RESPIRI

Data-Driven Asthma Management as a Service

Initiation of coverage

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Chris Kallos, CFA
Senior Research Analyst
chris.kallos@mstaccess.com.au

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Respiri enters new era with SaaS model

Respiri is approaching a key inflection point as its lead product, the 'wheezo', is set for market launch. New CEO Marjan Mikel has reduced overheads, realigned the business model to include recurring monthly 'software as a service' (SaaS) revenues, established a commercial partnership with a global pharmaceutical company and formed strategic alliances with notable Australian telehealth providers (Phenix, Instant Consult, GPNow). With CE mark & TGA approval in place and FDA approval pending (expected near term), Respiri is well positioned to realise the latent value of its core Acoustic Respiratory Monitoring technology. Preparations are underway for the Australian launch of wheezo in October 2020 through the community pharmacy channel with major distribution partner Cipla, laying the foundations for its global commercial roll-out thereafter.

wheezo represents a new monitoring approach

wheezo allows asthmatics to measure, manage, and monitor their condition before an acute attack occurs. Unlike current self-monitoring devices, such as the peak flow meter, which require patients to exhale, it represents a passive and therefore objective assessment of the presence of wheezing (a common sign of asthma). Its ergonomic design and ease of use makes it well suited for chronic monitoring of asthma in children and the elderly.

Major distribution partner with global reach

Respiri's commercial partner, Cipla (NSEI: CIPLA; market capitalisation ~ INR 622 million or ~ US$8.3 billion), is a leading Indian multinational pharmaceutical company with significant sales and marketing infrastructure covering over 80% of the pharmacy market in Australia. Partnering with Cipla bodes well for growing sales in Australia and entry to other international markets.

Enormous asthma market opportunity

Asthma is a chronic condition affecting approximately 10% of the population, providing Respiri with a target addressable market in Australia alone of around 2.7m people. Despite new treatments, asthma remains poorly controlled due in part to non-adherence to medication, inconsistent inhaler technique and sub-optimal self-monitoring of lung function by patients in home settings.

Clear strategy on track with CY21 revenue guidance of A$6m–A$8m

Respiri's restructured management team is delivering on milestones and has rapidly reduced overheads, with commercial partnerships and strategic alliances now in place for the imminent launch of wheezo in 2HCY20. Given the commercial contracts progressively signed during this period, management has issued CY21 revenue guidance of A$6m–A$8m, heralding its transition from the development stage to the commercial stage.

Valuation

We value Respiri at A$244m (A$0.37/share). Our base case is conservative and does not include US market entry. Our bull-case scenario, assigning 60% probability to a FY23 US market launch, yields a valuation of A$0.63/share.

RESPIRI

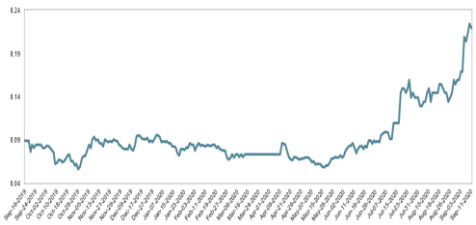
Respiri Limited is a commercial stage health-tech company developing mHealth and SaaS solutions for respiratory health management. It has proprietary technology and mobile health tools that specifically detect wheeze (an indicator of asthma, COPD, and respiratory disease more broadly) to provide an objective measure of airflow limitation. The company's flagship 'wheezo' device and platform analyses breathing objectively, allowing for environmental factors; record, monitor and schedule medication including reminders; and share data with healthcare providers. Both CE (Conformite Europeene) mark and Therapeutic Goods administration (TGA) approval received.

Stock	RSH
Price	A$0.22
Market cap	A$143.4m

Company data	
Net cash	A$3.5m (30 June '20)
Shares on issue	651.7m
Code ASX	RSH

Next steps	
2HCY20	Australian launch of wheezo
2HCY20	FDA approval of wheezo

RSH share price (one year, A$)



Investment Thesis: Commercialisation Within Reach

Company Profile: Med-Tech Developer Transitioning to eHealth SaaS Model

Flagship asthma monitoring product set to launch 2HCY20

Melbourne-based Respiri Limited is a commercial-stage digital health technology company. The company specialises in the development and commercialisation of non-invasive devices and medical mobile health (mHealth) apps which support the management of chronic respiratory disorders such as asthma and chronic obstructive pulmonary disease (COPD). COVID-19 has brought respiratory health into sharp focus and highlighted the need for better ways of monitoring lung function, including for conditions such as asthma.

Respiri's near-term focus is the launch of its flagship 'wheezo' product and associated subscription asthma monitoring service. The wheezo product is a novel patient-driven electronic wheeze monitoring device which uses next-generation proprietary listening technology to identify the sound of wheezing – a clinical indicator of obstructive airway disease strongly correlated with the presence of asthma. The company plans to generate revenues from one-time device sales as well as ongoing annuity-like revenue streams relating to its 'software-as-a-service' (SaaS) subscription monitoring service, allowing users to capture and retain data in the cloud and make this information available remotely to their healthcare providers. Respiri's SaaS offering will be charged monthly.

Enabling technologies redefine Respiri's business model and commercial prospects

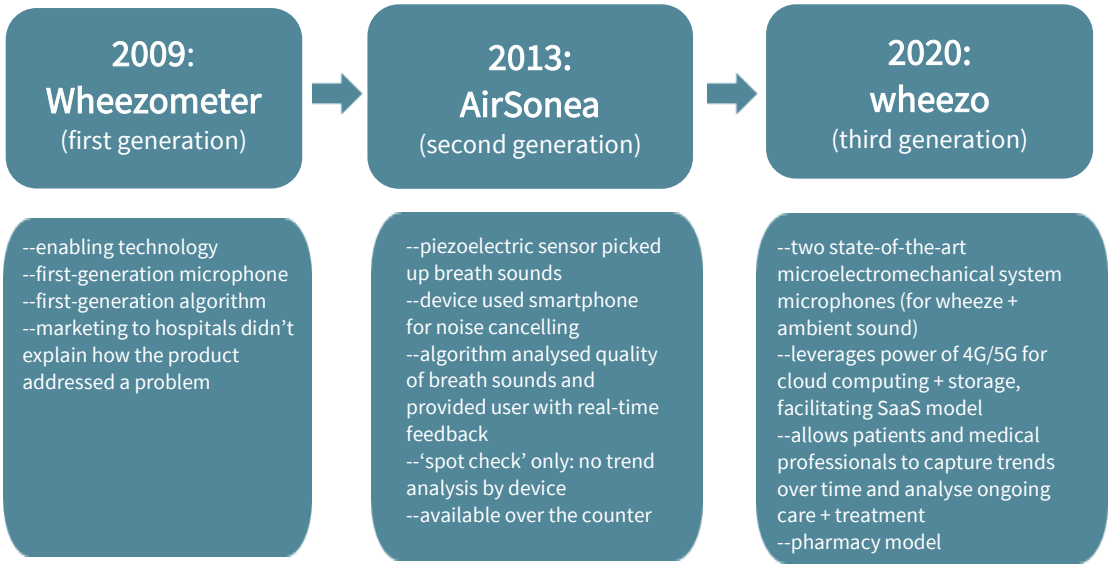
New technologies have transformed commercial prospects for digital health providers of remote patient monitoring devices, including Respiri. Increased cloud-based computation and expanded storage capacity from the migration to 4G (and soon 5G) is enabling real-time data to be captured and processed at an unprecedented level, enhancing the clinical utility of cloud computing–based medical applications and making remote patient monitoring more reliable.

These technical advances address hurdles previously faced by Respiri, including unstable transmission of audio sample data and Bluetooth data to the app. Larger digital audio files, such as those captured by Respiri's wheezo system, can now be processed and stored in the cloud to support Respiri's expanded business model. The company seeks to leverage these technological advances through cloud-based delivery of processed data to generate additional annuity revenue streams through fees for SaaS.

Technological development and refinement of the algorithm

While the wheezo is the first product being brought to market by the company in its current incarnation, the technology behind the wheezo has been in development for many years, with previous devices providing an opportunity for Respiri to refine the underlying technology (see Exhibit 1).

Exhibit 1 – Product development through to the wheezo



Source: Respiri.

Strategic Initiatives: Cipla Distribution Agreement and Australian Pharmacy Market

Respiri's restructured management team, headed by new CEO, Marjan Mikel, is delivering on milestones and has rapidly reduced overheads, with commercial partnerships and strategic alliances now in place in preparation for the imminent launch of wheezo in 2HCY20. These include a binding sales/marketing and distribution agreement with leading Indian multinational pharmaceutical company, Cipla (NSEI: CIPLA; market capitalisation ~INR 622 million or ~US$8.3 billion). Cipla has significant sales and marketing infrastructure covering over 80% of the pharmacy market in Australia. Under the terms of the agreement, Cipla is committed to an initial minimum order of 2,000 wheezo devices. A manufacturing partner, SRX Australia, has been secured for production at scale of the wheezo device.

Recent Events

December 2019	• Marjan Mikel commences as the company's Chief Executive Officer
March 2020	• First batch of 500 wheezos delivered by SRX • Request from three Chinese hospitals to trial wheezo to monitor lung function • Raises $5.2m in capital to develop next-generation wheezo respiratory device
April 2020	• Partners with two telehealth service providers: Phenix Health and Practice Innovators 2
June 2020	• Service agreement with Pharmacy Guild of Australia • Agreement with UK Data Research Centre
July 2020	• Exclusive international sales agreement with Cipla • Signs merchant service agreement with pay later provider ZIP
August 2020	• Partners with Australian Patients Association for wheezo real-world study

Potential Near-Term Catalysts

- Completion of stethoscope study (preliminary results promising)
- Resumption of experiential study with Swinburne (on pause due to COVID-19)
- Launch of wheezo in Australian pharmacies (October 2020)
- FDA clearance and 510(k) approval (expected late 2020)
- Manufacturing scale up

Financials

We view the near-term launch of wheezo as heralding a new and transformational phase for the company with first meaningful product revenues from FY21. It is well capitalised with cash of A$3.6m at end-FY20 and distribution partner Cipla carrying the bulk of marketing costs in upcoming launches. The key components of our P&L forecasts for FY21 and FY22 pertain to revenue, other income, COGS, operating expenditure, and tax.

Valuation

We value Respiri at A$244m, or A$0.37 per share, using DCF methodology and based on a commercial roll-out with distribution partner Cipla in Australia and New Zealand in FY21, followed by our probability-weighted expectation (we have applied 60%) of Cipla extending its agreement with Respiri for commercial roll-out into the United Kingdom, France, Germany and Italy in FY22. Our bull-case scenario assumes FDA approval of wheezo and applies a 60% probability to US market launch in FY23 to generate a valuation of ~ A$400m, or A$0.63 per share. The company appears to be on track to receive FDA approval and the partnership with Cipla is mutually beneficial for both companies. However, the less transparent path to approval in the US as well as the longer-term timeframe on this rollout have led us to exclude US sales from our base case, potentially providing substantial upside to our valuation.

Risks and Sensitivities

A key aspect of the company's commercial strategy is to leverage its partnership with Cipla to access the Australian pharmacy market and potentially other markets internationally. However, this does make Respiri reliant on Cipla to promote the device, with any changes to Cipla's Australian sales strategy directly impacting Respiri's profitability.

Company Outlook: Mobile Health Tool for Remote Monitoring of Asthma

Respiri Limited listed on the ASX in 2004 and, following the acquisition of Pulmosonix and KarmelSonix in 2007 (which brought in proprietary sound technology), has primarily focused on developing non-invasive devices for chronic respiratory health disorders such as asthma and COPD. Over that time, the company has refined its sound technology and streamlined its product offering.

Respiri's near-term focus is the launch of its flagship 'wheezo' product (see Exhibit 2), a novel self-monitoring device for asthma patients which uses the company's patented Acoustic Respiratory Monitoring (ARM) technology to identify sound, specifically wheeze – a clinical indicator of obstructive airway disease strongly correlated with the presence of asthma, especially in children.

The wheezo asthma management platform uses proprietary algorithms to cancel ambient background noise and analyse sound files captured by the wheezo's proprietary biosensors to detect wheeze. The app keeps track of wheeze episodes, enabling logging of potential trigger factors including local specific environmental factors (pollen, pollutants) and response to medication, as well as identifying trends, and includes the ability to digitise asthma action plans allowing for health care providers to manage their patients' treatments with a more tailored approach.

The device is paired with an app and a secure cloud-based account, and under the new SaaS model, users pay a monthly subscription to use the wheezo system to log, monitor and communicate their wheeze rate as well as associated triggers, symptoms and treatment.

Exhibit 2 – wheezo device (left) and paired app (right)

Source: Respiri.

Respiri Targeting a Large and Growing Addressable Market for Asthma Monitoring

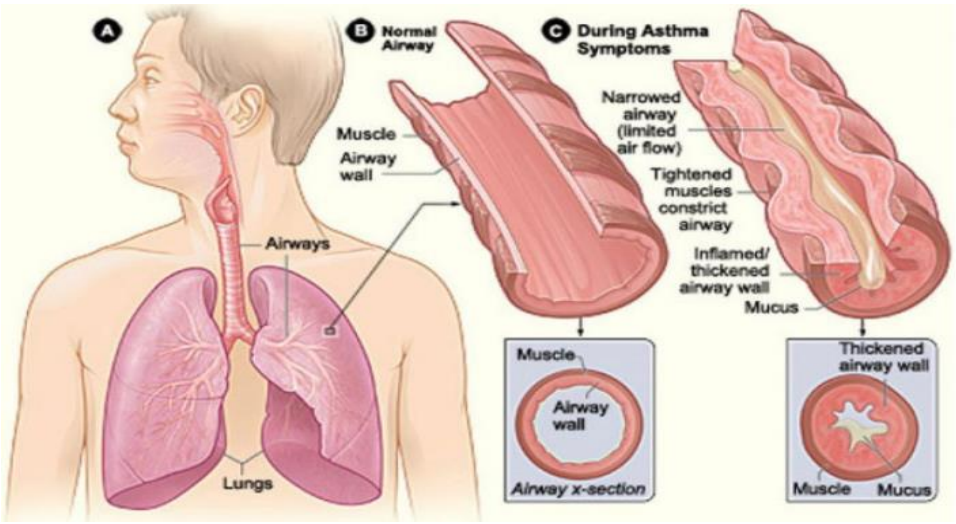
Asthma is a chronic inflammatory respiratory condition affecting approximately 10% of the population, providing Respiri with a target addressable market in Australia alone of around 2.7m people. Notably, the prevalence of asthma in Australian children is amongst the highest in the world. Patients with severe asthma make up 3%–10% of the population of adults with asthma. Despite a significant decrease in asthma-related deaths in Australia since the peak of 964 in 1989, the number of deaths has remained consistently high at around 400 per year for the past decade. Co-morbidities of asthma, according to the latest report published in April 2020 by the Global Initiative for Asthma (GINA), include rhinosinusitis, gastroesophageal reflux, obesity, anxiety and depression, and obstructive sleep apnoea.

There is currently no gold standard test available to diagnose asthma. As such, diagnosis relies on a combination of lung function testing, typically using spirometry, and review of medical history taken by an experienced clinician. The boxed text on the next page gives an overview of this disease and its symptoms and complications.

Understanding asthma: a quick overview of the disease and treatment

What is asthma? Asthma is a common lung condition in which the airways swell and narrow, causing sporadic breathing difficulties (see Exhibit 3). It often starts in childhood (and is the most common chronic disease among children globally), but can also develop in adults, and affects people of all ages—more than 339m people have the disease worldwide. There is currently no cure, but treatment can help control the symptoms, allowing patients to live full and rewarding lives. Over 80% of asthma-related deaths occur in low- and lower-middle-income countries.

Exhibit 3 – Pathophysiology of asthma



Source: www.nationalasthma.org.au/understanding-asthma/what-is-asthma.

What causes asthma? The fundamental causes of the disease are likely to be a combination of:

- genetics (e.g., if your parents have it or it is common in your family)
- external triggers: allergies (dust mites, pollen, fur); respiratory illness; tobacco smoke and pollution; cold air; chemical irritants (paint, varnishes, adhesives); extreme emotional duress; exercise; and certain medicines.

What are the symptoms? Symptoms include breathlessness, coughing, chest tightness and pain, and wheezing. Their severity and frequency vary from person to person. For some, they become worse with physical activity and at night, leading to sleeplessness and thus fatigue and disruptions to daily life. Asthma attacks are episodes where asthma symptoms worsen significantly, sometimes preventing the patient from speaking, eating or sleeping. Asthma attacks can be fatal but are largely preventable and manageable through regular checkups and the right treatment. Severe and difficult-to-treat asthma is asthma that requires treatment with high-dose inhaled glucocorticoids or other controllers or that cannot be controlled by such treatment. The criteria for uncontrolled asthma include exacerbations, poor symptom control, lung-function impairment, or a combination of these.

What treatment is available? Asthma is incurable but can be managed with regular medical checks and treatment. People with ongoing symptoms will need to take daily medication long term—often an inhaler to breathe in medicines—and work with their doctor to identify and avoid their triggers. Therapies include inhaled 'relievers' (which open the airways to relieve symptoms short term) and 'preventers' (which, when taken regularly, prevent symptoms from occurring and reduce the risk of flare-ups). Inhaled corticosteroids alone or in combination with long-acting bronchodilators or leukotriene pathway inhibitors are the cornerstone for treatment of asthma.

Traditional tools for diagnosing and monitoring asthma can be inconsistent and hard to access

Although incurable, asthma symptoms can be improved through continuous monitoring and appropriate therapies. Doctors use a variety of lung function tests in clinical settings to diagnose asthma and to monitor its progression. However, current approaches for patient-directed self-monitoring in home settings, such as peak flow meter tests and self-assessment questionnaires, have significant limitations. Respiri is aiming to provide a solution to these limitations with its asthma management platform, wheezo (see Exhibit 4).

Exhibit 4 – Commonly used lung function tests: methods currently in use present problems for ongoing monitoring

Name of tool	Purpose of tool	Overview	Setting	Advantages/disadvantages	Price
Spirometry before and after bronchodilator	Diagnosis Monitoring	Measures forced expiratory volume (FEV)	Clinician's office (conducted by specially trained respiratory therapist or physician)	Most common lung function test; problematic with children and the elderly	~A$2,000
Challenge tests	Diagnosis Monitoring	Measures lung function after inhaling a substance known to trigger asthma	Clinician's office (conducted by specially trained respiratory therapist or physician)	Needs to be administered in a control setting by a clinician and not appropriate for home use	N/A
Peak flow meter tests and incentive spirometers	Diagnosis Monitoring	Measures how well lungs push out air or peak expiratory flow (PEF)	Clinician's office (conducted by specially trained respiratory therapist or physician) or patient-administered readings at home	Quality of reading reliant on multiple factors. Patient-administered lung function readings are typically subject to errors due to patient bias or incorrect technique	~A$25-A$50
Self-assessment asthma control questionnaires	Monitoring	Subjective assessment	Clinician's office (in consultation with doctor) or home (tracking changes to treatment remotely)	Works well in exam settings. Consistent at-home application of these methods to self-monitor is subjective and unreliable, especially for children under 8	N/A
Wheezo	Monitoring	Hand-held device and app system	Clinician's office or home setting	Passive, easy to use, consistent reading, cloud-based data storage supports remote patient monitoring	Device cost ~A$299 & SaaS ~A$8 per month

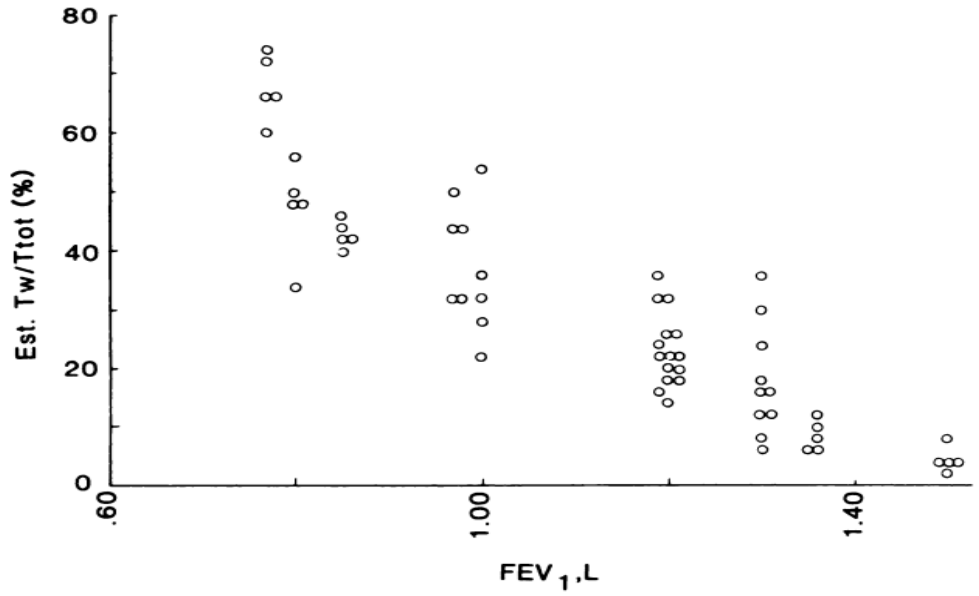
Source: MST Access.

wheezo: A passive, non-invasive, quantitative, easy-to-use, and readily standardised solution

Why monitoring wheeze matters

Monitoring levels of wheeze (a high-pitched sound produced by airflow through an abnormally narrowed or compressed airway), as well as tracking whether the patient is adhering to their prescribed treatment regimen, are vital to improving the effectiveness of respiratory care management and treatments. Studies have found a relationship between characteristics of wheezing and the severity of airway obstruction. Further, studies have found that wheeze is strongly related to a decline over time in forced expiratory volume (FEV), which measures how much air a person can exhale during a forced breath (see Exhibit 5). These correlations suggest a meaningful clinical benefit from monitoring wheeze.

Exhibit 5 – Comparison of FEV_1 to estimated wheeze rate – T_w/T_{tot} (%) (r=0.89, p< 0.001)



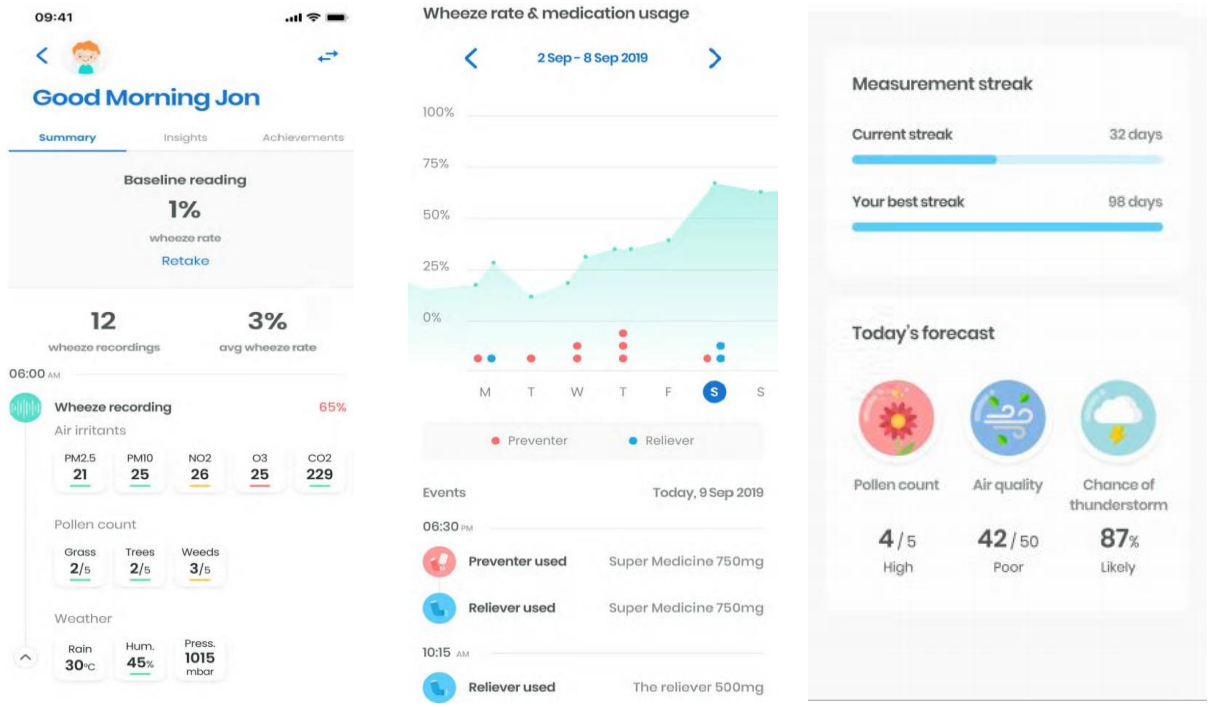
Source: 'Lung sound analysis for continuous evaluation of airflow obstruction in asthma', Baughman & Loudon (CHEST 1985: 88: 364-368).

How the wheezo platform works

Respiri's wheezo detects wheeze based on time-frequency analysis of breath sounds. The wheezo platform (see Exhibit 6) comprises:

- **the wheezo breath sensor device:** a small device that is held against the patient's windpipe to take a reading of their breathing. This takes about 30 seconds. These readings are transferred to the app in real time where they are filtered for ambient sound and digitised.
- **the wheezo eHealth App:** a companion app for iPhone or Android that is paired with the device via Bluetooth. The app is used to:
    - manage recording sessions on the Bluetooth connection, providing feedback on status and progress. After the recording is finished, it is automatically transferred to the app, which calculates and displays a wheeze rate, defined by Respiri as 'the percentage of the recorded breath sounds occupied by wheeze'
    - log information about the patient's symptoms (coughing, wheezing, shortness of breath, wakefulness, etc); medication frequency and amount; and exacerbating triggers. This information is input manually by the user and then synthesised by the app to provide feedback (see Exhibit 6)
    - send local weather alerts about environmental asthma triggers (such as high pollen count), known to exacerbate asthma symptoms for some patients
    - view historical data
    - share data on a one-off basis with another person by sending a code that gives the person one-time access to the patient's data on the wheezo website.
- **a user account stored on a secure cloud server:** this account contains user information, recordings and an asthma diary. Recorded data is transferred to the server once the phone is connected to the internet. The data is collected and stored in line with the company's privacy statement and is held securely to prevent data breaches.

Exhibit 6 – wheezo app allows users to see trends such as wheeze rate over time, relationship with medication use and relevant triggers



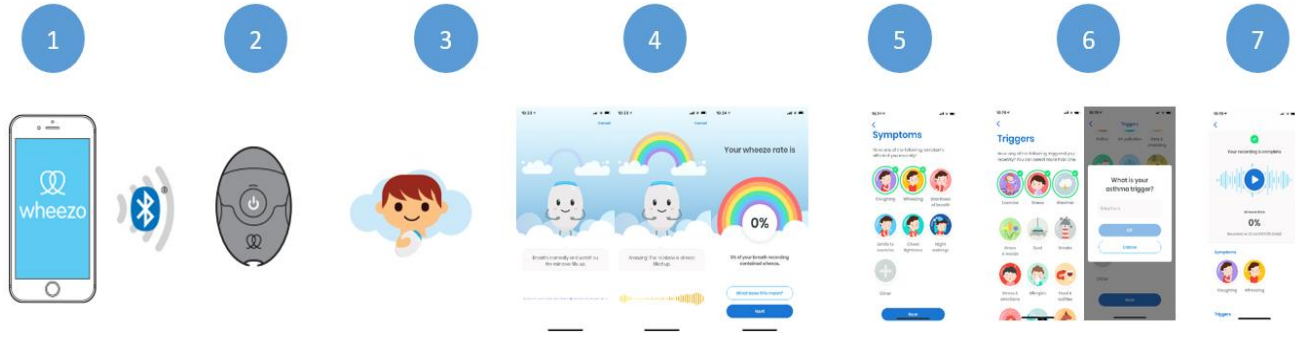
Source: Respiri.

Step-by-step: Using wheezo

Exhibit 7 shows the simple procedure used to take a recording with wheezo. The steps are:

- Choose the app on the phone (Step 1 in Exhibit 7) and pair it with the wheezo device on Bluetooth (2).
- Choose the relevant patient profile (3) on the app (there may be more than one if the user is monitoring asthma for several children, for example).
- Hold the device against the patient's windpipe and click Record on the app (4).
- Instruct the patient to breathe deeply for 30 seconds. The app will show the progress of the recording, which will stop automatically when it is finished. It will then calculate the wheeze rate as a percentage of breathing.
- Enter manual data about the patient's symptoms (5) and triggers (6) experienced at the time of recording.
- View the summary page, which displays the wheeze data generated by the recording, along with the symptom and trigger data (7).

Exhibit 7 – Taking a wheezo recording



Source: Respiri.

The benefits of the wheezo asthma management platform

wheezo provides important benefits to asthma sufferers in monitoring their disease and managing their care plan. Its assessment is:

- **objective:** unlike self-reporting of symptoms, wheezo represents an objective measure of wheezing severity
- **passive:** unlike conventional self-monitoring devices such as the peak flow meter which require patients to exhale, wheezo represents a passive approach, making it simpler to use and generating standardised readings
- **ergonomic and easy to use:** the device's design makes it well suited for chronic monitoring of asthma in children and the elderly
- **integrated:** with the tracking of other triggers by the app, the wheeze itself becomes one parameter out of several, allowing patients and care providers to consider the severity of symptoms in the context of environmental factors.

Validation: Multiple Initiatives Build Clinical Validation and Highlight Subjectivity in Current Monitoring Protocols

Self-monitoring by asthma patients currently relies on the use of peak flow meters, with highly variable outcomes given the subjectivity of this method. The appeal of Respiri's wheezo device and platform as a self-monitoring asthma management ambulatory tool stems from its ability to accurately measure, manage, and monitor chronic asthma passively before an acute attack occurs.

Melbourne study suggests that wheezo performs well compared to gold-standard stethoscope method of detecting wheeze

wheezo assessment similar to physician assessment of chest and trachea in preliminary study results

Preliminary results from a study (not yet peer reviewed or published in a scientific journal) evaluating wheezo's ability to assess the severity of wheeze objectively when compared to the gold standard clinician-based stethoscope measurement of wheeze showed a strong correlation on the all-important dimensions of specificity and sensitivity.

Data from the 56-patient study, conducted at Eastern Health Clinical School (associated with Monash University in Melbourne), was reanalysed using Respiri's new and improved proprietary algorithm (Acoustic Respiratory Monitoring) and was found to perform well in distinguishing wheeze when compared to an assessment of the chest and trachea by a physician. The wheezo device demonstrated substantial agreement with physicians' assessments in detecting true positives (the presence of wheeze: 'sensitivity') and true negatives (the absence of wheeze: 'specificity') in the study.

As such, the results of this analysis represent an important step in the validation of the device and proprietary algorithm given the relatively high degree of accuracy compared to the gold-standard measurement of wheeze. Clinical validation provides evidence-based support for marketing to healthcare professionals.

Possible further refinements could allow wheezo to provide objective severity assessment of wheeze

Notably, the study excluded data from two patients on whom physicians could not reach consensus thereby highlighting the subjective nature of physicians' ratings of wheeze severity. This was addressed in the study design by visually and audibly scoring the breathing recordings. The company thinks this scoring approach could allow standardisation of wheeze severity measurement, thereby adding to wheezo's functionality.

Prior to the COVID-19 pandemic, Respiri had entered into a clinical study agreement with Swinburne University, Melbourne, to examine the measurement of wheeze in the context of small airway function (asthma). The study is examining the correlation of wheeze rates with current standard hospital-/physician-used asthma measures such as Forced Oscillation Technique (FOT) and Multiple Breath Washout (MBW) and was due to be completed by April 2020. This study remains paused at the time of writing due to COVID-19.

wheezo Patient Experiential Program (PEP) – 360-degree feedback from free product trial

Respiri, in partnership with iQVIA, a data science company, has commenced a free product trial, the wheezo Patient Experiential Program (PEP), designed to provide 360-degree feedback on the impact of the wheezo system on the management of asthma. The PEP will run for 6 months and provide asthma patients and doctors with access to the wheezo device and SaaS platform to monitor and log their wheeze, asthma symptoms, and medication usage, and offering the opportunity for their asthma management plans to be digitised.

Respiri aims to enrol 300 asthma patients in the program and 100 medical professionals (general practitioners, pharmacists, and medical specialists). During the program, Respiri will provide asthma patients enrolled in the study with a wheezo device at no cost along with four months' free access to the eHealth App. Data collected in the eHealth App will be will be presented, subject to the patient's permission, to their doctor in the form of detailed reports to inform and adapt the patient's asthma action plan.

Respiri recently entered separate joint development agreements with telehealth service providers Phenix Health (Phenix) and Practice Innovators (PII) to integrate Respiri's wheezo SaaS offering onto their respective platforms. Beyond commercial telehealth opportunities being explored, both partnerships will support recruitment of participants into the PEP study.

Exhibit 8 – wheezo system: an integrated breath sensor device, app and cloud storage that facilitates monitoring and communication among stakeholders (patients, carers, medical professionals)

Source: Respiri.

We view this program as an innovative and useful initiative, as the company will be able to use outcomes to generate several benefits to the business:

- increased product awareness among patients and health care providers
- the provision of data to inform future enhancements
- the ability to assess health economic benefits for future discussions with payors
- information about real-world cases of the wheezo in action to support additional marketing on social media platforms.

BREATHE – UK data research centre partnership builds clinical relevance and brand awareness

In June 2019, Respiri entered an agreement to partner with the University of Edinburgh, Scotland, in a new health data research hub, called BREATHE, one of seven centres of excellence established by the UK government to support development of new therapies, in this case respiratory health. These seven hubs are formal collaborations between the NHS, academic organisations, patients, charities, and industry. BREATHE, in particular, is partnered with a raft of major industry players including Novartis Pharmaceuticals UK, GE Healthcare and the British Lung Foundation.

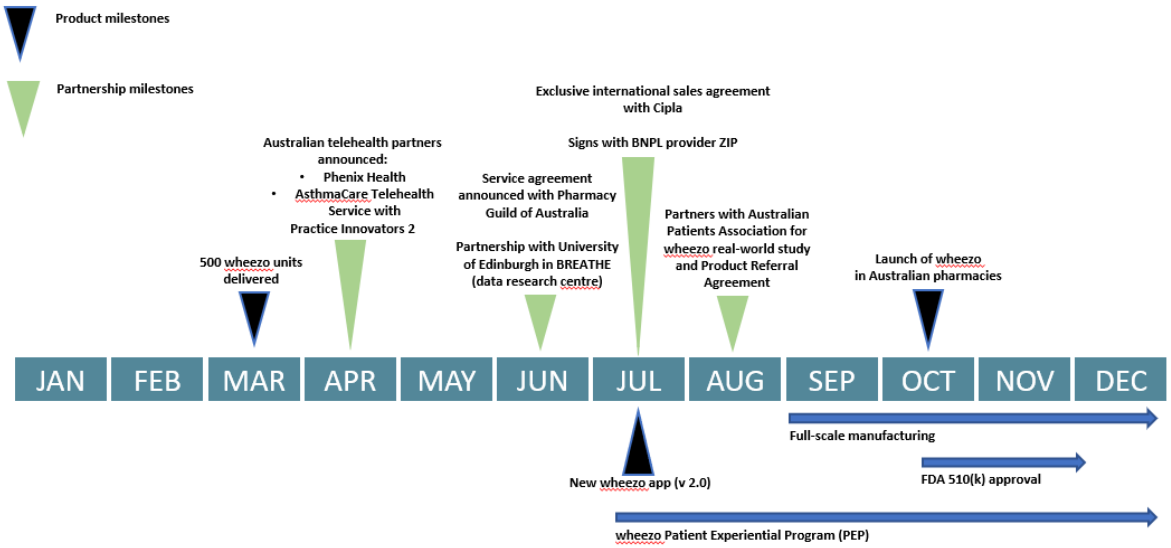
Data collected from Respiri's PEP, currently underway in Australia, will be added to BREATHE's dataset and be used by collaborators to inform ongoing research in respiratory medicine. Respiri also plans to expand PEP to the United Kingdom in conjunction with BREATHE ahead of a potential launch of wheezo in Europe in 2021.

As such, we think the BREATHE research agreement should be positive for clinical validation and building advocacy amongst healthcare stakeholders (potential inclusion into clinical trial programs and increasing product awareness to potential distribution partners) and thereby laying the foundations for UK market entry of wheezo in CY2021.

Commercialisation strategy for wheezo – near- and medium-term goals

CY2020 continues to be a transformative year for Respiri as management executes on multiple fronts.

Exhibit 9 –The steps to commercialisation: milestones in CY2020



Source: Respiri, MST Access.

In August 2020, Respiri partnered with Australian Patients Association (APA) for a patient experiental program, to allow a free trial or experience of the wheezo. It also entered a definitive Product Referral Agreement (PRA) with the APA to provide patient referrals from its database to Respiri, to coincide with the wheezo launch in October 2020. In exchange for referrals directly attributable to APA, Respiri will pay APA a small commission on device sales.

APA is an independent not-for-profit organisation with access to over 1.5 million Australian patients and 15,000 health care practitioners through its sponsors. The organisation provides patients with resources and advocacy support services; as such, it is well-positioned to support product awareness in the Australian market.

Regulatory Approval: TGA and CE Done; FDA to Come

The wheezo has received both TGA approval (Class 1 device - ARTG ID 327306) and CE mark clearance and is therefore approved for sale in Australia and 28 European countries, respectively.

The company has lodged the 510(k) regulatory submission with the FDA for approval to sell into the US market. Under this pathway, Respiri can secure approval for the wheezo device if it can demonstrate that:

- wheezo is substantially equivalent to another device already on the market
- the device does not raise any questions regarding its safety and effectiveness compared to the relevant predicate device.

An approved filing for a previous iteration of the device (iSonea's SonoSentry) provides Respiri with a predicate device pathway. The company expects approval to be secured by the end of CY20.

Manufacturing Capacity: Ample to Meet Expected Demand

All production was transferred to manufacturing partner SRX Australia in late 2019 with the first batch of 500 wheezos delivered in March 2020.

Manufacturing capacity is currently estimated at 4,000 per week which provides ample supply to meet anticipated demand for the Australian commercial roll-out in October 2020. This is consistent with FY21 guidance provided by management which suggests anticipated sales of 5,000–10,000 wheezos per month.

Commercialisation: Near-Term Focus on Australian Market Through Partnerships

The company's near-term commercial strategy is focused on the Australian market and has several related components:

- to build clinical evidence for marketing to healthcare professionals and promote adoption by end users
- to focus on the pharmacy channel for distribution
- to educate pharmacists through online professionally accredited courses delivered through the Pharmacy Guild
- to launch Respiri's own e-commerce platform offering buy now pay later options to patients
- to create strategic alliances with patient groups such as Asthma Australia to partner and go directly to patients
- to develop its new business model, which is structured to generate revenues through sales of the device in the first instance followed by a monthly subscription to the companion app for a minimum period of 6 months but with incentives offered to have patients extend.

Cipla deal is a major step towards commercial success

We see Respiri's main path to market as aligning the wheezo device with respiratory focused pharmaceutical companies. Respiri has signed a deal with a global pharmaceutical company, Cipla, that launches its efforts to penetrate the Australian and other global markets in this way, which we view as a strong start.

In July 2020, Respiri entered an exclusive 5-year distribution (3-year renewal option) agreement with Cipla Australia, a subsidiary of Indian-based Cipla Limited (BSE: 500087, NSE: CIPLA), a global generic pharmaceutical manufacturer with operations in 52 countries and a large portfolio of devices and molecules targeting respiratory disorders.

Cipla Australia has significant sales and market infrastructure with reach to more than 15,000 general practitioners and covering over 80% of the pharmacy market or around 4,000 pharmacies in Australia. Cipla Australia has over 200 registered formulations with the Australian Therapeutics Goods Administration (TGA).

The agreement includes an initial minimum order quantity of 2,000 units upon signing of the agreement with first delivery in October 2020. Initial markets will be Australia and New Zealand with a first right of refusal for Cipla to distribute into other key markets. Product revenues under the agreement will commence from the second half of CY20, with transfer price gross margins expected of 30%–40% according to Respiri.

Market entry: Australia first then planned launch of wheezo globally

Respiri has developed a staggered launch schedule for the wheezo globally. The company plans to launch wheezo in:

- Australia in October 2020
- the UK and EU in 4Q CY2021
- the USA by mid CY2022.

The company plans its initial launch in the Australian market, a country with one of the world's highest asthma rates. With prevalence estimated at around 10% of the population, the target market could be around 2.7 million people. However, current estimates of asthma patients being actively managed with asthma action plans total around 900,000. We think this reflects under-treatment of the condition in the general population and a significant opportunity for an objective monitor such as the wheezo. Further, the Australian launch will provide valuable input and inform Respiri's international growth strategy.

The business model in Australia will generate revenues from two sources:

- **device sales:** upfront sales of the wheezo device with distribution through the pharmacy channel in the first instance supported by Cipla's marketing capabilities
- **SaaS revenues:** ongoing monitoring service charges for access to the eHealth App and cloud-based data analytics and storage facility (Respiri's SaaS platform).

Pricing is currently set at A$299 for the wheezo device and A$8 per month for the SaaS offering. Management will be offering a tiered pricing structure based on bundling of the wheezo device with varying lengths of SaaS contracts. A similar model is expected to be rolled out into the New Zealand market through the Cipla agreement. Purchases of the device or related SaaS subscription charges are not currently covered by Medicare in Australia. However, we expect clinical evidence and health economic benefit data generated by PEP will be valuable inputs to future Medicare submissions. Further, Respiri's agreements with Phenix and PII provide an opportunity to pursue a more telehealth-focused strategy in the medium term which could provide opportunities to bulk-bill through Medicare.

Details around launches into European and the US market at this stage have yet to be finalised. We note, however, that under the agreement, Cipla retains a first right of refusal to distribute into other key markets.

Intellectual Property and History of Technological Development

The key asset: Acoustic Respiratory Monitoring algorithm

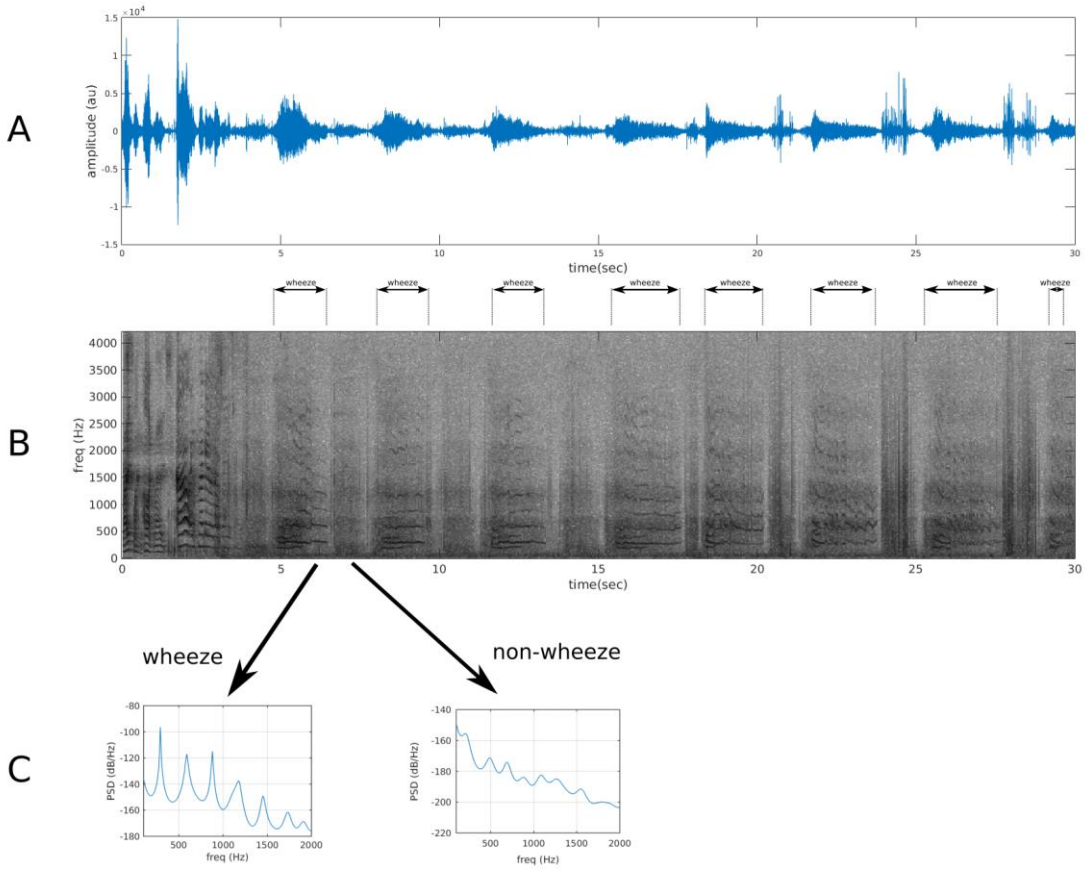
Respiri's most important asset, its proprietary sound processing algorithm called Acoustic Respiratory Monitoring, works with two microphones to capture sound: the first records wheeze, while the second captures ambient sound in order to distinguish the wheeze from other noises.

The algorithm powering this analysis provides several sources of competitive advantage to Respiri:

- **trend analysis:** capturing this longitudinal data allows Respiri to provide trend analysis over time
- **objectivity:** this visual representation of wheeze allows severity to be objectively scored, making monitoring more reliable
- **completeness:** this objective, automated analysis allows Respiri to do comprehensive monitoring and data collection for patients, so health care providers can better assess symptoms and treatment options.

Exhibit 10 shows samples of a sound recording from the wheezo device. Row A shows a rendering of the sounds of 8 breath cycles (inhales and exhales). In Row B, this sound recording is translated into a spectrogram—a visual representation of the various sound frequencies, with darker areas denoting more dominant frequencies. (The X-axis is time, while the Y-axis shows the frequencies from low to high). A brief snippet of the recording (Row C) is broken up into wheeze and non-wheeze sections, showing the difference in the frequencies present in the aggregated sound of wheeze (left) as opposed to non-wheeze (right). Wheeze has characteristic pitches which appear in a particular way in the spectrogram, allowing the algorithm to interpret the presence of wheeze from these sound recordings. The clear presence of specific frequencies in the wheeze is evident when compared with the non-wheeze recording.

Exhibit 10 – Graphical representations of wheeze monitoring algorithm



Source: Respiri.

Protecting IP: patents and patent applications

Respiri has a portfolio of 8 granted patents covering the wheezo apparatus and aspects of cough detection. The earliest to expire (dated February 2021) relates to the patent covering 'method of determining lung condition indicators'. The Acoustic Respiratory Monitoring algorithm is currently the subject of a patent application (see Appendix for the company's portfolio of patents).

Competitive Landscape – Primed for Disruption and Ready for wheezo

The competitive landscape for Respiri's wheezo is relatively homogeneous. The key competitors to the wheezo are spirometers (expensive) and peak flow meters (inexpensive), both of which are manufactured by many pharmaceutical and medical device companies. Although widely used, these approaches require the patient to actively exhale and perform the test in a consistent manner for a meaningful reading of trends and, given the low level of patient compliance, have proved to be suboptimal in managing chronic patients. Further, accurate measures of asthma monitoring in children and the elderly remain difficult in community settings. In contrast, the wheezo is a passive device that is easy to use. Further, with the system priced at A$299 for the device and SaaS at A$8 per month, it is relatively affordable in developed markets, in our opinion, when compared to other less clinically validated health-tech devices.

In May 2020, Japanese health tech conglomerate Omron launched its own wheeze monitor in the form of the 'Wheezescan', priced at around A$270 per device. Unlike the wheezo, the Omron device only detects the presence or lack thereof of wheeze and does not provide a measure of severity.

As such, we see the wheezo as having a competitive advantage given its more sophisticated algorithm which lends itself to a more graduated and standardised approach. From a market perspective, we think the arrival of Omron's Wheezescan validates the clinical approach and should help define and grow the wheeze monitoring market.

Financials - Emerging from a Transition Phase

Since listing in 2004, Respiri has incurred operating losses. This has been largely due to significant investments into research and development and is consistent with the usual pattern for a technology company refining its product offering and strategy over a long period of time.

We think the confluence of multiple technological advances over that time and a strategic reorientation brought in by new management has paved the way for Respiri to finally realise its potential. As such, we view the near-term launch of wheezo as heralding a new and transformational phase for the company, with first meaningful product revenues from FY21.

Respiri is well capitalised with cash of A$3.6m at end-FY20 and distribution partner Cipla carrying the bulk of marketing costs in upcoming launches. The key components of our P&L forecasts for FY21 and FY22 are as follows (see Exhibit 11 for summary financial statements):

Revenues: Our near-term forecasts assume a staged commercial launch of wheezo by distribution partner Cipla in Australia and New Zealand in FY21. As such, our FY21 forecast of device and associated SaaS revenues stands at the high end of management's guidance of A$6m–A$8m, issued on 27 July 2020. Despite Cipla's first right of refusal for rest of world, we have applied a 60% probability to that agreement going ahead in the proposed commercial rollout of wheezo in the United Kingdom, France, Germany, and Italy in FY22. We have not included entry into the US market in our forecasts at this stage, despite Cipla's first right of refusal, pending FDA approval of the wheezo at the time of writing. While Respiri reports interest payments on cash as revenue, we include interest in the financing (net interest) line.

R&D tax credits: Respiri's 'other income' line included R&D tax credits of A$1m and A$2.2m for FY19 and FY20, respectively. We forecast R&D tax credits of A$916K for FY21 and FY22 based on current R&D expense being maintained and include this amount in our total revenue forecasts.

COGS: We assume gross margin on device sales of 40% consistent with Respiri's stated agreement with Cipla. We apply a conservative gross margin of 95% on SaaS revenues to reflect platform fees charged by Apple.

Operating expenses:

- R&D: we forecast R&D spend of ~A$2m in FY21 and remaining flat in FY22
- SG&A: we model annual SG&A expenditure of A$4.8m in FY21 and A$7.8m in FY22 to reflect increased spend in marketing (including in-country wheezo experiential programs) and headcount associated with the European launches
- manufacturing costs captured in capex reflect spend on tooling supplied for assembly of devices.

Tax: we do not expect Respiri to pay tax until FY26 based on our financial projections given accumulated losses on the balance sheet of ~A$115m at 30 June 2020. This does not include entry into the US market at this point.

Exhibit 11 – Summary financial statements

Financial Summary (AUD 000's)	FY19a	FY20a	FY21e	FY22e	FY23e	FY24e
PROFIT & LOSS						
Total Revenue	1,031	2,207	8,664	28,425	79,309	93,901
Operating Costs	-9,501	-9,458	-10,553	-22,833	-44,932	-45,739
EBITDA	-8,475	-7,252	-1,889	5,592	34,377	48,162
EBIT	-8,480	-7,263	-1,903	5,576	34,351	48,119
Tax	0	0	0	0	0	0
NPAT (Reported)	-8,475	-7,261	-1,902	5,579	34,370	48,161
NPAT (Underlying)	-8,475	-7,261	-1,902	5,579	34,370	48,161
Minority Interest	0	0	0	0	0	0
Shares Outstanding (m)	525.9	651.7	651.7	651.7	651.7	651.7
EPS (Underlying) cps	-1.70	-1.27	-0.29	0.86	5.27	7.39
Dividend per share (cps)	0	0	0	0	0	0
BALANCE SHEET						
Current Assets	1,003	4,431	2,513	8,078	42,376	90,416
Cash	307	3,552	1,634	7,199	41,497	89,537
Receivables	162	8	8	8	8	8
Inventory	0	309	309	309	309	309
Other Assets	535	561	561	561	561	561
Non-Current Assets	11	188	204	218	290	411
PP&E	10	188	204	218	290	411
Goodwill	0	0	0	0	0	0
Other Non-current Assets	1	0	0	0	0	0
Current Liabilities	2,576	1,996	1,996	1,996	1,996	1,996
Payables	1,757	1,131	1,131	1,131	1,131	1,131
Short Term Debt	806	717	717	717	717	717
Provisions & Tax	0	0	0	0	0	0
Other financial liabilities	13	148	148	148	148	148
Non-Current Liabilities	0	128	128	128	128	128
Long Term Debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Other financial liabilities	0	128	128	128	128	128
Net Assets	-1,563	2,495	593	6,172	40,542	88,703
Share Capital	106,043	113,695	113,695	113,695	113,695	113,695
Reserves	1,590	4,106	4,106	4,106	4,106	4,106
Retained Earnings	-109,197	-115,306	-117,208	-111,629	-77,259	-29,098
Minority Interests	0	0	0	0	0	0
Total Equity	-1,563	2,495	593	6,172	40,542	88,703
CASH FLOW						
Operating Cash Flow	-6,411	-4,688	-1,889	5,595	34,396	48,204
Working Capital Change	-576	-1,101	807	0	0	0
Maintenance Capex	-3	-13	-30	-30	-98	-163
Expansion Capex	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0
Investing Cash Flow	-3	-13	-30	-30	-98	-163
Equity Issued	3,750	8,532	0	0	0	0
Debt Issued	800	0	0	0	0	0
Dividends	0	0	0	0	0	0
Financing Cash Flow	4,332	7,959	0	0	0	0
Change in Cash Balance	-2,083	3,259	-1,919	5,565	34,298	48,040

Source: Respiri, MST Access.

Valuation

We value Respiri at A$244m, or A$0.37 per share, using DCF methodology and based on:

- a commercial roll-out with distribution partner Cipla in Australia and New Zealand in FY21
- our probability-weighted expectation (we have applied 60%) of Cipla extending its agreement with Respiri for commercial roll-out into the United Kingdom, France, Germany and Italy in FY22.

See Exhibit 12 for details of our DCF valuation.

The US market has not been included in our base-case valuation given the still-pending FDA approval of wheezo, the lack of a distribution partner at time of writing, and the longer-term timeframe on this potential market launch. However, we view this as a source of substantial potential upside to our conservative valuation.

Exhibit 12 – Base-case DCF valuation and key metrics (A$)

	2020	2021	2022	2023	2024	2025
	2020	**2021**	**2022**	**2023**	**2024**	**2025**
EBIT	-7,262,595	-1,902,711	5,575,620	34,350,759	48,119,169	66,615,721
Tax at standard rate	0%	0%	0%	0%	0%	0%
Post-tax EBIT	**-7,262,595**	**-1,902,711**	**5,575,620**	**34,350,759**	**48,119,169**	**66,615,721**
Depreciation	10,380	13,380	16,380	26,193	42,538	59,572
Amortisation	0	0	0	0	0	0
Post-tax cash flow	**-7,252,215**	**-1,889,331**	**5,592,000**	**34,376,952**	**48,161,707**	**66,675,293**
Less capex	-12,863	-30,000	-30,000	-98,127	-163,456	-170,334
Less change in working capital	0	0	0	0	0	0
Provisions/other	0	0	0	0	0	0
Acquisitions/disposals	0	0	0	0	0	0
Free cash flow	**-7,265,078**	**-1,919,331**	**5,562,000**	**34,278,825**	**47,998,251**	**66,504,959**
Discount coefficient	0	1	2	3	4	5
Discounted cash flow	-7,435,732	-1,746,288	4,498,621	24,646,590	30,668,941	37,775,470
Sum of discount streams	145,704,390					
Terminal growth	3.0%					
Future value into perpetuity	298,205,833					
NPV of terminal value	94,003,579					
PV of cash flows	239,707,969					
PLUS: Value of investments	0					
PLUS: Value of tax losses	0					
LESS: Minority interests	0					
LESS: Net debt	2,835,189					
Equity value	242,543,158					
Ordinary shares	**651,714,790**					
Value per share (A$)	**0.37**					
Discount Rate	12.5%					

Source: MST Access.

Key Assumptions in Base-Case DCF

We have used government and industry sources of population data, asthma prevalence and percentage of asthma patients using management plans to inform our modelling of the addressable market in all targeted geographies.

We view asthma patients on management plans as most relevant for wheezo adoption at this point, segmented across two broad population cohorts according to age (0–14 years, 15 and over). Our adult segment in markets outside of Australia and New Zealand uses severe-to-difficult to treat asthmatics which represent 10% of the asthma population according to prevalence.

Our revenue model assumes one-off payment for purchase of the device of A$299 plus ongoing charges for SaaS subscription of A$8 per month. Additionally, we assume a 20% churn in new patients per annum and a further churn

of 20% of patients after a five-year subscription period. Our modelling of the Australian and New Zealand market has market penetration peaking at 25% after 5 years.

Key Assumptions in Bull-Case DCF

Our bull-case scenario also assumes FDA approval of wheezo and applies a 60% probability to US market launch in FY23 under the same distribution terms as the current Cipla agreement. This generates a valuation of ~ A$400m, or A$0.63 per share, for Respiri using DCF methodology and similar key metrics to our base case.

Exhibit 13 shows the key assumptions in our valuation.

Exhibit 13 – Key assumptions for our DCF valuation

Ages 0-14		
	Prevalence	10%
# patients with an asthma management plan		57%
Adults 15 and over *		
	Prevalence	11%
# patients with an asthma management plan		28%
Business metrics		
Lost patient (churn) per year		20%
SaaS contract length and attrition (after 5 years)		20%
Sales (A$)		
wheezo device sales revenue (A$)		299
	Price inflation	0%
	Gross margin	40%
wheezo SaaS revenue per 12 months (A$)		96
	Price inflation	0%
	Gross margin	95%

* **Adults 15 and over** - # patients with asthma management plans in Australia/New Zealand uses 28%. All other markets uses 10% for this cohort to reflect severe and difficult-to-treat adults with asthma.

Source: MST Access.

Sensitivity Analysis

Our base-case valuation of A$0.37 per share incorporates a discount rate of 12.5% and terminal growth rate of 3%. As such, we include a sensitivity matrix to highlight the impact to our valuation of both these key metrics.

Exhibit 14 – Sensitivity matrix: impact of discount rate and terminal growth rate assumptions on Respiri valuation

Terminal growth rate \ Discount rate	0.370	11.0%	11.5%	12.0%	12.5%	13.0%
0%		0.38	0.37	0.35	0.33	0.32
1%		0.40	0.38	0.36	0.34	0.33
2%		0.42	0.40	0.38	0.36	0.34
3%		0.44	0.42	0.39	0.37	0.35
4%		0.47	0.44	0.41	0.39	0.37
5%		0.51	0.47	0.44	0.41	0.39
6%		0.57	0.52	0.48	0.44	0.42

Source: MST Access.

Sensitivities and Key Risks

Product Concentration

Respiri's near term revenues and commercial prospects at this stage are heavily reliant on the success of the wheezo offering. As such, should the wheezo be rendered uncompetitive due to technological advances or aggressive pricing, profitability could be significantly impacted.

Commercial Rollout Requires a Coordinated Effort

A staged commercial roll out of the wheezo commencing with its Australian launch through the Australian pharmacy channel represents a more narrow and disciplined approach compared with previous management and positions the product as clinical grade. Education of pharmacists through accredited professional development courses aligns both point of sale healthcare support with wheezo's target patient market and should support Respiri's SaaS model over the longer term. Commercial risks include disruptions to supply chains, manufacturing production capacity, marketing and sales support provided through the Cipla contract.

Reliance on Cipla Distribution Agreement and Marketing Support

Indian-based Cipla is a global generic pharmaceutical manufacturer with operations in 52 countries and a large portfolio of devices and molecules targeting respiratory disorders. Cipla's initial minimum order of 2,000 wheezos earmarked for sale to general practitioners and into the Australian pharmacy channel heralds Respiri's transition to commercial status. Respiri's exclusive agreement with Cipla has a 5-year term, with a 3-year renewal option for the Australian and New Zealand markets and a first right of refusal for Cipla to distribute into other key markets. As such, Respiri's near-term prospects are highly reliant on the support and promotional support provided by Cipla both in Australia and in other markets.

Adoption, Clinical Validation, and Clinical Trial Delays

Adoption of the wheezo by clinicians will be driven by evidence of its clinical utility in the management of patients with asthma. As such, we think Respiri's experiential program provides a valuable opportunity to demonstrate the product's value proposition and, in combination with the stethoscope trial, build confidence in its role for the management of asthma. Furthermore, and beyond the risk of not meeting objectives of utility, any delays in clinical trials such as that caused by the COVID-19 pandemic at Swinburne could have an indirectly negative impact on this process.

Competition and New Technologies

Explosive growth in mHealth over the past five years has attracted significant levels of early-stage venture capital investment targeting a multitude of applications. Nonetheless, and notwithstanding the recent launch of Omron's Wheezescan, competition in remote asthma monitoring remains low. However, we expect validation of wheeze detection in asthma management will attract new entrants over time. There is also a risk that new technologies in the monitoring of asthma emerge before Respiri has fully realised the commercial potential of the wheezo.

Cybersecurity and Data Privacy

A key aspect of the wheezo's value proposition is continuous patient-directed monitoring of the condition and the storage of personal health data in the cloud for remote access by a healthcare provider. Users may experience concerns surrounding privacy breaches and the loss of data in the event of discontinuation of the service or a change of healthcare provider. In order to mitigate this, the company has reviewed and updated its privacy policies and codified its data breach process.

Intellectual Property, Know-How and Patent Position

A solid patent position represents a significant barrier to entry in medical technology. Although Respiri has a reasonable patent portfolio (Exhibit 15), a provisional patent is scheduled to be lodged for its core algorithms to coincide with its Australian launch in October 2020. The company intends to apply for separate patents as it expands

internationally, on a country-by-country basis. As such, Respiri will be exposed to patent infringement risk and potential litigation costs.

Regulatory Approvals – FDA Approval Expected by End-CY20

Respiri has secured TGA approval and has received CE mark clearance. At this stage, the FDA 510(k) approval remains pending. Previous approval of iSonea's SonoSentry provides a predicate device pathway. Although the two devices have different technological characteristics, evidence demonstrates that the technological characteristics of the wheezo do not raise new or different questions in relation to safety or effectiveness. Although low, there is the risk that regulatory decisions by the FDA may be delayed and thereby slow down plans to launch in the United States.

Reimbursement – Upside Risk Should Health Economic Data Be Supportive

Payor models for the wheezo will vary in different countries. A lack of government reimbursement in Australia and New Zealand represents a hurdle to commercialisation of the wheezo at this point. However, growing evidence of health economic benefits to government (reduced hospital visits, improved compliance with medication and generally lower healthcare costs) could support a case for reimbursement by Medicare. Similarly, reimbursement in the UK and Europe remains contingent on evidence-based utility and health economic benefits.

Subject to FDA approval being granted for the wheezo, expected by end-CY20, Respiri will qualify for reimbursement in the US market. Current CPT codes in the US provide reimbursement for the wheezo device and its SaaS offering to attending physicians of patients for self-monitoring of chronic conditions. Asthma management and the delivery of a monthly report allows the physician to claim reimbursement of US$69–US$102 per month.

Board and Management

Directors

Marjan Mikel, CEO and Managing Director. Mr Mikel is a highly experienced managing director and board member, with a career focused on the healthcare industry from pharmaceuticals and information services and technology to medical devices and sleep disorder solutions. He has held a range of executive and board positions and is currently a non-executive director of several small companies in the medical devices and diagnostics space. Mr Mikel also founded and later sold Healthy Sleep Solutions after collaborating with shareholder and joint venture partner ResMed to develop the business.

Mr Mikel's international experience spans Australia, Europe and Japan. He served as an executive board member for IMS Consulting and Services (Japan, Asia Pacific and AustralAsia/New Zealand), where he developed product and portfolio strategies for pharmaceutical and healthcare clients.

Nicholas Smedley, Executive Chairman. Mr Smedley is an experienced Investment Banker and M&A Advisor, with 14 years' experience at UBS and KPMG. He has worked on M&A transactions in the UK, Hong Kong, China, and Australia with transactions ranging from the A$9bn defence of WMC Resources through to the investment of $65m into Catch.com.au. Mr Smedley currently oversees investments in the property, aged care, technology and medical technology space. Key areas of expertise include M&A, debt structuring, corporate governance and innovation. He holds a Bachelor of Commerce from Monash University.

Dr Thomas Duthy, Non-Executive Director. Dr Duthy has over 15 years of direct financial market and medical device industry experience. Dr Duthy is the Founder and CEO of Nemean Group Pty Ltd, a boutique corporate advisory, investor relations and equity research group based in Adelaide, Australia with a focus on micro to small cap ASX-listed companies. Prior to establishing Nemean Group, he was Global Head of Investor Relations and Corporate Development at Sirtex Medical Limited (ASX: SRX), which was sold for $1.9 billion in late 2018, the largest medical device transaction in Australian corporate history to date. Additionally, he spent 10 years as a leading sector analyst at Taylor Collison Limited, specialising in healthcare and biotechnology companies, with approximately $200 million in equity capital raised during that period for selected companies.

Key Management

Philippe Ludekens, General Manager Commercial. Mr Ludekens has enjoyed a 25+ year career in life sciences, specifically in the pharmaceutical industry, having worked with multiple organisations of varying sizes, cultures and therapeutic interests. Mr Ludekens has a strong commercial background in sales, key account management, marketing and most recently in a commercial operations Senior Director role at Gilead Sciences based in Australia.

Samaneh Sarraf, Chief Research Officer. Ms Sarraf is a biomedical engineer with both academic and practical experience. As an academic, she has published in peer reviewed journals and completed a PhD at the University of Manitoba, Canada. Ms Sarraf has practiced as an engineer in the development of medical devices in the areas of firmware development, electronic circuit design, and medical diagnostic algorithms.

Peter Hildebrandt, Operations Director. Mr Hildebrandt is an MBA-educated internationally experienced business leader with an understanding of large corporations, SME and start-ups. He has a track record of building and growing innovative B2B technology businesses across a range of industrial applications.

Kush Ajam, Senior Manager, Commercial. Ms Ajam is an executive with commercial experience spanning over 20 years in many well-known pharmaceuticals, healthcare and biotechnology companies. More recently, Ms Ajam has been consulting in roles with MSD and Novartis Oncology.

Marc Van Hoof, Chief Technical Officer. Mr Van Hoof has been in the technology industry for 25 years, with experience across Asia Pacific, Europe and the US. He has engineering and technical strategy experience across multinationals as well as niche start-ups and is responsible for overseeing the technology direction for Respiri.

Appendices

Patent Portfolio

Exhibit 15 – Respiri's current patents and pending patent applications in USA and Australia

Title	Case status	Country	Renewal deadline
Apparatus for detecting breath sounds	Application pending	Australia	N/A
Measuring tissue mobility	Registered	USA	No more renewals due
Cough detector	Registered	USA	14-Feb-2024
Cough detector	Registered	USA	08-Jan-2022
Method and apparatus for determining conditions of biological tissues	Registered	USA	No more renewals due
Method and apparatus for determining conditions of biological tissues	Registered	USA	04-Nov-2021
Method and apparatus for determining conditions of biological tissues	Registered	USA	14-Jun-2022
Method of determining lung condition indicators	Registered	USA	27-Feb-2021
Compliance monitoring for asthma inhalers	Registered	USA	19-Feb-2022

Source: Respiri.

Shareholder Register and Institutional Support

Exhibit 16 –Top 20 shareholders in Respiri

Ordinary Shareholders	Number	Percentage
INVESTMENT HOLDINGS PTY LTD <INVESTMENT HOLDINGS UNIT A/C>	72,008,027	11.03%
NETWEALTH INVESTMENTS LIMITED <SUPER SERVICES A/C>	14,700,101	2.25%
NETWEALTH INVESTMENTS LIMITED <SUPER SERVICES A/C>	14,306,181	2.19%
MR PETER KARL BRAUN	13,654,325	2.09%
P & A MIHAILOU PTY LTD <MIHAILOU FAMILY A/C>	8,506,184	1.23%
HSBC CUSTODY NOMINEES (Australia) LIMITED	7,820,614	1.20%
LUHOPI PTY LTD <THE RIBOT FAMILY STTLMT A/C>	7,533,614	1.15%
DR BERLINDA DEBORAH JACKSON	7,269,429	1.11%
COONAN FAMILY SUPERANNUATION FUND PTY LTD <COONAN FAMILY S/F A/C>	7,000,000	1.07%
EQUITAS NOMINEES PTY LIMITED <PB-600812 A/C>	6,642,449	1.02%
ATLANTIS INVESTIGATIONS PTY LIMITED <LARAYNE PORTER S/FUND A/C>	6,105,078	0.94%
MALLAMANDA PTY LTD <MALLAMANDA A/C>	6,087,203	0.93%
TORRES INVESTMENTS	5,712,035	0.87%
MR ROSS SPENCE BAYNES	5,500,000	0.84%
MR WILLIAM JOHN RICHARDS & MRS MARY MITCHELL RICHARDS <RICHARDS FAMILY S/F A/C>	5,490,000	0.84%
MR GARY RONALD HEATH + MRS MARY MITCHELL RICHARDS (RICHARDS FAMILY S/FUND A/C>	5,201,819	0.80%
MORE INVESTMENT GROUP PTY LTD <BEAR SUPERFUND A/C>	5,151,818	0.79%
CLEMWELL PTY LTD <THE WELLS FAMILY A/C>	5,035,678	0.77%
BNP PARIBAS NOMINEES PTY LTD HUB24 CUSTODIAL SERV LTD	4,998,877	0.77%
MRS MARY MITCHELL RICHARDS + MS KERRY MITCHELL MCCARTHY <EST ELEANOR MARY RYLANCE A/C>	4,985,000	0.77%

Source: Respiri.

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