Paradigm Biopharmaceuticals

Pivotal Phase III progressing as planned

Paradigm has announced the completion of patient recruitment for stage one (dose selection) of its pivotal Phase III trial, PARA_OA_002, a multi-centre (US/Australia/UK/EU/Canada), two-stage, adaptive, randomised, double-blind, placebo-controlled study to assess injectable pentosan polysulfate (iPPS) in patients with knee osteoarthritis (kOA) pain. Paradigm has efficiently recruited participants for the trial through various initiatives, such as through its partnership with NFL Alumni Health. Management expects stage one to be complete in Q3 CY23, and for stage two to commence with the most effective dose later in H2 CY23. The selected dose will also be used in the initiation of the separate confirmatory Phase III trial in H2 CY23. These events represent key milestones for Paradigm, in our view.

Paradigm's Phase III trial, PARA_OA_002, is a two-stage study assessing iPPS as a potential treatment for kOA pain, and is the company's most advanced clinical programme. In stage one, kOA patients are randomised to receive either placebo twice weekly, or one of three iPPS dose regimens, issued for six weeks to confirm the lowest effective dose of subcutaneous iPPS. Stage two will assess the efficacy of the selected stage one dose versus placebo across six weeks. The primary endpoint is change from baseline at day 56, measured by the WOMAC score (Western Ontario and McMaster Universities Arthritis Index), a widely employed, self-administered questionnaire assessing pain, stiffness and physical function.

Paradigm has announced that recruitment for stage one of this trial has been completed (n=468). The participants are undergoing screening and randomisation, expected to be completed early in Q3 CY23, consistent with prior guided timelines. Once all stage one participants reach the pre-specified timepoint (84 days post initial treatment), an independent data monitoring committee (DMC) will determine the optimal stage two dose. Further, the selected dose will also be used to proceed with PARA_OA_003, a separate confirmatory Phase III trial, for which management expects a similar recruitment rate. We note that the DMC is responsible for assessing safety and efficacy, while ensuring validity and scientific merit throughout the PARA_OA_002 study. In the most recent DMC review (20 June 2023), it was recommended that the trial proceed without any modifications.

Management anticipates stage two of the trial to commence in H2 CY23, representing an important milestone for Paradigm, in our view. We also note that the timeline of Paradigm's New Drug Application with the US FDA remains on track for end-CY25, which may represent a significant catalyst, provided the data continue to be supportive.

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

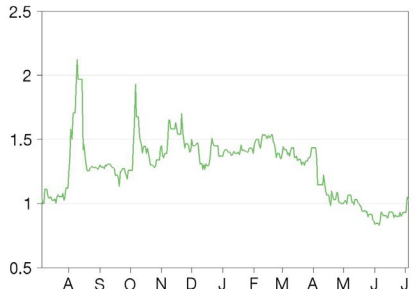
Source: Refinitiv. Note: *FY24 revenue may reflect market expectations on potential licensing revenue.

Pharma and biotech

5 July 2023

Price	A$1.03
Market cap	A$290m

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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