EDISON

# Medlab Clinical

Initiation of coverage

## Novel drug delivery and cannabinoids against pain

Pharma & biotech

**Medlab's proprietary platform, NanoCelle, is a patented nanomicellar formulation that can improve the delivery of drugs. Medlab's lead product is NanaBis, a combination of THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, which enable a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, which will allow it to move away from a botanical extract. Once the product reformulation is completed (guidance is eight to 10 months), NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug optimised with proprietary delivery technology aimed at a vast market. Our valuation of Medlab is A$201m or A$0.59/sh.**

| Year end | Revenue (A$m) | PBT* (A$m) | EPS* (A$) | DPS (A$) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 06/19 | 8.1 | (8.2) | (0.04) | 0.0 | N/A | N/A |
| 06/20 | 5.8 | (13.5) | (0.06) | 0.0 | N/A | N/A |
| 06/21e | 9.3 | (10.2) | (0.03) | 0.0 | N/A | N/A |
| 06/22e | 9.5 | (10.9) | (0.03) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalised, excluding exceptional items.

## Synthetic cannabinoids mean clear regulatory path

As Medlab announced in May 2021, it has successfully produced with its suppliers two synthetic cannabinoids, THC and CBD, which will replace the botanical extract in its lead drug candidate NanaBis. Although the transition to a new formulation will require additional work, the guided delay to previous R&D timelines is less than a year. Management expects that no bridging studies will be required, subject to final confirmation. The advantage a synthetic formulation offers is significant, as regulators typically prefer synthetic compounds. With the opioid crisis unravelling, we believe support for non-opioid pain killers from various stakeholders will only grow.

## Building on positive Phase I/II data

The Phase I/II trial with a botanical extract version of NanaBis was completed in March 2020 in advanced cancer patients with intractable pain, who self-administered NanaBis. The patient group as a whole reported a 12% (p=0.02) improvement in pain score vs baseline, while those with bone metastases had a highly significant improvement of 40% unadjusted or 33% (p<0.01) adjusted for rescue medication. The PK/PD data also showed that NanaBis is clearly differentiated through its delivery mechanism from other product Sativex (GW Pharmaceuticals) that has been unsuccessfully tested in cancer pain previously. The data and the commercial opportunity were attractive enough for Medlab to proceed into Phase III programme.

## Valuation: A$201m or A$0.59 per share

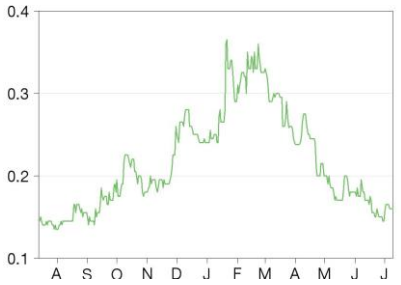
We value Medlab at A$201m or A$0.59 per share, based on an rNPV model, which includes A$10.9m in net cash (current debt of A$94k) estimated at end-FY21 (end of calendar H121). We include NanaBis for cancer-induced bone pain only, but do not yet value potential expansion to a broader chronic pain setting, nor other NanoCelle projects due to their early stage. Using a bottom-up approach, we assume NanaBis launches in 2025 with a success probability of 40% and calculate peak sales of $410m in just this one indication.

**12 July 2021**

| | |
|---|---|
| **Price** | **A$0.16** |
| **Market cap** | **A$55m** |

| | |
|---|---|
| Net cash (A$m) at end of calendar Q121 | 13.8 |
| Shares in issue | 342.2m |
| Free float | 90% |
| Code | MDC |
| Primary exchange | ASX |
| Secondary exchange | N/A |

### Share price performance




| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (11.1) | (41.8) | 6.7 |
| Rel (local) | (11.4) | (44.1) | (14.1) |
| 52-week high/low | | A$0.37 | A$0.14 |

### Business description

Medlab Clinical is an Australian biotechnology company that 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. Medlab is now developing a synthetic THC/CBD analogy of NanaBis, which should significantly streamline the regulatory approval pathway. A pivotal Phase III study could start within the next 12 months.

### Next events

| | |
|---|---|
| Update on synthetic NanaBis development progress | H221 |
| Potential NanoCelle/NanaBis partnering updates | H221 |

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Edison profile page

# Medlab Clinical investment case summary

## Drug delivery company at its core

Medlab is an Australian biotechnology company that is developing therapeutics using its proprietary delivery platform NanoCelle, which enables a convenient buccal spray delivery. It was founded in 2012 and then listed on the ASX on 14 July 2015 with, initially, a broad focus on exploring the potential of NanoCelle in several areas, including consumer health, reformulation of generic drugs (eg atorvastatin) and pharmaceutical development. The listed Medlab Clinical Ltd has a wholly owned subsidiary Medlab Pty Ltd, which in turn owns or co-owns: Medlab Research Pty Ltd (100% ownership), Medlab Clinical US Inc (100%), Medlab Nutraceuticals Inc (60%) and Medlab IP Pty Ltd (100%).

Medlab had developed a portfolio of consumer health products combining NanoCelle delivery technology with established nutraceuticals. Sales, comprised of revenues from nutraceuticals in Australia and cannabinoid products offered via Special Access Scheme, grew to A$4.1m in 2018 and A$5.4m in 2019, before being affected by the pandemic (A$2.8m in 2020). In parallel to the nutraceutical business, Medlab explored the feasibility of its NanoCelle delivery technology in combination with many different pharmaceutical compounds searching for a product that could be protectable via fresh IP, but also would offer an attractive commercial opportunity. With the growing appreciation of the medicinal properties of cannabis, the lead product became NanaBis, a tetrahydrocannabinol (THC) and cannabidiol (CBD) (1:1) cannabis extract encapsulated in NanoCelle particles. This is now Medlab's primary focus area. Furthermore, according to the latest indications, Medlab is considering divesting from the consumer health business, so that it can fully focus on the development of pharmaceuticals.

## NanaBis: Lead asset, fully synthetic cannabinoids for pain

The clinical development of NanaBis gained speed with the initiation of the Phase I/II trial in cancer patients with pain. The trial was completed in March 2020, and subsequently Medlab initiated a large observational study (n=2,000) to gather real world evidence of NanaBis use in cancer patients via the Special Access Scheme in Australia. The accumulated data so far have been positive, so much so that Medlab decided to pursue the registration of NanaBis as a drug.

The most recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, thus significantly streamlining the regulatory pathway. Two synthetic cannabinoids, THC and CBD, will replace the botanical extract in the new version of NanaBis. Although the transition to a new formulation will require additional work, the guided delay to previous R&D timelines is less than a year. NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug optimised with proprietary delivery technology. The advantage that a synthetic formulation offers is significant, as regulators typically prefer synthetic compounds. Botanical extracts can still have trace amounts of many other molecules and the quality of the source material (cannabis plants in this case) can vary depending on cultivation conditions.

From our clinical evidence review, it seems there is a growing consensus in the medical community that medicinal cannabis has a place in chronic pain management. The situation is complex, however, primarily a result of the fact that cannabis has become accessible to patients before rigorous investigation of it in well-designed trials. There is a plethora of cannabis-related and cannabis-derived products that can be used in a variety of ways. Many products are poorly differentiated and difficult to protect from a commercial perspective, which explains underinvestment in clinical research. Medlab's strategy is to develop a differentiated product

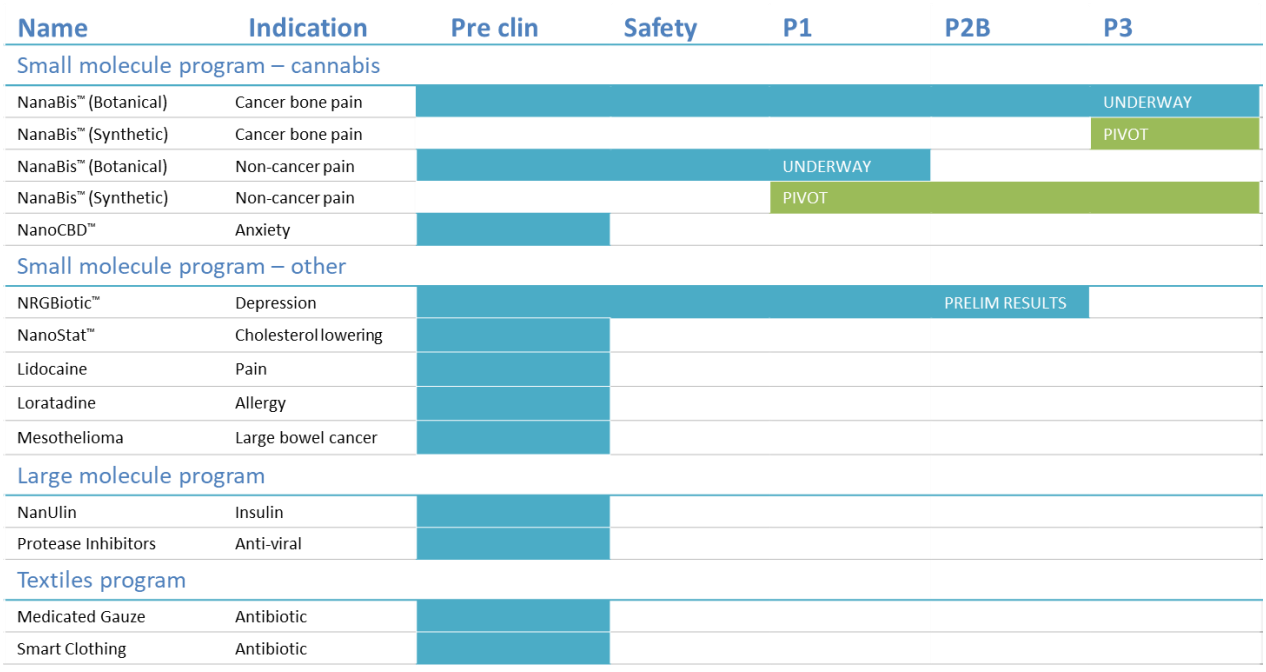
(synthetic cannabinoids with a proprietary delivery technology) and conduct a well-designed pivotal trial proving non-inferiority to opioids in chronic pain. If the data are positive, we believe NanaBis will become the first differentiated, cannabis-related pain relief product. With the opioid crisis unravelling in the United States (one of the key markets for Medlab), we believe that support for non-opioid pain killers from various stakeholders (regulators, patient and physician groups, investors, etc) will only grow. The initial indication is cancer-induced bone pain. Although it is a fairly small niche in pain disorders, Medlab believes it represents the fastest route to market. If the data are positive, NanaBis' label could be expanded via a bridging trial to other pain disorders.

## Many more NanoCelle applications in the R&D pipeline

Looking beyond pain, Medlab has done preclinical work with NanoCelle in combination with various other compounds in areas such as obesity, depression, cholesterol lowering, allergy, diabetes, antivirals and antibiotics. Currently the primary focus is on pain, therefore Medlab is allocating most of its available resources to this programme. However, if needed several other projects could be fast-tracked into clinical trials (Exhibit 1).

The second most advanced project is NRGBiotic for depression. It is a probiotic formulation that contains *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Streptococcus thermophilus* species with orotic acid. The preliminary results from a Phase IIa study were announced in February 2021 and showed a significant reduction in depression scores and a significant improvement in quality of life from baseline. Medlab has not yet confirmed further plans in this area, but should do so sometime in the future.

**Exhibit 1: R&D pipeline**



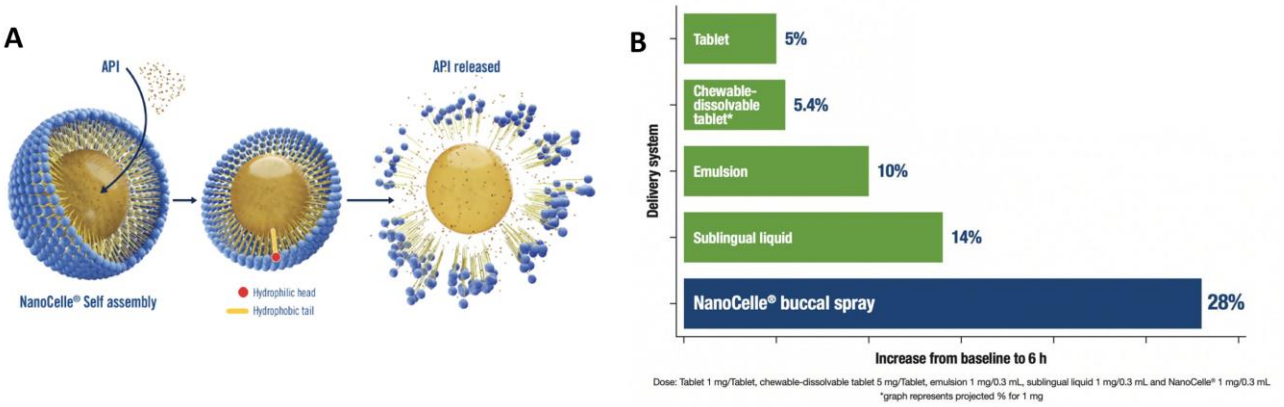

Source: Medlab

# NanoCelle

NanoCelle is Medlab's patented, proprietary drug delivery platform, designed to bypass the digestive tract pathway and first-pass metabolism by allowing the active pharmaceutical ingredient (API) to be absorbed via a buccal or nasal delivery system using a spray. NanoCelle's particles (micelles) have a hydrophobic core and hydrophilic shell, therefore the formulation is water-soluble

and stable at room temperature despite the original solubility characteristics of the API. NanoCelle particles range from 0.004 to 0.09µm in size (for comparison the size of a red blood cell is approximately 7–8µm) (Exhibit 2A). 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 Australia, Europe and Canada and pending in the United States and Singapore. The protection period extends to at least 2036.

**Exhibit 2: NanoCelle schematic composition and comparison versus other delivery methods (vit B12 study)**




Source: Medlab. Note: *Result is adjusted, see text for explanation.

The benefits of trans-buccal 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 potential interactions with food), but without intervention. Medlab's Director of medical research Prof Luis Vitetta, in his capacity as professor at the University of Sydney, Sydney Medical School, has conducted an illustrative study of how different routes of administration influence the absorption. For the results to be comparable, the researchers used vitamin B12 (water soluble) in different formulations, namely a tablet, emulsion, liposome and NanoCelle. In total, 16 volunteers were given each of the formulations and the serum levels of B12 were measured during the six hours after administration. The results showed that on an equivalent dose basis (1,000µg dose), NanoCelle performed best in terms of rapid increase and sustained levels in serum (Exhibit 2B). 'Chewable-dissolvable tablets' had a B12 dose of 5,000µg, five times higher than other formulations. Exhibit 2B shows the adjusted result, while the unadjusted result was 27%. In other words, the NanoCelle formulation of B12 was bioequivalent to a tablet formulation with a five-times higher dose, which demonstrates the dramatic effect of drug bioavailability in the intestinal tract and first-pass metabolism.

One of the benefits of the transbuccal route of administration is the lower dose. Medlab has bioequivalence data in humans, where NanoCelle is used to deliver atorvastatin transbuccally. The amount of API needed to reach the same level of cholesterol lowering effect was established to be around one-tenth of the peroral dose. This translates to fewer side effects associated with pharmaceutical use and a lower cost per dose. In total, Medlab has explored more than 20 different compounds and NanoCelle combinations (and many more combinations with nutraceuticals). Medlab is actively exploring the opportunity to non-exclusively out-license NanoCelle delivery technology to other parties and, to date, several multi-nationals have indicated interest.

Medlab started working on a product based on cannabis and NanoCelle in 2015. The NanaBis botanical extract (*Cannabis sativa L./Cannabis indica L.*) is standardised 1:1 THC and CBD. One actuation of the pump is equal to a dose of 1.25mg Δ9-THC and 1.25mg CBD in a 150µL volume. Management believes an equimolar formulation is optimal.

## Medicinal cannabis

The dried leaves of *Cannabis sativa* plant have long been used for both medicinal and recreational purposes (Bonini et al, 2018), but research into its potential medicinal applications started growing significantly only in the 1990s following the discovery of the cannabinoid system in the brain.

At the same time, efforts to liberalise marijuana laws have led to breakthroughs in several Western nations, including in 36 states in the United States that provide some access to cannabis at the moment (NCSL.org). Growing political acceptance and more importantly medical research have made cannabis an increasingly accepted part of the cultural fabric (Carliner et al, 2017). From a medical standpoint, the emergence of cannabis-related products as potential therapeutics has become a challenge for physicians. Medical cannabis is now accessible to many patients who have an interest to try it, often as a last resort measure, but robust data are still lacking. The demand is outpacing the clinical evidence, leaving it unclear how and when it should be prescribed.

*Cannabis* is a genus of plants that includes marijuana (*Cannabis sativa*) and hemp. These plants contain hundreds of compounds, including terpenes and flavonoids, but cannabinoids are the most important compounds for medicinal applications. Phytochemistry and medical studies have identified several potentially useful cannabinoids. The psychoactive compound tetrahydrocannabinol (Δ9-THC) is also the most abundant cannabinoid in marijuana. The next most abundant cannabinoid is cannabidiol (CBD), which is the non-psychotropic. THC and CBD are the most extensively studied cannabinoids, together and in isolation, but there are many others, the investigation of which are more problematic due to low concentrations, for example cannabichromene (CBC), cannabigerol (CBG) and others (ElSohly et al, 2017). Evidence suggests that other cannabinoids and terpenoids may also hold medical promise and that cannabis's various compounds can work synergistically to produce a so-called entourage effect; however, this is still being debated (Russo and Marcu, 2017).

Compounding the issue of lack of data there is now a range of cannabis-related products, which can differ considerably in terms of the ratios and amounts of THC and CBD they contain, as well in how they are consumed (ie via smoke, vapor, ingestion, topical administration or oromucosal spray), all of which can alter their effects. To date the FDA has approved one cannabis-derived product Epidiolex (purified CBD, GW Pharmaceuticals, approved in 2018, expected 2021 sales of $730m) for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients aged two years and older. The FDA has also approved three synthetic cannabis-related drug products: Marinol / Syndros (dronabinol, synthetic THC, approved in 1985), and Cesamet (nabilone, a synthetic cannabinoid similar to THC, approved in 1985). All three are indicated for treatment-related nausea and anorexia associated with weight loss in AIDS patients. Another cannabis-derived product Sativex (nabiximols, 1:1 THC and CBD extract, GW Pharmaceuticals; oromucosal ethanol spray formulation) is approved in Europe, but not in the United States, to alleviate muscle spasticity resulting from multiple sclerosis.

$CB_1$ and $CB_2$ have been characterised as two major types of cannabinoid receptors, however, both THC and CBD have been found to exert their therapeutic effects via several other targets (Bih et al, 2015). Because of these varied targets, THC and CBD induce varying pharmacologic responses depending on the formulation, dose and patient characteristic (Borgelt et al, 2013).

Historically, cannabis has been listed as a scheduled drug in most countries. In the United States, the FDA has issued guidance for researchers who wish to investigate treatments using *Cannabis sativa* or its derivatives in which the THC content is >0.3%. Such research requires regular interactions with several federal agencies, including the Drug Enforcement Administration. Regulatory restrictions regarding medical cannabis vary considerably throughout the world, which makes it difficult to conduct well-designed, large-scale international trials. However, and somewhat paradoxically, medicinal cannabis is being made available by many governments at the discretion

of a prescribing physician. This disincentivises investments in large, well-designed trials with the most common formulations, as it will be difficult to protect the product from generic competitors. We believe a differentiated product with a good data package is what is needed for a commercially viable product. Epidiolex is a good example. Developed by UK-based GW Pharmaceuticals, it demonstrated a clear benefit in a niche indication. The consensus expectation is for sales of $730m in 2021, growing to $1.4bn in 2026 (EvaluatePharma). In February 2021, Jazz Pharmaceuticals announced the acquisition of GW Pharmaceuticals for a total consideration of $7.2bn (or $6.7bn net of GW cash). In addition to Epidiolex's commercial success, Jazz cited the potential to expand the label with other forms of epilepsy and GW's pipeline of other cannabinoid products in earlier stages.

## Cannabis and pain

In the context of medicine, relief from chronic pain (cancer or non-cancer related) is the most common reason cited by patients for the use of cannabis (Ilgen et al, 2013). In 2015, a systematic literature review assessed 28 randomised controlled trials of the use of cannabinoids for chronic pain (Whiting et al, 2015). The researchers found that a variety of formulations resulted in a ≥30% reduction in pain compared with placebo. Another systematic review and meta-analysis conducted by Aviram and Samuelly-Leichtag (2017) reviewed 43 randomised controlled trials and concluded that cannabis-based treatment could be effective for chronic pain. However, another meta-analysis of five randomised control trials involving patients with neuropathic pain found 'the proportion of patients with an at least 30% reduction in chronic pain as minimally clinically important difference ... about one in every five to six patients treated' with inhaled, vaporized cannabis (Andreae et al, 2015). The US National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that there was a substantial body of evidence that cannabis is an effective treatment for chronic pain in adults.

Other studies have found that cannabinoid-based therapeutics could be useful add-ons or a replacement to other types of pain medication (Yanes et al, 2019). The potential of cannabis to reduce or replace the use of opioids is a major interest area in pain medicine currently. One study found that patients with chronic pain who undergo treatment with medical cannabis can reduce their intake of opioids by >60% (Boehnke et al, 2016).

With evidence of efficacy growing in chronic neuropathic pain in general, efforts have been made to investigate cannabis-related prodcuts in a subset of patients with cancer-induced pain. Five clinical trials performed to date, however, did not meet the primary efficacy endpoint (Boland et al, 2020). These were the efforts by GW Pharmaceuticals to develop its cannabis-derived product Sativex for pain, which were not successful (Sativex is now approved for muscle spasticity resulting from multiple sclerosis). NanaBis, however, has been demonstrated to have a different pharmacokinetic/pharmacodynamic (PK/PD) profile to Sativex (as described below).

The types of cannabis-related product formulations in clinical trials ranged from vaporised cannabis to oral/oromucosal routes of administration of cannabis as herbal crude or dry leaf cannabis extracts, to synthetics of THC (dronabinol, nabilone) and plant-derived extracts of THC/CBD oromucosal spray (nabiximols, Sativex, GW Pharmaceuticals). Oral administration with gastrointestinal absorption leads to highly variable systemic concentrations of active compounds leading to slow and erratic onset of action (Russo, 2019). Inhaled cannabis preparations require too frequent dosing to maintain the pain relief, as the half-life is less than 20 minutes. In addition, the THC blood concentration reaches very high levels via this administration route leading to unwanted psychoactive effects, which is a side effect in this setting. The non-optimal delivery via oral or inhaled administration routes of medicinal cannabis led to a search for novel routes of administration (Bruni et al, 2018). Cannabinoids are lipophilic molecules and the delivery is a challenge. In this context, Medlab decided to investigate its nanomicellar delivery technology NanoCelle for the transbuccal delivery of cannabinoids for cancer-induced pain.

# Phase I/II study

## Design

The Phase I/II trial with the botanical extract version of NanaBis was completed in March 2020. The study was conducted at a single site the Royal North Shore Hospital, Sydney. The goal was to investigate the safety, tolerability and preliminary efficacy in advanced cancer out-patients with uncontrolled pain, who self-administered NanaBis. The study was conducted in two stages.

- Stage I was a two-day single ascending dose PK/PD investigation of NanaBis in five participants. On day one, all patients were administered 2.5mg of THC and 2.5mg of CBD (two actuations of the pump bottle) to the oro-buccal mucosa. On day two, all patients were administered 7.5mg of THC and CBD each (six actuations of the pump).
- Stage II was a multiple ascending dose study that recruited 25 eligible patients with advanced cancer and uncontrolled pain. This part can be broken down into three phases that altogether lasted for 30 days. The first nine days were dose escalation, days 10–15 were treatment phase and days 16–30 were the follow-up phase. The dose was titrated and selected by principal investigator for each patient in the dose escalation phase. In the follow-up phase, the patients were observed after treatment cessation. In total, 22 of 25 patients completed all phases of Stage II.

Patients enrolled in this study had to be diagnosed with advanced cancer and used opioid analgesics for at least a week to relieve pain associated with the malignancy. The endpoints included:

- Primary: safety and tolerability; PK/PD; quality of life as assessed by The European Organisation for Research and Treatment of Cancer Quality of Life for Cancer Patients Questionnaire.
- Secondary: pain relief as assessed by Mean Numerical Pain Rating Scale (NPRS, patients rate pain intensity from 0 to 10) scores; Mean Brief Pain Inventory scores, Short Form; morphine milligram equivalent (MMeq) doses; and rescue analgesia (opioid) doses.

## Results

In total, eight of the 25 patients enrolled into Stage II had bone metastases. Peak plasma concentration was achieved in less than an hour and efficacy was durable enough to support dosing every four hours (with multiple sprays). The most common treatment-related adverse event was drowsiness (mild, moderate and severe in 68%, 44% and 16% of patients, respectively). Fatigue was experienced as mild in 4%, moderate in 20% and severe in 12% of patients. Vomiting was reported as mild in 20%, moderate in 4% and severe in 12% of patients (most likely related to anticancer treatment). The quality-of-life questionnaire established improvements in multiple domains, some of which were statistically significant (emotional functioning, fatigue, dyspnoea, insomnia and appetite loss).

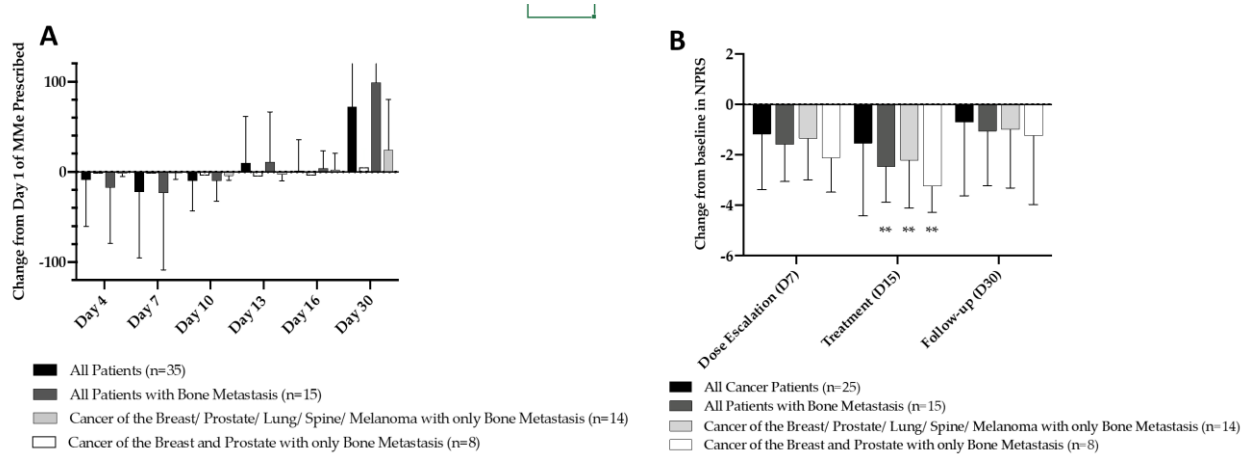
Because all patients were prescribed opioid analgesics before enrolment, the dose needed to sustain pain relief was a useful surrogate metric to evaluate the benefit of NanaBis. Patients were prescribed different forms of opioids (oxycodone, hydromorphone and morphine), which can be standardised using a so-called MMeq dose.

During the progression of the study from day one to day 30, all patients (n=25 of Stage II) as a group recorded an increase in MMeq. Mean MMeq on day one (baseline) was 152mg (±70.6mg SD); on day 16 (the end of the intervention) it was 153.6mg (±71.1mg SD); and on day 30 (end of follow-up) it was 224.3mg (±124.2mg SD), respectively (Exhibit 3A). However, MMeq administered in participants diagnosed with bone metastases (breast or prostate cancers, n=8) recorded significantly fewer changes as the study progressed. Mean MMeq values were 61mg (±13.8mg SD)

on day one; 57.1mg (±12.9mg SD) on day 16; and 64.5mg (±18.1mg SD) on day 30. In addition, this group of patients required less rescue medication for pain.

During the treatment phase of Stage II (days 10 to 15; after the dose escalation phase) patients self-administered on average 3 to 3.5 doses of NanaBis every four hours, unless asleep. By the end of the treatment phase, pain measured with the NPRS scale was significantly reduced by 12% (p=0.02) for the whole group of patients from base level, namely, there was no placebo control (Exhibit 3B). The effect was particularly pronounced in patients who had bone metastasis (n=8) with the NPRS average score decreased from 7.5 to 3.5, an unadjusted pain improvement from baseline of approximately 40%. Adjusting the improvement for rescue pain medications the improvement was calculated at 33%, still highly significant (p<0.01). After the treatment phase, NanaBis administration was discontinued and the pain scores worsened again.

**Exhibit 3: Phase I results highlights**




Source: Medlab

## Key takeaways

Being Phase I, the study was open label and there was no control. However, the study met its primary endpoints in terms of safety and tolerability. The secondary efficacy endpoints indicate significant pain relief in the whole group of patients, but more pronounced in those with metastases to bones (40% unadjusted or 33% adjusted for rescue medication). For comparison, the systematic and meta-analysis (Aviram and Samuelly-Leichtag, 2017) concluded that cannabis-based medicines probably increase the number of people achieving pain relief of 30% or greater compared with placebo. Notably, the mean increase in MMeq was minimal in patients with bone metastases. In addition, patient-reported outcome questionnaires suggest the treatment also significantly improved quality of life. Quality of life as an endpoint should not be underestimated, in our view, as it is one of the key goals in end-of-life medicine.

In the pre-print version of the article with NanaBis Phase I data, the investigators compared the PK/PD findings with those published for nabiximols (Sativex, 50% ethanol CBD:THC extract). The data showed that NanaBis provides a similar plasma level of THC and CBD at half the dose, with a faster rate of absorption. Furthermore, NanaBis PK data showed one peak, which is consistent with mostly mucosal delivery, whereas it has been reported that Sativex provides two peaks and inconsistent serum levels (Stott et al., 2012), indicating inefficient mucosal absorption with substantial swallowing of the medicine and less effective gastrointestinal absorption. As discussed above, Sativex was unsuccessfully investigated by the originator GW Pharmaceuticals in cancer-induced pain in several trials. The formulations of NanaBis and Sativex, however, are very different and with Phase I, Medlab saw further differences in PK/PD data and pronounced NanaBis efficacy

signals in patients. This formed the basis for the decision to move directly into Phase III programme.

## The observational study

In 2019 Medlab initiated an observational study, with the goal of establishing how doctors tend to use NanaBis in the treatment of chronic pain. NanaBis had been available via Australian Special Access Scheme (SAS) for several years now. To leverage this scheme to generate insights from real-world data, with the approval from the ethics committee Medlab was able to set up and launch an observational study in 2020, which is ongoing. There are several centres in Australia that participate in this study. If a physician decides to prescribe patients with NanaBis via the SAS pathway, they have an opportunity to join the trial. So, although there is no predefined treatment protocol, the study is prospective. Patients receive NanaBis for chronic pain, but not necessarily related to cancer. Participating patients are followed-up every month for a maximum of 12 months. To ensure data consistency, the treating physician and the patients commit to complete surveys during the follow up visits about the use of NanaBis and its effects, but no tests are carried out. According to the latest update from Medlab:

- 801 (40%) patients have been enrolled to the study, while the goal is to include some 2,000 patients in total;
- Of those, 119 patients have completed six- or 12-month observation periods.
- Pain scores were measured using Brief Pain Inventory (BPI), which evaluates the severity of pain on a 0–10 scale, like NPRS in the Phase I/II, in addition to the impact on functioning; the BPI scores decreased 55% on average and patients also reported quality of life improvements areas of ‘general activities’, ‘sleep’ and ‘mood’.
- No new safety or tolerability issues have been reported.

The study is still in progress, but the reduction in pain scores recorded so far is consistent or exceeds the level obtained in the Phase I/II. Since it is an observational study, the data will be used to support the controlled trials. From a practical perspective, these observational data will be valuable to inform the Phase III trial design and subsequent expansion into broader chronic pain indication.

Since all patients with chronic pain are accepted, Medlab will gain first insights in how patients with non-cancer pain benefit from NanaBis. At the moment, Medlab’s R&D strategy is to focus on a specific subset of chronic pain patients with cancer-induced pain and bone metastasis, partly because this group showed the best response in the Phase I/II study and partly because this would provide a homogenous group of patients for the registrational study. However, the plan after that is to expand the label as soon as possible into chronic pain in general. The ongoing observational study is already collecting data in a variety of chronic pain conditions. For example, according to the latest update, 50% had muscular/neuropathic pain, 32% had soft tissue pain with muscular pain, 11% had visceral pain, while 7% had other types of pain. The patient sex distribution was 65% female and 35% male.

## Phase III trial design

Medlab had already received green light for the Phase III trial in the UK and Australia. The trial protocol has been developed and submitted (NCT04808531). The study is designed to demonstrate that NanaBis is effective as monotherapy for the management of opioid-requiring bone pain due to metastatic cancer and that NanaBis monotherapy is non-inferior to opioid treatment. Oxycodone was selected as a benchmark drug for non-inferiority analysis. The main endpoints of the study are below.

**Primary endpoints**

- Demonstrate that at the end of the six-week study period, the proportion of responders in the NanaBis treated group is significantly greater than the proportion of responders in the placebo group.
- Demonstrate that at the end of the six-week study period, the proportion of responders in the NanaBis patient group is non-inferior to the proportion of responders in the oxycodone patient group.

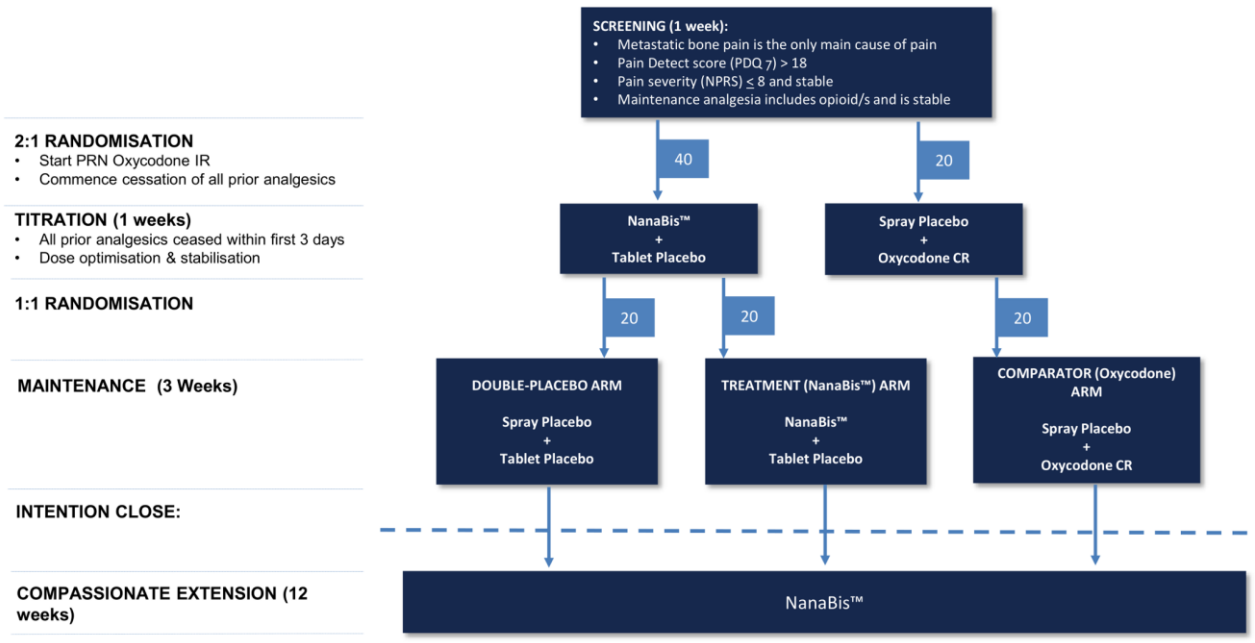
**Secondary endpoints**

- Demonstrate that at the end of the six-week study period the Health-Related Quality of Life scores in the NanaBis group are significantly greater than in the placebo group and non-inferior to the oxycodone group.
- Demonstrate that NanaBis is safe and tolerable.
- Demonstrate that half or more of the NanaBis-treated group preferred further treatment with NanaBis in the open-label extension study (all participants will be offered open label extension if appropriate).

A responder is defined as a patient who completes the treatment phase with an acceptable level of pain (NPRS≤5) without requiring excessive amounts of rescue (breakthrough analgesia) medication. Unlimited breakthrough analgesia (oxycodone) is allowed throughout the study, however, excessive use will result in discontinuation.

In total, 360 patients are expected to be enrolled and they will cease all prior pain relief medication. After two-step randomisation and titration (two weeks), patients will be assigned to one of the three study arms: double placebo, active NanaBis treatment arm and active placebo (oxycodone) arm. The maintenance treatment phase will last for three weeks with patients self-administering two to three doses per four hours, unless asleep. Subsequently, all patients will be offered NanaBis on a compassionate-use basis (which is also one of the secondary endpoints). So, the total expected duration from patient in to patient out is 17 weeks.

**Exhibit 4: Phase III trial design**




Source: Medlab. Note: PRN, prescription drug is taken as needed

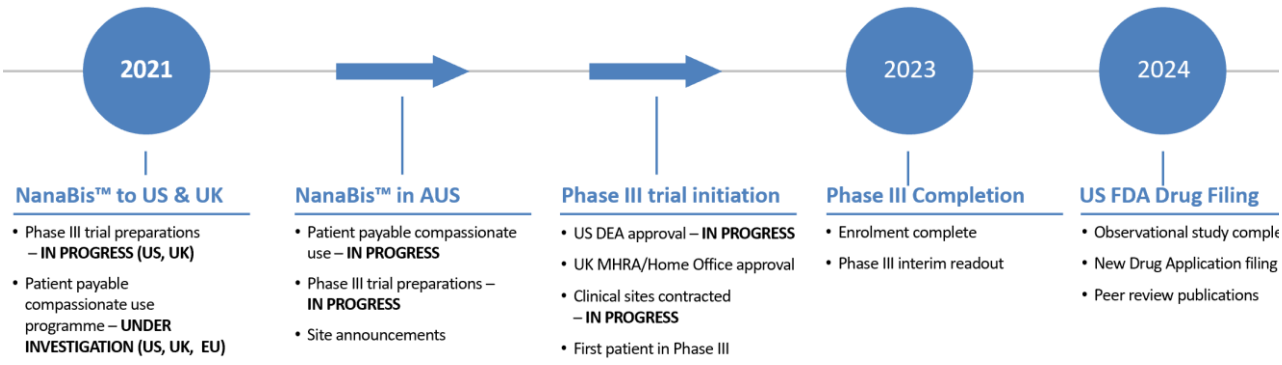
## NanaBis 2.0: Introducing fully synthetic NanaBis

The most recent significant development was Medlab's announcement that it had decided to replace the botanical extract NanaBis with fully synthetic cannabinoid formulation of THC/CBD. Following interactions with regulators in preparations for the Phase III trial, Medlab's conclusion was that synthetic formulation would be more straightforward to develop as a drug. This would avoid the need to characterise many other compounds present in extracts. In addition, batch-to-batch variations, quality control, manufacturing scale-up can all cause issues with botanical extracts as registered as pharmaceuticals. Synthetics should also have lower manufacturing costs.

It was possible to source synthetic CBD, which has a Drug Master File (DMF) recognised by the FDA, but there was no 100% synthetic, so-called neat, dronabinol available until now. There are DMFs for dronabinol formulated in sesame oil (eg Marinol) or ethanol, but these were not suitable for delivery with NanoCelle technology. Medlab is now working with its contract manufacturer to submit the DMF for neat dronabinol to the FDA. Formulation work to prepare the synthetic NanaBis for clinical development is expected to take eight to 10 months (from the beginning of June 2021 when the announcement was made).

As the next step, Medlab will file the IND for the synthetic NanaBis with the FDA and other regulators. After that, management expects no bridging studies will be required to continue the NanaBis development programme as communicated before. However, this is subject to confirmation with the regulator. If no substantial bridging trials are required, Medlab expects to initiate the Phase III trial next year, with completion envisaged in 2023 and NDA filing in 2024.

**Exhibit 5:NanaBis programme and expected catalysts**




Source: Medlab

## Chronic pain: Fragmented market with high unmet needs

By definition, nociceptive pain is the result of activity in signalling pathways caused by actual tissue (non-neural) damage or potentially tissue-damaging stimuli (eg arthritic pain, sport injuries). Nociceptive pain often is acute and disappears if the underlying problem heals. Neuropathic pain is due to an injury or disease affecting the peripheral or central nervous system and often is chronic. Pain sensation is felt even though there is no clear organic cause. Chronic pain can have a profound and debilitating effects on the patient's life, which includes the ability of the individual to work and engage in social and leisure activities. Neuropathic pain affects a total of approximately 7–8% of the adult population. People with conditions such as diabetes and HIV experience chronic pain in as many as 25% and 35% of cases. Peripheral neuropathic pain results from various types of damage to the nerve fibres, such as toxic, traumatic, metabolic, infectious or compressional injuries. Common symptoms are painful tingling or itching that can be described as a stabbing or burning pain, including a sensation of getting an electric shock. Three common conditions that

cause neuropathic pain are diabetes, postherpetic neuralgia (shingles) and neuropathic pain induced by chemotherapy.

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 aging 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.

## Metastatic cancer-induced bone pain

Because of such vast and diversified group of indications, Medlab decided to focus on a more homogenous group of patients hoping it would streamline the design of the clinical trials. Metastatic cancer-induced bone pain is a type of chronic pain with unique and complex pathophysiology, characterised by nociceptive and neuropathic components.

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 (Zajaczkowska et al., 2019). A systematic meta-analysis of the literature published between September 2005 and January 2014 on pain and pain severity (122 studies were selected) looked into this issue in more detail. The authors found that pain prevalence rates were 39.3% after curative cancer treatment, 55.0% during anticancer treatment and 66.4% in advanced, metastatic or terminal disease. Moderate to severe pain (numerical rating scale score ≥5) was reported by 38.0% of all cancer patients (Marieke et al., 2016).

Bones are the third most frequent (after the lungs and liver) target sites of metastases. The most common bone metastases arise from multiple myeloma, as well as cancer of the breast, prostate, lungs, thyroid, kidneys and ovaries (Li et al., 2014). Cancer metastases to the skeletal system are most often located in the vertebrae (69%), followed by the pelvic bones (41%), long bones (usually the proximal femur) (25%) and skull (14%) (Zajaczkowska et al., 2019). The mechanism of pain experienced by patients as a result of metastases to the bone is complex and involves various interactions between tumour cells, bone cells, activated inflammatory cells and bone-innervating neurons. It includes inflammatory and neuropathic processes, therefore it can be characterised as mixed nociceptive and neuropathic pain.

Cancer-induced bone pain treatment goal is not only pain relief but also the prevention of pain progression and skeletal-related events. Therefore, treatment of bone pain in cancer patients relies on causal anticancer and symptomatic analgesic treatment. Anticancer treatment reduces the tumour mass and local tissue infiltration and thus decreases the pain intensity, so it can also be regarded as symptomatic treatment. Analgesic treatment relies on an analgesic ladder principle, an approach proposed by the World Health Organization (WHO) in 1986 as a part of Cancer Pain and Palliative Care Program:

- 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 (added in the updated version of the ladder). Invasive or minimally invasive treatments.

The term adjuvant refers to a vast set of drugs belonging to different classes. Their administration is typically for indications other than pain treatment, but these medications can be of particular help in various painful conditions (eg antidepressants, anticonvulsants such as gabapentin and pregabalin, topical anaesthetics such as lidocaine patch, topical therapies such as capsaicin, corticosteroids and bisphosphonates). A systematic review on pain relief based on the WHO ladder, 20 years after its introduction, demonstrated adequate pain relief in 45–100% of patients (Azevedo Sao Leao Ferreira et al., 2006), which indicates high variability. A systematic review published in 2014 on the quality of cancer pain management found that around one-third of the patients did not receive pain medication proportional to their pain intensity levels (Greco et al., 2014).

## Sensitivities

So far, Medlab has employed a mixed business model. Income from the commercialisation of premium nutraceuticals was used to partially fund the R&D activities. The company indicated it is reviewing its strategy and looking for all options to divest the nutraceutical business and fully focus on the development of novel pharmaceuticals. With the divestment of nutraceuticals, the investment thesis will be based purely on the pharmaceutical development and primarily on the cannabis product. As a result, it will become a pure biotech, so higher risk but higher reward.

Typical drug development risks include clinical development delays or failures, IP protection, regulatory risks, competitor successes, partnering setbacks, financing and commercial risks. So far, the most advanced project is NanaBis in chronic pain and we believe the largest part of the company's value is concentrated in this project. However, Medlab has initiated or explored the feasibility of a number of other projects using its NanoCelle drug delivery platform, which could be fast-tracked to clinical development. One specific risk is related to the transition to synthetic NanaBis product and how this will affect the development timelines.

Given the nature of the drug development business, Medlab will need additional funding to carry out the clinical trials. As the company has indicated, it will seek to partner the development or commercialisation of its drug candidates, hence the ability to successfully negotiate a deal is key.

Future drug pricing and market dynamics are hard to predict. Medlab is targeting a large market, where current treatment is very fragmented and many generic drugs for pain exists. Although not always effective, they are cheap. The success of NanaBis will depend on how effective it will be, the potential to reduce or replace the opioid use and the pricing. Finally, Medlab's key patent protecting NanoCelle has been granted in Australia, Europe and Canada, but is still pending in the US and Singapore. The priority date is 2016, so NanoCelle will be protected until at least 2036 with potential to extend the period.

## Financials

Since IPO, Medlab has established a nutraceutical business in Australia and has made several cannabinoid products available via Special Access Scheme in Australia: NanaBis, NanoCBD and a combined product Mg Optima (magnesium) with CBD. In total, Medlab booked revenues of A$4.4m in 2017, A$5.5m in 2018, A$8.1m in 2019 and A$5.8m in 2020. Of that, sales revenues were A$3.3m in 2017, A$4.1m in 2018, A$5.4m in 2019 and A$2.8m in 2020.

The remaining income was comprised of R&D tax incentive, government grants and R&D services. The nutraceuticals business was affected by the pandemic, but Medlab managed to reorient its sales online and in fiscal H121 (calendar H220) sales were A$2.0m. In its 2020 annual report Medlab indicated it is exploring strategic options to divest the nutraceuticals business, so it can fully focus on the development of novel pharmaceuticals. But Medlab plans to continue offering its

cannabinoid products via a special access programme in Australia and plans similar initiatives in the UK, other European countries and the US. Revenues from the cannabinoid products were A$281k in 2019 and A$843k in 2020.

Medlab's total operating expenses were A$16.2m and A$19.1m in 2019 and 2020 respectively, with net loss of A$8.2m and A$13.5m for the same periods. For 2020, the nutraceuticals business segment reported an EBITDA loss of A$6.8m, which implies operating costs of A$8.9m. Depending on the nature of the divestment from the nutraceuticals business, it is likely some of the associated costs would decrease, but probably not all, as the business segments share some of the management team, for example. The costs associated with the pharmaceutical research should increase once the Phase III trial starts. Given the ongoing process to switch to fully synthetic NanaBis the timing of this is not yet clear, but according to plans this could happen in 2022. Medlab is open to partnering at any point if the deal economics are beneficial.

Medlab had cash of A$9.1m at the end of FY20 and raised another A$15m in April 2021 (debt of A$198k). According to our model, this should provide funding well into FY22. We assume an illustrative long-term liability of A$2.6m in FY22 and A$15.6m in 2023 (as per our research principles in lieu of equity funding).

## Valuation

We value Medlab at A$201m or A$0.59 per share, based on a risk-adjusted net present value (rNPV) analysis, which includes an estimated A$10.9m in net cash (current debt of A$94k) at the end of FY21 (end of calendar H121). A breakdown of our rNPV valuation, which uses a discount rate of 12.5%, is shown in Exhibit 6.

**Exhibit 6: NanaBis valuation**

| Product | Indication | Launch | Peak sales* ($m) | NPV (A$m) | Probability of success | rNPV (A$m) | rNPV/share (A$) |
|---|---|---|---|---|---|---|---|
| **NanaBis** | Cancer-induced bone pain | 2025 | 410 | 485.7 | 40.0% | 188.0 | 0.55 |
| | | | | | | | |
| Net cash, est at end-FY21 | | | | 13.1 | 100.0% | 10.9 | 0.04 |
| **Valuation** | | | | **498.8** | | **201.1** | **0.59** |

Source: Edison Investment Research. Note: WACC = 12.5%. *Peak sales are rounded to the nearest $100m.

We include only NanaBis for cancer-induced bone pain. We do not include potential expansion to a broader chronic pain setting or other NanoCelle projects due to their early stage. We also do not explicitly value the nutraceuticals business or the income associated with compassionate use of NanaBis. However, these revenue streams help to lower cash burn and preserve cash (which we include in the SOTP table as an asset). Our bottom-up valuation model is based on a number of assumptions:

- We use a probability of success of 40%. This is somewhat lower than for a typical non-oncology asset in Phase III (Wong and Siah, 2018). Currently, Medlab has data from its Phase I/II trial. The company feels confident in moving directly to a Phase III trial, as the observational study is reporting comparable data and there is a large amount of third-party data from various cannabis-related products in pain.
- Target population. As described above, cancer-induced bone pain can be a result of many cancer types and patients undergo very different treatment schedules. If pain is present, the treatment of it varies substantially. For these reasons, the estimation of absolute numbers of patients that could be considered as the target population is not straightforward. Working on the basis that NanaBis Phase III trial is designed to demonstrate non-inferiority to opioids, we chose to consider patients with more pronounced pain (numerical rating scale score ≥5). As mentioned in the epidemiology review above, the prevalence of such intensity pain is 38% in all

cancer patients. Because most newly diagnosed patients undergo cancer treatment, the chronic treatment of pain is likely established later in the disease course, depending on needs. We chose to apply the 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 520k in the US, 60k in Canada, 40k in Australia and 637k in the top 15 wealthy European countries. So, the total target population for NanaBis we use in our model is c 1.26m in a chronic setting.

- Pricing, market penetration and peak sales. NanaBis peak sales will depend on the interplay of the strength of Phase III data, pricing and market penetration. We calculate peak sales of c US$410m, which are based on US$3,000 price tag per patient per year in the US (we applied 33% discount to other geographies) and a market penetration of 10% due the fragmented nature of it. Pricing and market penetration are the two key assumptions that our model is most sensitive to. Exhibit 7 provides a two-dimensional sensitivity analysis of peak sale to these two underlying assumptions.

**Exhibit 7: Peak sales' sensitivity to price and market penetration**

| | | Market penetration | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 4% | 6% | 8% | 10% | 12% | 14% | 16% |
| Pricing, $ | 2,000 | 110 | 160 | 220 | 270 | 320 | 380 | 430 |
| | 2,500 | 140 | 200 | 270 | 340 | 410 | 470 | 540 |
| | 3,000 | 160 | 240 | 320 | **410** | 490 | 570 | 650 |
| | 3,500 | 190 | 280 | 380 | 470 | 570 | 660 | 760 |
| | 4,000 | 220 | 320 | 430 | 540 | 650 | 760 | 860 |

Source: Edison Investment Research. Note: Pricing is per patient per year; ex-US the pricing is adjusted with 33% discount.

- R&D costs, launch date and margins. We assume the Phase III trial will cost A$15m. The treatment and follow-up parts of the trial are fairly short, so it should be less expensive to run than, for example, anticancer treatment trials. A recent study (Moore et al., 2020) calculated that median cost per patient in a Phase III trial involving musculoskeletal conditions is US$58k. Considering Medlab plans to enrol 360 patients, our assumption of A$15m is closer to the lower end of that range. With regards to timelines, the pool of accessible patients is large, so there should not be any delays. We use the company's guidance that the trial could be finished in 2023/2024 and NanaBis could be launched in 2025. We assume 25% COGS and 35% S&M margin in the NanaBis NPV project, which gives the 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 would consider licensing out 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. As mentioned, the ongoing process to change NanaBis to a fully synthetic cannabinoid-related product presents some uncertainty about the timelines. To assess what effect any delay could have on the valuation of the project we developed a scenario where the transition to the synthetic product takes longer (two additional years) and additional A$4m in R&D costs. This scenario yields a valuation of A$150m or A$0.44 per share all else equal.
- Intellectual property. Medlab's key patent protecting NanoCelle has been granted in Australia, Europe and Canada, but is still pending in the US and Singapore. The priority date is 2016, so NanoCelle will be protected until at least 2036 with potential to extend the period.

**Exhibit 8: Financial summary**

| Year-end 30 June | A$000s | 2019 | 2020 | 2021e | 2022e | 2023e |
|---|---|---|---|---|---|---|
| | | Local GAAP | Local GAAP | Local GAAP | Local GAAP | Local GAAP |
| **PROFIT & LOSS** | | | | | | |
| Sales | | 5,364 | 2,848 | 5,700 | 6,270 | 6,897 |
| Other income | | 2,723 | 2,965 | 3,600 | 3,200 | 3,400 |
| Total revenues | | 8,087 | 5,814 | 9,300 | 9,470 | 10,297 |
| Raw materials and consumables used | | (3,064) | (2,805) | (2,934) | (3,081) | (3,235) |
| Employee benefits expense | | (6,465) | (6,666) | (6,566) | (6,894) | (7,239) |
| Amortisation and depreciation | | (147) | (961) | (554) | (554) | (554) |
| Professional and consulting fees | | (1,004) | (1,257) | (1,320) | (1,386) | (1,455) |
| Operating lease costs | | (501) | (199) | (350) | (274) | (312) |
| Finance costs | | (80) | (197) | (197) | (197) | (197) |
| Selling & marketing expenses | | (1,534) | (1,750) | (1,838) | (1,930) | (2,026) |
| R&D/trial expenses | | (1,026) | (1,947) | (2,045) | (2,147) | (2,254) |
| Other Operating Expenses | | (2,440) | (3,520) | (3,696) | (3,881) | (4,075) |
| Reported PBT | | (8,174) | (13,488) | (10,199) | (10,874) | (11,050) |
| Income tax expense | | 0 | 0 | 0 | 0 | 0 |
| Minority Interests | | (83) | (89) | (89) | (89) | (89) |
| Reported net income | | (8,091) | (13,399) | (10,110) | (10,785) | (10,961) |
| Basic average number of shares, m | | 209.0 | 225.7 | 305.7 | 342.2 | 342.2 |
| Basic EPS (A$) | | (0.04) | (0.06) | (0.03) | (0.03) | (0.03) |
| Diluted EPS (A$) | | (0.04) | (0.06) | (0.03) | (0.03) | (0.03) |
| **BALANCE SHEET** | | | | | | |
| Property, plant and equipment | | 632 | 592 | 592 | 592 | 592 |
| Right of use assets | | 0 | 2,288 | 2,288 | 2,288 | 2,288 |
| Other non-current assets | | 483 | 483 | 483 | 483 | 483 |
| Total non-current assets | | 1,115 | 3,364 | 3,364 | 3,364 | 3,364 |
| Cash and equivalents | | 11,442 | 9,063 | 13,205 | 2,420 | 1,000 |
| Trade and other receivables | | 3,814 | 3,379 | 3,379 | 3,379 | 3,379 |
| Inventories | | 2,218 | 1,473 | 1,473 | 1,473 | 1,473 |
| Other current assets | | 1,616 | 509 | 509 | 509 | 509 |
| Total current assets | | 19,090 | 14,425 | 18,566 | 7,782 | 6,362 |
| Non-current loans and borrowings* | | 0 | 0 | 0 | 0 | 9,541 |
| Provisions | | 173 | 478 | 478 | 478 | 478 |
| Lease liabilities | | 0 | 1,630 | 1,630 | 1,630 | 1,630 |
| Other non-current liabilities | | 55 | 0 | 0 | 0 | 0 |
| Total non-current liabilities | | 228 | 2,107 | 2,107 | 2,107 | 11,649 |
| Trade and other payables | | 3,622 | 3,218 | 3,218 | 3,218 | 3,218 |
| Employee benefits | | 389 | 504 | 504 | 504 | 504 |
| Borrowings | | 972 | 94 | 94 | 94 | 94 |
| Lease liabilities | | 0 | 610 | 610 | 610 | 610 |
| Total current liabilities | | 4,983 | 4,426 | 4,426 | 4,426 | 4,426 |
| Equity attributable to company | | 15,050 | 11,397 | 15,537 | 4,752 | (6,209) |
| **CASH FLOW** | | | | | | |
| Net cash used in operating activities | | (10,315) | (10,422) | (10,110) | (10,785) | (10,961) |
| Capex | | (340) | (243) | 0 | 0 | 0 |
| Cash used in investing activities (CFIA) | | (340) | (243) | 0 | 0 | 0 |
| Net proceeds from issue of shares | | 1,303 | 10,398 | 14,250 | 0 | 0 |
| Movements in debt | | 472 | (1,513) | 0 | 0 | 9,541 |
| Other financing activities | | 0 | (563) | 0 | 0 | 0 |
| Cash flow from financing activities | | 1,775 | 8,321 | 14,250 | 0 | 9,541 |
| Increase/(decrease) in cash and equivalents | | (8,889) | (2,379) | 4,140 | (10,785) | (1,420) |
| Cash and equivalents at beginning of period | | 20,333 | 11,444 | 9,065 | 13,205 | 2,420 |
| Cash and equivalents at end of period | | 11,444 | 9,065 | 13,205 | 2,420 | 1,000 |
| Net (debt) cash | | 10,470 | 8,969 | 13,110 | 2,326 | (8,636) |

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

| Contact details | Revenue by geography |
|---|---|
| 11–13 Lord St Botany<br>Building A, Unit A5–A6<br>Botany Quarter<br>NSW, 2019<br>Australia<br>hello@medlab.co<br>www.medlab.co<br>+61 2 8188 0311 | N/A |

**Key team members**

| CEO: Dr Sean Hall | Director of medical research: Professor Luis Vitetta |
|---|---|
| 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 US. 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 Researcher, The World Medical Association, A4M and Special Operations Medical Association. | Prof Vitetta is director of medical research at Medlab and adjunct professor at the University of Sydney, Sydney Medical School. He has an extensive depth of knowledge of the science behind effective probiotics and biologic medicines. His focus on clinical research and its relevance to commercialisation informs Medlab's product portfolio. |
| **Director of science: Dr David Rutolo** | **Non-executive chairperson: Michael Hall** |
| Dr Rutolo 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 was Cofounder of Micelle Laboratories, where he served for over 20 years as executive vice-president and as a board member. | Mr Hall has a long history in the management and building of successful nutritional companies. He sold Bioglan to AusPharm (1980s), built HealthComm USA with Dr Jeffrey Bland, relaunched VitaPlex then sold to Health Minders, built PharmaFoods and sold it to FIT-BioCeuticals. Mr Hall began his career as working in chartered accountants' offices. Together with Dr Sean Hall, current CEO of Medlab, Michael Hall sold FIT-BioCeuticals to Blackmores in 2012. |

| Top shareholders | (%) |
|---|---|
| Sean Michael Hall | 16.9 |
| Farjoy | 9.0 |
| Fit Investments | 3.6 |
| Realm Group | 3.1 |
| Richard Albarran | 1.6 |
| Rolay | 1.6 |
| United Trolley | 1.5 |

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