

ASX Announcement

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CLINICAL TRIAL VALIDATES HEARING BENEFITS OF NUHEARA'S SELF-FITTED HEARING AIDS AND SOFTWARE

Key highlights

- **Clinical trial of Nuheara's self-fit hearing aid has concluded with final report from National Acoustic Laboratories (NAL)**
- **Trial successfully validated the hearing benefits of the Nuheara self-fitted hearing aids compared to unaided listening across a range of settings and situations**
- **Participants included those with normal hearing and those with mild to moderate hearing loss**
- **Clinical performance of self-fitting IQbuds Ear ID™ software has also been validated as Software in a Medical Device (SiMD)**
- **Nuheara now well positioned to complete 510(k) FDA submission by end of March 2022 to support the planned expansion into regulated medical devices market**

Nuheara Limited (**ASX:NUH**) (**Company** or **Nuheara**) is pleased to advise that it has successfully concluded its hearing aid clinical trial with the final report received from National Acoustic Laboratories (**NAL**). The clinical trial completes a very complex and important milestone for Nuheara on its pathway to an FDA 510(K) submission¹ and pending entrance into the regulated U.S. hearing aid market segment with world leading hearing aid products.

The clinical trial was conducted in Australia using Audiology best practices on participants with normal hearing and those with mild and moderate hearing loss by professional clinical Audiologists and clinical researchers at NAL. The trial successfully validated the hearing benefit of the Nuheara self-fitted hearing aids compared to unaided listening with benefits including:

- Improved speech understanding in noise
- Improved ability to follow conversations
- Ability to reduce background noise levels
- Overall hearing improvement when listening in everyday conversations

In relation to the unaided listening condition, the study data provided evidence of the superiority of Nuheara hearing aids with FOCUS enabled over unaided listening, and of substantial effectiveness of the Ear ID™ self-fitted hearing aid devices in the overall experience of listeners. Furthermore, clinical assessment showed improvement in speech understanding by 30% in noise when the Nuheara hearing aids FOCUS feature was enabled. This outcome is consistent with other studies showing advantages in speech understanding in noise

with conventional directional microphones in hearing aids ranging from 25% to 30% improvement, depending on the familiarity to the speech, physical fitting, and design of the hearing aids^{2 3}.

The effectiveness data of the Nuheara Ear ID™ self-fitting method was also validated, as Software in a Medical Device (SiMD), through clinical and real-world data demonstrating positive outcomes as compared to the expected NAL-NL2 clinical targets that would be performed by an audiologist fit hearing aid in a clinic.

Commenting on Nuheara’s progress in relation to its expansion plans into regulatory approved hearing aids, Co-founder, Managing Director & CEO Justin Miller said:

“This clinical study is a further critical step in the transformation of Nuheara into a medical device manufacturer of hearing aids. With the five major hearing aid companies commanding 99% of the worlds hearing aid market⁴, there are very few emerging companies who have successfully completed hearing aid clinical trials and gone on to commercialise.

“This is a pivotal development for Nuheara as we position ourselves to complete a US FDA 510(k) submission by the end of March 2022 and, pending FDA clearance, entering the U.S. regulated hearing aid market with world leading hearing aid products.”

-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. As a global pioneer in Hearable products, Nuheara 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 hearable the IQbuds² MAX. In 2021, Nuheara transformed its operations to include medical device manufacturing for its hearing aid products to meet global demand for mild to moderate hearing loss. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies and speciality retailers 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/>.

References

- 1: Refer to previous NUH ASX announcements of 17 August, 15 September, 15 October, 25 November 2021, and 6 January 2022
- 2: Keidser G, Dillon H, Convery E, Mejia J. Factors influencing individual variation in perceptual directional microphone benefit. J Am Acad Audiol. 2013 Nov-Dec;24(10):955-68. doi: 10.3766/jaaa.24.10.7. PMID: 24384081
- 3: Ricketts TA. Directional Hearing Aids. Trends in Amplification. 2001;5(4):139-176. doi:10.1177/108471380100500401
- 4: UBS, Longer Term Investments – Medical Devices, 11 April 2019, Page 13