

ASX Announcement

Half year ended 31 December 2022



Release date: 9 March 2023

Nuheara delivers on strategy to open FDA regulated US OTC market

Key Highlights – H1 FY 23

- Nuheara’s addressable market in the US opened up to 38 million potential customers following US Food and Drug Administration (FDA) establishment of a new regulated over-the-counter (OTC) category of hearing aids.
- Nuheara cements transformation into medical device company with historic and world first US FDA certification for its 510(K) self-fitting hearing aids.¹
- Global agreement with Hewlett Packard (HP) Inc. to develop, manufacture and market Nuheara hearing aids under HP brand – HP Hearing PRO – within the OTC category.¹
- Continued expansion of Traditional Retail with more US Best Buy stores added (over 300 in total), Amazon marketing, and an MOU to reach into Walmart, Rite Aid and Independent Pharmacies (4,000 and Point of Sales).²
- Expansion into Target.com⁴ and Fuel Medical³ which reaches millions of consumers across the US.
- On the 510(k) certification, pre-production commenced which allowed for the new year milestones of the HP Hearing PRO launch at CES in Las Vegas and subsequent mass production and shipping to commence.
- First shipment of HP Hearing PRO completed and deployed to US market in February 2023.⁴
- Strategic cornerstone investor secured in July 2022 from Taiwan based Semi-Conductor company Realtek (\$9 billion market cap) as a 14.5% shareholder.⁵
- R&D tax rebate of \$2 million received.⁶

Nuheara Co-founder & Managing Director Justin Miller said:

“The last six months cemented Nuheara’s strategy over the last five years – transforming the company from a hearable technology company to a medical device company.

“In one sweep, the US FDA revolutionised the way people can access hearing aids in the US. The US FDA hasn’t just created an extra OTC category, it has completely overhauled the categorisation of all hearing aids into two categories – OTC and prescription.

“Now, the 38 million people in the US with mild to moderate hearing loss, can access a medical device hearing aid through retail that they can self-fit and afford. Nuheara, through its licencing partnership with global technology leader HP, is at the forefront of this market development.

“Nuheara’s five years of Direct-To-Consumer [DTC] and traditional retail sales experience places us at the forefront in leading the way with OTC offerings. We are in the prime position of delivering the US market more

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accessible and affordable hearing devices through our strong relationships with existing retailers as well as new relationships such as Target.com that will unlock significant opportunities to reach more online consumers.

“This is also a direct challenge to hearing aid incumbents, who have traditionally had only select channels to market their products with audiologists. In this sense, Nuheara has a five year head start with existing retail and marketing relationships.

“Looking ahead, we now have an exciting opportunity to execute our strategy. Our agreement with HP enables us to sell HP branded hearing aids in the new regulated OTC market. In addition, Nuheara’s cornerstone investor, Realtek, came on board as a strategic partner, with their chipsets to be used across all Nuheara’s future hearing devices, ensuring the supply chain security will be a tremendous advantage in hastening manufacturing and deliveries.”

-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 Securities Exchange (ASX). The Company also has a USA office located in Seattle, Washington.

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. In 2022, Nuheara’s HP Hearing PRO was the first product cleared through the FDA’s 510(k) process for both 874.3325 self-fitting and the 800.30 OTC hearing aid classifications under a new product classification code “QUH”.

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: ASX – Nuheara receives US FDA Approval and Launches HP Hearing PRO, 31 Oct 2022
- 2: ASX – Nuheara expands US Retail Footprint, 12 Dec 2022
- 3: ASX – NUH to distribute HP PRO via 3000 Fuel Medical ENT clinics, 20 Feb 2023
- 4: ASX- NUH expands with Target.com and ships HP Hearing PRO, 28 Feb 2023
- 5: ASX – NUH Strategic partner & cornerstone investment with Realtek, 1 Jul 2022
- 6: ASX – Nuheara receives \$2M R&D Tax Cash Rebate, 1 Dec 2022