

Medlab Clinical

Clinical update

Observational trials to support development

Pharma and biotech

20 September 2022

Price **A\$12.3**
Market cap **A\$28m**

Net cash (A\$m) at end-June 2022	5.2
Shares in issue	2.3m
Free float	69%
Code	MCD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



Business description

Based in Australia, Medlab Clinical is developing therapeutics using its proprietary delivery platform NanoCelle. Its most advanced programme is in cancer pain management with lead drug candidate NanaBis, a medicinal cannabis product for cancer-related bone pain.

Analysts

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Medlab Clinical has [announced](#) it has received ethics approval to conduct two new observational clinical trials in Australia for its lead developmental programmes, NanaBis and NanoCBD. The studies aim to investigate the long-term efficacy, tolerability and safety profiles of the products in the target populations. In our view these studies are an important milestone in the clinical progression of NanaBis and NanoCBD as, assuming positive readouts, the results will help generate data packages to support future regulatory approvals. We believe this will be of particular importance for NanaBis, Medlab's lead asset, which is anticipated to begin FDA Phase III studies for the treatment of cancer-related bone pain in mid-2023. Additional real-world data would also potentially help expansion into a broader indication for chronic pain management. Recruitment for both studies will commence in H222. We maintain our valuation of Medlab at A\$236.1m or A\$103.5/share.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/21	8.1	(12.4)	(6.3)	0.0	N/A	N/A
06/22	6.0	(8.4)	(3.1)	0.0	N/A	N/A
06/23e	7.7	(8.8)	(3.8)	0.0	N/A	N/A
06/24e	7.7	(9.6)	(4.2)	0.0	N/A	N/A

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

As a reminder Medlab Clinical is focused on the clinical development of NanaBis, a 50:50 formulation of synthetic CBD and Dronabinol (synthetic THC) for the treatment of cancer-induced bone pain. NanaBis is awaiting approval for the initiation of Phase III studies, which we [view](#) as the next significant catalyst for the share price performance. In addition, the company is also developing NanoCBD, a 100% CBD formulation to treat occupational stress and mental health.

The NanaBis study intends to build upon positive results reported from an ongoing observational study with the drug (c 1,200 patients), investigating its use in managing cancer and non-cancer related pain. Highlights from this include a non-serious adverse events profile of 12.3%, sustained pain reduction across six to 12 months and the ability to be tolerated in patients being treated with checkpoint inhibitors. Checkpoint inhibitors are critical therapies that form part of the high growth [immunoncology](#) market, so we see this as a significant result.

As these are observational studies, the drugs are currently being prescribed under compassionate use by clinicians in Australia allowing for data generation without the need to conduct capital intensive trials. We see this as a cost-effective method to collate clinically relevant data to support future drug applications.

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