

Paradigm Biopharmaceuticals

Funded past near-term inflection points

Cash flow figures from Paradigm Biopharmaceuticals' [latest update](#) show that it remains funded past key near-term inflection points. In Q223, management reported a net cash outflow from operating activities of A\$7.8m (A\$17.8m for the first six months of FY23), including an A\$7.4m R&D tax incentive rebate, and no capital expenditure. R&D expenditure increased 54% q-o-q to A\$13.2m, corresponding with ongoing recruitment and site identification for the pivotal PARA_OA_002 Phase III trial of iPPS in knee osteoarthritis and an increase in other clinical activities. With cash of A\$83.9m at end Q223 and at the current quarterly burn rate (adjusted for the non-recurring R&D tax incentive, A\$15.2m), management estimates that operations are funded into 2024 (5.5 quarters), past important clinical milestones in Paradigm's osteoarthritis programme in 2023.

We expect many share price catalysts for Paradigm over CY23–25. Management's estimated cash runway (into FY24) will see the company funded through several of these important inflection points in CY23, including dose selection from PARA_OA_002, long-term data readouts from PARA_OA_008 and supportive canine studies. Paradigm's end-December 2022 cash balance of A\$83.9m was boosted by a capital raise of A\$66m in August 2022. We believe that reported cash flows from the recent announcement and an anticipated increase in cash burn as clinical activities ramp up over CY23–25 support management's communicated estimated cash runway into CY24. We note that management's runway estimate is sensitive to clinical delays or any future R&D tax incentive rebates. For a comprehensive overview of the company, see our recent [initiation note](#).

As a reminder, Paradigm Biopharmaceuticals is an Australia-based, late-stage pharmaceutical company focused on the development of an injectable formulation of PPS (iPPS, Zilosul) for the treatment of knee osteoarthritis (kOA) and mucopolysaccharidosis types I and VI. The company is currently conducting a comprehensive clinical programme in kOA for which the global pivotal Phase III PARA_OA_002 trial began enrolment in H222 and completed the first formal safety review in [December 2022](#). In our view, demonstrating that iPPS has a disease-modifying profile, which current clinical biomarker data and animal studies suggest it could, is key to maximising the commercial impact of the drug. Management expects the clinical programme in kOA to support an NDA filing with the US Food and Drug Administration at end CY25.

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

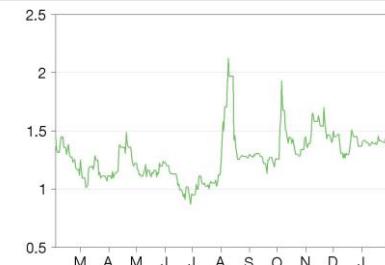
Source: Refinitiv. Note: *Revenue may reflect market expectations on potential licensing revenue.

Pharma and biotech

2 February 2023

Price **A\$1.43**
Market cap **A\$392m**

Share price graph



Share details

Code PAR
Listing Australian Stock Exchange
Shares in issue 285m
Cash at end December 2022 A\$83.9m

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 Phase III programme.

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