



## MEDICAL DEVICE PATH TO MARKET UPDATE

RESPIRI LIMITED (ASX:RSH) is pleased to update shareholders on the company's progress in the commercialisation of wheezo™ the world's first wheeze monitor.

### Product Manufacturing

Production is now established and being scaled up through a series of increasing volume builds as we approach product launch. 10 wheezos were produced for testing in January this year; all testing has now been completed. The current production build will produce 120 fully functional wheezo devices which will be used for beta testing, clinical trials, clinician briefing and other marketing purposes. This production build is labelled the 'pre-production' build as it's the full dress rehearsal before we enter full scale production. All aspects of production, including testing apparatus, automated machine programming, assembly and test procedures and production tooling are being evaluated prior to full scale production.

SRX Global has completed the production of electronics for the pre-production build, and these electronic assemblies have passed initial testing (in-circuit testing) at their factory, ready for functional testing and assembly into the wheezo plastic enclosure.

The wheezo enclosure is a 'co-molded' composite of a soft elastomer outer and hard plastic core. Tooling for this type of enclosure is more complex, however there is a significant advantage of a higher quality 'soft-touch' feel at a lower unit price. Initial enclosures from the tool failed to meet our quality standards, and subsequent adjustments to the plastic and elastomer formulations are addressing the issue. The 'tuning' of material and holding parameters is often required to achieve the right level of performance from these composite parts. Around 80% of the housings currently produced are still acceptable and will be used for trials and demonstration.

The delay caused by additional material tuning does affect the timing of safety and compliance testing required to be performed as part of medical device certification. Testing must be conducted on the formulation used in full scale production and therefore, cannot start until the issue is completely resolved. Whilst there is no delay on the beta testing and clinical trials, there will be an eight week delay on final certification as a result of this issue.

### Safety & Compliance Testing | Submission to Notified Body for CE Mark

Pending the finalisation of the material tuning process for the enclosure and the manufacturing process at SRX, Safety and Compliance testing is now scheduled to commence 18 March with completion towards the end of May. Once the lab report is supplied, Respiri will compile the technical file for submission to the Notified Body responsible for ISO 13485 certification and the CE mark approving wheezo for sale in Europe. TGA approval for sale in Australia and HSA for sale in Singapore will follow approximately six weeks later. From this point on, the process for Class IIa approval of wheezo is prescriptive and **timelines are determined by the regulatory authorities**. We are confident we will achieve approval as the company has been successful in obtaining the CE mark for all its products.

## Mitigation | Clinical Trials and Beta Testing on time

In order to keep to our schedule for mandatory clinical trials and beta testing, we are building 20 pre-production wheezo devices now. Professor Bruce Thompson has engaged Professor Frank Thien, Director of Respiratory Medicine at Eastern Health, as Principal Investigator for the short-term studies. We will update shareholders on the study protocols once they are underway.

**Why clinical trials?** A successful launch of wheezo is dependent not only on customer brand awareness and engagement, but on endorsement from key opinion leaders in respiratory medicine, asthma bodies and GPs. As reported, the London Medical and Scientific Advisory Board Meeting and our recent multi-territory survey confirmed that GPs need to understand the meaning and relevance of 'wheeze rate' in order to assist their patients with treatment plans. The first short term comparison study to support the promotional claim that wheezo is as good as a stethoscope will be underway shortly with a duration of about six weeks. The second short term study designed to assess the correlation between wheeze rate and a relevant clinical measure of lung function e.g. FEV1 is more complex with ethics approval dictating the commencement date.

Customers will go to their GP with their valuable wheezo data and it is imperative that the GP is a) familiar with the product and b) understands the meaning of the data in relation to the wheezes symptom they hear with their stethoscope. For example, what does '5% wheeze rate' mean as part of the patient's asthma action plan? Further, the clinical trial 'evidence' is all Respi needs to win endorsement from the asthma bodies, the authorities, other than GPs and peers, our customers turn to for advice.

### Beta testing and investor demonstrations

Respi will also use the pre-production wheezo devices for beta testing with asthma patients and their carers in our target market, along with healthcare professionals, to make sure our instructions for use are clear, and to catch any minor product issues that have not been detected in the extensive test program that has already taken place. Beta testing is the last stage of product evaluation and is used to polish the overall experience for the user before full scale production takes place. We expect positive feedback for the wheezo experience, and look forward to sharing video and customer verbatims captured during this exercise.

Further, we will use these units to demonstrate wheezo to investors in a series of roadshows. We will provide more information on these events as they are scheduled.

### Asthma experts call for new way forward

Respi is encouraged by the discussion paper released from the National Asthma Council (Media Release 18 February) calling for a rethink of current asthma management practices. The paper "Current practice and new approaches in asthma: perspectives of asthma practitioners and patients" is a collective response from top asthma health professionals, researchers and patients on how the objectives of the 2018 National Asthma Strategy can be achieved. The points listed below are of particular relevance to Respi and our launch plans for wheezo.

- The next frontier for asthma care will be the use of more sophisticated technology and the emerging precision medicine approach to asthma management.
- Rethinking the key self-management tool of asthma action plans.
- A requirement of more effective self-management practices that consider the patient's personal disease experience and their social and environment context.

## Customer Lead Capture Campaign | [wheezo.com](http://wheezo.com) Launch

As advised, Respiri is launching wheezo to customers with a 'Register your Interest' campaign via [wheezo.com](http://wheezo.com) supported by PR and social media initiatives leveraging a relevant event calendar to drive people to the website. We are currently producing shareable content for our primary target market of parents to distribute via their social networks and will implement an influencer strategy, whereby parents searching for information on their child's asthma will be introduced to the product by direct asthma groups, parent support groups and individuals with an interest in children's health. This includes our first ambassador, **Michael Clarke** and his family, who are living the asthma story.



The microsite will be live next Monday, 25 February with the launch of social pages to follow in a staged rollout. [wheezo.com](http://wheezo.com) enables us to build a database of interested people and implement a lead nurture strategy to take them through to purchase of wheezo and an ongoing relationship with Respiri. We will harness a community of early adopters/users to create compelling social proof and aid in the execution of a targeted, but flexible direct response media plan across owned, earned and paid channels. Importantly, when we are closer to confirmation of the date for regulatory approval, we will commence pre-sales communications for wheezo.

## Healthcare Professionals (HCP) Campaign

Respiri is launching a new category as the world's first wheeze monitor, so in tandem with the consumer campaign, we are developing the narrative for our **healthcare professionals' strategy** to raise awareness of wheezo and educate GPs about the benefits of wheezometry in assisting them with the design of individual patient treatment plans. The HCP communications campaign will be driven by the clinical evidence captured in the trials. With a focus on key associations such as the Royal Australian College of General Practitioners (RACGP) The Thoracic Society of Australia and New Zealand (TSANZ) of which Professor Bruce Thompson is president elect, The Pharmacy Guild of Australia and Asthma Australia and the National Asthma Council, we will leverage the key opinion leaders who form our Medical and Scientific Advisory Board and use various clinical conferences, meetings, paid digital education/content and online forums to effectively reach this audience.

Respiri will be exhibiting and demonstrating wheezo at **The Annual Scientific Meeting of TSANZ**, 29 March - 2 April 2019. This is an excellent platform for the introduction of wheezo to the respiratory medicine community.

## Target Launch Markets

As previously discussed, the initial target launch markets for wheezo are the UK, Australia and Singapore. Respiri remains positive that the rationale for prioritising these markets is strong. In addition to these launch plans, the company is also encouraged by industry interest from additional overseas markets that in some cases, will include the assistance of local partners. China and India, in particular, are huge markets with the opportunity for Respiri to make a positive difference to asthma care in these regions, and create significant shareholder value. We look forward to updating the market with progress as our launch plans progress into additional territories.

## Path to Market Timeline



\*There could be an additional 1 month lag due to the number of submissions examined by Notified Body and Respiro's place in the queue  
 \*\*Shortly after Safety & Compliance testing commences, we look forward to investor/partner product demonstrations

## Conference Call Planned for Early March

Respiro has convened a 'wheezo Launch Committee' as activities ramp up. CEO, Mario Gattino, Professor Bruce Thompson, CXO, Wani Wall, Jefferson Harcourt (Grey Innovation) and Evan Davey (Two Bulls) very much look forward to providing a shareholder update and answering your questions in a conference call planned for early March. Details will be announced shortly.

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# RESPIRI



## About Respiri Limited

Respiri's mission is to help improve quality of life for millions of children and adults around the world and dramatically reduce hospital admissions and the economic burden of asthma. The Company offers sensors, mobile apps and analytics to support respiratory health management. Its world first technology detects wheeze, a typical symptom of asthma, COPD and respiratory disease to provide an objective measure of airway limitation. Respiri's innovative platform provides personalised feedback and education based on the user's data and enables the sharing of that data with caregivers and health care providers. Respiri Limited's operations are based in Melbourne, Australia.

## Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward looking statements are not historical facts but rather are based on Respiri's current expectations, estimates and projections about the industry in which Respiri operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Respiri, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Respiri cautions shareholders and prospective shareholders not to place undue reliance on these forward looking statements, which reflect the view of Respiri only as of the date of this release. The forward looking statements made in this announcement relate only to events as of the date on which the statements are made. Respiri will not undertake any obligation to release publicly any revisions or updates to these forward looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.