





A Respiratory eHealth SaaS Company extending patient care beyond the clinic.

# TRANSITION TO LAUNCH PHASE

- Strategy Change from Device
   Manufacturer to eHealth SaaS
- Clinical Validation close to publication with
   2 more trials in the planning
- Wheezo® Production
- CE Mark & TGA Approval granted
- Cost cuts
- New CEO & World Class Team
- Transformation in 2020









## **COMPANY OVERVIEW**



### **CAPITAL STRUCTURE (ASX:RSH)**

Market Cap. as of 16 March 2020	AU\$41M
Share Price as of 16 March 2020	AU\$0.074
Shares on Issue	556M
Performance shares	NIL
Incentive Options <sup>1</sup>	19M
Cash Balance as of 31 December 2019	AU\$1.015M

<sup>1.</sup> Issued to directors, staff and scientific advisory board subject to various vesting conditions. Note that 14m of the 19m on issue are subject to shareholder approval. A further 20m (which are not on issue) are the subject of a dispute with the previous managing director.

#### **BOARD OF DIRECTORS**

#### MR NICHOLAS SMEDLEY EXECUTIVE CHAIRMAN

Investment banker and M&A Advisor at UBS and KPMG. Global M&A transactions ranging from \$9BnN defence of WMC Resources through to the investment of \$65M into Catch.com.au

#### MR MARJAN MIKEL CHIEF EXECUTIVE OFFICER

Non-Executive Director & Nomination & Remuneration Committee Chair of Memphasys Ltd. Commercial advisor to Portt, Research Fellow at University of NSW, formerly CEO & Founder of Healthy Sleep Solutions.

#### Dr THOMAS DUTHY NON-EXECUTIVE DIRECTOR

Former Global Head of Investor Relations and Corporate Development at Sirtex Medical Limited (ASX:SRX). Prior to Sirtex was a leading sector analyst for 10 years specialising in Healthcare and Biotechnology companies.

#### SUBSTANTIAL SHAREHOLDERS

Investments Holdings Pty Ltd: 13%
Netwealth Custodians: 5%
Mr Peter Braun: 2%

## **ASTHMA IN AUSTRALIA**

- In 2017-18, 2.7 million Australians (11.2%) had asthma.<sup>1</sup>
- Over 400 Australians die due to asthma each year (most recently, 441 deaths due to asthma in 2017). <sup>2</sup>
- Excess SABA use is a reliable predictor of asthma exacerbations<sup>3</sup> and deaths.<sup>4</sup>
- 45.3% have poorly controlled asthma.<sup>5</sup>
- 10% of people with asthma attended hospital or ED one or more times in the previous year.<sup>5</sup>
- 51% saw their GP for a non-urgent asthma review in the previous year.<sup>5</sup>
- 20% had discussed their asthma with a pharmacist in the previous year.<sup>5</sup>
- 11% visited a specialist about their asthma in the previous year.<sup>5</sup>
  - https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4364.0.55.001~2017-18~Main%20Features~Asthma~35
  - https://www.aihw.gov.au/reports/chronic-respiratory-conditions/asthma/contents/deaths
  - Stanford RH et al Short-acting β-agonist use and its ability to predict future asthma-related outcomes. Ann Allergy Asthma Immunol 109 2012; 109:403-407.
  - Suissa S et al A cohort Analysis of Excess Mortality in Asthma and the Use of Inhaled β-Agonists. Am J Respir Crit Care Med 1994; 149:604–610.
  - 5. Reddel HR et al Asthma control in Australia: a cross-sectional web-based survey in a nationally representative population. MJA 2015; 202(9):492-497



Extending asthma care beyond the clinic





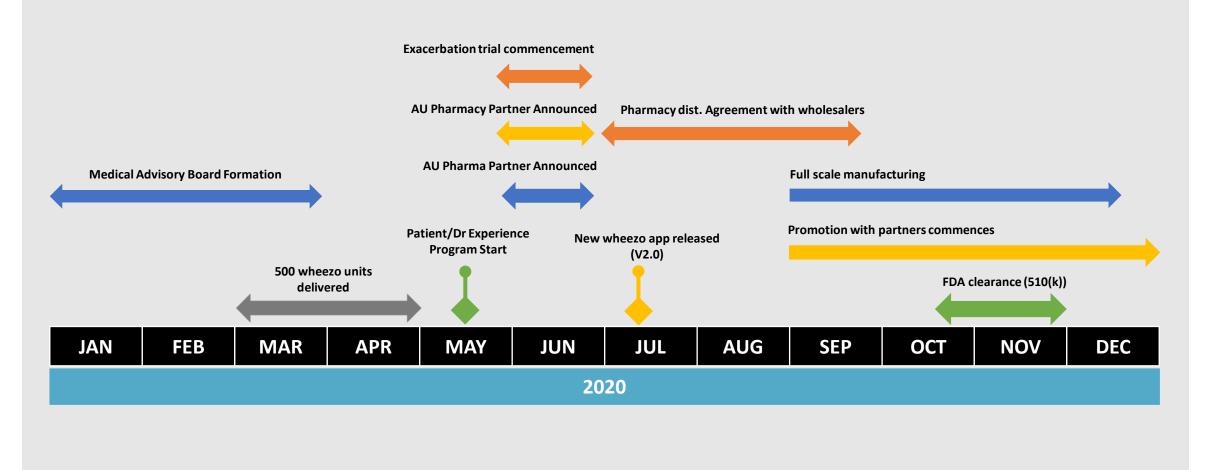
## **ASTHMA IS SUB-OPTIMALLY MANAGED**

## Personal ongoing monitoring asthma control could help.

- There are more than 340M people with asthma in the world and this number is growing.
- In an Australian study involving 4,274 patients, **70% of asthmatics** who believe they are managing their condition, are not and putting themselves in danger of serious health events.
- Accurately measuring effective asthma control in children and the elderly remains very difficult in a community setting.
- Currently there are **no easy solutions** that allow patients, parents, carers and physicians to monitor asthma on an ongoing basis in the community setting.
- Economic cost of poorly managed asthma, Deloitte Access Economics estimate this economic burden to be > AUD24.7B in Australia alone and about USD400B+ in the USA

## INDICATIVE TIMELINE OF MILESTONES

in calendar 2020

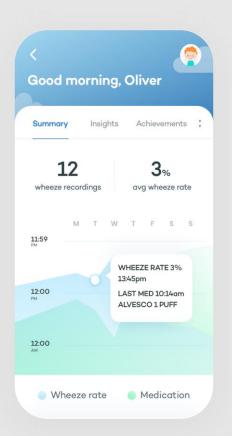


## **eHEALTH SaaS STRATEGY**



## Building an ongoing annuity stream from App subscription

- World Class Respiri team, experienced Chief Clinical Officer leading algorithm development and clinical content, CTO with Silicon Valley pedigree leading app build & data management infrastructure & Respiri competency development & structure to support SaaS strategy.
- Accelerating application 2.0 that will become an asthma/COPD asthma management system incorporating:
  - Ambulatory monitoring of patient's asthma using wheeze
  - Environmental factors such as pollen count, weather factors etc.
  - Events diary
  - Medication usage.
- Clouded data to be used as a predictive tool allowing patients, carers and doctors to monitor disease management
- A Respiri customer for life!
- Longitudinal outcomes data. Useful with payers (and others) demonstrating effective control & outcomes





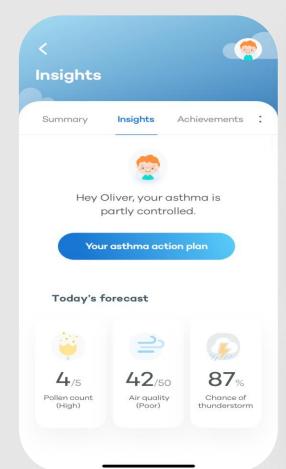


## **eHEALTH SaaS STRATEGY**

Asthma is poorly managed by patients particularly children and

the aged

- 70% of "treated" asthma sufferers are not aware of their condition (controlled vs uncontrolled). Improving patients' education around their respiratory health, symptoms & triggers is critical.
- Having the correct diagnosis, regular preventers, correct medication and asthma management plan are the keys to managing one's respiratory health.
- Carer/parent remote access improves health outcomes
- Empower asthma sufferers that it's ok to have asthma & there's a sense of fun in doing these (filling in questionnaires, logging their breathing, symptoms & triggers, medication use, setting reminders)
- Demonstrate the benefits of controlled asthma (better control over time, they feel better over time, show correlation of their input visually over time)







## **eHEALTH SaaS STRATEGY**

## Australian focus will optimise resources, cash and tune launch strategy

- 1,000 Respiratory Physicians who see about 70 patients per week
- Patients are difficult to treat asthmatics
- Respiri's goal is to secure 3 patients/week/physician (<0.5% of patient consultations) = 150,000 patients annualised
- Total targeted revenues:
  - App subscription fees of \$16,000,000pa
  - Device revenues of \$15,000,000pa
  - Total revenues of \$31,000,000pa

## PATHWAY TO COMMERCIALISATION

## Accelerating & optimizing launch through partnerships

- Newly appointed General Manager of Commercial Operations. Extensive experience in health, successful launches, building teams
- Sole 2020 Commercialisation focus is the Australian market. Launch Q4 2020
- Well advanced MoU discussions regarding a potential partnership with the local subsidiary of a multinational pharmaceutical company
   to act as Respiri's marketing/distribution partner in the pharmacy channel.
- Advanced discussions with the local subsidiary of another multinational pharmaceutical company that will potentially partner with Respiri in helping position its eHealth SaaS platform and device as an accepted part of asthma management to Respiratory Physicians.
- Launch focus on Respiratory physicians who treat target patients (refractory moderate to severe asthmatics referred by GPs)
- Channel strategy to involve
  - Pharmaceutical wholesalers (Sigma etc.) delivering to pharmacies. Benefit single account established distribution.
  - Pharmacy partnership to identify asthma patients at the dispensary that may require wheezo to manage condition
  - Respiri's own e-Commerce platform offering Point of Sale Finance (POSF) options to patients
- In discussions with Asthma Australia to partner & go directly to patients through their established channels
- Pricing SaaS \$8 per month with device RRP \$299



## **CLINICAL VALIDATION**

## Building credibility with the medical community

- Professor Bruce Thompson joined by leaders in respiratory medicine, Professors Frank Thien, Sarath
   Ranganathan & Greg King on Australian Medical & Scientific Advisory Board
- Study 1 Eastern Health (Stethoscope Comparison) near completion with abstract submitted to American Thoracic Society
- Study 2 (Correlation of wheeze rate with other clinical measures) in recruitment
- Meeting with leading respiratory experts in UK confirms demand for wheezo® for use in research and push for 'wheezometry' to be included as standard care in NICE guidelines for NHS adoption
- Study 3 Multi-site AUS-UK-US (Longitudinal health outcomes) in planning

## WHEEZO® PRODUCTION

## **Building Supply Capacity**

- wheezo® breath sensor manufacturing package complete
- Supply chain management forecasting, planning,
   procurement, strategic sourcing in progress
- First batch of 500 scheduled for production by SRX
   Dandenong March/April 2020
- Transfer of production to SRX Malaysia for lower labour costs and greater capacity



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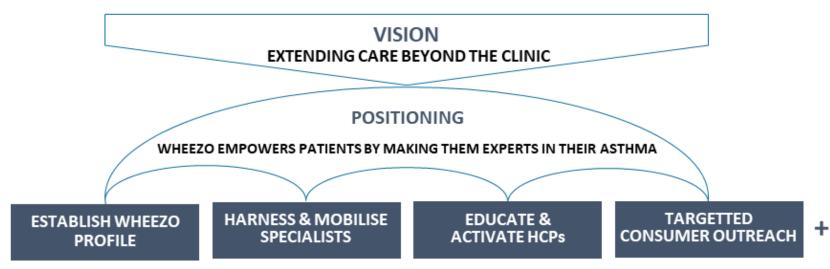
their asthma

Our Q4 2020 launch will empower patients by making them experts in





## VISION, POSITIONING & PLANNING



Pre-Marketing: Establish Unmet Need, Evidence & Narrative for wheezo

Marketing: Harness evidence-based narrative to drive HCP recommendation

#### KEY ACTIONS

STRATEGIC

**IMPERATIVES** 

#### CLINICAL

- Ad Board of top KOLs.
- Research program to establish evidence.
- Publications to communicate evidence.
- Posters & presentations at clinical meetings to cascade narrative to practicing KOLs.

#### COMMERCIAL

- Ad Board of practicing specialists & partners.
- Real World Study.
- Referral pathways & financial dynamics for HCPs (e.g. GPs, Pharmacists, other).
- Editorial & PR content to cascade to HCPs.
- Advocacy.

#### MEDICAL

- Trade publication editorial.
- · Content marketing.
- PR & Advertising
- · Offline / online.
- Sampling & trial.
- Virtual & remote sales representatives.

#### CONSUMER

- Sharply targeted Pt outreach.
- Digital & social Word of mouth.
- Patient association support (NAC & AA).
- Elevate & celebrate successful case studies.

#### **ESTABLISH PROCESSES**

#### INTERNAL

- · Reg. requirements.
- Technical limitations & literacy.
- · Pharma partnership.
- S&M model [clinician & pharmacy.
- Reimbursement opportunities (e.g. CDMP)
- HCP segmentation & adoption model.
- Est. & confirm supply chain.
- · Resourcing & KPIs



## PROPOSED USE OF FUNDS

Wheezo Product Development	\$0.4 million
Clinical Development	\$0.3 million
Manufacturing	\$0.5 million
Sales & marketing	\$0.5 million
Regulatory, general, admin	\$0.2 million
Costs of the offer	\$0.1 million
TOTAL	\$2.0 million

### **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.

#### **Respiri Limited (The Company) Risk Factors**

This report identifies some of the major risks associated with an investment in the Company. The risk factors below ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company.

#### Speculative nature of investment

An investment in Shares of the Company should be considered very speculative. No assurance as to future profitability or dividends can be given as they are dependent on successful product development, future earnings and the working capital requirements of the Company. The Board does not envisage in the immediate future that the Company will generate sufficient revenue to be profitable or be in a position to declare any dividends. The financial prospects of the Company are dependent on a number of factors, including successfully completing further product development, gaining regulatory approvals, the degree of market acceptance or take-up of its products and the amount of competition encountered from competitive or alternative products developed by third parties. There is no guarantee that the Company's development work will result in commercial sales or that the Company will achieve material market penetration.

Competition: The medical device and digital health industries are highly competitive and include companies with significantly greater financial, technical, human, research and development, and marketing resources than the Company. There are companies that compete with the Company's efforts to develop, and commercialise its products.

Reliance on Key Personnel & Service Providers: The Company currently employs a small number of key personnel, and the Company's future depends on retaining and attracting suitably qualified personnel. There is no guarantee that the Company will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the business, operating results and financial prospects. The Company operates a significant amount of its key activities through a series of contractual relationships with independent contractors and suppliers. All of the Company's contracts carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations. Such failure can lead to termination and/or significant damage to the Company's product development efforts.

Sufficiency of Funding: The Company has limited financial resources and will need to raise additional funds from time to time to finance the complete development and commercialisation of its products. The Company's ability to raise additional funds will be subject to, among other things, factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally. The Directors can give no assurance that future funds can be raised by the Company on favourable terms. if at all.

**Technological Development:** Medical device research and product development involve scientific, software and engineering uncertainty and long lead times. There is no certainty as to whether any particular event or project will occur within a set period or by a certain date.

Regulatory Risk: Medical device products are regulated by government agencies and must be approved prior to commercial sales. Complex government health regulations increase uncertainty and are subject to change at any time. As such the risk exists that the Company's new products may not satisfy the stringent requirements for approval and/or the approval process may take longer than expected. This may adversely affect the Company's competitive position and the financial value of the medical devices to the Company.

Product Liability & Manufacturing Risks: As with all new products, even after the granting of regulatory approval, there is no assurance that unforeseen adverse events or manufacturing defects will not arise. Adverse events could expose the Company to product liability claims or litigation, resulting in the removal of the regulatory approval for the relevant products and/or monetary damages being awarded against the Company. In such event, the Company's liability may exceed the Company's insurance coverage. If any products do not meet suitability or quality assurance standards, this may result in increased costs and may delay sales.

Trade Secrets & Patents: The Company relies on its trade secrets and patent rights. It cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology, or that the Company will be able to meaningfully protect its trade secrets and unpatented know-how and keep them secret. The Company's existing intellectual property rights include its copyright in source code used in its digital health technologies, its know-how in the development of digital health products and data arising from the use of its digital health products. There is no guarantee that the Company's intellectual property comprises all of the rights that the Company may require to freely commercialise its product candidates.

The granting of a patent in one country does not mean the patent application will be granted in other countries and competitors may at any time challenge granted patents and a court may find that the granted patent is invalid or unenforceable or revoked.

#### Stock Market Volatility & Currency Risk

The performance of the share market may affect the Company and the price at which its shares trade on a share market. The share market has in the past and may in the future be affected by a number of matters. Revenue and expenditures will be received in overseas jurisdictions and will be subject to the risk of fluctuations in foreign exchange.