Paradigm Biopharmaceuticals

Active pipeline and catalysts ahead

Paradigm has shared its March 2023 quarterly update. In Q323, net cash outflow from operating activities was A$10.3m (A$28.1m for the first nine months of FY23). R&D costs amounted to A$9.0m, attributed to ongoing recruitment and analytical activities for the PARA_OA_008 Phase II clinical trial assessing injectable pentosan polysulfate (iPPS, or Zilosul) as a potentially disease-modifying treatment for knee osteoarthritis (kOA), site operations for Phase II studies in mucopolysaccharidosis (MPS I and MPS VI), and ongoing NDA-enabling non-clinical studies. This expenditure is comparable to the prior quarter (A$13.2m), and we anticipate an increase in burn rate in the near-term to support the company's active pipeline. With a cash position of A$73.2m at end-Q323 and at the current quarterly burn rate, management estimates that operations remain funded into CY24.

In the last quarter, Paradigm shared encouraging top-line data from the PARA_OA_008 trial, positioning iPPS as a potential disease-modifying OA drug. Further details are discussed in our previous update on the study, and we note that 12-month data are expected in H2 CY23. The company is preparing for discussions with key regulatory agencies to reach an agreement on a potential disease-modifying label.

The pivotal PARA_OA_002 Phase III trial to assess iPPS in patients with kOA pain is ongoing. The study has activated 102 sites and is recruiting participants across 6 countries; recruitment is due to be complete by the end of the current quarter. In March, Paradigm received regulatory and ethics approvals for this trial, enabling start-up activities at additional sites in Europe. Paradigm continues to engage with NFL Alumni Health regarding developments in osteoarthritis treatment options, highlighting strong interest from this community, in our view.

iPPS is also being investigated as a potential treatment for mucopolysaccharidosis (MPS I and VI). Paradigm's Phase II trial in MPS VI recently completed enrolment and top-line data are expected in Q4 CY23.

We continue to anticipate multiple catalysts for Paradigm's share price over CY23–25. While the Q323 report shows a quarter-on-quarter decline in R&D costs, we expect a general increase in cash burn to support ongoing clinical activities in kOA and MPS. The company has guided that its cash position of A$73.2m at end-Q323 will provide a runway through key upcoming events into CY24. However, we note that this cash runway is sensitive to clinical delays or future R&D tax incentive rebates (A$7.4m rebate reported in Q223), and management has communicated that a similar R&D rebate being received in H1 FY24 is probable.

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	0.005	(58.5)	(0.20)	0.0	N/A	N/A
06/24e	64.5*	(12.7)	0.04	0.0	33.6	N/A

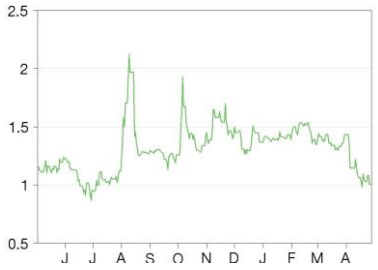
Source: Refinitiv. Note: *FY24 revenue may reflect market expectations on potential licensing revenue.

Pharma and biotech

2 May 2023

Price	A$1.01
Market cap	A$285m

Share price graph



Share details

Code	PAR
Listing	Australian Stock Exchange
Shares in issue	282.1m
Net cash at end-March 2023	A$73.2m

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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