

ASX Announcement

Release Date: 17 August 2021

NUHEARA TO COMMENCE MEDICAL DEVICE CLINICAL TRIAL

Nuheara Limited (**ASX: NUH**) (**Company** or **Nuheara**), transforming the way people hear by creating smart and affordable hearing solutions, is pleased to announce that it will commence a clinical trial to test the safety and effectiveness of Nuheara's newly developed range of hearing aid products, to support Nuheara's planned expansion into clinically tested and regulatory approved medical devices.

Nuheara has engaged National Acoustics Laboratories (**NAL**) under the terms of a Clinical Trial Agreement (**CTA**), the pricing of which is not considered material, to assist with conducting the clinical trial.

The results of the clinical trial will allow Nuheara to expand its global hearing solutions by meeting hearing aid compliance requirements initially with the U.S. Food and Drug Administration (FDA), the European Union (CE Mark) and the Australian Therapeutic Goods Administration (TGA).

Commenting on the medical device clinical trial, Nuheara Co-founder and CEO Justin Miller said: "This clinical trial is the first step of our evolution to a medical device company, specifically in the over US\$8 billion regulated global hearing aid market¹. Our breakthrough hearable products, which are non-regulated, have laid a solid foundation for our technology and future products to operate in."

"Nuheara is well positioned for clinical trial success, with our Ear ID already clinically validated. We are a global pioneer in embedding the hearing aid prescription protocols (NAL-NL2) into our range of IQbuds. A successful clinical trial will enable us to tackle any regulated hearing device market in the world, with our end-to-end range of affordable and accessible hearable and hearing aid devices," said Mr Miller.

Nuheara's CTA project team is led by US based audiologist and clinical/regulatory consultant, Deborah Arthur. Ms Arthur has been providing regulatory, clinical, and quality leadership over the last 30 years in the medical device environment, shepherding novel products, especially for Ear, Nose and Throat (ENT) applications, through the regulatory approval process including the *De Novo* hearing aid applications for Earlens Corporation and Bose Corporation. She has previously held executive management roles in regulatory, clinical, and/or quality at Cochlear Americas, MED-EL NA, Smith & Nephew, Symphonix Devices, Inc, and MetaCure Inc.

As previously announced, Nuheara has registered its company with the FDA². A successful medical device clinical trial will provide Nuheara with the basis to enter any regulated hearing device market, globally. It will also provide potential pathways for the Company to enter the Over-The-Counter (OTC) hearing aid market as the FDA releases their OTC guidelines, expected in October 2021.

The detailed structure of the trial is being determined by Nuheara and NAL and will be responsive to trial results and circumstances; NAL is developing detailed protocols for the trial. The Company expects to provide updates to the market as it reaches relevant milestones throughout the clinical testing including ethical approval, recruitment, trial commencement, and results. The timing of those milestones will depend on the success or otherwise of the trial. As is usual for clinical trials of this type, the ethical approval will be sought externally, in this instance from the Hearing Australia Human Research Ethics Committee.

-ENDS-

References:

1 - Fortune Business Insights, Oct 2019

2 – NUH ASX Release, “NUH receives FDA Registration and Hearing Aid Device Listing”, 9 March 2021

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ABOUT NUHEARA

Nuheara is a global leader in smart hearing technology which change people’s lives by enhancing the power to hear. Nuheara has developed proprietary, multi-functional, personalised intelligent hearing devices that augments a person’s hearing. Nuheara is headquartered in Perth, Australia and was the first consumer wearables technology company to be listed on the Australian Stock Exchange (ASX).

In 2016, the Company released its revolutionary wireless earbuds, IQbuds, which allow consumers to augment their hearing according to their personal hearing preferences and connect hands free with their voice-enabled smart devices. In 2020 Nuheara released its third generation IQbuds² MAX. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies and optical chains around the world.

The Company’s mission is to transform the way people hear by creating smart hearing solutions that are both accessible and affordable. For further information, please visit <https://www.nuheara.com/>.

ABOUT NATIONAL ACOUSTICS LABORATORIES

The National Acoustic Laboratories (NAL) is the research division of Hearing Australia. Hearing Australia is a statutory body established under the Australian Hearing Services Act 1991. Since 1947, NAL’s research into hearing has opened new ways in which people with hearing problems can be helped.

NAL researchers carry out research within four departments:

- Audiological Science – conducts innovative research to improve hearing health and quality of life across the lifespan. Also provides expert audiological consultation and clinical oversight to projects at NAL.
- Behavioural Sciences – using psychology and other sciences to investigate and implement campaigns to promote hearing health.
- Communication Science – Investigating the efficacy of early intervention and other factors influencing children’s communication and psychosocial outcomes.
- Signal Processing – research and development of innovative technologies arising from and leading to new scientific discoveries at NAL. Also provides technical support for hearing technologies to industry partners.

The results of NAL research are published in leading scientific journals and presented at conferences. Several NAL inventions have been taken up internationally and are used worldwide, including the ‘NAL Prescriptions’, a series of hearing aid prescriptions, the most used methods to prescribe hearing aids worldwide.

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