



*Digital healthcare for respiratory disease*

Tony Keating  
Chief Executive Officer and Managing Director  
[tony@resapphealth.com.au](mailto:tony@resapphealth.com.au)

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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 for smartphones
  - **No additional hardware** needed
  - Unique opportunity to integrate into **telehealth** providers' existing platforms
  - Apps to provide clinical-quality diagnostic tests and chronic disease management tools to consumers and healthcare providers
- Huge global market, 700M+ doctor visits annually for respiratory disease<sup>1</sup>
- Compelling clinical evidence from multiple pediatric clinical studies, adult study underway
- Successful Pre-Submission meeting held with the US FDA in Q1 2016
- Fully-funded to bring product to US 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)

|  |                     |
|--|---------------------|
| Market Cap.                            | \$125M              |
| Share Price<br>as of 4 April 2016      | \$0.215             |
| Shares on Issue <sup>1</sup>           | 580M                |
| Performance Shares <sup>2</sup>        | 93.75M              |
| Options <sup>3</sup>                   | 15.47M              |
| Staff Incentive Options <sup>4</sup>   | 25M                 |
| Cash Balance<br>as of 31 December 2015 | \$2.7M <sup>5</sup> |

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

5. Cash balance does not include an additional \$475,312 received from exercises of unlisted options in Q1 2016

## 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    |

## Substantial Shareholders

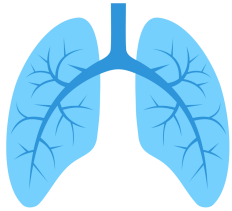
Freeman Road: 7.59%

UniQuest Pty Ltd: 7.28%

Mr Brian Leedman: 5.28%

Top 20 Shareholders: 42.64%

# 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

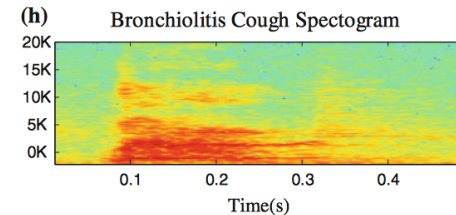
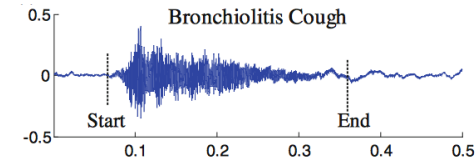
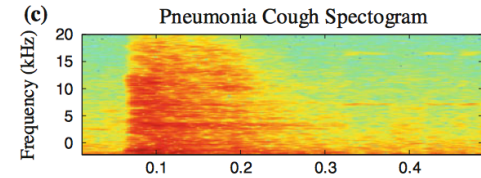
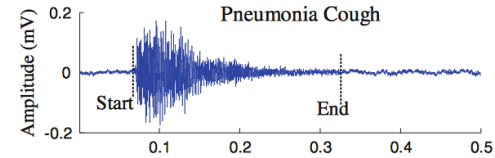


- **700M+** doctor visits p.a. globally<sup>1</sup> for respiratory disease
  - **125M** in US<sup>2</sup> (10% of all visits)
  - **6-8M** in Australia<sup>3</sup>
- **US\$10.5B p.a. US hospital costs** for pneumonia<sup>4</sup>
- **US\$62B+ p.a. economic burden** for asthma and COPD in US<sup>5</sup>
- High prevalence and growth in Asia

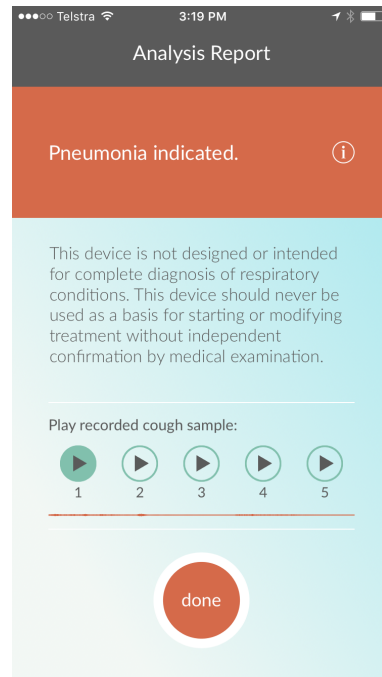
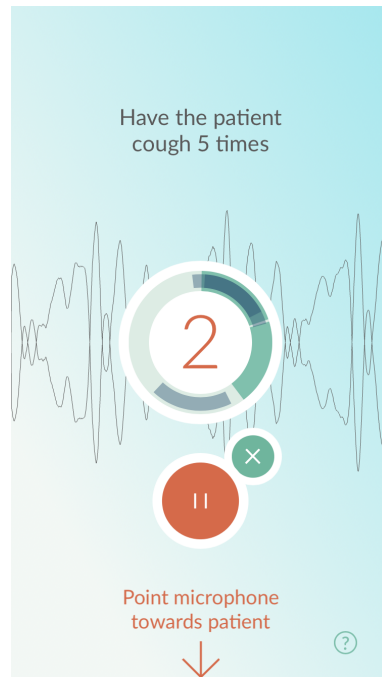
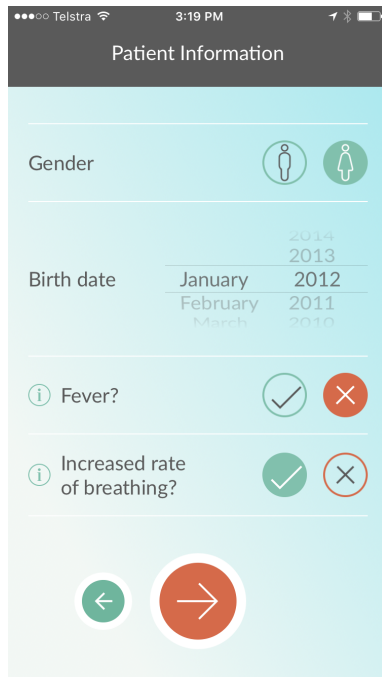
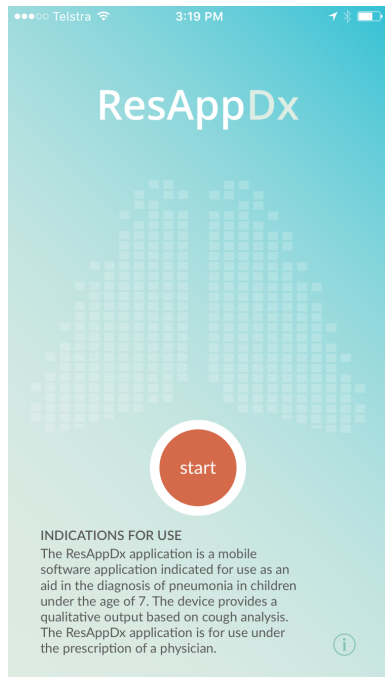
Currently diagnosed using stethoscope, imaging (x-ray, CT), blood and/or sputum tests

# Revolutionary tool to diagnose respiratory disease based on sound signatures

- Exclusive worldwide license to machine learning technology developed by A/Prof. 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
- Can use microphones in today's smartphones  
→ **No additional hardware required**



# Easy to use, instant diagnosis using only a smartphone



# Compelling pediatric 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
- 598 pediatric patients enrolled to date

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
4. ResApp Press Release 10 November 2015
5. ResApp Press Release 31 March 2016

| 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> |



# 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

- Deliver ResApp's diagnostic test anywhere, anytime while retaining a clinician's input
- US telehealth is already large, and growing rapidly

**75M**

consults p.a.

(US telehealth 'evisits' in 2014  
estimated by Deloitte)<sup>1</sup>

**56%**

growth

(Growth rate until 2018  
estimated by IHS)

**US\$12B**

US TAM

(Goldman Sachs US total  
addressable market estimate)



**MDLIVE**



*Walgreens*

**CVS/pharmacy**



**KAISER PERMANENTE**



- Telehealth benefits all: payors, patients and healthcare providers
- **30% of telehealth consults for respiratory disease<sup>1</sup>, no accurate remote diagnosis available**

1. Deloitte, eVisits: the 21<sup>st</sup> century housecall (August 2014)

2. HIS, 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)

# Market segments and business model

|                            | 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  |

# 2015: An outstanding year of achievements

- ✓ Raised AU\$4 million and listed on the ASX
- ✓ Initiated and enrolled 598 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

# Milestones for 2016

- ☒ Obtained approval to enroll adult patients at second hospital site, The Wesley Hospital (Q1)
- ☒ Demonstrated superiority to stethoscope for low respiratory tract disease diagnosis (Q1)
- ☒ Secured partnership with global humanitarian organisation for developing world trial (Q1)
- ☒ Successfully held Pre-Submission meeting with the US FDA (Q1)
- ☒ New benchmark results achieved using expanded 524 pediatric subject dataset (Q1)
- ☒ Reported preliminary results for separation of viral, bacterial and atypical pneumonia (Q1)
- ☐ Report preliminary results from adult clinical study (Q2)
- ☐ Initiate pivotal clinical study in US and Australia (Q2)
- ☐ File *de novo* 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
- Compelling pediatric clinical evidence
- New breakthrough results:
  - Detecting lower respiratory tract involvement which may be missed by auscultation
  - Diagnosing the cause of pneumonia (viral, bacterial or atypical)
- Successful US FDA Pre-Submission meeting held in Q1 2016
  - Confirmed *de novo* regulatory pathway, combined US and Australian pivotal clinical study
- Results from adult clinical study due in Q2 2016
- **On-track to bring product to market by end of 2016**, launch via telehealth partner to reach millions of patients quickly