Resapp HEALTH

Digital healthcare for respiratory disease

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Broker Meets Biotech
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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
  - No additional hardware needed
- Huge global market, 700 million+ doctor visits annually for respiratory disease[1]
- Compelling clinical evidence with 2,600+ patients enrolled in Australian paediatric and adult studies
- Well-funded to execute our ongoing clinical strategy
  - Execution issues identified in first US pivotal study – not an accurate evaluation
  - Revised US paediatric study recruitment complete, results expected August 2018
  - Australian paediatric prospective study recruitment complete, results expected August 2018
- Broadening product portfolio
  - Chronic respiratory disease management, at-home screening of obstructive sleep apnoea

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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.	**AU$148M**
Share Price as of 8 August 2018	AU$0.225
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: 6.84%
Ian Francis Reynolds: 5.60%

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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]
- Most common reasons for hospital admission[4]
  - → Bronchiolitis (infants)
  - → Asthma and pneumonia (children)
- US$10.5B p.a. direct US hospital costs for pneumonia[5]
- 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**

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 #148
5. HCUP Statistical Brief #160

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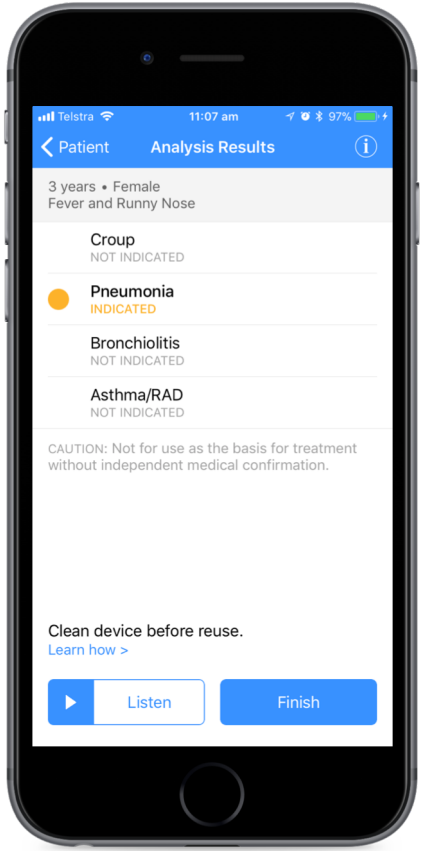
Easy to use, instant diagnosis using only a smartphone

- 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, in national phase examination in Australia, Europe, China, Japan, South Korea; three 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

2013 Paediatric Proof-of-Concept Study

Sardijto Hospital, Indonesia - 91 patients

- Funded by the Bill & Melinda Gates Foundation
- Achieved >90% accuracy for diagnosis of pneumonia and asthma vs pneumonia

Breathe Easy Paediatric Study (2015-18)

Joondalup Health Campus and Princess Margaret Hospital, Perth Australia - 1,127 patients

- Latest analysis (announced 22/6/17) optimised to match design of US SMARTCOUGH-C study
- Comparison to clinical diagnosis (incl. CXR, lab tests)
- Achieved 90-100% PPA and 89-96% NPA for URTI, croup, LRTD, asthma and bronchiolitis
- Achieved 89% PPA and 79% NPA for pneumonia

2013 Paediatric Proof-of-Concept	Sensitivity	Specificity	Accuracy
Pneumonia *vs. all respiratory*	94%	100%	96%
Asthma *vs. pneumonia*	100%	80%	90%

Published in peer-review publications: Abeyratne et al., Annals of Biomedical Engineering (2013) and Kosashi et al., IEEE Transactions in Biomedical Engineering (2015)

Breathe Easy Paediatric Study *(population of patients with broad respiratory symptoms)*	Positive Percent Agreement	Negative Percent Agreement
Primary Upper Respiratory Tract Infection (n=53)	92% (95%CI, 82-98)	89% (95%CI, 86-91)
Croup (n=57)	100% (95%CI, 94-100)	96% (95%CI, 94-97)
Lower Respiratory Tract Disease (n=492)	90% (95%CI, 87-93)	92% (95%CI, 86-96)
Asthma/Reactive Airways Disease (n=234)	92% (95%CI, 88-95)	89% (95%CI, 85-92)
Bronchiolitis (n=101)	95% (95%CI, 89-98)	94% (95%CI, 92-96)
Pneumonia (n=123)	89% (95%CI, 82-94)	79% (95%CI, 75-83)

As per FDA guidance, positive and negative percent agreement (rather than sensitivity and specificity) are used when a new test is 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)

- Latest analysis targeted intended use populations to prepare for pivotal studies
- Achieved high levels of accuracy in diagnosis of pneumonia and acute asthma
- Diagnosis of COPD and chronic asthma compared to the gold standard of LFT

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
(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]
  - 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) and UnitedHealthcare Presentation

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 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 medical consultation examples:

春雨医生

Chunyuyisheng (Spring Rain Doctors)

92M active users
229 questions per minute

Raised $183M in 2016

中国平安 PING AN

Ping An Haoyisheng (Good Doctor)

192.8M registered users
370,000 online consultations per day

Listing on HKEX in 2018[3]
Raised US$500M in 2016

- Active 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
3. http://www.hkexnews.hk/app/SEHK/2018/2018012901/Documents/SEHK201801290023.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.	• 13.4M US ED visits for respiratory disease p.a.[1] (~4.6M for children)	• 1M child deaths due to pneumonia p.a.[3] • 151M cases of pneumonia in developing countries p.a.[3]	• 400M iPhone users[4] • 1.6B Android users[4] • mHealth app market expected to grow to $25B by end of 2017[5]
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 10s of millions of patients	Initial use in emergency departments (ED), extending to regular clinics **LOI w/ German Hospital Group**	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. NHAMCS (2011)
3. WHO estimate
4. Statista (2014 estimates)
5. Research2guidance mHealth App Developer Economics (2014)

Top-line results from two pivotal clinical studies for acute diagnosis in Q3 CY2018

- Prospective, double-blind Australian paediatric study, Breathe Easy
  - Recruitment complete, 681 patients
  - **Top-line results in August 2018**
- Revised US paediatric study, SMARTCOUGH-C-2
  - 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 with less subjective case definitions
  - Audio QA showing high quality audio (<3% found to be unacceptable)
  - **Top-line results in August 2018**

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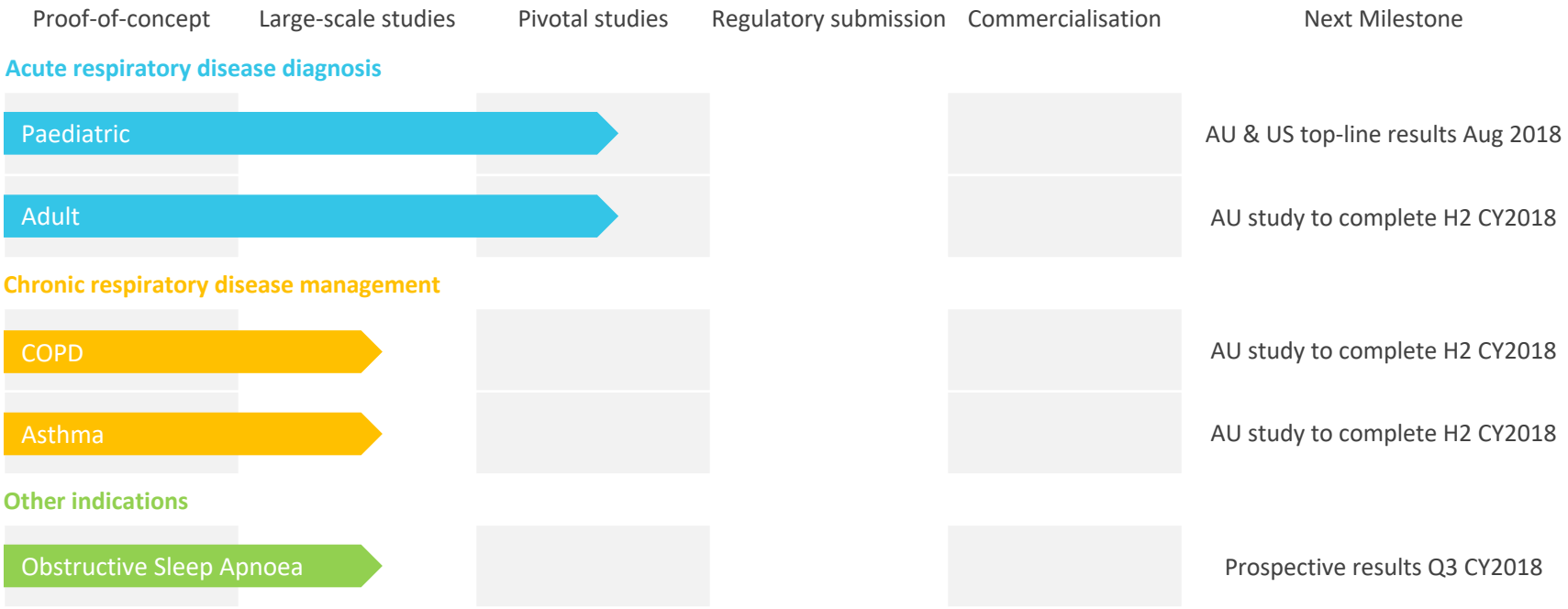
Broadening product portfolio



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, primarily caused by smoking
  - 3M+ people died of COPD in 2012, 6% of all deaths globally[5]

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
  - 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

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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

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

- More than 3 in 10 men, and nearly 2 in 10 women have sleep apnoea[1]
- 80% with moderate or severe sleep apnoea are undiagnosed[2]
- Untreated, sleep apnoea has been linked to heart disease, stroke and type 2 diabetes
- 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 $150-$500 per test Uncomfortable

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1. Peppard et al., Am J Epidemiol (2013)
2. American Academy of Sleep Medicine

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
- Prospective in-laboratory and at-home study underway, 312 patients recruited as of July 11, 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 from Australian studies of over 2,600 patients
- Multiple clinical programs underway
  - **Revised US paediatric clinical study completed recruitment, on-track for results in August 2018**
  - **Australian prospective paediatric study completed recruitment, on-track for results in August 2018**
  - Australian prospective adult study currently recruiting, 567 adults enrolled as of June 27
- Well understood regulatory pathway
  - Held US FDA Pre-Submission meeting in Q1 CY2016, confirmed *de novo* regulatory pathway strategy
  - FDA submission following US paediatric study completion
  - CE (Europe) and TGA (Australia) submissions following Australian prospective study completion
- Beginning to execute on commercial strategy with LOI 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**

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