

ASX Announcement

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NUHEARA CLINICAL TRIAL AND FDA 510(K) PATHWAY UPDATE

Key highlights

- **Candidate recruitment complete for Nuheara's clinical trial to support the planned expansion into regulatory approved hearing aids**
- **More than 50% of recruited candidates have now commenced the clinical trial, with the remaining candidates expected to commence within the coming week**
- **Successfully completed product biocompatibility testing incorporating cytotoxicity, irritation, and sensitisation tests**

Nuheara Limited (**ASX:NUH**) (**Company** or **Nuheara**), is pleased to provide an update on its clinical trial and pathway to FDA 510(K) approval for the Company's clinically tested and regulatory approved hearing aids, in line with its expansion plans into medical devices.

Recruitment of candidates for the clinical trial being conducted by National Acoustics Laboratory has now been completed. This is an important milestone on the path to regulatory approval. Of further significance, more than 50% of candidates have now commenced the trial, with the remaining candidates expected to commence within the next week.

Nuheara has also engaged NAMSA, the world's only 100% medical device-focused contract research organisation, and a U.S. FDA ASCA-accredited medical device biocompatibility laboratory, to conduct Cytotoxicity, Irritation and Sensitisation testing. The testing was conducted in accordance with ISO standards, to demonstrate biocompatibility of Nuheara's proposed hearing aid devices. In accordance with these standards, the following excellent results were recorded:

- Cytotoxicity testing was found to meet requirements.
- Irritation testing outcomes resulted in a Primary Irritation Index of zero.
- Sensitisation testing showed no evidence of contact sensitisation.

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

"We are very pleased with the excellent progress Nuheara has been making with its clinical trial and successful completion of the biocompatibility testing. These are important milestones on our planned path to FDA 510(K) submission, which remains on target for the first quarter of 2022."

“With regulatory changes being implemented to the hearing sector in the US, we have a company defining and vast opportunity to expand into medical devices in advance of future Over the Counter [OTC] hearing aid products and sales in the US. The proposed and pending FDA OTC Regulations are expected to be enacted in late 2022, and the work we are doing now to support regulatory approved hearing aids will allow Nuheara to reach and service the approximately 38 million American adults who report some level of hearing difficulty¹.”

References 1: fda-issues-landmark-proposal-improve-access-hearing-aid-technology-millions-americans,
19 October 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/>.