PARADIGM BIOPHARMA

Investor Update July 2022

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Leadership

Experienced team to drive clinical execution of Paradigm's multiple clinical and R&D programs.

About Paradigm

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

Repurposing

FDA-approved drug with 60-year track record of treating inflammation, pentosan polysulfate sodium for subcutaneous use (PPS, iPPS, ZILOSUL®).

Lead Programs

Osteoarthritis (OA)

- Phase 3 clinical program commenced.
- Sites enrolling in US and AUS with EU and UK to commence imminently.
- OA program has received FDA Fast Track Designation.
- Harmonised protocol to achieve simultaneous registration in key jurisdictions.

Mucopolysaccharidosis (MPS I & VI)

- MPS I: Phase 2 clinical trial nearing completion (Australia).
- MPS VI: Phase 2 double-blinded, placebo-controlled study commenced in two sites in Brazil.

Established Safety & Efficacy

Phase 2 trial provided encouraging evidence of meaningful treatment effects in responses to SC iPPS compared to placebo overall for pain, ADL and PGIC.

Real world evidence via SAS and EAP > 600 subjects

IP & protection

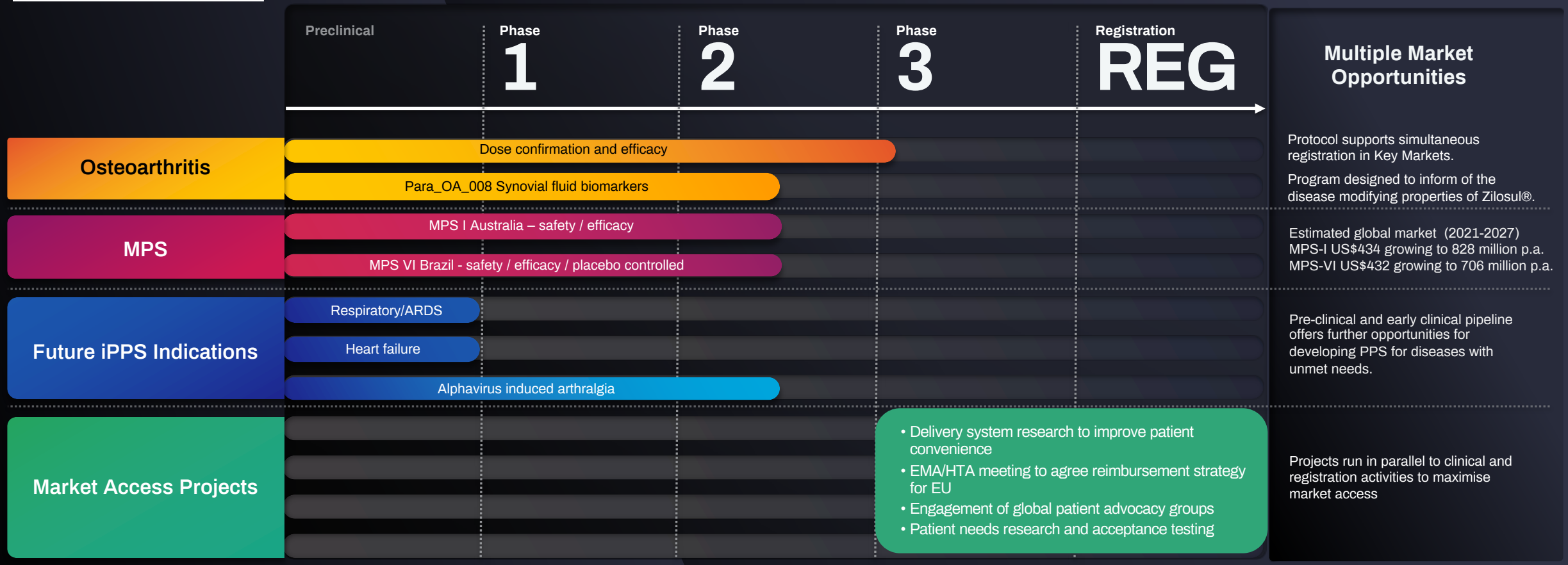
- Exclusive supply agreement with originator and the only FDA-approved manufacturer for 25 years post marketing
- Protection comparable with composition of matter patents
- Complex molecular structure - biosimilar-like difficult to replicate

SAS - Special Access Scheme
EAP – Expanded Access Program

Recent Company Milestones

- FDA Fast Track designation granted for OA program
- First phase 3 OA subjects dosed in US
- Further IP protection reported with acceptance of AUS patent
- 100% recruitment in phase 2 synovial fluid biomarker trial – near term clinical data
- First UK site activated
- Canada regulatory and ethics approval for phase 3 OA trial
- Research partnership with NFL Alumni Health

Development Pipeline



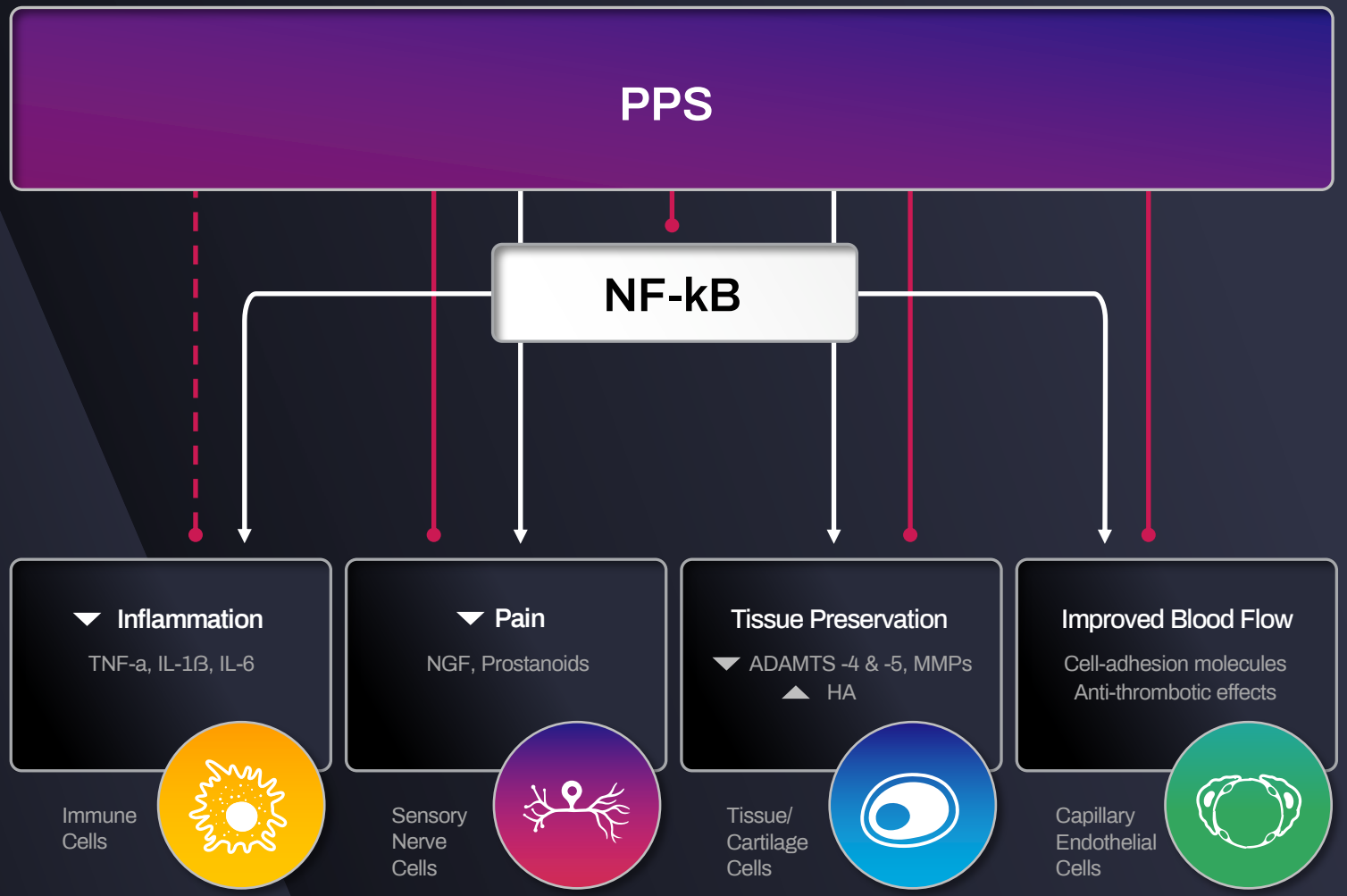
EMA = European Medicines Agency; HTA = Health Technology Assessment (funding authorities)

Mechanism of action

- Multiple modes of action
- Previous phase 2B, SAS and EAP experience

OA
MPS
ARDS
HFpEF
Alphavirus Induced Arthralgia

Current hypothesis for PPS mechanism of action



MOA Video: Click HERE to view, or via https://www.youtube.com/watch?v=rjZ-L_cHbm0

Osteoarthritis

OA

Blockbuster market opportunity

Zilosul® aims to meet a significant unmet need in osteoarthritis.

Market size potential US$10B+ p.a.[4]

People affected by OA in 2020[3]

72m+

People affected by OA by 2030[3]

120m+

Markets: US, EU5, Canada and Australia.

In the US alone, OA is predicted to increase by 86% to 67 million by 2030.[3]

Knee and Hip (Global)

69% of all OA

OA patients dissatisfied with current treatments[1]

81%

Target uptake: 10% dissatisfied market[1]

Zilosul® indicative price: US$2500 per year[2]

1. National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.
2. Global Pricing Research conducted by Paradigm. EU5: Germany, UK, Spain, France, Italy
3. OARSI. Osteoarthritis: A Serious Disease, Submitted to the U.S. Food and Drug Administration December 1, 2016
4. Calculation based on 10% penetration dissatisfied patients with Knee and Hip OA in the 72m addressable market, at price of US$2500.

Osteoarthritis - Global Phase 3

PARA_002 Global Progress

United States

- Approximately 56 sites have been selected
- 41 sites activated and participant screening commenced late in Q1 CY22 following site activation.
- Large pool of subjects being screened by activated sites.
- **Randomisation commenced.**

Australia

- All 8 sites have been activated.
- Sites activated and enrolling participants in WA, VIC, NSW, SA and QLD.

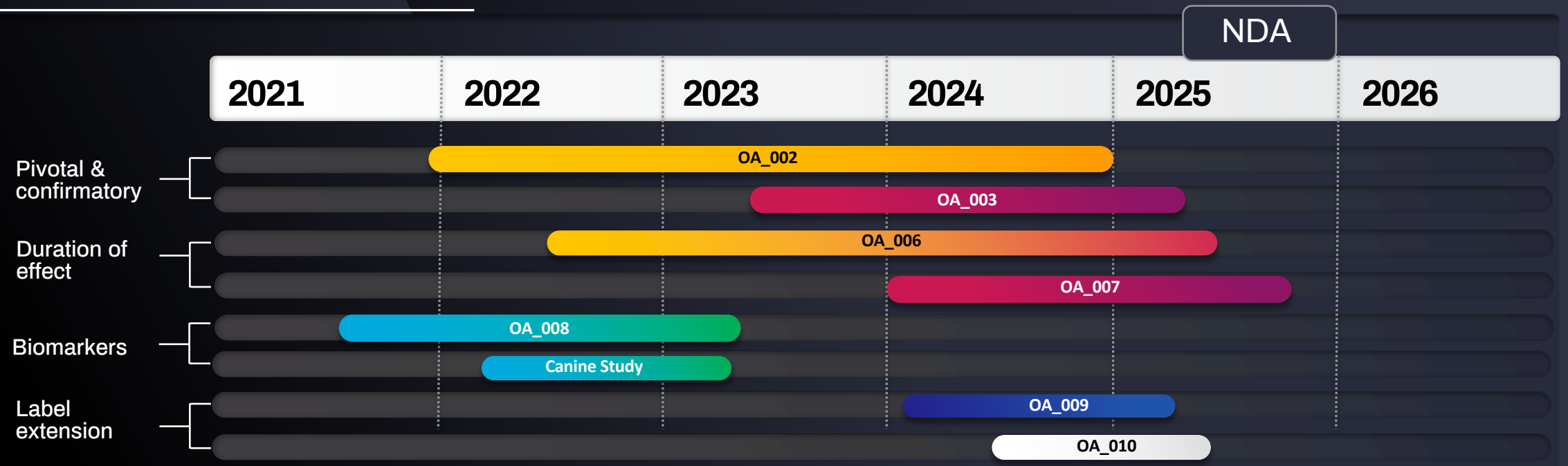
UK and Europe

- 12 sites selected.
- UK Reg & Ethics approval received.
- First UK Site activated and commenced screening activities.

Canada

- Regulatory and ethics approval received.
- Site activation and enrollment in Q3 2022.
- Up to 10 sites to be activated.

Timeline for OA



Study	Objective	Key Milestone
002	NDA pivotal	First subjects randomised Q4 2021, dose selection 1H CY2023
003	NDA confirmatory	First subject randomised 1H CY2023
006 / 007	Establish durability of effect	First subject enters 006 observational study 2H CY2022
008	DMOAD	Primary endpoint readout Q3 CY2022
Canine study	DMOAD (equivalent to 3-year follow-up)	Data available 1H CY 2023
009	Retreatment	Timelines will be confirmed following dose selection
010	Establish safety and efficacy in hip OA	

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

DMOAD

Current programs to inform of Zilosul® potential as a DMOAD

PARA_008 - Australia

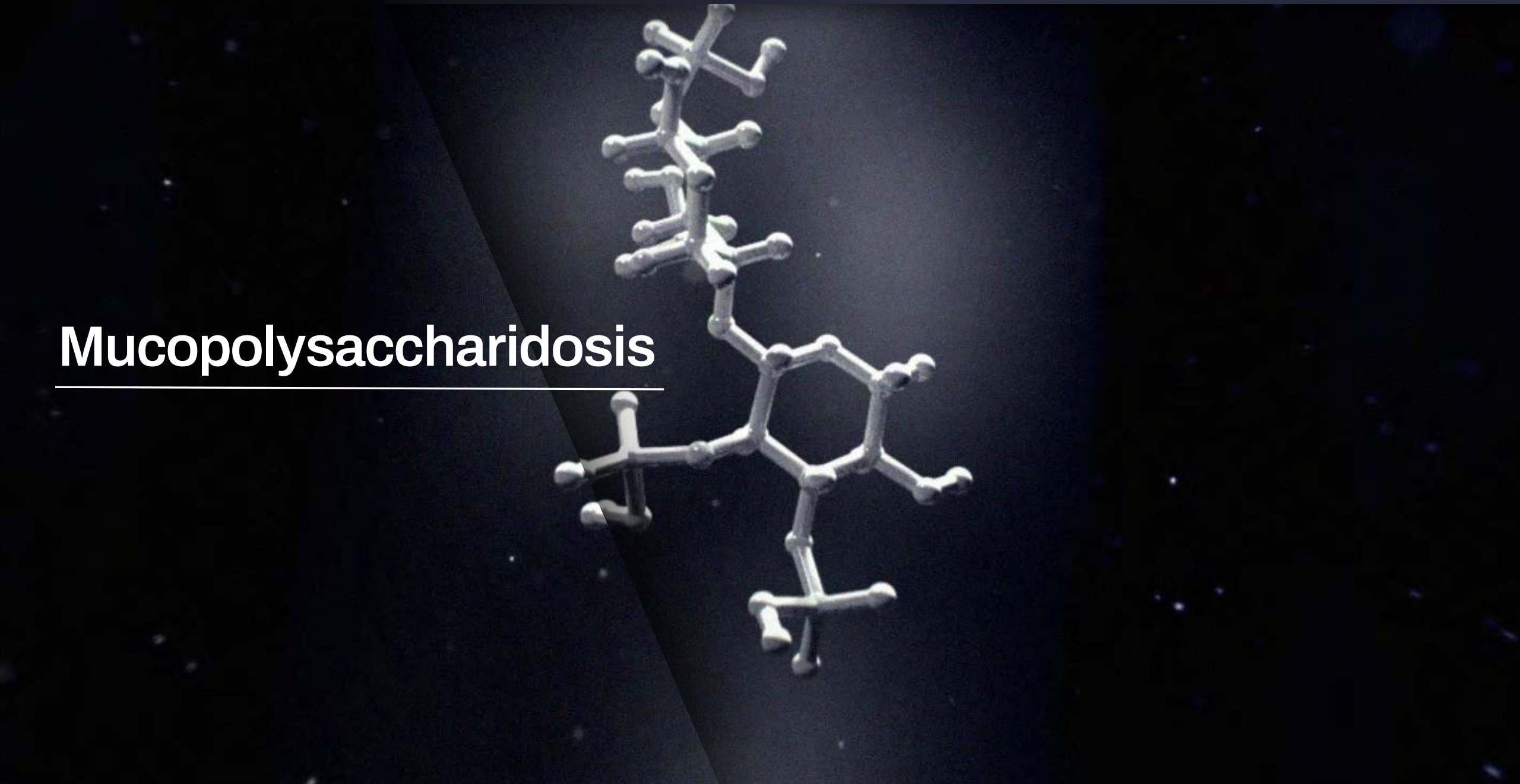
- Biomarker study assessing change from baseline in multiple objective measures associated with disease progression of OA.
- 60 participants randomised to PPS or placebo.
- Enrolment completed
- **Near term clinical data, Q3 2022**
- Study will explore:
  - Synovial fluid biomarker
  - Serum biomarkers
  - Clinical outcomes – WOMAC® Pain and Function
  - Structural changes – MRI

PARA_002 - Global

- Pivotal phase 3 OA knee
- 700+ participants randomised to PPS or placebo.
- MRI: Subchondral BML area and volume, joint synovitis/effusion volume, cartilage volume, bone shape, joint space width

Canine OA Study

- 21 Dogs with OA of the stifle joint are treated with PPS at a dosing of 3mg/kg (1.7mg/kg human equivalent) or placebo (2:1) weekly for 6-weeks.
- Day 56 data available to coincide with PARA_OA_008 interim data.
  - Study will explore:
  - Pain and function (gate analysis)
  - Structural changes (X-ray and MRI)
  - Synovial fluid and serum
  - 20 weeks follow-up period (equates on average to a period of 3 years in human lifespan)



Mucopolysaccharidosis

Mucopolysaccharidosis (MPS)

Phase 2 Asset – 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.
- PPS was well tolerated, demonstrating reduction in pain and GAGs and improvement in function.
- Fully enrolled.

MPS VI - Brazil

- A double-blind placebo-controlled trial with 12 subjects. Dosed weekly SC for 24-weeks.
- Primary endpoint is safety, key secondary endpoints are pain and function.
- Study design presented at LSD World Symposium Feb 2022.
- 50% patients enrolled with the potential remaining participants identified.

Upcoming near-term news flow

- MPS clinical program update
- PARA_OA_002 global progress update
- PARA_OA_006 extension study commencement
- FY22 tax rebate
- Further IP generation and protection
- Canine OA model preliminary data readout
- PARA_OA_008 top-line data readout

Summary

- De-risked phase 3 asset in blockbuster indication
- FDA Fast-Track designation for OA program
- **Promising pipeline**
- **Near-term clinical data**

For more information please visit:
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