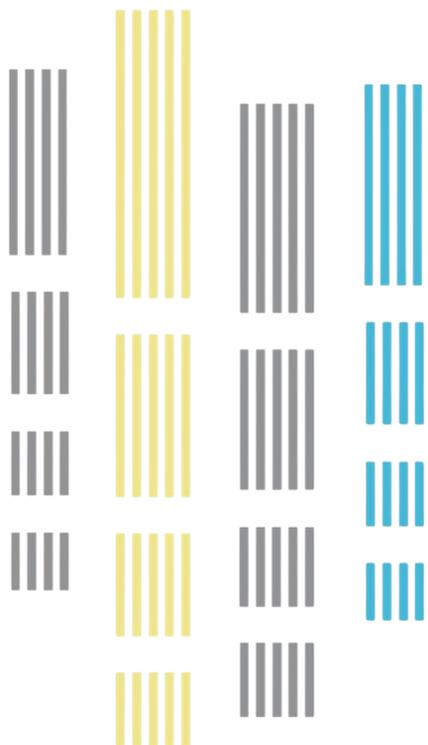
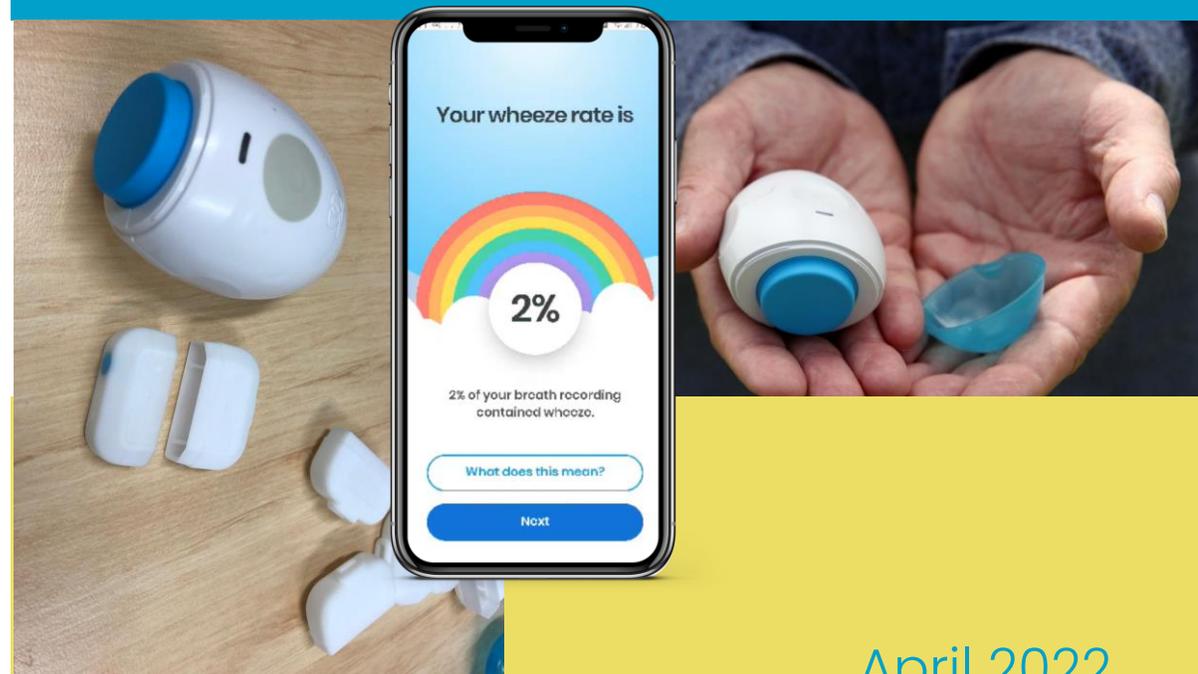


# RESPIRI



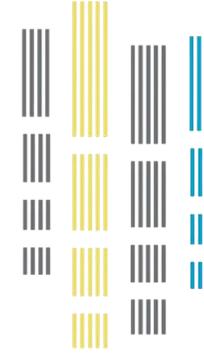
## RESPIRI (ASX:RSH) e-Health SaaS Company

Investor update on US expansion



April 2022  
Marjan Mikel, CEO & Managing Director

# 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 Respiro's current expectations, estimates and projections about the industry in which Respiro 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 Respiro, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. Respiro cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Respiro 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. Respiro 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.

## OUR MISSION

To improve asthma management by extending care beyond the clinic



## OUR VISION

A world without the challenges of asthma

## CAPITAL STRUCTURE

Market Capitalisation – 26 Apr 2022	A\$36.9M
Closing Share Price – 26 Apr 2022	A\$0.051
Shares on Issue	723M
Management Performance Options*	174.5M
Cash Balance – 31 Dec 2021	\$5.1M
Wheezo stock on hand – 31 Dec 2021	22k units (A\$1.4M)
Projected Cash Burn – Q2 & Q3 FY22	A\$550k / month

\* Average strike price \$0.187

## MAJOR SHAREHOLDERS (APRIL 2022)

Investment Holdings Pty Ltd	9.2%
Netwealth Investments Limited	4.0%
Richards Family	3.3%
Directors	2.4%
Peter Braun	2.2%
<b>Top 20 Shareholders</b>	<b>31.33</b>



## OPERATIONAL SNAPSHOT

Proven wheeze detection IP	wheezo®
Regulatory approvals	FDA / CE / TGA
Indication	Wheeze detection
Addressable Market – USA	~US\$40B; CAGR 30%+
Business model	RPM* provider partners
Market drivers (USA)	Reimbursements
US Revenue – YTD22	US\$179.3k (A\$250k)

\* Remote Patient Monitoring

## BOARD OF DIRECTORS & ADVISORS

Nicholas Smedley	Executive Chairman
Marjan Mikel	CEO & Managing Director
Dr Andrew Weekes	Medical Advisor
Dr Mark Levy	UK Medical Advisor
EAS Advisors, LLC	Corporate Advisors

Respiratory disorders are a significant burden to healthcare systems globally, however, payors in the United States understand the importance of RPM services and pay for it.



**1 in 13<sup>1</sup>**  
living with asthma

**1 in 20<sup>2</sup>**  
living with COPD

**1.6 million<sup>3</sup>**  
ED visits with asthma

**873k<sup>2</sup>**  
ED visits with COPD

## CURRENT RPM SOLUTIONS

1. Asthma control tests which are subjective, relying on unreliable patient self-assessments
2. Digital spirometry devices which are difficult for patients to use in supervised environments & extremely difficult remotely.

**\$8,238<sup>4</sup>**  
cost per in-patient  
medical event

**\$27,597<sup>4</sup>**  
cost per in-patient  
medical event

The USA respiratory health market is forecast to grow by more than 30% p.a. to US\$85 billion by 2026. wheezo actively addresses this market and has now won its first hospital customer. This is expected to lead to further take-up and represents a significant opportunity for RSH.



## Attractive market dynamics

- ✓ Circa 25 million (8%) of Americans have asthma
- ✓ Market forecast to grow at 30%+ p.a. to US\$85B by 2026
- ✓ Remote Patient Monitoring (RPM) is reimbursed in the US
- ✓ RPM services can be outsourced to third parties
- ✓ US payors (e.g. health funds and insurers) understand & fund preventative medicine



## Proven & unique product attributes

- ✓ Wheeze is indicative of significantly reduced lung function
- ✓ RSH's wheezo product provides proven detection & monitoring of wheeze
- ✓ The presence of wheeze has been shown to be associated with a significant reduction in forced exhaling volume
- ✓ wheezo has been well received by US pulmonologists



## Robust business model

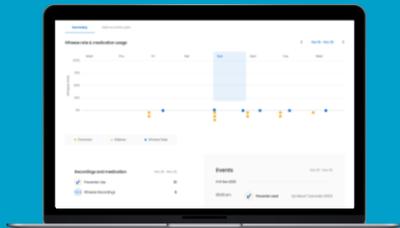
- ✓ Bespoke model through world class RPM provider partners
- ✓ Revenue is generated through device sales and ongoing patient SaaS
- ✓ First hospital customer secured (**Michigan Children's Hospital**)
- ✓ 120+ qualified leads hospitals, Payors & Doctors
- ✓ Minimal competition

wheezo® is an e-Health SaaS platform that uses a device and app to detect and record wheeze remotely as effectively as experienced respiratory specialists. Revenue is generated through devices sales and ongoing patient SaaS.



## Easy to use

Normal tidal breathing makes wheezo easy to use in an RPM environment by the patient.



## Wheeze detection

The device easily records breath sounds over 30 seconds to be analysed in the app for the presence of wheeze

## Algorithm: 5% wheeze rate

Equates to clinically significant wheeze. For wheeze to manifest lung function must be significantly compromised

## Continuous monitoring

App allows users to also log symptoms, triggers, medication and local environmental factors

## Patient portal

Data collected is used to build a personalised asthma profile and displays graphic analytics

## Data sharing

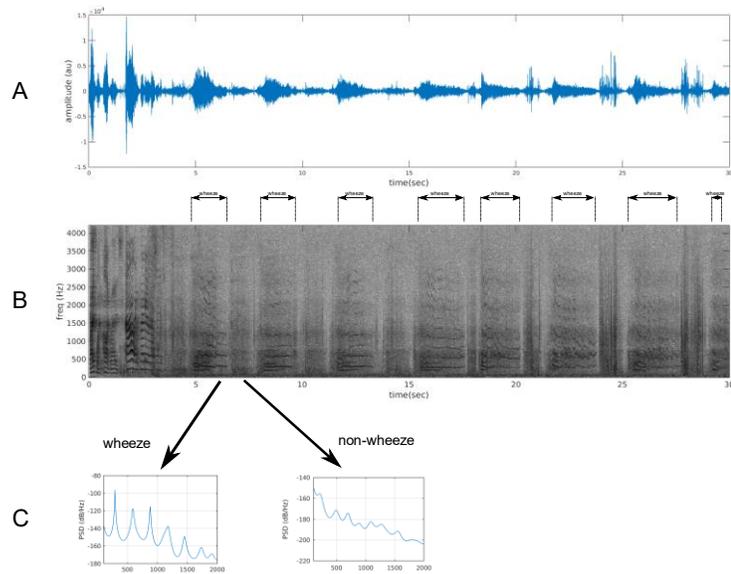
Patients can easily share their data with healthcare professionals on demand allowing RPM reimbursement



# wheezo<sup>®</sup> – HOW IT WORKS

wheezo<sup>®</sup> detects and records wheeze remotely, as well as a respiratory specialist

wheezo<sup>®</sup> algorithm analyses the breath recording spectrogram to detect wheeze



**Figure A** shows the amplitude of the recording and eight breath cycles can be seen as the waxing and waning of the sound amplitude.

**Figure B** shows the spectrogram of the recording. This recording contains significant wheeze shown by the equally spaced lines. By listening to the recording and viewing the spectrogram, portions containing wheeze were identified.

**Figure C** shows power spectrum estimates of very short segments of the sound recording, showing the difference between wheeze and non wheeze.

Algorithm detects wheeze as well as experienced respiratory specialists<sup>1</sup>

Comparison of the wheeze rate algorithm with expert analysis

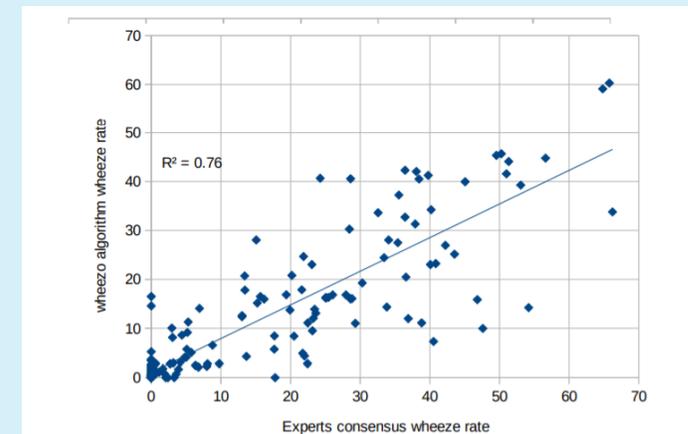


Figure 4: Algorithm vs Experts wheeze rate. The x-axis is the wheeze rate calculated using the experts consensus and the y-axis is the wheeze rate calculated by the Wheezo algorithm.

Accuracy

91%

Specificity

93%

Sensitivity

87%

Cohen's Kappa Coefficient

0.81



**References:** 1. Data on File. 2. Data on File. 3. Eising JB, Uiterwaal CS, van der Ent CK. Nocturnal wheeze measurement in preschool children. *Pediatr Pulmonol.* 2014 Mar;49(3):257-62. 4. Lea Bentur, Raphael Beck, Charles S. Irving, and Simon Godfrey, Nocturnal Wheeze Measurement in Young Asthmatics *Pediatric Asthma, Allergy & Immunology* 2004 17:3, 191-197. 5. Boner AL, Piacentini GL, Peroni DG, Irving CS, Goldstein D, Gavriely N, Godfrey S. Children with nocturnal asthma wheeze intermittently during sleep. *J Asthma.* 2010 Apr;47(3):290-4.

RSH's algorithm has been extensively studied for 20+ years in USA, Europe, the United Kingdom and Israel, with further leading peer studies being undertaken through 2022.

## Previous clinical research studies have demonstrated that:

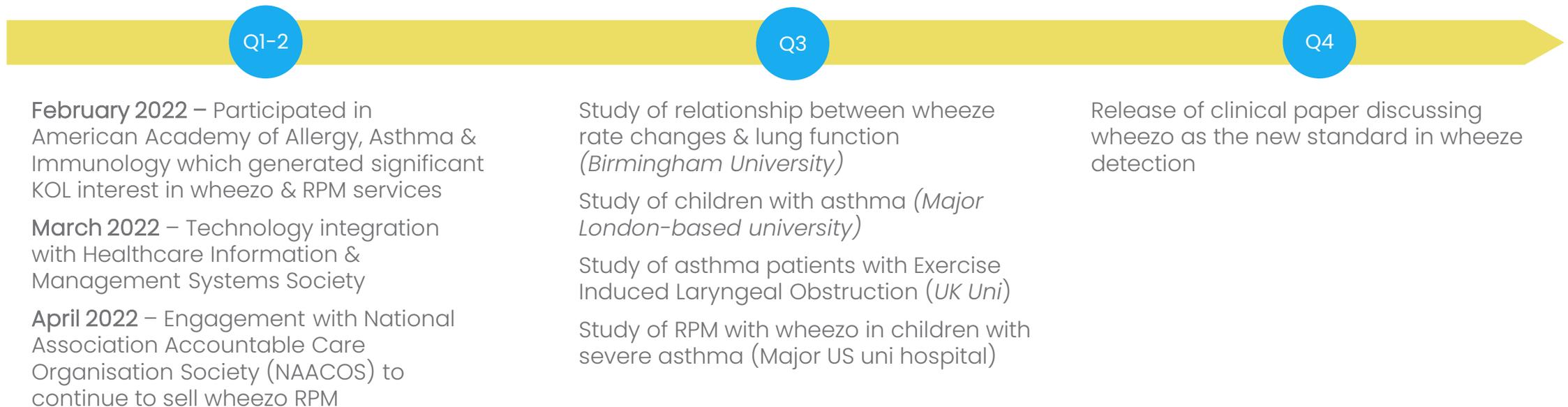
RSH's algorithm is as good as a specialist with a stethoscope

A wheeze-rate of >5% indicates clinically significant wheeze

Lung function must be significantly reduced for wheeze to manifest (20% to 30%)

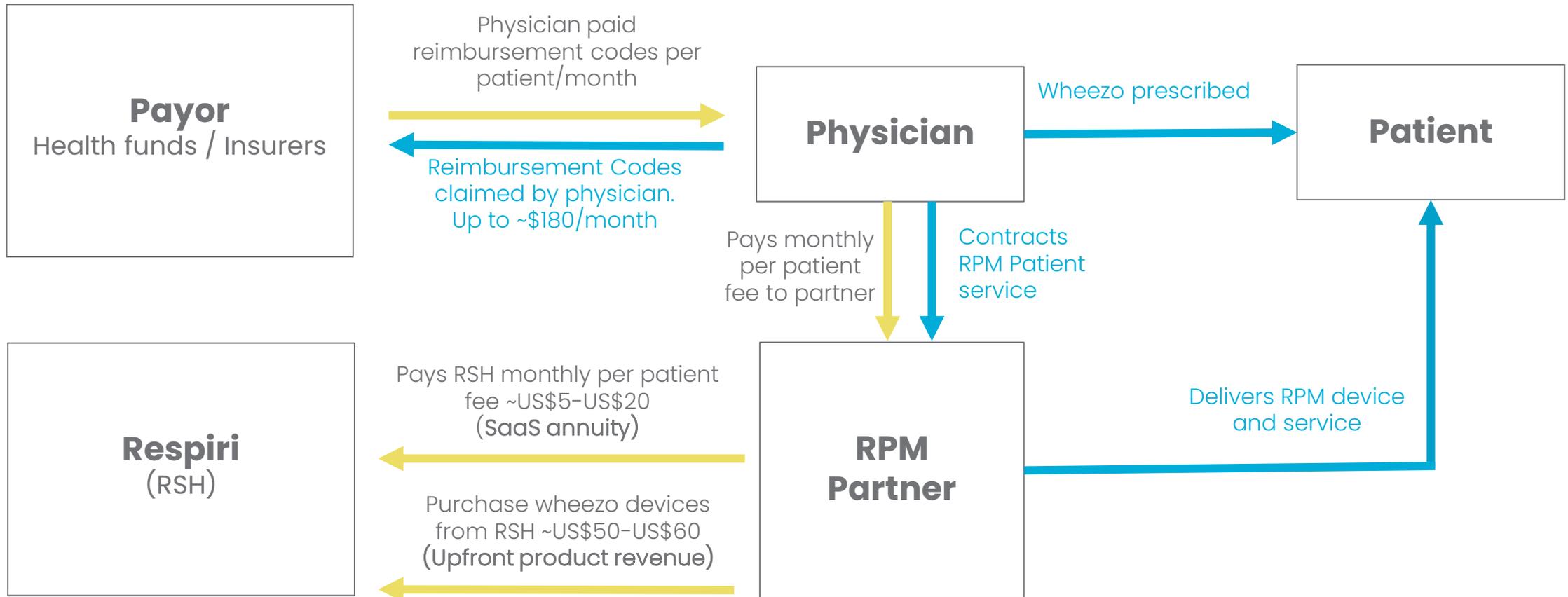
Compromised lung function is a lead indicator for exacerbations, attacks and hospitalisations

## Key Opinion Leader (KOL) Engagement & Planned Studies (2022)



# USA – ACTIVE REIMBURSEMENT MARKET

A strong focus on funding preventive measures exists in the US market. RPM partners purchase wheezo devices from RSH and also pay RSH monthly SaaS fees. RPM partners are remunerated through monthly patient fees from physicians who in turn are reimbursed by health funds / insurers



# USA – REIMBURSEMENT OPPORTUNITY

A US patient generates up to 5X the annual revenue of an Australian patient, with little or no out of pocket expense for the user

**1** Provider sets patient up on a remote monitoring platform/system



Provider bills **once**

**2** Physiological data is captured/recorded over at least 16 days



Provider bills **monthly**

**3** Data sent in real time & clinical staff review RPM data & interact with the patient



Provider bills **monthly**

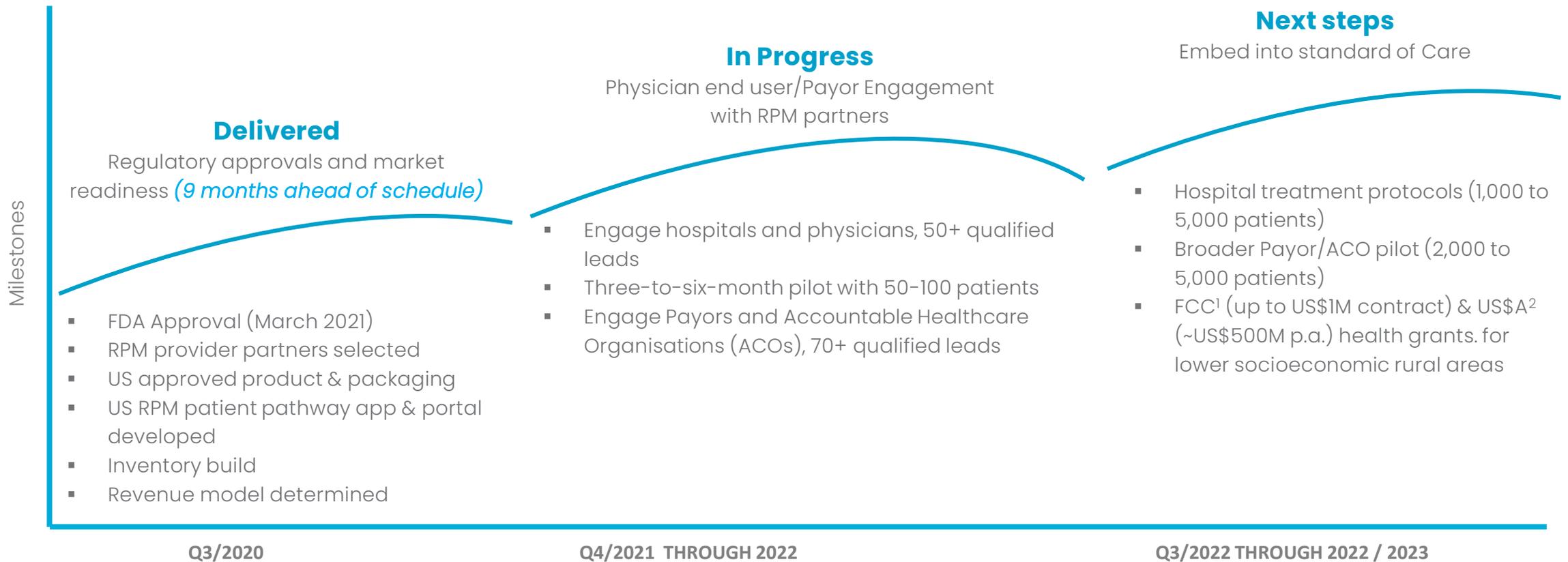
- ✓ Physician’s billable RPM amount per patient per year **US\$1,270+**
- ✓ Physician’s additional billable CCM amount per patient per year **US\$744-US\$1,300+**
- ✓ **Private payors reimburse 10%-20% more than the CMS rate**

## CURRENT PAYMENT RATES

RPM CPT code	Descriptor	Value \$US\$
99453	Patient set up (once per episode of care)	\$19.04
99454	Device delivery/supply (every 30 days, min.16 days of data collection)	\$55.72
99457	Patient monitoring & interactive communication. First 20 mins (every 30 days)	\$50.18
99458	Patient monitoring & communication. Each additional 20 mins (every 30 days)	\$40.84
99091	Collection & Review of Physiological Data (every 30 days)	\$56.88

CCM CPT code	Descriptor (clinical staff)	Value \$US\$
99490	20 minutes	\$62
99490 + 99439	40 minutes	\$109
99490 + 99439 (x2)	60 minutes	\$156
G0511	20 minutes (rural)	\$76

RSH’s US regulatory approvals and market readiness were delivered nine months ahead of schedule. The business is now engaging with key stakeholders with a pathway to being embedded into the US standard of care during 2022



Respiri has seen strong growth in the initial stages of its US expansion with its long-term success to be shaped by partnership and US reimbursement model

## Strong growth in the early stages of US expansion

- ✓ 1st hospital customer secured
- ✓ 120+ qualified leads, including major payors & ACOs
- ✓ Positive KOL wheezo AAAAI feedback
- ✓ 3 interested clinical study partners
- ✓ Good synergy with RPM partners

## Continued penetration and long-term success in the US market will be shaped by the following factors

Partnerships with providers who have established relationships and experience, current partners include:



Access Telehealth, RAMP like model, 1st hospital customer



mTelehealth broad network, FCC<sup>1</sup> and US\$A<sup>2</sup> healthcare grants for lower socioeconomic rural areas expertise

Continued focus on RPM reimbursement model which wheezo qualifies for

The Centres for Medicare & Medicaid Services (CMS) reimburse RPM across the US  
RPM reimbursements are mandated in 28 states, with most providers covering RPM in non-mandated states  
Physicians can outsource RPM patient management to third parties (including RSH's partners)  
No other RPM solutions in respiratory medicine

The Australian market headwinds are mitigated in the US through physician leadership and a robust reimbursement regime

## RAMP Program

Physician led Remote Asthma Monitoring Program (RAMP) has been successful in improving patient engagement and satisfaction in Australia

## Pharmacy uptake

Current uptake in Australian pharmacies and patients has been disappointing

Cipla still engaged as the Respiri partner to target a smaller group of Australian pharmacies

## TGA engagement

Respiri has voluntarily decided to update its advertising materials to remove references to “asthma” on the basis that it does not hold the relevant authorisations from the TGA use the term “asthma” in its advertising materials.

## Differences in the reimbursement model have significantly impacted Australian market penetration

**Previously earmarked Australian investment capital has now been redeployed to partially fund the US expansion.**

The US expansion will be enhanced through lessons learned in Australia, including:

- ✓ Success of the RAMP model
- ✓ Need for a physician-led patient introduction to wheezo
- ✓ Focus on reimbursements to fund purchases

Respiri's has sufficient inventory to meet its medium-term growth expectations with steps taken to mitigate the impact of global semi-conductor shortages and improve long-term margins

## **Inventory holdings**

Business has sufficient inventory to meet increasing US demand in the medium term with Australian inventory being redirected

## **Continuous improvement**

Wheezo 4.0 will meet COGS objectives of <AUD50 or US\$35/device

## **Semi-conductor shortages**

Semi-conductor shortages impacting all sectors have been mitigated by securing an alternative superior chip and componentry has been purchased and is in inventory ready for future manufacturing batch runs

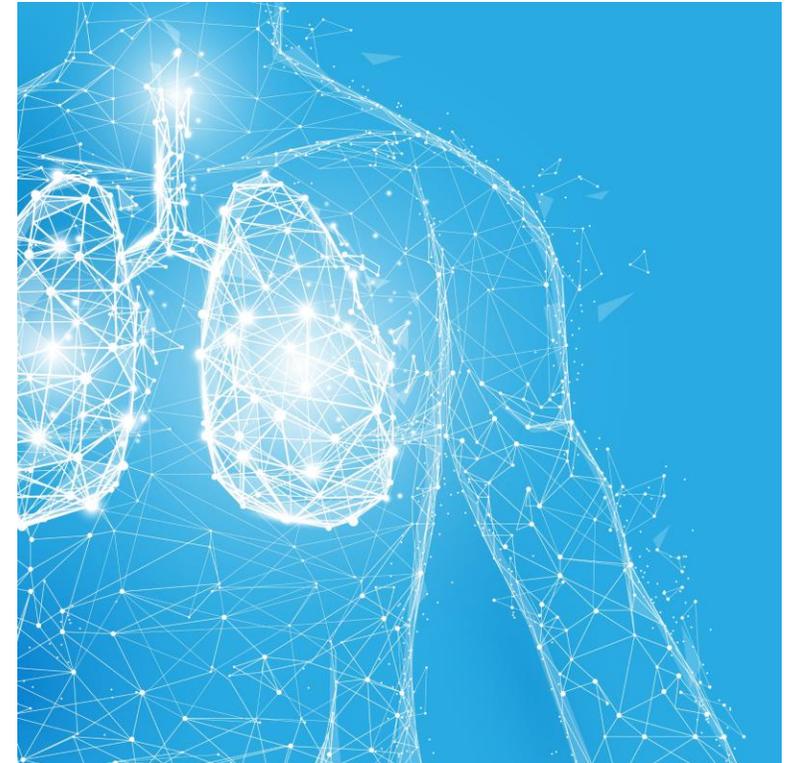
Respiri's US expansion represents the company's most significant opportunity and remains ahead of schedule. With recent wins and an encouraging sales pipeline of SaaS based deals, RSH is well placed to grow in the large, physician-led and reimbursement focused US market

Across the United States, asthma creates a US\$81.9 billion financial burden on the health system.

RSH has partnered with aligned, best-in-class RPM providers who are excited by wheezo, the RPM opportunity and annuity remuneration.

Key milestones:

- ✓ **Signed its first US patient reimbursement deal with Michigan Children's Hospital**
- ✓ **Over 120 active partner leads**
- ✓ **Received FDA approval (Class II, (510k, k202062) for wheezo®**
- ✓ Wheezo very well received by payors and physicians
- ✓ Breath sounds/Wheeze considered an important physiological parameter in guidelines and by treating physicians



Respiri is seeking to raise A\$1.5 million in equity capital which will be used to pursue the company's commercialisation and roll-out strategy in the USA, taking advantage of the strong interest in wheezo

## Equity capital raising overview

<b>Offer Size &amp; Type</b>	<ul style="list-style-type: none"> <li>Seeking to raise A\$1.5 million through the issuance of ordinary shares, ranking pari passu with existing RSH shares on issue</li> <li>Discretion for RSH Board to accept oversubscriptions</li> <li>Offer to be made by way of placement to sophisticated investors under Listing Rule 7.1</li> </ul>
<b>Pricing</b>	<ul style="list-style-type: none"> <li>Fixed issue price of A\$0.045 per share:                             <ul style="list-style-type: none"> <li>11.8% discount to last RSH price*</li> <li>23.6% discount to RSH's 5-day VWAP*</li> <li>26.0% discount to RSH's 15-day VWAP*</li> </ul> </li> </ul>
<b>Use of Proceeds</b>	<ul style="list-style-type: none"> <li>Funds raised will be used to accelerate Respiri's commercialisation and roll-out strategy in the USA</li> </ul>

\* calculated as at close of trade on the day prior to the trading halt (26 Apr)

## Equity capital raising indicative timetable\*

<b>Trading halt &amp; Placement launch</b>	27 April 2022
<b>Announce completion of Placement</b>	29 April 2022
<b>Trading Halt lifted</b>	29 April 2022
<b>Settlement of new shares issued under Placement</b>	4 May 2022
<b>Allotment and normal trading of new shares issued under Placement</b>	5 May 2022

\* Indicative only and may be subject to change

# RESPIRI



THANK YOU



MARJAN MIKEL, CEO  
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This presentation 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 or existing products may not satisfy the stringent requirements for approval, the approval process may take longer than expected or previous approvals may be altered or revoked. 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:** 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.

**Customer contracts:** The Company's ability to distribute and ultimately sell its products is subject to a small number of commercial agreements. There is a risk that these contracts could be breached, not complied with according to their terms, terminated or substantially modified in a way which adversely affects the ability for the Company to sell its products or creates a significant liability for the Company.