ResApp HEALTH

Digital healthcare for respiratory disease

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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[1]
  - 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 $12M cash

1. ResApp estimate based on OECD doctor visits per capita data and assuming 10% of visits are for respiratory disease (based on US data)

Company overview

Capital Structure (ASX:RAP)

Market Cap.	$234M
Share Price as of 17 February 2017	$0.355
Shares on Issue[1]	659M
Performance Shares[2]	93.75M
Options[3]	6.37M
Incentive Options[4]	46.35M
Cash Balance as of 31 December 2016	$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)
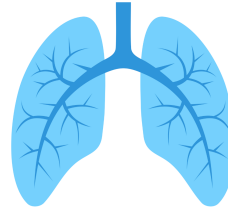
Substantial Shareholders

Freeman Road: 6.84%
Fidelity International: 6.15%

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

- **700M+** doctor visits p.a. globally[1] for respiratory disease
  - → **125M** in US[2] (10% of all visits)
  - → **6-8M** in Australia[3]
- **US$10.5B p.a. US hospital costs** for pneumonia[4]
- High prevalence and growth in Asia

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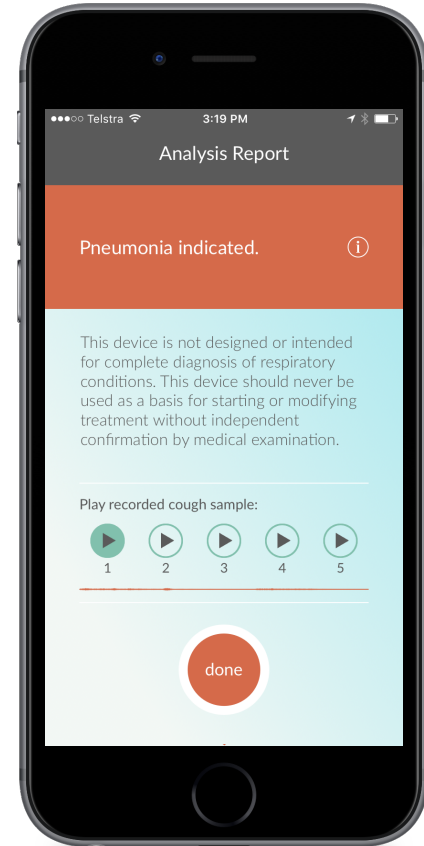URTIs, influenza, bronchitis, bronchiolitis, pneumonia, pertussis, croup

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**

1. ResApp estimate based on OECD doctor visits per capita data and assuming 10% of visits are for respiratory disease (based on US data)
2. Ambulatory case visits, National Ambulatory Medical Care Survey 2010
3. Australian Lung Foundation
4. HCUP Statistical Brief #160

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**

Analysis Report

Pneumonia indicated. ⓘ

This device is not designed or intended for complete diagnosis of respiratory conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.

Play recorded cough sample:
▶ 1 ▶ 2 ▶ 3 ▶ 4 ▶ 5

done

Verified by compelling pediatric clinical evidence

2013 Pediatric Proof-of-Concept Study

Funded by the Bill and Melinda Gates Foundation

- Sardijto Hospital, Indonesia
- 91 pediatric patients enrolled

2015/16 Australian Pediatric Study

- Joondalup Health Campus and Princess Margaret Hospital
- 976 pediatric patients enrolled to date

Latest results released March 2016
Enrolment and analysis continuing

1. Abeyratne et al., Annals of Biomedical Engineering, 2013
2. Kosashi et al., IEEE Transactions in Biomedical Engineering, 2015
3. ResApp Press Release 30 September 2015, 211 subject dataset
4. ResApp Press Release 10 November 2015, 338 subject dataset
5. ResApp Press Release 31 March 2016, 524 subject dataset

2013 Study	Sensitivity	Specificity	Accuracy
Pneumonia *vs. all respiratory*[1]	94%	100%	**96%**
Asthma *vs. pneumonia*[2]	100%	80%	**90%**
2015 Study Preliminary Results	**Sensitivity**	**Specificity**	**Accuracy**
Pneumonia *vs. no respiratory*[4]	100%	95%	**97%**
Asthma *vs. no respiratory*[3]	97%	92%	**95%**
Bronchiolitis *vs. no respiratory*[4]	100%	100%	**100%**
Croup *vs. no respiratory*[4]	94%	100%	**99%**
URTI *vs. no respiratory*[4]	100%	95%	**96%**
Pneumonia, croup or bronchiolitis *vs. URTI*[4]	89-100%	90-95%	**89-98%**
Differential diagnosis of pneumonia, croup, URTI and bronchiolitis[5]	91-99%	89-98%	**89-98%**

Building strong clinical evidence in adults

2015/16 Australian Adult Study

🏥 Joondalup Health Campus and Wesley Hospital

🧍 772 adult patients enrolled to date

Latest results released October 2016
Enrolment and analysis continuing

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%**

1. ResApp Press Release 3 October 2016

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**

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1. US Department of Health and Human Services Press Release, Feb 25, 2015
(http://www.cdc.gov/media/releases/2015/p0225-pneumonia-hospitalizations.html)

Res**App**
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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)[1]

56%
growth
(Growth rate until 2018 estimated by IHS)[2]

US$12B
US TAM
(Goldman Sachs US total addressable market estimate)[3]

TELADOC · amwell · MDLIVE · Dr DOCTOR ON DEMAND · sherpaa · Walgreens · CVS/pharmacy · KAISER PERMANENTE · VA

- 30-50% of telehealth consults for respiratory disease[4], no accurate remote diagnosis 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

ResApp HEALTH

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[1]
  – High prevalence of respiratory disease and nationwide shortage of doctors in China[2]
  – Chinese mobile online consultation examples:

92M active users
229 questions per minute

Chunyuyisheng

25M active users
95,000 appointments per day

Ping An Haoyisheng

- **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	700M doctor visits in OECD for respiratory disease p.a.[1]		• 1M child deaths due to pneumonia p.a.[3] • 151M cases of pneumonia in developing countries p.a.[3]	• 400M iPhone users[4] • 1.6B Android users[4] • mHealth app market expected to grow to $25B by end of 2017[5]
	• 22.5M respiratory-related US telehealth consults p.a.	• 13.4M US ED visits for respiratory disease p.a.[1] (~4.6M for children)		
Value proposition	✓ The only remote clinically-accurate diagnostic tool available ✓ Easily integrated into existing platforms	✓ Reduce costs (<$10 vs >$200 for x-ray) ✓ Reduce time (x-ray adds ~30 mins, cultures can take days)	✓ Low cost, accurate & fast ✓ Usable by non-medical personnel ✓ Integrates into IMCI framework	✓ 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

1. ResApp estimate based on OECD per capita data
2. NHAMCS (2011)
3. WHO estimate
4. Statista (2014 estimates)
5. Research2guidance mHealth App Developer Economics (2014)

ResApp HEALTH

Improving chronic respiratory disease management

- 334M people have asthma[1]
  - 17.7M in US[2], 30M in Europe[3], 2.3M in Australia[4]
  - $30B+ p.a. US economic burden[2]
  - Patient adherence to asthma medications is generally very poor
- 65M people have moderate to severe COPD[5]
  - Emphysema and chronic bronchitis, primary caused by smoking
  - 3M+ people died of COPD in 2012, 6% of all deaths globally[5]
- 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
- Exploratory clinical studies underway at Joondalup Health Campus and the Wesley Hospital

1 in 7 children has asthma[6]

1 in 5 adults over 45 has COPD[7]

1. The Global Asthma Report 2014 (Global Asthma Network)
2. US CDC
3. European Lung White Book
4. Asthma Australia
5. WHO
6. International Study of Asthma and Allergies in Childhood
7. COPD Foundation

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H E A L T H

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 (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