



28 August 2020

Company Announcements Office
Australian Securities Exchange
Exchange Centre
20 Bridge Street
Sydney, NSW 2000

FULL YEAR FINANCIAL RESULTS FY20

Medlab Clinical (ASX.MDC) a company with a portfolio of novel drug candidates, including cannabinoids and nutraceuticals, enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, has today released its Financial Results for the full year ending June 30, 2020.

FY20 has been a pivotal year which saw Medlab Clinical accelerate its drug development program – leading with its cannabinoid portfolio – to create a portfolio of clinically validated products, enhanced by the NanoCelle™ drug delivery platform to improve absorption and effectiveness.

Medlab successfully completed a Phase I/II clinical trial of its lead candidate NanaBis™ which is targeting the treatment of bone pain in cancer patients. Additionally, demand for the company's four cannabinoid based products – sold via the Special Access Scheme and into export markets continue to grow.

Medlab is now planning to commence the process of filing an investigational new drug application with the US Food and Drug Administration and commencing a multi-centre, international Phase III study. This will be a key area of focus for FY21.

Operational Highlights:

- **Successful completion of Phase I/II study:** The trial of 30 advanced cancer patients conducted at Royal North Shore Hospital met its primary and secondary endpoints, demonstrating safety, tolerability, and efficacy. Results showed a 40% improvement in baseline pain scores, within a significant subset of patients with cancer and bone metastases.
- **NanaBis™ 12 month observation study:** As of August 2020, 432 of 2000 patients had been enrolled in the trial, which is designed to gather real world evidence. The third monitoring report has demonstrated positive data with a 59.5% reported reduction in pain (unadjusted), based on average dose of four sprays per day, consistent with the findings of the RNSH trial.
- **Demand for NanaBis™ under Special Access Scheme continues to grow:** Shipment of units under the Special Access Scheme have continued to steadily increase over the past year. Sales in June hit a record monthly high of 910 units. Accumulative sales was 8238 units.
- **Two additional cannabinoid products launched:** Initial sales of NanoCBD™ have commenced under the special access scheme in Australia, and a further 1500 units have been exported to Hong Kong. In addition, an initial order of 5000 units of MgOptima and CBD a hybrid cannabinoid, have been shipped to Cultech Limited, our exclusive distribution partner in the UK.
- **Supply and manufacturing agreement with TASALK:** Manufacturing of NanaBis™ was transferred to Tasmanian Alkaloids (TASALK) ensuring sufficient supply of product to growing demand under the special access scheme and to support a Phase III clinical trial at quality standards required to meet regulatory requirements.

- **Nutraceuticals portfolio:** Sales were tracking strongly up until the end of Q3 – up 27% YOY in invoiced sales. Sales softened in the final quarter reflecting the challenges facing bricks and mortar retail due to COVID-19 restrictions. This was in a stark contrast to the June quarter FY 19 when we launched into banner pharmacy and reported the pipe fill. Some of this impact was offset by our shift to a greater presence in digital sales channels, including establishing a telehealth service, to support direct to consumer sales alongside our distribution into pharmacies via Symbion, API and Sigma Australia-wide.
- **NRGBiotic™ study** of 120 patients for the use of NRGBiotic™ in combination with commonly prescribed treatments for depression, to investigate how these products used in combination could provide better outcomes completed in April. Release of results has been delayed due to COVID-19, but we are working with the lab on a new anticipated completion date. .

Financial Commentary

Total revenue was down 28% to \$5.8m. This is predominantly due to an increase of promotional costs to \$1.8m.

While sales of the cannabinoid products has grown, this reflects a small portion of overall revenue.

The company delivered a net loss after tax of \$13.4M. This is attributed to the acceleration of research programmes, noting that the company records this as expenditure and does not capitalise R&D as a balance sheet asset. The company received an R&D tax incentive payment of \$2.1m.

Medlab has continued to manage cash and as a result, normalised cash burn (excluding government subsidies) has continued to improve over the past 12 months.

During the year, Medlab raised \$11.97M before costs via two placements and an SPP (completed July 2020). The funds raised provide us with capital to support us as we prepare to launch the Phase III study of NanaBis™. The company's cash balance as of June 30, was \$9M.

Summary

“This has been a pivotal year for Medlab which has seen us solidify our focus to drug development, initially focused on our cannabinoid portfolio. While we are generating early revenues, our focus is to achieve US regulatory approval, a move which will greatly expand our market opportunity and enable us to create significant shareholder value,” said Dr Sean Hall, CEO of Medlab Clinical.

“We are generating very positive clinical and real-world data for our lead candidate, NanaBis™ as well as establishing a growing user base under the Special Access Scheme which is generating early revenue. There will be several important milestones ahead of us in the next 12 months as we prepare to file investigational new drug application with the US Food and Drug Administration and commence a Phase III study.

“From a financial performance perspective, we have delivered a meaningful reduction in cash burn over the course of the year. Looking forward, we are assessing the right strategy for our nutraceuticals business in the context of the resources required to grow a business with meaningful earnings, and given our focus on drug development.”

ENDS

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

About Medlab – www.medlab.co

Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and the United States. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, NanoCelle™ is being applied to its medicines, nutritional products and off-patent drugs like statins, Medlab has a growing patent portfolio.

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medlab

MEDLAB CLINICAL LIMITED

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**APPENDIX 4E (RULE 4.3A)
PRELIMINARY FINAL REPORT
FOR THE YEAR ENDED 30 JUNE 2020**

RESULTS FOR ANNOUNCEMENT TO THE MARKET

CURRENT REPORTING PERIOD:
PREVIOUS CORRESPONDING PERIOD:

Financial Year Ended 30 June 2020
Financial Year Ended 30 June 2019

KEY INFORMATION	<u>2020</u> \$	<u>Up/Down</u>	<u>Movement</u>
Sale of goods (net discounts)	5,451,436	down	10.3%
Sales returns	(473,549)	Up	-
Provision for sale returns	(300,000)	Up	-
Promotional costs and other rebates	(1,829,492)	Up	157,3
Other revenue	<u>2,965,418</u>	Up	11.7%
Revenue from ordinary operations	5,813,813	Down	28.1%
Loss from ordinary activities after tax attributable to members of the company	(13,399,374)	up	65.6%
Net loss after tax attributable to members of the company	(13,399,374)	up	65.6%

No dividends have been proposed during the period

	<u>2020</u> \$	<u>2019</u> \$
Net tangible assets per security	0.033	0.071

For additional 4E disclosures, this report should be read in conjunction with the consolidated financial report of Medlab Clinical Limited for the year ended 30 June 2020 which has been audited by ESV Accounting and Business Advisors. An unqualified opinion has been issued by the auditor.



Sean Hall
Managing Director
Dated this 28th day of August 2020
