Paradigm Biopharmaceuticals

Q1 results recap iPPS progress in OA & MPS

Paradigm announced Q1 results (for the quarter ending 30 September) and a A$30m capital raise to potentially extend its cash runway through to mid CY25. Management attributed increased spending in the quarter to increased clinical and recruiting activity, which translated into a higher net cash outflow from operating activities of A$22.5m (vs A$17.1m in Q423). With the PARA_OA_008 programme now concluded, as well as the upcoming completion of the mucopolysaccharidosis (MPS) VI Phase II trial and anticipated lower costs for PARA_OA_002, management expects R&D spend to decline in Q224, from A$21.9 in Q124 (vs A$16.1m in Q423). At the quarter end, the company had a cash balance of A$33.6m.

PARA_OA_008: Durable responses demonstrated

In its quarterly update, management highlighted the significant reduction in pain and durable improvements in functionality (based on WOMAC, alongside other measures of personal effectiveness and reduced need for rescue medication) in its day-365 data for PARA_OA_008, the Phase II programme assessing injectable pentosan polysulfate (iPPS) as a potential disease-modifying osteoarthritis drug (DMOAD). The determined optimal dosing regimen of iPPS (2mg/kg) was identified to be twice weekly. This was a follow up from the six-month MRI data. With these results, Paradigm is pursuing provisional approval with the Australian Therapeutic Goods Administration (TGA), and plans to submit a next-stage determination application in Q1 CY24.

PARA_OA_002: Planning stage 2 with optimal dosing

Another clinical highlight in the quarter was the successful recruitment for stage 1 of PARA_OA_002 across 120 sites, 40 more than initially planned due to interest from clinicians and patients in the US (announced in July 2023). This Phase III programme lacks the iPPS (2mg/kg) twice-weekly dosing regimen but, based on the Phase II data, Paradigm now intends to include this regimen into its registrational studies. Management plans to request a protocol review from the FDA to move forward with this dose regimen, and with Fast Track designation already granted, the review is expected in Q1 CY24. The company intends to commence the next stage of PARA_OA_002 in H1 CY24.

Consensus estimates

Year end	Revenue (A$m)	PBT (A$m)	EPS (A$)	DPS (A$)	P/E (x)	Yield (%)
06/22	0.08	(39.2)	(0.17)	0.0	N/A	N/A
06/23	0.05	(51.9)	(0.21)	0.0	N/A	N/A
06/24e	32.3*	(32.4)	(0.07)	0.0	N/A	N/A
06/25e	35.7*	12.9	0.04	0.0	17.7	N/A

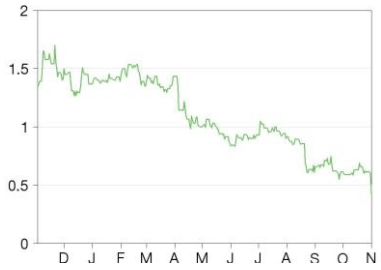
Source: Refinitiv. Note: *Revenue may reflect market expectations on potential licensing revenue.

Pharma and biotech

2 November 2023

Price	A$0.66
Market cap	A$169m

Share price graph



Share details

Code	PAR
Listing	ASX
Shares in issue (excluding capital raise proposed in October)	282.1m
Net cash at end-September 2023 (excluding capital raise proposed in October)	A$33.6m

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.

Analysts

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Capital raise to extend runway through mid CY25

Paradigm also announced a capital raise with gross proceeds of A$30m and subsequently reported a successful capital raise of A$18m through a private placement and A$3.1m from a share entitlement offer to institutional investors (with a 78% take-up rate from eligible investors). The remaining retail share entitlement offer, worth A$9m, is now fully underwritten and is due to open on 6 November 2023. The company estimates that following completion of this funding exercise, the pro-forma cash balance will stand at A$69.4m (excluding potential proceeds of A$33.8m from the options exercise), which should provide a cash runway of three additional quarters, based on the current quarterly burn rate of A$22.5m. If the options are fully exercised, the company anticipates a pro-forma cash balance of A$103.2m, which, according to management, should fund the company's operations through mid CY25, and provide adequate operational headroom through the following key (upcoming) catalysts:

- Topline data for the Phase II MPS VI clinical trial – Q4 CY23.
- FDA protocol review for stage 2 of the PARA_OA_002 programme – Q1 CY24.
- Submission of the next-stage determination application to the TGA – Q1 CY24.
- Commencement of enrolment for stage 2 of the PARA_OA_002 programme – H1 CY24.

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