RESPIRI

ASX ANNOUNCEMENT

23 March 2021

Respiri Receives US FDA Clearance for wheezo™ and App

Key Points

- US Food and Drug Administration (FDA) clears wheezo and App for marketing and sale in the key US market
- The Regulatory approval is for OTC and indication agnostic broadening the selling channels available
- Significant milestone for Respiri, utilising second generation device and mobile App platform
- Initial focus on asthmatic patients, representing a large and growing market opportunity of 24.7 million patients

Respiri to undertake an investor webinar at 9.30am AEDT today, dial-in details provided below, to discuss the FDA clearance and next steps.

Respiri Limited (ASX:RSH)("Respiri" or the "Company"), an eHealth SaaS Company supporting respiratory health management, is pleased to announce the Company has received 510(k) clearance from the United States Food and Drug Administration (FDA) for wheezo, thereby permitting Respiri to market and sell wheezo in the United States as a class II medical device, along with the wheezo App.

The Company was able to secure a very broad Indication for Use (IFU) for wheezo, which is intended to detect and record abnormal breath sounds (continuous adventitious breath sounds/CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2 years and older). The initial target market, as in Australia and Europe, will be asthmatic patients in order to monitor wheeze severity and resolution, in collaboration with their treating doctor.

Mr Marjan Mikel, CEO and Managing Director of Respiri said "The regulatory clearance of wheezo and our App in the United States represents a highly significant and major milestone for the Company as we continue to expand our regulatory footprint for wheezo and enter substantial new markets. The FDA is one of the most stringent regulatory bodies in the world and this clearance further validates the efficacy and utility of our wheezo device and algorithm. To our knowledge the first time the FDA has cleared a device/mobile application for the detection, recording and changes of wheeze rates. This represents a step-change in technology for patients with respiratory wheeze seeking an effective, replicable and rapid device measurement and associated App that monitors this important measurement of lung function.

Asthma represents a significant disease burden in the United States with approximately 8% of the adult population and 7.5% of children under the age of 18 living with the disease, equating to 24.7 million asthmatic patients, which accounts for 9.8 million physician office visits and 1.6 million emergency department visits per annum.[1] The burden of uncontrolled asthma in the US is substantial, equating to US$300 billion in direct costs and $964 billion including indirect costs over a 20 year period with better adherence to evidence-informed asthma management strategies by care providers and patients offering the potential to substantially reduce costs and improve quality of life.[2]

As part of Respiri's planned entry into the US, the Company intends to focus initially on the 60% of children with persistent and severe asthma representing 3.3 million patients where the wheezo device and App provides significant analytical information on wheeze for patients and their caregivers, as part of their overall asthma management plan. The Company plans to launch into the US market in Q3 2022, with Cipla retaining a first right of refusal to distribute wheezo in the US under the Sales/Marketing, Distribution & Logistics Agreement signed in July 2020.

[1] https://www.cdc.gov/nchs/fastats/asthma.htm
[2] Yaghoubi M. et al. The Projected Economic and Health Burden of Uncontrolled Asthma in the United States. American Journal of Respiratory and Critical Care Medicine. 2019; 200: 1102-1112.

Unlike a number of major healthcare markets, over the past several years, the Centers for Medicare and Medicaid Services (CMS) in the US have expanded reimbursement codes available for remote patient monitoring (RPM) with devices allowing for prescribed payments relating to set up, supply and monitoring of devices. The establishment of these codes provides Respiri and/or its partners in the US market with an opportunity whereby clinicians and qualified medical professionals advising patients on the purchasing of the device and the associated Software as a Service (SaaS) monthly subscription fee are able to receive financial compensation for the time spent and the equipment used for patient care delivered remotely.

Mr Mikel said "It is important to note that our regulatory approval is OTC (over-the-counter) which means wheezo can be provided to patients with or without a prescription broadening our selling channel options to include reimbursed physician prescribed Remote Patient Monitoring (Current Procedural Terminology, CPT Codes) and also available without prescription in pharmacy and online. Further, although we remain heavily focused on asthma, we are pleased that the approval was indication agnostic where wheezo can be used in any respiratory condition where wheeze is a symptom."

The Company is in discussions with a number of potential commercial partners in the US that are familiar with the US Current Procedural Terminology (CPT) code market and who have established relationships with physicians and the various payor groups including Medicare/Medicaid and other private and public Health Maintenance Organisations (HMOs).

Investor Conference Call

Mr Marjan Mikel, CEO will host an investor webinar commencing at 9.30am Australian Eastern Daylight Time (AEDT) today followed by a question-and-answer session.

In order to pre-register for the webcast, please follow the link below.

https://us02web.zoom.us/webinar/register/WN_K5-5fFtYSz22NZP9INwE4A

After registering, you will receive a confirmation email containing information about joining the webinar as well as dial-in details for those that would prefer to join by phone.

For the Q&A session, investors are invited to send questions prior to the webinar to matt@nwrcommunications.com.au

Please note a replay of the webinar will be available at the above-mentioned Zoom link shortly following the conclusion of the live session.

- ENDS -

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This ASX announcement dated 23 March 2021 has been authorised for release by the Board of Directors of Respiri Limited.

About Respiri Limited

Respiri is an e-Health SaaS company supporting 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. wheezo, Respiri's innovative technology, comprises an eHealth app combined with a simple, easy to use, handheld device. wheezo is the first smart device to help improve asthma management by monitoring wheeze and documenting symptoms, signs, triggers, weather conditions and medication use. The asthma management platform also facilitates the sharing of data with caregivers, physicians, and other health care professionals.

Respiri's mission is to help improve quality of life for hundreds of millions of children and adults around the world and dramatically reduce hospital admissions and the economic burden of asthma. Respiri Limited's operations are based in Melbourne, Australia.

For additional information about Respiri and its products, please visit www.respiri.co

About wheezo

Developed in Australia, with the support of respiratory specialists and other healthcare professionals, the innovative wheezo device analyses breath sounds for wheeze, and the eHealth App assists patients with managing their asthma by tracking symptoms, triggers, medication use and geo-specific weather conditions. The platform has been designed to extend asthma management beyond the clinic and make it easy to share information with doctors and make appropriate adjustments to asthma action plans. Better active management may lead to better outcomes and improved quality of life for the asthma patient.

For further information about wheezo, follow the online link https://wheezo.com

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 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.