EDISON

Medlab Clinical

CY23 outlook

NanaBis development centre stage in 2023

Pharma and biotech

As Medlab Clinical moves into 2023, the expected commencement of a Phase III trial for NanaBis (the company's cannabinoid based analgesic therapy) in cancer-induced bone pain will be the focus for investors. Management made considerable progress towards Phase III in 2022, by switching to a purely synthetic cannabinoid formulation and gathering encouraging real-world data on NanaBis use. We believe these actions should maximise the potential for NanaBis in both a regulatory and a commercial setting. We note that successful progression of the company's programmes will be contingent on Medlab's ability to raise capital, given the short cash runway (funded into March 2023) and recent setback with the Nasdaq listing plans. We update our estimates to reflect the financing risk and macro uncertainty, resulting in our valuation decreasing to A$183.5m or A$80.4/share, from A$236.1m or A$103.5/share.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (A$)	P/E (x)	Yield (%)
06/21	4.4	(12.4)	(6.27)	0.0	N/A	N/A
06/22	1.3	(8.4)	(3.14)	0.0	N/A	N/A
06/23e	1.5	(13.9)	(6.04)	0.0	N/A	N/A
06/24e	1.8	(21.7)	(9.44)	0.0	N/A	N/A

Note: *Normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS adjusted for 1:150 share consolidation in August 2022.

Important development catalyst for NanaBis

Company attention in 2023 will be largely focused on preparations for and the commencement of the global Phase III trial investigating the use of NanaBis as a treatment for cancer induced bone pain. Preparations so far (real-world data gathering, reformulation work) have de-risked the development programme somewhat, and we see the timely commencement of a Phase III trial (expected in H223) as a key catalyst for the company in 2023.

Imminent need to raise funds

Timely trial commencement and progression, however, requires Medlab to be sufficiently capitalised, which has now been challenged by its recent decision to shelve the Nasdaq listing plans (to raise US$7m in net proceeds), driven in part by the unfavourable macro environment. With a cash balance of A$2.8m at end December 2022 (and a monthly cash burn rate of c A$1m to meet corporate needs) providing a runway up to March 2023, Medlab needs to raise funds imminently to support its development plans. We estimate the need to raise A$10m in H223 plus A$20m in FY24, which we model as illustrative debt as per Edison's approach. We note, however, that the company may need to raise funds through an equity issue instead (as has been the case historically), resulting in shareholder dilution.

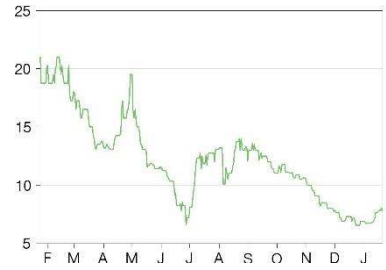
Valuation: A$183.5m or A$80.4 per share

While our underlying assumptions for NanaBis's clinical progression and long-term potential remain unchanged, we now factor in the broader macroeconomic instability and the aforementioned financing risk for Medlab in our valuation, by paring the probability of success from 45% to 35%. As a result, our undiluted valuation falls to A$183.5m or A$80.4/share, from A$236.1m or A$103.5/share.

23 January 2023

Price	**A$7.82**
Market cap	**A$18m**
	A$1.45/US$
Net cash (A$m) at 31 December 2022	2.8
Shares in issue	2.3m
Free float	69%
Code	MDC
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	8.2	(26.6)	(64.2)
Rel (local)	1.6	(33.7)	(64.2)
52-week high/low	A$21.00		A$6.55

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

NanaBis Phase III trial commencement	Q4 CY23

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Edison profile page

Investment summary

A pure-play biotech with a proprietary platform

Medlab is an Australian biotechnology company that is developing therapeutics using its proprietary delivery platform NanoCelle. The company's lead asset, NanaBis (a 1:1 synthetic tetrahydrocannabinol (THC) and cannabidiol (CBD) formulation), is anticipated to enter an FDA approved, global Phase III trial for the treatment of cancer-induced bone pain in Q4 CY23. We believe that, if approved, NanaBis could represent a valuable alternative to opioid analgesic use and associated problems (additional injuries, abuse, safety). During 2022 management made significant strides to progress NanaBis toward Phase III development, including switching to a fully synthetic formulation (preferred by regulators) and gathering supportive real-world data for the drug's use. We expect the company to continue its focus on progressing NanaBis towards Phase III in 2023. If results are positive, we expect management could file a New Drug Application (NDA) with the FDA as soon as late-2024.

Valuation: A$183.5m or A$80.4/share

We value Medlab on a risk-adjusted but undiluted net present value (rNPV) methodology, focusing solely on its lead asset NanaBis. We do not include the intrinsic value of the company's NanoCelle delivery platform or Nanabis's possible expansion to a broader chronic pain setting or other projects based on the platform (including the Phase I ready asset NanoCBD), but note the upside potential from each as development continues. We previously assumed a 45% probability of success for the NanaBis programme, but have now revised it downwards to 35% to discount for the negative macroeconomic environment and increased financing risk for Medlab (given the short cash runway and Nasdaq IPO halt), which may likely have an impact on clinical timelines. As a result, our overall undiluted valuation resets lower to A$183.5m or A$80.4/share (vs A$236.1m or A$103.5/share, previously).

Financials: Limited funding headroom

As a late-stage clinical development company, Medlab is yet to generate commercial revenues, although it recognises a small income stream through the sale of its drugs under the Australian special access scheme and R&D tax incentives. In FY22, Medlab's total revenue from continued operations increased 35.3% y-o-y to A$6.0m and operating expenses stood at A$14.3m. We expect R&D expenses to increase materially between FY23 and FY25 with the planned commencement of Phase III clinical trials. With a net cash balance of A$2.8m at end December 2022 and an expected monthly near-term cash burn rate of ~A$1m for general corporate purposes alone, we estimate the company has cash to fund its operations only up to March 2023, requiring it to raise funds imminently to continue supporting its development plans and stay on track for the Phase III trials. With plans for the Nasdaq listing now stalled, we expect Medlab to explore other avenues to raise capital. We estimate the need to raise A$10m in H223 and A$20m in FY24 to progress NanaBis through Phase III and to a planned launch in 2025. As per Edison standards, we model the estimated fund raises as illustrative debt but note that the company may resort to equity funding instead, resulting in material shareholder dilution.

Sensitivities: Pure-play biotech and funding risks

Medlab is subject to the typical drug development risks, including clinical development delays or failures, IP protection, regulatory risks, competitor successes, partnering setbacks, financing and commercial risks. The development of NanaBis in cancer-related bone pain comprises the largest part of the company's value, in our view, and a major near-term risk for the company would be the

failure to demonstrate meaningful efficacy in Phase III trials, as the current treatment market is highly fragmented with many generic drugs available. Failure here could significantly hinder NanaBis's likelihood of approval. Medlab will need to raise extra capital soon, which, if done through an equity raise, may dilute current investors.

A growing pipeline based on the NanoCelle platform

Medlab continues to leverage its proprietary NanoCelle platform to develop new drug formulations to address unmet medical needs. Currently, the company is primarily developing NanaBis, a NanoCelle encapsulated cannabinoid formulation, for the treatment of cancer bone pain. Following positive safety, efficacy and pharmacokinetic/pharmacodynamic (PK/PD) data from an Australian Phase I/II trial (for more detail see our initiation report), Medlab is now progressing NanaBis to a potentially registrational, global Phase III trial. The timely commencement of this trial, which we expect in late-2023, will be a significant catalyst for the company, in our view. NanaBis's use in this setting is supported by positive data from a handful of real-world studies. We expect 2023 to be populated by several other catalysts from Medlab's secondary drug development programmes (Exhibit 1).

Exhibit 1: Medlab Clinical's development pipeline

NanoCelle®	PRIMARY Drug Development	SECONDARY Drug Development
Core product offering Alternative, more effective method of consuming medical products, compared to the traditional methods, which include intravenous, intramuscular, subcutaneous, oral, rectal, inhalation and transdermal.	**NanaBis™** Cannabinoids (THC+CBD) with FDA recognized API DMF's for proposed indication of cancer bone pain (bone METs) + larger neuropathic pain populations. Regulatory Filing expected late 2024.	**NanoCBD™** - Cannabinoid (CBD) with a FDA recognised API DMF for proposed indication of occupational stress, + mild, chronic pain populations. **MDC2000** - Proposed FDA program using earlier, approved drug substance for depression. **Nasal RNA** - Nucleic Acid collaboration with Woolcock Institute at Macquarie University and UNSW in pre-clinical stages for a nasal vaccine delivery utilising nucleic acid leading to new vaccine and/or anti-viral technologies.

Source: Medlab Clinical corporate presentation

In addition to NanaBis, Medlab is leveraging its NanoCelle platform to develop three other products, thus diversifying the company's pipeline risk. These products are:

- **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 available in the UK for compassionate use. The product has significant overlap with NanaBis including the Drug Master File (DMF) and chemistry, manufacturing, and controls (CMC) components and US manufacturing and packaging. NanoCBD is currently Phase I ready.
- **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 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 is investigating 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.

NanoCelle: The heart of the Medlab pipeline

At the heart of Medlab's innovation is NanoCelle, a patented drug delivery platform designed to bypass the digestive tract and first-pass metabolism. NanoCelle's particles (micelles) have a hydrophobic core and hydrophilic shell, therefore the formulation is water-soluble (suitable for the delivery of insoluble drugs) and stable at room temperature despite the original solubility characteristics of the active pharmaceutical ingredient (API).

The API encapsulated in NanoCelle can be absorbed via buccal or nasal delivery using a spray, as opposed to a peroral or intravenous route. The benefits of transbuccal delivery are closer to those of intravenous administration versus peroral (quick resorption, avoids first-pass metabolism in the liver, so the dose can be lowered, no issues with interactions with food), but without intervention. With minor adjustments to the manufacturing procedure, the NanoCelle technology can be applied to a wide variety of active ingredients, both nutritional and pharmaceutical. The exact composition, possible variations of it and combinations with various APIs are protected by a patent that was first filed in 2016, and now granted in all key markets including Australia, Europe, Canada and the United States. The protection period extends to at least 2036. See our initiation report for a more detailed introduction to NanoCelle.

NanaBis development the core focus in CY23

The company's lead asset NanaBis is a 1:1 formulation of THC and CBD encapsulated in Medlab's proprietary NanoCelle particles. Following divestment of its nutraceuticals business, Medlab's core focus over CY23 will be the commencement of FDA approved Phase III trials of NanaBis in cancer-induced bone pain, a goal that the company made significant steps towards in 2022.

Synthetic APIs bring Phase III into view

As per the regulator's preference, the reformulation of NanaBis to contain synthetic CBD and THC (dronabinol), rather than botanical extracts, was completed in mid-2022. 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. In our view, Medlab's decision to use synthetic APIs should somewhat de-risk further development by removing any confounding factors associated with product quality variability and reducing the likelihood of regulator push pack.

After much effort over FY22, Medlab has prepared a DMF for the synthetic CBD and dronabinol NanaBis formulation. This 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. 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 an NDA. We view the company's possession of a DMF as an encouraging development for the progression of NanaBis and we expect the company to submit the

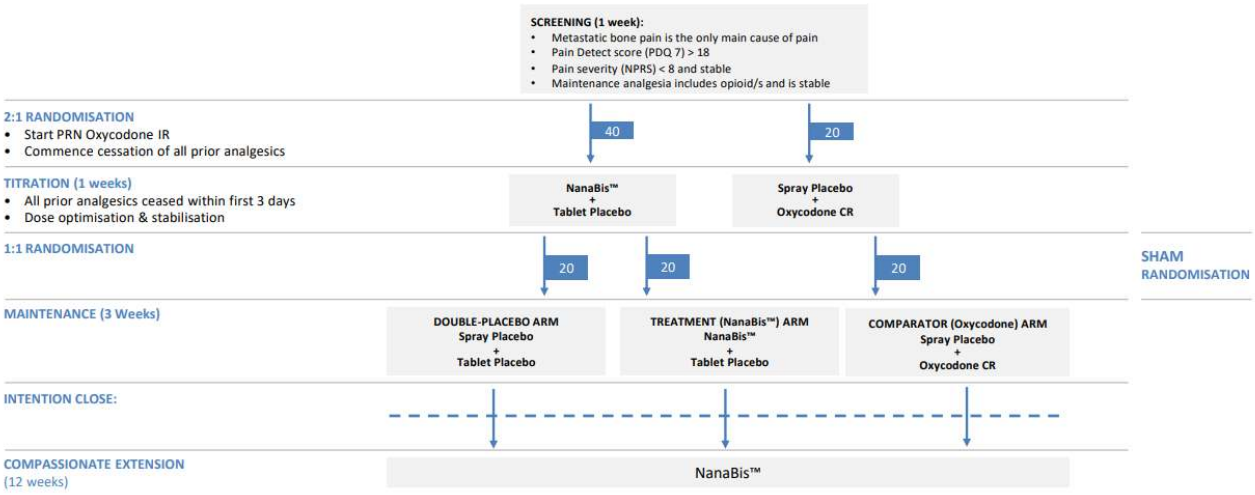
DMF, along with an advanced CMC package and IND application, to the FDA in Q1 CY23. As it is the core driver of our valuation for the company, we believe the timely commencement of a Phase III trial, which we expect in Q4 CY23, represents a significant catalyst for the company's share price.

Phase III designed to maximise NanaBis potential

Details of Medlab's Phase III trial design (NCT04808531) for NanaBis in cancer-induced bone pain 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 Medlab, the trial design is 17 weeks long per participant (1 week screening, 1 week titration, 3 weeks maintenance and 12 weeks extension; Exhibit 2), meaning top-line results should not take long to gather, providing enrolment proceeds on schedule. The trial will enrol patients at sites in the United States, UK and Australia. Assuming positive results from the regulators (the company is expected to approach the FDA with an IND in Q1 CY23), we expect the initiation of the Phase III trial of NanaBis around late-2023 could support an NDA filing date in late-2024, as communicated by management.

In our view, the demonstration of meaningful efficacy versus placebo in the Phase III trial will be important. However, the key to maximising NanaBis's commercial impact will be the demonstration of non-inferiority versus oxycodone (an opioid analgesic). Set against the backdrop of the opioid crisis in the United States, we believe support for nonopioid pain killers with comparable efficacy from various stakeholders will only grow. The study is designed to demonstrate that NanaBis is effective as a monotherapy for the management of opioid-requiring bone pain due to metastatic cancer and that NanaBis monotherapy is non-inferior to opioid treatment (see our initiation report for more detail on the design). Although it is a niche in pain disorders, Medlab believes it represents the fastest route to market and, if the data are positive, we expect label expansion into other pain disorders via bridging trials would be an attractive prospect for the company.

Exhibit 2: NanaBis Phase III trial design



Source: Medlab Clinical corporate presentation

Real-world data continues to support clinical results

In January 2023, Medlab announced positive interim data from its real-world evidence study for NanaBis (Medcare observational study). The 12-month study comprised 1,172 patients (with both cancer and non-cancer related pain) and exhibited a good safety, tolerability and sustainability profile for NanaBis use. The enrolled patients reported a 55% improvement in pain relief, along with

reduced opioid use in 75% of the patients. Importantly, 92% of the patients with cancer bone metastasis reported reduced pain severity and pain interference scores after six months. Overall, 454 patients withdrew from the programme, while at least 77 patients have continued to receive NanaBis treatment post study completion. We believe this represents encouraging support for NanaBis's use as an analgesic and as an alternative to opioids; however, randomised placebo-controlled data will be essential for regulatory approval. Nevertheless, we expect this data could support Medlab in securing approval for the planned Phase III trials and may also help in optimising the trial design. The final data are expected in July 2023 and Medlab plans to relaunch the study as the ENHANCE study in March 2023, with the objective to generate more focused data. We expect data from both studies to support Medlab's efforts in securing regulatory approval to initiate Phase III trials for NanaBis.

Compassionate use status granted in the UK

Medlab announced in November 2022 that it had received approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for its lead product NanaBis (NanaDol in the UK) to be used under its Named Patient Program and other compassionate areas. In our opinion the MHRA approval is an encouraging development, as it allows Medlab to generate additional real-world data to support the anticipated Phase III clinical trial of synthetic NanaBis in cancer bone pain. Positive feedback from compassionate use may create patient advocates and key opinion leaders for the drug. In our view, this new approval provides further regulatory validation for Medlab's NanaBis/NanaDol product.

Cancer-induced bone pain: A market with high unmet needs

The neuropathic pain market is characterised by high unmet medical need in all indications and in all major markets, where only half of patients respond to existing treatments. The patient population is expected to continue to grow, due to factors such as an ageing population, an increased incidence of type 2 diabetes, and cancer that requires chemotherapy. Because of the risk of abuse, overdose and secondary injuries, doctors avoid prescribing opioid drugs as first-line treatment for pain. Despite this problem they are still frequently used and the need for new non-opioid treatments is large.

Bone pain is one of the most common types of pain in cancer patients and approximately 60–84% of patients with advanced cancer are estimated to experience varying degrees of bone pain. The treatment of such pain often follows a ladder of different interventions categorised by severity:

- Step one. Mild pain: non-opioid analgesics such as nonsteroidal anti-inflammatory drugs with or without adjuvants.
- Step two. Moderate pain: weak opioids (hydrocodone, codeine, tramadol) with or without non-opioid analgesics, and with or without adjuvants.
- Step three. Severe and persistent pain: potent opioids (morphine, methadone, fentanyl, oxycodone) with or without non-opioid analgesics, and with or without adjuvants.
- Step four. Invasive or minimally invasive treatments.

We expect the most impactful application of NanaBis, if clinical results are positive, will be in the replacement or reduction of opioid-based pain treatment regimens (steps two and three). We believe the advantageous safety and tolerability profile of the formulation and low potential for abuse and addition should work in NanaBis's favour versus opioid analgesics.

Planned Nasdaq listing to support pipeline development

In June 2022, Medlab announced that it would be pursuing a dual listing to the US Nasdaq stock market. As part of the offering, the company plans to issue c 1.8m share units (ordinary shares plus

an equivalent number of warrants) at US$4.45/share and c 1.8m pre-funded warrants at US$4.4999/unit (nominal exercise price of US$0.0001/unit) to raise c US$8m in gross initial public offering (IPO) proceeds (c US$7m net). The company filled the IPO registration statement with the US Securities and Exchange Commission in January 2023; however, the company has now communicated that it will delay the proposed listing, given the prevailing biotech market conditions in the United States.

Management intended to use the funds from the Nasdaq listing to support the upcoming IND submission for NanaBis in the United States (to commence Phase III trials) and to progress Medlab's development pipeline (NanoCBD for stress and MDC2000 in depression). The company is now exploring potential options to pivot its financing strategy.

Sensitivities

Medlab is subject to the typical drug development risks, including clinical development delays or failures, IP protection, regulatory risks, competitor successes, partnering setbacks, financing and commercial risks. The development of NanaBis in cancer bone pain comprises the largest part of the company's value, in our view. However, Medlab has initiated or explored the feasibility of several other projects using its NanoCelle drug delivery platform. A major near-term risk for the company would be the failure to demonstrate non-inferiority to opioid pain medications in Phase III trials, which could significantly hinder NanaBis's likelihood of approval.

Given the nature of the drug development business, Medlab will need to raise extra capital soon, which, if done through an equity raise, may dilute current investors. For the purposes of our valuation, we model any potential capital raises as illustrative debt, thus excluding any potential equity dilution. As the company has indicated it will seek to partner the development or commercialisation of its drug candidates, its ability to successfully negotiate a deal is key.

Medlab is targeting a large market, where current treatment is very fragmented and there are many generic drugs for pain. Although not always effective, they are cheap. The success of NanaBis will depend on its efficacy, the potential to reduce or replace opioid use, and the drug's pricing.

Financials

Following divestment of its nutraceutical business in October 2021 (H122), Medlab now generates revenues solely from pharmaceutical research, which includes recurring income from the sales of its cannabinoid-based therapeutics NanaBis and NanoCBD via a special access scheme in Australia (A$1.3m in FY22 and A$733k in FY21). Medlab plans to continue offering its cannabinoid products via this programme in Australia and plans similar initiatives in the UK, other European countries and the United States, so there is potential to grow the top line even before NanaBis completes the Phase III trial. In addition to product sales, the company receives grants and R&D tax incentives from the Australian government.

In FY22, Medlab's total revenue from continued operations grew 35.3% y-o-y to A$6.0m, out of which A$4.7m was from R&D tax incentives, government grants and other revenues, while the rest was attributed to the pharmaceutical research segment (A$1.3m). Including the divested nutraceutical business, total group revenue was up 5.3% y-o-y to A$8.6m in FY22. Net income from the divested business was recognised as discontinued operations in the accounts (A$1.2m). Medlab's total operating expenses were A$14.0m, broadly in line with the FY21 figure of A$13.9m, due to no major R&D related activities undertaken during the period as the company is awaiting regulatory approval to commence Phase III trials in 2023. We note that in November 2021 Medlab was granted an Advanced and Overseas Finding rebate from the Australian government to advance

its lead programme NanaBis through clinical development (43.5% cash rebate on estimated future R&D expenses of A$27m). As part of agreement, Medlab received a tax refund of A$3.6m in September 2022. The net loss for the full year was reported at A$8.4m, compared to A$9.6m (restated figure) in FY21.

We have updated our FY23 revenue estimates to reflect the A$0.85m in sales receipts in H123. For FY24, we assume 20% y-o-y growth in this figure, assuming Medlab's products continue to be made available under the special access scheme. We have also updated our estimates for the R&D tax credit based on the A$3.6m tax credit received in September 2022 and our revised expectation for FY24. We make certain adjustments to our operating expense estimates, primarily R&D, which we raise materially in FY23 and FY24 to reflect the higher expenses related to Phase III trials for NanaBis, expected to commence in H223 (360 patients planned for enrolment although this number is subject to change as talks with regulators advance). As a result, our estimates for R&D expenses increase to A$7.0m in FY23 and A$12.0m in FY24, versus A$1.6m and A$1.7m previously. Overall, our profit before tax forecasts for FY23 and FY24 reduce to A$13.9m and A$21.7m, respectively. We highlight that any delay in these expected clinical timelines would lead to a revision to our R&D estimates.

We note that Medlab had a net cash balance of A$2.8m at the end of December 2022, which, at an expected monthly burn rate of A$1m (as no clinical trials are currently ongoing), provides a runway only into March 2023, requiring the company to raise funds imminently. With the planned Nasdaq IPO listing now being put on hold, we expect the company to explore other avenues to raise the required capital, including an equity issue at the ASX. We estimate the need to raise a total of A$45m (including A$10m in H223) before reaching break even in FY26, contingent on the company successfully completing Phase III trials followed by launch in FY25. These raises are reflected in our model as illustrative debt. We note, however, that the company may need to raise the said funds through an equity issue instead (as has been the case historically), resulting in shareholder dilution.

Valuation: A$183.5m or A$80.4 per share

We value Medlab on a risk-adjusted, undiluted net present value (rNPV) methodology, based only on its lead asset NanaBis, currently in clinical development for cancer-induced bone pain. We do not include the intrinsic value of the company's NanoCelle delivery platform or NanaBis's possible expansion to a broader chronic pain setting or other projects based on the platform (including the Phase I ready asset NanoCBD) due to their early stage, but note the upside potential from each as development continues. We also do not explicitly value the income associated with compassionate use of NanaBis as this figure is likely to be small. However, these revenue streams may help lower cash burn and preserve cash. We previously assumed a 45% probability of success for the NanaBis programme, but have now revised it downwards to 35% to reflect the negative macroeconomic environment and increased financing risk for Medlab (given the short cash runway and Nasdaq IPO halt), which may have an impact on clinical timelines. We continue to use a discount rate of 12.5%, in line with Edison standards. As a result, our overall valuation resets lower to A$183.5m or A$80.4/share (versus A$236.1m or A$103.5/share, previously), which is undiluted by any potential future equity raise to bring the development of NanoBis forward.

Exhibit 3: NanaBis valuation

Platform	Launch	Peak sales (US$m)	NPV (A$m)	NPV/share (A$)	Probability of success	rNPV (A$m)	rNPV/share (A$/share)
NanaBis for cancer-induced bone pain	2025	390	538.2	235.7	35%	180.8	79.17
Net cash at end-December 2022			2.8	1.21	100.0%	2.8	1.21
Valuation			**541.0**	**236.92**		**183.5**	**80.37**

Source: Edison Investment Research

Our underlying assumptions for the valuation remain unchanged. We have considered patients with more pronounced pain (numerical rating scale score ≥5, estimated at 38% of all cancer patients) as the target population, in line with the NanaBis Phase III trial design to demonstrate non-inferiority to opioids. Because most newly diagnosed patients undergo cancer treatment, the chronic treatment of pain is likely established later in the disease course, depending on needs. To estimate the potential patient target population, we apply 38% to annual cancer death rates, which is around 160 per 100,000 (US data, but likely similar in most wealthier countries). We calculate addressable patient populations of 529k in the United States, 62k in Canada, 41k in Australia and 640k in the top 15 wealthy European countries. So, the total target population for NanaBis we use in our model is c 1.27 million in a chronic setting.

We estimate NanaBis peak sales (which will be dependent on the strength of Phase III data, pricing and market penetration) at c US$390m, which is based on a US$3,000 price tag per patient per year in the United States, based on a similar price tag for the approved drug Sativex, which is also a 1:1 combination of THC and CBD and is currently approved in Europe for pain related to multiple sclerosis (MS). We apply a 33% discount to other geographies and use a market penetration of 10% due the fragmented nature of the market. Pricing and market penetration are the two key assumptions that our model is most sensitive to. Also, we use the company's guidance that the trial could be finished in 2023 or 2024 and NanaBis could be launched in 2025. We assume 25% COGS and a 35% S&M margin in the NanaBis NPV project, which gives a total operating margin of 40%. This is theoretical at the moment, as the commercialisation of NanaBis could play out in a variety of different ways. For example, Medlab could consider out-licensing NanaBis at any point if management thinks the economics of the deal are good. There are no recent comparable deals to use as a benchmark for NanaBis, in our view. Therefore, we do not include out-licensing in our model. However, if a partner comes on board while NanaBis is in development, the remaining R&D costs would be absorbed by the partner, while Medlab would receive royalties in the future. Exhibit 4 provides a two-dimensional sensitivity analysis of peak sales to these two underlying assumptions.

Exhibit 4: Peak sales – sensitivity to price and market penetration

		Market penetration						
		4%	6%	8%	10%	12%	14%	16%
Pricing ($)	**2,000**	100	160	210	260	310	370	420
	2,500	130	200	260	330	390	460	520
	3,000	160	230	310	**390**	470	550	630
	3,500	180	270	370	460	550	640	730
	4,000	210	310	420	520	630	730	840

Source: Edison Investment Research. Note: Pricing is per patient per year.

Furthermore, to better understand the value of Medlab's core technology, NanoCelle, we have looked at comparable deals involving drug delivery platforms (as opposed to product-centric deals). Exhibit 5 summarises notable drug delivery platform deals since 2019. The upfront payments averaged US$28m, while potential milestone payments averaged US$510m. We note that most of these deals were classified as preclinical, meaning that the licensee companies paid for access to the delivery technology and then spent their own funds to continue product development (while the licensor companies collected the payment without involvement in clinical development). With minor

adjustments to the manufacturing procedure, the NanoCelle technology could be applied to a wide variety of active ingredients. Since NanoCelle's key patent has recently been granted in the key US market, in theory there are now no obstacles to Medlab engaging in more concrete out-licensing discussions.

Exhibit 5: Deals involving drug delivery platforms (2019–22)

Date	Licensor	Licensee	Stage	Upfront (US$m)	Milestones (US$m)	Comments
24/03/2022	Chugai Pharmaceuticals	Halozyme Therapeutics	Preclinical	25	185	Global rights to Halozyme's Enhanze drug delivery technology (recombinant human hyaluronidase PH20 enzyme) for subcutaneous formulation of four HIV drug targets.
29/06/2020	Bioasis Technologies	Chiesi	Preclinical	3	141	Bioasis xB^3 platform for the delivery of therapeutics across the blood-brain barrier of undisclosed enzymes to treat four lysosomal storage disorders.
22/06/2021	ViiV Healthcare	Halozyme Therapeutics*	Preclinical	40	700	Global rights to Halozyme's Enhanze drug delivery technology (recombinant human hyaluronidase PH20 enzyme) for subcutaneous formulation of four HIV drug targets.
26/03/2020	Evox Therapeutics	Takeda	Preclinical	44	842	Global rights to Evox's exosome-based targeting and delivery technology.
28/03/2019	StrideBio	Takeda	Preclinical	30	680	Adeno-associated viral (AAV) capsids for delivery of gene therapies for Friedreich's Ataxia and two additional targets.
Average				**28**	**510**	

Source: Edison Investment Research, EvaluatePharma. Note: *There are multiples other deals involving Halozyme and other parties, which licensed rights to Enhanze.

Exhibit 6: Financial summary

Accounts: Local GAAP; year end June; A$000s	2020	2021	2022	2023e	2024e
Income statement					
Sales	2,848	4,399	1,282	1,539	1,847
Other income	2,965	3,725	4,749	4,986	2,493
Total revenues	5,814	8,125	6,031	6,525	4,340
COGS	(2,805)	(2,940)	(336)	(404)	(484)
Employee benefits expense	(6,666)	(7,935)	(7,105)	(7,460)	(7,833)
Amortisation and depreciation	(961)	(873)	(851)	(851)	(851)
Professional and consulting fees	(1,257)	(1,731)	(1,858)	(1,951)	(2,049)
Operating lease costs	(199)	(186)	(207)	(150)	(178)
Selling & marketing expenses	(1,750)	(771)	(187)	(196)	(206)
R&D / trial expenses	(1,947)	(2,103)	(1,503)	(7,000)	(12,000)
Other Operating Expenses	(3,520)	(3,850)	(2,270)	(2,315)	(2,362)
Share-based payments	0	0	0	0	0
Exceptional items	0	0	0	0	0
Operating profit/(loss)	(13,291)	(12,264)	(8,287)	(13,802)	(21,623)
Finance costs	(197)	(139)	(102)	(102)	(102)
Reported PBT	(13,488)	(12,403)	(8,388)	(13,904)	(21,725)
PBT - normalised	(13,488)	(12,403)	(8,388)	(13,904)	(21,725)
Income tax expense	0	0	0	0	0
Minority Interests	(89)	(79)	(66)	(110)	(172)
Reported net income	(13,399)	(12,324)	(7,162)	(13,794)	(21,553)
Basic average number of shares, m	1.5	2.0	2.3	2.3	2.3
Basic EPS (A$)	(8.90)	(6.27)	(3.14)	(6.04)	(9.44)
Basic EPS (A$) - adjusted	(8.90)	(6.27)	(3.14)	(6.04)	(9.44)
Diluted EPS (A$)	(8.90)	(6.27)	(3.14)	(6.04)	(9.44)
Balance sheet					
Property, plant and equipment	592	483	344	373	402
Right of use assets	2,288	1,601	1,071	1,071	1,071
Other non-current assets	483	483	709	709	709
Total non-current assets	3,364	2,567	2,125	2,153	2,182
Cash and equivalents	9,063	13,435	5,191	3,000	3,000
Trade and other receivables	3,379	3,356	3,869	4,062	4,265
Inventories	1,473	792	80	200	200
Other current assets	509	496	102	102	102
Total current assets	14,425	18,079	9,242	7,364	7,567
Non-current loans and borrowings*	0	0	0	11,321	32,525
Provisions	478	233	186	186	186
Lease liabilities	1,630	989	555	555	555
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	2,107	1,222	741	12,062	33,266
Trade and other payables	3,218	2,991	1,462	2,083	2,664
Employee benefits	504	516	541	541	541
Borrowings	94	68	0	0	0
Lease liabilities	610	638	568	568	568
Total current liabilities	4,426	4,519	2,877	3,498	4,079
Equity attributable to company	11,397	15,144	8,081	(5,713)	(27,266)
Cashflow statement					
Net cash used in operating activities	(10,422)	(10,353)	(9,268)	(13,486)	(21,176)
Capex	(243)	(83)	(29)	(29)	(29)
Cash used in investing activities (CFIA)	(243)	(83)	1,747	(29)	(29)
Net proceeds from issue of shares	10,398	15,449	0	0	0
Movements in debt	(1,513)	(26)	(68)	11,321	21,204
Other financing activities	(563)	(612)	(657)	0	0
Cash flow from financing activities	8,321	14,810	(725)	11,321	21,204
Increase/(decrease) in cash and equivalents	(2,379)	4,372	(8,244)	(2,193)	0
Cash and equivalents at beginning of period	11,444	9,065	13,437	5,193	3,000
Cash and equivalents at end of period	9,065	13,437	5,193	3,000	3,000
Net (debt) cash	8,969	13,367	5,191	(8,321)	(29,525)

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

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Management team

CEO: Dr Sean Hall	Director of research: Jeremy Henson
Dr Hall founded Medlab in August 2012. He has over 20 years of experience in nutraceutical sales and development, and early drug discovery in Australia, Asia and the United States. Previously, Dr Hall was a founder of FIT-BioCeuticals, which was acquired by Blackmores in 2012. Dr Hall is a medical doctor with an MBA in clinical pharmaceutical management. He is an active member of Medicines Australia, the European Medical Association, the American Federation for Medical Research, The World Medical Association, A4M and Special Operations Medical Association.	Jeremy has 18 years' experience in cancer research. He is the principal investigator of the Cancer Cell Immortality research group, UNSW Medicine, where his research involves the development of cancer treatments and diagnostics that target telomere maintenance mechanisms (telomerase and ALT). Jeremy is also chief career medical officer at Lakeview Private Hospital, where he is a member of the Medical Advisory and Root Cause Analysis Committees, and a clinical tutor at Prince of Wales Clinical School, UNSW Faculty of Medicine. At Medlab, Jeremy's responsibilities include overseeing pharmacovigilance, research, clinical trials and new product development.
CFO: Kerem Kaya	**Director of science: Dr David Rutolo**
Mr Kaya has extensive pharmaceutical industry and financial experience gained at one of the world's largest pharmaceutical companies, Novartis. Mr Kaya spent nearly 15 years at Novartis Pharmaceuticals working across several divisions, notably spending five years as global finance projects manager of Novartis AG, where he helped develop financial efficiencies across the business globally. Mr Kaya was most recently head of finance planning and analysis for the Australian and New Zealand operations.	David has 35 years of experience in research, product development, manufacturing and technical marketing support in the pharmaceutical and nutritional industry. He earned his PhD in organic chemistry at the University of California at Irvine and a JD from Western State University, College of Law. In addition, he holds a Certificate of Completion in FDA Law from the University of Southern California. David manages and is a shareholder of InMed Technologies, Medlab's 60% owned US company.

Principal shareholders	(%)
Hall Sean Michael	38.4%
Farjoy Pty Ltd	18.0%
Realm Group Pty Ltd	6.1%
Hall Michael Jack	4.6%
Other	32.9%

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