Paradigm Biopharmaceuticals

Progressing toward key near-term objectives

Paradigm has shared its June 2023 quarterly update. In Q423, net cash outflow from operating activities was A$17.1m (up from A$10.3m in Q323) or A$45.2m for FY23. R&D costs were A$16.1m (versus A$9.0m in Q3) or A$47.0m for FY23, and were attributed to recruitment initiatives and new site identification for the PARA_OA_002 trial, analytical activities for the PARA_OA_008 trial as well as the canine model studies of naturally occurring osteoarthritis (OA), and clinical activities assessing iPPS for mucopolysaccharidosis (MPS) types I and VI. The full year figures were partially offset by a A$7.4m R&D tax incentive rebate (reported in Q223). Paradigm reported a cash balance of A$56.4m at end-June 2023 (versus A$73.2m at end-March 2023). Assuming the cash burn rate remains at the FY23 level of A$45m, the company should have sufficient funds to bring it through near-term key inflection points, as described below.

In Paradigm's Q423 report, the company highlighted several operational milestones from the period. In April 2023, top-line data were reported for the six-month readout of the PARA_OA_008 Phase II trial assessing iPPS as a potential disease-modifying OA drug (DMOAD). Management expects to share 12-month data in late Q3 CY23. Paradigm also shared encouraging data from a canine model of naturally occurring OA, demonstrating that iPPS gives durable effects on pain, function and cartilage volume at the three-year human equivalent timepoint. Collectively, we believe that these results add to a growing data package supportive of iPPS as a potential DMOAD. Paradigm is preparing to present this data package to the FDA in Q4 CY23 with the aim of reaching an agreement on the DMOAD label, and the outcome of this meeting could represent a significant catalyst for the company, in our view.

Paradigm is also assessing iPPS for knee OA pain in the pivotal PARA_OA_002 Phase III trial. In July 2023, the company announced that patient recruitment for stage one (dose selection) was complete. Post dose selection, expected by the company in early Q1 CY24, management plans to commence stage two (anticipated n=468), slightly later than the previous guided timeline of H2 CY23, as well as the PARA_OA_003 confirmatory trial (anticipated n=700), the initiation of which represents a key milestone, in our view.

iPPS is also being investigated as a potential treatment for MPS I and VI. In June 2023, Paradigm announced that primary and secondary endpoints were attained for the MPS I Phase II trial. Additionally, in April 2023, the company reported that the MPS VI Phase II trial had completed patient enrolment. Topline data for this study are expected in Q4 CY23, potentially representing another key catalyst for the company.

Consensus estimates

Year end	Revenue (A$m)	PBT (A$m)	EPS (A$)	DPS (A$)	P/E (x)	Yield (%)
06/21	8.94	(34.3)	(0.17)	0.0	N/A	N/A
06/22	0.08	(39.3)	(0.17)	0.0	N/A	N/A
06/23e	0.01	(58.5)	(0.20)	0.0	N/A	N/A
06/24e	64.5*	(12.7)	0.04	0.0	22.5	N/A

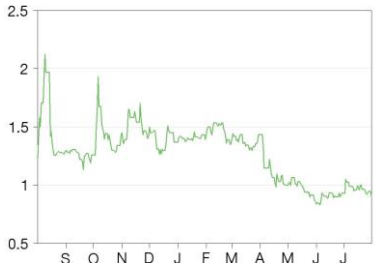
Source: Refinitiv. Note: *FY24 revenue may reflect market expectations on potential licensing revenue.

Pharma and biotech

1 August 2023

Price	A$0.90
Market cap	A$254m

Share price graph



Share details

Code	PAR
Listing	Australian Securities Exchange
Shares in issue	282.1m
Net cash at end-June 2023	A$56.4m

Business description

Paradigm Biopharmaceuticals is an Australian biotechnology company focused on the development of injectable pentosan polysulfate (iPPS). The company's most advanced clinical programme is investigating the drug's use as a potentially disease-modifying treatment for knee-osteoarthritis, a degenerative disease with significant unmet medical needs. iPPS is in pivotal Phase III trials.

Bull

- Knee osteoarthritis (kOA) is a prevalent indication with large commercial potential.
- Comprehensive late-stage development programme to maximise opportunity in kOA.
- iPPS has a known safety profile, which somewhat de-risks development.

Bear

- Failure to meet clinical endpoints would significantly affect the value of iPPS.
- Historically the development of disease-modifying drugs in OA has been unsuccessful.
- Funding is needed to complete the Phase III programme.

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