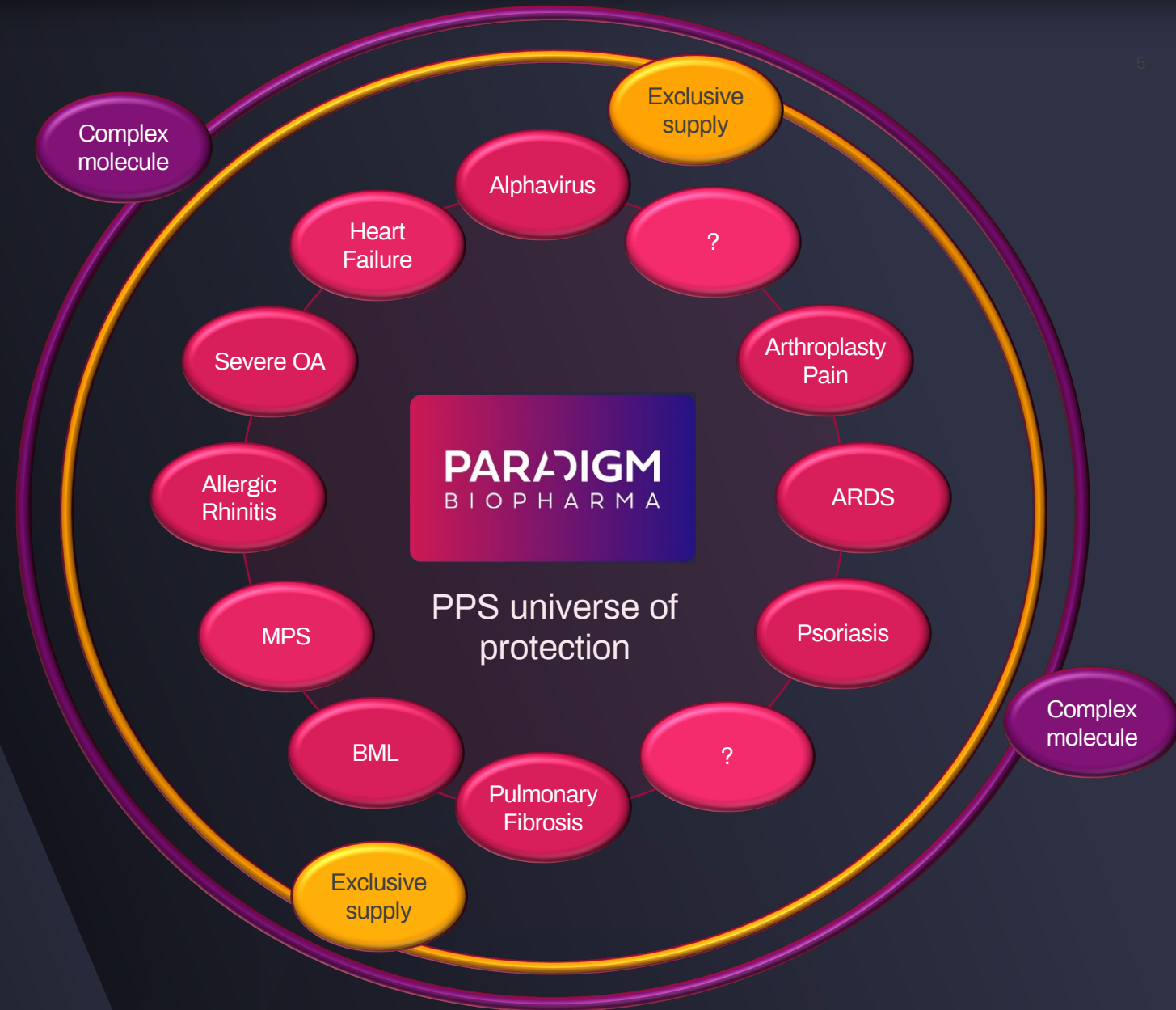
- Zilosul® is a **phase 3 asset** being studied to treat pain & function, inflammation, and cartilage degeneration in OA.
- OA program granted FDA Fast Track
- Globally Harmonised protocol to secure simultaneous approval in all key jurisdictions

Mucopolysaccharidosis (MPS I & VI)

- Phase 2 asset in ultra rare disease
- PPS has demonstrated potential to treat residual musculoskeletal symptoms in MPS as adjunct to standard of care therapy.
- Phase 2 OA trial provided encouraging evidence of **meaningful treatment effects** compared to placebo overall for pain, ADL, and PGIC.
- Real world evidence with 700+ OA patients treated via SAS in Australia and EAP in the US.

Extensive market protection

- Molecular platform technology and a complex trade-secret manufacturing process makes it extremely difficult to replicate
- The starting material is extracted from a plant-based biological source and then chemically modified using a multi-step manufacturing process
- Exclusive supply for 25-years post marketing and ongoing development agreements with the originator and only FDA-approved API manufacturer for human use
- Multiple method of use patents, continually refined and expanded with additional patents being pursued

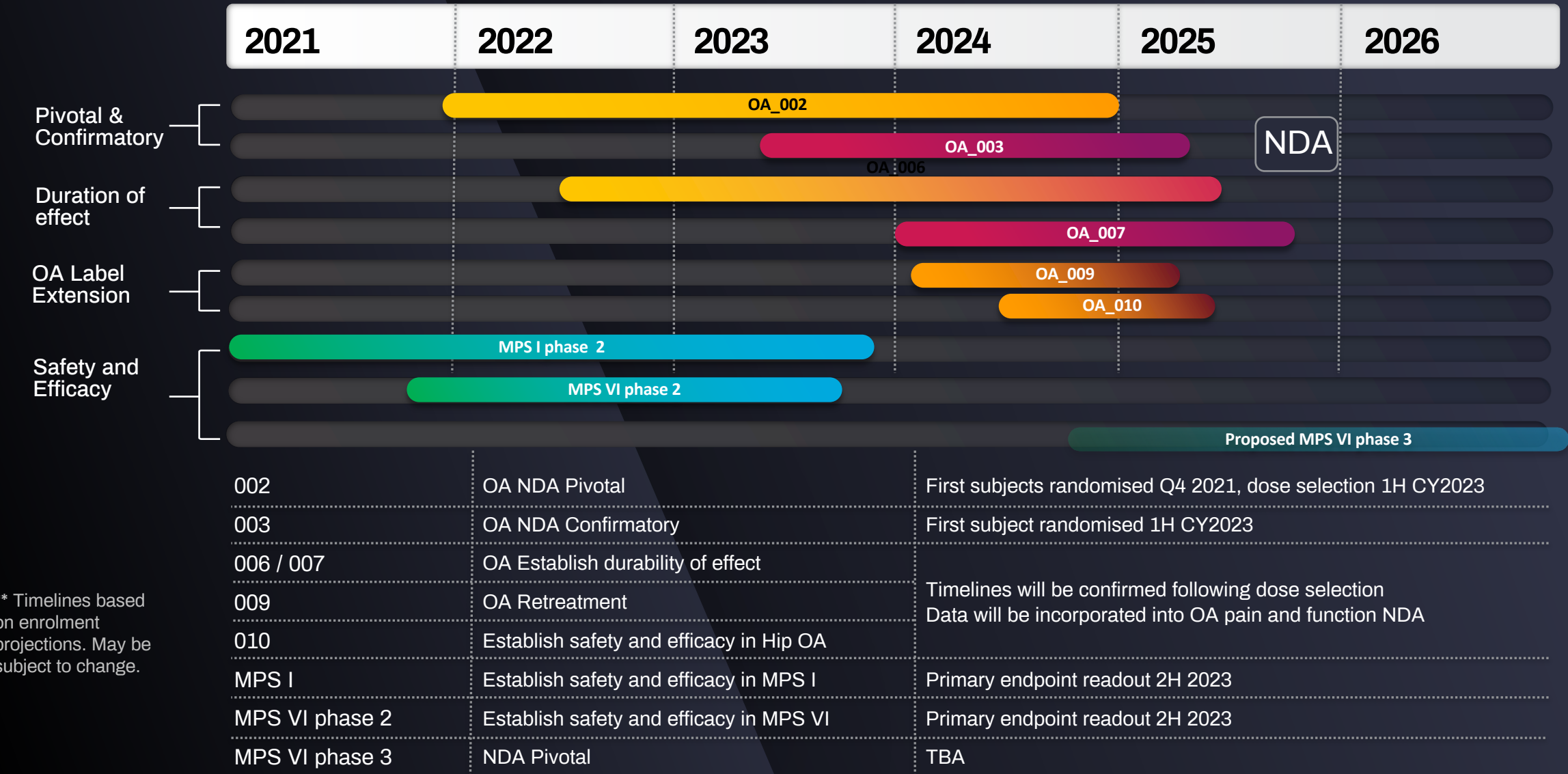


Recent Company Milestones

- FDA Fast Track designation granted for OA program
- Canada regulatory and ethics approval for phase 3 OA trial
- Research partnership with NFL Alumni Health
- MPS clinical program update – safety review of phase 2 clinical study
- A\$66m capital raising – funding the Company into 2024
- Positive top-line data from a phase 2 synovial fluid biomarker trial. Primary endpoint achieved and significant reduction in WOMAC scores compared to placebo.
- First phase 3 OA subjects dosed in UK
- PARA_OA_006 extension study commenced



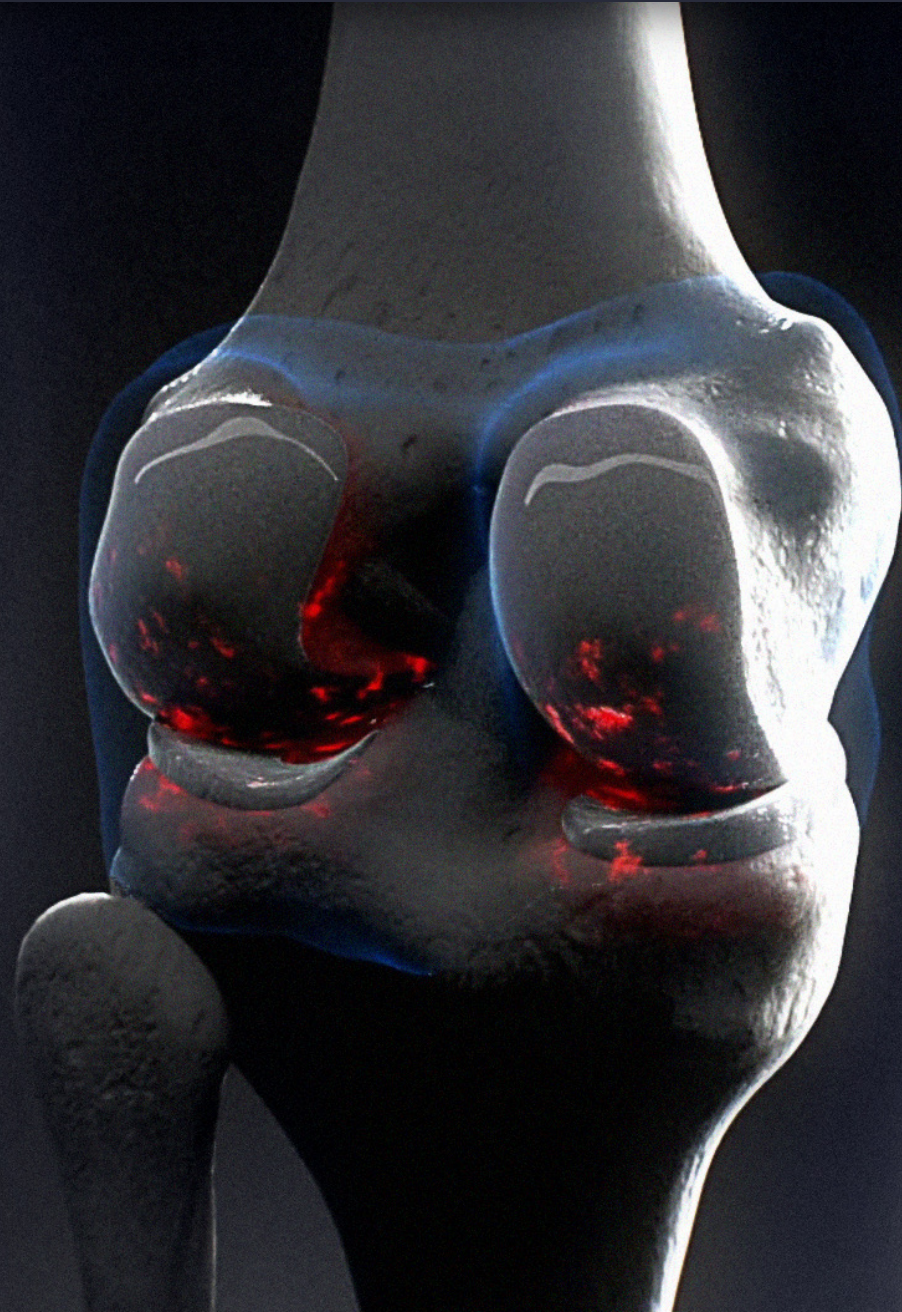
Lead Programs



** Timelines based on enrolment projections. May be subject to change.

Osteoarthritis

OA



Osteoarthritis - Global Phase 3

PARA_OA_002 Global Progress

United States

- Fast Track Designation
- 50+ sites activated
- Enrolling participants
- DSMB review December

Australia

- 8 sites activated
- Enrolling participants

UK and Europe

- 12 sites selected
- UK reg & ethics approval received
- First UK site activated and commenced screening activities
- First UK subject randomised

Canada

- Regulatory and ethics approval received
- Up to 10 sites to be activated in Q3 2022



PARA_OA_008 – Top-Line Results

Day 56 Top-Line Results – Changes in Synovial Fluid Biomarkers

- iPPS impacted multiple biomarkers measured in the synovial fluid:
 - NGF reduction indicates mechanisms relating to pain reduction;
 - Reductions in TNF- α and IL-6 indicate mechanistic effects on inflammatory pathways;
 - Reductions in COMP and ARGS and increases in TIMP-1 provide important insights on iPPS mechanisms impacting cartilage preservation.
- In all cases, the synovial biomarker changes in iPPS-treated subjects at day 56 were favourable compared to placebo control.



PARA_OA_008 - Clinical Outcomes

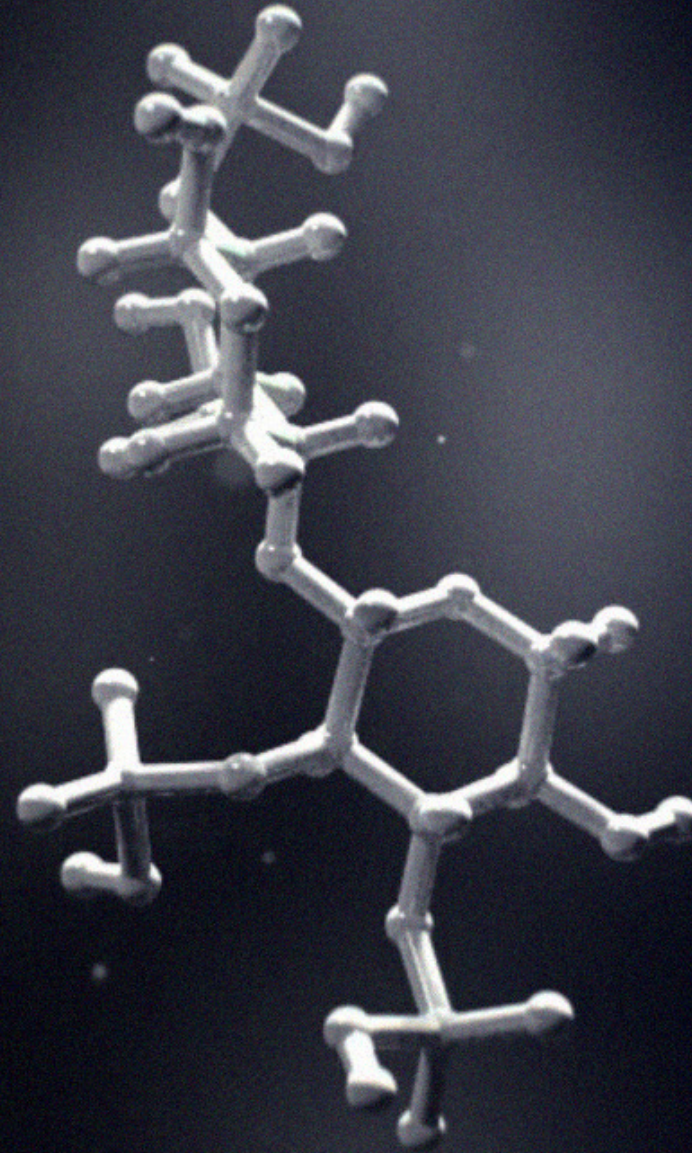
Day 56 Top-Line Results – Changes in WOMAC Pain and Function from Baseline

- Participants in the study were asked to provide baseline pain scores using the WOMAC Osteoarthritis Index.
- iPPS treatment showed statistically significant improvements at day 56 in pain, function, stiffness, and overall WOMAC scores for twice-weekly iPPS compared to the placebo arm.
- The proportions achieving $\geq 30\%$ and $\geq 50\%$ improvement in pain were 73% and 60%, respectively.
- The reduction in pain for iPPS-treated subjects are consistent with the clinical effects observed in this and prior studies of iPPS in osteoarthritis.



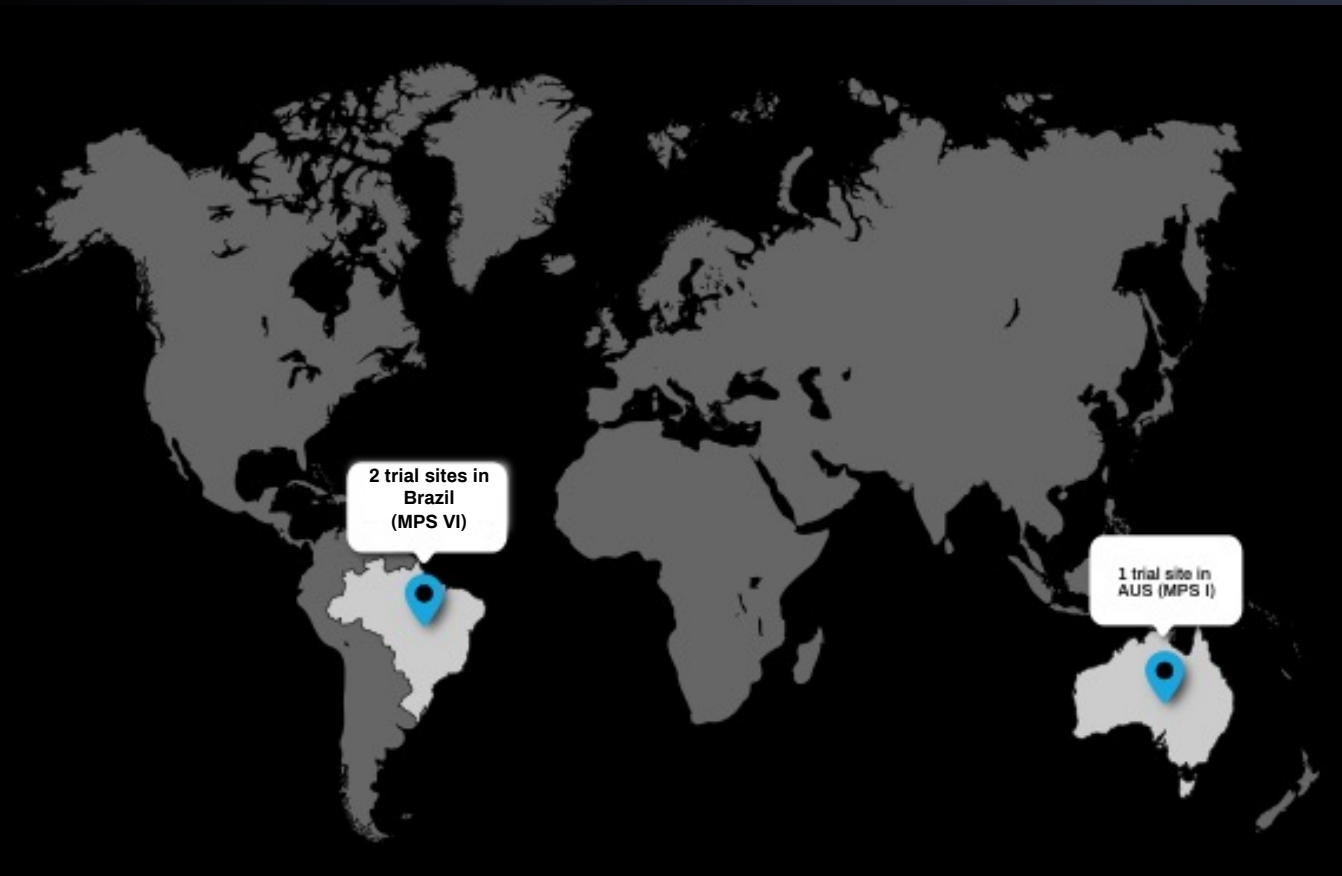
Mucopolysaccharidosis

MPS



Mucopolysaccharidosis (MPS)

Phase 2 asset in rare disease associated with inflammation and ongoing musculoskeletal pain – PPS has FDA and EMA orphan designation for MPS



MPS I - Australia

- Open-label trial dosing subjects weekly SC for 12 weeks, then every other week for a total of 52 weeks.
- Primary endpoint is safety, key secondary endpoints are pain and function, as well as PK.
- Interim top-line data presented at ICEIM 2021 by primary investigator Dr Drago Bratkovic showed PPS is well tolerated, demonstrating reduction in pain and GAGs, and improvement in function.
- Data to be presented by Dr Bratkovic at ICLD 2023 and will cover information on pain, function, urinary GAGs and change in biomarkers.

MPS VI - Brazil

- A double-blind placebo-controlled trial with 12 subjects. Dosed weekly SC for 52 weeks.
- Primary endpoint is safety, key secondary endpoints are pain and function.
- 100% recruitment expected by the end of CY 2022.
- Safety Monitoring Physician confirmed two successful safety reviews in participant aged 9-16 and 16+ cohort with the clinical trial now assessing the youngest cohort (5-9 year old's).



Upcoming Milestones

Upcoming near-term news flow

- PARA_OA_002 – first data safety monitoring board review Q4 CY2022
- FY22 tax rebate Q4 CY2022 circa ~A\$7m
- Further IP generation and protection
- MPS-VI – 100% recruitment expected Q4 CY2022
- MPS-I – data presented at International Conference on Lysosomal Diseases Q1 CY2023
- PARA_OA_008 – 6-month data Q1 CY2023
- Canine OA model – 20-week follow-up (3-year human equivalent) data 1H CY2023
- PARA_OA_002 – stage 1 dose selection 1H CY2023.





For more information please visit:
paradigmbiopharma.com

