

Medlab Clinical

Novel drug delivery and synthetic cannabinoids

Medlab is a drug delivery biotechnology company with a proprietary platform, NanoCelle, which is a patented nanomicellar formulation that can improve the delivery of drugs. With the growing appreciation of the medicinal properties of cannabis, Medlab's lead product became NanaBis, a THC:CBD (1:1) cannabis extract encapsulated in NanoCelle particles, which enable a convenient buccal spray delivery. The most recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, thus significantly streamlining the regulatory pathway. Once the product reformulation is done (current 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.

A drug delivery technology company at its core

Historically Medlab had developed a large portfolio of consumer health products using its NanoCelle delivery technology with established nutraceuticals and several medicinal cannabis extract products available via special access programmes. Sales grew to A\$8.1m and A\$5.8m in 2019 and 2020. However, the clinical development of NanaBis (Phase I/II completed; observational study ongoing, n=2,000) delivered such attractive data in pain management that Medlab decided to focus on drug development and now aims to divest its consumer health business.

Synthetic cannabinoids mean clear regulatory path

As Medlab <u>announced</u> 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. The advantage that a synthetic formulation offers is significant, as regulators typically prefer synthetic compounds. The initial indication is cancer-related bone pain, but this could be expanded to general chronic pain. With the opioid crisis unravelling, the support for non-opioid pain killers from various stakeholders (regulators, patient and physician groups, investors, etc) will only grow, we believe.

Valuation: EV of A\$47.8m

Source: Refinitiv

As a drug developer Medlab has loss-making operations, so a relative valuation is not feasible. At the end of calendar Q121, Medlab had a cash position of A\$14.0m and A\$198k in debt (implied EV of A\$47.8m). Synthetic NanaBis development progress, any news on consumer health portfolio divestment and any potential NanoCelle partnering updates are the main near-term catalysts.

Financial highlights							
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	

Pharma & biotech

1 June 2021

Price A\$0.18 Market cap A\$62m



Share details				
Code	MDC			
Listing	ASX			
Shares in issue	342.2m			

Business description

Medlab is an Australian biotechnology company that is developing therapeutics using its proprietary delivery platform NanoCelle. The most advanced programme is in cancer pain management with its 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.

Bull

- Synthetic cannabinoids will help streamline interactions with regulators.
- Proprietary, patented delivery technology.
- A buccal spray not only provides convenient dosing, it has many other advantages compared to ingestion (eg it has a faster onset of action and avoids first pass metabolism).

Bear

- The COVID-19 pandemic, although increasingly under control in developed markets, can still affect clinical trials (which is true for all drug developers).
- R&D risk is unavoidable in the development of novel therapies.
- The transition to a synthetic product introduced additional work, although the guided delay to previous timelines is less than a year.

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