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Nuheara positioned for US regulated Hearing Aid market

Key highlights – Q3 FY22

- **Successfully completed the clinical trial of Nuheara's Hearing Aid** in preparation for US regulatory certification.
- **Nuheara took the final step in its expansion plan into the regulatory approved medical device market** following the submission of US FDA 510(k) application.
- **Global agreement with HP Inc.** to develop, manufacture and market Hearing Aid products under the HP Brand. Provides significant brand firepower to Nuheara's new Hearing Aids (announced post Q3 end).
- **Driven by the increased focus on US based Traditional Retail (TR) sales to support future hearing aid sales,** TR sales represented 73% of total sales in Q3 FY22, up from 66% in Q2 FY22 and 29% in Q3 FY21.
- **Invoiced product revenue down 37% to $0.75 million** on previous quarter (Q2 FY22: $1.2 million – traditionally largest quarter to holiday sales periods). However, with a primary focus on building Traditional Retail sales, and not Direct to Consumer (DTC) sales, marketing expenses were reciprocally down 35%.
- **Strong inventory levels to support transition,** with more than $7 million worth of stock on hand (based on current ASPs) in 5 global warehouses at end of quarter, strategically provide the necessary consumer electronics stock buffer as new Hearing Aid products are brought to market next financial year.
- **Customer product receipts down 55% to $0.72 million** (Q2 FY22: $1.67 million) as more sales move to trading terms with Traditional Retail partners, rather than cash upfront DTC Sales.
- **7% uplift in Average Selling Price (ASP)** of IQbuds² MAX implemented, increasing ASP to $434 from $405 (FY21)
- **$1.07 million capital raised from Share Purchase Plan SPP) to fund US growth opportunities** announced on 23 December 2021 and closed on 17 January 2022.

Nuheara Co-founder & CEO Justin Miller said:

"The current quarter marked a substantial transition for the Company, shifting from a consumer electronics to medical device company. This occurred on completion of the Nuheara Hearing Aid clinical trials and subsequent US FDA 510(k) submission. On FDA certification, the Company is prepared for new US FDA OTC Hearing Aid regulations to allow sales to commence in September 2022.

"This submission required a huge amount of effort, particularly over the past quarter. It is interesting to note, that according to the FDA, the average medical device 510(k) submission takes 7-10 years to complete, and yet Nuheara achieved it in under 12 months.

"Our fantastic employees aside, this timeframe was only achievable due to Nuheara having consumer electronic augmented hearing products in market over the past five years. We learnt so much, not just about what customers would need in a hearing aid, but also on how we reach and self-empower them, as we developed new and unexplored retail channels.

"OTC Hearing Aids are Nuheara's future. As such, our sales focus has turned to furthering the expansion and development our Traditional Retail partners. As an example, Best Buy continued to expand with the addition of 50 more stores during the quarter. This channel will take time and is certainly not as responsive as DTC. However, it is far more cost effective and scalable for our business as we push towards sales of our OTC Hearing Aids in September.

"We have strived to bring accessibility, affordability, and credibility to a new global market of self-fit hearing devices. Proudly, what we have built is now backed by these changing regulations, our maturing mainstream retail partnerships and, coupled with a brand as powerful and recognisable as HP, we are more than ready to service this ever-growing hearing audience."

Released: 29 April 2022

Perth, 29 April 2022: Nuheara Limited (ASX: NUH), transforming the way people hear by creating smart and affordable hearing solutions, is pleased to present this quarterly activities report alongside its Appendix 4C for the quarter ended 31 March 2022 (Q3 FY22).

NUHEARA SUBMITS 510(k) FOR US FDA CLEARANCE

In early April 2022, Nuheara announced that it had taken the final step in its plans to secure US Food and Drug Administration (FDA) clearance for its self-fitting hearing aid by providing its 510(k) submission to the FDA.

This follows completion of Nuheara's successful clinical trial by National Acoustic Laboratories (NAL) in January 2022. The trial successfully validated the effectiveness of the Nuheara self-fitted hearing aids compared to unaided listening across a range of settings and situations.

The Nuheara hearing aids are designed to be self-fitted by the user, with a software application interface for both iOS and Android smartphones, intended for direct-to-consumer sale and use without the assistance of a hearing care professional. They are intended for individuals 18 years of age or older with perceived mild to moderate hearing loss, which makes up 85% of the US market, or approximately 40 million people.

Creating and manufacturing self-fit hearing aid technology that is clinically validated to perform as effective as a professionally fit hearing aid has been a feat that incumbent hearing aid companies have been unable to achieve. Nuheara's in-market innovation has been building towards this moment for the past five years, and the Company is prioritising its marketing initiatives in the US to ensure that the maximum number of growth opportunities are capitalised on in the short-term.

The FDA submission for clearance is the final step of Nuheara's expansion plans into the regulatory approved medical device market, which also aligns with the much-awaited US Over-The-Counter Hearing Aid final rule publication in the Federal Register by the FDA expected for northern hemisphere mid-summer 2022.

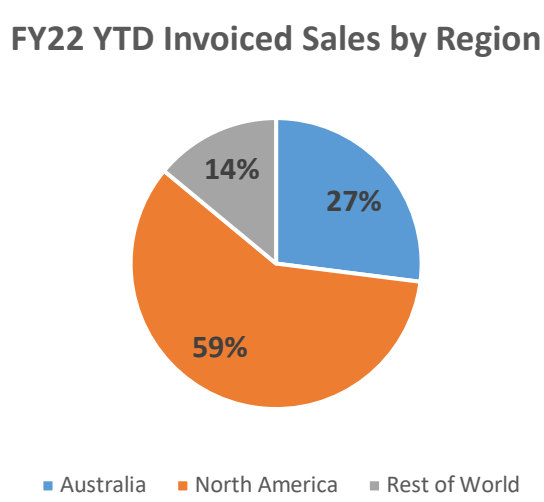
SALES AND REVENUE

US Sales and Marketing Focus

With Nuheara's focus on its US expansion into the regulated hearing aid market, the March retirement of Australian based Director and Chief Marketing Officer provided the Company with an opportunity to reposition key strategic executives to drive and support the expected US growth. Nuheara opened its US headquarters in Seattle Washington in March 2022. Managed by Chief Revenue Officer and President of Americas, John Luna, this has already seen the recent additions of VP of Sales and Marketing, Tony Sulsona and eCommerce Manager, Robert Barone.

Sales by Region

73% of all sales in Q3 FY22 were offshore (Q2 FY22: 75%). North America accounted for 59% of sales for the quarter (Q2 FY22: 61%). Domestic product sales increased slightly over the quarter with 27% of all sales in Q3 FY22 originating in Australia, up from 23% in Q3 FY21 and 25% in Q2 FY22.

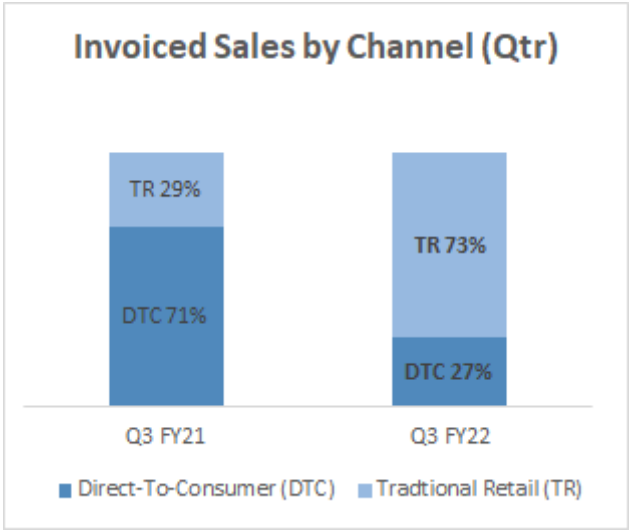


Sales by Channel

Nuheara's hybrid channel strategy continued to deliver on its strategic intent to reach the consumer through multiple sales channels. However, pursuant to Nuheara's short term plan of extending sales in Traditional Retail, this channel represented 73% of all sales during the quarter.

This is significant to the Company's preparation for OTC Hearing Aid sales. Traditional retail's physical store presence is expected to be the mainstay of OTC Hearing sales in the US, as product comparisons and demonstrations can be easily made.

Nuheara remains committed to an omni channel presence. However, in the lead up to OTC Hearing aid sales, which are expected to commence in September 2022, the next six months' focus will be in the development of more traditional retail store presence. This has some benefit in providing a more scalable and affordable growth trajectory, as DTC marketing spend is decreased accordingly.



NUHEARA

COMPLETION OF SHARE PURCHASE PLAN

The Share Purchase Plan (SPP), announced to the market on 23 December 2021, closed on 17 January 2022 with valid applications totalling $1,067,200. The SPP allowed eligible shareholders the opportunity to subscribe for up to $30,000 worth of New Shares in Nuheara at an issue price of $0.016 per share.

Funds raised will be used to underpin growth initiatives including:

- 510(k) submission to the US FDA for approval of a Class II, self-fitting air conduction, wireless hearing aid.
- Transitioning customers to payment terms arising from resurgent traditional retail sales growth through the Company's retail partners, particularly in the US.
- Supporting the newly developed range of hearing aid products to underpin Nuheara's planned expansion into clinically tested and regulatory approved medical devices, particularly in the US.

66,700,000 Ordinary Shares were allotted and issued under the SPP at $0.016 per share on 24 January 2022.

EXPENDITURE

Research and development

Research expenditure that is directly attributable to development activities is capitalised as an intangible asset under Australian Accounting Standards. As a result, expenditure of $1.0 million has been capitalised this quarter (Q3 FY22), on par with the comparative quarter last year (Q3 FY21: $1.0 million), and is shown as "Payments to Acquire Intellectual Property" under cash flows from investing activities at item 2.1(e). This movement is mainly attributable to work on new generation of products, including work performed towards accreditation as a medical device Company.

Product manufacturing and operating costs

The manufacture and sale of IQbuds^2 MAX and accessory products continued during the quarter. A cash outlay of $1.4 million in Q3 FY22, up 73% over the comparative quarter last year (Q3 FY21: $833k), is predominantly attributable to payment for completed units. With $7 million worth of stock on hand (at current Average Selling Price), the Company does expect to manufacture again this financial year. The Company is preparing to commence Hearing Aid manufacture in the new financial year. Orders have been placed for these production runs.

The Company has also incurred considerable costs in the clinical trials and FDA submission.

Advertising and marketing

Invoiced product revenue was down 37% on the previous quarter. With a primary focus on building Traditional Retail sales, and not DTC sales , advertising and marketing spend of $0.7 million in Q3 FY22 was reciprocally down 37% over the same quarter last year (Q3 FY21: $1.1 million).

Staff costs

Consistent with R&D expenditure noted above, employment expenses related to employees working on R&D activities are also capitalised as an intangible asset under Australian Accounting Standards. Staff costs of $834k in Q3 FY22 represented a 24% increase over the same quarter last year (Q3 FY21:

$675k) with movement mainly attributable to the timing of payments, amounts capitalised and new headcount.

The remaining staff costs represent corporate, operations, finance, administration, and marketing employees, including related party payments for non-executive Director fees, and salaries paid to executive Directors during the period (refer item 6.1).

Payments to related parties in Q3 FY22 were $218k, which related to fees paid to non-executive directors and the executive directors' cost of payroll for the period.

Administration and corporate costs

Administration and corporate costs of $1.1 million in Q3 FY22, were up 57% over the same quarter last year (Q3 FY21: $0.7 million). The movement relates mainly to the timing of creditor payments, and specific one-off or non-recurring payments for the ISO13485:2016 application and external audit, and other annual expenditure particular to the start of the calendar year such as IT subscriptions.

MINERAL ASSETS

There has been no change in mineral assets held during the quarter.

Nuheara's remaining mining asset consists of an 80% interest in a Net Smelter Royalty located in Northern Peru, held by its subsidiary Terrace Gold Pty Ltd. Nuheara intends to divest the asset as soon as it is commercially practical to do so.

INVESTOR BRIEFING DETAILS

Justin Miller (Co-founder & CEO) and Jean-Marie Rudd (CFO) will host an investor webinar at 11.00am AEST / 9.00am WST on Tuesday 3 May 2022. Following the presentation, participants will have an opportunity to ask them questions.

To attend the webinar, please pre-register at:

https://us02web.zoom.us/webinar/register/WN_aYMTWP_uRBixGxcQY7Dcyw

-ENDS-

AUTHORISED BY:
Justin Miller
Managing Director and CEO
Nuheara Limited

INVESTORS:
Ronn Bechler, Market Eye
Email: ronn.bechler@marketeye.com.au
Phone: + 61 400 009 774

MEDIA – US:
Maura Yepez, Firebrand
Email: mauray@firebrand.marketing
Phone: +1 415 848 9175

MEDIA – AUSTRALIA:
Ranya Alkadamani
Email: ranya@impactgroupinternational.com
Phone: +61 434 664 589

ABOUT NUHEARA

Nuheara is a medical device company with smart hearing technology, designed to change people's lives by enhancing the power to hear. As a global pioneer in Hearable products, 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 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. 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/.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
NUHEARA LIMITED	
ABN	**Quarter ended ("current quarter")**
29 125 167 133	31 March 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	724	3,522
1.2	Pa ments for		
	(a) research and development[1]	(287)	(1,177)
	(b) product manufacturing and operating costs[2]	(1,438)	(3,000)
	(c) advertising and marketing[3]	(690)	(2,638)
	(d) leased assets	-	-
	(e) staff costs	(834)	(2,392)
	(f) administration and corporate costs[4]	(1,114)	(2,705)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	2
1.5	Interest and other costs of finance paid	(5)	(25)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,774
1.8	Other (provide details if material)[5]	(811)	(778)
1.9	**Net cash from / (used in) operating activities**	**(4,454)**	**(7,417)**

Consolidated statement of cash flows	Current quarter $A'000	Year to date (9 months) $A'000

1) These numbers exclude expenditure directly attributable to development activities that are capitalised as an intangible asset under Australian Accounting Standards. These capitalised development costs are shown as "Payments to Acquire Intellectual Property" under cash flows from investing activities at 2.1(e).

2) Comprising payments for production of IQbuds^2 MAX to stock warehouses to provide the Company with the necessary consumer electronics stock buffer as new Hearing Aid products are brought to market next financial year.

3) Advertising and marketing is lower than previous quarters as the Company set up its team in the new US operational centre to capitalise on the growth opportunities that lie ahead in that region, including medical devices and expanding retail presence.

4) Expenditure is higher than last quarter due to timing of creditor payments due to the Christmas/New Year period, and specific one-off or non-recurring payments for the ISO13485:2016 application and external audit, and other annual expenditure particular to the start of the calendar year such as IT subscriptions.

5) International legal fees for protection of the Company's IP (trademarks and patents)

2.	**Cash flows from investing activities**		
2.1	Pa ments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) propert , plant and equipment	(2)	(85)
	(d) investments	-	-
	(e) intellectual propert (1)	(1,065)	(3,606)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) propert , plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual propert	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(1,067)**	**(3,691)**

1) Comprising capitalised development costs of $1,044k (YTD $3.6m) and capitalised patent and trademark applications of $20k (YTD -$33k).

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equit securities (excluding convertible debt securities)	1,067	2,688
3.2	Proceeds from issue of convertible debt securities	-	3,000
3.3	Proceeds from exercise of options	-	63

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
3.4	Transaction costs related to issues of equit securities or convertible debt securities	(91)	(211)
3.5	Proceeds from borrowings(1)	100	100
3.6	Repa ment of borrowings(1)	(21)	(21)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**1,055**	**5,619**

1) Insurance premium funding

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,253	7,276
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,454)	(7,417)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,067)	(3,691)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,055	5,619
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,787**	**1,787**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	1,620	6,086
5.2	Call deposits	167	167
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**1,787**	**6,253**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of pa ments to related parties and their associates included in item 1	218
6.2	Aggregate amount of pa ments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Directors fees paid to non-executive Directors and salaries paid to executive Directors

7.	Financing facilities *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
7.1	Loan facilities	2,400	2,400
7.2	Credit standb arrangements	-	-
7.3	Other (please specif)	-	-
7.4	**Total financing facilities**	2,400	2,400

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facilit above, including the lender, interest rate, maturit date and whether it is secured or unsecured. If an additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Secured Redeemable Convertible Security

Lender: Healthcare 2030, LLC

Amount: $3.0 million for $3.18 million worth of shares (Subscription Shares)

Conversions: $600k @ $0.013 on 07/02/2022

Interest: Nil

Maturit Date: 30/06/2023

Securit : Securit provided b wa of the issue of 9.8 million Subscription Shares that will be credited or returned to the Compan upon expiration or termination of the Funding Agreement.

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(4,454)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,787
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (Item 8.2 + item 8.3)	1,787
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entit expect that it will continue to have the current level of net operating cash flows for the time being and, if not, wh not?

Answer:

No. There were significant one-off or non-recurring expenses in the March quarter that will not be repeated in the next quarter. These include

- $1.4m in production costs to stock our warehouses. We are not planning an mass production activit in the next quarter. This will enable the Compan to focus its attention on product sales through our existing established DTC channel and gains in mainstream retail partnerships in the lead up to the development of medical devices into the market (see further below).
- $811k for international legal fees for protection of the Compan s IP (trademarks and patents) with the majorit of costs now incurred.
- Specific one-off or non-recurring uncapitalised pa ments for the clinical trials and FDA submission.
- ISO13485:2016 application and external audit, and other annual expenditure particular to the start of the calendar ear such as subscriptions for IT software.

As a result, we anticipate cash outflows for operating activities to be more in line with the usual quarterl working capital levels and therefore significantl lower in the next quarter.

8.6.2 Has the entit taken an steps, or does it propose to take an steps, to raise further cash to fund its operations and, if so, what are those steps and how likel does it believe that the will be successful?

Answer:

The Compan continues to review appropriate funding opportunities in accordance with its growth strateg that are in the interests of its shareholders.

The business also has the opportunit to draw on funding facilities relating to its R&D tax offsets. R&D tax offset credits for FY22 are expected to be up to $2m.

8.6.3 Does the entit expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

On 12 April, Nuheara announced it had taken the final step in its plans to secure US FDA clearance for its self-fitting hearing aid b providing its 510(k) submission to the FDA. This submission solidifies Nuheara s expansion plans into the regulator approved medical device market, which also aligns with the much-awaited US Over-the-Counter Hearing Aid final rule publication expected b the end of September 2022.

The Compan s growth opportunities are expected to increase significantl as a result of its entr into the medical device market.

Importantl , in the interim, sales focus has turned to furthering the expansion and development of our maturing Traditional Retail partners and Nuheara has built a stock level in excess of $7m in anticipation of increased sales in this channel.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which compl with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 April 2022

Authorised b : BY THE BOARD
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

Further Information

Webinar/Conference Call

Nuheara Co-founder, MD & CEO Justin Miller and CFO Jean-Marie Rudd will hold a webinar to discuss the quarterly results.

Date: Tuesday May 3, 2022

Time: 11.00am AEST/9.00am WST

Registration Link :

https://us02web.zoom.us/webinar/register/WN_aYMTWP_uRBixGxcQY7Dcyw

Authorised by:

Justin Miller
Co-founder, MD & CEO
Ph: +61 8 6555 9999

Investor enquiries:

Ronn Bechler
Market Eye Pty Ltd
E: ronn.bechler@marketeye.com.au
Ph: +61 400 009 774

CORPORATE INFORMATION

Directors
The Hon Cheryl Edwardes *AM*
Independent Non-Executive Chairman

Justin Miller
Managing Director/CEO

David Cannington
Non-Executive Director

Kathryn Giudes
Independent Non-Executive Director

David Buckingham
Independent Non-Executive Director

Company Secretaries

Susan Park - Company Secretary
Jean-Marie Rudd - Joint Company Secretary

Securities Exchange
ASX: NUH

Registered Office

190 Aberdeen Street
Northbridge WA 6003
Phone: + 61 8 6555 9999
Fax: + 61 8 6555 9998

Principal Place of Business

190 Aberdeen Street
Northbridge WA 6003
Phone: + 61 8 6555 9999
Fax: + 61 8 6555 9998

Share Registry

Computershare Investor Services
Phone: 1300 850 505 (within Australia)
Phone: +61 3 9415 4000 (outside Australia)

Website and Email

www.nuheara.com
administration@nuheara.com