

# Quarterly Activities Report

For the quarter ended 31 December 2022

## Nuheara achieves world first US FDA clearance for its self-fitting hearing aid

### Key highlights for Q2 FY23

- US over the counter (OTC) hearing aid market now open for Nuheara following receipt of world first US FDA clearance for self-fitting OTC hearing aid
- HP Hearing PRO launched following US FDA clearance
- Stage set for new and multiple global revenue streams from Realtek partnership and OTC Hearing Aid opportunities
- Ongoing strategic partnership with Realtek to develop next generation hearing aid products with Realtek's advanced chipset
- Successful capital raising via placement, with Realtek cornerstoning the placement

**PERTH, AUSTRALIA: Nuheara Limited** (ASX:NUH) (**Nuheara**) is pleased to present this quarterly activities report alongside its Appendix 4C for the quarter ended 31 December 2022 (Q2 FY23).

**Commenting on the progress made over Q2 FY23, Nuheara Co-founder and Managing Director Justin Miller said:**

“The December 2022 quarter was a pivotal period for Nuheara. We identified the US regulated market opportunity several years ago, and have been very focused on getting to this point as the first US FDA approved self-fit OTC hearing aid for over the counter sales. With key strategic partners in technology, product and distribution, Nuheara is uniquely placed to deliver on the tremendous opportunity we see ahead to improve peoples’ hearing via affordable medical devices.

“Over many years, we have helped to drive regulatory change within the hearing healthcare market and as a consequence, I have never been more excited than I am now. During the quarter we successfully completed our transition to a medical device company and with it, opened a significant US opportunity for Nuheara.”

“As the first US FDA cleared self-fit OTC hearing aid, we can now support everyday Americans in hearing better, a market estimated at over 30 million people. We are looking forward to shortly shipping the first devices and seeing our medical device products on US retail shelves.”

## FIRST EVER US FDA CLEARANCE FOR SELF-FITTING OTC HEARING AID

On 31 October 2022, Nuheara announced that it had received world first US FDA 510(k) clearance for both an 874.3325 Self fitting hearing aid and the 800.30 Over The Counter (OTC) hearing aid classification.

The OTC hearing aid rule enactment in the US allows hearing aids within the OTC category, for perceived mild to moderate hearing loss, to be sold directly to consumers in retail stores or online. Access to hearing solutions in retail is something that Nuheara has been developing with its hearable products sales over the past 5 years. As such, the business is well placed to take immediate and significant advantage of the regulation changes.

This historical rule change (87 FR 50698) will forever upend the hearing aid industry in the US and unlock historical barriers to entry for the estimated 38 million Americans who experience some hearing loss and do not own a hearing aid due to the past barriers of access and affordability<sup>1</sup>. Historically in the US, hearing aids are sold at an average cost of US\$4,672 per pair and can be as much as US\$10,000 or more per pair through licensed audiologist and licensed hearing aid retailers<sup>2</sup>. Now, with the ability for those with perceived mild to moderate hearing loss to purchase devices over the counter, the cost to the consumer is expected to come down substantially, averaging less than US\$1,000 per pair.

## HP HEARING PRO LAUNCHED

Following the landmark law establishing a regulatory category for over-the-counter (OTC) Hearing Aids in the United States (enacted on 17 October 2022) Nuheara is now bringing to market its first medical device as the HP Hearing PRO under its worldwide Trademark License Agreement for use of HP trademarks on Nuheara's hearing aids, personal sound amplification devices and accessories. The HP Hearing PRO by Nuheara was successfully launched at CES in Las Vegas on January 5, 2023.



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<sup>1</sup> On Tech: Hearing Aids for the Masses, New York Times, Apr 12, 2021

<sup>2</sup> Technological Advancements in the Hearing Aid Industry, Ahlstrand and Green, 2021; Best Hearing Aids for 2022, Everyday Health, Aug 29, 2022

The HP Hearing PRO self-fitting OTC hearing aid brings superb medical grade hearing aid technology combined with highly desired features of wireless ear buds into a multifunctional device that will be sold in the US online and in retail stores, including Best Buy, Crutchfield, Amazon.com, and [www.HPHearingPRO.com](http://www.HPHearingPRO.com).

Initial orders have been placed from retailers and ecommerce partners for expected availability in Q3 throughout the US. The recommended retail price for a pair of HP Hearing PRO hearing aids along with a charge case for on-the-go charging is US\$699.00.

### **INTERNATIONAL MEDICAL DEVICE QUALITY CERTIFICATION**

On 17 November 2022, Nuheara was certified to the international standard for Medical device quality ISO 13485:2016. This certification is in addition to the ISO 9001:2015 the Company achieved for non-regulated devices.

This certification was an important next milestone following the Company's US FDA cleared HP Hearing PRO OTC (over the counter) self-fit hearing aid. Nuheara's quality management system has been certified by accredited body TÜV SÜD to ISO 13485:2016 for the Design and Development, Production, Distribution of Wireless Air Conduction Hearing Aids.

### **US PATENTS GRANTED FOR HEARING AND ACCESSORY TECHNOLOGY**

Further building on the US FDA clearance received, during Q2 FY23 Nuheara was issued two patents from the US Patent and Trademark Office covering a hearing device configuration system and audio accessory:

- (i) Patent US 11,445,313 "System for configuring a hearing device" discloses a system for configuring a hearing device by a user (ie self-fitting), such that the device can assist the hearing of the person.
  
- (ii) Patent US 11,463,821 "Audio Accessory" discloses an audio transmitter that receives external audio and wirelessly transmits the audio to an audio reproducing device such as an ear bud.

### **\$2 MILLION CASH R&D TAX REBATE**

Nuheara received a Research and Development Tax Incentive cash rebate from the Australian Tax Office of \$2,049,329.37. The R&D Tax Incentive provides a tax cash rebate to support Australian companies undertaking research & development. The rebate is representative of Nuheara's ongoing commitment to provide research leadership in the rapidly changing landscape of global hearing healthcare and leading-edge medical devices.

## **EXPANDED US RETAIL FOOTPRINT**

### ***Memorandum of Understanding (MoU) signed with InnerScope to sell Nuheara OTC self-fit hearing aids in c1,500 Walmart and c1,700 Rite Aid stores***

Nuheara and InnerScope Hearing Technologies, Inc. a US publicly traded company on the OTC Markets (OTCPink: INND) (**InnerScope**) agreed to partner together to penetrate the US hearing aid market, creating and providing retail and technology solutions to build a strong market share in the Over The Counter (**OTC**) self-fit hearing aids segment.

InnerScope, headquartered in Roseville, California, develops and markets OTC hearing aids and related hearing healthcare products, hearing aid & ear care products, and hearing treatment therapies. Its omnichannel marketing approach, including a distribution network of wholesale and retail partners, gives the ability to reach the estimated 70 million people in North America that currently need hearing help.

InnerScope offers innovative point-of-sale Hearing Screening Kiosks, deployed in over 100 independent US pharmacies with another 1,000 pharmacy locations by mid 2023. In addition, InnerScope currently has product displays in circa 1,500 Walmart Vision Centers, and in early 2023 will roll out freestanding displays across circa 1,700 Rite Aid pharmacy stores.

Nuheara will supply its FDA OTC certified hearing products to InnerScope (including the HP Hearing PRO) at an agreed wholesale price. In addition, in return for an agreed royalty fee or service fee, the Company will license its technology and clinical know-how to implement and support the adoption of Nuheara's self-fit technology into InnerScope products for FDA self-fitting clearance.

InnerScope will market, at its cost, Nuheara OTC products into new and existing retail chains, including, but not limited to, Walmart, Rite Aid, and other pharmacy brands. InnerScope will also provide first-level customer and warranty support for Nuheara products sold via InnerScope's sales channels. To retain retail chain exclusivity, InnerScope will need to meet minimum order quantities in defined time periods.

## **STRONGLY SUPPORTED CAPITAL RAISING UNDERPINS US GROWTH**

During Q2 FY23, Nuheara successfully completed a capital raise of \$3 million (gross proceeds) through a Placement to sophisticated and professional investors. Existing shareholder, and strategic investor, Realtek invested a further \$1.5 million via the Placement. Funds raised from the Placement will support working capital to ramp up production for the ongoing rollout of the Company's US FDA cleared over the counter (OTC) hearing aids in the US.

## **CASH RECIEPTS**

In anticipation of the growth opportunities arising from Nuheara's OTC self-fitting hearing aid approval from the US FDA, limited marketing expense was invested and US retailers were resetting their hearing categories for OTC. As a result, lower cash receipts of \$300k were derived predominantly from non-regulated hearing device sales.

## **CASH EXPENSES**

### **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 \$769k was capitalised in Q2 FY23 and is shown as “Payments to Acquire Intellectual Property” under cash flows from investing activities at item 2.1(e). Expenditure is mainly attributable to work on new generation products, including work performed towards accreditation as a medical device Company.

### **Product manufacturing and operating costs**

In preparation for the forthcoming US OTC opportunity, the Company did not undertake any production activities during Q2 FY23, resulting in a significant quarter-on-quarter reduction in product manufacturing and operating spend. Cash outlays of \$205k were incurred during Q2 FY23, with production of Hearing Aid manufacture now recommenced for the US OTC market.

### **Advertising and marketing**

With a primary focus on building traditional Retail sales partnerships in advance of a US OTC launch in 2023, advertising and marketing spend was increased marginally in Q2 FY23 to \$373k to prepare for key product launches including the new HP Hearing PRO.

### **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 cash costs of \$949k were incurred in Q2 FY23 in line with the prior quarter.

Staff costs also include 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**

Payments to related parties in Q2 FY23 were \$165k, 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 benefitted from significant cash management of working capital in Q2 FY23 resulting in a positive movement of \$29k in the quarter.

## **MINERAL ASSETS**

In May 2022, Nuheara announced that it had entered into an agreement for the sale of its remaining non-core mining royalty asset to SilverStream SEZC (SilverStream), a wholly owned subsidiary of Vox Royalty Corp. (TSX-V: VOX) (Vox).

The upfront consideration issued to Terrace Gold was paid as US\$50,000 in common shares of Vox. The shares were subject to a voluntary escrow period of 4 months and 1 day, expiring on 12 October 2022. Subsequent sale of VOX shares during the current quarter totalled \$62k of cash receipts in Q2 FY23. A further payment of US\$450,000 is payable in cash following the registration of the El Molino royalty rights on the applicable mining title in Peru and the satisfaction of other customary completion conditions.

-ENDS-

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**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. In 2020 Nuheara released its third generation IQbuds<sup>2</sup> MAX, recognised by Time Magazine as one of the Best Inventions of the year. 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 April 2022, Nuheara submitted an FDA 510(k) for its self-fit hearing aid and signed a worldwide trademark licensing agreement with HP Inc to sell its hearing aid products under the HP brand name.

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

29 125 167 133

#### Quarter ended ("current quarter")

31 December 2022

| Consolidated statement of cash flows                         | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$A'000 |
|--|----------------------------|---------------------------------------|
| <b>1. Cash flows from operating activities</b>               |                            |                                       |
| 1.1 Receipts from customers                                  | 300                        | 768                                   |
| 1.2 Payments for   |                            |                                       |
| (a) research and development <sup>(1)</sup>                  | (325)                      | (676)                                 |
| (b) product manufacturing and operating costs <sup>(2)</sup> | (205)                      | (1,319)                               |
| (c) advertising and marketing <sup>(3)</sup>                 | (373)                      | (370)                                 |
| (d) leased assets  | -                          | -                                     |
| (e) staff costs  | (949)                      | (1,918)                               |
| (f) administration and corporate costs                       | 29                         | (359)                                 |
| 1.3 Dividends received (see note 3)                          | -                          | -                                     |
| 1.4 Interest received  | 5                          | 5                                     |
| 1.5 Interest and other costs of finance paid                 | (6)                        | (17)                                  |
| 1.6 Income taxes paid  | -                          | (6)                                   |
| 1.7 Government grants and tax incentives                     | 2,086                      | 2,086                                 |
| 1.8 Other (provide details if material)                      | 18                         | 18                                    |
| <b>1.9 Net cash from / (used in) operating activities</b>    | <b>580</b>                 | <b>(1,788)</b>                        |

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 components for future Hearing Aid products.

3) Advertising and marketing costs have been much lower than previous quarters as the Company sets 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 distribution presence.

| <b>Consolidated statement of cash flows</b>               | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(6 months)<br/>\$A'000</b> |
|---|------------------------------------|--|
| <b>2. Cash flows from investing activities</b>            |                                    |  |
| 2.1 Payments to acquire or for:                           |                                    |  |
| (a) Entities  | -                                  | -  |
| (b) Businesses  | -                                  | -  |
| (c) property, plant and equipment                         | (5)                                | (5)  |
| (d) investments   | -                                  | -  |
| (e) intellectual property <sup>(1)</sup>                  | (769)                              | (1,451)  |
| (f) other non-current assets                              | -                                  | -  |
| 2.2 Proceeds from disposal of:                            |                                    |  |
| (a) entities  | -                                  | -  |
| (b) businesses  | -                                  | -  |
| (c) property, plant and equipment                         | -                                  | -  |
| (d) investments (held for sale)                           | 62                                 | 62   |
| (e) intellectual property                                 | -                                  | -  |
| (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)                   | -                                  | -  |
| <b>2.6 Net cash from / (used in) investing activities</b> | <b>(712)</b>                       | <b>(1,394)</b>                                 |

1) Comprising capitalised development costs of \$1,426k and capitalised patent and trademark applications of \$25k.

|   |              |              |
|---|--------------|--------------|
| <b>3. Cash flows from financing activities</b>  |              |              |
| 3.1 Proceeds from issues of equity securities (excluding convertible debt securities)       | 2,925        | 4,790        |
| 3.2 Proceeds from issue of convertible debt securities                                      | -            | -            |
| 3.3 Proceeds from exercise of options   | -            | -            |
| 3.4 Transaction costs related to issues of equity securities or convertible debt securities | (16)         | (39)         |
| 3.5 Proceeds from borrowings  | (14)         | 2,486        |
| 3.6 Repayment of borrowings   | (1,272)      | (1,346)      |
| 3.7 Transaction costs related to loans and borrowings                                       | -            | -            |
| 3.8 Dividends paid  | -            | -            |
| 3.9 Other (provide details if material)   | -            | -            |
| <b>3.10 Net cash from / (used in) financing activities</b>                                  | <b>1,623</b> | <b>5,891</b> |



| <b>Consolidated statement of cash flows</b> | <b>Current quarter<br/>\$A'000</b> | <b>Year to date<br/>(6 months)<br/>\$A'000</b> |
|---|------------------------------------|--|
|---|------------------------------------|--|

|            |  |              |              |
|------------|--|--------------|--------------|
| <b>4.</b>  | <b>Net increase / (decrease) in cash and cash equivalents for the period</b> |              |              |
| 4.1        | Cash and cash equivalents at beginning of period                             | 1,660        | 442          |
| 4.2        | Net cash from / (used in) operating activities (item 1.9 above)              | 580          | (1,788)      |
| 4.3        | Net cash from / (used in) investing activities (item 2.6 above)              | (712)        | (1,394)      |
| 4.4        | Net cash from / (used in) financing activities (item 3.10 above)             | 1,623        | 5,891        |
| 4.5        | Effect of movement in exchange rates on cash held                            | -            | -            |
| <b>4.6</b> | <b>Cash and cash equivalents at end of period</b>                            | <b>3,151</b> | <b>3,151</b> |

| <b>5.</b>  | <b>Reconciliation of cash and cash equivalents</b>  | <b>Current quarter<br/>\$A'000</b> | <b>Previous quarter<br/>\$A'000</b> |
|------------|---|------------------------------------|-------------------------------------|
|            | at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts |                                    |                                     |
| 5.1        | Bank balances   | 2,998                              | 1,502                               |
| 5.2        | Call deposits   | 153                                | 158                                 |
| 5.3        | Bank overdrafts   | -                                  | -                                   |
| 5.4        | Other (provide details)   | -                                  | -                                   |
| <b>5.5</b> | <b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>                                      | <b>3,151</b>                       | <b>1,660</b>                        |

**6. Payments to related parties of the entity and their associates**

|     |   |     |
|-----|---|-----|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 165 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | -   |

**Current quarter  
\$A'000**

*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.*

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

|  | <b>Total facility amount at quarter end \$A'000</b> | <b>Amount drawn at quarter end \$A'000</b> |
|--|---|--|
|  | 2,828   | 2,828                                      |
|  | -   | -  |
|  | -   | -  |
|  | 2,828   | 2,828                                      |

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

|   |
|---|
| - |
|---|

- 7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any 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.

**Convertible Note**

Lender: Realtek Semiconductor Corporation (Realtek)

Subscription: 2,500,000 convertible notes each with a face value of \$1.00. Issued under the Company's Listing Rule 7.1 placement capacity

Amount: \$2.5 million

Maturity Date: 07/09/2024

Conversion Price: \$0.16

Conversion:

- (a) Convertible (in whole or part) by Realtek at any time prior to the Maturity Date.
- (b) Converted into such number of shares as is determined by dividing the conversion amount by the Conversion Price.

Interest: 8% pa payable quarterly either (at Realtek's election):

- (a) in cash; or
- (b) converted into such number of shares as is determined by the amount of accrued interest payable divided by the Interest Conversion Price.

**Interest Conversion Price** means the 30-trading day VWAP of shares immediately prior to the relevant interest payment date, subject to a floor price of \$0.16.

Security:

- (a) Following shareholder approval under Listing Rule 10.1, the Company granted a first ranking security interest over all of its assets to Realtek (Security Interest) to secure payment of the outstanding amount and any accrued interest owed to Realtek (Outstanding Amount).

**Insurance Premium Funding**

Nuheara has entered into short-term funding arrangements for its annual insurance premiums.

Lender: Elantis Premium Funding

Date: 28/02/2022

Amount: \$100,020

Interest: 4.9% flat rate of interest

Term: 10 months

Lender: West Premium Funding

Date: 30/04/2022

Amount: \$137,940

Interest: 2.69% flat rate of interest

Term: 10 months

| <b>8.</b> | <b>Estimated cash available for future operating activities</b>               | <b>\$A'000</b> |
|-----------|---|----------------|
| 8.1       | Net cash from / (used in) operating activities (item 1.9)                     | 580            |
| 8.2       | Cash and cash equivalents at quarter end (item 4.6)                           | 3,151          |
| 8.3       | Unused finance facilities available at quarter end (item 7.5)                 | -              |
| 8.4       | Total available funding (Item 8.2 + item 8.3)                                 | 3,151          |
| 8.5       | <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b> | N/A            |

*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.*

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

8.6

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

Answer:

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

Answer:

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

Answer:

*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 comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 January 2023

Authorised by: 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.