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

HALF-YEAR FINANCIAL RESULTS FY21

- Revenue from ordinary operations rose 77.4%
- Net loss after tax of $5.3M (2020: $7.1M), a decrease of 25.4%
- NanaBis™ get US FDA IND Approval
- NanoCBD™ HoA executed with Arrotex Australia Group Pty Ltd for Australian Pharmacy

Medlab Clinical (ASX: MDC, Medlab, the Company), a biotech company with a portfolio of novel medicinal candidates enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, has today released is Financial Results for the half-year ended 31 December 2020.

Medlab's pursuit of a differentiated path to market for its medicinal cannabis products – undertaking comprehensive clinical trials and pursuing global opportunities, starting with regulatory clearance from the US Food and Drug Administration – yielded success during the first half of the 2020-21 financial year.

In H1, Medlab continued to make strong progress in the development of its lead drug candidate, NanaBis™, for the treatment of cancer-induced bone pain, and the advancement of NanaBis™ towards its pivotal Phase III trial. Of note was the Company's application to the US Food and Drug Administration (FDA) for Investigational New Drug (IND) status for NanaBis™. Subsequent to H1, the FDA granted IND approval for NanaBis™.

In parallel with clinical development, Medlab focused on driving partnering activities for NanaBis™ in H1.

During H1, Medlab also made strong progress in the development of its NanoCelle® drug delivery platform, with the Company demonstrating additional applications for NanoCelle®.

Medlab continues to advance partnering activities to drive value from NanoCelle® with significant partnership opportunities for NanoCelle® across pharmaceuticals, food technology, consumables and other industries.

Medlab is now planning to progress its Phase III trial of NanaBis™, which will be a key focus for H2.

Operational Highlights

- **Progress towards NanaBis™ Phase III trial in H1:** In the December quarter, Medlab applied to the US Food and Drug Administration (FDA) for Investigational New Drug (IND) status for NanaBis™. Medlab announced the FDA's grant of IND status for NanaBis™ on January 19, 2021. FDA approval permits Medlab to commence the Phase III trial of NanaBis™ at sites in the US. The US joins Australia and the UK as Phase III trial jurisdictions. Medlab is submitting a second IND application to the US FDA for the expanded access scheme, which is similar to the compassionate use program in Australia. If successful, NanaBis™ could be the first cannabis-derived drug candidate that is able to be prescribed under the expanded access scheme in the US.

- **Strong validation for NanaBis™:** In H1, Medlab received third-party validation, and support, from the UK National Institute of Health Research (NIHR), one of the world's leading healthcare research organisations, for the UK arm of the NanaBis Phase III trials.
- **Strong NanaBis™ observational study results:** Medlab received positive results across all criteria in its 12-month observational study of NanaBis™. The study was initiated following talks with the US FDA regarding the pathway for regulatory approval. The results from the observational study were consistent with existing clinical data. Data from the study demonstrated a 55% reduction in pain scores and indicated significant improvements in quality-of-life outcomes such as "general activities", "sleep" and "mood". In November 2020, the NanaBis™ observational study had recruited 668 of 2000 (33.5%) patients.
- **George Clinical signed to provide Phase III trial clinical support services:** In September 2020, the Company signed an agreement with George Clinical Pty Ltd, a leading clinical contract research organisation, to provide clinical services support for Medlab's NanaBis™ Phase III trials, including site selection and feasibility, trial recruitment and ongoing site management for US trial sites.
- **Australian patent granted for NanoCelle®:** The Company was granted its first patent for its NanoCelle® drug delivery platform, validating the science behind the platform. NanoCelle® is a key feature of NanaBis™ and other research programs involving known pharmaceutical ingredients. NanoCelle® is used to greatly improve drug solubility issues, providing Medlab with options to improve prescription and over-the-counter medicines.
- **Additional applications for NanoCelle®:** In December 2020, the Company announced it had demonstrated that NanoCelle® can absorb a nanoparticle compound with an intended action (such as cooling) onto a textile, which has potential for use in responsive smart clothing. Progress was also made in investigations employing NanoCelle® to deliver larger protein-based molecules via buccal administration. Laboratory investigations with primary cancer cells were also completed during H1, demonstrating that specific metabolites can positively impact chemotherapeutic drugs and enhance cancer cell-killing potential.
- **HoA executed with Arrotex:** The execution of an Australian exclusive non-binding Heads of Agreement (HoA) with Arrotex Australia Group Australia Pty Ltd (Arrotex) for the development and distribution of its proprietary cannabinoid formulation NanoCBD™ for Australian Pharmacies.
- **Positive Preliminary NRGBiotic™ trial data:** In H1, the Company awaited a results readout of the NRG Biotic™ Phase IIa depression trial completed in March 2020, with 120 of 150 patients treated. However, analysis by the Queensland University of Technology and the Queensland Medical Research Institute (QMRI) was delayed because of COVID-19 restrictions. Preliminary results delivered in February 2021, subsequent to H1, were positive. The results showed a significant reduction in depression and improvement in quality of life from baseline. It was also demonstrated to be safe and tolerable, with no reported adverse effects.

Financial Commentary

Revenue from ordinary operations rose 77.4% to $4.5M over the corresponding period last year.

During H1, early revenue from Special Access Sales (SAS) sales of NanaBis™ and NanoCBD™ continued to increase, generating proof of concept. Sales for NanaBis™ in Australia continued to show steady growth under the TGA's Special Access Scheme (SAS).

A total of 3,033 bottles of NanaBis™ were dispensed during H1, representing an increase of 6% compared to the prior corresponding period.

SAS sales for NanoCBD™ have shown early growth, with H1 reflecting the first full half of sales since NanoCBD™ was launched in Q4 FY2020.

In H1, Medlab's nutraceutical business continued to undergo a period of rationalisation. Following the initial impact of COVID-19 which saw a decrease in bricks-and-mortar sales, sales in H1 indicated improvement and recovery, supported by the launch of digital sales and marketing channels and telehealth services prior to the period. Nutraceutical sales (after promotional costs and rebates) were up Bricks-and-mortar nutraceutical sales were up 75% compared to corresponding period last year.

Medlab continues to evaluate options regarding the strategic direction of the nutraceutical business.

The Company recorded a net loss after tax of $5.3M (2020: $7.1M), a decrease of 25.4% on the prior corresponding period.

Medlab held a cash balance of $6.9M as of December 31, 2020. The Company continued to reduce cash burn during H1, and cash continues to be managed responsibly.

At period end, the consolidated entity had total assets of $13.6M and total liabilities of $5.6M.

Summary

"In the first half, and subsequent to the first half, Medlab has achieved many significant milestones, especially in relation to NanaBis™," said the Managing Director of Medlab, Dr Sean Hall.

"The grant of IND status for NanaBis™ by the US FDA places Medlab in a leading position given that NanaBis™ is the only cannabinoid-based drug candidate under development ready to start a Phase III trial.

"The support of the NIHR is also a very important validation because it shows that clinicians and regulators want a medicinal cannabis product that can be clinically validated for the management of cancer-induced bone pain.

"The progress of NanaBis™ and the diversification of the NanoCelle® show that Medlab has made solid clinical and regulatory progress that will generate commercial opportunities. The Company has had a strong and very pleasing H1 and has had a good start to H2.

"Medlab's announcement this month (February) that the Company has executed a Heads of Agreement with Arrotex, Australia's largest supplier of generic and over-the-counter drugs, to develop and distribute Medlab's proprietary cannabinoid formulation, NanoCBD™, for Australian pharmacies, is yet another example of the positive momentum across the Company's various activities.

The Board of Medlab would like to thank shareholders for their ongoing support and are very excited as the Company enters the next very exciting stage.

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 pharmaceuticals like statins, Medlab has a growing patent portfolio.

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MEDLAB CLINICAL LIMITED

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APPENDIX 4D (RULE 4.2A3)
HALF-YEAR REPORT
FOR THE PERIOD ENDED 31 DECEMBER 2020

RESULTS FOR ANNOUNCEMENT TO THE MARKET

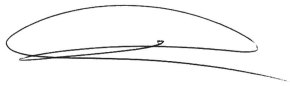
CURRENT REPORTING PERIOD: Half-Year Ended 31 December 2020
PREVIOUS CORRESPONDING PERIOD: Half-Year Ended 31 December 2019

KEY INFORMATION	Amount $	Up/Down	Movement
Sale of goods (net discounts)	2,481,737	Down	9.0%
Sales returns	(139,169)	Up	100.0%
Provision for sale returns	(50,000)	Down	83.3%
Promotional costs and other rebates	(262,982)	Down	76.2%
Other revenue	2,444,259	Up	103.6%
Revenue from ordinary operations	4,473,845	Up	77.4%
Loss from ordinary activities after tax attributable to members of the company	(5,293,960)	Down	25.4%
Net loss after tax attributable to members of the company	(5,293,960)	Down	25.4%

No dividends have been proposed during the period

	31 December 2020 $	31 December 2019 $
Net tangible assets per security	0.021	0.042

This report should be read in conjunction with the consolidated financial report of Medlab Clinical Limited for the half-year ended 31 December 2020 which were subject to a review by ESV Business Advice and Accounting. The review report is attached part of the Interim Report.



Sean Hall
Managing Director
Dated this 24th day of February 2021