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-approved 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 US approval in H1 2017
- Pediatric US FDA registration study to begin shortly at leading US hospitals
- Strong balance sheet with $13.7M cash

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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. | $307M |
| Share Price<br>as of 14 October 2016 | $0.47 |
| Shares on Issue[1] | 653M |
| Performance Shares[2] | 93.75M |
| Options[3] | 12.8M |
| Staff Incentive Options[4] | 31M |
| Cash Balance<br>as of 30 June 2016 | $13.7M |

1. Includes 59.6M escrowed shares (until 14/7/17)
2. Issued on achieving $20M of annual revenue or on an acquisition
3. 6.4M, exercise price of 2.6c, expire 31/12/16; 4.5M, exercise price of 28c, expire 29/4/19; 1.87M, exercise price of 30c, expire 29/4/19
4. Issued to 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

(Chair of AusBiotech-WA, Non-Executive Director of Alcidion Ltd, co-founder of Imugene Ltd and Oncosil Medical Ltd and formerly VP, IR at pSivida Corp.)

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%

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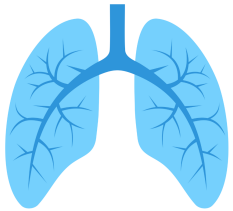
# Diagnosis of respiratory disease is the most common outcome from a visit to the doctor

- **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

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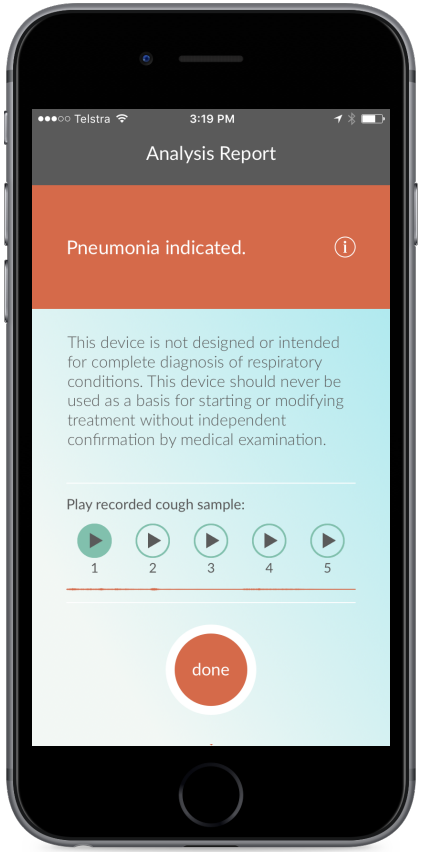
# Easy to use, instant diagnosis using only a smartphone

- 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**

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# 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

| 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%** |


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


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# 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

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# 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)

# 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]


- 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**

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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 opportunity

- Significant growth in telehealth in Europe and Australia

babylon Everyone's personal health service. | Dr Now | LloydsPharmacy Online Doctor | Push Doctor Dr. | mee doc | MEDGATE | HEALTH

  - **Plan to file for CE Mark in early 2017 in parallel with FDA submission**

- 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:

春雨医生 *Chunyuyisheng*

92M active users
229 questions per minute

中国平安 PING AN *Ping An Haoyisheng*

25M active users
95,000 appointments per day

- **Active partnership discussions in all regions**

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

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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)

# 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

**1 in 7 children has asthma[6]**

**1 in 5 adults over 45 has COPD[7]**

- 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

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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

# Pivotal milestones leading up to first FDA approval

## H2 2016

- ☑ 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
- ☐ Additional Australian pediatric study results

## H1 2017

- ☐ Additional Australian adult study results
- ☐ Start pivotal US adult clinical study
- ☐ Primary data from SMARTCOUGH-C
- ☐ File *de novo* premarket submission with FDA for lead ResApp product (pediatric)
- ☐ File for CE Mark in Europe
- ☐ FDA marketing approval for lead ResApp product

## 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/viral wheeze and lower respiratory tract involvement

Three confirmed US sites:

1. Massachusetts General Hospital
2. Unnamed, top-tier academic medical center
3. Unnamed, top-tier children's hospital

Supported by INC Research, a global leading CRO

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# 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 Q1 2016
  - Confirmed *de novo* regulatory pathway as Class II Medical Device
  - Commencing 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

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