



Digital healthcare for respiratory disease

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Investor Presentation
April 2018

ASX: RAP

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Digital healthcare for respiratory disease

- Developing the world's first clinically-tested, regulatory-cleared respiratory disease diagnostic test and management tools for smartphones
 - No additional hardware needed
- Huge global market, 700 million+ doctor visits annually for respiratory disease¹
- Compelling clinical evidence with 2,600+ patients enrolled in Australian pediatric and adult studies
- Well-funded to execute our ongoing clinical strategy
 - Execution issues identified in first US pivotal study – not an accurate evaluation
 - Revised US pediatric study now recruiting, on-track for completion mid CY2018
 - Recruiting in prospective Australian studies, results expected H1 CY2018
- Broadening product portfolio
 - Chronic respiratory disease management, at-home screening of obstructive sleep apnea

Company overview

Capital Structure (ASX:RAP)

Market Cap.	AU\$99M
Share Price as of 6 April 2018	AU\$0.15
Shares on Issue	659M
Performance Shares ¹	93.75M
Options ²	6.37M
Incentive Options ³	51.45M
Cash Balance as of 31 December 2017	AU\$5.8M

1. Issued on achieving AU\$20M of annual revenue or on an acquisition
2. 4.5M, exercise price of 28c, expire 29/4/19; 1.87M, exercise price of 30c, expire 29/4/19
3. Issued to directors, staff and scientific advisory board

Board of Directors

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

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

Mr Nathan Buzza Non-Executive Director
(formerly founder of Commtech Wireless, EVP Azure Healthcare and non-executive director of Alcidion)

Mr 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: 9.23%

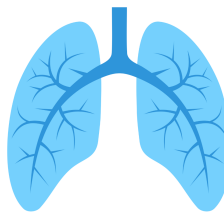
Freeman Road: 6.84%

Ian Francis Reynolds: 5.60%

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



- **700M+** doctor visits p.a. globally¹ for respiratory disease
 - **125M** in US² (10% of all visits)
 - **6-8M** in Australia³
- Most common reasons for hospital admission⁴
 - Bronchiolitis (infants)
 - Asthma and pneumonia (children)
- **US\$10.5B p.a. direct US hospital costs** for pneumonia⁵
- High prevalence and growth in Asia



Acute conditions

URTI, influenza, bronchitis, bronchiolitis, pneumonia, pertussis, croup, reactive airways disease

Chronic conditions

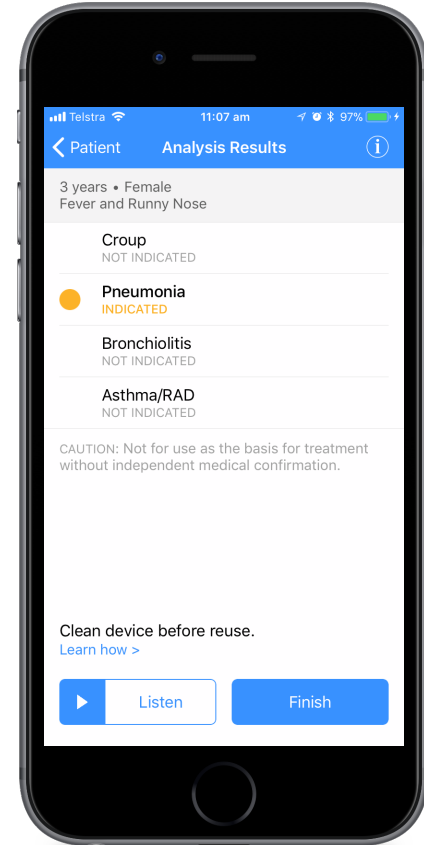
asthma, COPD, cystic fibrosis, bronchiectasis

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

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

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 instantly differentially diagnose respiratory disease
 - 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
- Growing patent portfolio and data assets
 - Core patent in national phase examination in US, Australia, Europe, China, Japan, South Korea; three patent applications
 - Proprietary data set, over 3,800 patients' (including US SMARTCOUGH-C data) cough and breathing sounds and matching clinical signs, symptoms and diagnosis



Verified by compelling pediatric clinical evidence

2013 Pediatric Proof-of-Concept Study

Sardijto Hospital, Indonesia - 91 patients

- Funded by the Bill & Melinda Gates Foundation
- **Achieved >90% accuracy for diagnosis of pneumonia and asthma vs pneumonia**

Breathe-Easy Pediatric Study (2015-)

Joondalup Health Campus and Princess Margaret

Hospital, Perth Australia

1,127 patients (continuing)

- Latest analysis (announced 22/6/17) optimised to match design of US SMARTCOUGH-C study
- Comparison to clinical diagnosis (incl. CXR, lab tests)
- **Achieved 90-100% PPA and 89-96% NPA for URTI, croup, LRTD, asthma and bronchiolitis**
- **Achieved 89% PPA and 79% NPA for pneumonia**

2013 Pediatric Proof-of-Concept

	Sensitivity	Specificity	Accuracy
Pneumonia vs. <i>all respiratory</i>	94%	100%	96%
Asthma vs. <i>pneumonia</i>	100%	80%	90%

Published in peer-review publications: Abeyratne et al., Annals of Biomedical Engineering (2013) and Kosashi et al., IEEE Transactions in Biomedical Engineering (2015)

Breathe-Easy Pediatric Study

(population of patients with broad respiratory symptoms)

	Positive Percent Agreement	Negative Percent Agreement
Primary Upper Respiratory Tract Infection (n=53)	92% (95%CI, 82-98)	89% (95%CI, 86-91)
Croup (n=57)	100% (95%CI, 94-100)	96% (95%CI, 94-97)
Lower Respiratory Tract Disease (n=492)	90% (95%CI, 87-93)	92% (95%CI, 86-96)
Asthma/Reactive Airways Disease (n=234)	92% (95%CI, 88-95)	89% (95%CI, 85-92)
Bronchiolitis (n=101)	95% (95%CI, 89-98)	94% (95%CI, 92-96)
Pneumonia (n=123)	89% (95%CI, 82-94)	79% (95%CI, 75-83)

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.

Building strong clinical evidence in adults

Breathe-Easy Adult Study (2015-)

Joondalup Health Campus, Perth Australia and
Wesley Hospital, Brisbane Australia
1,387 adult patients (continuing)

- Latest analysis targeted intended use populations to prepare for pivotal studies
- **Achieved high levels of accuracy in diagnosis of pneumonia and acute asthma**
- **Diagnosis of COPD and chronic asthma compared to the gold standard of LFT**

Breathe-Easy Adult Study

*(compared to clinical diagnosis,
population of patients with
broad respiratory symptoms)*

	Positive Percent Agreement	Negative Percent Agreement
Community-acquired pneumonia (n=360)	90% (95%CI, 86-93)	88% (95%CI, 83-92)
Acute asthma (n=54)	91% (95%CI, 80-97)	88% (95%CI, 85-91)

Breathe-Easy Adult Study

*(compared to lung function
testing, population of patients
referred to lung function testing)*

	Sensitivity	Specificity
COPD (n=41)	89% (95%CI, 74-96)	87% (95%CI, 79-92)
Chronic asthma (n=34)	87% (95%CI, 73-97)	90% (95%CI, 83-95)

Achieving breakthrough performance in diagnosis

- Lower respiratory tract disease diagnosis
 - Effective treatment needs identification of lower respiratory tract involvement
 - Correctly detected lower respiratory tract involvement in 97% of cases initially “missed” by experienced clinicians using a stethoscope
- Cause of pneumonia diagnosis

“We need faster, less-expensive diagnostic tests for doctors to accurately diagnose the cause of pneumonia so they can effectively treat it” US CDC (2015)¹

 - Incorrect diagnosis leads to unnecessary and ineffective antibiotic use
 - Identifying the cause today is time consuming, costly and only available in tertiary hospitals
 - Preliminary results demonstrated separation of bacterial and atypical from viral pneumonia with 89%-90% accuracy

Unique opportunity to deploy alongside telehealth, one of the fastest growing trends in healthcare

- US telehealth is large, and growing rapidly
- Provides benefits across the healthcare system: payors, patients and healthcare providers

75M

consults p.a.

(US telehealth 'evisits' in 2014
estimated by Deloitte)¹

56%

growth

(Growth rate until 2018
estimated by IHS)²

US\$12B

US TAM

(Goldman Sachs US total
addressable market estimate)³



MDLIVE



CVS/pharmacy



- 30-50% of telehealth consults are for respiratory disease⁴
 - 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. IHS, World Market for Telehealth (2014)

3. Goldman Sachs Equity Research, The Digital Revolution Comes to US Healthcare (June 2015)

4. Uscher-Pines and Mehrotra (Health Affairs, 2014) and UnitedHealthcare Presentation

Pursuing a truly global telehealth opportunity

- Significant growth in telehealth in Europe and Australia



- Plan to file for CE Mark in CY2018
- Huge potential in Asia Pacific where there are over 1 billion smartphone users¹
 - High prevalence of respiratory disease and nationwide shortage of doctors in China²
 - Chinese mobile online medical consultation examples:



Chunyuyisheng
(Spring Rain Doctors)

92M active users
229 questions per minute

Raised \$183M in 2016



Ping An Haoyisheng
(Good Doctor)

192.8M registered users
370,000 online consultations per day

Listing on HKEX in 2018³
Raised US\$500M in 2016

- Active discussions in all regions

Targeting multiple market segments

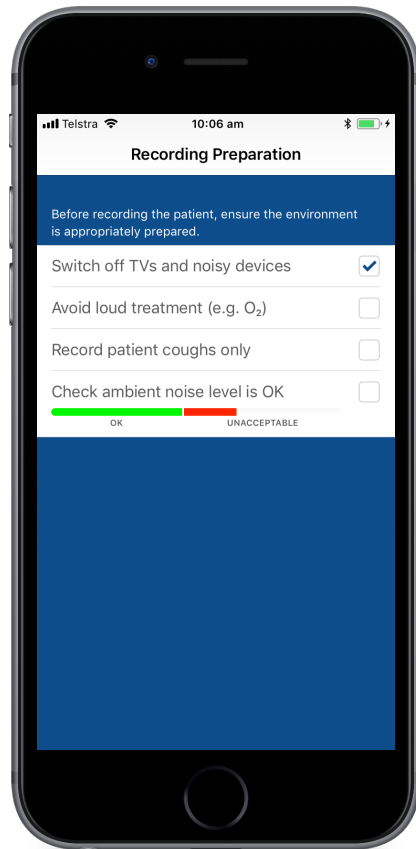
	Telehealth	Clinical use	Developing world	Direct to consumer
Market size	<p>700M doctor visits in OECD for respiratory disease p.a.¹</p> <ul style="list-style-type: none"> • 22.5M respiratory-related US telehealth consults p.a. • 13.4M US ED visits for respiratory disease p.a.¹ (~4.6M for children) 		<ul style="list-style-type: none"> • 1M child deaths due to pneumonia p.a.³ • 151M cases of pneumonia in developing countries p.a.³ 	<ul style="list-style-type: none"> • 400M iPhone users⁴ • 1.6B Android users⁴ • mHealth app market expected to grow to \$25B by end of 2017⁵
Value proposition	<ul style="list-style-type: none"> ✓ The 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"> ✓ Convenience ✓ Low cost ✓ Consumer empowerment
Commercial strategy	Partner with telehealth providers to reach 10s of millions of patients	Initial use in emergency departments (ED), extending to regular clinics	Partner with leading international aid agencies to equip field personnel	Direct to consumer via app stores to target growth in consumer-led health
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 per test fee direct from consumers

SMARTCOUGH-C study

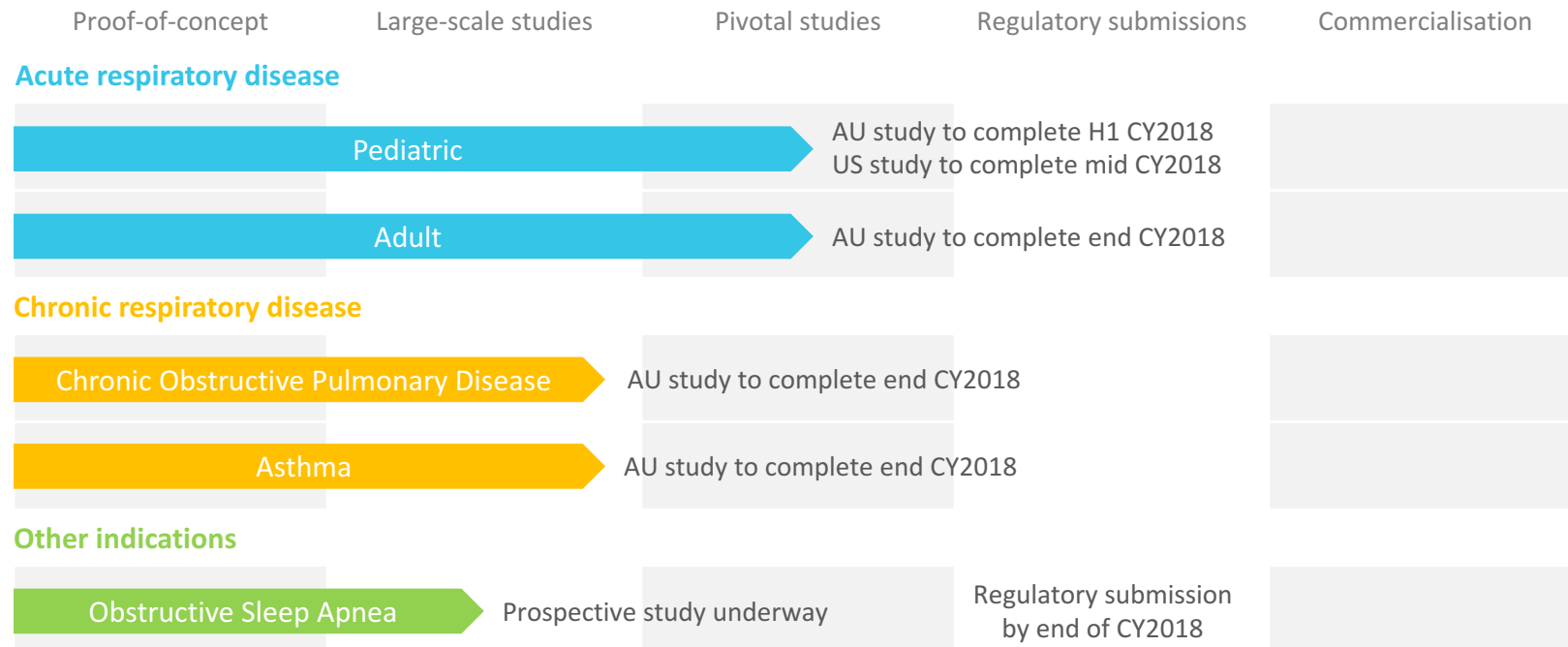
- Prospective, multi-site, double-blind US study with endpoints of URTI, bronchiolitis, asthma/reactive airways disease, pneumonia and lower respiratory tract involvement
 - Top-tier US hospitals: Massachusetts General Hospital, Cleveland Clinic & Texas Children's Hospital
 - Recruited 1,245 patients aged 29 days to 12 years (December 2017 – June 2017)
 - Details on www.clinicaltrials.gov (NCT0973282)
- Top-line analysis showed predefined endpoints not met
- **Study execution issues identified as skewing top-line results**
 - Patients treated before cough recording made (particular impact on croup and asthma/RAD)
 - Poor audio recording quality (non-patient coughs, background noise and machine noise interference)
 - Material variance in final clinical diagnoses

A clear path forward

- Revised US pediatric study, SMARTCOUGH-C-2 underway
 - Details on www.clinicaltrials.gov (NCT03392363)
 - Recruiting up to 1,667 patients aged 29 days to 12 years
 - Same recruitment sites at SMARTCOUGH-C
 - Upgraded recording app and training, on-site data verification
 - Centralised, independent clinical adjudication
 - **640 patients recruited as of 9th of March 2018**
 - **Audio QA showing high quality audio, on-track for completion in mid CY2018**
- Broadened pediatric strategy with prospective, double-blind Australian study underway to support CE and TGA filings
- Prospective, double-blind Australian adult clinical study underway (US adult studies planned)



Broadening product portfolio



Improving chronic respiratory disease management

- 334M people have asthma¹
 - 17.7M in US², 30M in Europe³, 2.3M in Australia⁴
 - \$30B+ p.a. US economic burden²
 - Patient adherence to asthma medications is generally very poor
- 65M people have moderate to severe COPD⁵
 - Emphysema and chronic bronchitis, primarily caused by smoking
 - 3M+ people died of COPD in 2012, 6% of all deaths globally⁵
- Opportunity to measure the severity of asthma and COPD, without the cost of additional hardware or the need to carry an extra device
 - Demonstrated 94% accuracy in identifying asthma patients who require additional treatment
 - Identified infective exacerbations in COPD patients at 91% (95% CI, 84-96) PPA and 90% (95% CI, 80-96) NPA



1 in 7 children has asthma⁶



1 in 5 adults over 45 has COPD⁷

Sleep apnea is the most common sleep breathing disorder and is significantly underdiagnosed

- More than 3 in 10 men, and nearly 2 in 10 women have sleep apnea¹
- 80% with moderate or severe sleep apnea are undiagnosed²
- Untreated, sleep apnea has been linked to heart disease, stroke and type 2 diabetes
- 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 rate
\$150-\$500 per test
Uncomfortable



Convenient, at-home screening of obstructive sleep apnea

- Replace the HST device with a smartphone on the bedside table
- Easy to use and comfortable, no cables
- Software-only, simple app download
 - Uses audio signatures in overnight breathing and snoring sounds to identify sleep apnea
- Proof-of-concept clinical study
 - Compared to simultaneous, in-laboratory PSG
 - 731 patients, 62% male, mean age of 53 years (range: 18-87), mean ahi of 24 (range: 0-196)
 - **86% sensitivity, 83% specificity, 0.91 AUC ROC**
- Prospective study underway with regulatory submission planned by end of CY2018



Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical evidence from Australian studies of 2,600+ patients
- Multiple clinical programs underway
 - **Revised US pediatric clinical study recruiting well, on-track to complete mid CY2018**
 - **Australian prospective pediatric and adult studies recruiting, expecting pediatric results in H1 CY2018**
- Well understood regulatory pathway
 - Held US FDA Pre-Submission meeting in Q1 CY2016, confirmed *de novo* regulatory pathway strategy
 - FDA submission following US pediatric study completion
 - CE (Europe) and TGA (Australia) submissions following Australian prospective study completion
- Broadened product portfolio
 - Chronic respiratory disease (asthma, COPD) management
 - **At-home screening of obstructive sleep apnea, regulatory submission by end of CY2018**