



ASX & MEDIA RELEASE

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**MEDLAB GRANTED ETHICS APPROVAL FOR PHASE 2A DEPRESSION STUDY  
USING MEDLAB'S PATENT PENDING FORMULATION CURRENTLY AVAILABLE IN AU AND NZ  
MARKETS (NRGBIOTIC™)**

Medical life science company, Medlab Clinical Limited (ASX: MDC), has been granted ethics approval for a Phase 2a human trial for its anti-depression program following positive outcomes from two Phase 1 clinical trials.

The phase 2a clinical trial is testing Medlab's product *NRGBiotic™* on patients diagnosed with depression. Previous trials demonstrated that the formulation effectively improved symptoms and quality of life for patients with drug resistant depression.

*NRGBiotic™* (patent pending) is a bacteria-based (probiotic) medicine that targets the gut-brain axis and improvement of gut health, with the intention of improving the body's ability to absorb medicine. The product (*NRGBiotic™*) is currently available in Australia and New Zealand as part of Medlab's nutritional range.

According to Medlab CEO, Mr Sean Hall, it was encouraging to get such support from the ethics committee, representing an accelerated progression of the trial into Phase 2a.

"Potential outcomes from the Phase 2 trial could be significant given the size of the market and the number of people in our Australian and NZ communities with depression. Medlab strongly believes that our *NRGBiotic™* product will have global demand," Mr Hall said.

"We anticipate the clinical trial to involve the recruitment of 130 participants who fall into the particular category of depressed patients, following a similar design to the prior, successfully completed Phase 1 trials"

Depression is the leading cause of disability worldwide. In Australia, it is estimated 45 per cent of people will experience a mental health condition in their lifetime and, in any one year, around 1 million Australian adults suffer from depression.<sup>1</sup>

In 2015-16, the Australian government spent \$564 million on subsidised prescriptions, with prescription for antipsychotics and antidepressants accounting for the majority of mental health related PBS and RPBS expenditure during this period.<sup>2</sup>

According to the World Health Organisation, depression will be the highest level of disability of any physical or mental disorder by 2030.<sup>3</sup>

In 2015, an estimated 16 million adults in the United States had at least one major depressive episode.<sup>4</sup>

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<sup>1</sup> [http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/6AE6DA447F985FC2CA2574EA00122BD6/\\$File/43260\\_2007.pdf](http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/6AE6DA447F985FC2CA2574EA00122BD6/$File/43260_2007.pdf)

<sup>2</sup> <https://mhsa.aihw.gov.au/resources/expenditure/>

<sup>3</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/EB130/B130\\_9-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_9-en.pdf)

<sup>4</sup> <https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml>

Dr Matthew Bambling will continue as the Principal Investigator, with the trial being conducted at the University of Queensland, Clinical Centre for Research.

Patients recruited for this trial could have been prescribed standard anti-depressant medication (SSRI), with no symptoms improvement and divided into either the control or experimental group.

Dr Bambling is a clinical psychologist and coordinates the postgraduate mental health programs at the University of Queensland's School of Medicine. Dr Bambling has a strong track record in conducting clinical treatment trials and has made internationally recognised contributions to psychological treatments for major depressive disorder and novel online treatment delivery modalities.

Mr Hall further commented that "the predominance of Depression as a major disability internationally has highlighted the importance of this phase 2a trial and emphasised the success to date of Medlab's nutraceutical product, NRGBiotic™."

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

Medlab Clinical is an Australian based medical life science company, with a certified biologics facility in Sydney and sales arms in Australia and California. Medlab's research relates to five health areas - obesity, chronic kidney disease, depression, ageing and muscular skeletal health and pain management. A lot of Medlab's research is on the role bacteria in the gastrointestinal tract play in health and disease, leading to drug discovery and development of new medicines involving bacteria (pharmacobiotics) as well as nutritional products. Medlab is also about to commence a human trial of a cannabis-based medicine for oncology patients with intractable pain, utilising its small particle medicine delivery system, Nanocelle™. Medlab has a growing patent portfolio, multiple published research papers and conference presentations and the Pharmacobiotic trademark – a therapeutic term referring to both probiotics and biologics.