



**ASX & MEDIA RELEASE**

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**RECRUITMENT BEGINS FOR MEDLAB'S PHASE 2A CLINICAL TRIAL FOR DEPRESSION MEDICINE**

- Recruitment targeting 150 people suffering depression
- Trial led by QUT (Queensland University of Technology)
- Trial designed to meet TGA requirements for expedited drug approval

A recruitment campaign has begun for participants in a clinical trial of a medicine for treatment of depression, developed by Australian life sciences company, Medlab Clinical Ltd (ASX: MDC).

The trial is being led by Brisbane located QUT which is running the recruitment campaign.

Principal investigator of the trial will be QUT's Dr Esben Strodl, senior lecturer in the School of Psychology and Counselling, QUT Institute of Health and Biomedical Innovation.

A trial co-investigator will be Dr Matthew Bambling who supervised two Phase 1 trials which showed significant patient improvement on the combination of Medlab's NRGBiotic™ product with a standard anti-depressant medicine, a selective serotonin reuptake inhibitor (SSRI).

The Phase 2a study is designed to strengthen those initial findings in a wider group of patients, with the recruitment campaign intended to enrol 150 people diagnosed with depression, with progressive implementation of the trial as recruitment continues.

Trial design is also intended to meet requirements of a new [expedited drug approval mechanism](#) being developed by the Department of Health's Therapeutic Goods Administration to provide faster access to new medicines which have a community benefit.

Medlab has received approval of a grant from the Federal government towards cost of this trial.

Research underlying the trial is based on a connection between gut health and inflammation and its subsequent effect on mental health <sup>1</sup>.

According to Professor Luis Vitetta, Medlab's Director of Medical Research and Adjunct Professor at the University of Sydney's Medical School, there was increasing evidence demonstrating the association between poor gut health and depression.

"Medlab has developed a bacteria-based medicine, NRGBiotic™, that targets the gut-brain axis and in Phase 1 trials showed that its positive effect on gut health also boosted the body's ability to absorb a standard anti-depressant," Professor Vitetta said.

The relevance of this development is shown by the following research around depression<sup>2</sup>:

- Depression is a prevalent illness with a burden of care second only to heart disease

<sup>1</sup> [Luis Vitetta, David Briskey, Hollie Alford, Sean Hall, Samantha Coulson, Probiotics, prebiotics and the gastrointestinal tract in health and disease, \*Inflammopharmacology\*, June 2014, Volume 22, Issue 3, pp 135-154](#)

<sup>2</sup> Quoted in [Matthew Bambling, Sophie C. Parham, Samantha Coulson, Luis Vitetta, S-adenosylmethionine \(S-AdoMet\) and Magnesium Orotate as adjunctives to SSRIs in sub-optimal treatment response of depression in adults: A pilot study, \*Advances in Integrative medicine\*, 2 \(2015\), pp 56-62](#)

- Lifetime prevalence rates for depression in Australia have been estimated at 25 per cent for females and 12 per cent for males
- Antidepressant medication treatment assists with at least 30 per cent of acute episodes and one third of patients treated for depression relapse within a year
- Those who have experienced two episodes have a 90 per cent chance of experiencing a third with 40 per cent relapsing within 15 weeks
- Pharmacotherapy achieves acceptable results for about 30 per cent of patients, mixed results for 40 per cent and poor results for 30 per cent of patients
- Those for whom treatment is sub-optimal often present with health problems such as gastrointestinal dysfunction

Globally, more than [300 million people](#) suffer from depression and in Australia, [45 per cent of people](#) aged 16-85 years have met the criteria for a diagnosis of a mental disorder at some point in their lives and the annual cost of mental illness is [A\\$20 billion](#).

Medlab managing director, Dr Sean Hall, said there was a clear community need to develop more effective medicines for treatment of depression.

“Recruitment for our trial is underway and we hope that in reaching out to those with treatment-resistant depression we can make a difference to their lives as well as developing a medicine for the wider community,” Dr Hall said.

As well as developing bacteria-based medicines for treating depression, diabetes and chronic kidney disease, Medlab has developed two cannabis-based medicines for oncology patients, one in pain management and the other in seizures, nausea and vomiting, with the first undergoing a clinical trial with seriously ill cancer patients at Royal North Shore Hospital in Sydney.

In the cannabis clinical trial Medlab’s NanaBis™ will be administered by Medlab’s small particle medicine delivery platform, NanoCelle™.

Published papers on results of Medlab’s Phase 1 depression trial are available on request and for the Phase 2a trial, further information and registration is available at [qut.to/c8b7r](http://qut.to/c8b7r), with participation inquiries to Dr Sophie Parham or Dr Gabrielle Ritchie at [depression@qut.edu.au](mailto:depression@qut.edu.au) or 07 3138 6090. The media release from QUT can be found here: <https://www.qut.edu.au/news?id=133508>.

#### **ADMISSION TO RESEARCH AUSTRALIA**

Medlab also advises it has become a member of Australia’s peak research community, Research Australia, which represents and works to position the country’s health and medical research pipeline as a driver of a healthy population and a healthy economy.

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**ISSUED FOR:** MEDLAB CLINICAL LTD (ASX: MDC) – [www.medlab.co](http://www.medlab.co)

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**ABOUT MEDLAB – [www.medlab.co](http://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.