

ASX:RSH OTCQB:RSHUF

10<sup>th</sup> May 2023

## RESPONSE TO ASX - APPENDIX 4C QUERY LETTER

Ms. Melissa Kostopoulos  
Adviser, Listings Compliance  
ASX Limited  
Melbourne VIC.

Email: [listingscompliancemelbourne@asx.com.au](mailto:listingscompliancemelbourne@asx.com.au)

Dear Melissa,

Respiri Limited (Respiri or the Company) responds to ASX letter dated 4 May 2023 with respect to the company's Quarterly Activities Report (QAR) and Appendix 4C Cash Flow Report (App4C) for the quarter ended 31 March 2023 lodged with ASX on 26 April 2023

*A: Please confirm that RSH expects to continue to have the same level of net operating cash outflows of approximately \$1,170k*

YES.

With respect to item 8.1 of the March 2023 App4C, the Company expects to continue having the same level of net operating cash outflows in the next two quarters. This is due to the Company's continued expansion of operations in the USA with:

- a) The rollout and execution of Respiri's wheezo<sup>®</sup> medical device, in association with Respiri's partner company Access Telehealth who distribute the wheezo<sup>®</sup> medical device, that's novel with an improved standard of care service for patients with Respiratory Disease who require on-going monitoring of their health condition, thus reducing un-necessary hospital ER visits
- b) On-going engagement with new major medical institutions/healthcare organisations and private payors across the USA to implement the wheezo<sup>®</sup> Remote Patient Monitoring (RPM) program as part of a standard of care focused on Respiratory Disease intervention using the wheezo<sup>®</sup> device to track and monitor physiologic data post care.
- c) Respiri's recent appointment of a Chief Operating Officer-US operations to lead and grow these relationships plus appointment of Respiri personnel to assist with training of hospital and medical staff on the use of the wheezo<sup>®</sup> Remote Patient Monitoring (RPM) for the recruitment and onboarding of patients into the wheezo<sup>®</sup> RPM program.
- d) Continued assessment of various strategic opportunities to improve monthly recurring per-patient revenue levels and broaden the existing RPM reimbursed business opportunity.

*B: Does RSH expect the reimbursements described in Paragraph A(v) to materially affect RSH's net cashflows in the next two quarters?*

NO.

ASX:RSH OTCQB:RSHUF

Reimbursements reported in the March 2023 QAR and as revenue in the App4C were received from King's College London for the provision of wheezo® devices, access to remote patient monitoring (RPM) platform/portal and patient application technologies and data support services for use in National Institute for Health Research (NIHR) funded clinical trial with leading UK clinicians. The trial will assess the impact of introducing remote patient monitoring RPM technology to paediatric asthma patients.

Respiri's US revenues are driven from device sales, recurring RPM revenues per patient per month for reimbursed services claimed by "prescribing" physicians for the ongoing patient use of the wheezo® RPM program under Current Procedural Terminology (CPT) reimbursement through Centers for Medicare and Medicaid Services (CMS) and private insurers. Respiri's US based RPM partner, Access Telehealth, invoices these physicians for patient services rendered and Respiri invoices the RPM partner a monthly, per patient, recurring fee.

Revenues from Access Telehealth were not received in the March 2023 quarter; however, an insignificant amount was received as pre-paid revenue in the December 2022 quarter.

The receipt of revenues from sale to, and ongoing use by, patients of Respiri's wheezo® medical device are based upon the following approximate timelines:

- Medical institution/healthcare organisation (HCO) executes the initial contract with Respiri's Remote Patient Monitoring (RPM) partner company who distribute the wheezo® medical device as part of RPM services in the USA.
- patient eligibility and protocol finalisation, patient management and alert plan development, product training for physicians and medical staff, technical integration (billing and reporting alignment) into existing medical institution systems: +6 months
- wheezo® device sale to RPM partner by Respiri once HCO readiness is achieved in the steps outlined above
- Under the RPM partner contract with the medical institution/healthcare organisation
  - On-boarding of patient commences: +1 month
  - Patient monitoring - at least 16 days of data with the device must be achieved to qualify for reimbursement payments: +1 month
  - Claim processed by Medical institution/healthcare organisation: +2 weeks
  - Reimbursement payment to RPM partner varies depending on the different paying private insurers: up to +6 weeks
  - Payment to Respiri by RPM partner: +2 weeks

Monthly recurring revenues will continue to grow over the next 12+ months as we drive utilisation in the large approved Medical institution/healthcare organisation as well as continued focus on new Acute care facilities utilising the wheezo® Remote Patient Monitoring (RPM) program.

The increased exposure of the wheezo® RPM program the US medical market and potential for future revenues from the sale and ongoing use of the wheezo® device is considered significant by Respiri where Chronic obstructive pulmonary disease (COPD), US nation's third leading cause of death, affects approximately 4% (12.7 million) Americans and approximately 8% (25 million) live with asthma. Each year, COPD leads to more than 700,000 hospitalizations. ~19.6 percent of COPD patients hospitalised in the US are readmitted within 30 days, accounting for \$17 billion in annual expenses. (Reference: [Chronic Obstructive Pulmonary Disease Readmissions and Other Measures of Hospital Quality \(atsjournals.org\)](https://atsjournals.org))

ASX:RSH OTCQB:RSHUF

*C: As the response provided in Question 2 is NO, this question is not applicable.*

*D: As the response provided in Question 2 is NO, please explain how RSH intends to improve and/or address its net operating cashflows during this quarter (June 2023) and next quarter (September 2023)*

Respiri is currently planning an equity raise that is expected to fund the Company's operations for the next 12 months as it grows its US revenue base through its RPM partner(s).

*E: As at the date of this letter, does RSH expect to be able to continue its operations and to meet its business objectives? (Please provide further details for this view).*

YES.

Respiri anticipates that increased exposure of the wheezo<sup>®</sup> RPM program in the US medical market, the continued expansion of its operations in the USA, the onboarding of patients into the wheezo<sup>®</sup> RPM program and continued use of its wheezo<sup>®</sup> device, that it will reach operating financial breakeven in late calendar year 2024.

*F: Does RSH consider that the financial condition of RSH is sufficient to warrant its continued listing on ASX as required under Listing Rule 12.2?*

**ASX listing Rule 12.2** (financial condition) 'an entity's financial condition, including operating results, must in ASX's opinion, be adequate to warrant the continued quotation of its securities and its continued listing.'

- (i) Respiri's current operating net cash outflow is expected to improve from increased exposure of the wheezo<sup>®</sup> RPM program in the US medical market, the continued expansion of its operations in the USA, and the onboarding of patients into the wheezo<sup>®</sup> RPM program and continued use of its wheezo<sup>®</sup> device.
- (ii) Respiri's available funding at 31 March 2023 will be supported by the planned equity raise that is expected to fund the Company's operations for the next 12 months as it grows its US revenue base through its RPM partner.
- (iii) Commencing from a zero-revenue base in 2022, the initial commencement of on-boarding patients by each medical institution/healthcare organisation is not initially financially material; however, commercialisation of the wheezo<sup>®</sup> device in the USA, the world's largest medical services market, is considered material to the Company. These contracts and subsequent patient onboardings are two distinct commercial steps and in combination signal acceptance of the wheezo<sup>®</sup> RPM program by physicians and medical institution/healthcare organisations who drive demand which is a fundamental commercialisation indicator for the Company. As each larger and small medical institution/healthcare organisation are engaged and onboarding of patients commences and increases, and with regular recurring RPM revenues from each patient earned from using the wheezo<sup>®</sup> device, Respiri will be able to provide forecasts in the future.
- (iv) The timelines provided in paragraph B above are based upon contracting with large medical institution/healthcare organisations who have a higher level of processing requirements. Smaller medical institution/healthcare organisations are nimbler and therefore the process for approval and commencement for onboarding of patients (leading to receipt of revenues) can be shortened by up 3 months. Respiri's RPM partners are contracting with these smaller medical institution/healthcare organisations and the receipt of

ASX:RSH OTCQB:RSHUF

revenues from sale to, and ongoing use by, patients of Respiro's wheezo® medical device are expected to be received by Respiro in the June 2023 quarter. Monthly recurring revenues are anticipated to grow from the continued use of the wheezo® medical device from current patients and as new patients are on-boarded by existing and newly contracted medical institution/healthcare organisations.

- (v) The statement made in the auditor's half-year review of the Company's December 2022 half year financial reports of the material uncertainty regarding Respiro's ability to continue as a going concern, is based upon the Company's financial position and performance at that reporting date and forecast revenues and necessity for Respiro to raise additional capital to support its ongoing operations in the next 12 months.

Under the Going Concern statement in Note 1 to those financial statements the directors stated that: "The Directors believe that there are reasonable grounds to believe that the Group will be able to continue as a going concern, after consideration of the following factors:

- The Group has prepared budgets and cash flow forecast for the next 12 months from the date of this report which indicate the Group will have a positive cash balance during this period. The cash flow forecasts include further capital raising over the next 12 months.
- The Group has generated revenue in the half year ended 31 December 2022 and is expecting to continue to generate revenue over the next 12 months after entering into distribution agreements into the USA.
- As described in Note 13 (to the financial statements) the Group successfully raised \$1,500,000 post period end through a placement offering.
- The Directors believe that there are reasonable grounds to expect that the Group has the capacity to raise capital. The Group has a strong track record of accessing capital when it is required to advance its portfolio."

*G. Please provide any other information that RSH considers may be relevant to ASX forming an opinion whether RSH is complying with Listing Rule 12.2.*

Respiro does not have any additional information to provide that it considers may be relevant to ASX forming an opinion whether RSH is complying with Listing Rule 12.2.

*H: Please confirm that RSH is complying with the Listing Rules and, in particular, Listing Rule 3.1*

Respiro is complying with the listing rules and in particular listing rule 3.1.

*I. Please confirm that RSH's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of RSH with delegated authority from the board to respond to ASX on disclosure matters.*

This letter has been approved by the Board of Respiro Limited.

**Mr Marjan Mikel**

CEO & Managing Director

Respiro Limited

P: +61 408 462 873

E: [marjan@respiro.co](mailto:marjan@respiro.co)

**Mr Nicholas Smedley**

Executive Chairman

Respiro Limited

P: +61 447 074 160

E: [nicholas@respiro.co](mailto:nicholas@respiro.co)

ASX:RSH OTCQB:RSHUF

wheezo<sup>®</sup> is a registered trademark of Respiri Limited.



4 May 2023

Reference: ODIN73633

Mr Andrew Metcalfe  
Company Secretary  
Respiri Limited  
Level 9, 432 St Kilda Road  
Melbourne, Vic 3004

By email: Andrew@accosec.com

Dear Mr Metcalfe

#### **Respiri Limited ('RSH'): Appendix 4C Query**

ASX refers to the following:

- A. RSH's announcement titled "Quarterly Activities/Appendix 4C Cash Flow Report" for the quarter ending 31 March 2023 lodged on the ASX Market Announcements Platform ('MAP') on 26 April 2023, which disclosed (relevantly, emphasis added):
- i. At item 8.1, that RSH incurred net operating cash outflows of \$1,170k.
  - ii. In response to the question in Item 8.6.1, as to whether RSH expected to continue to have the current level of net operating cash flows, RSH responded "Yes".
  - iii. At item 8.4, that RSH had 938k of funding available.
  - iv. At item 1.1, that RSH's receipts from customers were \$101k for the quarter and \$111k for the half-year.
  - v. Relating to its cash receipts, *"During the quarter, the Company recorded **cash receipts of \$0.1 million...** for use in National Institute for Health Research (NIHR) **funded clinical trial** with leading UK clinicians. The trial will assess the impact of introducing remote patient monitoring technology to paediatric asthma patients. **Revenues from the provision of wheezo® devices and recurring revenues, used for Remote Patient Monitoring (RPM) programs in the USA, were all prepaid in the December Quarter and the ongoing monthly recurring revenues have not yet been received as reimbursements** from Centers of Medicare and Medicaid Services (CMS) and private insurers first reimburse Respiri's US RPM Partners (i.e. Access Telehealth) who then pay Respiri."*
- B. RSH's announcement titled "Quarterly Activities/Appendix 4C Cash Flow Report" for the quarter ending 31 December 2022 and lodged on MAP on 25 January 2023, which disclosed (relevantly, emphasis added):
- i. At Item 8.1, that RSH incurred net operating cash outflows of \$1,207k.
  - ii. In response to the question in Item 8.6.1, as to whether RSH expected to continue to have the current level of net operating cash flows, RSH responded "Yes".
- C. RSH's announcement titled "Wheezo Remote Patient Monitoring (RPM) Successfully Reimbursed and Claimed by Physicians" and released on MAP on 6 February 2023, which disclosed (relevantly):
- "Respiri has become the first Australian medical device manufacturer to have its patented wheezo® device, used for Remote Patient Monitoring (RPM) programs prescribed by physicians, to be **successfully processed and receiving reimbursement** from Centers of Medicare and Medicaid Services (CMS) in the USA... Although **not financially material**, this event marks a key milestone in the execution of the Company's USA business strategy..."*

---

*Respiri earns US\$50-60 for each device sale to RPM partner organisations and **generates recurring revenues of US\$10-20 per month** from the ongoing RPM use of the device with revenue dependent upon the scope of future services outsourced to RPM partners."*

- D. RSH's response to ASX's Query Letter dated 10 January 2023 and released on MAP on 19 January 2023, which disclosed (relevantly, emphasis added):

*"...contract patient generation ("**on-boarding of patients**") may take 6 months to commence given the due diligence and authorisation processes..."*

*Respiri's US based RPM partner, invoices these physicians for patient services rendered and Respiri invoices the RPM partner a monthly, per patient, recurring fee. **Projected revenues are not provided** by Respiri as it is considered **too early in the execution of the Company's USA business strategy** to do so with any form of accuracy."*

- E. RSH's announcement titled "Respiri Announces First Patients Enrolled into Wheezo Remote Patient Monitoring Programs" and released on MAP on 7 November 2022, which disclosed that (relevantly, emphasis added):

*"Respiri is pleased to announce the enrolment of the first patients into the wheezo® Remote Patient Monitoring (RPM) program.*

*Although **not financially material**, this event marks a key milestone in the execution of the Company USA business strategy."*

- F. The Independent Auditor's Review Report by RSH's auditors, RSM Australia Partners, included in RSH's Half-Year Accounts released on MAP on 27 February 2023, which disclosed:

*"We draw attention to Note 1 in the half-year financial report, which indicates the consolidated entity incurred a net loss of \$2,577,622 and had net cash outflows from operating activities of \$2,475,808 for the half-year ended 31 December 2022. As stated in Note 1, these conditions, along with other matters as set forth in Note 1, indicate that **a material uncertainty exists that may cast significant doubt on the consolidated entity's ability to continue as a going concern**. Our conclusion is not modified in respect of this matter."*

- G. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

- H. Listing Rule 12.2, which states:

*"An entity's financial condition (including operating results) must, in ASX's opinion, be adequate to warrant the continued quotation of its securities and its continued listing."*

- I. Section 14 of Guidance Note 14, which states:

*"Any forward looking statements in an announcement... must be based on reasonable grounds or else by law they will be deemed to be misleading."*

### **Request for information**

Having regard to the above, ASX asks RSH to respond separately to each of the following questions and requests for information:

1. Please confirm that RSH expects to continue to have the same level of net operating cash outflows of approximately \$1,170k (paragraph A).
2. Does RSH expect the reimbursements described in Paragraph A(v) to materially affect RSH's net cashflows in the next two quarters?

- 
3. If the answer to Question 2 is “yes”, please:
    - 3.1 Provide the basis for responding “yes” to the question in Item 8.6.1, which asks if RSH expected to continue to have the current level of net operating cash flows.
    - 3.2 Provide a forecast of expected reimbursements in each of the June 2023 and September 2023 quarters.
    - 3.3 Provide the basis for each of the forecasts in Question 3.2.
  4. If the answer to Question 2 is “no”, please explain how RSH intends to improve and/or address its net operating cash outflows during this quarter (June 2023) and next quarter (September 2023).
  5. At the date of this letter, does RSH expect to be able to continue its operations and to meet its business objectives? Please provide further details for this view.
  6. Does RSH consider that the financial condition of RSH is sufficient to warrant its continued listing on ASX as required under Listing Rule 12.2? In answering this question, please explain the basis for this conclusion, commenting specifically on the following:
    - 6.1 RSH’s net operating cash outflow of \$1,170k in the quarter ending March 2023 and \$1,207k in the quarter ending December 2022.
    - 6.2 RSH’s total available funding at 31 March 2023 of \$938k, which suggests RSH has an estimated 0.80 quarters of funding available.
    - 6.3 RSH’s various disclosures that recent developments disclosed on MAP were either not financially material or too uncertain to be projects (paragraphs C, D and E).
    - 6.4 RSH’s disclosures that it had only recently commenced on-boarding patients (paragraph E), that it takes approximately 6 months to on-board patients (paragraph D), the lag in RSH receiving any reimbursements (paragraph A(v)) and the low monthly revenue per patient (paragraph C).
    - 6.5 The material uncertainty regarding RSH’s ability to continue as a going concern raised by RSH’s auditors in the auditor’s half-year review (paragraph F).
  7. Please provide any other information that RSH considers may be relevant to ASX forming an opinion on whether RSH is complying with Listing Rule 12.2.
  8. Please confirm that RSH is complying with Listing Rule 3.1 and that there is no information about its financial condition that should be given to ASX in accordance with that rule that has not already been released to the market.
  9. Please confirm that RSH’s responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of RSH with delegated authority from the board to respond to ASX on disclosure matters.

#### **When and where to send your response**

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9:30 AM AEST Wednesday, 10 May 2023**. You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, RSH’s obligation is to disclose the information ‘immediately’. This may require the information to be disclosed before the deadline set out in the previous paragraph and may require RSH to request a trading halt immediately.

Your response should be sent to me by e-mail at [ListingsComplianceMelbourne@asx.com.au](mailto:ListingsComplianceMelbourne@asx.com.au). It should not be sent directly to the ASX Market Announcements Office.



---

## **Suspension**

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in RSH's securities under Listing Rule 17.3.

## **Listing Rules 3.1 and 3.1A**

In responding to this letter, you should have regard to RSH's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure*: Listing Rules 3.1 – 3.1B. It should be noted that RSH's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

## **Release of correspondence between ASX and entity**

Although ASX does not currently intend to release a copy of this letter, your reply and any other related correspondence between us to the market, we nonetheless reserve the right to do so under Listing Rule 18.7A.

## **Questions**

If you have any questions in relation to the above, please do not hesitate to contact me.

Yours sincerely

---

**Melissa Kostopoulos**  
Adviser, Listings Compliance