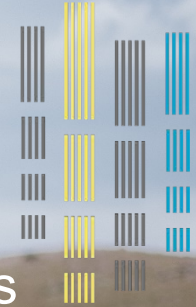




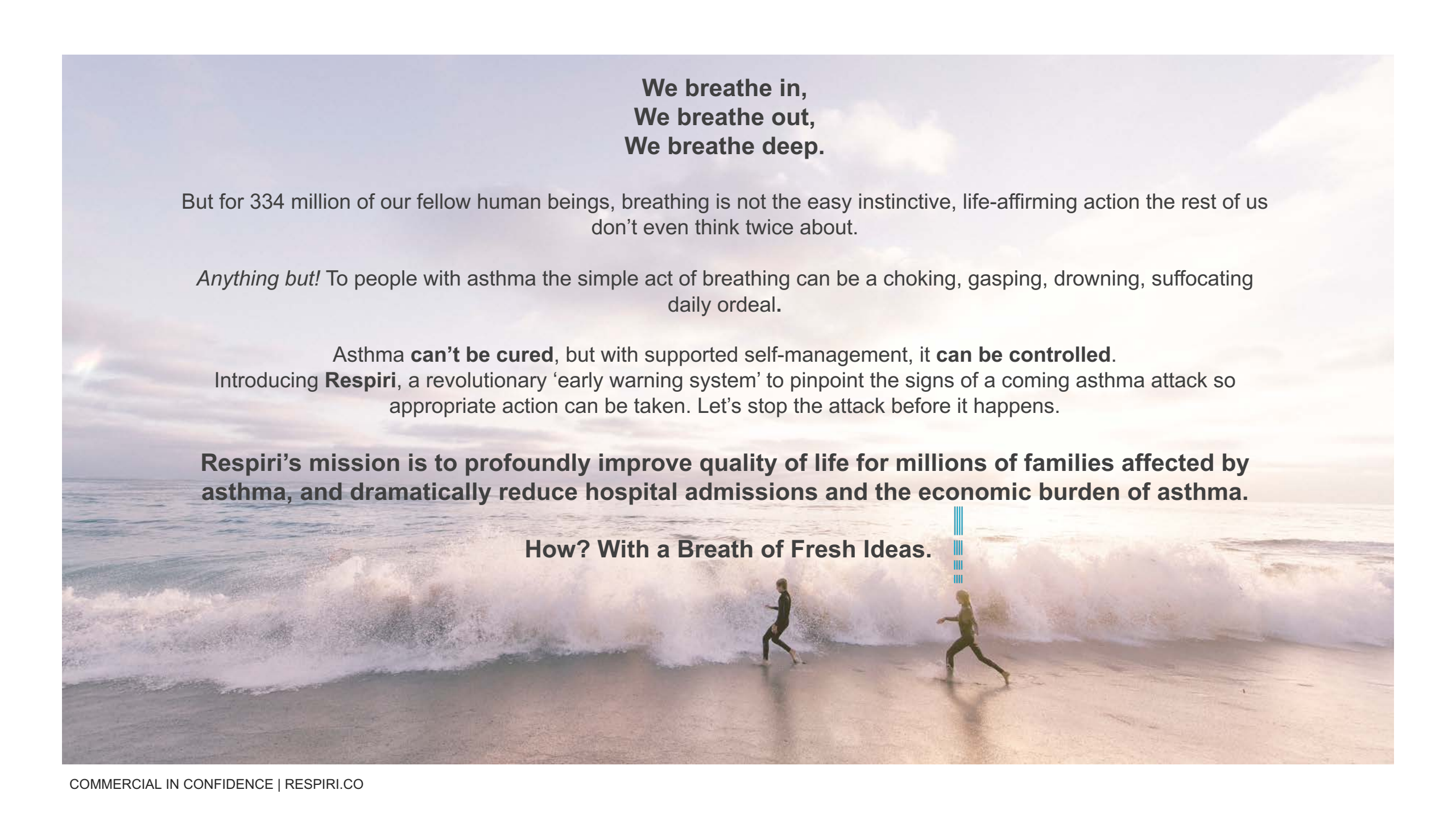
RESPIRI

A Breath of Fresh Ideas



**CEO'S '100 DAY'**  
UPDATE | SEPTEMBER 2018





**We breathe in,  
We breathe out,  
We breathe deep.**

But for 334 million of our fellow human beings, breathing is not the easy instinctive, life-affirming action the rest of us don't even think twice about.

*Anything but!* To people with asthma the simple act of breathing can be a choking, gasping, drowning, suffocating daily ordeal.

Asthma **can't be cured**, but with supported self-management, it **can be controlled**.  
Introducing **Respiri**, a revolutionary 'early warning system' to pinpoint the signs of a coming asthma attack so appropriate action can be taken. Let's stop the attack before it happens.

**Respiri's mission is to profoundly improve quality of life for millions of families affected by asthma, and dramatically reduce hospital admissions and the economic burden of asthma.**

**How? With a Breath of Fresh Ideas.**



# NOT YOUR TYPICAL STARTUP



Hybrid of early stage  
characteristics and  
late stage development  
and commercialization  
capabilities



## Late stage

R&D spend & time  
Market Research &  
Understanding  
Platform technology



## Early stage

Lean  
Small cap  
Capital focus

# BUSINESS MODEL

- Relatively small, high talent in-house team
- Supported by best available third parties (regulatory, quality, legal, accounting, auditing, tax, communications, investor relations etc.)
- Handpicked world class hardware (Grey Innovation) and software (Two Bulls) developers with global footprint developing portfolio
- Strong, committed Board with relevant global experience
- Institutional knowledge having commercialised and sold clinical products to world leading hospitals in the past (Stopped sales but continued servicing)
- Strategic pivot to focus on mobile health consumer products



Focus on consumer

Experienced Board

World-class engineering

Key third parties

Small in-house team





# **1. OPERATING ENVIRONMENT AND MACRO TRENDS IN INDUSTRY**

**Healthcare Delivery & Connected Medical Technology  
Burden of Asthma on Society  
Addressable Market**

# EXPLOSIVE FIELD OF DIGITAL HEALTH



## AirSonea Gen II Prototype



# FIRST WAVE

## Fitness & Wellness Devices (Fitbit launched May 2013, Apple Watch April 2015)

Rapid consumer adoption of wearable sensors and smart watches which produce data related to physical activity, although of limited clinical value



## SECOND WAVE

## Digital Health Platforms for Complex Diseases

Includes the monitoring of symptoms and behaviour in chronic disease management, such as wheeze detection and measurement in asthma, glucose monitoring for diabetics

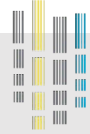


## THIRD WAVE

## Big Data for Health & Hospital Systems

Respiri products can partner with health systems, medical and data professionals to enable the capture of asthma data.

EHR /EMR is key to fulfilling the promise of Big Data



# + HUGE GLOBAL ASTHMA MARKET

COMPARED TO DIABETES 387M (2014) PROJECTED TO 471M (2035)

There has been a sharp increase in the global prevalence, morbidity, mortality, and economic burden associated with asthma over the last 40 years, particularly in children. Approximately 330 million people worldwide currently have asthma, and its prevalence increases by 50% every decade.

Asthma is underdiagnosed and undertreated. **The increasing number of hospital admissions for asthma, which are most pronounced in young children, reflect an increase in severe asthma, poor disease management, and poverty.**

Worldwide, approximately 250,000 deaths annually are attributable to asthma.

- **334 million people** have asthma (**400 million** by 2025)
- **14% of the world's children** experience asthma symptoms
- **8.6% of young adults** experience asthma symptoms
- **Approximately 250,000 people die** prematurely each year from asthma. Almost all these deaths are avoidable



**100**  
MILLION



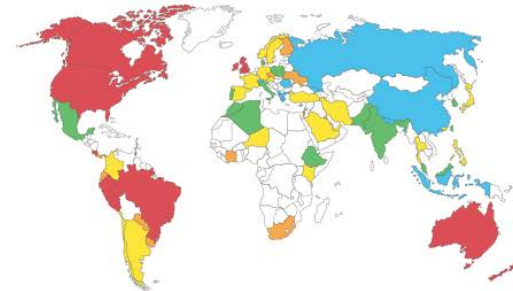
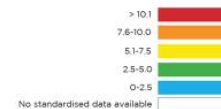
**30**  
MILLION



**25**  
MILLION

World Map of the Prevalance of Clinical Asthma

Source: Global Burden of Asthma; GINA




**5**  
MILLION



**2**  
MILLION



**600**  
THOUSAND



# BURDEN OF ASTHMA

The direct and indirect costs of asthma to societies are substantial. Recent calculations estimate direct costs across the 28 member countries of the **European Union** to be near €20 billion, indirect costs at €14 billion and a monetized value of DALYs (Disability Adjusted Life Years) lost €38 billion, which totals **€72 billion annually**.<sup>1</sup>

Asthma places a significant economic burden on the **United States**, with a total cost of asthma, including costs incurred by absenteeism from work and school and premature mortality, of **\$81.9 billion** in 2013.<sup>2</sup>

In the Asia-Pacific, respiratory diseases have a significant impact on health care resource use, cost burden, work impairment and health-related quality of life. The mean cost for patients is **US \$4191 per patient**.

Globally, the economic costs associated with asthma have exceeded that of tuberculosis and HIV/AIDS combined<sup>4</sup>. **Developed economies can expect increase in economic cost of asthma by >50% every 10 years**.<sup>5</sup>

1. European Lung White Book
2. Centers for Disease Control and Prevention
3. Value in Health Regional Issues Vol 9 May 2016 pg 72-77, Elsevier
4. WHO Factsheet 2006: Bronchial Asthma
5. Beasley R. The burden of asthma. J Allergy Clin Immunol 2002;109:S482-9



# EMERGING EPIDEMIC IN ASIA

Asthma is now one of the most common chronic disorders in Asian adults and children. Rapid urbanization, progressive loss of rural environments, uncontrolled pollution, high prevalence of cigarette smoking and poor asthma control are contributing factors to the increasing burden and morbidity related to asthma.

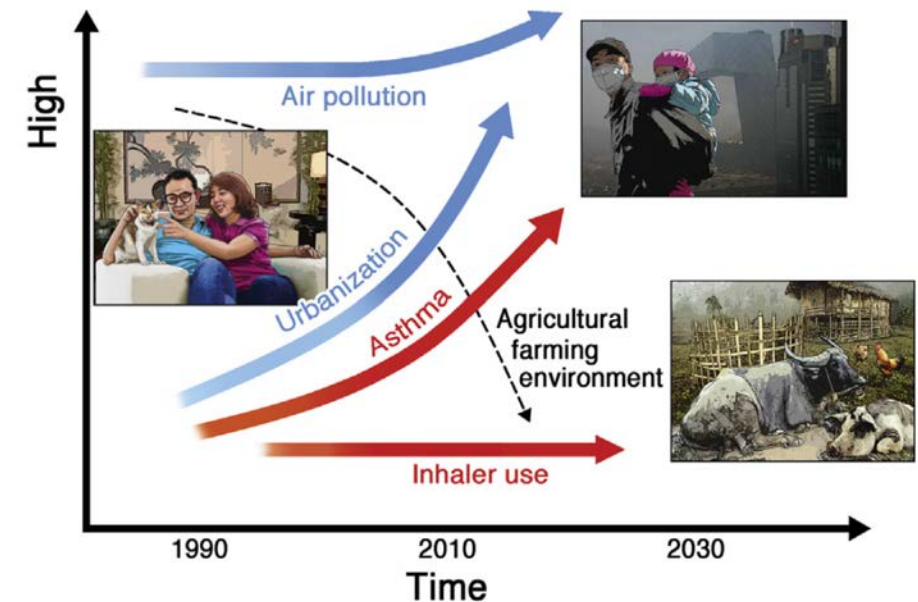
**Asia fares poorly compared to the rest of the world when it comes to asthma control.** According to the *Asthma Insight & Management Survey* conducted in 20 countries from 5 different global regions 2009 – 2011, the proportion of patients who achieved complete asthma control as defined by international criteria were:

- Asia – Pacific region 2%
- United States 29%
- Europe/Canada 16%

The cost of poor control is high, both in terms of patients' quality of life and the demand on healthcare resources, particularly in Asia where equitable access to affordable, quality care continues to be a challenge.



**Intervention and education is urgently needed. There is a huge opportunity for Respi's respiratory condition monitoring solutions to play an important role.**



**Increasing burden of asthma and related environmental risk factors in Asia**

*Changing trends and challenges in the management of asthma in Asia. Woo-Jung Song, MD, PhD<sup>a</sup> and Gary W.K. MD<sup>b</sup> Journal of Allergy & Clinical Immunology November 2017*



# AGGRESSIVE RISE OF ASTHMA IN SINGAPORE

20% of children in Singapore have asthma<sup>1</sup>  
Innovative solutions for self-management are needed



1. Ministry of Health Singapore

There is a rising tide of “allergy epidemic” in Singapore to the point where statistics show it to be **one of the highest asthma prevalence communities in the world**. 80% of university students have allergen sensitization and 18% reported asthma. People moving to Singapore develop increasing rates of sensitization and atopy year on year indicating environment is contributing to the allergic phenomenon. Despite the availability of asthma medications:

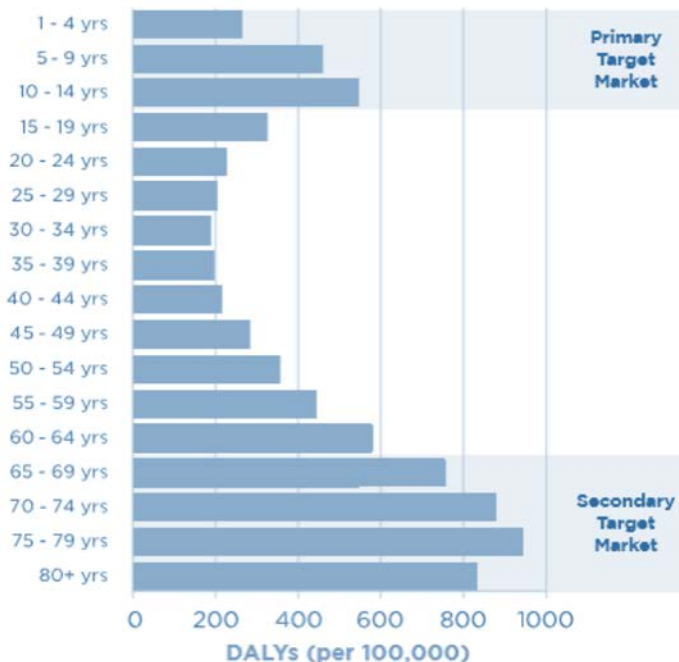
- Singapore's asthma mortality rate is 3 times that of developed nations such as the US and New Zealand
- 67% who had fatal or near-fatal asthma had 'untreated asthma'
- 73% of patients experienced 1 or more episodes in the past year yet 90% reported control of asthma

Ref: **Asthma in Singapore: Past, Present and Future** Mariko S Koh MBBS, MRCP, FCCP, Anthony CA Yui MBBChir, MRCP, Yong Yau Ong MBBS, FRACP, FRCP PubMed March 2017



# PRIMARY TARGET MARKET

(25 – 30 % OF TOTAL ASTHMA POPULATION)



Burden of disease, measured by disability  
Adjusted life years (DALYs) per 100,000 population  
Attributed to asthma by age group and sex.  
Global Population 2010  
Global Asthma Report 2014

## THE BURNING PLATFORM

**Asthma is the leading cause of hospitalisation in children.**

Young children cannot use lung function tests and peak flow meters, and their parents and carers have difficulty communicating wheezing episodes to their physician.

This represents some of the most costly patients to the health system.

**Health Authorities / Insurers are highly motivated to address this now**



“mHealth solutions are amongst the highest priority for research to optimise asthma management and prevent asthma attacks.”

**European Asthma Research and Innovation Partnership**



# NEED FOR A COMPANION DEVICE

Respiri technology detects and measures a major symptom of asthma in children and delivers a digital platform to provide parents/carers and children with information and skills

## Diagnosing asthma in children\*

- There is no single reliable test 'gold standard' and there are no standardized diagnostic criteria for asthma
- Episodic respiratory symptoms that suggest asthma include: wheezing, difficulty breathing, feeling of tightness in chest, coughing
- It can be difficult to diagnose asthma in children 0 – 6 as they cannot perform spirometry lung function tests



**MISSING PIECE**

## Managing asthma in children\*

- Written asthma action plan
- Assess and avoid triggers
- Correct use of medicines including inhaler technique
- Manage flare-ups when they occur
- Monitor pattern of symptoms (including frequency of episodes and pattern of symptoms between episodes)

**Effective home monitoring -  
objective real time measurement of  
wheeze with electronic asthma diary**

\*Asthmahandbook.org.au/diagnosis/children  
Asthmahandbook.org.au/management/children

RESPIRI



# WHY THE UK FOR EARLY LAUNCH?

Burning platform appears hottest | Long-standing relationships with leading clinicians



## Definition of basic care from Asthma UK:

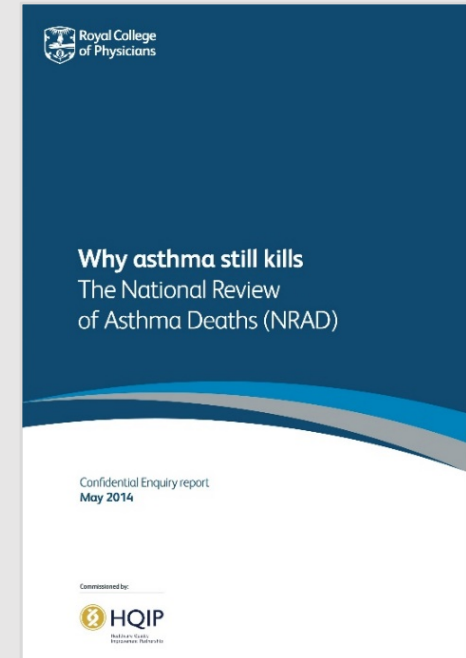
- Annual Asthma Review
- Written Asthma Action Plan
- Inhaler technique check

“Nearly two-thirds of people with asthma are still not receiving the **basic level of care** despite claims it could prevent two out of three asthma deaths a year.”

*Asthma UK survey 2017*

**Dr Mark Levy**, the clinical lead and author of the **National Review of Asthma Deaths** published by the Royal College of Physicians for the NHS began his relationship with Respiri 14 years ago when he collaborated with **Prof Andy Bush, Prof Aziz Sheikh and Prof Simon Godfrey** on a published paper validating our wheeze detection technology.

Dr Levy is currently developing protocols for clinical studies using the new product for launch in the UK.



**In 2015, 1,468 people in the UK died from asthma, the highest number for more than a decade**







## **2. INNOVATION OF THE PRODUCT/TECHNOLOGY**

**Disruptive vs Incremental Innovation**

**Competition**

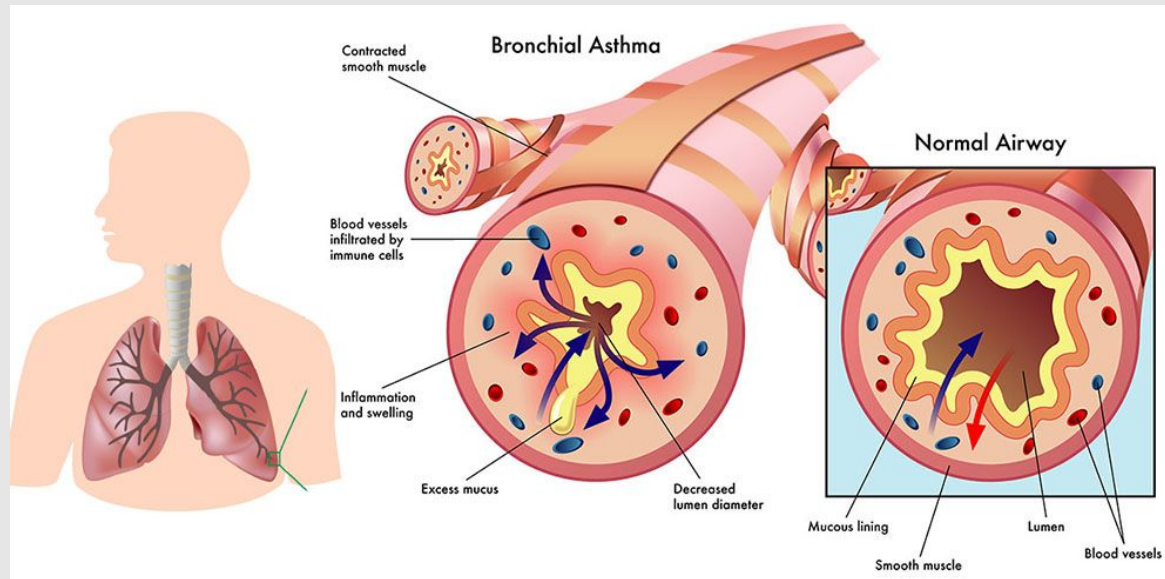
**Strength of IP**

**Regulatory Approvals**

**Clinical Study Program**

**Got-to-Market Strategy**

# WHEEZE IS A TYPICAL SYMPTOM OF ASTHMA



Respiri's new Breath Sensor & ARM™ technology puts the capabilities of a digital stethoscope with objective measurements in the hands of patients and carers to measure wheeze!

When airways become inflamed, flow pressure changes during respiration causing the airway wall to flutter. This flutter results in acoustic energy, or wheeze. The flutter or wheeze is a manifestation of airflow limitation.

Respiri Acoustic Respiratory Monitoring (ARM™) technology records airway sounds to **detect and measure the extent of wheezing caused by airway obstruction.**



*"Wheezing has earned its place as number one of the adventitious lung sounds. It warns patients, parents, and caregivers of potentially serious respiratory problems"*

*Hans Pasterkamp MD, FRCPC  
University of Manitoba, Winnipeg*



# COMPETITIVE LANDSCAPE

Few players & limited innovation compared to glucose monitors & heart/BP monitors



## Asthma Wheeze Monitor

No objective wheeze measurement devices on the market suitable for children who cannot perform lung function tests\*

(Disruptive technology –  
**Acoustic Respiratory Monitoring (ARM™)**)

## Lung Function Tests

Cohero Health Spirometry, Wing Spirometry, Peak Flow  
Manufacturers including digital (difficult to use, patient interpretation & data unreliable)

## Smart Inhalers / Compliance

Adherium, Propeller Health, Gecko Health Innovations (TEVA Pharmaceuticals), Cohero Health, 3M (probably most activity, lack of compliance a major issue)



Fevipirant (Novartis) – first new drug treatment in asthma for 20 years.  
Biological agent, reduces the severity (not a cure), most likely reserved for severe asthma patients.

\*as far as the company knows





# COMPETITIVE LANDSCAPE

By comparison, competition in monitoring diabetes with connected Blood Glucose Meters is fierce.

## LEADING CONNECTED BLOOD GLUCOSE METERS AVAILABLE IN THE MARKET (2015)

Company Name	Product
Sanofi (France)	• iBGStar Blood Glucose Monitoring System
Bayer Healthcare AG (Germany)	• Contour USB • Contour Next USB
Agamatrix (U.S.)	• BGStar • MyStar Extra
Roche Diagnostics (U.S.)	• ACCU-CHEK Aviva Connect meter • ACCU-CHEK Aviva Plus • ACCU-CHEK Smart View
LabStyle Innovations	• Dario Blood Glucose Management System
Philosys Co., Ltd. (Korea)	• Gmat SMART
Telcare, Inc. (U.S.)	• Telcare
iHealth lab Inc. (U.S.)	• iHealth Wireless Smart Gluco-Monitoring System • iHealth Align
LifeScan Inc. division of Johnson & Johnson (U.S.)	• OneTouch Verio Sync Meter • OneTouch Verio • OneTouch Verio IQ
Dexcom, Inc. (U.S.)	• Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System • Dexcom G4 PLATINUM System
Beurer GmbH (Germany)	• GL 50 evo
Visiomed Group (Spain)	• MyTensio BW-BA1

Note: The list is non-exhaustive and indicates only some of the products widely adopted by consumers

- Multi billion dollar global segment established
- Business model for monitoring of chronic conditions defined for glucose & blood pressure



## DEXCOM STORY

US\$1.54 Nov 2008

52 week high  
US\$102.10 June 2018

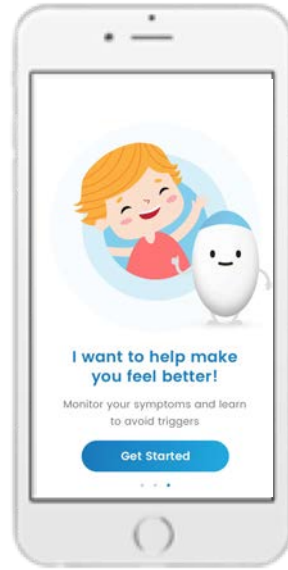
# IMAGINE IF YOUR DOCTOR & THEIR STETHOSCOPE WAS WITH YOU 24/7

Respiri technology listens to your breath sounds and detects wheeze as well as, if not better, than a doctor. The doctor's assessment of the presence of wheeze and its severity is based on their ears and their interpretation of what they're hearing. It's anecdotal, but a doctor will tell you that auscultation is more of an art than a science and they trust their own ears above all others.

Respiri's wheeze detection algorithm provides an objective measure of this typical asthma symptom and it can hear frequencies the stethoscope can't.

For parents of a child with asthma, we offer the peace of mind of a 'doctor in the house with a stethoscope' 24/7.





# HOME MONITORING + PRODUCTS

**Effective tools to improve patient self-management of asthma are critical**

“The development of robust acoustic devices for use at the bedside – as exemplified by electronic stethoscopes paired with small convenient recorders and perhaps in the form of a smartphone with an app – may provide the long-awaited portable objective means to record, analyze and store lung sounds just as any other clinical information is measured and stored. This development will make sound tracking possible, further enhancing the usefulness of auscultation.”

*Fundamentals of Lung Auscultation by Abraham Bohadana M.D., Gabriel Isbicki M.D., Steve S. Kraman M.D. New England Journal of Medicine 350;9 NEJM.org 20 February 2014*

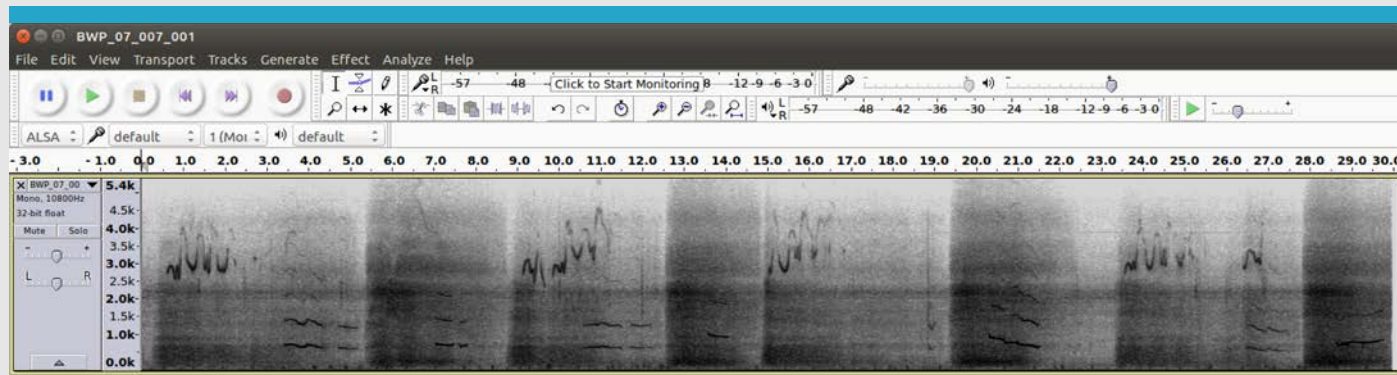


AirSonea Gen II Prototype

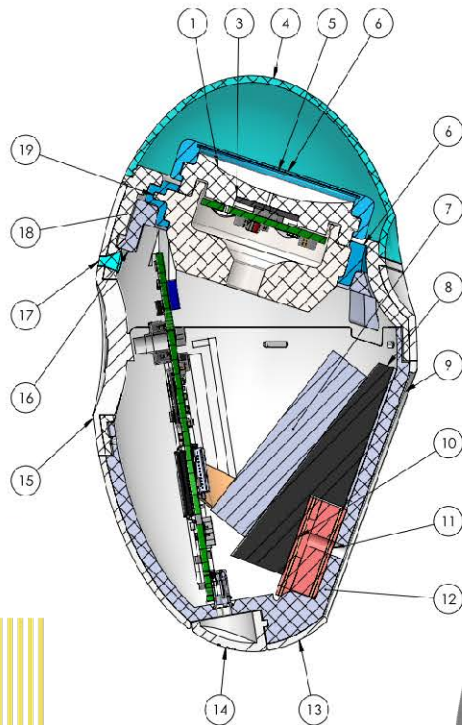
1. Hold the breath sensor to your trachea
2. Open the app and hit record
3. Breathe normally for 30 seconds – no effort required
4. The breath sounds are processed and the wheeze detection algorithm returns a wheeze rate in close to real-time
5. Recordings, measurements and related data are stored on the smartphone and uploaded to the cloud when there is a WiFi connection
6. Replay the sounds anytime and share data with your doctor



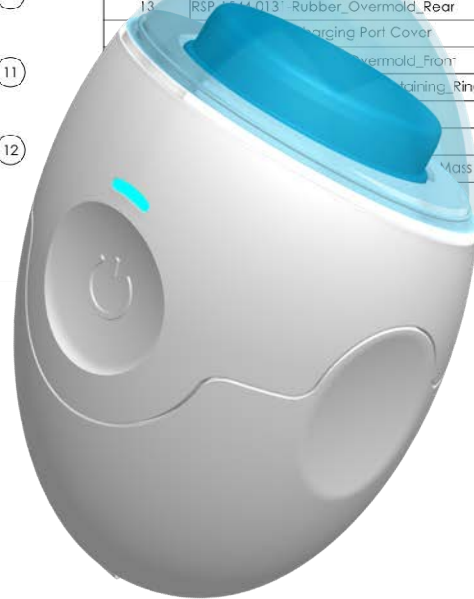
# HOW IT WORKS







ITEM NO.	PART NUMBER	QTY.
1	RSP-I 544-0155-Trachea Microphone Horn	1
3	RSP-I 544-0075-Microphone Seal	1
4	RSP-I 544-0163-Trachea Microphone Cap	1
5	RSP-I 544-0073-Microphone Diaphragm	1
6	RSP-I 544-0164-Diaphragm Cover	1
6	RSP-I 544-0175-Trachea Microphone Elastomer	1
7	Battery_LP_402030-2018-03-18	1
8	RSP-I 544-0159-Background Mic Mass	1
9	RSP-I 544-0104-Compliance Label	1
10	RSP-I 544-0085-Background Mic Flex Board	1
11	RSP-I 544-0170-Background Mic Tape Assembly	1
12	RSP-I 544-0129-Shell_Rear	1
13	RSP-I 544-0131-Rubber Overmold_Rear	1
	Charging Port Cover	1
	Overmold_Front	1
	Retaining_Ring	1
		1
	Mass	1



# GEN II DEVELOPMENT UPDATE

## Project on schedule

- Prototype (DVT1) tests completed
- Electronics and mechanical design updates completed
- System engineering completed
- Prototype (DVT2) build completed
- Pre-compliance EMC Tests completed and passed
- Design for Manufacturing Stage (DFM) by mechanical parts tool maker in progress
- Implementing PCB layout changes (as result of DFM)
- Grey Innovation and Two Bulls working together to finalise Bluetooth protocol implementation
- System tests ongoing – audio streaming, battery life test
- System tests scheduled – environmental & electrical tests, drop test, crush test, device service life, charging port cover & diaphragm pull force test
- Scoping integration test program
- Joint integration of device software with iOS and android app
- Tuning of audio filters on conclusion of acoustic and algorithm tests
- Design verification/pre-production development on schedule

# MANUFACTURING

Phase one of the manufacturing process is underway with the appointment of SRX Global as the company's Contract Manufacturer. SRX Global is a leader in the fast-paced electronic manufacturing marketplace, boasting a skilled labour force and vast state-of-the-art equipment housed in over 23,000 square metres of facilities in Dandenong, Victoria and Johor Bahru, Malaysia.

Being located in Melbourne, with our technology partners, Grey Innovation and Two Bulls, provides Respiri with the ability to easily share ideas and find solutions as we work through the development process to bring the new technology to market. As volumes scale and once the design is in a steady state, production will move to SRX's low-cost Malaysian facility.

The manufacturing package is being finalized with 130 verification units to be delivered for user testing and feedback and research studies leading up to full production in the new year.

SRX partners include; ResMed, Alere, ImpediMed, Biomerieux, Thales, Hella, Dorma and Northrop Grumman.



# ALL ABOUT ENGAGEMENT

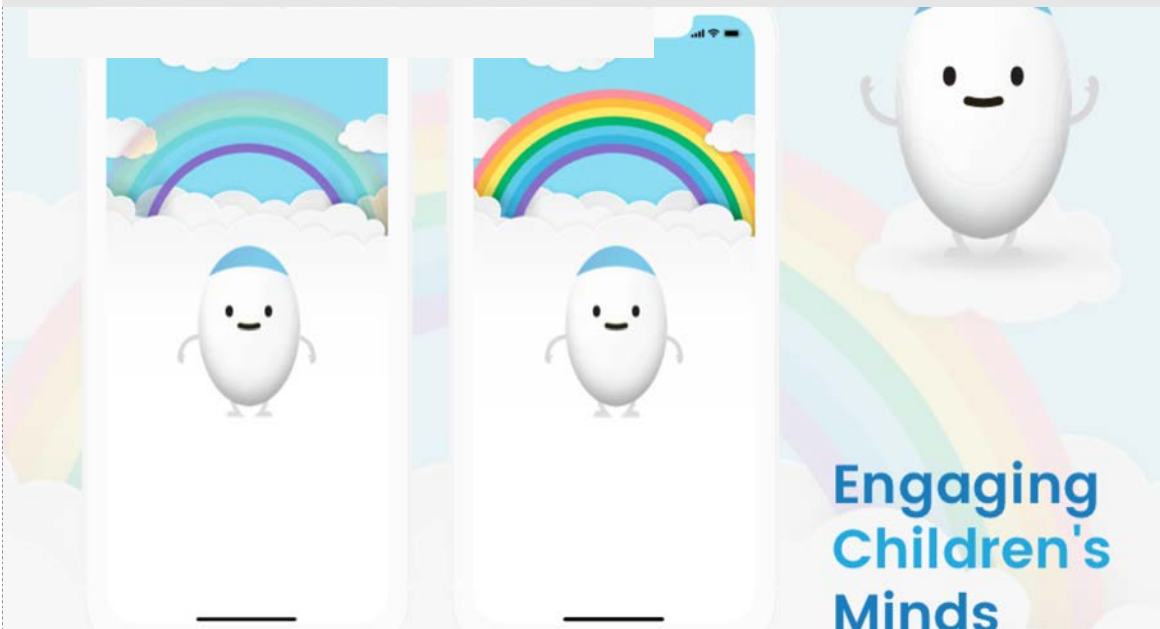


**We're developing an app experience to make wheeze monitoring fun for kids and their parents/carers. App stickiness is crucial to drive regular use for education, to help prevent asthma flareups and to capture personal data for machine learning purposes.**





# PERSONAL ASTHMA COACH



Using **machine learning**, we can correlate relevant events with wheeze rate, creating an even more compelling product for the proactive management of asthma. **It's a personalized early warning system.**

As the user is performing a wheeze rate measurement, the device connects to the Respiri backend and requests the current weather, pollen and pollution conditions in the user's location. Once the wheeze rate is determined, it will be combined with the atmospheric conditions, data from Apple Health/GoogleFit (such as heart rate) and time of day. It will also take into account other symptoms and triggers entered by the user.

This personal data is then fed into the machine learning model included in the app to determine when there is a heightened risk of asthma symptoms and alerts the user if there is.





# CUSTOMER JOURNEY



**Asthma Action Plan**  
For use with a Puffer and Spacer

Name: \_\_\_\_\_  
Date of birth: \_\_\_\_\_  
Confirmed Triggers: \_\_\_\_\_

Photo: \_\_\_\_\_

**Asthma foundation VIC**  
Child can self administer if well enough.  
Child needs to pre-medicate prior to exercise.  
Face mask needed with spacer.

**ALWAYS** give adrenaline autoinjector **FIRST** and then asthma reliever puffer if someone with known asthma and allergy to food, insects or medication has **SUDDEN BREATHING DIFFICULTY** (including wheeze, persistent cough or hoarse voice) even if there are no skin symptoms.

Adrenaline autoinjector prescribed: Y N Type of adrenaline autoinjector: \_\_\_\_\_

**SIGNS AND SYMPTOMS**

**MILD TO MODERATE**

- Minor difficulty breathing
- May have a cough
- May have a wheeze

Other signs to look for: \_\_\_\_\_

**SEVERE**

- Cannot speak a full sentence
- Sitting hunched forward
- Tugging in of skin near chest/ribs
- May have a cough or wheeze
- Obvious difficulty breathing
- Lethargic
- Skin turning (young children)

**LIFE-THREATENING**

- Unable to speak or 1-2 words
- Collapsed / Exhausted
- Gasping for breath
- May no longer have a cough or wheeze
- Drizzly / Confused / Unconscious
- Skin discoloration (blue lips)

**Emergency Contact Name:** \_\_\_\_\_  
Work Ph: \_\_\_\_\_  
Home Ph: \_\_\_\_\_  
Mobile Ph: \_\_\_\_\_

**Plan prepared by Medical or Nurse Practitioner:** \_\_\_\_\_  
Respiri asthma reliever medication (puffer or spacer) is to be used as follows: \_\_\_\_\_  
Signed: \_\_\_\_\_  
Date prepared: \_\_\_\_\_  
Date of next review: \_\_\_\_\_

**Blue/grey reliever medication is unlikely to harm, even if the person does not have asthma.**

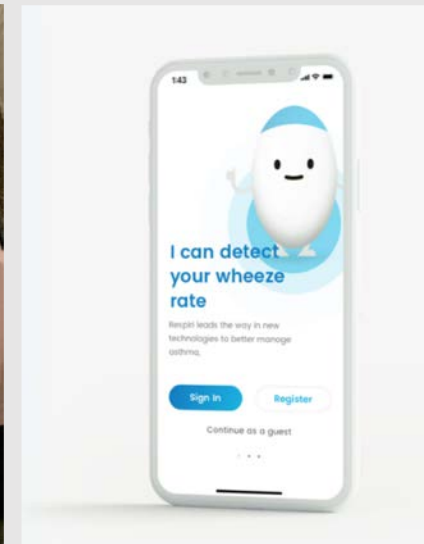
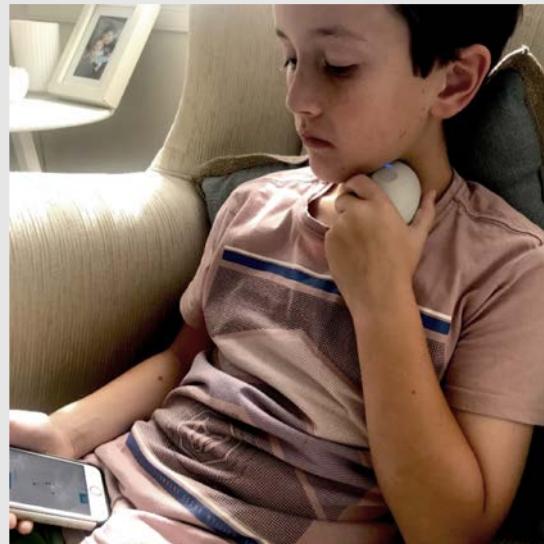
**ASTHMA FIRST AID**

**For Severe or Life-Threatening signs and symptoms, call for emergency assistance immediately on Triple Zero "000" until to moderate symptoms do not always present before severe or life-threatening symptoms.**

1. Sit the person upright.
  - Stay with the person and be calm and reassuring.
2. Give \_\_\_\_\_ separate puffs of Albuterol, Astmol or Ventolin.
  - Shake puffer before each puff.
  - Put 1 puff into the spacer at a time.
  - Take 4 breaths from spacer between each puff.
3. Wait 4 minutes.
  - If there is no improvement, repeat step 2.
4. If there is still no improvement call emergency assistance.
  - Dial Triple Zero "000".
  - Say "ambulance" and that someone is having an asthma attack.
  - Keep giving \_\_\_\_\_ puffs every 4 minutes until emergency assistance arrives.

Commence CPR at any time if person is unresponsive and not breathing normally.

**Illustration:** A person using a puffer with a spacer.



**Today** peak flow meters are recommended for symptom monitoring along with paper diaries for recording symptoms and triggers. Peak flow meters are not recommended for children, are difficult to use and unreliable. Parents rely on paper records and subjective observations for their doctor. It's stressful!

**2019** Respiri offers an easy-to-use, passive smartphone enabled digital solution with objective symptom monitoring and electronic diary correlating atmospheric conditions with other relevant data including inhaler use. Objective data is stored in the cloud for sharing with doctors. It provides alerts when conditions are threatening and removes the guesswork!

**2021** Respiri users can spot check using their 30 second symptom monitor during the day and then rely on the overnight monitor to provide peace of mind. Important overnight data can help inform treatment plans.

**Future** Continuous Symptom Monitoring as available for diabetes patients in Continuous Glucose Monitoring (CGM)

# MARKET RESEARCH

**Extensive studies in United States and Australia show strong need for Respiri self-management solution**

## Key findings | Parents of children with asthma

- Parents are constantly worrying about their child's health and wondering when the next attack will be
- They admit they could be more diligent and none feel like they are in complete control
- 'Asthma guilt' is pervasive. A function of the pressures of day-to-day life overwhelming the best of intentions coupled with a more 'reactive' approach to an asthma attack rather than a 'proactive' management
- Frustrated by difficulty in articulating severity of symptoms to doctors



## Key findings | Medical Professionals

- 80% of GPs and 62% of paediatricians in the study would recommend Respiri's Wheeze Monitoring solution to their asthma patients. Further scientific data on the technology would increase the percentage of these recommendations
- In general, the product was perceived as an important management tool for patients who would benefit from more frequent home monitoring, characterized as 75% of patients with unstable asthma and half of all patients with stable asthma

**Intent to purchase AirSonea Wheeze Monitor ranged from 60% to 90% in the various studies. Physicians noted poor compliance and reliability with existing solutions.**

**New consumer research planned in key markets, to inform launch strategy and marketing communications plan.**

**1-2 Observational Studies planned to compare Respiri monitoring solution to *Basic Care alone*.**

# INTELLECTUAL PROPERTY MULTI-FACETED



Copyright  
(software coding)

Trade Marks  
(branding)



Proprietary Information / Trade Secrets  
(algorithms, know-how, data)

Patents  
(algorithms, methods of diagnosis, related technologies)

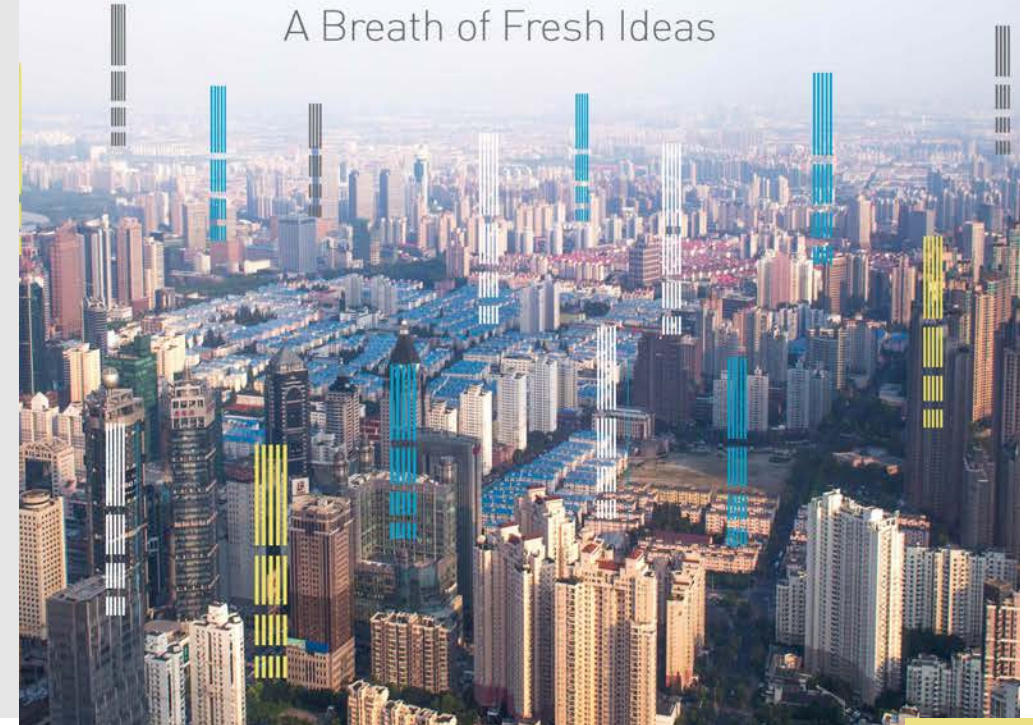
## Lead home monitoring product

- Over the counter (Class IIA) device for home use
- Detects, quantifies, and measures wheezing using ARM™ Algorithm
- Bluetooth connectivity to mobile devices
- Results can be uploaded to cloud for review by patient's doctor

# RESPIRI



A Breath of Fresh Ideas





RESPIRI



# OVERNIGHT MONITORING DEVICE



Based on the company's original Wholter™ product, Respiri is developing a wireless ambulatory wheeze and cough detector for nocturnal asthma assessment. The ability to evaluate the degree of asthma control in patients who wheeze at night will be an invaluable tool for physicians making treatment decisions and assessing therapy response. **Patients who wheeze at night are not well-controlled and their treatment should be stepped up (GINA/NHLBI).**

Sleepless nights are common for parents of children with asthma. Respiri's overnight monitoring solution will provide peace of mind that has never been possible before with continuous monitoring that will provide an alarm should there be an exacerbation.



# STAND ALONE WHEEZE MONITOR



- Target market: People with asthma or COPD who don't use a smartphone (elderly, nursing home residents, developing countries)
- Original Wheezometer™ concept
- Design new device with 2019 styling, not dependent on smartphone for operation
- Stand alone device with an LCD screen to show wheeze rate results.
- Algorithm analysis performed on the device
- Readings can be uploaded to a smartphone app or PC for review by carers and doctors



# REGULATORY APPROVALS

## Precedence



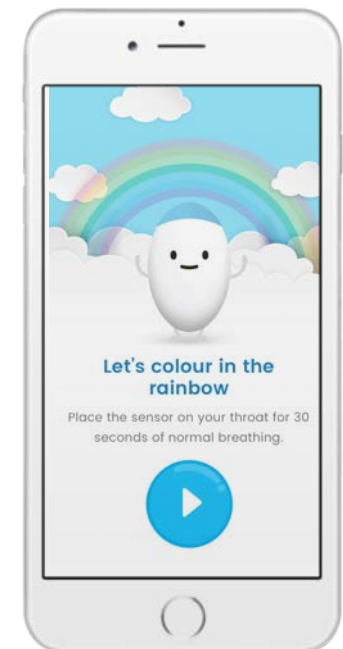
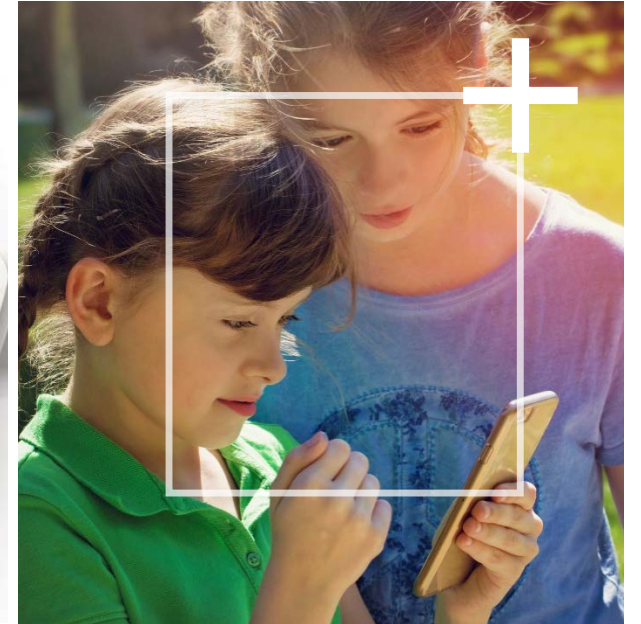
The company's portfolio of computerized wheeze detection products and apps has been approved by the TGA and carries the European Union's CE mark. All except AirSonea have FDA clearance. (Currently preparing application for AirSonea Gen II 510(k) targeting US market).

## Lowering risk



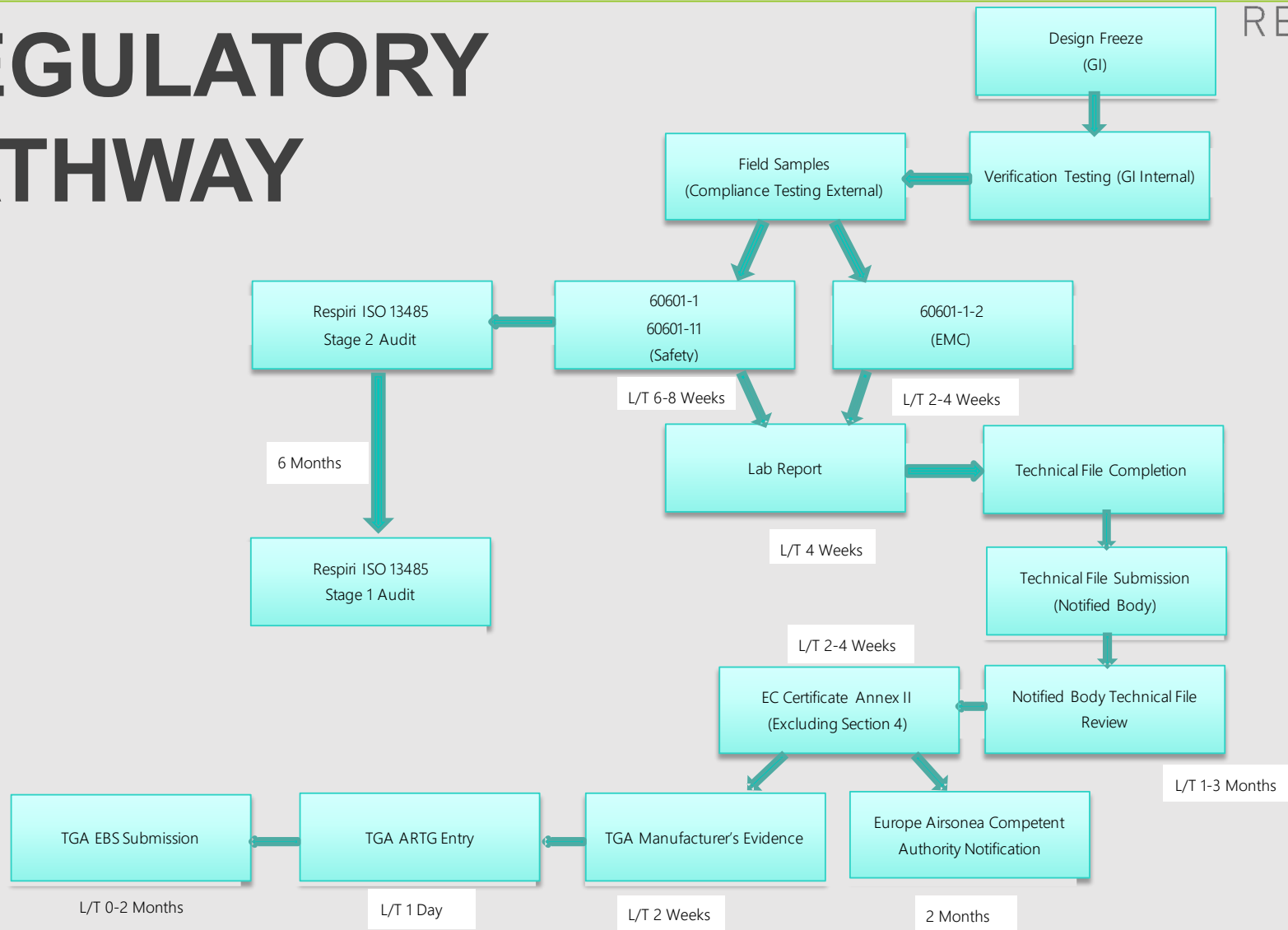
This precedence of approvals lowers the risk for speed to market and commercialization partners. Experienced Quality Assurance and Regulatory Manager contracted, Notified Body appointed and application for ISO13485 submitted for Respiri as manufacturer of new products.

**Once the CE Mark is granted, TGA Australia, HSA Singapore approvals will follow within weeks.**



# REGULATORY PATHWAY

RESPIRI





# RESEARCH STUDIES



A successful launch is dependent on acceptance of Respiri's technology by healthcare providers. In the UK, the product needs to be appraised by the National Institute for Health and Care Excellence (NICE), the public body servicing the National Health System (NHS) responsible for published guidelines in health technologies, clinical practice, health promotion and social care services. This will be achieved with validation of the new product through studies led by respected principal investigators in the UK and Australia. The first Medical and Scientific Advisory Board meeting is scheduled for 29 October in London. Delegates will agree on the protocols for studies to achieve the following outcome objectives.

- Respiri's digital wheeze detection product for use at home is as good as, if not better than a doctor's stethoscope.
- Assess correlation between wheeze rate and FEV<sub>1</sub> peak flow and symptom score.
- Children discharged from the emergency department after an asthma exacerbation and given Respiri's wheeze monitor for use at home use fewer medical resources and have better outcomes than children discharged without the wheeze monitor.



*MSAB Delegates include: L-R Prof Bruce Thompson, Head of Physiology Services, Alfred Hospital, Melbourne, President elect, The Thoracic Society of Australia & New Zealand, chair of Respiri Australian Medical & Scientific Advisory Board, Dr Mark Levy, Clinical Lead NW London Asthma Radar, Prof Aziz Sheikh OBE, Director, Usher Institute, University of Edinburgh. Director, NIHR Global Health Research Unit on Respiratory Health (RESPIRE). Director, Asthma UK Centre of Applied Research*



# GO-TO-MARKET STRATEGY PHASE 1

- 1 in 9 Australians affected by asthma
- 600,000 children affected by asthma
- 39,448 hospitalisations for asthma in 2105/16
- 51% of hospitalisations were children 0 – 14
- In 2020, the number of Facebook users in Australia is expected to reach 11.23 million
- 71% of millennials value the advice and insights they receive from parenting blogs, parenting websites, forums and social networks\*
- **Over a third of mums and half of dads state that they use social media daily for help in parenting**



\* US survey | Forbes March 5, 2018

RESPIRI 



It's time to start the conversation with 'connected' parents GPs & pharmacists and build the Respiri database



# CREATE GROUNDSWELL EARLY AUSTRALIAN PILOT PLAN

## Campaign Objectives & Key Considerations

Prior to kicking-off a full multinational marketing strategy, an initial digital only pilot will be deployed to gauge initial demand for Respiri's wheeze monitor in Australia only. **It's a marketing campaign with the added bonus of organic research.**

### Objective:

Gauge latent demand for the product and capture pre-registrations ahead of market launch in Q2 CY2019

### Pilot Considerations:

- Digital led with PR support to be cost-effective
- Potentially leverage reports and findings that are released in Asthma Awareness week Leverage local KOL supporters of Respiri
- Drive pre-registrations (no financial commitment) amongst parents of children with asthma
- Nurture leads with monthly updates through to in-market availability
- Develop facebook community and support with paid facebook advertising
- Consider engagement with influencers to build authenticity and intimacy with audience
- Consider a regional/rural PR opportunity to promote the use of self management tools for asthma care
- Share the vision for future product development eg. AI, overnight monitoring, wearables etc



### **3. CORE STRATEGY NEXT 18 – 24 MONTHS**

- a. Launch First Digital Connected Wheeze Monitoring Platform (Q1/2019)**
- b. Develop Overnight Monitoring Companion Device to Provide 24/7 Solution (2020)**

Organizational capability to execute and deliver plan  
Technology monetisation potential  
Partnerships and collaboration

# MAJOR MILESTONES & INFLECTION POINTS

AirSonea Generation II	2018	
Initial functioning demonstration quality prototype for technology demonstration purpose with partner & investors	Q2	✓
Fully functional medical device quality prototype with design completed	Q3	✓
Attend major industry tradeshows and healthcare conferences to showcase and generate interest for AirSonea Gen II with investors, customer and potential partners	Q3	✓
Manufacturing package and limited production of verification units by contract manufacturer	Q3	✓
One or more Memoranda of Understanding (MOU) or Letters of Intent (LOI) for collaboration will be established with targeted development & commercialisation partners to advance AirSonea Gen 2	Q3	
Final design updates and verification testing and Ideally handover to preferred manufacturing partners in key target regions. (Initial manufacturing planned to take place in Australia, with export to target market(s))	Q4	
Finalise planning and launch a significant pilot program in a major market (e.g. UK) to establish value proposition of AirSonea Gen II. (Observational community based studies compared to current practice)	Q4	
Regulatory approvals processes	Q3/Q4	







# REVENUE SCENARIO

## Initial target market penetration

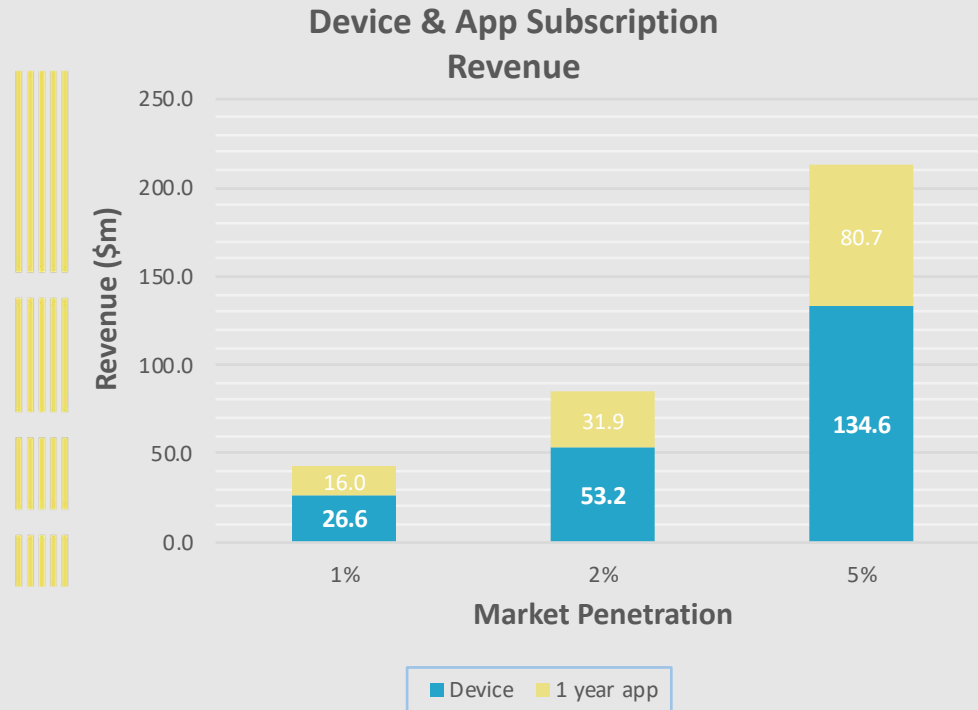
- Target market – Children and young people (CYP, 0-18 years old)
- Based on estimate that 10% of population are asthmatics, and 25% of asthmatics are CYP.<sup>1</sup> Initial target locations – UK, Germany, Australia, Singapore, US and Canada. (1 in 5 children (0-14) in Singapore have asthma).
- \$200-300 is an indicative device pricing range (supported by \$150-400 range for Fitbit/health devices)
- Initial target market of 13m CYP asthmatics, compares to over 340m of diagnosed asthmatics globally
- 5% penetration of target market would produce \$213m revenue (\$133m device, \$80m app) - assuming \$200 device price, \$10/month app subscription price)
- These scenarios don't include next phase revenues (Big Data, other products such as overnight monitor)
- Selling the device at \$100 would still be profitable at a gross margin level and after sales/distribution margin

1. Centers for Disease Control and Prevention  
National Current Asthma Prevalence (2015)  
[www.cdc.gov](http://www.cdc.gov)



# REVENUE SCENARIO

## Initial target market penetration



Singapore is one of the highest asthma prevalence communities in the world. An aggressive marketing strategy may result in higher market penetration.

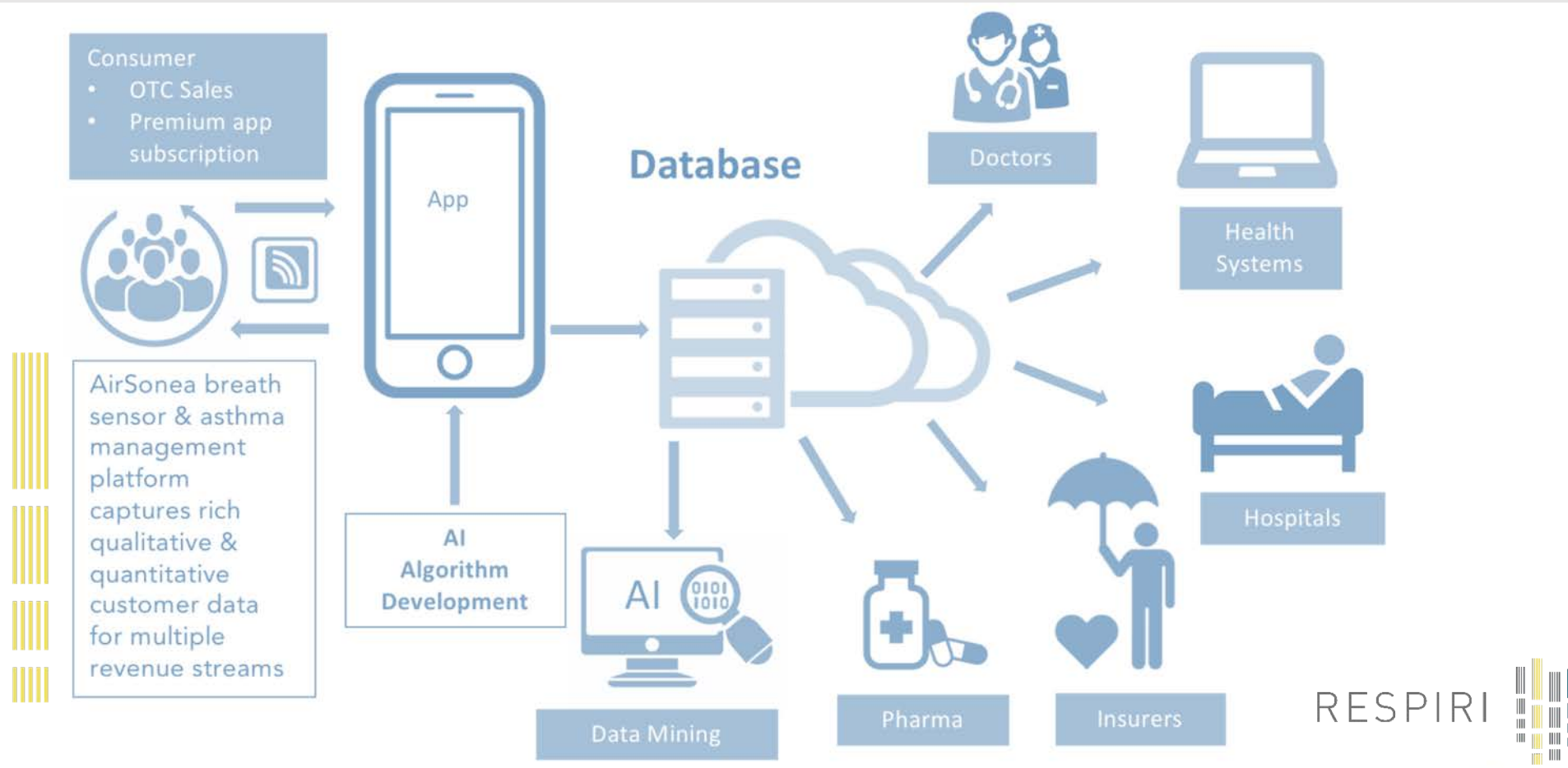
Device Target market penetration (\$200 device cost)			
	(1%) \$m	(2%) \$m	(5%) \$m
UK	3.3	6.6	16.4
Germany	4.1	8.3	20.7
Australia	1.2	2.5	6.2
Singapore			1.5
USA	16.2	32.3	80.8
Canada	1.8	3.6	9.1
<b>TOTAL Device</b>	<b>26.6</b>	<b>53.2</b>	<b>134.6</b>

App Target market penetration (\$120/year charged monthly)			
	(1%) \$m	(2%) \$m	(5%) \$m
UK	2.0	3.9	9.8
Germany	2.5	5.0	12.4
Australia	0.7	1.5	3.7
Singapore			.9
USA	9.7	19.4	48.5
Canada	1.1	2.2	5.4
<b>TOTAL APP</b>	<b>16.0</b>	<b>31.9</b>	<b>80.7</b>

Population	Total (m)	Asthmatics (10%)	CYP asthmatics (25%)
TARGET MARKET			
UK	65.6	6.6	1.6
Germany	82.7	8.3	2.1
Australia	25.0	2.5	0.6
Singapore	6.0	0.6	0.15
USA	323.0	32.3	8.1
Canada	36.3	3.6	0.9
<b>TOTAL</b>	<b>538.2</b>	<b>53.8</b>	<b>13.45</b>

# mHEALTH PLATFORM | REVENUE STREAMS

As we capture thousands, then millions of patient recordings, it will provide trend data and answer questions that today, we can't answer about asthma.





# BIG DATA

The McKinsey Global Institute estimates that applying big-data strategies to better inform decision making could generate **up to \$100 billion in value annually across the US health-care system**, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.



“It’s not the data, it’s the analytics. Up until three-to-five years ago, all that data was just sitting there. Now it’s being analyzed and interpreted. It’s the most radical change happening in health care.”

**Dr Eric Topol, Director SCRIPPS Translational Science Institute**

“Big Data is the Holy Grail of Healthcare; lowering cost measurably, managing chronic diseases better, measurably improving quality of life.”

**Mick Farrell, CEO ResMed**





# POTENTIAL PARTNERS

Many potential partners, but none are 'perfect'. They want certainty and de-risking to replace internal candidates.

**VS**

We want to maintain some control and commitment they will priorities our products.

## MOBILE HEALTH DEVICES

Apple, Samsung, Xiaomi, Sony, Huawei, FitBit, Garmin, iHealth Labs

## DIGITAL PLATFORMS

Google, Microsoft, Qualcomm, Neusoft, Yahoo

## MEDICAL DEVICE COMPANIES

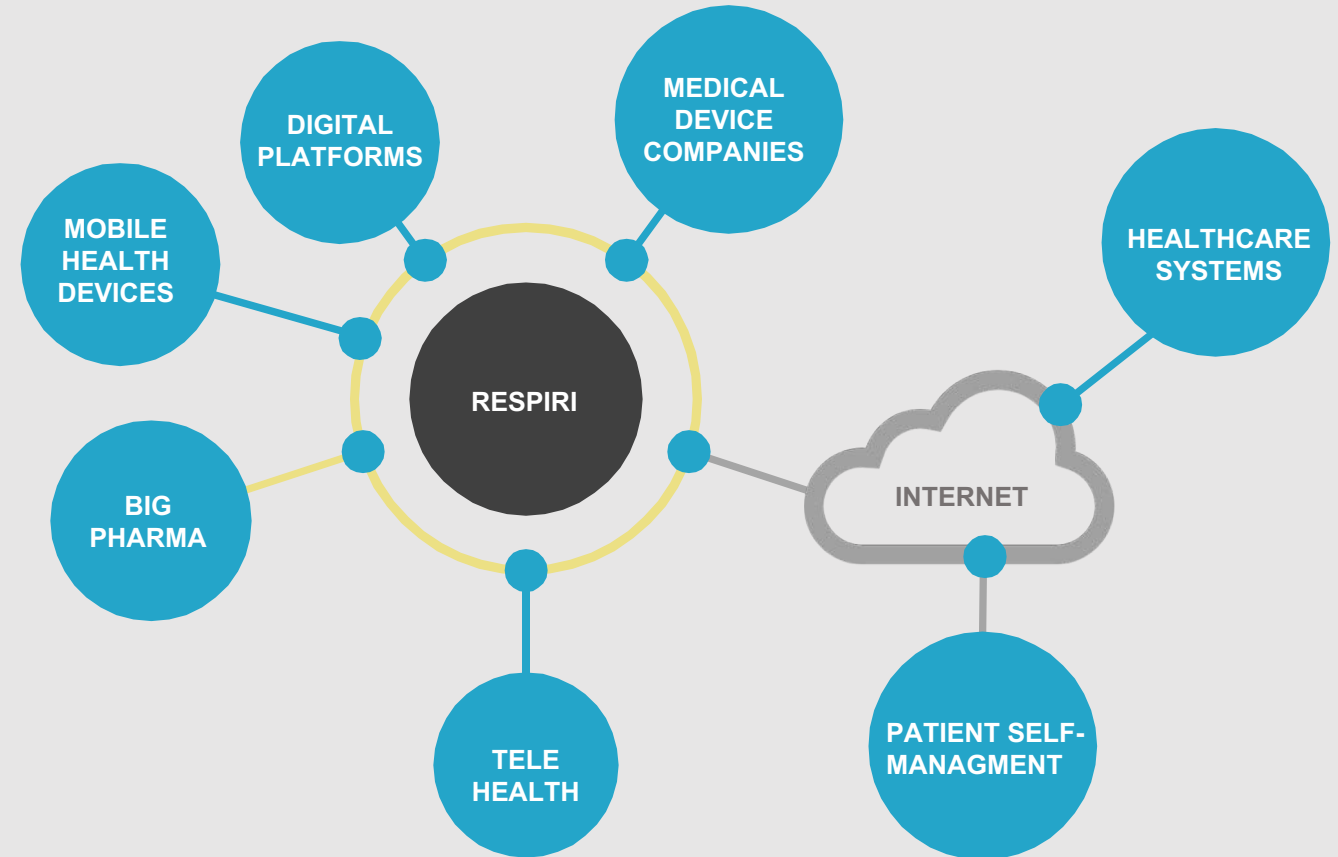
Philips, Omron, ResMed, GE Healthcare, CareFusion, Vectura, Propeller Health, Alere, Care Innovations, Dexcom, Medtronic, 3M

## TELEHEALTH

AT&T, Verizon, Telstra, Optus

## BIG PHARMA

GSK, Astra Zeneca, Schering-Plough, Boehringer Ingelheim, Novartis, Teva



# SUMMARY

## Very well placed to succeed

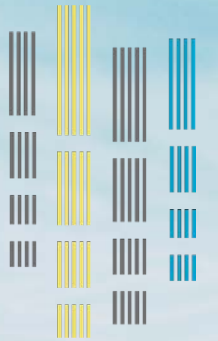
- Market opportunity and unmet need just as compelling
- Burden of disease is creating “the burning platform” with Govt / Payors and Asthma associations desperate for solutions
- Acceptance and pervasiveness of digital health and connected medical technologies in chronic diseases is much higher
- Respiri is bringing a superior product to the market through iterative learning and company better equipped to execute successfully
- ARM™ algorithm and software platform 20 years in the making; supports rest of potential portfolio in consumer and clinical based products
- Established a Melbourne (Australia) ecosystem to support excellence and efficiency in technology development, medical guidance and commercialisation to support globalisation





THANK YOU

RESPIRI



## 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.



## 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.

RESPIRI



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# APPENDIX | BOARD



## Mario Gattino | CEO & Director

Mr Gattino has held senior leadership positions at Pfizer, one of the world's largest pharmaceutical companies, in the USA and Europe.

He has a long successful track record in commercialising drug and device products globally and growing sales in multiple markets including the USA, Europe and Asia.

He is an expert in sophisticated stakeholder management, portfolio and business development via M&A and licensing, brand commercialisation, business innovation and profit generation.

His experience in launching and managing products in several countries, formulating and executing commercialisation plans, and dealing with local regulators will be invaluable to Respiri at this important juncture.

Qualifications MBA, Strategic Management & Marketing AGSM@UNSW Business School.



## Mark Ziirsen | Chairman

Former Director Finance and IT, Asia Pacific at Cochlear Limited (ASX:COH) and Chief Financial Officer of Admedus Limited (ASX: AHZ). Mark is a highly strategic senior finance leader with proven commercial acumen. He brings to Respiri a strong track record of delivering growth and significant improvement across multiple industry sectors and geographies in executive roles with market leading international organisations. His strong credentials in finance strategy and business performance management are complemented by extensive corporate finance, governance, risk management, strategy, M&A and investor relations skills. Mark is a Non-Executive Director and Chair of the Audit Committee of ASX listed SmartTrans Holdings Limited.

Qualifications: B.Comm, Business/Commerce, General, University of Queensland, MBA, International Business, University of New England (AU).

# APPENDIX | BOARD

## Brendan Mason | Non-Executive Director



· A med-tech and China market entry specialist, leading Cochlear Limited (ASX:COH) entry into Greater China as General Manager from 2007 to 2014. Brendan was responsible for market development, sales, marketing, distribution, regulatory affairs, customer support, IP protection and clinical trials for the Greater China region. He oversaw rapid growth of the business through drivers that required funding and reimbursement, infrastructure development and increasing consumer awareness through managing key opinion leaders and key government stakeholders. Previously, Brendan worked at Lucent as the Executive Director responsible for Telstra, Lucent's largest account in Asia. He is a past board member, treasurer, and chairman of the Australian Chamber of Commerce, Beijing, where he established the government relations committee to provide advice to Chinese government and Australian member companies. Brendan Mason is the Non-Executive Director of Australia China Technology Incubator a federal government funded program for MedTech companies who aspire to export. Brendan is currently CEO and Managing Director of ASX listed SmartTrans Holdings Limited.

Qualifications: Post Graduate Diploma in Operations, Business Operations, University Prize for Excellence in Strategy, Macquarie University, EMBA Business Administration and Management, General, Australian Graduate School of Management



# APPENDIX | MEDICAL & SCIENTIFIC ADVICE

Respiri is currently forming a new Medical & Scientific Board with leading professors of respiratory medicine with the first meeting in London late October 2018. The company has worked with a number of globally respected physicians and scientists including, but not limited to:

## **Professor Bruce Thompson**

Newly appointed Chair of Australian Medical & Scientific Advisory and Product Portfolio Development Lead. Bruce Thompson is Professor of Allergy, Immunology and Respiratory Medicine at the Central Clinical School, Monash University and Alfred Health, and Head of Physiology Services at the Alfred Hospital where his group performs lung function tests on more than 7,000 patients per year. Professor Thompson is also the President elect Thoracic Society of Australia and New Zealand.

## **Professor Noam Gavriely**

An international authority on pulmonary acoustics, Prof Gavriely has extensively published on various aspects of breath sound monitoring over the last 25 years and holds multiple patents on phonopneumography and other aspects of breath sounds monitoring.

## **Professor Simon Godfrey**

Emeritus Professor Pediatrics at the Hadassah-Hebrew University, Jerusalem, Prof Godfrey's main research interests are in pediatric pulmonary physiology and the application of novel investigative techniques for the diagnosis and management of pediatric pulmonary disease. He has published over 190 original papers and 16 books.

## **Professor Zahra Moussavi**

Director, Biomedical Engineering Program Professor & Canada Research Chair University of Manitoba, Prof Moussavi specialises in sleep apnea, respiratory sounds analysis and Alzheimer's diagnosis and treatment. She has published more than 180 papers.

## **Dr. David Danztker**

An internationally recognised expert in pulmonary medicine and critical care, Dr. Danztker has served on the faculty and in leadership positions of four major research-oriented medical schools and authored or co-authored 130 research papers and five textbooks. He is former Chair of the American Board of Internal Medicine, the largest physician certifying board in the US.

# APPENDIX | PUBLISHED RESEARCH PAPERS

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12. Levy ML, Godfrey S, Irving CS, Sheikh A, Hanekom W, Bush A, Lachman P. Wheeze detection: recordings vs. assessment of physician and parent. *Journal of Asthma*. 2004;41(8):845-53.
13. Bentur, L., Beck R., Berkowitz, Hasanin J., Berger I., Elias N., Gavriely Pulmonary Acoustics and Esophageal pH Monitoring in infantile Nocturnal Cough *Pediatric Asthma, Allergy and Immunology*. 2004 17:262-27
14. Bentur L, Beck R, Shinawi M, Naveh T, Gavriely N. Wheeze monitoring in children for assessment of nocturnal asthma and response to therapy. *European Respiratory Journal*. 2003 Apr;21(4):621-6