



*Digital healthcare for respiratory disease*

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ASX: RAP

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All amounts in Australian dollars unless stated otherwise.

# 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 disease<sup>1</sup>
  - Unique opportunity to integrate into **telehealth** providers' existing platforms
  - Strong demand also seen within clinics, emergency rooms and outpatient facilities
- Compelling clinical evidence with 2,600+ patients enrolled in Australian pediatric and adult studies
- Execution issues identified in the first US SMARTCOUGH-C pivotal study
  - **Not an accurate nor reliable evaluation of the ResApp technology**
- Well-funded to execute our ongoing clinical strategy
  - Follow-up revised US pediatric clinical study to begin this US winter
  - Prospective data from Australian pediatric clinical study to be used for CE/TGA submissions
  - Adult clinical studies for FDA/CE/TGA submissions being finalised

# Company overview

## Capital Structure (ASX:RAP)

<b>Market Cap.</b>	<b>\$54M</b>
Share Price as of 8 September 2017	\$0.082
Shares on Issue	659M
Performance Shares <sup>1</sup>	93.75M
Options <sup>2</sup>	6.37M
Incentive Options <sup>3</sup>	46.35M
<b>Cash Balance<sup>4</sup></b> as of 30 June 2017	<b>\$8.6M</b>

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
4. Does not include a \$516k R&D tax incentive cash refund received 21/8/17

## 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 Brian Leedman

Executive Director and VP

(Co-founder of Imugene and Oncosil Medical, formerly VP, IR at pSivida, former Chair of AusBiotech-WA)

### 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

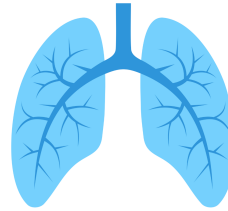
Fidelity International: 9.23%

Freeman Road: 6.84%

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



- **700M+** doctor visits p.a. globally<sup>1</sup> for respiratory disease
  - **125M** in US<sup>2</sup> (10% of all visits)
  - **6-8M** in Australia<sup>3</sup>
- Most common reasons for hospital admission<sup>4</sup>
  - Bronchiolitis (infants)
  - Asthma and pneumonia (children)
- **US\$10.5B p.a. direct US hospital costs** for pneumonia<sup>5</sup>
- High prevalence and growth in Asia



## **Acute conditions**

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

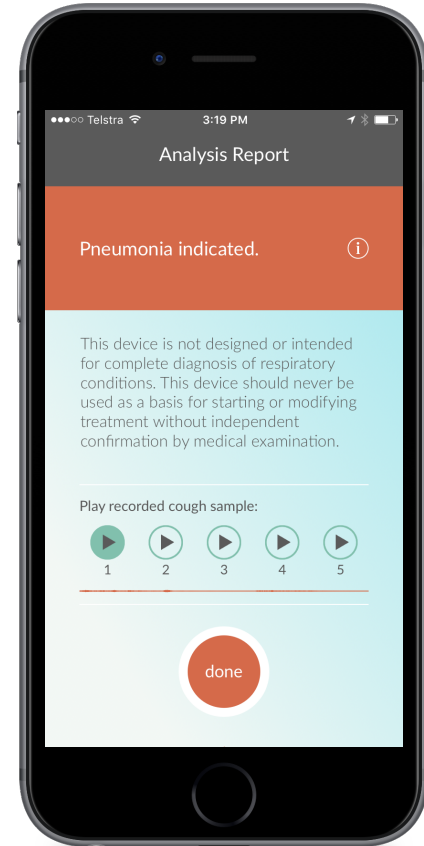
## **Chronic conditions**

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 Udantha 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 build-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 and South Korea, two additional patent applications filed
  - 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

- Latest analysis (announced 22/6/17) optimised to match design of US SMARTCOUGH-C study
- Comparison to clinical diagnosis (incl. CXR, lab tests) made using US case definitions
- **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
<b>Pneumonia vs. all respiratory</b>	<b>94%</b>	<b>100%</b>	96%
<b>Asthma vs. pneumonia</b>	<b>100%</b>	<b>80%</b>	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 (disease vs all respiratory)

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

- **Achieved high levels of accuracy in diagnosis of asthma, COPD, URTI and pneumonia**
- Additional results expected Q4 2017

### Breathe-Easy Adult Study Preliminary Results

	Sensitivity	Specificity	Accuracy
<b>COPD vs. no respiratory</b>	<b>100%</b>	<b>96-100%</b>	98-100%
<b>Asthma vs. no respiratory</b>	<b>91%</b>	<b>91-93%</b>	91-92%
<b>Pneumonia vs. no respiratory</b>	<b>97-100%</b>	<b>100%</b>	98-100%
<b>URTI vs. no respiratory</b>	<b>100%</b>	<b>100%</b>	100%
<b>Asthma or COPD vs. no respiratory</b>	<b>91-93%</b>	<b>91-93%</b>	91-93%
<b>Asthma vs. COPD</b>	<b>93%</b>	<b>96%</b>	94%
<b>Pneumonia vs. Asthma</b>	<b>92%</b>	<b>81%</b>	88%
<b>Pneumonia vs. COPD</b>	<b>92%</b>	<b>92%</b>	92%



# 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)<sup>1</sup>

- 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% and 90% accuracy**

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

- US telehealth is already 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)<sup>1</sup>

**56%**

growth

(Growth rate until 2018 estimated by IHS)<sup>2</sup>

**US\$12B**

US TAM

(Goldman Sachs US total addressable market estimate)<sup>3</sup>



MDLIVE



CVS/pharmacy



- 30-50% of telehealth consults for respiratory disease<sup>4</sup>
  - 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 21<sup>st</sup> 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 opportunity

- Significant growth in telehealth in Europe and Australia



- **Plan to file for CE Mark in 2018**
- Huge potential in Asia Pacific where there are over 1 billion smartphone users<sup>1</sup>
  - High prevalence of respiratory disease and nationwide shortage of doctors in China<sup>2</sup>
  - Chinese mobile online medical consultation examples:



Chunyu Yisheng

92M active users  
229 questions per minute



Ping An Haoyisheng

25M active users  
95,000 appointments per day

- **Active partnership 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.<sup>1</sup></p> <ul style="list-style-type: none"> <li>• 22.5M respiratory-related US telehealth consults p.a.</li> </ul>		<ul style="list-style-type: none"> <li>• 1M child deaths due to pneumonia p.a.<sup>3</sup></li> <li>• 151M cases of pneumonia in developing countries p.a.<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>• 400M iPhone users<sup>4</sup></li> <li>• 1.6B Android users<sup>4</sup></li> <li>• mHealth app market expected to grow to \$25B by end of 2017<sup>5</sup></li> </ul>
Value proposition	<ul style="list-style-type: none"> <li>✓ The only remote clinically-accurate diagnostic tool available</li> <li>✓ Easily integrated into existing platforms</li> </ul>	<ul style="list-style-type: none"> <li>✓ Reduce costs (&lt;\$10 vs &gt;\$200 for x-ray)</li> <li>✓ Reduce time (x-ray adds ~30 mins, cultures can take days)</li> </ul>	<ul style="list-style-type: none"> <li>✓ Low cost, accurate &amp; fast</li> <li>✓ Usable by non-medical personnel</li> <li>✓ Integrates into IMCI framework</li> </ul>	<ul style="list-style-type: none"> <li>✓ Convenience</li> <li>✓ Low cost</li> <li>✓ Consumer empowerment</li> </ul>
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	<b>\$5-\$10 per test fee</b> from telehealth providers	<b>\$5-\$10 per test fee</b> from healthcare payors	<b>annual subscription</b> from aid agencies	<b>download and per test fee</b> direct from consumers

# Improving chronic respiratory disease management

- 334M people have asthma<sup>1</sup>
  - 17.7M in US<sup>2</sup>, 30M in Europe<sup>3</sup>, 2.3M in Australia<sup>4</sup>
  - \$30B+ p.a. US economic burden<sup>2</sup>
  - Patient adherence to asthma medications is generally very poor
- 65M people have moderate to severe COPD<sup>5</sup>
  - Emphysema and chronic bronchitis, primarily caused by smoking
  - 3M+ people died of COPD in 2012, 6% of all deaths globally<sup>5</sup>
- High prevalence of asthma and COPD in China
- 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



**1 in 7 children has asthma<sup>6</sup>**



**1 in 5 adults over 45 has COPD<sup>7</sup>**

# SMARTCOUGH-C study

- Prospective, multi-site, double-blind study with endpoints of URTI, bronchiolitis, asthma/reactive airways disease, pneumonia and lower respiratory tract involvement
- Clinical adjudication used as a comparator
- Top-tier US hospitals: Massachusetts General Hospital, Cleveland Clinic & Texas Children's Hospital
- Details on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT0973282)
  
- 1,245 patients enrolled from December 2016 - June 2017
- Preliminary top-line analysis shows predefined endpoints are unlikely to be met
  - Although excellent results for bronchiolitis, 80% PPA (95% CI 66%-91%), 95% NPA (95% CI 94%-97%)
- **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 (background noise and interference)
  - Material variance in final diagnoses

# A clear path forward

- Enhance clinical study expertise via additions to scientific advisory board
- Conduct robust US pediatric clinical study this US winter
  - Fully supported and revised by the principal investigators at all hospital sites
  - Significantly upgraded clinical study team training and data verification regularly onsite
  - Improved audio recording smartphone app
  - Improved filtering to reduce impact of electrical interference
  - Improved clinical adjudication to reduce subjectivity
- Broaden pediatric strategy with Australian study reconfigured to support CE and TGA filings
- Conduct US and Australian adult clinical studies to support adult regulatory submissions

# Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical evidence from Australian studies
  - High accuracy from multiple adult and pediatric clinical studies, over 2,600 patients enrolled and analysed to date
  - Breakthrough results: Detecting lower respiratory tract involvement which may be missed by auscultation and diagnosing the cause of pneumonia (viral, bacterial or atypical)
- Well understood US regulatory pathway
  - Held US FDA Pre-Submission meeting in Q1 2016, confirmed *de novo* regulatory pathway strategy
  - **First FDA *de novo* submission targeted following US pediatric study completion in 2018**
- Clear path forward
  - Run revised US pediatric clinical study this US winter
  - Reconfigure Australian pediatric clinical study to support CE and TGA filings
  - Finalize design of adult clinical studies for FDA/CE/TGA submissions