



*Digital healthcare for respiratory disease*

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Australia-China Biotech Invest

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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, 700M+ 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 1,800+ patients enrolled in pediatric and adult studies
- Successful Pre-Submission meeting held with US FDA, targeting FDA submission in 2Q2017
- Pediatric US FDA registration study now enrolling at leading US hospitals
- Strong balance sheet with AU\$12M cash

# Company overview

## Capital Structure (ASX:RAP)

Market Cap.	AU\$214M
Share Price as of 17 March 2017	AU\$0.325
Shares on Issue <sup>1</sup>	659M
Performance Shares <sup>2</sup>	93.75M
Options <sup>3</sup>	6.37M
Incentive Options <sup>4</sup>	46.85M
Cash Balance as of 31 December 2016	AU\$12.1M

1. Includes 62.4M escrowed shares (until 14/7/17)
2. Issued on achieving AU\$20M of annual revenue or on an acquisition
3. 4.5M, exercise price of 28c, expire 29/4/19; 1.87M, exercise price of 30c, expire 29/4/19
4. Issued to directors, staff and scientific advisory board

## Board of Directors

Dr Roger Aston	Non-Executive Chairman
(Chairman of Oncosil Medical Ltd, formerly CEO of Mayne Pharma, Cambridge Antibody, co-founder of pSivida Corp.)	
Dr Tony Keating	Managing Director and CEO
(formerly Director, Commercial Engagement of UniQuest, engineering management roles with Exa Corporation)	
Mr Brian Leedman	Executive Director and VP
(Non-Exec. Director of Alcidion Ltd, co-founder of Imugene Ltd and Oncosil Medical Ltd and formerly VP, IR at pSivida Corp, former Chair of AusBiotech-WA)	
Mr Chris Ntoumenopoulos	Non-Executive Director
(Managing Director at Twenty 1 Corporate, Non-Executive Director at Race Oncology, formerly at Citigroup, Indian Ocean Capital and CPS Capital)	

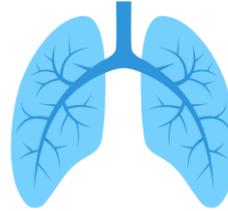
## Substantial Shareholders

Fidelity International: 7.18%  
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>
- **US\$10.5B p.a. US hospital costs** for pneumonia<sup>4</sup>
- High prevalence and growth in Asia



## Acute conditions

URTIs, influenza, bronchitis, bronchiolitis, pneumonia, pertussis, croup

## Chronic Conditions

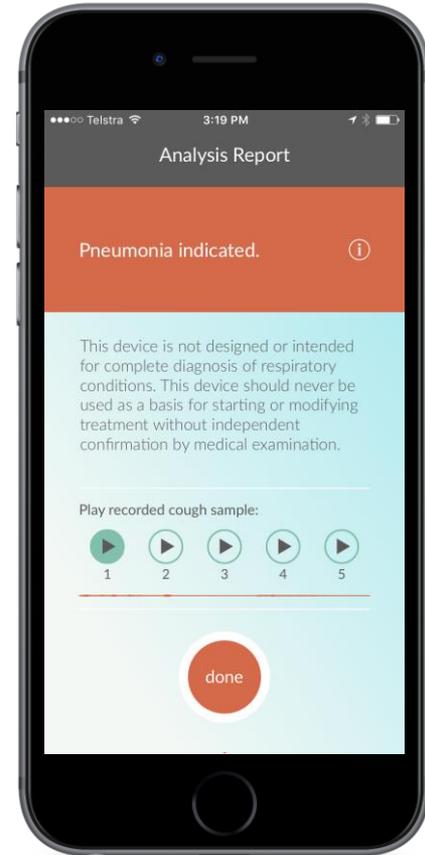
Asthma, COPD, cystic fibrosis, bronchiectasis

Currently diagnosed using stethoscope, imaging (x-ray, CT), blood and/or sputum tests  
→ **Time consuming, expensive and not very accurate**

**Fast, accurate differential diagnosis is the key to better clinical and economic outcomes**

# Easy to use, instant diagnosis using only a smartphone

- Exclusive worldwide license to machine learning technology developed by Associate Professor Udantha Abeyratne at The University of Queensland
- Uses signatures in cough sounds to diagnose disease
- Initial development funded by The Gates Foundation to reduce the 1M child deaths p.a. due to pneumonia in the developing world
- Patent application filed in US, Australia, Europe, China, Japan and South Korea
- Uses the microphones in today's smartphones  
→ **No additional hardware required**



# Verified by compelling pediatric clinical evidence

## Breathe-Easy Pediatric Study

Joondalup Health Campus and Princess Margaret Hospital  
976 patients aged 0 to 12 years

- Achieved high levels of accuracy for differential diagnosis of common childhood respiratory diseases
- Correctly detected lower respiratory tract involvement in 97% of cases initially “missed” by experienced clinicians using a stethoscope
- Preliminary results demonstrated separation of bacterial and atypical from viral pneumonia with 89% and 90% accuracy

Additional results expected 1H2017

Breathe-Easy Study Pediatric Results	Sensitivity	Specificity	Accuracy
<b>Pneumonia vs. no respiratory</b>	100%	95%	<b>97%</b>
<b>Asthma vs. no respiratory</b>	97%	92%	<b>95%</b>
<b>Bronchiolitis vs. no respiratory</b>	100%	100%	<b>100%</b>
<b>Croup vs. no respiratory</b>	94%	100%	<b>99%</b>
<b>URTI vs. no respiratory</b>	100%	95%	<b>96%</b>
<b>Pneumonia, croup or bronchiolitis vs. URTI<sup>4</sup></b>	89-100%	90-95%	<b>89-98%</b>
<b>Differential diagnosis of pneumonia, croup, URTI and bronchiolitis</b>	91-99%	89-98%	<b>89-98%</b>

# Building strong clinical evidence in adults

## Breathe-Easy Adult Study

Joondalup Health Campus and Wesley Hospital

772 patients aged over 12 years

- **Achieved high levels of accuracy in differential diagnosis of asthma, COPD and pneumonia**

Additional results expected 2H2017

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

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

- US telehealth is already large, and growing rapidly
- Telehealth benefits all: 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>



- 30-50% of telehealth consults for respiratory disease<sup>4</sup>, no accurate remote diagnosis available
- **ResApp's test can be delivered anywhere, anytime while retaining a clinician's input**

# Pursuing a truly global opportunity

- Significant growth in telehealth in Europe and Australia



- Plan to file for CE Mark in 2H2017

- 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 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

1. Forrester Research

2. "Dearth of Doctors in China Said to Put Children's Health at Risk, CaixinOnline, <http://english.caixin.com/2016-01-21/100902234.html>

# Targeting multiple market segments

	Telehealth	Clinical use	Developing world	Direct to consumer
<b>Market size</b>	<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>• 13.4M US ED visits for respiratory disease p.a.<sup>1</sup> (~4.6M for children)</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>
<b>Value proposition</b>	<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>
<b>Commercial strategy</b>	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
<b>Revenue model</b>	B2B per test fee (<\$10) from telehealth providers	B2B per test fee (<\$10) from healthcare payors	B2B annual subscription from aid agencies	B2C download and per test fee direct from consumers

# Pivotal milestones leading up to first FDA clearance

## 2H2016

- ✓ Clinical collaborations for asthma and COPD management
- ✓ Additional Australian adult study results
- ✓ Start field evaluation with humanitarian org.
- ✓ Start SMARTCOUGH-C, pivotal US pediatric study

## 1H2017

- ✓ Expanded partnership with Mass. General Hospital
- Additional Australian pediatric study results
- Primary data from SMARTCOUGH-C
- File *de novo* premarket submission with FDA for lead product (pediatric)

## 2H2017

- File for CE Mark in Europe for lead product (pediatric)
- Additional Australian adult study results
- Start pivotal US adult clinical study
- FDA clearance for lead ResApp product (pediatric)

## SMARTCOUGH-C study

Prospective, multi-site, double-blind study with primary endpoints of diagnosis of childhood pneumonia.

Secondary endpoints of diagnosis of URTI, croup, bronchiolitis, asthma/reactive airways disease and lower respiratory tract involvement

Up to 1,111 patients aged 29 days - 12 years

Three US sites:

1. Massachusetts General Hospital
2. Cleveland Clinic
3. Texas Children's Hospital

Details on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02973282)

First patient enrolled in December 2016

All sites actively recruiting

# Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical evidence
  - Very high accuracy from multiple adult and paediatric clinical studies, over 1,800 patients enrolled 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)
- Clear US regulatory pathway
  - Held successful US FDA Pre-Submission meeting in 1Q2016
  - Confirmed *de novo* regulatory pathway as Class II Medical Device with FDA submission targeted for 2Q2017
  - Commenced pivotal US clinical study, SMARTCOUGH-C, at top-tier hospitals to support *de novo* submission
- US market entry in 2017
  - Launch via US telehealth partner to reach millions of patients quickly
  - Potential European, Australian and Asian market entry in parallel to US
  - Deployment to low resource areas via partnerships with humanitarian organisations