



ASX Announcement

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NUHEARA CLINICAL TRIAL AND FDA 510(K) PATHWAY UPDATE

Key highlights

- All recruited participants have now completed the clinical trial for Nuheara's hearing aid to support the planned expansion into regulated medical devices
- Final clinical trial report expected by end of January 2022

Nuheara Limited (**ASX:NUH**) (**Company** or **Nuheara**) is pleased to provide an update on its clinical trial and pathway to FDA 510(K) submission¹ for the Company's pending entrance into the U.S. hearing aid market, in line with its expansion plans into global medical devices.

The Nuheara sponsored clinical trial, conducted by National Acoustics Laboratory (**NAL**), has been completed with all participants data now collected. NAL is expected to publish the final clinical trial report by the end of January 2022. This is an important milestone on the path to US FDA 510(K) submission and regulatory clearance.

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 is another critical milestone completed in our journey to become a recognised as a global medical device company. We appreciate the efforts of the team at NAL and those who have participated in this trial. We now look forward to the collation of the clinical trial data and the publication of the final report, which is due later this month."

References

Note¹: Please refer to previous NUH ASX announcements of 17 August, 15 September, 15 October, and 25 November 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. 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/>.