PARADIGM BIOPHARMA

AUSBIZ CAPITAL PRESENTATION

19 AUGUST 2025

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2025

Recent News-Flow

- Centralised Ethics Approval US and AUS
- Phase 3 OA program commencement – Site Activation, First Patient Consent, Patient screening ramping up.
- New IP Acquisition – Building out Paradigm OA portfolio.
- US$27M Secured to provide runway through many significant milestones including Interim Analysis.

Advancing iPPS Toward a Differentiated OA Therapy

Robust data and regulatory momentum underpin a well-defined path through Phase 3

01

SAFTEY & EFFICACY PROFILE

- Strong efficacy and safety shown across a broad dataset
- Durable benefits sustained to 12 months in Phase 2 studies
- Imaging and biomarker data suggest effects beyond symptom relief

02

PHASE 2 AND REAL-WORLD EVIDENCE

- Multiple Phase 2 studies underpin Phase 3, showing consistent efficacy across patient types and timepoints
- Real-world insights from Australia's SAS program show long-term benefits with repeat courses.

03

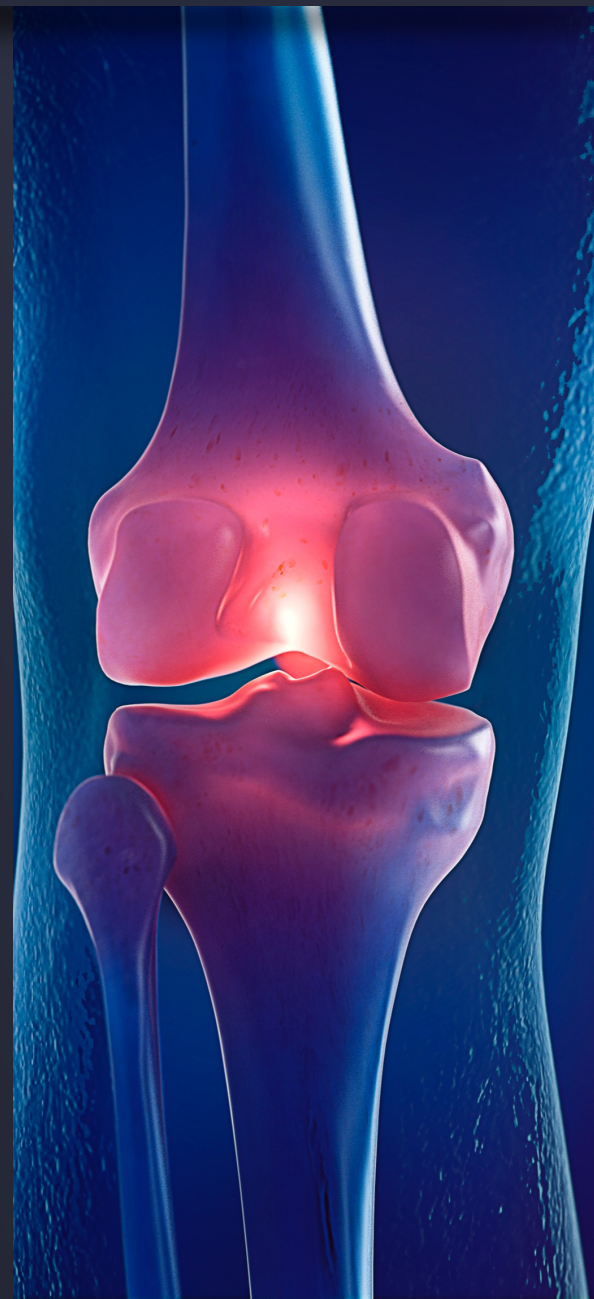
MECHANISM OF ACTION

- Demonstrated across preclinical models and human studies
- Anti-inflammatory, cartilage-protective, and matrix-restoring properties
- Biomarker data from Phase 2 suggests activity beyond symptom relief

04

OPTIMISED PHASE 3 PROGRAM

- Fast Track designation granted by FDA
- Protocol refined following extensive FDA engagement (Type C and D meetings)
- Endpoints, statistical powering, and assessment windows aligned with regulatory expectations



Blockbuster market opportunity

Zilosul® is a **non-opioid** subcutaneous injectable aimed to treat **pain and function in osteoarthritis.**

- FDA Fast Track Designation
- 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, UK, France, Germany, Italy, Spain, Canada and Australia.

Compared with 2020, cases of OA are projected to increase 74·9% for knee and 78·6% for hip by 2050.[5]

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.US, UK Germany, France
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.
5. **Global, regional, and national burden of osteoarthritis, 1990–2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021**

Confidence in IPPS | Clinical & Real-World Evidence

iPPS Study	Study Type	Dosing Regimen	Key Findings
Ghosh et al. (2005)	Randomised, double-blind, placebo-controlled (n=114)	3 mg/kg IM once weekly for 4 weeks	Significant pain reduction at rest (out to 24 weeks); Improved joint stiffness and global assessment
Kumagai et al. (2010)	Open-label clinical trial (n=20)	2 mg/kg SC once weekly for 6 weeks	Improved range of motion and pain reduction (out to 52 weeks); Reduced serum C2C (cartilage degradation marker)
PARA_OA_005	Phase 2b (n=128)	2 mg/kg SC twice weekly for 6 weeks	Clinically significant pain & function improvement; 5x lower rescue medication use; Sustained relief to 6 months
PARA_OA_008	Phase 2 (n=61)	2 mg/kg SC twice weekly for 6 weeks	Significant pain and function improvement out to 12 months; Reduced cartilage degradation biomarkers; MRI evidence of bone marrow lesion reduction
PARA_OA_002	Phase 2b/3 (n=601)	Dosing study, 6-week treatment, 18-week follow-up	Confirmation of minimum effective dose for Phase 3 trial; Safety profile consistent across all doses
TGA SAS	Real-World (n>700)	2 mg/kg SC twice weekly	Meaningful clinical improvements in pain and mobility

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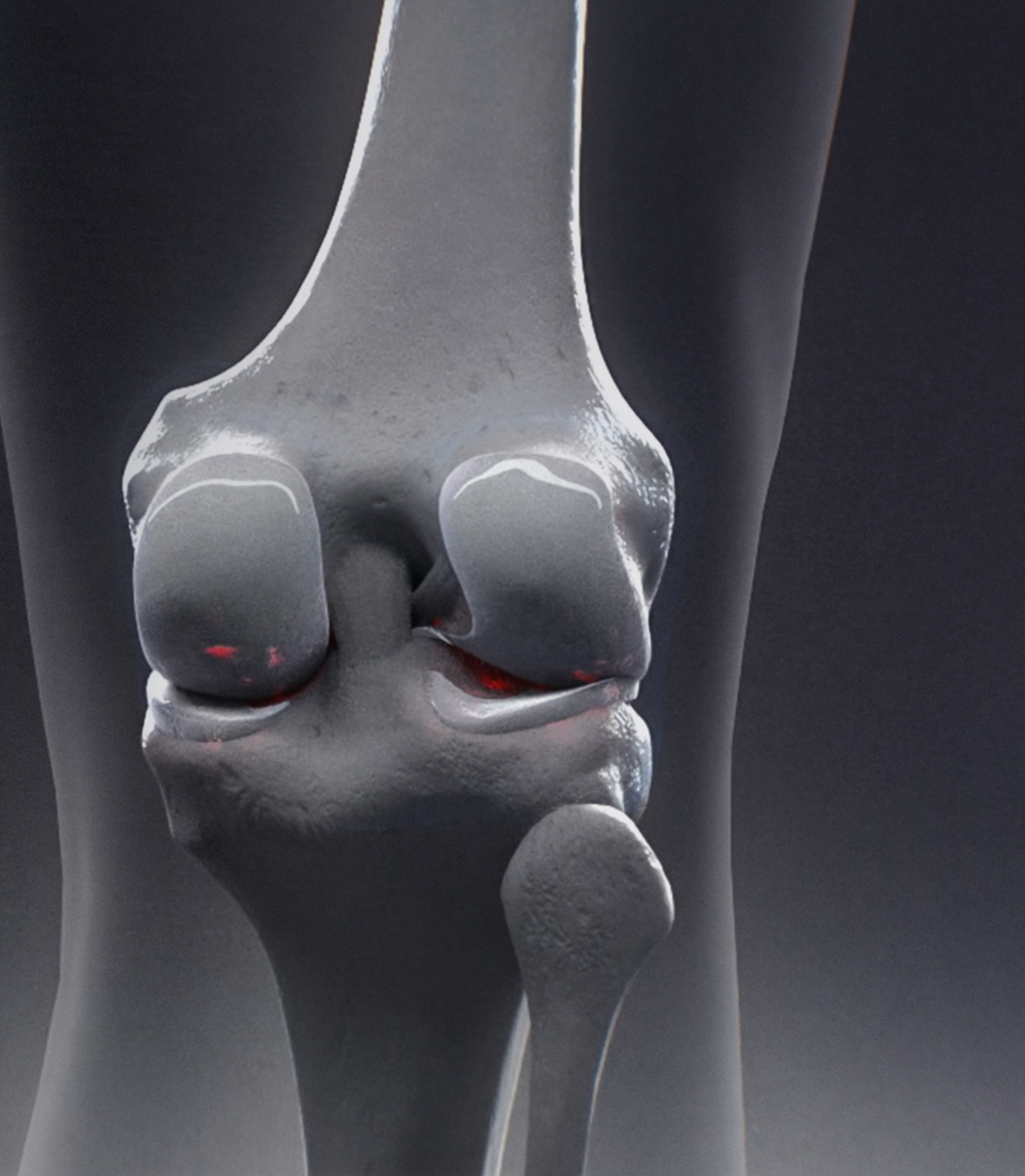
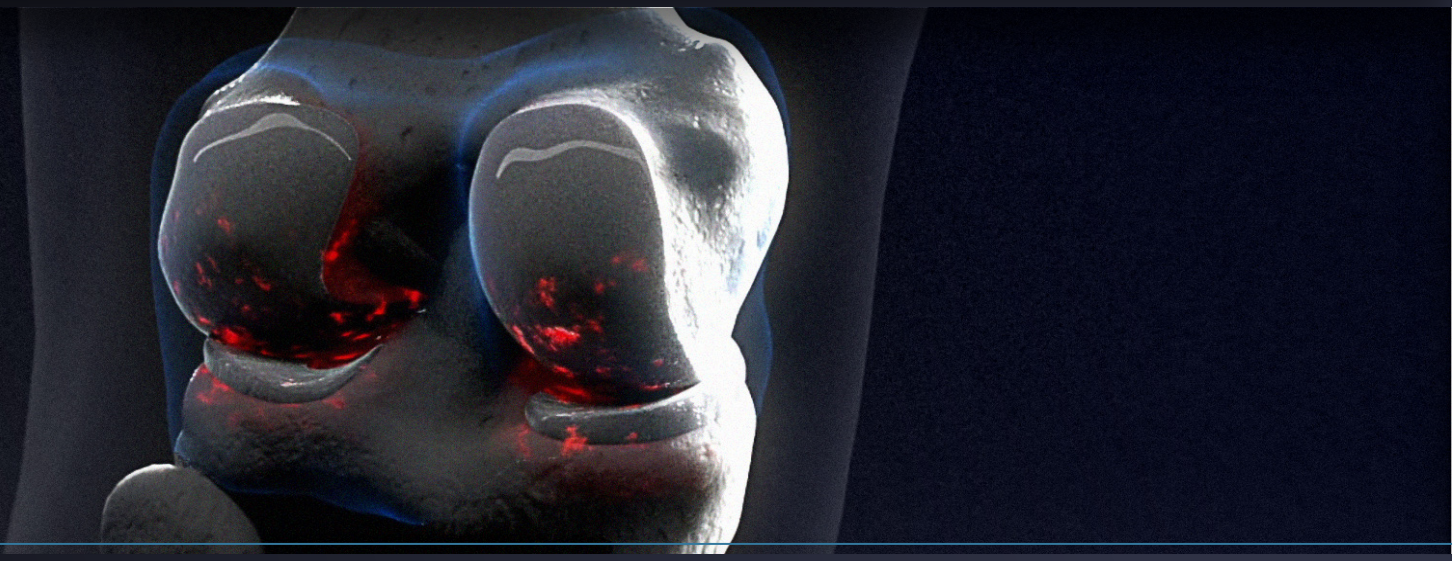
Osteoarthritis

Pivotal PH3 Trial



Phase 3 Objectives

Key objectives for the Phase 3
PARA_OA_012 study



Primary Objectives

- To evaluate the treatment effect of PPS on knee pain in participants with knee OA pain. (Weekly Average ADP Day 112)

Key Secondary Objectives

- To evaluate the treatment effect of PPS on knee pain function in participants with knee OA pain. (WOMAC Day 112)
- To evaluate the effect of PPS treatment on PGIC in participants with knee OA pain. (PGIC Day 112)
- To evaluate the efficacy of PPS treatment on knee pain, function, stiffness, and overall, in participants with knee OA pain.

Secondary Objectives

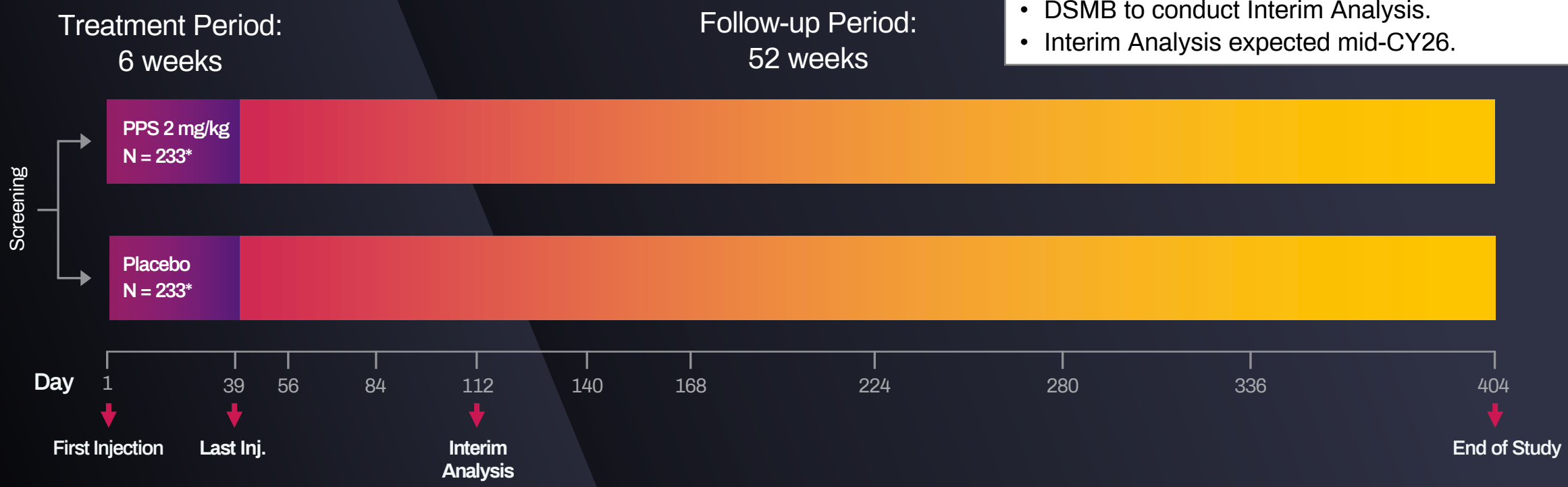
- WOMAC Pain and function assessments at multiple timepoints to Day 404.
- IPPS effects on Rescue Medication use.
- Structural changes via X-Ray and MRI from baseline day 168, 404

PARA_OA_012

Phase 3 trial design

Interim Analysis (IA)

- Conducted once 50% of subjects (~233) reach Day 112.
- Plan assess efficacy and possible early conclusion of trial based on target effect size.
- DSMB to conduct Interim Analysis.
- Interim Analysis expected mid-CY26.



Primary endpoint: Change from baseline in weekly ADP NRS pain score at Day 112.

Secondary endpoints: Function, PGIC, rescue medication, biomarkers of disease progression, including MRI & X-Ray.

*May be subject to change

PARA_OA_012 – Powered for Success

Statistical Power Based on Phase 2 Data Validates

The table summarises modelled power at effect sizes established in Phase 2 studies.

Effect Size (ES)	Estimated Power (n=233/arm)
0.3 *(Phase 2 pooled)*	>86%
0.4	>98%

- High statistical power supports confidence in replicating prior Phase 2 clinical benefit.
- Model assumes observed Phase 2 variance and full sample size.
- Success estimates based on historical trial performance and standard assumptions*.

* Does not account for executional risk.

ASX PH3 Comparison Table

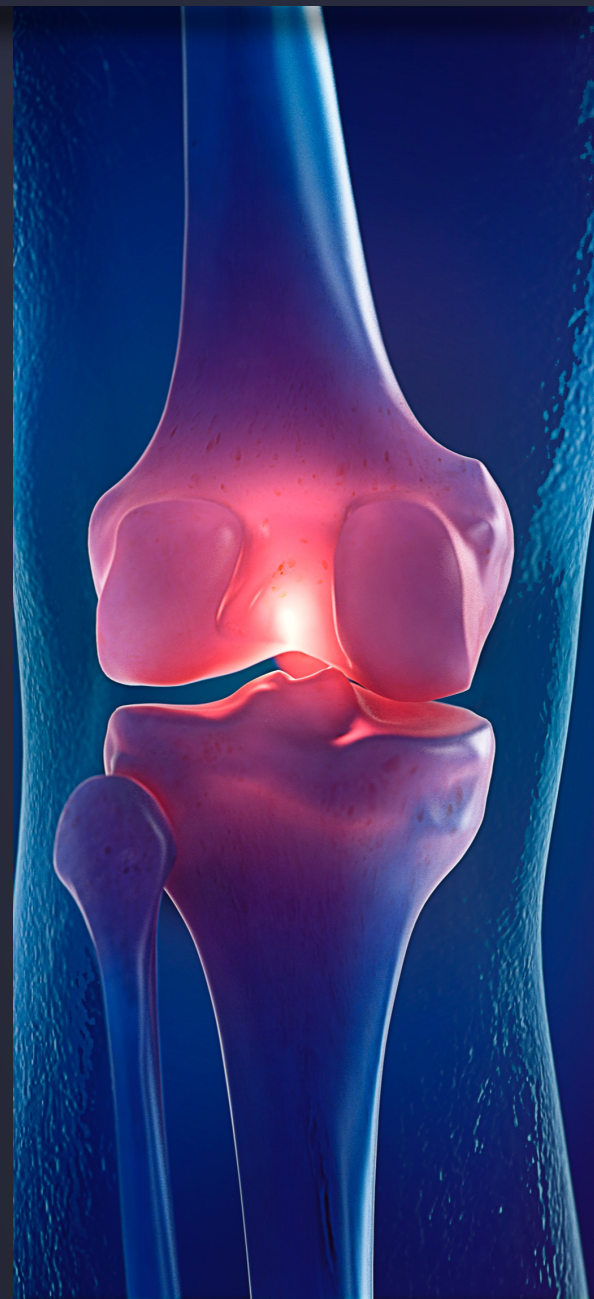
Upside from current valuation

Company	P3 Trial Indication	FDA Designations	Valuation (Market Capitalisation $Am)	
			At IND Clearance	Current
Mesoblast Ltd (MSB)	Chronic heart failure		~A$1,500	~A$2,931
Immutep Ltd (IMM)	Metastatic non-small cell lung cancer		~A$535	~A$382
Dimerix Ltd (DXB)	Focal segmental glomeruloscler osis (FSGS)	Orphan	~A$90 (May-22)	~A$291
Neuren Pharmaceuticals Ltd (NEU)	Phelan-McDermid syndrome (PMS)	Orphan	~A$500 (Mar-22)	~A$2,250
Botanix Pharmaceuticals Ltd (BOT)	Primary axillary hyperhidrosis		~A$190 (Oct-23)	~A$314
Paradigm Biopharmaceuticals Ltd (PAR)	**Osteoarthritis of the knee**	**Fast track**	**~A$112**	

Source: Market capitalisations are approximate only. IRESS as of 12 August 2025. NEU, MSB and BOT have since completed PH3 studies and are in production likely to positively effect current market capitalisation above.

Investment Highlights

- ✓ **Multiple Positive Phase 2 Trials:** Consistent efficacy and safety demonstrated across studies, with signals of disease-modifying activity on MRI and biomarkers.
- ✓ **Real-World Evidence:** Long-term benefits observed in Australia's SAS program, including sustained improvements with repeat courses.
- ✓ **Optimised Phase 3 Design:** Refined following extensive FDA engagement, aligned with regulatory expectations, and powered to detect clinically meaningful effects.
- ✓ **Fast Track Designation:** Accelerated regulatory pathway secured with the FDA.
- ✓ **Large, Unmet Global Market:** 500M+ people affected by OA, 81% of patients dissatisfied with current treatments
- ✓ **Near-Term Inflection Point:** Interim analysis expected mid-2026 at 50% patient completion, representing a major value catalyst.



News flow & catalysts

Upcoming Catalysts

Event	Target Date
PARA_OA_012 – First participant dosed.	Q3 2025
PARA_OA_012 – 50% Recruitment of participants	2H 2025*
PARA_OA_012 – 100% Recruitment	1H 2026*
PARA_OA_012 Interim Analysis – 50% participants reach Day 112	Mid-2026*

**The above is a statement of current intentions as at the date of this presentation. Investors should note that the above upcoming events are subject to funding or new circumstances.*

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