Resapp HEALTH

Digital healthcare for respiratory disease

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Company Update
September 2018

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
- Huge global market, 700 million+ doctor visits annually for respiratory disease[1]
- Compelling clinical evidence with 2,600+ patients enrolled in Australian clinical studies, including a recently completed 585 patient double-blind, prospective paediatric study
- Well-funded to execute our ongoing clinical strategy
  - Execution issues identified in first US pivotal study – not an accurate evaluation of ResApp's technology
  - Revised US paediatric study recruitment complete, results expected Q3 CY2018
- Broadening product portfolio
  - Chronic respiratory disease management, at-home screening of obstructive sleep apnoea
  - Partnership with Lockheed Martin on US DARPA WASH research program

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1. ResApp estimate based on OECD doctor consultations per capita data (http://stats.oecd.org), and assuming 10% of visits (US prevalence based on NAMCS 2015 data) are for respiratory disease.

Company overview

Capital Structure (ASX:RAP)

Market Cap. **as of 10 September 2018**	**AU$152M**
Share Price as of 10 September 2018	AU$0.23
Shares on Issue	659M
Performance Shares[1]	93.75M
Options[2]	6.37M
Incentive Options[3]	51.45M
Cash Balance as of 30 June 2018	**AU$3.4M**

1. Issued on achieving AU$20M of annual revenue or on an acquisition
2. 4.5M, exercise price of 28c, expire 29/4/19; 1.87M, exercise price of 30c, expire 29/4/19
3. Issued to directors, staff and scientific advisory board

Board of Directors

Dr Roger Aston — Non-Executive Chairman
(Chairman of Regeneus, PharmAust and Immuron, Non-Exec. Director of Oncosil Medical, formerly CEO of Mayne Pharma, Cambridge Antibody, co-founder of pSivida)

Dr Tony Keating — Managing Director and CEO
(formerly Director, Commercial Engagement at UniQuest, engineering management roles with Exa Corporation)

Mr Nathan Buzza — Non-Executive Director
(formerly founder of Commtech Wireless, EVP Azure Healthcare and non-executive director of Alcidion)

Mr Chris Ntoumenopoulos — Non-Executive Director
(Managing Director at Twenty 1 Corporate, Non-Exec. Director at Race Oncology, formerly at Citigroup, Indian Ocean Capital and CPS Capital)

Substantial Shareholders*

Fidelity International: 9.23%
Freeman Road: 6.68%
Ian Francis Reynolds: 5.60%

* Based on Substantial Shareholder Notices lodged by the respective holders

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Diagnosis of respiratory disease is the most common outcome from a visit to the doctor[1]

- 700M+ doctor visits p.a. globally for respiratory disease[2]
- Most common reasons for hospital admission[3]
  - → Bronchiolitis (infants)
  - → Asthma and pneumonia (children)
- US$10.6B p.a. direct US hospital costs for pneumonia[4]
- High prevalence and growth in Asia

Acute conditions
URTI, influenza, bronchitis, bronchiolitis, pneumonia, pertussis, croup, reactive airways disease

Chronic conditions
asthma, COPD, cystic fibrosis, bronchiectasis

Diagnosed today using stethoscope, imaging (x-ray, CT), spirometry, blood and/or sputum tests
→ **Time consuming, expensive, subjective and not very accurate**

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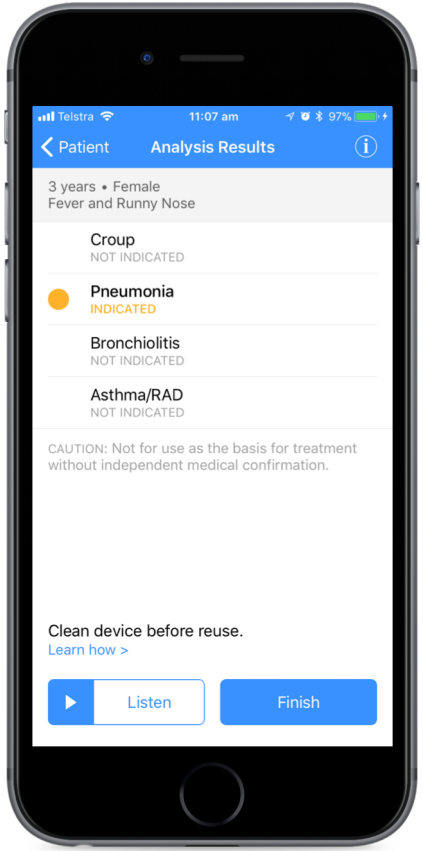
1. Ambulatory care visits (office and emergency department), National Ambulatory Medical Care Survey 2015
2. ResApp estimate based on OECD doctor consultations per capita data (http://stats.oecd.org), and assuming 10% of visits (US prevalence based on NAMCS 2015 data) are for respiratory disease.
3. HCUP Statistical Brief #148 (2010)
4. HCUP Statistical Brief #160

Easy to use, instant diagnosis using only a smartphone

- Machine learning technology developed by Associate Professor Abeyratne at The University of Queensland
  - Uses signatures in cough sounds to instantly differentially diagnose respiratory disease
  - Able to automatically improve performance and learn new diseases from new clinical datasets
- Uses the built-in microphone in modern smartphones
  - No additional hardware/accessories required
  - Real-time on-device analysis, no connectivity/cloud needed
- Growing patent portfolio and data assets
  - Core patent received notice of allowance in US and notice of acceptance in Australia, in national phase examination in Europe, China, Japan, South Korea; three additional patent applications
  - Proprietary data set, over 6,000 patients' cough and breathing sounds and matching clinical signs, symptoms and diagnosis



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Verified by compelling paediatric clinical evidence in a double-blind, prospective clinical study

Breathe Easy Paediatric Study

Double-blind, prospective study

- 585 patients, aged 29 days to 12 years, presenting to study site with signs and symptoms of respiratory disease
- Two Australian hospital sites
- Comparison to clinical diagnosis (including CXR, lab tests) formed by clinical adjudication committee
- Top-line results released 3 September 2018

	Patients[1]		Positive Percent Agreement[2]	Negative Percent Agreement[2]
	Y	N		
Lower respiratory tract disease	419	154	83% (95%CI, 79-86%)	82% (95%CI, 75-88%)
Asthma/reactive airways disease	149	381	97% (95%CI, 92-99%)	91% (95%CI, 88-94%)
Croup	68	500	88% (95%CI, 78-95%)	86% (95%CI, 82-89%)
Pneumonia	60	509	87% (95%CI, 75-94%)	85% (95%CI, 82-88%)
Primary upper respiratory tract disease	89	482	79% (95%CI, 69-87%)	80% (95%CI, 76-83%)
Bronchiolitis (patients aged < 2 years old)	131	26	84% (95%CI, 77-90%)	81% (95%CI, 61-93%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).
2. As per FDA guidance, positive and negative percent agreement (rather than sensitivity and specificity) are used when a new test I compared to a non-reference standard such as a clinical diagnosis.

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Building strong clinical evidence in adults

Breathe Easy Adult Study (2015-)

Joondalup Health Campus, Perth Australia and Wesley Hospital, Brisbane Australia

1,387 adult patients (continuing)

- Leave-one-out cross-validation results
- Achieved high levels of accuracy in diagnosis of pneumonia and acute asthma
- Diagnosis of COPD and chronic asthma compared to the gold standard of pulmonary function tests
- As of 27 June 2018, 567 adult patients enrolled in double-blind, prospective study

Breathe Easy Adult Study *(compared to clinical diagnosis, population of patients with broad respiratory symptoms)*	Positive Percent Agreement	Negative Percent Agreement
Community-acquired pneumonia (n=360)	90% (95%CI, 86-93%)	88% (95%CI, 83-92%)
Acute asthma (n=54)	91% (95%CI, 80-97%)	88% (95%CI, 85-91%)

Breathe Easy Adult Study *(compared to lung function testing, population of patients referred to lung function testing)*	Sensitivity	Specificity
COPD (n=41)	89% (95%CI, 74-96%)	87% (95%CI, 79-92%)
Chronic asthma (n=34)	87% (95%CI, 73-97%)	90% (95%CI, 83-95%)

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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%-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 large and growing rapidly
- Provides benefits across the healthcare system: payors, patients and healthcare providers

75M
consults p.a.
(US telehealth 'evisits' in 2014 estimated by Deloitte)[1]

56%
growth
(Global telehealth revenue growth rate until 2018 estimated by IHS)[2]

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

TELADOC · amwell · MDLIVE · dr. on demand · sherpaa · Walgreens · CVS/pharmacy · KAISER PERMANENTE · VA

- 30-50% of telehealth consults are for respiratory disease[4,5]
  - Today there is **no ability to use a stethoscope** and **no accurate remote diagnosis tools 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)
5. UnitedHealthcare Presentation (https://www.mobihealthnews.com/content/health-insurance-payer-related-digital-health-news-q2-2016)

Pursuing a truly global telehealth 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 CY2018
- Huge potential in Asia Pacific with 2 billion smartphone users expected by 2019[1]
  - Online consultations in China estimated by Frost and Sullivan to reach 4 billion p.a. by 2026[2]
  - Chinese mobile online medical consultation examples:

春雨医生

Chunyu Yisheng (Spring Rain Doctors)

92M active users[3]
330,000 inquiries per day[3]
Raised $183M in 2016[4]

中国平安 PING AN

Ping An Haoyisheng (Good Doctor)

228M registered users[5]
531,000 online consultations per day[5]
Listed on HKEX in 2018

- Active discussions in all regions

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1. Forrester Research, https://www.forrester.com/report/Asia+Pacific+Mobile+And+Smartphone+Adoption+Forecast+2014+To+2019/-/E-RES118824
2. Frost and Sullivan Research, commissioned by Ping An via http://www.pahtg.com/media/1144/e_1833ipo.pdf
3. http://www.chinadaily.com.cn/kindle/2016-02/20/content_23569330.htm
4. https://www.chinamoneynetwork.com/2016/06/23/cicc-backed-spring-rain-software-raises-183m-pre-ipo-round
5. Ping An Good Doctor June 2018 Interim Results, http://www.pahtg.com/media/1238/ping-an-good-doctor-2018-interim-results.pdf

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] • 22.5M respiratory-related US telehealth consults p.a.[2]	• 13.4M US ED visits for respiratory disease p.a.[3] (~4.6M for children)	• 1M child deaths due to pneumonia p.a.[4] • 151M cases of pneumonia in developing countries p.a.[4]	• 400M iPhone users[5] • 1.6B Android users[5] • mHealth app market expected to grow to $25B by end of 2017[6]
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 tens 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	**$5-$10 per test fee** from telehealth providers	**$5-$10 per test fee** from healthcare payors	**annual subscription** from aid agencies	**download and per test fee** direct from consumers

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1. ResApp estimate based on OECD per capita data
2. ResApp estimate based on 33% of Deloitte's estimated 75M telehealth 'evisits' (2014) being respiratory-related
3. NHAMCS (2011)
4. WHO estimate
5. Statista (2014 estimates)
6. Research2guidance mHealth App Developer Economics (2014)

Top-line results from US clinical study for acute diagnosis due in Q3 CY2018

- Revised US paediatric study, SMARTCOUGH-C-2
  - Double-blind, prospective study
  - Details on www.clinicaltrials.gov (NCT03392363)
  - Recruitment complete, 1,470 patients aged 29 days to 12 years
  - Top-tier US hospitals: Massachusetts General Hospital, Cleveland Clinic & Texas Children's Hospital
  - Upgraded recording app and training, on-site data verification
  - Centralised, independent clinical adjudication, less subjective case definitions
  - Audio QA showing high quality audio (<3% found to be unacceptable)
  - **Top-line results in Q3 CY2018**

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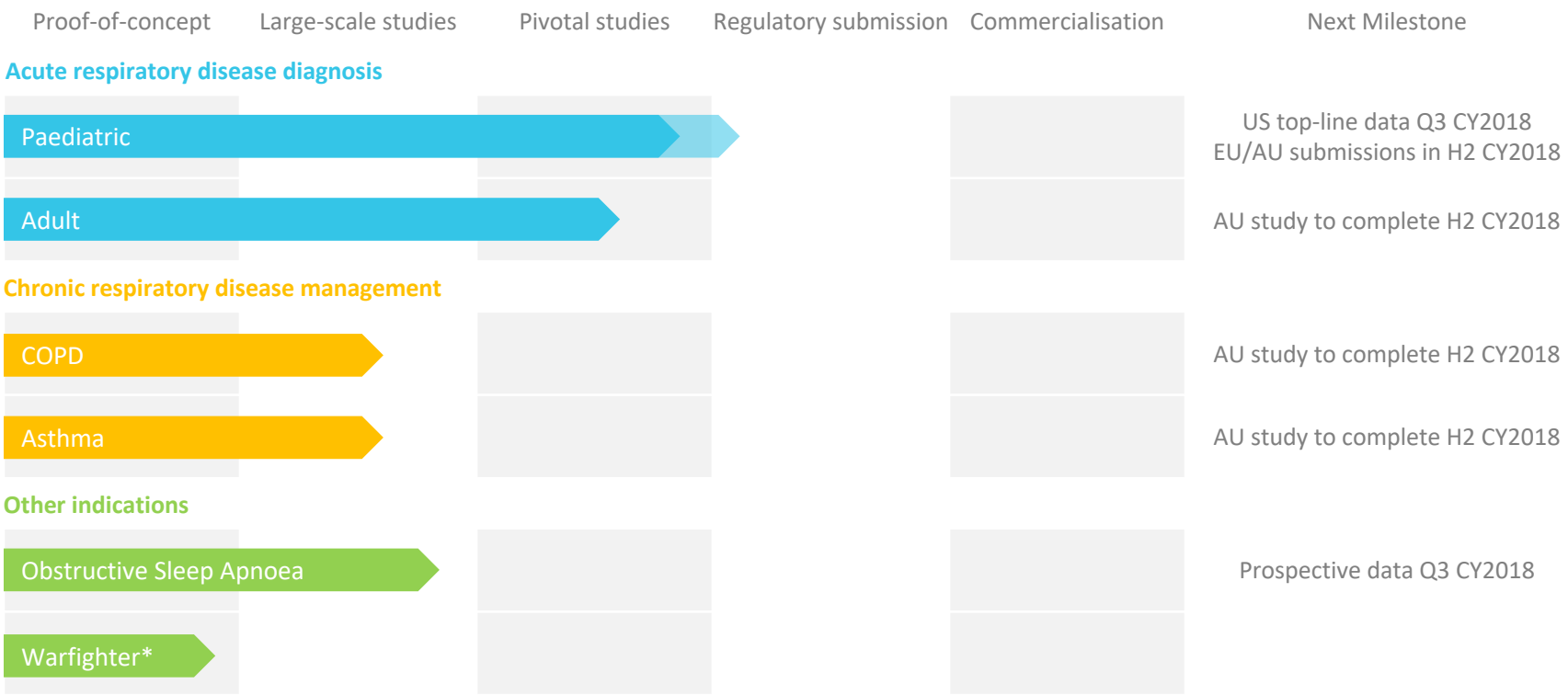
Broadening product portfolio



* Warfighter Analytics using Smartphones for Health (WASH) program, in collaboration with US DARPA and Lockheed Martin Corporation

Improving chronic respiratory disease management

- Estimated 339M people globally have asthma[1]
  - $80B+ p.a. US economic burden (2013)[2]
  - Patient adherence to asthma medications is generally very poor
- 251M cases of COPD in 2016[3]
  - Emphysema and chronic bronchitis, primarily caused by smoking
  - 3.17M people died of COPD in 2015, 5% of all deaths globally[3]

1 in 7 children has asthma[4]

1 in 5 adults over 45 has COPD[5]

- Opportunity to measure the severity of asthma and COPD, without the cost of additional hardware or the need to carry an extra device
  - Demonstrated 94% accuracy in identifying asthma patients who require additional treatment
  - Identified infective exacerbations in COPD patients at 91% (95% CI, 84-96) PPA and 90% (95% CI, 80-96) NPA

1. The Global Asthma Report 2018 (Global Asthma Network), citing the 2016 Global Burden of Disease Study
2. US CDC, https://www.ajmc.com/newsroom/cdc-study-puts-economic-burden-of-asthma-at-more-than-80-billion-per-year
3. WHO, citing the 2015 Global Burden of Disease Study, http://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd)
4. International Study of Asthma and Allergies in Childhood via 2014 Global Asthma Report, http://www.globalasthmareport.org/2014/priority/ncd.php
5. COPD Foundation, https://www.copdfoundation.org/About-Us/Press-Room/Press-Releases/Article/965/COPD-Foundation-Goes-Orange-for-National-COPD-Awareness-Month-in-November.aspx

Sleep apnoea is the most common sleep breathing disorder[1] and is significantly underdiagnosed

- Studies have found that more than 3 in 10 men, and nearly 2 in 10 women have sleep apnoea[1]
- Estimated 80% of adults with sleep apnoea are undiagnosed[2]
- Untreated, sleep apnoea has been linked to heart disease, stroke and type 2 diabetes[3]
- Major barriers to diagnosis:

Sleep laboratory polysomnography (PSG)	Requires referral Long wait times $600-$5,000 per test Uncomfortable & unfamiliar environment
Home sleep testing (HST)	Requires referral & training Up to 18% failure rate[5] $150-$500 per test Uncomfortable

1. American Thoracic Society, Breathing in America: Diseases, Progress and Hope, https://www.thoracic.org/patients/patient-resources/breathing-in-america/resources/chapter-23-sleep-disordered-breathing.pdf
2. Peppard et al., Increasing prevalence of sleep-disordered breathing in adults, Am J Epidemiol (2013)
3. Frost & Sullivan, Hidden Health Crisis Costing America Billions, https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf
4. American Academy of Sleep Medicine, Severe obstructive sleep apnea hurts hearts, https://aasm.org/severe-obstructive-sleep-apnea-hurts-hearts/
5. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients, American Academy of Sleep Medicine

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Convenient, at-home screening of obstructive sleep apnoea

- Replace the HST device with a smartphone on the bedside table
- Easy to use and comfortable, no cables
- Software-only, simple app download
  - Uses audio signatures in overnight breathing and snoring sounds to identify sleep apnoea
- Proof-of-concept clinical study
  - Compared to simultaneous, in-laboratory PSG
  - 731 patients, 62% male, mean age of 53 years (range: 18-87), mean AHI of 24 (range: 0-196)
  - 86% sensitivity, 83% specificity, 0.91 AUC ROC
- 312 patients recruited in prospective study (as of 11 July), with results expected in Q3 CY2018

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Summary

- Revolutionary technology – diagnosis and management of respiratory disease without the need for additional hardware
- Compelling clinical evidence, including a successful double-blind, prospective study in children
- Multiple clinical programs underway
  - **Recruitment in revised US paediatric clinical study complete, on-track for results in Q3 CY2018**
  - Australian prospective adult study currently recruiting, results expected in H2 CY2018
- Well understood regulatory pathway
  - CE (Europe) and TGA (Australia) submissions in H2 CY2018
  - FDA *de novo* submission following US paediatric study completion (Pre-Sub. Meeting with FDA held in 2016)
- Beginning to execute on commercial strategy with LOI signed for German hospital network pilot
- Broadened product portfolio
  - Chronic respiratory disease (asthma, COPD) management
  - **At-home screening of obstructive sleep apnoea, prospective results due in Q3 CY2018**
  - Partnership with Lockheed Martin on US DARPA WASH research program

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