



Digital healthcare for respiratory disease
呼吸系统疾病的数字健康服务

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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
开发世界首个经临床测试的，监管无障碍的智能手机呼吸疾病诊断和管理工具
 - **No additional hardware** needed 无需加装额外硬件
- Huge global market, 700M+ doctor visits annually for respiratory disease¹
 - 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 pediatric and adult studies
- Pediatric US FDA registration study underway at top-tier US hospitals
 - **Target recruitment numbers for all disease endpoints have been reached**
 - **Top-line results expected in July 2017**
- FDA *de novo* submission planned for 3Q2017

Company overview

Capital Structure (ASX:RAP)

Market Cap.	\$231M
Share Price as of 26 May 2017	\$0.35
Shares on Issue ¹	659M
Performance Shares ²	93.75M
Options ³	6.37M
Incentive Options ⁴	46.35M
Cash Balance as of 31 March 2017	\$10.3M

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 at 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)	

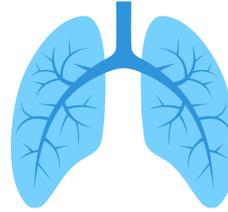
Substantial Shareholders

Fidelity International: 8.22%
Freeman Road: 6.84%

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
- **US\$10.5B p.a. US hospital costs** for pneumonia⁴
- High prevalence and growth in Asia



Acute conditions

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

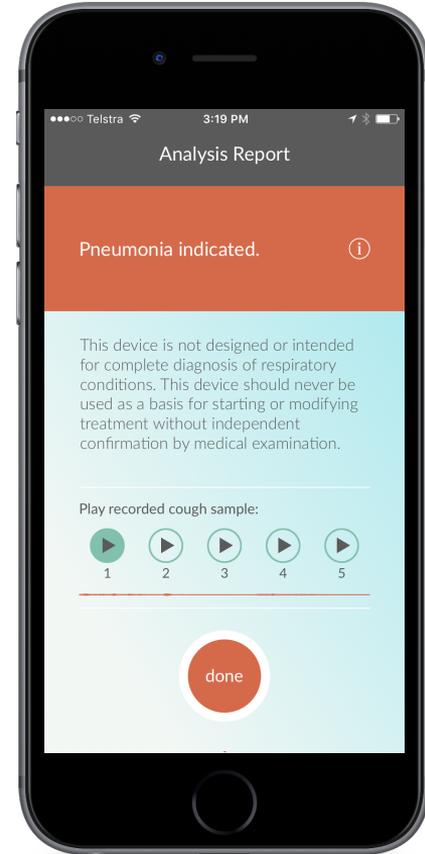
Chronic Conditions

asthma, COPD, cystic fibrosis, bronchiectasis

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

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 differentially diagnose respiratory disease
 - Able to automatically improve performance and learn new diseases from new clinical datasets
- Multiple patent applications filed in US, Australia, Europe, China, Japan and South Korea
- Uses the microphones in today's smartphones
 - **No additional hardware/accessories required**



Verified by compelling pediatric clinical evidence

2013 Pediatric Proof-of-Concept Study

Sardijto Hospital, Indonesia

91 patients

- Funded by the Gates Foundation
- **Achieved 96% accuracy for diagnosis of pneumonia**

Breathe-Easy Pediatric Study

Joondalup Health Campus and Princess Margaret Hospital, Perth Australia

1,127 patients (continuing)

- **Achieved >89% accuracy for differential diagnosis of common childhood respiratory diseases**
- Additional results expected 2Q2017

2013 Study	Sensitivity	Specificity	Accuracy
Pneumonia vs. all respiratory ¹	94%	100%	96%
Asthma vs. pneumonia ²	100%	80%	90%
Breathe-Easy Pediatric Study	Sensitivity	Specificity	Accuracy
Pneumonia vs. no respiratory	100%	95%	97%
Asthma vs. no respiratory	97%	92%	95%
Bronchiolitis vs. no respiratory	100%	100%	100%
Croup vs. no respiratory	94%	100%	99%
URTI vs. no respiratory	100%	95%	96%
Pneumonia, croup or bronchiolitis vs. URTI	89-100%	90-95%	89-98%
Differential diagnosis of pneumonia, croup, URTI and bronchiolitis	91-99%	89-98%	89-98%

1. Abeyratne et al., Annals of Biomedical Engineering, 2013

2. Kosashi et al., IEEE Transactions in Biomedical Engineering, 2015

Building strong clinical evidence in adults

Breathe-Easy Adult Study

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 and pneumonia**
- Additional results expected 4Q2017

Breathe-Easy Adult Study Preliminary Results

	Sensitivity	Specificity	Accuracy
COPD vs. no respiratory	100%	96-100%	98-100%
Asthma vs. no respiratory	91%	91-93%	91-92%
Pneumonia vs. no respiratory	97-100%	100%	98-100%
URTI vs. no respiratory	100%	100%	100%
Asthma or COPD vs. no respiratory	91-93%	91-93%	91-93%
Asthma vs. COPD	93%	96%	94%
Pneumonia vs. Asthma	92%	81%	88%
Pneumonia vs. COPD	92%	92%	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)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% 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)¹

56%

growth

(Growth rate until 2018 estimated by IHS)²

US\$12B

US TAM

(Goldman Sachs US total addressable market estimate)³



- 30-50% of telehealth consults 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**

Pursuing a truly global opportunity

- Significant growth in telehealth in Europe and Australia



- Plan to file for CE Mark in 4Q2017

- 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:



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
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. 	<ul style="list-style-type: none"> • 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	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

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, primary caused by smoking
 - 3M+ people died of COPD in 2012, 6% of all deaths globally⁵
- 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 asthma⁶



1 in 5 adults over 45 has COPD⁷

Pivotal milestones leading up to first FDA clearance

SMARTCOUGH-C study

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

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

Clinical adjudication used for comparison

Up to 1,500 patients aged 29 days - 12 years

Top-tier US sites: Massachusetts General Hospital, Cleveland Clinic & Texas Children's Hospital

Details on www.clinicaltrials.gov (NCT02973282)

As of 25 May 2017, 1,157 patients enrolled and target recruitment numbers for all diseases have been met

2Q2017

- Complete recruitment and lock clinical database for SMARTCOUGH-C study
- Additional Australian pediatric study results

3Q2017

- Top-line data from SMARTCOUGH-C (July)
- File *de novo* premarket submission with FDA for lead pediatric product

4Q2017

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

Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware 革命性科技 – 无需额外硬件的呼吸疾病的诊断和管理
- Compelling clinical evidence 临床证据令人信服
 - High accuracy from multiple adult and paediatric clinical studies, over 2,600 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 美国监管途径已明晰
 - Held successful US FDA Pre-Submission meeting in 1Q2016, confirmed *de novo* regulatory pathway strategy
 - Commenced pivotal clinical study at top-tier US hospitals, **top-line results expected 3Q2017 (July)**
 - **FDA *de novo* submission targeted for 3Q2017**
- US market entry in 2017 2017年进入美国市场
 - Launch via US telehealth partner to reach millions of patients quickly
 - Potential European (CE), Australian (TGA) and Asian market entry in parallel to US
 - Working with Médecins Sans Frontières/Doctors without Borders to evaluate performance in low income settings