



ASX & MEDIA RELEASE

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DEPRESSION TRIAL UPDATE

- Medlab's Depression Trial progressing **ahead of expectations**.
- The trials involve Medlab's NRGBiotic™ from its Nutraceuticals range.
- Current results are suggesting the trial will complete earlier than originally required.
- Whilst the Trial unit has been inundated with about 1,500 patients wanting to participate, trial inclusion requirements are strict, to which 90 people have been randomised into the trial. The inclusion requirements included those over 18 years of age, who have been on anti-depressants, with little to no improvement in symptoms and/or quality of life (QoL). This treatment resistant group accounts for about 1/3rd of all medicated depression patients.

The impact of the trials progressing ahead of expectations marks an important milestone to expanded commercialisation opportunities that drug registration would offer. The plan for NRGBiotic™ is to follow a drug development pathway, whereby after this trial, Medlab would expect results publication, product optimisation and further trial work. Medlab plans at the end of this trial to continue talks with the TGA for drug pathway development which would be critical for future NRGBiotic™ plans.

Trials focus on an adjunct to depression treatment which is globally estimated to be \$864 million USD market in 2015 and is expected to reach \$1.2 billion USD by 2024¹. Overall, the global depression market is estimated to be \$15.6 billion USD, at 2.4% CAGR.²

NRGBiotic™ is a multi-patented probiotic available throughout Australian Pharmacies as part of the national rollout that commenced in the first half of 2019.

NRGBiotic™, since the trial recruitment announcement has sold approximately 13,500 units Australian's outside the trial cohort.

Trial Update:

Medlab Clinical Ltd (ASX: MDC) is pleased to provide a progression update to the Phase 2 Depression Trial using a unique self-branded, in pharmacy formulation, NRGBiotic™.

In July 2018 Medlab announced the commencement of recruitment for an Australian Human Research Ethics and TGA approved Clinical Trial. It is an n=150 study to follow on from previous trials investigating the use of NRGBiotic™ versus placebo as an adjuvant to SSRI and or SNRI (common anti-depressant medications) for people diagnosed with depression that were getting little or no relief from standard medical treatment for major depression.

Progression of the Phase 2 trial to date with Principal Investigators (Dr Esben Strodl and Dr Matthew Bambling) at Queensland University of Technology, Brisbane, Queensland has seen about 1,500 potential candidates interviewed, but due to the strict inclusion criteria, to date 90 patients have been randomised and entered into the study.

Medlab CEO, Dr Sean Hall stated, "we understand this is a much-needed trial for a significant patient group, we further understand depression is an illness that can have life-long repercussions. Patient demand for trial entry exceeded our initial thoughts, and whilst we would ultimately like to help everyone, the trial entry criteria has specific requirements. We are looking at, in short, developing a medication that

¹ <https://www.researchandmarkets.com/reports/4199131/global-treatment-resistant-depression-market>

² <https://www.globenewswire.com/news-release/2019/05/15/1825506/0/en/Anxiety-Disorder-and-Depression-Treatment-Market-To-Reach-USD-18-90-Billion-By-2026-Reports-And-Data.html>

hopefully will address a unique cohort, those over 18 years of age, who have been on anti-depressants, with little to no improvement in symptoms and/or quality of life (QoL). Presently this treatment resistant group accounts for about 1/3rd of all medicated depression patients”.

Whilst trial participants and researchers are blinded to the active or placebo treatment, preliminary reports are highlighting a potential efficacious trendline, that may see the trial complete at 130 patients to report against statistically relevant powering to support the study outcomes.

As we navigate into the Christmas period, recruitment for the study will stop to ensure those patients under investigation are sufficiently monitored, with recruitment expected to recommence mid-January 2020.

Medlab CEO, Dr Sean Hall added “progression to date has the Board and Research team very excited and optimistic. The study timelines are progressing as planned, and at this point the trial should complete ahead of expectations.”

Dr Hall further added, “depression is a global epidemic, affecting just over 5% of the world’s population, scarier though, Health authorities are expecting this to rise to 7% within the immediate foreseeable future, resulting in a growing global patient group where medication strategies potentially will only work on 2/3rd of the patient group. We, (Medlab) believe we can offer novel, replicable and reliable intervention strategies that will reduce symptoms and improve QoL.”

ISSUED FOR: MEDLAB CLINICAL LTD (ASX: MDC) – www.medlab.co

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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.