

# ASX Announcement

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## NUHEARA COMMENCES MEDICAL DEVICE CLINICAL TRIAL AND PROVIDES PATHWAY TO FDA 510(K) SUBMISSION

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 has commenced its clinical trial with the National Acoustics Laboratories (NAL), to support Nuheara's planned expansion into clinically tested and regulatory approved hearing aids.

The clinical trial of Nuheara's proprietary hardware and software will allow people to self-fit Nuheara's hearing aids, that are designed to be sold over the counter, at retail stores and online.

Following the success of the trial, which is being completed in conjunction with biocompatibility testing and obtaining UL certification, Nuheara plans to proceed with a 510(k) submission to the U.S. Food and Drug Administration (FDA) for approval of a Class II, self-fitting air conduction, wireless hearing aid - 21 CFR Part 874.3325, Product Code: QDD (Self-fit Category). This FDA submission is expected to be made during Q1 of the 2022 calendar year.

The planned submission is also part of the Company's plan to secure broad FDA self-fit hearing aid clearance in time to meet the expected demand for a new category of Over-The-Counter (OTC) hearing aids in the US. In July 2021, President Biden ordered the FDA to produce regulations by mid-November for this OTC category, which is specifically targeting individuals with perceived mild to moderate hearing loss.

OTC hearing aids will be a different class of hearing aid from the current FDA Self-fit Category. Nuheara's clinical trial plan provides the potential of having multiple self-fit hearing aid products in the US market.

"Self-fit technology for hearing aids is the only way to solve the problem of providing better hearing for the millions of people who need hearing assistance but are locked out because of high prices and the lack of access to a professional intervention," said Justin Miller, CEO and Co-founder of Nuheara.

"This clinical trial is our next step as a medical device company, specifically in the US\$8 billion regulated global hearing aid market.<sup>1</sup>

"Following Bose's creation of the Self-fit Category of hearing aids with the FDA, Nuheara intends to be the second company in the world to seek approval for a self-fitting hearing aid. A successful clinical trial would enable us to tackle both the unregulated and regulated US hearing market with an end-to-end range of affordable and accessible hearable and hearing aid devices.

"We take pride in our innovation, our engineering and our determination to end the cost and disempowering process of obtaining hearing aids. Our excellent and award-winning technology is one factor, but ultimately our ability to

<sup>1</sup> Fortune Business Insights, Oct 2019

deliver a hearing aid with self-fit functionality, will be a gamechanger for those people who don't want the expense or inconvenience of the traditional hearing aid channel."

Following the US FDA submission, a successful clinical trial will also provide Nuheara with the basis to enter any regulated market globally, through further regional based regulatory submissions.

-ENDS-

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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 IQbuds<sup>2</sup> 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.