



Digital healthcare for respiratory disease

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Corporate Overview
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ResApp Health highlights

Leading digital health company developing the world's first clinically-validated, regulatory-approved respiratory disease point-of-care diagnostic test and management tools for smartphones



Huge global market opportunity with 700M+ doctor visits annually for respiratory disease¹



Compelling clinical evidence with positive results from three double-blind, prospective clinical studies



Regulatory approved in Europe (CE Mark) with submissions underway for Australia and the US



Broad portfolio of products including chronic disease management, sleep apnoea screening, and handheld and wearable devices



Well-advanced global strategy for commercialisation focused on telehealth and emergency department use

Company overview

Capital Structure (ASX:RAP)

Market Cap. as of 13 September 2019	AU\$136M
Share Price as of 13 September 2019	AU\$0.195
Shares on Issue	696M
Performance Shares ¹	93.75M
Incentive Options ²	57.55M
Cash Balance as of 30 June 2019	AU\$5.5M + AU\$1.8M expected R&D rebate from FY19

1. Issued on achieving AU\$20M of annual revenue, or on an acquisition, before 14 July 2020
2. Issued to directors, staff and scientific advisory board with various vesting conditions

Board of Directors

Roger Aston, Ph.D. Non-Executive Chairman
(Chairman of PharmAust and Immuron, Non-Exec. Director of Oncosil Medical, formerly CEO of Mayne Pharma, Cambridge Antibody, co-founder of pSivida)

Tony Keating, Ph.D. Managing Director and CEO
(formerly Director, Commercial Engagement at UniQuest, engineering management roles with Exa Corporation)

Nathan Buzza Non-Executive Director
(formerly founder of Commtech Wireless, EVP Azure Healthcare and Exec. Director of Alcidion)

Chris Ntoumenopoulos Non-Executive Director
(Managing Director at Twenty 1 Corporate, Non-Exec. Director at Race Oncology, formerly at Citigroup, Indian Ocean Capital and CPS Capital)

Substantial Shareholders*

Fidelity International: 8.74%

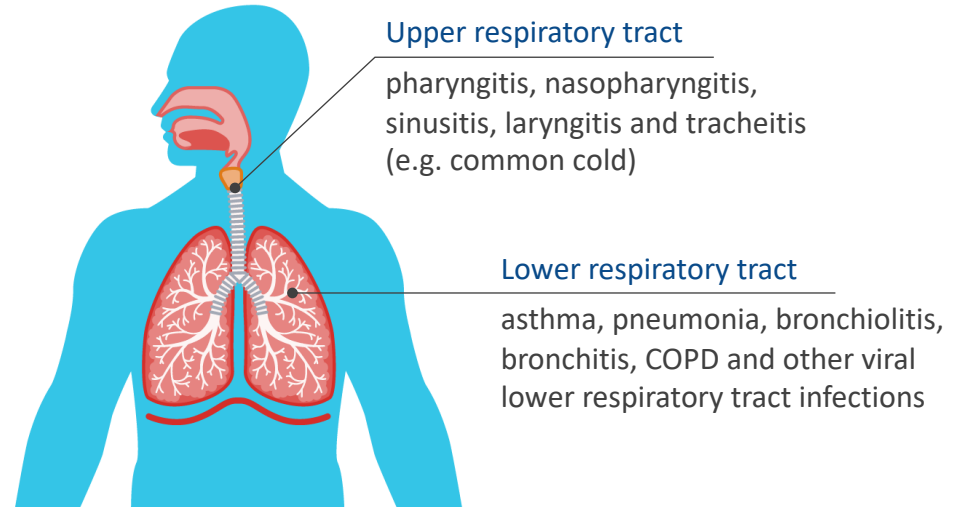
Freeman Road: 6.25%

Ian Francis Reynolds: 5.30%

* Number of shares based on Substantial Shareholder Notices lodged by the respective holders

Diagnosis of respiratory disease is the most common outcome from a visit to the doctor¹

- 700M+ doctor visits p.a. for respiratory disease²
- Most common reasons for hospital admission³
 - Bronchiolitis (infants)
 - Asthma and pneumonia (children)
 - Pneumonia and COPD (older adults)
- Large proportion of US direct hospital costs⁴
 - US\$10.6B p.a. for pneumonia
 - US\$5.7B p.a. for COPD
- High prevalence and growth in Asia
 - 100M adults in China with COPD⁵



Diagnosed today using stethoscope, imaging (x-ray, CT), spirometry, blood and/or sputum tests

→ **Time consuming, expensive, subjective and not very accurate**

1. Ambulatory care visits (office and emergency department), National Ambulatory Medical Care Survey 2015

2. ResApp estimate based on OECD doctor consultations per capita data (<http://stats.oecd.org>), and assuming 10% of visits (US prevalence based on NAMCS 2015 data) are for respiratory disease.

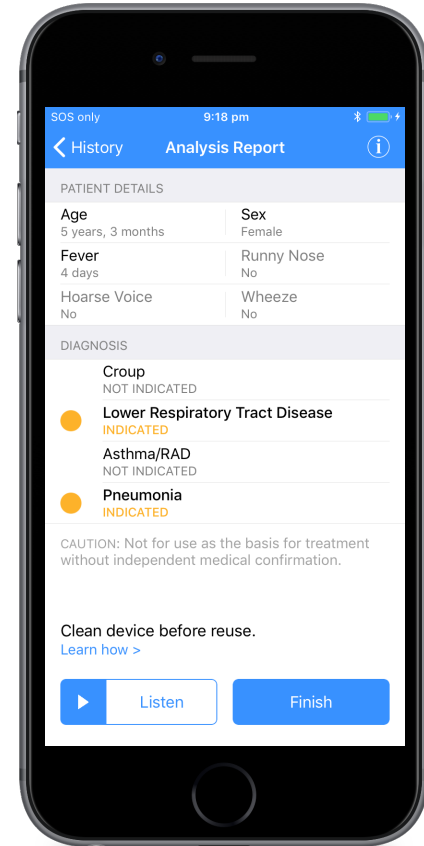
3. HCUP Statistical Brief #148 (2010)

4. HCUP Statistical Brief #160 (2013)

5. Fang, L, et al., Chronic obstructive pulmonary disease in China: a nationwide prevalence study, *The Lancet Respiratory Medicine* 6(6), 2018

Easy to use, instant diagnosis using only a smartphone

- Machine learning technology developed by Associate Professor Abeyratne at The University of Queensland
 - Uses signatures in cough sounds to differentially diagnose respiratory disease instantly
 - Able to automatically improve performance and learn new diseases from new clinical datasets
- Uses the built-in microphone in modern smartphones
 - No additional hardware/accessories required
 - Real-time on-device analysis, no connectivity/cloud needed
- Underpinned by growing patent portfolio and data assets
 - Core patent granted in US, Australia and Japan¹, in national phase examination in Europe, China, South Korea; four additional patent applications
 - Proprietary data set, over 6,000 patients' cough and breathing sounds and matching clinical signs, symptoms and diagnosis



Compelling clinical evidence from multiple prospective clinical studies in Australia and the US

Paediatric

Breathe Easy

ANZCTR: ACTRN12618001521213

585 patient, double-blind, prospective study at two Australian hospitals complete

83-97% PPA and 81-91% NPA compared to clinical diagnosis for lower respiratory tract disease, croup, bronchiolitis, pneumonia and asthma/RAD

Results published in *Respiratory Research*¹

SMARTCOUGH-C-2

ClinicalTrials.gov: NCT03392363

1,470 patient, double-blind, prospective study at MGH, Cleveland Clinic and Texas Children's Hospital complete

73-77% PPA and 70-86% NPA compared to clinical diagnosis for upper respiratory tract disease, LRTD, croup and asthma/RAD

Pneumonia and bronchiolitis <70% PPA and NPA due to clinical practice differences between US and Australia

Presented at ATS 2019, Dallas, TX

Adult

Breathe Easy

ANZCTR: ACTRN12618001521213

979 patient, double-blind prospective study complete

86-88% PPA and 87-89% NPA compared to clinical diagnosis for lower respiratory tract disease and pneumonia

83-89% PPA and 84-91% NPA compared to clinical diagnosis for acute exacerbations of COPD and asthma

86% PPA and 85% NPA for population screening of COPD

To be presented at ERS 2019, Spain and APSR 2019, Vietnam

Well-advanced multi-faceted strategy for commercialisation



Paediatric use for five indications approved in Europe (CE Mark) and submitted to TGA. De Novo for three key indications submitted to US FDA. CE Mark submission for adult use before end of CY2019.



Key Opinion Leader (KOL) engagement including key relationships with clinicians at top-tier Australian and US hospitals. Newly-formed industry advisory board.



Presentations at key medical meetings and conferences with presentation at ATS 2019 (USA) and upcoming presentations at the ERS 2019 (Spain) and APSR 2019 (Vietnam).



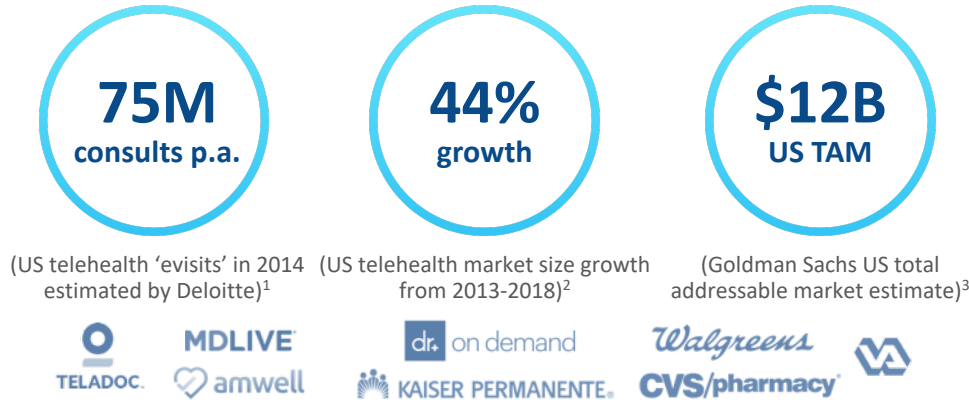
Publications and health-economic models including publication of Australian paediatric data in *Respiratory Research* and LOI with German hospital group for pilot to measure health-economic outcomes.



Proactive, outbound business development including calls to telehealth providers and healthcare systems, targeted digital marketing and participation in industry events.

Unique opportunity in telehealth, one of the fastest growing areas in healthcare globally

- Rapid growth in telehealth for US primary care



Accelerating growth in Europe and APAC:

- Online consultations in China estimated by Frost and Sullivan to reach 4 billion p.a. by 2026⁴
- Ping An Good Doctor performs 656,000 online consults per day⁵



- 30-50% of telehealth consults are for respiratory disease^{6,7}
- Today there is **no ability to use a stethoscope** and **no accurate remote diagnosis tools available**
- ResApp's test can be delivered anywhere, anytime while retaining a clinician's input

1. Deloitte, eVisits: the 21st century housecall (August 2014)
2. IBISWorld, Telehealth Services Industry in the US (2018)
3. Goldman Sachs Equity Research, The Digital Revolution Comes to US Healthcare (June 2015)
4. Frost and Sullivan Research, commissioned by Ping An via http://www.pahtg.com/media/1144/e_1833ipo.pdf
5. Ping An Good Doctor 2019 Interim Results
6. Uscher-Pines L and Mehrotra A, Health Affairs 33(2), 2014
7. UnitedHealthcare Presentation (<https://www.mobihealthnews.com/content/health-insurance-payer-related-digital-health-news-q2-2016>)

Targeting multiple market segments

	Telehealth	Clinical use	Developing world	Direct to consumer
Market size	<p>700M doctor visits in OECD for respiratory disease p.a.¹</p> <ul style="list-style-type: none"> 22.5M respiratory-related US telehealth consults p.a.² 	<ul style="list-style-type: none"> 13.4M US ED visits for respiratory disease p.a.³ (~4.6M for children) 	<ul style="list-style-type: none"> 1M child deaths due to pneumonia p.a.⁴ 151M cases of pneumonia in developing countries p.a.⁴ 	<ul style="list-style-type: none"> 728M iPhone users⁵ 2B+ Android users⁵ mHealth app market expected to grow to \$31B by end of 2020⁶
Value proposition	<ul style="list-style-type: none"> ✓ Only remote clinically-accurate diagnostic tool available ✓ Easily integrated into existing platforms 	<ul style="list-style-type: none"> ✓ Reduce costs (<\$10 vs >\$200 for x-ray) ✓ Reduce time (x-ray adds ~30 mins, cultures can take days) 	<ul style="list-style-type: none"> ✓ Low cost, accurate & fast ✓ Usable by non-medical personnel ✓ Integrates into IMCI framework 	<ul style="list-style-type: none"> ✓ Convenient ✓ Low cost ✓ Consumer empowerment
Commercial strategy	Partner with telehealth providers	Initial use in emergency departments (ED), extending to regular clinics	Partner with leading international aid agencies to equip field personnel	Initial strategy based around disease management and screening
Revenue model	\$5-\$10 per test fee from telehealth providers	\$5-\$10 per test fee from healthcare payors	annual subscription from aid agencies	download and subscription fees direct from consumers

Broad product portfolio

Proof-of-concept

Large-scale studies

Pivotal studies

Regulatory submission

Commercialisation

Next Milestone

Acute respiratory disease diagnosis

Paediatric

CE Mark approved in Aug 2019

De Novo submitted to US FDA Apr 2019

Adult

Adult CE submission planned for CY2019

Chronic respiratory disease management

COPD

CE submission for acute exacerbation identification planned for CY2019 (part of Adult CE submission)

Asthma

Other indications

Obstructive sleep apnoea

At-home study results expected in Q3 CY2019

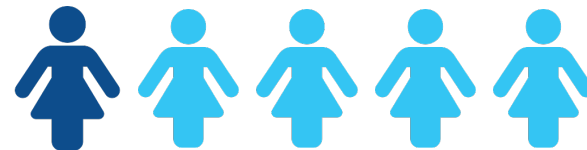
Warfighter*

Improving chronic respiratory disease management

- Estimated 339M people globally have asthma¹
 - \$80B+ p.a. US economic burden (2013)²
 - Patient adherence to asthma medications is generally very poor
- 251M cases of COPD in 2016³
 - Emphysema and chronic bronchitis, primarily caused by smoking
 - 3.17M people died of COPD in 2015, 5% of all deaths globally³



1 in 7 children has asthma⁴



1 in 5 adults over 45 has COPD⁵

- Opportunity to measure the severity of asthma and COPD, without the cost of additional hardware or the need to carry an extra device
 - Identified exacerbations in adult COPD and asthma patients at >83% PPA and >84% NPA (prospective study)
 - Demonstrated 94% accuracy in identifying paediatric asthma patients who require additional treatment (proof-of-concept study)

1. The Global Asthma Report 2018 (Global Asthma Network), citing the 2016 Global Burden of Disease Study
2. US CDC, <https://www.ajmc.com/newsroom/cdc-study-puts-economic-burden-of-asthma-at-more-than-80-billion-per-year>
3. WHO, citing the 2015 Global Burden of Disease Study, [http://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-\(copd\)](http://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd))
4. International Study of Asthma and Allergies in Childhood via 2014 Global Asthma Report, <http://www.globalasthmareport.org/2014/priority/ncd.php>
5. COPD Foundation, <https://www.copdfoundation.org/About-Us/Press-Room/Press-Releases/Article/965/COPD-Foundation-Goes-Orange-for-National-COPD-Awareness-Month-in-November.aspx>

Sleep apnoea is the most common sleep breathing disorder¹ and is significantly underdiagnosed

- Studies have found that more than 3 in 10 men, and nearly 2 in 10 women have sleep apnoea²
- Estimated 80% of adults with sleep apnoea are undiagnosed³
- Linked to heart disease, stroke and type 2 diabetes⁴
- Major barriers to diagnosis:

Sleep laboratory
polysomnography (PSG)

Requires referral
Long wait times
\$600-\$5,000 per test
Uncomfortable & unfamiliar environment

Home sleep testing
(HST)

Requires referral & training
Up to 18% failure rate⁵
\$150-\$500 per test
Uncomfortable



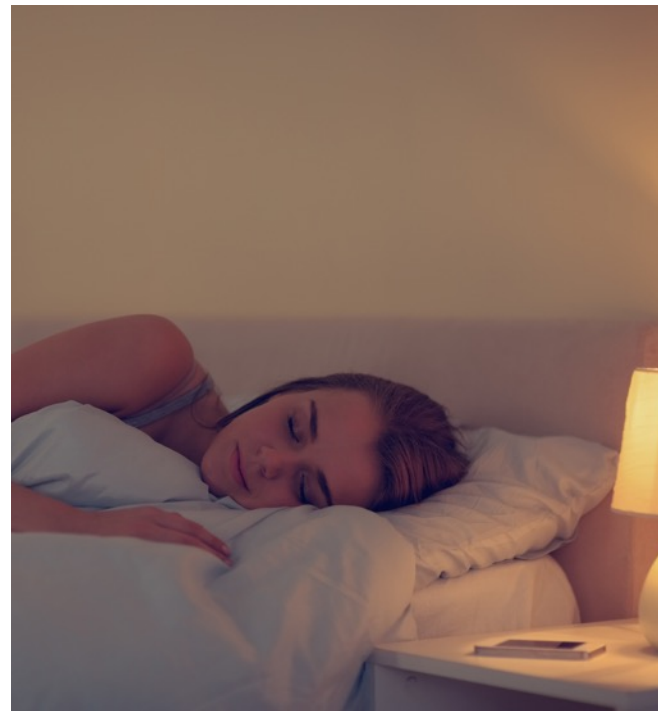
1. American Thoracic Society, Breathing in America: Diseases, Progress and Hope, <https://www.thoracic.org/patients/patient-resources/breathing-in-america/resources/chapter-23-sleep-disordered-breathing.pdf>
2. Peppard et al., Increasing prevalence of sleep-disordered breathing in adults, *Am J Epidemiol* 177(9), 2013
3. Frost & Sullivan, Hidden Health Crisis Costing America Billions, <https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf>
4. American Academy of Sleep Medicine, Severe obstructive sleep apnea hurts hearts, <https://aasm.org/severe-obstructive-sleep-apnea-hurts-hearts/>
5. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients, American Academy of Sleep Medicine

Convenient, at-home screening of obstructive sleep apnoea

- Using only a smartphone placed on the bedside table
 - Smartphone app uses audio signatures in overnight breathing and snoring sounds to identify sleep apnoea
- Excellent results from a 582 patient, double-blind, prospective clinical study compared to simultaneous in-laboratory PSG:

	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
AHI \geq 5/h (Mild)	0.90 (0.87-0.93)	84% (80-87%)	83% (69-92%)
AHI \geq 15/h (Moderate)	0.88 (0.85-0.91)	80% (75-84%)	80% (73-85%)
AHI \geq 30/h (Severe)	0.90 (0.87-0.93)	82% (76-87%)	82% (77-86%)

- Currently recruiting patients in an at-home study with simultaneous in-home PSG, results expected Q3 CY2019



Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical data from three double-blind, prospective clinical studies in adults and children
- First regulatory approval secured and well understood regulatory pathway
 - Approved for use in Europe (CE Mark) for acute diagnosis of childhood respiratory disease
 - Submitted De Novo to US FDA for acute diagnosis of childhood respiratory disease in April 2019
 - TGA submission made for paediatric use, CE Technical File for adult use to be submitted in CY2019
- Multi-faceted commercial strategy with clear, near-term opportunities in telehealth and emergency departments
- Broadened product portfolio
 - Chronic respiratory disease (asthma, COPD) management
 - Excellent results from double-blind, prospective obstructive sleep apnoea screening study
 - Actively working with Lockheed Martin on US DARPA-funded WASH research program
 - Handheld and wearable device development underway with prototypes expected in early CY2020

Detailed clinical study data

Australian double-blind, prospective paediatric clinical study

Breathe Easy Paediatric Study

(ANZCTR: ACTRN12618001521213)

- Double-blind, prospective study of 585 patients, aged 29 days to 12 years, presenting with signs and symptoms of respiratory disease at two Australian hospital sites
- Comparison to clinical diagnosis (including CXR, lab tests) formed by clinical adjudication committee

Porter, P et al., A prospective multicentre study testing the diagnostic accuracy of an automated cough sound centred analytic system for the identification of common respiratory disorders in children, *Respiratory Research* 20(18), 2019

	Patients ¹		Positive Percent Agreement ² (95% CI)	Negative Percent Agreement ² (95% CI)
	Y	N		
Lower respiratory tract disease	419	154	83% (79-86%)	82% (75-88%)
Asthma/reactive airways disease	149	381	97% (92-99%)	91% (88-94%)
Croup	68	500	88% (78-95%)	86% (82-89%)
Pneumonia	60	509	87% (75-94%)	85% (82-88%)
Primary upper respiratory tract disease	89	482	79% (69-87%)	80% (76-83%)
Bronchiolitis (patients aged < 2 years old)	131	26	84% (77-90%)	81% (61-93%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).

2. As per FDA guidance, positive and negative percent agreement (rather than sensitivity and specificity) are used when a new test is compared to a non-reference standard such as a clinical diagnosis.

US double-blind, prospective paediatric clinical study

SMARTCOUGH-C-2 Study

(ClinicalTrials.gov: NCT03392363)

- Double-blind, prospective study of 1,470 patients, aged 29 days to 12 years, presenting with signs and symptoms of respiratory disease at three US hospital sites (MGH, Cleveland Clinic and TCH)
- Comparison to clinical diagnosis (including CXR, lab tests) formed by clinical adjudication committee
- Pneumonia and bronchiolitis results <70% due to observed clinical diagnosis differences between US and Australia

Moschovis PP et al., A cough analysis smartphone application for diagnosis of acute respiratory illness in children, ATS 2019

	Patients ¹		Positive Percent Agreement ² (95% CI)	Negative Percent Agreement ² (95% CI)
	Y	N		
Lower respiratory tract disease	412	775	73% (68-77%)	77% (74-80%)
Asthma/reactive airways disease	176	886	71% (64-78%)	86% (83-88%)
Asthma/reactive airways disease (children aged > 2years old)	177	779	75% (68-82%)	84% (82-87%)
Croup	29	1207	74% (53-87%)	74% (71-76%)
Primary upper respiratory tract disease	722	453	76% (73-79%)	70% (66-74%)
Pneumonia (Focal)	52	1027	67% (53-80%)	64% (61-67%)
Pneumonia	100	1150	63% (53-72%)	62% (59-65%)
Bronchiolitis (children aged < 2 years old)	42	89	76% (60-88%)	60% (59-70%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).

2. As per FDA guidance, positive and negative percent agreement (rather than sensitivity and specificity) are used when a new test is compared to a non-reference standard such as a clinical diagnosis.

Australian double-blind, prospective adult clinical study

Breathe Easy Adult Study (ANZCTR: ACTRN12618001521213)

- Double-blind, prospective study of 979 subjects
- Comparison to clinical diagnosis (including CXR, CT, spirometry, lab tests) by expert clinicians

	Subjects ¹		Positive Percent Agreement ² (95% CI)	Negative Percent Agreement ² (95% CI)
	Y	N		
Lower respiratory tract disease	358	163	88% (84-91%)	89% (83-93%)
Pneumonia	159	163	86% (80-91%)	87% (80-91%)
Asthma exacerbation	46	73	89% (76-96%)	84% (73-91%)
COPD	117	381	86% (79-92%)	85% (81-89%)
COPD exacerbation	86	78	83% (73-90%)	91% (82-96%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).

2. As per FDA guidance, positive and negative percent agreement (rather than sensitivity and specificity) are used when a new test is compared to a non-reference standard such as a clinical diagnosis.