

ASX:RSH OTCQB:RSHUF

18<sup>th</sup> January 2023

## RESPONSE TO ASX 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 10 January 2023:

*A: Please identify the new and material information in the relevant announcement*

1. With respect to market announcement dated 18 November 2022 to contract with, and subsequent announcement dated 14 December 2022 to on-board patients by the Minnesota Lung Centre.

The first announcement informed the market that the medical institution/healthcare organisation (Minnesota Lung Centre) has executed the initial contract with Access Telehealth who distribute the wheezo<sup>®</sup> medical device as part of Remote Patient Monitoring (RPM) services in the USA. This demonstrates that the wheezo<sup>®</sup> RPM program was selected by the medical institution/healthcare organisation due to positive clinical outcomes that could be delivered to patients. The second announcement informed the market that the RPM program utilising the wheezo<sup>®</sup> medical device has commenced the recruitment of patients onto this program, a clinical/commercial result only possible after a successful integration of the new program into existing operations, systems and clinical pathways requiring careful account management and execution.

Both announcements were considered market sensitive due to the strategic significance to the Company in executing its business plan in the US medical market. Although the contract with Minnesota Lung Centre is initially a pilot program, the process required prior to onboarding patients under the pilot program is the same as for a normal contract. This contract will move to a full RPM contract on successful roll-out of the pilot program as measured by key performance indicators agreed with the client. Although a contract with, followed by initial commencement of on-boarding patients by the medical institution/healthcare organisation is not initially financially material, commercialisation of the wheezo<sup>®</sup> device in the USA, the world's largest medical services market, is considered material to the Company as it represents a significant step in the rollout and execution of Respiri's business plan that offers a new, novel and improved standard of care service by medical institutions to patients with Respiratory Disease who require regular monitoring of their health condition.. The contract and subsequent patient onboarding are two distinct commercial steps that in combination signal acceptance of the wheezo<sup>®</sup> RPM program by physicians and the Minnesota Lung Centre, a major US medical institution/healthcare organisation, who drive demand which is a fundamental commercialisation indicator for the Company. Between contracting and onboarding patients, there are a number of critical steps to be completed that, although not included in the second 'onboarding' announcement, are necessary to allow the wheezo<sup>®</sup> RPM program to commence leading to the reimbursement of services provided and recurring patient revenue inflow to Respiri. The enablement steps leading to onboarding patients and reimbursement steps

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leading to revenues earned by Respiri are listed below under 'Onboarding of Patients' and 'Reimbursement of wheezo<sup>®</sup> RPM program services' respectively.

2. With respect to market announcement dated 28 November to contract with, and subsequent announcement dated 23 December 2022 to on-board patients by the Arkansas Heart Hospital.

The first announcement informed the market that the medical institution/healthcare organisation (Arkansas Heart Hospital) has executed the initial contract with Access Telehealth who distribute the wheezo<sup>®</sup> medical device as part of Remote Patient Monitoring (RPM) services in the USA. This demonstrates that the wheezo<sup>®</sup> RPM program was selected by the medical institution/healthcare organisation due to positive clinical outcomes that could be delivered to patients. The second announcement informed the market that the RPM program utilising the wheezo<sup>®</sup> medical device has commenced the recruitment of patients onto this program, a clinical/commercial result only possible after a successful integration of the new program into existing operations, systems and clinical pathways requiring significant and involved account management and execution.

Both announcements were considered market sensitive due to the strategic significance to the Company in executing its business plan in the US medical market and with a major US medical institution/healthcare organisation in a separate US state to the announcements reported in '1' above. Although a contract with, followed by initial commencement of on-boarding patients by the medical institution/healthcare organisation is not initially financially material, commercialisation of the wheezo<sup>®</sup> device in the USA, the world's largest medical services market, is considered material to the Company as it represents a significant step in the rollout and execution of Respiri's business plan that offers a new, novel and improved standard of care service by medical institutions to patients with Respiratory Disease who require regular monitoring of their health condition. The contract and subsequent patient onboarding are two distinct commercial steps and in combination signal acceptance of the wheezo<sup>®</sup> RPM program by physicians and the Arkansas Heart Hospital, a major US medical institution/healthcare organisation, who drive demand which is a fundamental commercialisation indicator for the Company. Between contracting and onboarding patients, there are a number of critical steps to be completed that, although not included in the second 'onboarding' announcement, are necessary to allow the wheezo<sup>®</sup> RPM program to commence, leading to the reimbursement of services provided and revenue inflow to Respiri. The enablement steps leading to onboarding patients and reimbursement steps leading to revenues earned by Respiri are listed below under 'Onboarding of Patients' and 'Reimbursement of wheezo<sup>®</sup> RPM program services' respectively.

3. With respect to market announcement dated 18 August 2022 to contract with, and subsequent announcement dated 9 December 2022 to on-board patients by a major North Carolina based Healthcare Organisation.

The first announcement informed the market that the major medical institution/healthcare organisation, which could not be named in the initial disclosure notice due to agreed confidentiality under the contract, has executed the initial contract with Access Telehealth who distribute the wheezo<sup>®</sup> medical device as part of Remote Patient Monitoring (RPM) services in the USA. This demonstrates that the wheezo<sup>®</sup> Remote RPM program was selected by the medical institution/healthcare organisation due to positive clinical outcomes that could be delivered to patients. The second announcement informed the market that the RPM program utilising the wheezo<sup>®</sup> medical device has commenced the recruitment of patients onto this program, a clinical/commercial result only possible after a successful integration of the new program into existing operations, systems and clinical pathways requiring significant and involved account management and

execution.

The initial announcement was not considered market sensitive as it formed part of a general market update and Respiri was unable to name and hence was unable to emphasise the importance of contracting with this major medical institution/healthcare organisation. However, the second 'onboarding' announcement was considered market sensitive and of strategic importance to the Company in executing its business plan in the US medical market as it represented the third of three major hospital groups to contract with Access Telehealth, Respiri's partner in the US, and therefore the traction that the Company has achieved across a short time period across three different US states and for different patient cohorts, all demonstrating the broad clinical appeal of the wheezo<sup>®</sup> RPM program to different specialties, institutions and states highlighting the potential of the market opportunity for the Company.

Although a contract with, followed by initial commencement of on-boarding patients by the medical institution/healthcare organisation is not initially financially material, commercialisation of the wheezo<sup>®</sup> device in the USA, the world's largest medical services market, is considered material to the Company as it represents a significant step in the rollout and execution of Respiri's business plan that offers a new, novel and improved standard of care service by medical institutions to patients with Respiratory Disease who require regular monitoring of their health condition. The contract and subsequent patient onboarding are two distinct commercial steps and, in combination, signal acceptance of the wheezo<sup>®</sup> RPM program by physicians and the major North Carolina based Healthcare Organisation, who drive demand which is a fundamental commercialisation indicator for the Company. Between contracting and onboarding patients, there are a number of critical steps to be completed that, although not included in the second 'onboarding' announcement are necessary to allow the wheezo<sup>®</sup> RPM program to commence, leading to the reimbursement of services provided and revenue inflow to Respiri. The enablement steps leading to onboarding patients and reimbursement steps leading to revenues earned by Respiri are listed below under 'Onboarding of Patients' and 'Reimbursement of wheezo<sup>®</sup> RPM program services' respectively.

#### Onboarding of Patients:

Following execution of the contracted engagement with a medical institution/healthcare organisation by Respiri's RPM partner, contract patient generation ("on-boarding of patients") may take 6 months to commence given the due diligence and authorisation processes that each medical institution/healthcare organisation is required to undertake prior to rolling out the wheezo<sup>®</sup> RPM program. This includes securing approval from the medical advisory board and ethics committee to ensure that the wheezo<sup>®</sup> device fits within the standards of care used by the medical institution/healthcare organisation for its patients in the management of respiratory disease.

Prior to onboarding patients, Access Telehealth contracts with each medical institution/healthcare organisation to complete a number of critical milestone steps before a program is able to go 'live' prior to onboarding of patients. These include:

- 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,
- claims review to confirm the wheezo<sup>®</sup> RPM program qualifies for RPM Current Procedural Terminology (CPT) reimbursement through Centers for Medicare and Medicaid Services (CMS) and private insurers,
- Financial system integration to ensure payment,

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- Legal, privacy and data security assessment,
- device logistics, and
- marketing.

Reimbursement of wheezo<sup>®</sup> RPM program services:

Respiri earns revenues from both the initial device sale and recurring RPM revenues per patient per month for reimbursed services claimed by “prescribing” physicians for the ongoing patient use of the wheezo<sup>®</sup> device under the CPT reimbursement codes claimed for the wheezo<sup>®</sup> RPM program and processed through Centers for Medicare and Medicaid Services (CMS) and private insurers. 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. As each medical institution/healthcare organisation is engaged and onboarding of patients commences and increases, and with regular recurring RPM revenues from each patient earned using the wheezo<sup>®</sup> device, Respiri will be able to provide such forecasts in the future.

**B:** *For each of the announcements listed in paragraph A, please also identify the detail provided in the announcement that would enable investors or their professional advisers to understand the ramifications, and to assess the impact, of the new and material information in the relevant announcement on the price or value of RSH’s securities, as required by Guidance Note 8.*

1. With respect to market announcement dated 18 November 2022 to contract with, and subsequent announcement dated 14 December 2022 to on-board patients by the Minnesota Lung Centre.

The engagement represents the first time that the Minnesota Lung Centre (MLC) has accepted a program that allows for adopting a new standard of care, focused on respiratory disease intervention using the wheezo<sup>®</sup> device to track and monitor patient physiologic data between clinical visits and after acute care. It also represents a significant shift in the process for how physicians’ approach and manage patients in addition to the current “standard of care”. On-boarding of patients demonstrates acceptance of a new technology, providing significant exposure, endorsement and benefits of the wheezo<sup>®</sup> device and the benefits of the wheezo<sup>®</sup> RPM program. MLC was the first pulmonology specialty healthcare institution to adopt the wheezo<sup>®</sup> RPM program as part of the standard of care for patients with respiratory disorders.

2. With respect to market announcement dated 28 November to contract with, and subsequent announcement dated 23 December 2022 to on-board patients by the Arkansas Heart Hospital.

The engagement represents the first time that the Arkansas Heart Hospital (AHH) has accepted a program that allows for adopting a new standard of care, focused on respiratory disease intervention using the wheezo<sup>®</sup> device to track and monitor patient physiologic data between clinical visits and after acute care. It also represents a significant shift in the process for how physicians’ approach and manage patients in addition to the current “standard of care”. On-boarding of patients demonstrates acceptance of a new technology, providing significant exposure, endorsement and benefits of the wheezo<sup>®</sup> device and the benefits of the wheezo<sup>®</sup> RPM program. AHH was the first cardiac specialty healthcare institution to adopt the wheezo<sup>®</sup> RPM program as part of the standard of care for cardiovascular disease patients with Chronic Obstructive Pulmonary Disease (COPD).

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3. With respect to market announcement dated 18 August 2022 to contract with, and subsequent announcement dated 9 December 2022 to on-board patients by a major North Carolina based Healthcare Organisation.

The engagement represents the first time that the major North Carolina based Healthcare Organisation has accepted a program that allows for adopting a new standard of care, focused on respiratory disease intervention using the wheezo<sup>®</sup> device to track and monitor patient physiologic data between clinical visits and after acute care. It also represents a significant shift in the process for how physicians' approach and manage patients in addition to the current "standard of care". On-boarding of patients demonstrates acceptance of a new technology, providing significant exposure, endorsement and benefits of the wheezo<sup>®</sup> device and the benefits of the wheezo<sup>®</sup> RPM program. This major healthcare organisation became the first general care hospital to adopt the wheezo<sup>®</sup> RPM program as part of the standard of care for adult patients with respiratory disorders.

**C:** *Does RSH consider any of the announcements listed in paragraph A to contravene ASX's guidance on 'ramping announcements' in section 7.10 of Guidance Note 8*

No. Respiri is aware of and careful to ensure that each of its market sensitive announcements are not made with the view to 'ramping up' the price of the Company's securities. Each announcement is factual based and is considered market sensitive given the significant achievements in initially contracting and then on-boarding patients in these US medical institutions/healthcare organisations. These two critical milestones are major achievements for a medical device company. These achievements signify important commercial milestones which have culminated from many years of Research and Development and strategic investment by investors. Each of these developments are separate material commercial milestones.

The increased exposure the wheezo<sup>®</sup> RPM program has in the US medical market and potential for future revenues from the sale and ongoing use of the wheezo<sup>®</sup> device is considered by Respiri as significant, where approximately 4% of Americans have Chronic Obstructive Pulmonary Disease (COPD) (more than 12,500,000) and 8% live with asthma (circa 25,000,000) and more than 150,000 Americans die of COPD<sup>1</sup> every year making COPD the 3<sup>rd</sup> principal cause of death behind stroke and ischemic heart disease and is considered a major burden on US healthcare institutions.

Whilst the wheezo<sup>®</sup> RPM program is intended to move to the onboarding stage soon after initial contracted acceptance by the end-user customer with Access Telehealth, Respiri, along with its US based partner work diligently with these larger institutions to ensure all critically important milestones and requirements are met and delivered in accordance with local laws and governance (i.e., HIPAA). Smaller groups (i.e., medical clinics) would very likely move much more swiftly, however the larger institutions referred in paragraph 'A' above require broader stakeholder engagement and approvals throughout the contracted setup and establishment phase.

**D:** *Please provide ASX with a copy of each of the agreements underlying the programs referred to in the announcements listed in paragraph A (not for release to the market)*

The Respiri business model in the USA is built around contracted distribution agreements with its RPM service provider partners, such as Access Telehealth (refer ASX Announcement dated 7 February 2022). To this end, agreements with US medical institutions/healthcare organisations for the wheezo<sup>®</sup> RPM program are executed with Access Telehealth and not Respiri and as such are subject to the relevant confidentiality between those

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companies. Respiri does not contract with the US medical institutions/healthcare organisations.

**E:** *Does RSH consider that it has the appropriate policies and procedures in place to ensure compliance with its continuous disclosure obligations? Please outline any planned improvements to RSH's policies and procedures.*

Respiri has appropriate policies and procedures in place to ensure compliance with its continuous disclosure obligations. Respiri periodically reviews its governance charters and policies and publishes these on the company's website as well as make the necessary disclosures in its annual corporate governance statement and Appendix 4G.

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

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

**G:** *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*

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

**Mr Marjan Mikel**

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<sup>1</sup> COPD deaths - [COPD Statistics & Facts in the US \(2023\) \(cfah.org\)](https://cfah.org)



10 January 2023

Reference: 66321

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

By email: Andrew@accosec.com

Dear Mr Metcalfe

### Respiri Limited ('RSH'): Query Letter

ASX refers to the following:

- A. The following announcements of RSH, all marked "market sensitive":
- (1) "First Patients Selected and Enrolled into Respiri's Wheezo Minnesota Lung Center (MLC) Remote Patient Monitoring Program (RPM) Pilot Program" released on the ASX Market Announcements Platform ('MAP') on 14 December 2022;
  - (2) "Arkansas Heart Hospital (AHH) Commences Patients on Wheezo Remote Patient Monitoring (RPM) Program" released on MAP on 23 December 2022; and
  - (3) "Major North Carolina Based Healthcare Organisation Commences Wheezo Remote Patient Monitoring (RPM) Program Onboarding" released on MAP on 9 January 2023.
- B. The following announcements, all marked "market sensitive", informing the market of the existence of the Wheezo Remote Patient Monitoring Program and the upcoming onboarding of patients:
- (1) "Wheezo Remote Patient Monitoring (RPM) Pilot Program Selected by Minnesota Lung Center" released on MAP on 18 November 2022;
  - (2) "Wheezo Remote Patient Monitoring (RPM) Selected by Leading USA Heart Centre to Improve Management of COPD in Heart Patients" released on MAP on 28 November 2022; and
  - (3) "Investor USA Market Update and Presentation" released on MAP on 18 August 2022.
- C. 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 (emphasis added):
- "[RSH] 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."*
- D. 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.
- E. Section 4.15 of Guidance Note 8 *Continuous Disclosure* which states:
- "Wherever possible, an announcement under Listing Rule 3.1 should contain sufficient detail for investors or their professional advisers to understand its ramifications and to assess its impact on the price or value of the entity's securities."*



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F. Section 7.10 of Guidance Note 8 *Continuous Disclosure* which states:

*“ASX is alive to listed entities making market announcements with a view to “ramping up” the price of their securities. Ramping announcements come in many forms, including:*

- the release of a “business update” or something similar, which will typically be worded in an exuberant fashion but which on close examination contains little in the way of substance;*
- a series of announcements in close proximity, none of which is particularly material but which together are intended to pique investor interest in the entity...”*

### **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. For each of the announcements listed in paragraph A, please identify the new *and* material information in the relevant announcement. ASX observes that:
  - 1.1 all the relationships and impending onboarding of patients disclosed in these announcements appears to have been previously disclosed to the market (see the announcements listed in paragraph B); and
  - 1.2 RSH has previously disclosed to the market that the initial onboarding of patients was not financially material (see paragraph C).
2. For each of the announcements listed in paragraph A, please also identify the detail provided in the announcement that would enable investors or their professional advisers to understand the ramifications, and to assess the impact, of the new and material information in the relevant announcement on the price or value of RSH’s securities, as required by Guidance Note 8 (see paragraph E).
3. Does RSH consider any of the announcements listed in paragraph A to contravene ASX’s guidance on ‘ramping announcements’ in section 7.10 of Guidance Note 8 (see paragraph F)? For any announcement listed in paragraph A that RSH considers did not contravene this ASX guidance, please provide the basis for this view, commenting specifically on:
  - 3.1 The information available to the market at the time of the relevant announcement from previous disclosures to the market (including those listed in paragraph B), noting in particular that Wheezo programs generally move to the onboarding stage reasonably soon after commencement; and
  - 3.2 The portion of section 7.10 of Guidance Note 8 extracted in paragraph F above.
4. Please provide ASX with a copy of each of the agreements underlying the programs referred to in the announcements listed in paragraph A (not for release to the market).
5. Does RSH consider that it has the appropriate policies and procedures in place to ensure compliance with its continuous disclosure obligations? Please outline any planned improvements to RSH’s policies and procedures.
6. Please confirm that RSH is complying with the Listing Rules and, in particular, Listing Rule 3.1.
7. 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.

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### **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 AEDT Monday, 16 January 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**. It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

### **Trading halt**

If you are unable to respond to this letter by the time specified above, you should discuss with us whether it is appropriate to request a trading halt in RSH's securities under Listing Rule 17.1. If you wish a trading halt, you must tell us:

- the reasons for the trading halt;
- how long you want the trading halt to last;
- the event you expect to happen that will end the trading halt;
- that you are not aware of any reason why the trading halt should not be granted; and
- any other information necessary to inform the market about the trading halt, or that we ask for.

We require the request for a trading halt to be in writing. The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted. You can find further information about trading halts in Guidance Note 16 *Trading Halts & Voluntary Suspensions*.

### **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**

We reserve the right to release a copy of this letter, your reply and any other related correspondence between us to the market under listing rule 18.7A.

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## Questions

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

Yours sincerely

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**Melissa Kostopoulos**  
Adviser, Listings Compliance