



*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 for smartphones
  - **No additional hardware** needed
  - Unique opportunity to integrate into **telehealth** providers' existing platforms
  - Apps to provide clinical-quality ('Gold Standard') diagnostic tests and chronic disease management tools directly to consumers and healthcare providers
- Huge global market, 700M+ doctor visits annually for respiratory disease<sup>1</sup>
- Strong clinical evidence from multiple pediatric clinical studies
- Currently enrolling patients in adult clinical study
- Fully-funded to bring product to market in late 2016

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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)

Shares on issue <sup>1</sup>	580M
Share price as of 16 February 2016	\$0.14
Market Cap	\$81M
Performance Shares <sup>2</sup>	93.75M
Options <sup>3</sup>	15.47M
Staff Incentive Options <sup>4</sup>	25M
Cash Balance as of 31 December 2015	\$2.7M

1. Includes 121M escrowed shares

2. Issued on achieving \$20M of annual revenue or on an acquisition

3. Exercise price of 2.6c, expire 31 December 2016

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 Adam Sierakowski	Non-Executive Director
Mr Chris Ntoumenopoulos	Non-Executive Director

## Substantial Shareholders

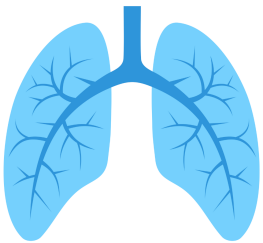
Freeman Road: 7.59%

UniQuest Pty Ltd: 7.28%

Mr Brian Leedman: 5.28%

Top 20 Shareholders: 43.7%

# 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



- **125M** doctor visits<sup>1</sup> in the US for respiratory disease (10% of all visits)
- **6-8M** doctor visits<sup>2</sup> in Australia for respiratory disease
- Est. **700M+** doctor visits globally<sup>3</sup> for respiratory disease
- High prevalence and growth in Asia

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

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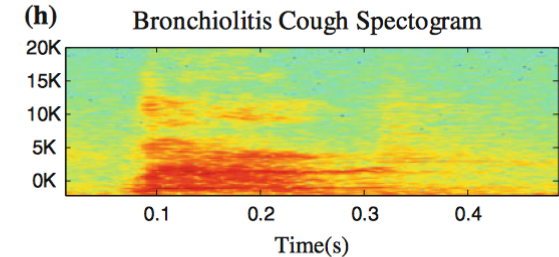
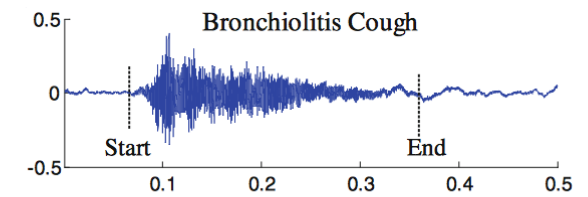
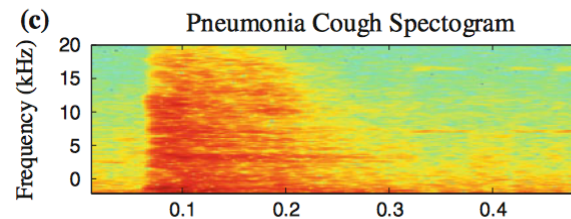
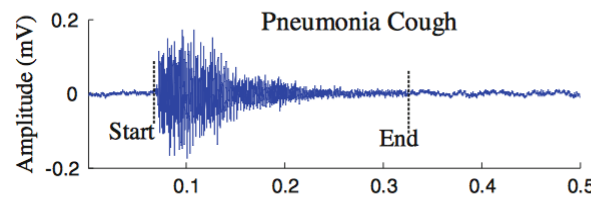
1. Ambulatory case visits, National Ambulatory Medical Care Survey 2010

2. Australian Lung Foundation

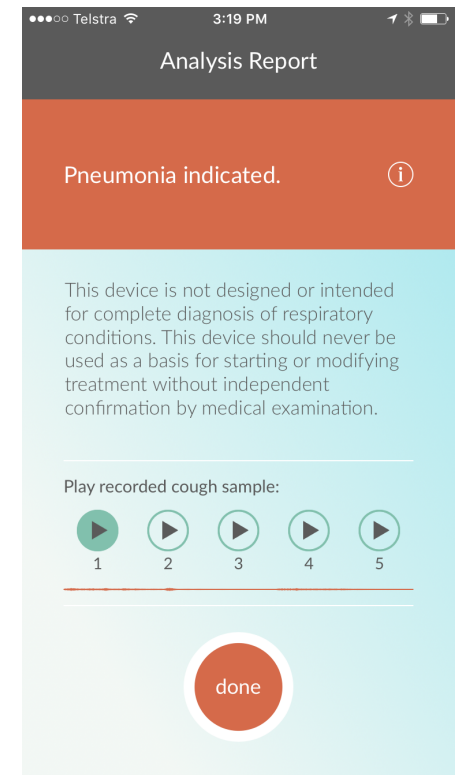
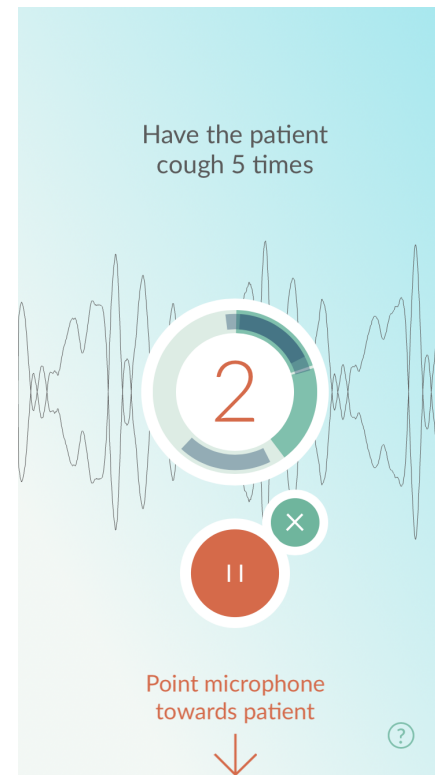
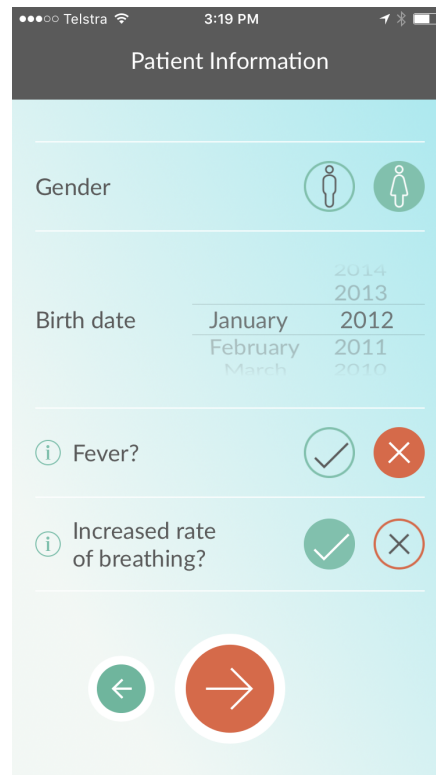
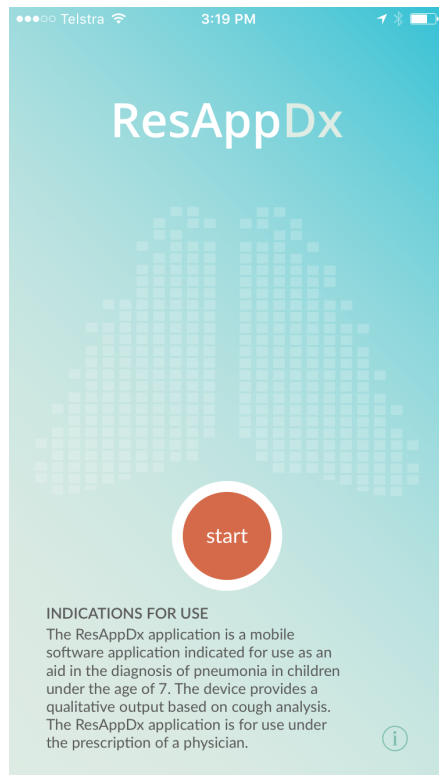
3. Based on OECD doctor visits per capita data and assuming 10% of visits are for respiratory disease (based on US data)

# Revolutionary tool based on sound signatures

- Exclusive worldwide license to machine learning technology developed by A/Prof. Abeyratne at The University of Queensland
- Uses signatures in coughing and breathing sounds to diagnose disease
- Patent application filed in US, Australia, Europe, China, Japan and South Korea
- Can be delivered using today's smartphones, no additional hardware required



# Easy to use, instant diagnosis on a smartphone



# Strong clinical evidence

## Proof of concept study (2013)

- Funded by The Bill and Melinda Gates Foundation and The University of Queensland
- Site: Sardjito Hospital, Indonesia
- 91 patients, majority under the age of 5
- Results published in peer-reviewed journals<sup>1,2</sup>

## Current study (started March 2015)

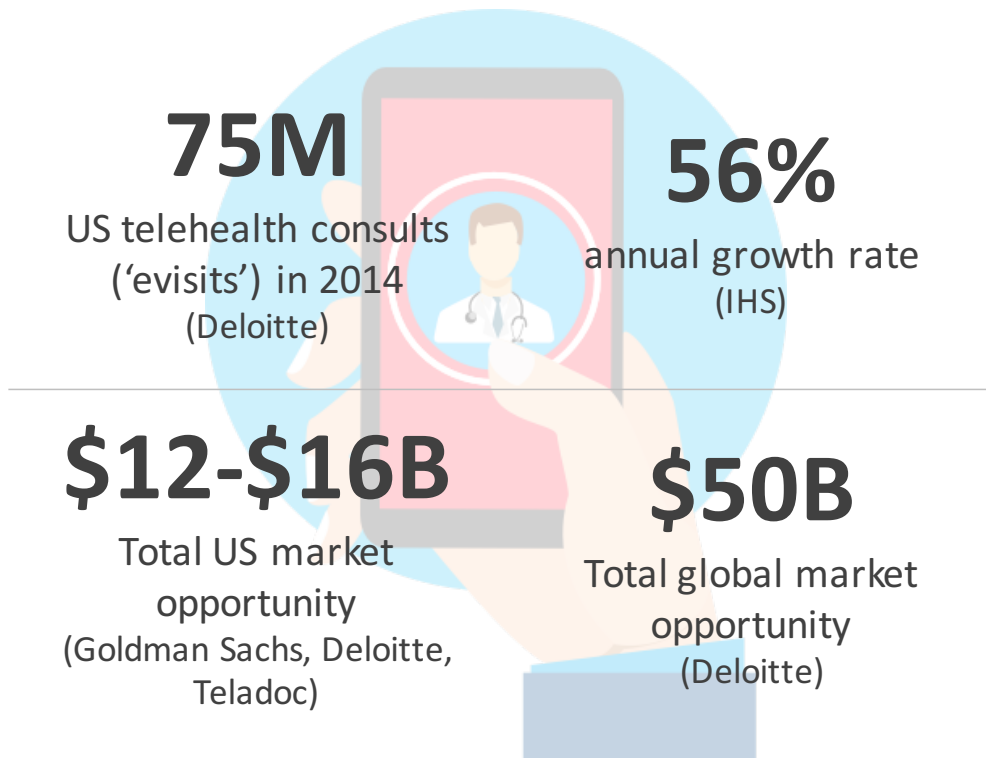
- Funded by ResApp
- Managed by The University of Queensland
- Sites: Joondalup Health Campus and Princess Margaret Hospital, Perth, Australia
- Over 500 pediatric patients enrolled to date (continuing)

1. Abeyratne et al., Annals of Biomedical Engineering, 2013  
2. Kosashi et al., IEEE Transactions in Biomedical Engineering, 2015

2013 Study	Sensitivity	Specificity	Accuracy
<b>Pneumonia vs. all respiratory</b>	94%	100%	<b>96%</b>
<b>Asthma vs. pneumonia</b>	100%	80%	<b>90%</b>
2015 Study Preliminary 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</b>	89-100%	90-95%	<b>89-98%</b>
<b>Differential diagnosis of pneumonia, croup, URTI and bronchiolitis</b>	92-100%	85-97%	<b>91-99%</b>



# Telehealth is one of the biggest trends in healthcare



- Teladoc and American Well: 10M+ customers each
- Insurers such as Cigna, Aetna, UnitedHealthcare
- Employers such as Bank of America, Volvo, Yahoo!
- Hospital systems such as Mount Sinai



- Two largest US pharmacy chains have recently announced partnerships with telehealth providers

# ResApp directly addresses the most common disease encountered by telehealth providers

The market segment addressed by ResApp is enormous



- **30%** of telehealth consults for acute respiratory disease<sup>1</sup>
- **22.5M** telehealth consults per year today for acute respiratory disease
- Number of telehealth consultations growing at 56% per year<sup>2</sup>
- **700M+** global doctor visits each year for respiratory disease<sup>3</sup>
  - Access through growth in telehealth plus in-person tests (in-clinic, in-hospital)

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1. Uscher-Pines and Mehrotra (Health Affairs, 2014)

2. IHS

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

# Market segments and business model

	Telehealth	Clinical use	Developing world	Direct to consumer
<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>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)</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>Revenue model</b>	B2B per test fee (<\$10) from telehealth providers	B2B per test fee (<\$10) from healthcare payors	B2B low cost annual subscription from aid agencies	B2C download and per test fee direct from consumers
<b>Market size</b>	<ul style="list-style-type: none"> <li>• 22.5M respiratory-related US telehealth consults p.a.</li> <li>• 56% growth rate</li> <li>• Major telehealth providers have 10s of millions of customers each</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> <li>• 700M+ ambulatory respiratory consultations p.a.<sup>2</sup></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>

# 2015: An outstanding year of achievements

- ✓ Initiated and enrolled over 500 patients in multi-site pediatric clinical study
- ✓ Reported positive preliminary results from pediatric clinical study
- ✓ Initiated adult clinical study
- ✓ Appointed best-in-class FDA regulatory consultant – Experien Group (Sunnyvale, CA)
- ✓ Filed Pre-Submission package with the US FDA
- ✓ Built up the team with three new hires (software development, clinical/regulatory operations)
- ✓ Developed high performance cross-platform software library that can be deployed via smartphone app, SDK or cloud-hosted Software-as-a-Service API
- ✓ Raised AU\$4 million and listed on the ASX

# Projected milestones for 2016

- ☐ Approval and commence enrolment at second hospital site for adult clinical study (Q1)
- ☐ Report updated results from pediatric clinical study (Q1)
- ☐ Meeting with FDA to discuss Pre-Submission filing (Q1)
- ☐ Report preliminary results from adult clinical study (Q2)
- ☐ Initiate pivotal clinical study in US (Q2)
- ☐ File premarket submission with FDA for first ResApp product (mid-year)
- ☐ FDA marketing approval for first ResApp product (Q4)

# Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Multi-site pediatric clinical study progressing very well with over 500 patients enrolled and positive preliminary results
  - Continuing enrolment beyond initial target patient numbers due to the high value of data collected
- Enrolment in adult clinical study progressing quickly, second site online in Q1 2016
- **FDA Pre-Submission meeting in Q1 2016**
  - Feedback on proposed regulatory pathway and clinical data requirements
- **Further results from pediatric and adult clinical studies due in Q1-Q2 2016**
- **On-track to bring product to market in late 2016**, launch via telehealth partner to reach millions of patients quickly