EDISON

Medlab Clinical

Company update

NanaBis – now with synthetic CBD and THC

Pharma and biotech

Following the company's transformation to a pureplay biotech, Medlab Clinical has focused on the development of key asset NanaBis, a 50:50 micellar formulation of CBD and THC, in the treatment of cancer-induced bone pain. Based on recommendations from the FDA, Medlab has switched to using synthetic active pharmaceutical ingredients (APIs) in NanaBis and is imminently expected to approach the regulators for approval of a Phase III trial. We expect a recently compiled drug master file (DMF) for NanaBis to support this application. To fund its development ambitions, the company is now pursuing a dual listing on the US Nasdaq stock market, pending shareholder approval. We value Medlab at A$239.8m or A$0.70 per share.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/20	5.8	(13.5)	(0.06)	0.0	N/A	N/A
06/21	8.1	(12.4)	(0.04)	0.0	N/A	N/A
06/22e	6.5	(9.3)	(0.03)	0.0	N/A	N/A
06/23e	7.7	(10.1)	(0.03)	0.0	N/A	N/A

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

Phase III draws closer

Medlab now has a DMF prepared for the use of synthetic CBD and Dronabinol (synthetic THC) in its NanaBis formulation. The DMF will support the company's Investigational New Drug (IND) application to the FDA for the commencement of a Phase III study for NanaBis in the treatment of cancer-induced bone pain. We expect Medlab to approach the FDA with an IND application in H2 CY22. We believe the timely commencement of a Phase III trial represents a significant catalyst for the company.

US listing potential

Following an announcement in June 2022, management is pursuing a dual listing to the US Nasdaq stock market, subject to shareholder approval. If approved, the company will consolidate existing shares 150:1 and issue up to 4m new securities in an initial public offering (IPO) on the US Nasdaq market. A listing on the Nasdaq is likely to improve liquidity and investor awareness for the company, in our view. However, we note that, at the time of writing, the company has no binding agreement with an underwriter.

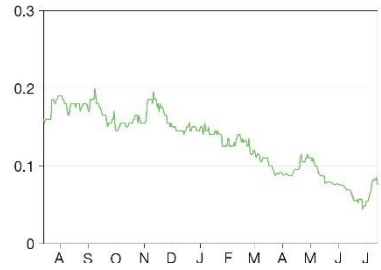
Valuation: A$239.8m or A$0.70 per share

Our valuation of Medlab Clinical is unchanged at A$239.8m or A$0.70 per share. Our model is based on a risk-adjusted NPV calculation for NanaBis in the treatment of cancer-induced bone pain and includes a net cash position of A$8.6m at the end-March 2022. Considering the company's H122 results, we have lowered our financial forecasts for FY22 (FY22e revenue A$6.5m vs A$8.0m previously). At the current reported quarterly burn rate of A$2.7m (unaudited), we estimate the company has sufficient cash to fund operations into Q323.

14 July 2022

Price	**A$0.05**
Market cap	**A$16m**
	A$1.47/US$
Net cash (A$m) at end-March 2022	8.6
Shares in issue	342.2m
Free float	69%
Code	MDC
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(10.1)	(19.1)	(53.9)
Rel (local)	15.6	(7.7)	(48.5)
52-week high/low	A$0.20		A$0.04

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.

Next events

FDA IND application	H2 CY22
Extraordinary general meeting for Nasdaq listing approval	28 July 2022

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Edison profile page

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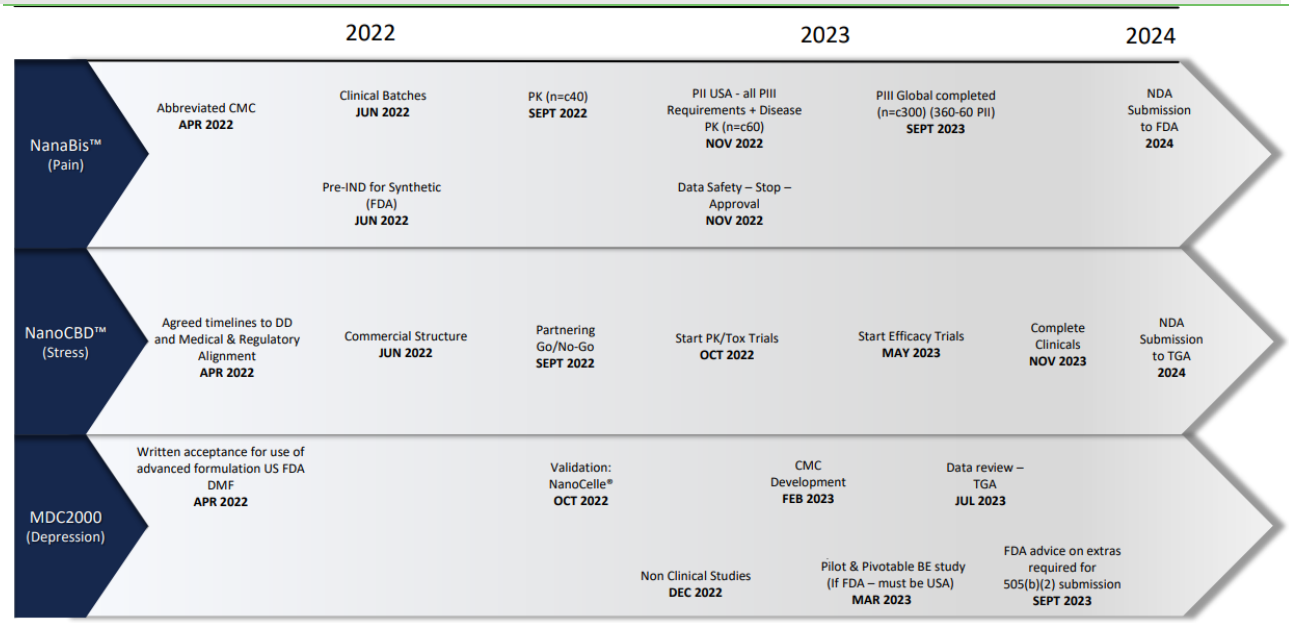
Synthetic APIs bring NanaBis Phase III closer

After much development work in 2021, Medlab is now fully utilising synthetic cannabidiol (CBD) and Dronabinol (synthetic tetrahydrocannabinol (THC)) in the company's NanaBis formulation. The advantages of using synthetic APIs, as opposed to natural isolates, are clear and recognised by regulators worldwide: quality control, especially in relation to purity and concentration, is far easier and much more reliable with synthetic compounds. Medlab now has a DMF prepared for both 100% CBD and 100% Dronabinol. A DMF is a comprehensive package of information relating to the full manufacturing process of APIs. While not compulsory to submit, the recognition of a DMF by the FDA could expedite a timely review of a New Drug Application (NDA). Medlab has not yet submitted the DMF to the FDA for review. However, we view the company's possession of a DMF as an encouraging development for the progression of both NanaBis and NanoCBD. We expect the company to submit the DMF, along with an advanced CMC Package and IND application, to the FDA in H2 CY22.

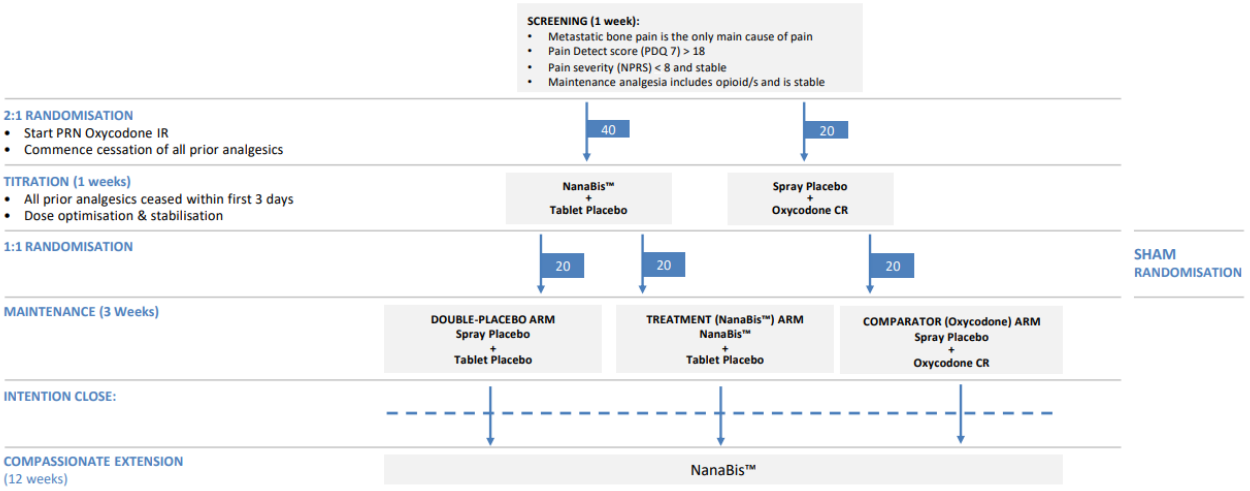
Exhibit 1: Medlab development schedule



Source: Medlab Clinical Biotech Investors Luncheon Presentation June 2022

We anticipate the FDA will set a meeting with management in H2 CY22 to discuss the commencement of a Phase III study investigating NanaBis in the treatment of cancer induced bone pain. As the core driver of our valuation for Medlab, the timely commencement of Phase III trials represents a significant catalyst for the company. Details of the Phase III design (NCT04808531) have already been disclosed (Exhibit 2). The randomised, multi-centre trial will investigate the analgesic efficacy of NanaBis (delivered as an oro-buccal spray) against a placebo and a comparator (oxycodone spray and controlled release, non-inferiority) and aims to enrol 360 participants. Importantly for US approval, the trial will enrol patients at sites in the United States, UK and Australia. We expect initiation of the Phase III trial in mid-2023, assuming a positive results from the regulators, and management expects the study could complete in early 2024. We will revisit our valuation assumptions for NanaBis in bone pain as additional information is communicated. With the US opioid crisis as a background, NanaBis could address the significant medical need for non-opioid based long-term pain management, in our view.

Exhibit 2: NanaBis Phase III trial design



Source: Medlab Clinical Jefferies Healthcare Conference Presentation

Potential Nasdaq listing in the works

In June 2022, Medlab announced that it will be pursuing a dual listing to the US Nasdaq stock market, subject to shareholder approval at an extraordinary generally meeting scheduled for 28 July 2022. Under the proposal, the company will consolidate existing shares 150:1 (adjusting all convertible securities and options as necessary) and issue up to 4m new securities in an IPO on the US Nasdaq market. Management has communicated THAT it intends to use the proceeds of the potential IPO to further develop NanaBis in cancer bone pain, NanoCBD for stress and MDC2000 in depression. The company has resolved that the issue price of new shares will be no less than 80% of the volume weighted average price for shares traded on the ASX (which will remain the primary listing post-IPO) over five trading days prior to the execution of an underwriting agreement between Medlab and its underwriters. Due to the high activity and liquidity associated with the US biotech market, we see a listing on the Nasdaq as potentially beneficial for Medlab. However, we note that at the time of writing, the company has no binding agreement with an underwriter.

Additional activity in the pipeline

In addition to NanaBis, Medlab is developing several other products, all based on the company's underlying NanoCelle technology:

- **NanoCBD:** a 100% CBD formulation that the company is developing to treat occupational stress and mental health issues. It is currently under joint venture discussions for over-the-counter pharmacy sales in Australia and is ready to be exported to the UK for compassionate use. The product has significant overlap with NanaBis including the DMF, CMC components and US manufacturing and packaging.
- **MDC2000:** Medlab will also pursue the development of MDC2000, a newly optimised form of the NRGBiotic product (a probiotic supplement previously part of Medlab's nutraceutical arm), in the alleviation of depression and mental health issues. This strategy will involve the company combining MDC2000 with its proprietary NanoCelle delivery platform. The global market for depression treatments in 2021 was estimated at US$5.49bn dollars and is expected to grow to c US$12.8bn by 2028 (source: EvaluatePharma), highlighting the potential for MDC2000 in this indication.
- **Nasal nucleic acid delivery programme:** in collaboration with the University of New South Wales and The Woolcock Institute, Medlab will begin investigation of the use of the NanoCelle platform to deliver nucleic acid payloads nasally, to ultimately develop a nasal vaccine for

COVID-19. While this programme is still very early stage, validation of a new method of delivery for NanoCelle (nasally) would represent a widening of the commercial potential of the platform, in our view.

Valuation and financials

We value Medlab Clinical at A$239.8m or A$0.70 per share, unchanged from our previous valuation. Our valuation is based on a risk-adjusted NPV calculation for NanaBis in the treatment of cancer-induced bone pain. Our underlying assumptions are unchanged (a breakdown of these can be found in our recent update report) and we will revisit them as the results of Medlab's Phase III FDA IND application are made public. We use a 12.5% discount rate and have rolled our model forward nine months and updated our foreign exchange estimates. We include a net cash position of A$8.6m at the end-March 2022 (our previous valuation used A$13.0m as at November 2021). We note this cash figure is an unaudited figure reported by the company. At the current reported burn rate of A$2.7m (again unaudited), we estimate the company has sufficient cash to fund operations into Q323.

Exhibit 3: Risk-adjusted NPV model

Platform	Launch	Peak sales (US$m)	NPV (A$m)	NPV/share (A$)	Probability of success	rNPV (A$m)	NPV/share (A$)
NanaBis for cancer-induced bone pain	2025	410	558.4	1.63	45.0%	231.2	0.68
Net cash at end-March 2022			8.6	0.03	100.0%	8.6	0.03
Valuation			**567.0**	**1.66**		**239.8**	**0.70**

Source: Edison Investment Research

Medlab reported A$3.04m in revenue for H122 (an increase from A$2.8m in the same period a year prior), due largely to a A$1.2m payment from the sale of the nutraceutical business arm. Medlab recorded additional revenues in H122 from the sale of nutraceuticals (A$52k) and pharmaceuticals (A$383k, from compassionate use sales). The company also recorded an R&D tax incentive from the Australian government totalling A$2.6m in the period. We note that the company has an approved R&D cash back claim of A$12m annualised over three years against the future expenses of NanaBis development. Operating expenses for H122 totalled A$7.3m, c 30% lower than our estimated figure for FY22, on an annualised basis. This resulted in an operating loss of A$4.2m in H122 (c 7% lower than a H121). Net cash used in operating activities for H122 was A$3.6m, an increase of c 13% from the same period a year prior (H121: A$3.2m). Cash and cash equivalents at end-H122 were A$11.2m, down from A$13.4 at the beginning of the period.

In light of the H122 figures, we have adjusted our financial estimates for the company's performance in FY22. We adjust our revenue estimate for FY22 to A$6.5m, from A$8.0m previously. We believe this suitably reflects the phasing out of nutraceutical sales while providing for a modest increase in compassionate pharmaceutical sales during the period. Our estimated operating expenses for FY22 are A$15.7m, down from A$20.5 previously, reflecting a reduced spend on all fronts (bar professional and consulting fees) as the company approaches the FDA for approval of the Phase III NanaBis trial. If the NanaBis Phase III trial IND application is approved by the FDA, we expect expenses to increase in FY23 to A$17.7m, as preparations for the trial begin and patients are enrolled from mid-CY23. We estimate an operating loss for FY22 of A$9.2m, from A$12.4m previously, rising to A$10.0m in FY23. On 14 April, Medlab reported an end-March 2022 cash position of A$8.6m (unaudited), which at the current reported quarterly burn rate of A$2.7m in Q322, we estimate will fund operations into 2023. However, we estimate the company will initiate a Phase III trial in 2023, hence we expect the company will need to raise c A$25m in early 2023 to fund further development of NanaBis to the anticipated Phase III readout in early-2024. A portion of this capital may be provided by the potential Nasdaq listing. We estimate the company will need c A$50m before reaching sustainable profitability.

Exhibit 4: Financial summary

Accounts: Local GAAP, year-end: 30 June, A$000s	2019	2020	2021	2022e	2023e
INCOME STATEMENT					
Sales	5,364	2,848	4,399	1,300	1,300
Other income	2,723	2,965	3,725	5,200	6,400
Total revenues	8,087	5,814	8,125	6,500	7,700
Raw materials and consumables used	(3,064)	(2,805)	(2,940)	(500)	(500)
Employee benefits expense	(6,465)	(6,666)	(7,935)	(7,500)	(7,875)
Amortisation and depreciation	(147)	(961)	(873)	(873)	(873)
Professional and consulting fees	(1,004)	(1,257)	(1,731)	(2,200)	(2,310)
Operating lease costs	(501)	(199)	(186)	(192)	(189)
Selling & marketing expenses	(1,534)	(1,750)	(771)	(260)	(273)
R&D / trial expenses	(1,026)	(1,947)	(2,103)	(1,750)	(1,838)
Other Operating Expenses	(2,440)	(3,520)	(3,850)	(2,400)	(3,844)
Share-based payments	0	0	0	0	0
Exceptional items	0	0	0	0	0
Operating profit/(loss)	(8,094)	(13,291)	(12,264)	(9,176)	(10,002)
Finance costs	(80)	(197)	(139)	(139)	(139)
Reported PBT	(8,174)	(13,488)	(12,403)	(9,315)	(10,141)
PBT - normalised	(8,174)	(13,488)	(12,403)	(9,315)	(10,141)
Income tax expense	0	0	0	0	0
Minority Interests	(83)	(89)	(79)	(79)	(79)
Reported net income	(8,091)	(13,399)	(12,324)	(9,236)	(10,062)
Basic average number of shares, m	209.0	225.7	294.8	342.2	342.2
Basic EPS (A$)	(0.04)	(0.06)	(0.04)	(0.03)	(0.03)
Basic EPS (A$) - adjusted	(0.04)	(0.06)	(0.04)	(0.03)	(0.03)
Diluted EPS (A$)	(0.04)	(0.06)	(0.04)	(0.03)	(0.03)
BSLSNCE SHEET					
Property, plant and equipment	632	592	483	567	650
Right of use assets	0	2,288	1,601	1,601	1,601
Other non-current assets	483	483	483	483	483
Total non-current assets	1,115	3,364	2,567	2,650	2,733
Cash and equivalents	11,442	9,063	13,435	4,118	1,000
Trade and other receivables	3,814	3,379	3,356	3,356	3,356
Inventories	2,218	1,473	792	792	200
Other current assets	1,616	509	496	496	496
Total current assets	19,090	14,425	18,079	8,763	5,052
Non-current loans and borrowings*	0	0	0	0	6,435
Provisions	173	478	233	233	233
Lease liabilities	0	1,630	989	989	989
Other non-current liabilities	55	0	0	0	0
Total non-current liabilities	228	2,107	1,222	1,222	7,657
Trade and other payables	3,622	3,218	2,991	2,991	2,991
Employee benefits	389	504	516	516	516
Borrowings	972	94	68	68	68
Lease liabilities	0	610	638	638	638
Total current liabilities	4,983	4,426	4,519	4,519	4,519
Equity attributable to company	15,050	11,397	15,144	5,909	(4,153)
CASH FLOW STATEMENT					
Net cash used in operating activities	(10,315)	(10,422)	(10,353)	(9,236)	(9,470)
Capex	(340)	(243)	(83)	(83)	(83)
Cash used in investing activities (CFIA)	(340)	(243)	(83)	(83)	(83)
Net proceeds from issue of shares	1,303	10,398	15,449	0	0
Movements in debt	472	(1,513)	(26)	0	6,435
Other financing activities	0	(563)	(612)	0	0
Cash flow from financing activities	1,775	8,321	14,810	0	6,435
Increase/(decrease) in cash and equivalents	(8,889)	(2,379)	4,372	(9,319)	(3,118)
Cash and equivalents at beginning of period	20,333	11,444	9,065	13,437	4,118
Cash and equivalents at end of period	11,444	9,065	13,437	4,118	1,000
Net (debt)/cash	10,470	8,969	13,367	4,050	(5,503)

Source: Company accounts, Edison Investment Research. Note: *Long-term debt modelled instead of equity issue.

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