PARADIGM BIOPHARMA

Bell Potter Healthcare Conference 2022

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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

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.

Lead Programs

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)

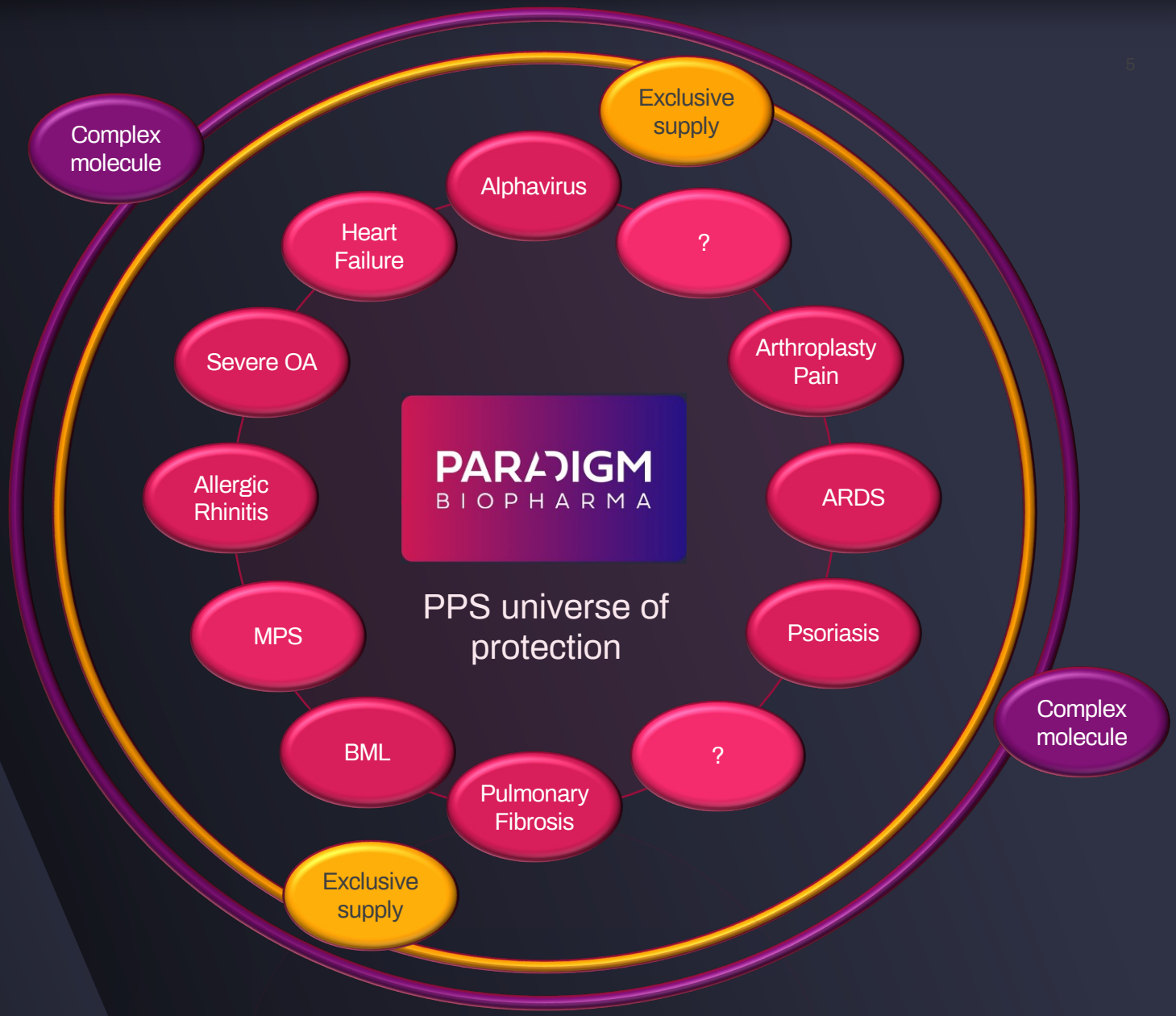
- Phase 2 asset in ultra rare disease
- PPS has demonstrated potential to treat residual musculoskeletal symptoms in MPS as adjunct to standard of care therapy.

Established Safety & Efficacy

- 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

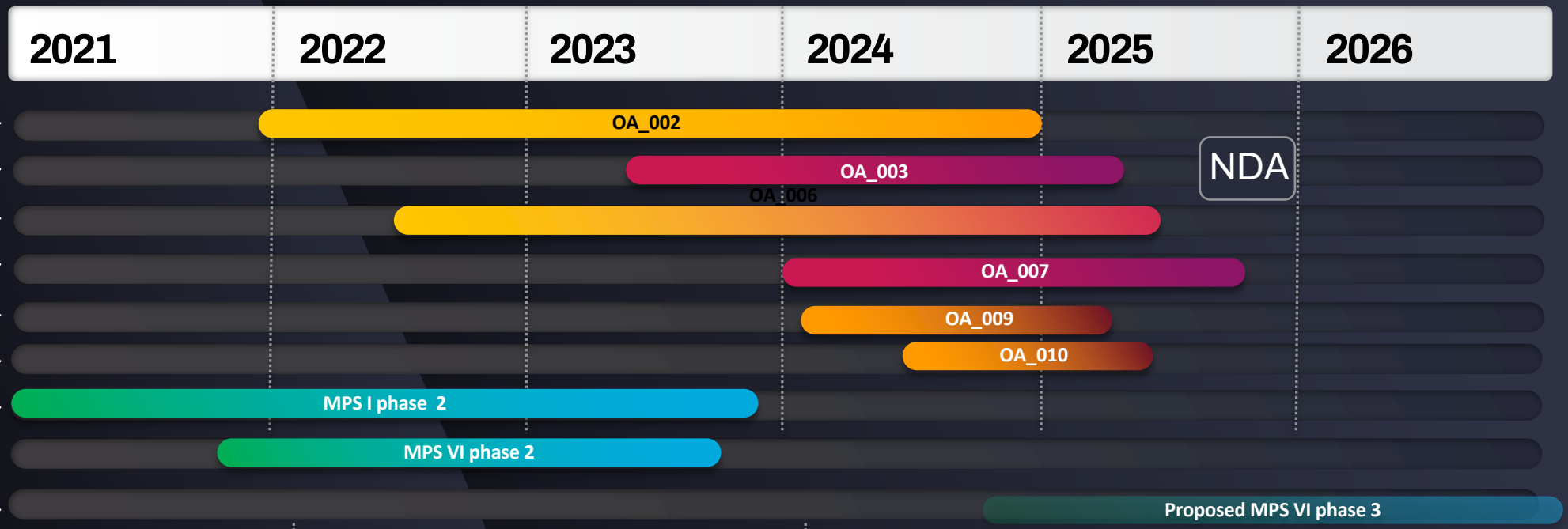
- Molecular platform technology and a complex trade-secret manufacturing process makes it extremely difficult to replicate
- The starting material is extracted from a plant-based biological source and then chemically modified using a multi-step manufacturing process
- Exclusive supply for 25-years post 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



002	OA NDA Pivotal	First subjects randomised Q4 2021, dose selection 1H CY2023
003	OA NDA Confirmatory	First subject randomised 1H CY2023
006 / 007	OA Establish durability of effect	Timelines will be confirmed following dose selection Data will be incorporated into OA pain and function NDA
009	OA Retreatment	
010	Establish safety and efficacy in Hip OA	
MPS I	Establish safety and efficacy in MPS I	Primary endpoint readout 2H 2023
MPS VI phase 2	Establish safety and efficacy in MPS VI	Primary endpoint readout 2H 2023
MPS VI phase 3	NDA Pivotal	TBA

** 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.

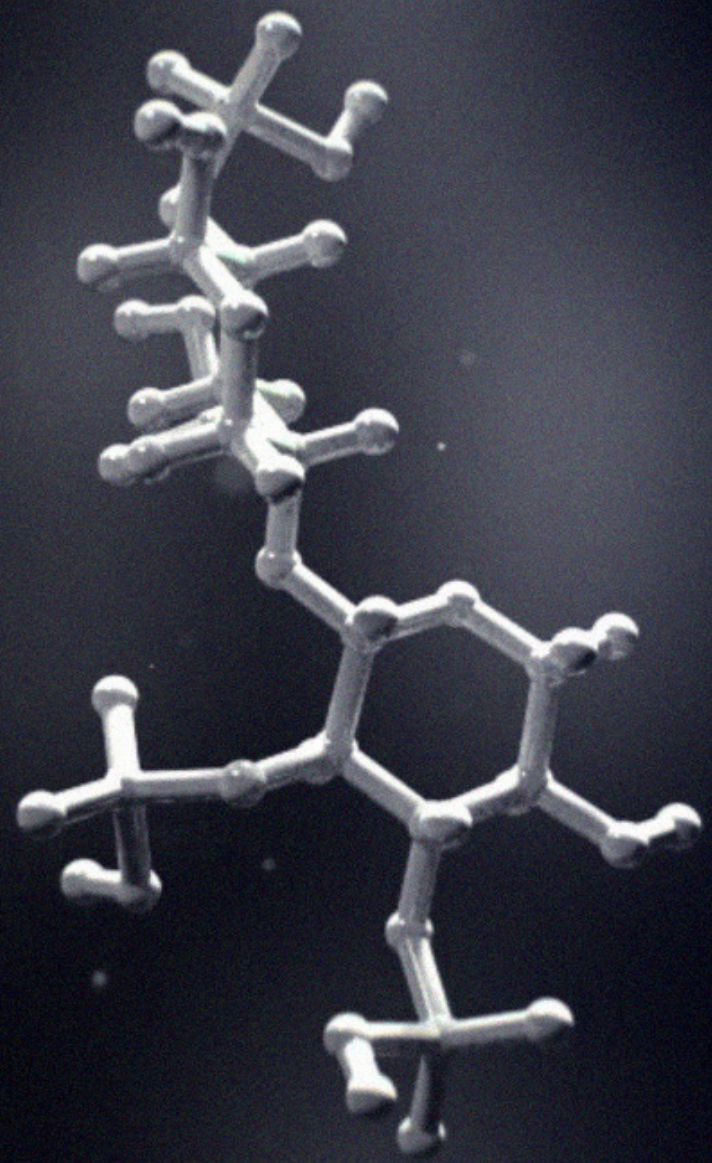
PARA_OA_008 - Clinical Outcomes

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 ≥30% and ≥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