



*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-approved 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 1,430 patients enrolled in pediatric and adult studies
- Successful Pre-Submission meeting held with US FDA, targeting US approval in early 2017
- US clinical study to begin in Q3 2016, Massachusetts General Hospital announced as first site
- Strong balance sheet with \$12.5M raised in March 2016

# Company overview

## Capital Structure (ASX:RAP)

Market Cap.	\$240M
Share Price as of 25 July 2016	\$0.37
Shares on Issue <sup>1</sup>	650M
Performance Shares <sup>2</sup>	93.75M
Options <sup>3</sup>	15.5M
Staff Incentive Options <sup>4</sup>	25M
Cash Balance as of 29 April 2016	\$14.9M

1. Includes 57.2M escrowed shares (until 14/7/17)
2. Issued on achieving \$20M of annual revenue or on an acquisition
3. 10M, 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 MD, 5M options at exercise price of 2.5c, 5M at 5c and 10M at 10c, 5 year expiry; Issued to Dr Abeyratne, 3M at 5c and 2M at 10c

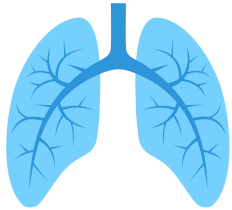
## Board of Directors

Dr Roger Aston	Non-Executive Chairman
(Chairman of Oncosil, former CEO of Mayne Pharma, Cambridge Antibody, cofounder of pSivida Corp)	
Dr Tony Keating	Managing Director and CEO
(former Director, Commercial Engagement of UniQuest, engineering management roles with Exa Corporation)	
Mr Brian Leedman	Executive Director and VP
(Chair of AusBiotech-WA, co-founder of Imugene Ltd and Oncosil Medical Ltd, former VP, IR at pSivida Corp. and Group Marketing Manager at E&Y-WA)	
Mr Chris Ntoumenopoulos	Non-Executive Director
(14+ years investment banking, Associate Director at CPS Capital, formerly at Citigroup, Indian Ocean Capital)	

## Substantial Shareholders

Freeman Road: 6.84%  
Fidelity International: 5.06%

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



## Acute conditions

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

## Chronic Conditions

Asthma, COPD, cystic fibrosis, bronchiectasis

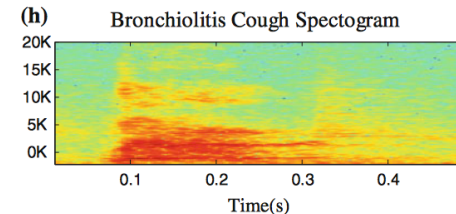
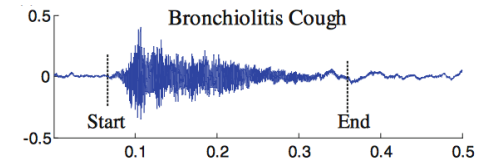
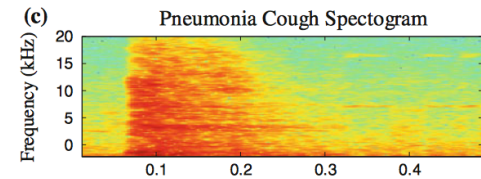
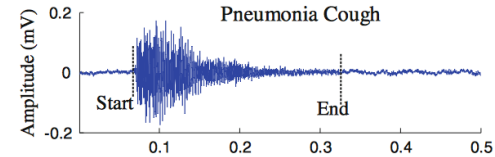


- **700M+** doctor visits p.a. globally<sup>1</sup> for respiratory disease
  - **125M** in US<sup>2</sup> (10% of all visits)
  - **6-8M** in Australia<sup>3</sup>
- **US\$10.5B p.a. US hospital costs** for pneumonia<sup>4</sup>
- High prevalence and growth in Asia

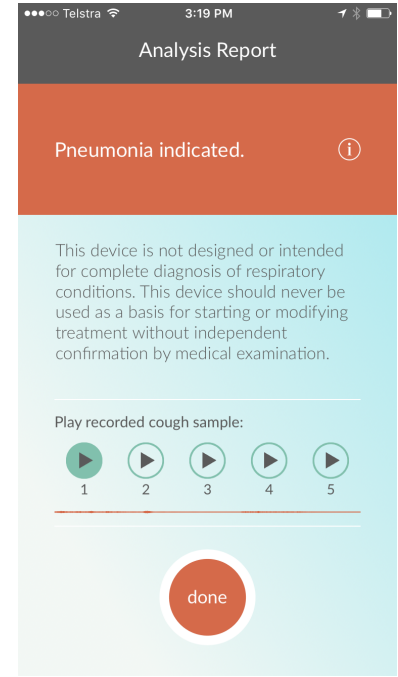
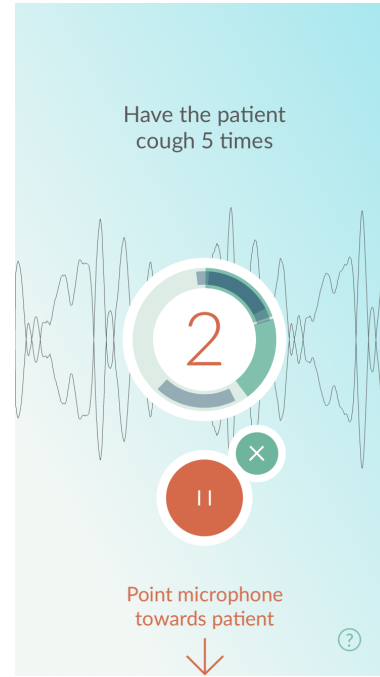
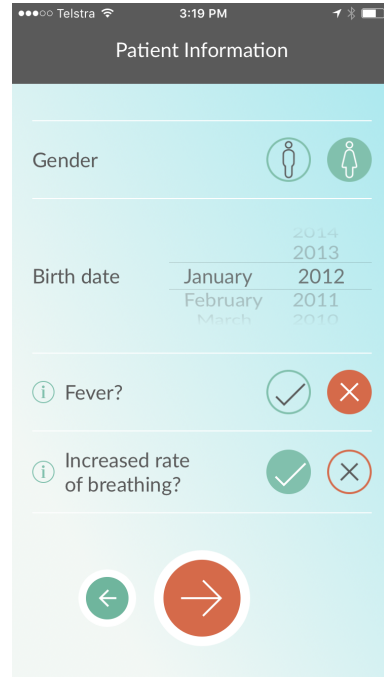
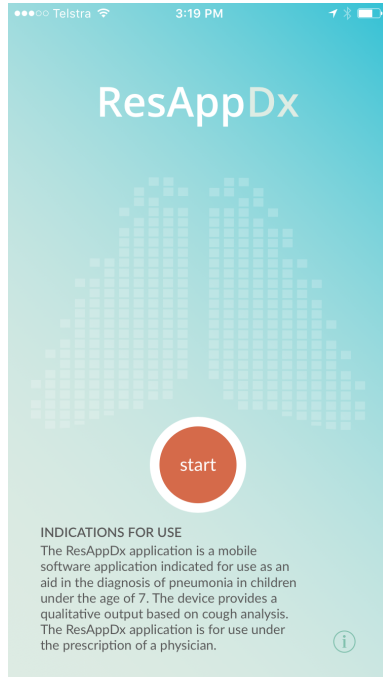
Currently diagnosed using stethoscope, imaging (x-ray, CT), blood and/or sputum tests

# Revolutionary tool to diagnose respiratory disease based on sound signatures

- Exclusive worldwide license to machine learning technology developed by Associate Professor Abeyratne at The University of Queensland
- Uses signatures in coughing and breathing sounds to diagnose disease
- Initial development at UQ 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**



# Easy to use, instant diagnosis using only a smartphone



# 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 Australian Pediatric Study



Joondalup Health Campus and Princess Margaret Hospital



880 pediatric patients enrolled to date

### 2013 Study

	Sensitivity	Specificity	Accuracy
<b>Pneumonia vs. all respiratory</b> <sup>1</sup>	94%	100%	<b>96%</b>
<b>Asthma vs. pneumonia</b> <sup>2</sup>	100%	80%	<b>90%</b>

### 2015 Study Preliminary Results

	Sensitivity	Specificity	Accuracy
<b>Pneumonia vs. no respiratory</b> <sup>4</sup>	100%	95%	<b>97%</b>
<b>Asthma vs. no respiratory</b> <sup>3</sup>	97%	92%	<b>95%</b>
<b>Bronchiolitis vs. no respiratory</b> <sup>4</sup>	100%	100%	<b>100%</b>
<b>Croup vs. no respiratory</b> <sup>4</sup>	94%	100%	<b>99%</b>
<b>URTI vs. no respiratory</b> <sup>4</sup>	100%	95%	<b>96%</b>
<b>Pneumonia, croup or bronchiolitis vs. URTI</b> <sup>4</sup>	89-100%	90-95%	<b>89-98%</b>
<b>Differential diagnosis of pneumonia, croup, URTI and bronchiolitis</b> <sup>5</sup>	91-99%	89-98%	<b>89-98%</b>

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



# Building strong clinical evidence in adults

## 2015 Australian Adult Study



Joondalup Health Campus and Wesley Hospital



510 adult patients enrolled to date

Preliminary results released on 21 June 2016 using initial 143 patient dataset

Expecting further results in Q3 and Q4 2016

Adult Study Preliminary Results	Sensitivity	Specificity	Accuracy
<b>COPD vs. no respiratory</b>	100%	93-98%	<b>96-99%</b>
<b>Asthma vs. no respiratory</b>	92-100%	92-93%	<b>92-95%</b>
<b>Pneumonia vs. no respiratory</b>	100%	100%	<b>100%</b>
<b>Asthma or COPD vs. no respiratory</b>	94-96%	93-94%	<b>94-95%</b>
<b>Asthma vs. COPD</b>	96%	95%	<b>96%</b>
<b>Pneumonia vs. Asthma</b>	94%	96%	<b>95%</b>

# 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
- 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>



MDLIVE



Walgreens

CVS/pharmacy



KAISER PERMANENTE



- 30% 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**

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)

# Pursuing a truly global opportunity

- Significant growth in telehealth in Europe and Australia



- Plan to file for CE Mark in Q4 2016

- 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

# 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, primary 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
- **Clinical collaborations to be announced shortly**



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



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

# An outstanding 12 months of achievements

## Clinical

- ✓ Initiated and enrolled 880 patients in multi-site pediatric clinical study
- ✓ Released preliminary results from pediatric study (Q3 2015, Q4 2015 and 2x Q1 2016)
- ✓ Demonstrated superiority to stethoscope for lower respiratory disease diagnosis (Q1 2016)
- ✓ Reported preliminary results for separation of viral, bacterial and atypical pneumonia (Q1 2016)
- ✓ Initiated and enrolled 510 patients in multi-site adult clinical study
- ✓ Released preliminary results from adult study (Q2 2016)
- ✓ Announced Massachusetts General Hospital as first US clinical study site (Q3 2016)

## Regulatory

- ✓ Appointed best-in-class FDA regulatory consultant – Experien Group (Sunnyvale, CA)
- ✓ Filed Pre-Submission package with the US FDA (Q4 2015)
- ✓ Held Pre-Submission meeting with the US FDA (Q1 2016)

## Corporate

- ✓ Raised AU\$4M and listed on the ASX (Q3 2015)
- ✓ Raised AU\$12.5M from institutional investors to expand market opportunity (Q1 2016)
- ✓ Secured partnership with global humanitarian organisation for developing world trial (Q1 2016)
- ✓ Built up the team with four new hires (software development, clinical/regulatory operations)

# Pivotal milestones leading up to first FDA approval

- Announce additional US pediatric clinical study sites (Q3 2016)
- Initiate US pivotal pediatric clinical study (Q3 2016)
  - To be supported in the US by INC Research, a leading global CRO
- Announce clinical collaborations for asthma and COPD management (Q3 2016)
- Release updated and expanded adult clinical study results (Q3 and Q4, 2016)
- Release results from US pivotal pediatric clinical study (early Q4 2016)
- File *de novo* premarket submission with FDA for first ResApp product (early Q4 2016)
- File for CE Mark in Europe (Q4 2016)
- FDA marketing approval for first ResApp product (early 2017)
- Initiate pivotal adult clinical study in US (early 2017)



# Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical evidence
  - Very high accuracy from multiple paediatric clinical studies, over 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)
  - Positive preliminary results from adult clinical study
- 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 US clinical study to support *de novo* submission in Q3 2016
- **US market entry in early 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