



ASX Announcement

**US Patent Office issues Notice of Allowance status for NRGBiotic™
for treating, preventing, or Ameliorating depression or a Depressive disorder.**

SYDNEY, July 27, 2021 - Medlab Clinical Ltd (ASX.MDC), an Australian biotech using delivery platforms to enhance medicines is very pleased to announce the United States Patent Office (USPTO) has issued a Notice of Allowance for Application number 15/523,271 for the formulation known as NRGBiotic™, currently available in Australian Pharmacies.

The Notice of Allowance refers to a USPTO designation that the Patent is allowed to be granted, and Medlab is expecting this pending formality should occur within the next 3 to 4 months.

For context, The World Health Organization (WHO) in January 2020 stated, Depression is a leading cause of disability worldwide with more than 264 million people suffering from Depression.¹ With close to 800,000 deaths associated annually, overall, costing approximately US\$1 trillion per year in lost productivity.²

In today's environment and somewhat exaggerated by the COVID-19 related issues, Australian peer group, Beyond Blue estimates 3,000,000 Australians live with Depression, over 10% of the Australian population and is reflected globally.

The patent covers both the formulation of NRGBiotic™ and a method for treating, preventing, or ameliorating at least one symptom of depression or a depressive disorder and is valid through to 28 October 2035.

Dr Sean Hall, CEO of Medlab stated *"the USPTO decision to allow is welcoming news. NRGBiotic™ has both the formulation and capabilities of that formulation previously approved in Australia. Receiving this notification off the back of successful trial outcomes (announced on 5 July 2021) attests to the robust work Medlab undertakes. From a commercial aspect, NRGBiotic™ is a branded line here in Australia, and will now go to our partnering network in the Northern Hemisphere."*

On 5 July 2021, Medlab announced the NRGBiotic™ Depression Trial conducted at Queensland University of Technology (QUT) under Australian Clinical Trial Research Number *ACTRN12617000419369 / HREC Approval: 2017000186*, NRGBiotic™ MET 4 of the 5 endpoints:

The Primary Outcomes (2/2 MET) were:

1. MET – Participants taking both NRGBiotic™, and an anti-depressant had greater symptom remission over the 8 weeks period than those on an anti-depressant alone (p=0.015)*.

¹ <https://www.who.int/news-room/fact-sheets/detail/depression>

² <https://www.who.int/teams/mental-health-and-substance-use/mental-health-in-the-workplace>

2. MET - Incidence of dysbiosis assessed by faecal analysis showed both groups were dysbiotic, holding to the premise that anti-depressant medications adversely affect the intestinal bacteria leading to an unbalanced dysbiotic gut.

The Secondary Outcomes (2/3 MET) were:

1. MET - Participants taking both NRGBiotic™ and an anti-depressant had greater proportional increase in Quality of Life (QoL) Scale from baseline to 8 weeks, than those on anti-depressants alone (p=0.015).
2. MET - Participants taking both NRGBiotic™ and an anti-depressant had greater improvement in non-clinical levels of symptoms (e.g., interpersonal, social, etc) than those on anti-depressant medications alone (p=0.003).
3. NOT MET - Proportion of participants with a reduction in lipopolysaccharides (LPS) showed no noticeable differences between the groups.

* The lower the p-value, the greater the statistical significance of the observed difference, for example, a p-value of 0.0254 is 2.54%. This means there is a 2.54% chance your results could be random (i.e., happened by chance).

About Depression

Depression is classified as a mood disorder. It may be described as feelings of sadness, loss, or anger that interfere with a person's everyday activities.³ Depression can be mild, moderate, or debilitating. Conditions known to worsen due to depression include Arthritis, Asthma, Cardiovascular Disease, Cancer, Diabetes and Obesity.

ENDS

Authorisation & Additional information

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

About Medlab Clinical:

Medlab Clinical LTD (ASX:MDC) is pioneering the development and Commercialisation of a delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab's pipeline comprises a number of small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies. Patented lead drug candidate NanaBis™ has been developed for cancer bone pain as a viable alternative to opioid use. Data to date, strongly suggests NanaBis™ may be equally effective in non-cancer neuropathic pain. NanoCelle®, the patented delivery platform is wholly owned by Medlab and developed in Medlab's owned OGTR Registered Laboratory. NanoCelle® is designed to address known medication problems, addressing global unmet medical needs. Medlab operates in Australia (Head Office), USA, and the UK. For more information, please visit www.medlab.co

Medlab – *better medicines, better patient care*

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³ <https://www.healthline.com/health/depression>