Percheron Therapeutics

Regulatory update

HMBD-002 moves closer to clinic with FDA greenlight

Pharma and biotech

2 November 2026

Percheron Therapeutics has taken a key step towards the clinic for lead asset HMBD-002, with FDA regulatory clearance for Vanderbilt Health-led investigator-sponsored trial in acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS). The study will evaluate HMBD-002 alongside standards of care azacitidine and venetoclax in up to 20 patients with relapsed/refractory (r/r) AML or AML/MDS, with dose optimisation the immediate focus. With trial drug product already in place, we believe the current announcement removes another execution hurdle. While we note that the cohort size is smaller than the 29–38 patients previously anticipated, we continue to view the investigator-sponsored approach as a credible, capital-efficient route to generating preliminary clinical evidence, albeit with reduced control over recruitment and timelines. Management expects recruitment to initiate in H1 CY27, and we believe that establishing preliminary efficacy and securing funding for broader development will be the key de-risking milestones.

Year end	Revenue (AUDm)	PBT (AUDm)	EPS (AUD)	DPS (AUc)	P/E (x)	Yield (%)
6/24	2.4	(11.7)	(1.33)	0.00	N/A	N/A
6/25	1.4	(13.4)	(1.31)	0.00	N/A	N/A
6/26	0.7	(4.4)	(0.38)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

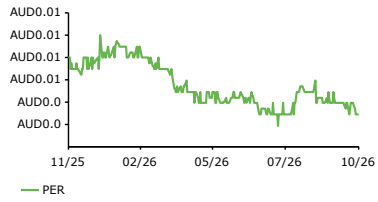
FDA clearance removes a key outstanding hurdle for the trial. Vanderbilt will design and operate the study under Dr Somedeb Ball, with Percheron supplying HMBD-002, technical input and a financial grant (supported by the A$2.3m raise in September 2026). Importantly, Percheron will retain full access to study data for future regulatory and partnering discussions. The smaller cohort and dose-optimisation focus suggest that safety and tolerability will be central to the initial assessment. Early efficacy signals could inform subsequent development, although attributing benefit specifically to HMBD-002 may prove challenging without a comparator arm. Management had previously communicated that enrolment is expected to commence in H1 CY27, with initial data potentially by end-CY27.

The scientific rationale for VISTA inhibition in AML is supported by preclinical evidence. VISTA is highly expressed on AML blasts, with elevated expression linked to poorer survival, while its blockade has shown antitumour activity in AML models. This provides a rationale for adding an immune-directed therapy to azacitidine/venetoclax, although clinical synergy and, importantly, a favourable safety profile with this combination would need to be established.

We believe the investigator-sponsored structure offers an attractive, capital-efficient route to clinical evidence while preserving resources for other development priorities. While this may mean less direct control over execution and timelines for Percheron, Vanderbilt's involvement provides valuable clinical expertise. The A $2.3m September placement was intended to fully fund its Vanderbilt commitments, with cash of A$4.9m at end-September providing additional financial flexibility. The recent preclinical collaboration with Invion provides a parallel avenue to explore HMBD-002's potential in solid tumours. We see trial initiation, dose selection and emerging clinical data as important milestones that could strengthen HMBD-002's development proposition and inform future partnering discussions.

Price	**AUD0.003**
Market cap	**AUD6m**
	US$/A$1.43
Net cash/(debt) at end-September 2026	AUD4.9m
Shares in issue	1,982.4m
Free float	56.0%
Code	PER
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



Business description

Percheron Therapeutics is a clinical-stage biotech advancing HMBD-002, a differentiated VISTA-targeting checkpoint inhibitor with potential to address PD-1 resistance across a range of cancer indications. HMBD-002 has completed a Phase I clinical trial in patients with advanced solid cancers, with favourable safety and tolerability. An investigator-sponsored Phase IIa trial in AML/MDS is expected to commence in H1 CY27.

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