NDF RESEARCH

Providing independent research coverage of
ASX-listed Life Science companies

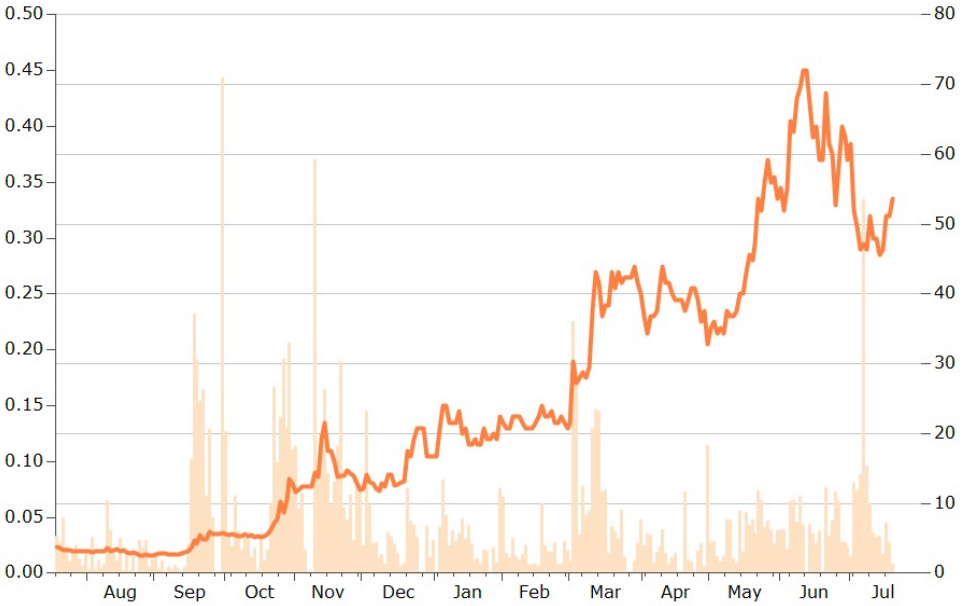
ResApp Health (ASX: RAP)

Initiation of Coverage – Monday 25 July 2016

The Next Big Thing in respiratory diagnostics

ResApp Health is a Perth-based company developing a smartphone-based diagnostic for respiratory disease. The technology, originally developed at the University of Queensland, can detect, through the measurement of coughs and breathing sounds, a range of respiratory disorders including pneumonia, asthma, and COPD with sensitivities and specificities greater than 90% and improving all the time thanks to machine learning. The technology works on existing smartphones with no extra specialised hardware required, making rapid deployment post-regulatory approval a relatively straightforward and highly scalable proposition. ResApp Health is now preparing for a registration study of the technology, ahead of a filing for FDA approval expected in early 2017.

Rating	Risk	Current price	Target price
Buy	Medium	$0.35	$0.85



Stock details

Daily Turnover: $1.03m
Market Cap: A$227.2m
Shares Issued: 649.2m
52-Week High: $0.45
52-Week Low: $0.016

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Please note: Please refer below for risks related to ResApp as well our General Advice Warning, disclaimer and full disclosures. Also please be aware that the investment opinion in this report is current as at the date of publication but that the circumstances of the company may change over time, which may in turn affect our investment opinion.

About NDF Research

NDF Research is an independent equity research firm based in Sydney, Australia. The firm focuses on Life Sciences companies that are publicly traded on the Australian Securities Exchange (ASX), one of the world's premier equity markets for biotechnology and medical device companies. NDF Research's Founder and Senior Analyst, Stuart Roberts, has been involved in Life Sciences since 2002 as a sell-side analyst as well as an executive of two ASX-listed immune-oncology drug developers.

NDF Research believes that ASX-listed companies have been largely overlooked in the global Life Sciences boom that began in late 2008, partly because of a paucity of quality research on them. NDF Research's goal is to help fill this great need, and introduce investors to some potential future billion dollar companies from 'Down Under'.

To learn more about the Life Sciences sector on the ASX and our firm, please visit ndfresearch.com.

Ferry at the end of a rainbow on Sydney Harbour, August 2014

In this report

Financial summary

Code	RAP
Analyst	Stuart Roberts
Date	22 July, 2016
Share price	$0.3500
Market capitalisation	$227m
Year end	30 June

Rating	BUY
Price target	$0.850
Upside/downside	142.9%
Valuation	$0.518 / $1.237
Valuation method	Probability-weighted DCF
Risk	Medium

PROFIT AND LOSS (A$m)

Y/e June 30 (A$m)	FY14A	FY15A	FY16E	FY17E	FY18E
Revenue	0.0	0.2	0.0	2.1	9.1
EBITDA	**-0.6**	**-0.5**	**-5.5**	**-5.9**	**0.1**
D&A	0.0	0.0	0.0	0.0	0.0
EBIT	**-0.6**	**-0.5**	**-5.5**	**-5.9**	**0.1**
Net interest	0.0	0.0	0.0	0.0	0.0
Pre-tax profit	**-0.6**	**-0.5**	**-5.4**	**-5.9**	**0.1**
Tax	0.0	0.0	0.0	0.0	0.0
NPAT	-0.6	-0.5	-5.4	-5.9	0.1
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit after minorities	-0.6	-0.5	-5.4	-5.9	0.1

BALANCE SHEET (A$m)

Y/e June 30	FY14A	FY15A	FY16E	FY17E	FY18E
Cash	0.0	4.1	11.4	5.9	6.1
Current receivables	0.0	0.1	0.1	0.2	0.5
Inventories	0.0	0.0	0.0	0.1	0.4
Other current assets	0.3	0.6	0.3	0.3	0.3
Current assets	**0.3**	**4.8**	**11.9**	**6.6**	**7.2**
PPE	0.0	0.0	0.0	0.1	0.1
Intangible assets	0.0	0.0	2.4	2.4	2.4
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	0.0	0.0	2.4	2.5	2.5
Total assets	0.3	4.8	14.3	9.1	9.7
Payables	0.2	0.5	0.2	0.2	0.4
Debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.0	3.8	0.0	0.0	0.0
Total liabilities	0.2	4.3	0.2	0.2	0.4
Shareholders' equity	0.1	0.5	14.2	8.9	9.3
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	**0.1**	**0.5**	**14.2**	**8.9**	**9.3**
Total funds employed	**0.3**	**4.8**	**14.3**	**9.1**	**9.7**
W/A shares on issue	172	205	401	634	634

CASH FLOW (A$m)

Y/e June 30	FY14A	FY15A	FY16E	FY17E	FY18E
NPAT plus discontinued ops.	-0.6	-0.5	-5.4	-5.9	0.1
Non-cash items	0.0	0.0	-0.3	0.4	0.4
Working capital	0.2	0.1	0.8	-0.2	-0.3
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**-0.3**	**-0.4**	**-4.8**	**-5.7**	**0.2**
Capex	0.0	0.0	0.0	0.0	0.0
Investments	-0.3	-0.2	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.3**	**-0.2**	**0.0**	**0.0**	**0.0**
Change in borrowings	0.0	0.0	0.0	0.0	0.0
Equity raised	0.5	0.7	12.5	0.3	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	4.0	-0.3	0.0	0.0
Financing cashflow	**0.5**	**4.7**	**12.2**	**0.3**	**0.0**
Net change in cash	**-0.1**	**4.1**	**7.3**	**-5.5**	**0.1**
Cash at end of period	0.0	4.1	11.4	5.9	6.1

EARNINGS (A$m)

Y/e June 30	FY14A	FY15A	FY16E	FY17E	FY18E
Net profit ($m)	-0.6	-0.5	-5.4	-5.9	0.1
EPS (c)	-0.3	-0.2	-1.4	-0.9	0.0
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-104.2	-147.0	-25.9	-37.6	2092.4
CFPS (c)	-0.2	-0.2	-1.2	-0.9	0.0
Price/CF (x)	-172.6	-183.3	-29.0	-38.9	1320.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-392.4	-435.8	-39.6	-37.3	2166.6
EV/EBIT	-392.4	-435.8	-39.6	-37.2	2630.4

PROFITABILITY RATIOS

Y/e June 30	FY14A	FY15A	FY16E	FY17E	FY18E
EBITDA/revenue (%)	N/A	-339.1%	-14438.6%	-282.3%	1.1%
EBIT/revenue (%)	N/A	-339.1%	-14438.6%	-282.7%	0.9%
Return on assets (%)	-171.0%	-10.2%	-37.8%	-64.9%	1.1%
Return on equity (%)	-477.7%	-101.0%	-38.2%	-66.6%	1.1%
Return on funds empl'd (%)	-469.9%	-101.0%	-38.2%	-66.6%	1.1%
Dividend cover (x)	N/A	N/A	N/A	N/A	0%
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY14A	FY15A	FY16E	FY17E	FY18E
Net debt/(cash) ($m)	0	-4	-11	-6	-6
Net debt/equity (%)	-29.8%	-846.5%	-80.8%	-67.0%	-65.0%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	1.6	1.1	78.0	27.8	18.2

INTERIMS

Y/e June 30 ($m)	1H15A	2H15A	1H16A	2H16F	1H17F
Revenue	0.2	0.0	0.0	0.0	0.0
EBITDA	**0.0**	**-0.5**	**-1.5**	**-3.9**	**-3.8**
D&A	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
EBIT	**0.0**	**-0.5**	**-1.5**	**-3.9**	**-3.8**
Net interest	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Pre-tax profit	0.0	-0.5	-1.5	-3.9	-3.8
Tax	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
NPAT	0.0	-0.5	-1.5	-3.9	-3.8
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Net profit after minorities	0.0	-0.5	-1.5	-3.9	-3.8

VALUATION

	Base	Optimistic
Value of ResApp technology	405.2	969.4
Value of tax losses	2.7	2.7
Corporate overhead	-20.6	-20.6
Cash now (A$m)	15.0	15.0
Cash to be raised (A$m)	0.0	0.0
Option exercises (A$m)	3.8	3.8
Total value (A$m)	406.1	970.3
Total diluted shares (million)	784.2	784.2
Value per share	$0.518	$1.237
Valuation midpoint	$0.878	
Share price now (A$ per share)	$0.350	
Upside to midpoint	150.7%	

Introducing ResApp Health (ASX: RAP)

- **ResApp is developing a smartphone-based diagnostic for respiratory disease.** The ResApp diagnostic, which we call the ResApp System and which was originally developed by Associate Professor Udantha Abeyratne at the University of Queensland (UQ), is able to detect from patient breathing and coughs whether or not the patient has respiratory disease, and what kind of disease, with a very high degree of sensitivity and specificity. Remarkably, the technology is able to work with existing smartphones and requires no extra hardware in order to work, making rapid deployment post-regulatory approval a relatively straightforward proposition. ResApp Health is now preparing for registration study of the technology, ahead of a filing for FDA approval expected in early 2017.

- **What is the technology behind the ResApp System?** In developing the ResApp System, Udantha Abeyratne and his colleagues at UQ worked from two basic premises: Firstly, that individual respiratory diseases have certain 'signatures' that are more or less uniform across the population, in terms of soundwaves as measured using various advanced mathematical tools. Secondly, that the microphones in standard smartphones could capture these signatures in cough and breathing sounds. Abeyratne et. al.'s approach, beginning around 2009, was to use machine learning to return progressively more accurate diagnoses as more patient sound recordings and ancillary information (such as fever and runny nose) were fed into their system. The ResApp System is now able to detect a variety of respiratory diseases with sensitivity and specificity above 90% and in some cases approaching 100%, and can do so against a background of other diseases or healthy controls. ResApp also believes that the technology could be useful in management of respiratory disease through measurement of disease severity.

THE RESAPP SYSTEM HAS A SPECIFICITY AND SENSITIVITY >90% AND SOMETIMES APPROACHING 100%

- **What is the evidence of the effectiveness of ResApp's technology?** The >90% specificity and sensitivity ratings of the ResApp System has been established in an ongoing study in paediatric patients in Australia which initiated in March 2015, as well as another Australian study in adult patients which initiated in late 2015. The pediatric study has now evaluated >600 subjects. Probably the most compelling aspect of ResApp's studies has been the demonstration that pediatric lower respiratory tract infections cases initially missed by experienced clinicians using a stethoscope could be detected by the ResApp System in 97% of cases.

- **What is the regulatory path for the ResApp System?** ResApp's investigators are currently preparing for a single US-based study of the ResApp System in adult patients ahead of potential FDA approval. The company expects to be able to conduct this study in the second half of calendar 2016. As with the Australian studies, this study will seek to demonstrate the clinical utility of the ResApp System in a range of respiratory diseases. Subject to favourable data from this study, we expect ResApp Health to be filing with the FDA for marketing authorisation in late 2016, gaining first approval in early 2017. There will likely be multiple approvals through 2017 and beyond as the Agency considers the data for each individual respiratory condition. We believe the data from this study and the Australian studies will also form the backbone for approvals in Europe and other jurisdictions.

- **What is the market opportunity for the ResApp System?** In the US roughly one in ten doctor visits results in diagnosis of a respiratory disorder, which can translate into 125 million diagnoses annually. The comparable figure globally is believed to be in the order of 700 million, costing, we estimate, US6-7bn for old-fashioned procedures involving X-Rays, and CT scans, and pathology tests. We argue in this note that much of this market is addressable for ResApp given the rapidity, accuracy and hardware-neutral nature of its technology.

RESAPP CAN POTENTIALLY RECEIVE ITS FIRST FDA APPROVAL IN EARLY 2017

- **ResApp stock has already had a good year. Why should I look now?** ResApp Health stock has proved very popular since it was back-door listed on the ASX in July 2015 after a A$4m capital raising at 2 cents per share. The company was able to raise another $12.5m in April 2016 at 20 cents per share, and the stock has since been as high as a 45 cent ASX close on 13 June 2016. This performance is due in part to the obvious advantages of the ResApp System over current diagnostic modalities, as well as the nearness to first US regulatory approval. In this note we argue for a high value for the technology given its apparent cost effectiveness and scalability in an era when digital health can be said to have truly arrived.

Ten reasons to consider ResApp Health

- **ResApp Health has developed an important breakthrough in respiratory diagnosis**. The ResApp System enables the rapid diagnosis of a range of respiratory conditions at sensitivities and specificities north of 90% (and improving all the time) using only smartphones with no added hardware. The data suggests that this technology will prove highly cost effective against current modalities such as auscultation, diagnostic imaging and pathology.

THE LAST THREE YEARS HAS SEEN THE DIGITAL HEALTH SECTOR BOOM

- **The ResApp technology fits into an ongoing boom in digital health**. The last three years has seen the digital health sector boom, driven by the obvious diagnostic advantages of gathering biomedical data through smartphones and wearable devices, the potentially favourable healthcare economics, and the ease with which such technology can scale. As information technology and healthcare start to converge, the leading technologies in the field are likely to attract favourable enterprise valuations due to the large patient numbers involved.

- **The ResApp data is good and is getting better**. The ResApp System has shown in the last twelve months that it is capable of superior outcomes to existing modalities. For example, in its currently ongoing study in pediatric patients, 97% of patients with lower respiratory tract infections that were initially missed by experienced clinicians using auscultation were correctly diagnosed the first time using the ResApp System. With the ResApp System being based on machine learning, the sensitivities and specificities get better all the time.

- **ResApp is a late stage development opportunity**. After a favourable proof-of-concept study in Indonesia in 2013, ResApp initiated a large registration-oriented study in pediatric patients in early 2015. A comparable study in adult patients initiated in late 2015 and a US study in adults, where Massachusetts General Hospital in Boston (MassGen) is one of the trial sites, is expected to initiate shortly. We believe

that ResApp will be in a position to file for its first FDA approval in late 2016, with first approval in 2017 subject to favourable data and regulatory review.

- **The markets for respiratory diagnostics are large**. With around one in ten doctor visits resulting in a respiratory diagnosis, there are potentially 700 million diagnoses each year worldwide that could be aided by the ResApp System. The large patient populations for various respiratory conditions such as asthma (8% of the US population) and COPD (6% of the US adult population) suggest a large market opportunity in the billions for technology which can help manage these conditions. We estimate ResApp's global addressable market at US$6-7bn p.a.
- **ResApp has multiple commercialisation avenues to pursue**. As well as its use in conventional clinical settings, we foresee uptake of ResApp products from companies involved in Telehealth as well as companies providing Direct-to-Consumer healthcare.
- **ResApp benefits from the support its technology has received from the Gates Foundation**. The ResApp System has its origins in funding from the Bill & Melinda Gates Foundation for the development of a smartphone-based pneumonia diagnostic, which is highly relevant in the Third World. We think the future use of the ResApp System in emerging healthcare systems will draw favourable attention to the breakthrough nature of the technology.
- **ResApp has favourable news flow**. We expect that preliminary results from adult clinical study as well as a pivotal clinical study in US and Australia, followed by a De Novo premarket submission with the FDA, and a filing for CE Mark in Europe, will continue to generate investor interest through the rest of 2016. In 2017 we expect the first FDA marketing approval to come through. ResApp has a track record since its July 2015 listing of meeting its development milestones in a timely manner.
- **ResApp Health has a capable management team**. CEO Dr Tony Keating brings a track record of helping to foster biomedical startups through his years at the University of Queensland's Uniquest commercialisation arm. Backing Keating is a board Chaired by the UK-based serial bio-entrepreneur Roger Aston. Another director is Brian Leedman, a Perth-based biotech veteran.
- **ResApp Health is undervalued on our numbers**. We value ResApp using a probability-weighted DCF approach at $0.52 per share base case and $1.24 per share optimistic case. Our $0.85 target price sits at around the midpoint of our valuation range. We see ResApp being re-rated by the market as data continues to build from the clinical studies, and as FDA approval for the device grows nearer.

RESAPP HAS A TRACK RECORD OF MEETING ITS DEVELOPMENT MILESTONES IN A TIMELY MANNER

The reason ResApp stock increased 22-fold

From 2 cents per share to 45 cents in just 11 months - the market has responded well to the ResApp story. ResApp Health is a spinout company from the University of Queensland developing a smartphone-based tool for the diagnosis and monitoring of respiratory diseases. The company was taken public in mid- 2015 when it was backdoor-listed[1] on the ASX after a A$4m capital raising at 2 cents per share. At the first day close of 2.2 cents on 14 July 2015 ResApp had a market capitalisation of just A$12.4m[2], however the next 11 months saw a considerable re-rating:

- By April 2016 the share price had increased 11-fold, to 23.5 cents, when a A$12.5m raising took place at 20 cents per share;
- The stock continued to increase after the placement until it had reached 45 cents by 13 June. At that price ResApp enjoyed a market capitalisation of A$292m[3].
- Between 13 June and 14 July a minor reaction set in, sending the share price down to a 28.5 cent close on 14 July 2016. This was in part due to Uniquest selling. The stock has since stabilised.

Why the enthusiasm over ResApp? We argue that ResApp became a 22-bagger between July 2015 and June 2016 for three main reasons

- **The technology itself** – Up until the present time medicine has had no diagnostic tool for respiratory diseases that only requires smartphones and no other hardware. The sensitivities and specificities now being recorded with ResApp's technology in clinical studies suggests that it is sufficiently disruptive to displace current modalities such as the stethoscope, X-Rays and pathology tests.
- **The nearness to market of the technology**. ResApp is currently preparing for a US registration study of its device which puts it on track for its first FDA approval in early 2017, subject to favourable clinical data and regulatory oversight;
- **The digital health trend** – Over the last three years, digital health has become a big story in capital markets, with investors sensing large profits to come from the convergence of medicine and the smartphone. ResApp is well placed to benefit from this trend.

RESAPP IS CURRENTLY PREPARING FOR A U.S. REGISTRATION STUDY OF ITS DEVICE

Is the enthusiasm justified? In this note we argue that the re-rating of ResApp Health in the first half of 2016 was not unreasonable, and that there is potential for considerable medium-term upside from here:

- We see no other technology in the respiratory space that rivals ResApp's in terms of diagnostic power, ease of deployment and use, and notional cost effectiveness;

[1] 'Backdoor listing' is an Australian term for what is known in US equity markets as a 'Reverse Takeover'. The original UQ spin-out was merged into a defunct HIV drug developer called Narhex Life Sciences, old ASX Code NLS. Narhex acquired the privately held ResApp Health, which had been founded in late 2014, for the equivalent of 93.75 million shares in today's capital structure.
[2] US$9.2m.
[3] US$216m.

- ResApp's technology is scalable and therefore a potential beneficiary of the network effect. In addition, it is based on machine learning, so it continues to improve all the time in terms of sensitivity and specificity. Consequently, it's reasonable to expect the inherent value of the technology to rise over time;
- The range of respiratory diseases for which ResApp's technology is applicable continues to expand, with particular upside still to be explored in the large market opportunities of asthma and COPD;
- First FDA approval of the device, to be followed by subsequent FDA approvals for other indications as well as approvals in other jurisdictions, has the potential to attract multiple commercial discussions with major healthcare payors for whom respiratory diseases are a significant cost burden.
- The digital health trend has gathered pace over the last three years thanks to initiatives at the smartphone companies, other makers of wearable devices, and major players in the information revolution such as Google and the social media companies.

ResApp's great data is getting even better

The ResApp System is a suite of respiratory diagnostic algorithms that only need smartphones to work. As we noted in the Introduction above, ResApp's technology is able to detect respiratory disorders simply by identifying the relevant 'signature' soundwaves in the coughing and breathing sounds of patients. We say 'simply', but in fact the mathematics behind the algorithms has required teams of PhDs and multiple person-years at UQ to optimise. We believe four main factors make the ResApp System a breakthrough in the field of respiratory disorders:

THE RESAPP SYSTEM CAN WORK ON SMARTPHONES ALONE

1) It is a genuine smartphone diagnostic, meaning that it can work on smartphones alone, unlike other systems which require an extra hardware component or do not integrate with smartphones at all;
2) It is rapid, in some cases requiring only a few minutes of recorded sound before a result is returned;
3) It has demonstrated superiority to other modalities in terms of specificity and sensitivity;
4) It is evolutionary – Abeynatne et. al. built machine learning into their system so over time the diagnoses have improved both in terms of specificity and sensitivity.

The good word from Bill and Melinda Gates - ResApp technology was considered world-beating when it first got funded seven years ago. Abeyratne et. al., working in UQ's School of Information Technology and Electrical Engineering, originally focused their diagnostic system on sleep apnea, where the clinical need was low-cost home-based diagnostics to replace expensive sleep laboratories[4]. However, in 2009 the Abeyratne group won some valuable grant funding from the Bill and Melinda Gates Foundation to develop a pneumonia diagnostic[5]. The assumption was that pneumonia had identifiable soundwave signatures and that a smartphone-based diagnostic could thereby detect pneumonia faster and more reliably than auscultation. This project attracted the interest of the Gates Foundation because pneumonia is estimated to kill in excess of 900,000 children under the age of five

[4] See *Cough into my smartphone* by Nigel Bowen, Australia Unlimited, 14 August 2015.
[5] See the Gates Foundation press release dated 20 October 2009 and headlined *'Funding 76 New Ideas to Improve Global Health'*.

globally[6], with the vast majority of deaths occurring in the Third World. The Abeyratne team only received US$100,000 from the Gates Foundation, as part of an initiative called 'Grand Challenges Explorations'. However, we argue that this funding was very significant from a peer-review perspective because only 3% of all applications to the initiative were successful. The Gates money was used to initiate a proof-of-concept study of the ResApp System, from which published data became available in 2013.

RESAPP'S TECHNOLOGY WAS ORIGINALLY DEVELOPED WITH GATES FOUNDATION FUNDING

The original clinical data from 2013 showed that the ResApp technology was good. The ResApp System's proof-of-concept study took place at Sardjito Hospital, associated with Gadjah Mada University in Yogyakarta, Indonesia. The study, which evaluated 91 pediatric patients, showed that the ResApp System was able to detect pneumonia at a sensitivity of 94% and a specificity of 100% once easily-obtainable supporting data such as age and the presence of fever, runny nose etc. were added to the soundwave analyses. Later on, when the ResApp System was tested for its ability to diagnose asthma, the result was 100% sensitivity and 80% specificity[7]. Two peer-reviewed papers resulted from the Sardjito work:

- Swarnkar et. al., January 2013[8]. This paper, in the *Annals of Biomedical Engineering*, showed that the ResApp System could distinguish between 'wet' and 'dry' cough (ie one with or without phlegm) in 87-88% of cases for a 'training/validation dataset' and 76-85% prospectively;
- Kosasih et. al., December 2014[9]. This paper, in an IEEE[10] journal called *Transactions on Biomedical Engineering*, showed how a 94% sensitivity and 88% specificity for pneumonia diagnosis could be achieved with various aspects of the ResApp technology.

The clinical data from the currently ongoing pediatric study shows the versatility of the ResApp System. In March 2015 ResApp initiated a large study of the ResApp System in pediatric patients at the Joondalup Health Campus in Perth. In this study the predictive ability of the ResApp System was evaluated using the 'leave-one-out cross-validation' approach where the performance of the algorithms was evaluated against conventional clinical diagnosis by hospital staff. The study initially intended to recruit 150 patients with various respiratory conditions, and these patients had all come on board by July 2015[11]. ResApp added a second Perth site, Princess Margaret Hospital, in August 2015 and raised its recruitment target to 400. The enlargement of the study was designed to further optimise the ResApp System's diagnostic ability in pneumonia and asthma, but also to add other indications such as bronchiolitis and upper respiratory tract infections. The study represented a step change for the ResApp System from the proof-of-concept study, since new respiratory conditions were tested, healthy controls were added, and voluntary coughs were used, as against only spontaneous coughs previously. Favourable data from the study started to become available within six months of initiation:

- **September 2015[12]** – ResApp was able to show > 95% accuracy in diagnosing asthma and >96% accuracy in diagnosing viral pneumonia over healthy controls, where 'accuracy' was the combined measure of

[6] See World Health Organisation Fact Sheet No. 31 at www.who.int.
[7] Source: ResApp presentation at Australia Biotech Invest, 6 October 2015, slide 5
[8] Swarnkar et. al., Ann Biomed Eng. 2013 May;41(5):1016-28. pub 2013 Jan 25.
[9] Kosasih et. al., IEEE Trans Biomed Eng. 2015 Apr;62(4):1185-94. Epub 2014 Dec 18.
[10] Institute of Electrical and Electronics Engineers.
[11] See ResApp's market release dated 14 July 2015 and headlined '*ResApp shares commence trading on the ASX and patient enrolment complete for clinical study*'.
[12] See the ResApp market release dated 30 September 2015 and headlined '*Positive preliminary results from current clinical study for diagnosing respiratory disease*'.

sensitivity and specificity[13] (asthma >97% sensitivity, 92% specificity; viral pneumonia (> 91% sensitivity, >95% specificity). This result, achieved only by analysis of patient coughs, was clear evidence that the machine learning aspect of the ResApp System was working.

- **November 2015[14]** – ResApp showed, against a background of healthy controls[15], that the ResApp System could detect bronchiolitis with 100% accuracy, croup with 99% accuracy, and upper respiratory tract infection (URTI) with 96% accuracy[16]. What was particularly encouraging was that the ResApp System was now demonstrated to be able to pick out one respiratory condition from another. Against a background of URTI, the accuracy level for various other conditions was >87%, and when the background was varied with the disease being assayed for, the lowest accuracy reading was 85%.
- **Early March 2016[17]** – ResApp showed 99% accuracy in detecting lower respiratory tract disease against healthy controls, and 91% accuracy in detecting lower respiratory tract disease versus either upper respiratory tract infections or no discernible respiratory tract disease.
- **Late March 2016[18]** – ResApp was able to separate bacterial and atypical pneumonia from viral pneumonia with respective accuracies of 89% and 92%.

The Australian adult study looks set to repeat the track record of success of the pediatric study. ResApp initiated a 400-patient study in adults at Joondaulp and at the Wesley Hospital in Brisbane in late 2015 and early 2016 respectively. By late June 2016 this study had enrolled in excess of 300 patients and the first preliminary analysis showed some promise:

- In adults the ResApp System could distinguish COPD, asthma and pneumonia against health controls with at least 92% accuracy;
- For patients with both asthma and COPD the accuracy rate against healthy controls was 94%;
- The ResApp System could pick out COPD against asthma, and pneumonia versus asthma, with 95%-96% accuracy.

THE RESAPP SYSTEM HAS THE MAKINGS OF A RELIABLE TOOL IN MANAGING COPD

Conclusion from the available data: For the ResApp System, machine learning seems to work. Probably the only downside of this suite of data points is that we don't know the level of statistical significance. ResApp's investigators didn't power the current two studies beforehand because part of the purpose of these studies was to allow a pivotal study to be properly powered. That said, we think data that have become available to date shows that the ResApp System as it stands today has the capability to detect any respiratory condition, based on cough soundwaves alone, against any other respiratory condition, with accuracy levels north of 90% and gradually headed towards 100%. This shows the power of the machine learning which Abeyratne et. al. built into their system.

[13] Sensitivity is the percentage of diseased patients who test positive whereas specificity is the percentage of healthy patients who test negative. Accuracy is the combined measure of both.
[14] See the ResApp market release dated 10 November 2015 and headlined '*Further Positive Preliminary Results from Clinical Study*'.
[15] Where that dataset had increased from 39 subjects to 51.
[16] The accuracy for viral pneumonia also increased slightly, to 97%.
[17] See the ResApp market release dated 2 March 2016 and headlined '*ResApp Achieves Breakthrough Performance in Paediatric Clinical Study*'.
[18] See the ResApp market release dated 31 March 2016 and headlined '*ResApp Provides Updated Paediatric Clinical Study Results*'.

ResApp has outperformed the clinicians

The ResApp System was able to discover lower respiratory tract disease before the clinicians. A significant aspect of ResApp story in 2016 has been its outperformance against trained clinicians:

- **Early March 2016**[19] –ResApp's investigators found that the ResApp System could detect lower respiratory tract disease in 80% of cases (19 out of 24) where physicians with stethoscopes had initially found no lower respiratory tract disease but did so subsequently.
- **Late March 2016**[20] – With an enlarged database[21] ResApp's investigators found the ResApp System had in fact had managed to detect lower respiratory tract disease where the doctors had initially missed it in 97% of cases, rather than the 80% reported earlier in the month.

Given that this outperformance for the ResApp System happened in pediatric patients, we think it provides a compelling case for the adoption of the ResApp System by clinicians, subject to its being repeated in larger studies.

THE RESAPP SYSTEM IS ABLE TO DETECT LOWER RESPIRATORY TRACT INFECTION BEFORE EXPERIENCED CLINICIANS CAN

ResApp's relatively short path to market

ResApp will be seeking Marketing Authorisation from the FDA for the ResApp System using the De Novo pathway. Diagnostics such as the ResApp System are regulated as medical devices by the FDA. ResApp had a Pre-Submission Meeting with the FDA in March 2016, after which the company announced that it would be pursuing approval for the ResApp System via the De Novo pathway.

- Traditionally, device developers went for marketing authorisation either via the 510(k) route (where there was a predicate device on the market) or the PMA route (for new devices). The De Novo pathway has been around since the Food and Drug Administration Modernization Act of 1997 but was little used until a 2012 change to the regulations made it an ideal route for low risk devices with no predicate[22].
- The ability to go down the De Novo path is, in our opinion, favourable for ResApp because it accords with ResApp's assessment that the device is a Class II device.
- The only minor downside for De Novo is that the Agency's Review Cycle for the product is 120 days rather than 90 days for the 510(k) route.

ResApp now has only one more study to run, this one in the US, prior to first approval. The FDA's guidance at the Pre-Submission Meeting was that the Agency would like to see a pivotal study for the ResApp System at one or more US hospitals to augment the data that has been gathered from the Australian studies. ResApp is currently

[19] See the ResApp market release dated 2 March 2016 and headlined '*ResApp Achieves Breakthrough Performance in Paediatric Clinical Study'*.
[20] See the ResApp market release dated 31 March 2016 and headlined *'ResApp Provides Updated Paediatric Clinical Study Results'*.
[21] By this time ResApp's dataset was 524 subjects, versus 338 previously.
[22] Before 2012 sponsors had to first submit a 510(k) and be told that their device was 'NSE', that is, Not Substantially Equivalent with the predicate the sponsor would suggest, and then go down the De Novo route.

preparing for this study with the intention of initiating and potentially completing it in the second half of calendar 2016

- ResApp announced in June 2016 that it was negotiating with two 'Top 10' US hospitals to host its US sites.
- The first site to be disclosed by name, on 20 July 2016, was Massachusetts General Hospital in Boston (MassGen), a real coup for ResApp given that the well-regarded US News and World Report survey rated MassGen the fourth best hospital in America for pulmonary disease in its 2015/16 rankings, and the best hospital overall[23].

RESAPP HAS MASSGEN HAS THE FIRST U.S. TRIAL SITE FOR ITS PIVOTAL STUDY

We expect that ResApp's study will have a Primary Endpoint of Accuracy at or greater than 80%, which is what is obtainable using a chest X-Ray[24].

ResApp will initially be applying for pediatric use. With the first major clinical study of the ResApp System having been a pediatric study, ResApp's investigators will likely be in a position to file its pediatric dossiers first, with adult dossiers to follow. We see potential for the first submission to be made in the last quarter of 2016 and initial FDA approval to be gained in early 2017. Other approvals would then follow depending on the quality of the data.

ResApp's first FDA approval is not far away. An important aspect of ResApp's clinical development is its speed. We noted above that ResApp recruited the first patient into the current pediatric study at Joondalup in March 2015. Just over a year later there were 524 subjects in the dataset from this study[25] and by early May 2016 there were 598[26]. Basically this study has tested one or two patients a day since launch, which is a function of Joondalup being one of Perth's busiest public hospitals, and the ResApp test not taking long to perform. This is why we're reasonably confident that ResApp can be filing for FDA approval before the end of 2016, ahead of an early 2017 approval.

[23] Visit http://health.usnews.com/best-hospitals/rankings/pulmonology for the top-rated pulmonology hospitals in the list.
[24] Chest X-Rays typically have high sensitivity (90%) but low sensitivity (60-70%) – see Am J Emerg Med. 2015 May;33(5):620-5. Epub 2015 Jan 28.
[25] See the ResApp market release dated 31 March 2016 and headlined *'ResApp Provides Updated Paediatric Clinical Study Results'*.
[26] See ResApp's corporate presentation as filed with ASX on 3 May 2016, slide 8.

ResApp's US$6-7bn global market opportunity

Respiratory complaints are a leading diagnosis after doctor visits in the US. In the US in 2012 there in excess of 900 million physician office visits, and in ~9% of cases, representing 82 million office visits, the primary diagnosis is a disease of the respiratory system[27]. Only diseases of the musculoskeletal and connective tissue were more common.

- While the numbers can be variable depending on how cold the winter is, a not unreasonable number for respiratory diagnoses across both primary care and hospitals is 125 million out of 1.25 billion physician visits, or 10% of the total[28].
- Of these 1.25 billion visits, the principal reason for the visit, in around 3% of cases, will be cough.

In the US, the prevalence of many respiratory conditions is high. Consider simply the respiratory diseases for which the ResApp System has provided a diagnosis in the current clinical studies:

- **Asthma**. Around 7% of US adults and 9% of US children have asthma[29]
- **Bronchitis and bronchiolitis** caused 170,000 hospitalisations in the US in 2010, with average length of stay around 2.9 days[30]. There has been a trend since 2000 towards lower levels of hospitalisation for bronchiolitis but greater use of mechanical ventilation has continued to increased hospital costs[31].
- **COPD**. Around 6% of US adults have COPD[32].
- **Croup**. There are probably 1.4 million cases of croup in the US each year in US children[33].
- **Pneumonia**. While pneumonia may only cause ~50,000 deaths in the US each year it is still the primary diagnosis in 1.1 million hospital stays, or 3% of all hospital stays, with an average length of stay of 5.2 days[34].
- **URTI.** Typically, Americans catch a cold (ie experience a non-influenza-related viral respiratory tract infection) about 1.8 times a year[35], driving, it is believed, something like 75 to 100 million physician visits annually[36].

AROUND 7% OF U.S. ADULTS HAVE ASTHMA AND 6% HAVE COPD

While the smoking rate is declining in America, it is still high. Around 1% of the US adult population quits smoking for good every 2.4 years[37]. However, that still leaves ~17% of the current US adult population as smokers. Unsurprisingly, smoking plays a significant role in respiratory disease:

[27] Source: CDC, National Ambulatory Medical Care Survey data for 2012.
[28] Source: CDC, combined data for 2009 and 2010 from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey. This is the part of the source of ResApp's assertion that 'diagnosis of respiratory disease is the most common outcome from a visit to the doctor' - see the company's May 2016 corporate presentation, slide 5.
[29] Source: CDC, 2014 National Health Interview Survey.
[30] Source: CDC, National Hospital Discharge Survey for 2010
[31] Pediatrics. 2013 Jul;132(1):28-36.Epub 2013 Jun 3.
[32] MMWR Morb Mortal Wkly Rep. 2012 Nov 23;61(46):938-43.
[33] Estimated from BMJ Clin Evid. 2009; 2009: 0321.
[34] Source: CDC, National Hospital Discharge Survey for 2010.
[35] Arch Intern Med. 2003 Feb 24;163(4):487-94.
[36] Int J Pharm Compd. 2012 Nov-Dec;16(6):480-3.
[37] Estimated from MMWR Morb Mortal Wkly Rep. 2015 Nov 13;64(44):1233-40 and MMWR Morb Mortal Wkly Rep. 2005 Nov 11;54(44):1121-4.

- The 25-year risk of COPD from continuous smokers is ~25%[38].
- Smoking is known to increase the risk of developing asthma[39], however in the US the percentage of adults with asthma who smoke is 21% versus 17% for the general population[40].
- Smoking has long been known to increase susceptibility to the common cold[41].

Respiratory diseases are a significant health factor globally. One estimate[42] has suggested that ~5% of the world's population has asthma and another ~3% has COPD[43]. In terms of physician visits for respiratory complaints globally, ResApp has suggested a figure of around 700 million[44]. The smoking rate globally is around the same as the US at 17-19%[45].

We estimate the global respiratory diagnostics market to be worth US$6-7bn p.a. On our estimates the global direct costs of managing respiratory diseases is US$340bn, which is around 4-5% of total direct healthcare spending. In turn we estimate that around 1.7-2% of that value is spent on diagnostic imaging and pathology testing to manage that disease burden. Any diagnostic tool that can markedly reduce that US$6-7bn impost to healthcare systems, while improving on the accuracy of testing and increasing its timeliness, is likely to be very successful commercially.

The ResApp System may come into its own next time there's a serious influenza pandemic. In a typical flu season in the US around 12,000 people are hospitalised with a confirmed case of influenza[46] and there are 3,000 -4,000 deaths[47].The speed with which an influenza case can be confirmed can affect treatment outcomes given the availability of modern anti-virals like Tamiflu and Relenza. Consequently, we see considerable potential for upside for ResApp in the detection of influenza. Should the ResApp System be able to be adapted here it could come into its own in the event of a severe pandemic like, say, 1985/86.

DEVELOPMENT OF ALGORITHMS TO IDENTIFY INFLUENZA INFECTION WOULD GREATLY INCREASE MARKET RECOGNITION OF THE RESAPP SYSTEM

ResApp's timing is right for its diagnostic system

We argue there three factors working in ResApp's favour to enable it to address a large market opportunity from next year:

1) **The fact that it works so well, at little cost.** As we note below using pneumonia as a classic example, respiratory diseases are often misdiagnosed, and the diagnostic tools to correct these errors tend to be expensive. ResApp offers a solution to this problem;

[38] Thorax. 2006 Nov; 61(11): 935–939.
[39] See, for example, Eur Respir J. 2004 Nov;24(5):734-9.
[40] Source: CDC, Behavioral Risk Factor Surveillance System data for 2010.
[41] Am J Public Health. 1993 September; 83(9): 1277–1283.
[42] Estimated from the World Health Organization's 2007 report entitled '*Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach*'.
[43] Another estimate for COPD has suggested a figure of 11% for world COPD prevalence in people over 30 – see J Glob Health. 2015 Dec; 5(2): 020415.
[44] Assuming 125 million US doctor diagnoses of a respiratory complaint and then extrapolating using OECD data for the rest of the world.
[45] Estimates from JAMA. 2014 Jan 8;311(2):183-92.
[46] MMWR Morb Mortal Wkly Rep. 2013 Jun 14;62(23):473-9.
[47] Source: CDC, National Vital Statistics Reports, Volume 64, Number 2 (16/2/2016) - Deaths: Final Data for 2013.

2) **The rise of Telehealth.** With providers of Telehealth rapidly growing their membership base in the US and elsewhere, there will be increasing use of digital-based tools like ResApp's in the future;

3) **The ease with which ResApp's system can roll out.** Since it's only smartphones, there is no need for healthcare providers to worry about onerous capital costs when implementing the ResApp System, so for ResApp the roll-out is more a marketing exercise with its future commercial partners.

We look at each of these factors in the next three sections below.

Resapp can beat the competition on accuracy

Existing respiratory diagnostic modalities leave a lot to be desired. Currently respiratory disorders are diagnosed using auscultation (ie listening to the chest with the stethoscope), diagnostic imaging (X-Rays and CT scans) and pathology tests (blood and/or sputum). The drawbacks of current best practice can be shown by the example of pneumonia diagnosis, where in many cases diagnosis needs to happen quickly in order to initiate treatment, but the wrong diagnosis can lead to unneeded and ineffective antibiotic use. And the wrong diagnosis tends to happen with alarming frequency. For example, in one hospital in suburban Chicago in mid-2008 fully 26% of all patients admitted to the Emergency Department with a diagnosis of pneumonia did not in fact have pneumonia[48]. There are three main reasons for this high level of diagnostic error:

- **Even trained human ears can be deceived**. The humble stethoscope may have a long history of clinical use in pneumonia[49] and come with no added diagnostic costs, but is notoriously inaccurate. One study at a US Veterans hospital across a group of examiners found that their diagnosis of pneumonia using auscultation had a sensitivity of only 47% to 69% and specificity of 58% to 75%[50]. We noted above that the ResApp System in pediatric use has been able to detect lower respiratory tract disease in 97% of cases where the doctors with stethoscopes had initially missed it.

- **Trained human eyes can also be deceived**. Images on an X-Ray or CT scan are often equivocal. One 2007 study at the USCF Medical Center found that 20% of patients passing through the Centre's Emergency Department with an initial diagnosis of community-acquired pneumonia did not in fact have it. That was in spite of 43% of these patients having shown an abnormal chest radiograph[51]. The record is, admittedly, better for lung ultrasonography, where sensitivity and specificity is generally >90% and the device is comparatively inexpensive as well as portable[52].

- **Good pathology testing just isn't fast enough, or is too expensive.** Rapid point-of-care diagnostics for respiratory disorders have yet to achieve very high levels of sensitivity and specificity. This leaves reference laboratories to do the heavy lifting in an environment where one authority at Johns Hopkins

ABNORMAL CHEST RADIOGRAPHS CAN BE DECEIVING

[48] Am J Emerg Med. 2012 Jul;30(6):881-5. Epub 2011 Aug 19.
[49] Indeed, it is now two centuries old, having been invented in France in 1816 by a French doctor named René Laennec (1781-1826). Going further back, auscultation as a diagnostic tool is more like 2,500 years old given that it was Hippocrates who first used the method of applying the ear directly to the chest.
[50] Arch Intern Med. 1999 May 24;159(10):1082-7.
[51] Ann Emerg Med. 2007 May;49(5):553-9. Epub 2007 Jan 8.
[52] Respir Res. 2014 Apr 23;15:50.

has gone so far as to suggest that 'diagnostic microbiological characterization is disappearing as a component of high-quality care'[53].

All this does not mean that diagnostic tools for pneumonia and other respiratory conditions are not improving. As we note above, the recent data on lung ultrasonography, which is lower cost and portable, has been particularly encouraging[54]. Also, PCR-based and molecular diagnostics are emerging where costs are likely to come down over time. However, it does highlight the opportunity for a truly the opportunity for disruptive new modalities like that on offer from ResApp, where the new diagnostic is easy to introduce into clinical practice in terms of no specialised hardware requirements.

The era of Telehealth has arrived

Telehealth has reached the tipping point. Telehealth is simply the delivery of healthcare services remotely, where the patient is in one place and the physician in another, using the Internet as the medium for transferring diagnostic information and treatment solutions, and the Cloud for storage of patient information. Futurists have been talking about Telehealth for years. However, it has only been in the last three or four years that Telehealth has made substantial steps towards becoming reality. Eight main factors are at work here:

- **Internet and smartphone connectivity**. We believe that the key tipping point for Telehealth in America happened in late 2012 or early 2013 when the percentage of the population with Internet access reached 80%, and the percentage of the population which owned a smartphone crossed the 40% threshold. We believe the current figures are over 90% for Internet usage and close to 65% for smartphone ownership.

OBAMACARE RAISES THE FINANCIAL IMPORTANCE OF ACCURATE DIAGNOSES IN U.S. HEALTHCARE

- **Obamacare**. A much-talked about feature of Obamacare has been the financial penalties imposed on hospitals for patients readmitted within 30 days of discharge. These penalties, in the form of lower Medicare payments[55], were first imposed in 2011. Telehealth is an obvious low-cost way of following up on discharged patients so as to avoid a readmission event.
- **The Internet of Things**, in which devices such as ECG machines or pacemakers, are increasingly connected to the Internet to be monitored or managed remotely. The Internet of Things probably started taking off around 2014 in terms of enterprises, including hospitals, routinely connecting their physical assets to the Internet[56].
- **The 'wearable'.** The introduction of various wearable devices that routinely gather data on sleep, heart rate etc, - kick-started by Fitbit[57], Jawbone[58] and, importantly, Nike[59] and then taken to the next level by the

[53] Clin Infect Dis. 2011 May;52 Suppl 4:S296-304.
[54] Anesthesiology. 2004 Jan;100(1):9-15.
[55] Two of the five conditions for which readmission penalties apply are pneumonia and chronic lung problems. The other three are heart attack, heart failure and elective hip or knee replacements.
[56] See *Looking Back at 2015 – A Tipping Point for the Internet of Things* by Stuart Taylor, Cisco Blogs, 5 January 2016.
[57] San Francisco, Ca., privately held, www.fitbit.com.
[58] San Francisco, Ca., privately held, www.jawbone.com. Jawbone's activity tracker is called Jawbone Up.
[59] The presence of Nike in this space is significant because it leverages off that company's valuable fitness brand (34th in Millward Brown's 2014 list of the world's most valuable brands). Nike (Beaverton, Or., NYSE: NKE, www.nike.com) is a Fortune 500 company.

launch of the celebrated Apple Watch in April 2015 - has gotten people used to the idea of their vital signs being monitored via the Internet.

- **Electronic Health Records.** The percentage of office-based physicians in America who use Electronic Health Records (EHRs) of some type crossed the 50% mark in 2010. By 2015 the percentage that had certified EHRs[60] had risen to 74%.
- **A shortage of doctors.** The ageing of the US population has meant that in recent years it has become more difficult to get a conventional doctors' appointment. The Association of American Medical Colleges believes that one doctor per 1,000 people is a good ratio, but the current ratio is more like one doctor per 1,100 people[61].
- **HealthKit.** Apple released its iOS8 operating system in September 2014, shortly after the release of iPhone 6. A key feature of iOS8 was HealthKit [62], a Cloud API for integrating health and fitness data from multiple apps and monitoring devices into a digital repository. We believe HealthKit has paved the way for standards in which health data can be gathered via smartphones.
- **The arrival of Big Data.** One estimate, from McKinsey, has suggested that US$300-450bn can be cut from US healthcare costs from various Big Data initiatives[63]. Telehealth is well-placed to benefit from the Big Data analytics it can access.

APPLE'S HEALTHKIT HAS PAVED THE WAY FOR STANDARDS FOR HEALTH DATA GATHERING VIA SMARTPHONES

Telehealth is now showing up everywhere. As a result of these seven factors, most traditional elements of healthcare delivery, both public and private, now have a growing Telehealth component to them:

- As is common with a lot of progress in US healthcare, the Veterans Administration Health System has been at the forefront of innovations in Telehealth. In fiscal year 2014 the VA delivered more than 2 million Telehealth visits to around 690,000 veterans. The VA estimated that the annual cost of treating veterans via Telehealth dropped 4% over the three years to 2012[64].
- At the Mercy Health System in St Louis, Mo., which was established in 1986, a 'Virtual Care Center' which supports ICUs and EDs in 38 smaller hospitals has reduced average length of stay in the supported hospitals[65].
- At Oregon Health & Science University doctors used Telehealth to save US$6.4m in travel costs for the 45% of state patients who didn't need to travel to see them[66].
- UnitedHealth, America's largest health insurer, commenced coverage of 'virtual care provider visits' to its self-funded employer customers in April 2015[67]. A 2014 survey found that 37% of US employers

[60] That is, certified by the Office of the National Coordinator for Health Information Technology, a branch of the US Department of Health and Human Services.
[61] See *Doctor Shortage Worsens, Particularly in Southern States* by Bruce Japsen, Forbes, 29 December 2015.
[62] See www.apple.com/au/ios/ios8/health.
[63] See *The big-data revolution in US health care: Accelerating value and innovation* by Basel Kayyali, David Knott, and Steve Van Kuiken, McKinsey.com, April 2013.
[64] See *ECRI Update: Telehealth – Have We Passed the Tipping Point in Clinical Use?*, TechNation, 1/12/2015.
[65] See *Mercy Officially Opens World's First Virtual Care Center* by Sonya Kullmann, Mercy Health System, 6 October 2015.
[66] See *Virtual Doctor's Visits: The Promises of Telemedicine* by Lila Abassi, American Council on Science and Health web site, 18 January 2016.
[67] See the UnitedHealth press release dated 30 April 2015 and headlined '*UnitedHealthcare Covers Virtual Care Physician Visits, Expanding Consumers' Access to Affordable Health Care Options'*.

planned to offer their workers Telehealth consultations in 2015, with another 34% planning to do so by 2017[68].

- In 2015 CMS paid US$17.6m for Telehealth services, up 25% on the previous year[69]. For private insurers, the regulatory environment appears to be favourable, with over 30 US states having laws in place requiring private insurers to reimburse doctors for services delivered remotely if the same service would be covered in person[70].

Telehealth is creating new, fast-growing companies. One recent survey has suggested that around two-thirds of Americans would be willing to have doctor consultations via video[71], which suggests that Skype has helped condition to the public towards accepting Telehealth. No wonder, then, that an estimated 15 million Americans sought some kind of Telehealth service in 2015, up 50% from 2013[72]. The arrival of Telehealth has prompted a number of new companies in the space:

- Teladoc[73], which did its IPO last year, is widely considered the leading Telehealth company in America and is now capitalised at >US$700m. This company's 3,100 doctors performed over 575,000 Telehealth visits in 2015 and in the first quarter of 2016 Teladoc grew visits 61% year-on-year. At the start of 2016 Teladoc forecast US$116-122 in 2016 revenue, up 55%, on visits of 860,000-900,000.
- MDLive[74] , understood to be Teladoc's nearest competitor, has a similar business model in terms of pricing and the ability to do virtual visits either by video or phone.
- American Well[75] seems to have an advantage in terms of patient reach through Amwell, a mobile app which facilitates virtual doctor visits. Amwell was the most downloaded Telehealth app across both the App Store and Google Play in both 2014 and 2015[76]. American Well started allowing patients to pick their doctor in mid-2016[77].
- Doctor on Demand[78] has sought to differentiate itself by its pricing, in which customers don't pay a flat monthly fee but do pay for each doctor visit.

The patients like Telehealth – a lot. In an era when Uber is rapidly replacing taxis and Netflix has replaced DVDs, people in America and elsewhere in the Western world are starting used to getting things being 'on demand', rapidly, at their convenience. Telehealth taps into this requirement for patient convenience in a serious way. Teladoc, for example, estimates that its median response time for patients is less than 11 minutes, and that its physicians consistently get patient satisfaction ratings north of 95%. The other providers make similar claims. When you compare an 11-minute wait with the 123 minutes a conventional doctor visit will take in America

TELEHEALTH CAN MARKEDLY CUT THE WAIT TIME FOR A DOCTOR

[68] See the Towers Watson press release dated 11 August 2014 and headlined *'Current Telemedicine Technology Could Mean Big Savings'*.
[69] See *Medicare Payments for Telehealth Increased 25% in 2015: What You Need to Know* by Nathaniel M. Lackman, Health Care Law Today, 3 March 2016.
[70] See *How Telemedicine Is Transforming Health Care* by Melinda Beck, The Wall Street Journal, 26 June 2016.
[71] Source: Press release from American Well dated 21 January 2015, concerning a ~2000-person survey conducted by Harris.
[72] That's an estimate from the American Telemedicine Association (www.americantelemed.org), the Washington, DC-based organisation that advocates for the sector. You know a new industry has arrived in America when it gets its own lobbyists.
[73] Dallas, Tx., NYSE: TDOC, www.teladoc.com.
[74] Sunrise, Fl., privately held, www.mdlive.com.
[75] Boston, Ma., privately held, www.amwell.com.
[76] See the American Well press release dated 11 January 2016 and headlined *'Amwell is Again the Most Popular Telehealth App of the Year'*.
[77] See *American Well Will Allow Telemedicine Patients to Pick Their Doctor* by Reed Abelson, The New York Times, 16 May 2016.
[78] San Francisco, Ca., privately held, www.doctorondemand.com.

(according to a much-publicised recent study from Harvard[79]), there's really no contest. We think this patient convenience aspect, more than anything else, will drive rapid Telehealth uptake in the next few years.

Telehealth is particular good for respiratory disease. That was the finding of a June 2016 report[80] from the Agency for Healthcare Research and Quality (AHRQ), a research arm of the US Department of Health and Human Services. The AHRQ researchers looked at 58 systematic reviews on Telehealth and concluded that Telehealth provided benefits in terms of lower mortality, improved quality of life and reductions in hospital admissions when used for remote patient monitoring for certain chronic conditions, chief among them cardiovascular and respiratory disease. The AHRQ paper cited two reviews in particular related to COPD:

- McLean et. al., 2011, found that Telehealth-based management of COPD was associated with a clinically significant increase in quality of life, and a significant reduction in Emergency Department visits and hospitalisations[81].
- Kamei et. al., 2013, in Japan found a similar benefit in terms of decreased hospitalisation rates and emergency department visits, and also found Telehealth reduced exacerbations and mean duration of bed days of care[82].

TELEHEALTH IS KNOWN TO HAVE GENERATED BENEFICIAL PATIENT OUTCOMES IN CHRONIC RESPIRATORY DISEASE

The demand for respiratory diagnostics from Telehealth providers is likely to be strong. One 2014 report[83], for example, has suggested that around 30% of Telehealth visits at that time related to respiratory disease of some kind.

ResApp can easily tap into the current Telehealth trend. Obviously fitting the ResApp System to a Telehealth provider's system will take some integration work, however that is fundamentally just a minor software engineering exercise. The upside for the Telehealth provider is, by contrast, significant. It's not hard to imagine, during a virtual doctor visit, the attending physician simply saying to the patient 'Now, could you please hold the microphone on your tablet close to your mouth…yes, that's it, at the bottom of your tablet…could you hold that close to your mouth and then cough five times', and then having a reasonably reliable diagnosis not long thereafter. The key to ResApp's success here will be twofold:

1) Demonstrating to the Telehealth providers and the health insurers the accuracy of the ResApp system;
2) Developing a pricing model that adds value to the payors.

ResApp will also be a player in Telehealth 'Version 2.0'. At the moment Telehealth is mostly about getting patients in front of doctors remotely. Which is to say, it's about making simple primary care more efficient. We call this Telehealth Version 1.0. However, we argue that the next stage of the journey will be to quickly gather and process as much data as possible from the patients for diagnostic purposes. We argue that will involve two trends that ResApp is well placed to benefit from:

[79] See JAMA Intern Med. 2015;175(12):1983-1986.
[80] See *Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews,* Agency for Healthcare Research and Quality, Technical Brief Number 26, June 2016.
[81] Cochrane Database Syst Rev. 2011 Jul 6;(7):CD007718.
[82] Jpn J Nurs Sci. 2013 Dec;10(2):180-92. Epub 2012 Oct 1.
[83] See the Deloitte report from 2014 headlined '*eVisits: The 21st century housecall*'.

- **Diagnostics that only need smartphones and no other hardware to work.** We expect in the future that all sorts of diagnostics will dispense with the need for specialised devices. One Norwegian company called digiDoc Technologies[84], for example, has released a pulse oximeter app that measures both Heart Rate and Oxygen Saturation and integrates with Apple Health, with no need for an external device. We think other kinds of diagnostics will follow where they replace biology and work by physics instead. Take a UK company called Glucowise, which has developed a non-invasive glucose monitor that works by the transmission of low-power radio waves through the area between the thumb and forefinger[85]. It's reasonable to expect the hardware for such devices to be included in smartphones in the not-too-distant future, banishing the traditional pinprick to the history books[86].

THE RESAPP SYSTEM POTENTIALLY HAS BIG DATA APPLICATIONS

- **Diagnostics that work through Big Data**. The ResApp System keeps getting more efficient because it is based on machine learning. However once the system gets into clinical practice and the principals of Big Data analytics can be applied to it, the accuracy can take a step change. For example, it's conceivable that the ResApp System could detect the emergence of influenza pandemics before traditional surveillance systems, and thereby hasten vaccination campaigns.

ResApp's multi-step roll-out process

ResApp is currently working on a multi-step rollout process for the ResApp system, to be pursued after the first regulatory approvals start coming through from early 2017. These will likely to involve discussions with:

- **Telehealth providers.** We envisage that discussions with companies like Teladoc potentially yielding a flat fee per test, with the fee to decline after a certain number of tests have been ordered, providing the Telehealth operator with a 'first mover advantage'.
- **Conventional healthcare providers, especially payors**. We see the ResApp System rolling out through the 'non-Telehealth' part of healthcare systems through the usual reimbursement channels for diagnostics, with early use in the Emergency Departments of big city public hospitals extending to more widespread use among primary care physicians.
- **Organisations seeking to improve developing world healthcare outcomes**. We expect that ResApp will work with the Gates Foundation as well as other charitable organisations such as, say, Médecins Sans Frontières, to make the ResApp System available for developing world use, probably with pneumonia as an early priority. This work would likely not make money for ResApp shareholders but lead to increased physician recognition of the utility of the ResApp System.

[84] Egersund, Norway, privately held, www.digidoctech.no.
[85] London, UK, privately held, www.gluco-wise.com.
[86] See the press release from the Optical Society dated 18 June 2014 and headlined *'Making Smartphones Smarter with See-through Sensors'*.

- **Consumer-oriented providers of healthcare information.** We expect to see ResApp making diagnostic apps available on the App Store and Google Play for consumer use, where the reimbursement model is a pay-per-test model but where the app directs the user to seek medical attention from Board-certified professionals. Such apps could, for example, be a blessing to parents worried about managing a young child's asthma, for example.

THE RESAPP SYSTEM COULD CUT THE COST OF DIAGNOSIS 20-FOLD

ResApp will likely have to study the healthcare economics of the ResApp System. ResApp has talked publicly about the benefits of the ResApp System in terms of cost, noting in particular that its test could potentially reimburse for under US$10 per test whereas a chest X-Ray would cost >US$200 and take 30 minutes to run. This suggests the sort of 'Silicon Valley economics' (ie where the next generation product is orders of magnitude less costly that the generation that preceded it) that can be genuinely disruptive. However, this will need to be substantiated. We envisage ResApp commencing a study around healthcare economics once the first FDA approvals and CE Mark have been received in 2017.

ResApp may find common cause with Big Pharma. Respiratory medicine provided two significant franchises until recently for GlaxoSmithKline (Advair, US$8.3bn in 2013 global sales) and AstraZeneca (Symbicort, US$3.5bn in 2013 sales) before those franchises went generic. We expect that as Big Pharma works on new drugs in the respiratory space that they will look for the potential to better segment the relevant patient population through diagnostics, or at the very least look for more efficient ways to gather patient data. The ResApp System could have utility in this setting.

ResApp's unique technology

ResApp can beat the competitors. As we note below, various groups are working on devices that have a digital respiratory diagnostic aspect to them. However, we believe ResApp is ahead of the pack in digital respiratory diagnostics, because the ResApp System:

WE BELIEVE RESAPP IS AHEAD OF THE PACK IN DIGITAL RESPIRATORY DIAGNOSTICS

- Has proved very versatile in terms of the number of respiratory conditions that it can detect and measure;
- Has proven its utility in the diagnosis of respiratory disorders related to infections;
- Requires no extra hardware other than what comes as standard issue with a smartphone;
- Involves machine learning so the accuracy improves all the time;
- Is ahead of the pack in terms of the amount of clinical work that has been done; and
- Has the potential to be FDA approved by early 2017, subject to favourable experience in the clinic and through the regulatory process.

Here are seven examples of other players in the field: Observe how, with the exception of Breathresearch, all require extra hardware of some kind beyond the smartphone. While there is potential for these companies to dispense with the extra hardware in the future, ResApp has a valuable 'first-mover advantage'.

- **Breathresearch**[87]. This company has developed a smartphone-based breathing diagnostic that the Mayo Clinic is now evaluating as a respiratory monitor for chronic lung and heart disease.
- **Cohero Health**[88]. This company has developed inhaler sensors that track adherence for asthma medications, as well as a mobile spirometer, and these sync with a mobile app that sends the data to caregivers.
- **Health Care Originals**[89]. This company, working on technology originally developed at the University of Rochester in upstate New York, has developed a patch-type wearable asthma management device with a rechargeable battery that measures cough, respiration, wheeze and heart rate.
- **Respiri**[90]. This Melbourne-based company, publicly traded on the ASX, is developing a digital wheeze-detection system that is based on analysis of soundwaves. Its system involves the capture of sound via a specialised sensor, after which mobile phones are used to upload the data to the Cloud.
- **Spire**[91]. This company has developed a wearable device that tracks the wearer's breathing patterns looking for patterns that indicate stress. By telling the wearer that he or she is stressed, the claim is that the device can help manage stress better. There's a number of years of development science from Stanford behind Spire.
- **Spirometrix**[92]. This company is developing an asthma diagnostic based on exhaled nitric oxide, known as a promising biomarker. The company's solid-state sensors can detect Nitric Oxide at very small quantities based on just ten seconds of exhaled breath. Spirometrix have connected this device to a system which allows physicians to follow patients up remotely.
- **Sparo Labs**[93]**.** This company has developed an app-connected spirometer called 'Wing' that returns a green, yellow or red indicator on the smartphone screen showing the current state of the patient's lungs.

Valuing ResApp Health

WE VALUE RESAPP AT $0.52 PER SHARE BASE CASE AND $1.24 PER SHARE OPTIMISTIC CASE

Base case $0.52 / Optimistic case $1.24. We value ResApp Health using a probability-weighted DCF approach at $0.52 per share base case and $1.24 per share optimistic case. Our $0.85 target price sits at around the midpoint of our valuation range. Our DCF of ResApp was built on the following core assumptions:

- Our WACC was ~10%, appropriate in our view for a 'Medium' risk rating[94];

[87] Walnut Creek, Ca., privately held,
[88] New York, NY, privately held, www.coherohealth.com.
[89] West Henrietta, NY, privately held, www.healthcareoriginals.com.
[90] Melbourne, Australia, ASX: RSH, www.respiri.com.au.
[91] San Francisco, Ca., privately held, www.spire.io.
[92] Pleasanton, Ca., privately held, www.spirometrix.com.
[93] St. Louis, Mo., privately held, www.sparolabs.com.
[94] For a relevant discount rate, we use WACCs of between 10.1% and 14.5% depending on the risk for Life Science companies. This is derived from a RFR of 1.88%; a MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies; and an ungeared beta of 1.1 . We regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'.

- We assume a 90% probability of clinical success in the upcoming US pivotal study, followed by FDA approval;
- We assumed a further US$5-10m expenditure on clinical development for the ResApp System over the next three years;
- We assumed about A$1m p.a. on R&D related to further development of the ResApp System;
- We assume the AUD/USD exchange converges on 0.7 over a three-year period from now;
- We valued only the US and European market opportunity for the ResApp System, and assumed that ResApp did its own marketing of the system, however for conservatism's sake we did not value usage in other jurisdictions;
- We assume a US launch of the ResApp System in FY17 (optimistic case) or FY18 (base case) and a European launch in FY18 (optimistic case) or FY19 (base case);
- We modelled steady revenue growth for the first 14 years of the ResApp System's commercial life, after which we assumed a moderate (ie 3-5% p.a.) decline, assuming that by the early 2030s there will be competing, Big Data-based diagnostic systems with similar accuracy. The ResApp system is covered by a UQ patent application with a 2013 priority date as well as the trade secrecy of the relevant algorithms;
- We assumed peak sales of ~US$190-330m for the ResApp System;
- We assume 80-90% gross margins for ResApp at launch, alongside SG&A expenses equal to 20-30% of sales. In the case of SG&A, the 30% figure goes with the optimistic case, on the assumption that the higher sales outcome comes with a heavier investment in the field force for the ResApp System. We assume both COGS and SG&A decline by 0.1%-0.2% of revenue annually;
- We assume a 3% p.a. royalty is payable to UQ through to the end of patent life in 2033.

THE RESAPP SYSTEM IS COVERED BY A U.Q. PATENT APPLICATION WITH A 2013 PRIORITY DATE

We assume no further capital needs to be raised, with ResApp in a position to fund itself from ResApp System revenues from FY19.

Re-rating ResApp Health

We see a number of events helping to re-rate ResApp stock towards $0.85

WE SEE A NUMBER OF EVENTS HELPING TO RE-RATE RESAPP STOCK TOWARDS $0.85

- Further preliminary and final data both from the pediatric and the adult studies in Australia;
- Initiation and progress of the US registration study;
- Filing of Premarketing Submission dossier with the FDA and filing for CE Mark;
- Publications related to the clinical work on the ResApp System;
- First FDA approval of the ResApp System;
- Patent grants covering the ResApp System.
- Wining the 'Global Grand Final' in the 2016 Talent Unleashed Awards. ResApp announced on 22 July 2016 that it had been awarded 'Best Tech IPO/Venture Capital Raising' at the Awards for the Asia Pacific Division. The Global Grand Finals, in which ResApp is now a contender, get announced in Sydney on 18 August.

ResApp has a capable board

Dr Roger Aston (Non-Executive Chairman) brings many years of experience as a Life Sciences entrepreneur with involvement stretching back to the 1980s in companies such as Peptech[95], Cambridge Antibody[96], Cambridge Drug Discovery[97], Clinuvel[98], pSivida[99], Halcygen[100] and Ascent Pharmaceuticals[101]. While many of Aston's Life Science ventures have been oriented towards biotechnology his involvement in OncoSil Medical, a developer of localised radiation therapy devices[102], has provided valuable medical device experience.

Dr Tony Keating (CEO), whose PhD was in Mechanical Engineering, joined ResApp in 2015 from Uniquest, the commercialisation arm of the University of Queensland, where he was Director of Commercial Engagement for Engineering and ICT projects. Working at Uniquest gave Keating a strong feel for the commercial prospects of startup companies across a range of sectors including resources, cleantech, medical devices and software. Keating's willingness to leave Uniquest to work full-time on ResApp says a lot about the upside potential of the ResApp System. ResApp isn't Keating's first involvement with a university spinout – prior to Uniquest he worked in in senior business development and engineering management roles at Exa Corp, an MIT spinout that provides engineering simulation software to the ground transportation industry.

TONY KEATING'S WILLINGNESS TO LEAVE UNIQUEST TO WORK FULL-TIME ON RESAPP SAYS A LOT ABOUT THE UPSIDE POTENTIAL OF THE RESAPP SYSTEM

Brian Leedman (Executive Director and Vice President, Corporate Affairs), a co-founder of ResApp, originally licensed the technology from UQ and arranged for the 2015 ASX listing. His decade at the ASX and Nasdaq-listed pSivida, as well as his involvement in the listing process of other ASX-listed Life Science companies, most notably Oncosil Medical and Imugene, provide ResApp with valuable corporate smarts. He is also the Chairman of the Western Australian branch of AusBiotech, Australia's industry association of biotechnology companies.

Chris Ntoumenopoulos (Non-Executive Director), who is a partner at the Perth-based stockbroking and corporate advisory firm CPS Capital, provides valuable links to the Australian investment community.

[95] An Australian antibody drug developer which as Arana was sold in 2009 to Cephalon for A$318m. Cephalon was bought by Teva in 2011.
[96] A UK antibody company bought by AstraZeneca for £702m in 2006.
[97] A UK developer of biological assay systems for drug discovery, CDD was bought in 2001 for £27.5m by BioFocus, which was in turn bought by Belgium's Galapagos in 2005.
[98] An Australian developer of dermatology drugs (Melbourne, , ASX: CUV, www.clinuvel.com).
[99] Watertown, Ma., Nasdaq: PSDV and ASX:PVA, www.psivida.com. pSivida is currently a developer of ophthalmic drug delivery systems.
[100] A developer of generic drugs which bought the oral pharmaceutical group of Mayne Pharma from Hospira in 2009 and changed its name to Mayne Pharma (ASX: MYX) in 2010.
[101] An Australian generic drug company bought by Watson in 2012 for A$375m. Watson was bought by Actavis later that year. Actvavis became Allergan in 2015 after the merger of the two companies in 2015.
[102] Sydney, Australia, ASX: OSL, www.oncosil.com.au

Risks related to ResApp Health

Risks specific to ResApp Health. We see five major risks for ResApp Health as a company and as a listed stock.

- **Timing risk.** There is the risk that ResApp Health may take longer to complete the clinical studies for the ResApp System than the time we have postulated in this note;
- **Clinical risk.** There is the risk that the currently ongoing and planned clinical may generate data considered sub-standard for a respiratory diagnostic in terms of specificity and sensitivity.
- **Regulatory risk.** There is the risk that the FDA and other regulators may decline to grant Marketing Authorisation for the ResApp System even if ResApp consider the data submitted to the regulators to be adequate.
- **Commercial risk**. There is the risk that the ResApp System may fail to gain adequate reimbursement even if the product is deemed safe and effective in clinical studies and gains regulatory approval.
- **Commercial practice risk**. There is the risk that the ResApp System may fail to displace existing clinical modalities for the diagnosis of respiratory disorders given their longstanding use and the inherent conservatism of many clinicians.

Risks related to pre-revenue Life Science companies in general.

- The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.
- Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the 'term' speculative can reasonably be applied to the entire sector.
- The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology and medical device stock mentioned on this report, including ResApp Health.

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General Advice Warning.

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Recommendations

NDF Research issues a BUY recommendation in case of an expected total shareholder return (TSR, share price appreciation plus dividend yield) in excess of 25% within the next twelve months, an ACCUMULATE recommendation in case of an expected TSR between 5% and 25%, a HOLD recommendation in case of an expected TSR between -5% and +5% within the next twelve months and a SELL recommendation in case of an expected total return lower than -5% within the next twelve months.

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Appendix I – A ResApp glossary

Asthma – A chronic respiratory condition marked by periodic spasms in the bronchi, causing difficulty in breathing.

Atypical pneumonia – Pneumonia caused by certain bacteria (such as *Legionella pneumophila*, the cause of Legionnaire's Disease) where the symptoms differ from pneumonia caused by common bacteria.

510(k) – Regulatory approval for a medical device in the US where the device has been found to be functionally equivalent to a device (called the 'predicate device') that was on the market before 1976.

Accuracy – A composite measure of sensitivity and specificity to show how well a diagnostic works.

Auscultation – The diagnosis of internal medical conditions using a stethoscope.

Bronchi, bronchioles – The bronchi are the two large airways that branch off from the lower end of the windpipe, one for each lunch. Each bronchus divides into many branches that end with smaller tubes called bronchioles.

Bronchiectasis – A condition where damage to the bronchi causes them to widen and become flabby and scarred.

Bronchiolitis – Infection of the bronchioles.

Bronchitis – Inflammation of the bronchi.

CE Mark – European approval for a medical device. CE stands for Conformité Européenne.

Class – In US medical device regulation, a device goes in one of three classes – Class I (low risk), Class II (moderate risk) and Class III (high risk).

Comorbidity – A disease that is occurring simultaneous with another disease.

COPD – Short for Chronic Obstructive Pulmonary Disease, COPD is an umbrella term for a number of progressive, long-term lung conditions characterised by shortness of breath due to reduced airflow. The most common COPD conditions are emphysema, chronic bronchitis and chronic asthma.

Croup – An infection that causes inflammation of the windpipe and voice box.

Cystic Fibrosis – A genetic disorder that affects the lung's ability to clear mucus, resulting in breathing difficulties and frequent lung infections.

De Novo – An FDA regulatory pathway for medical devices. Basically De Novo is for novel devices where there is no 510(k)-relevant predicate but where the device is deemed a low or moderate risk. The De Novo process leads to a Class I or Class II classification and has a 120-day review cycle, compared to a 90-day review period for a 510(k).

Emphysema – A condition in which air sacs called alveoli at the end of the bronchial tubes become damaged.

FDA – The Food and Drug Administration, the American government body which regulates the pharmaceutical industry and from whom approval must be received before a drug can be marketed in the US.

Influenza – A disease mainly of the upper respiratory tract caused by the influenza virus and characterised by high fever and severe malaise, among other things.

Leave-One-Out Cross-Validation – A validation method for a machine-learning algorithm in which individual parts of a dataset (those 'left out') are used to 'train' the algorithm, which is then tested against other parts of the dataset.

LRTI – Short for Lower Respiratory Tract Infection, that is, infections of the windpipe and lungs. LRTIs include bronchitis, bronchiolitis, croup, influenza and pneumonia.

Machine learning – A computing paradigm in which computers are programmed to use example data or past experience to solve a given problem.

Pivotal study – A clinical trial in humans to test efficacy in a large sample.

Pertussis – The correct name for 'whooping cough', which is caused by an infection of the nose and throat with the bacterium *Bordetella pertussis*.

Pneumonia – An acute lung infection, caused by either viruses or bacteria, in which the air sacs become inflamed or filled with fluid.

Pre-Submission Meeting – A meeting with FDA officials where medical device developers can gain guidance on the regulatory pathway for their product.

Sensitivity – The ability of a diagnostic to detect what is being looked for, regardless of how little of the marker in question is available. Sensitivity is represented by the proportion of patients with the relevant disease who test positive.

Specificity – The ability of a diagnostic to only detect what is being assayed for. Specificity is the proportion of patients without the disease who receive a negative test result.

Telehealth – Healthcare delivered remotely where the patient and physician interact via the Internet or smartphones and tablets.

URTI – Short for Upper Respiratory Tract Infection, that is, infections of the throat, nose and sinuses. Basically, this is the common cold.

Viral wheeze – A wheezing sound caused by viral infection which is similar to wheezing caused by asthma.

Wet cough – Also called a 'productive' cough, a wet cough is one that produces phlegm.

Appendix II - ResApp's IP position

- ResApp Health holds an exclusive worldwide license to UQ's Intellectual Property related to the ResApp System.
- There are patents pending over the basic system, with the initial filing from UQ providing coverage out to 2033[103]
- The algorithms behind the system are, of course, a valuable trade secret and are being continually optimised.

Appendix III – ResApp's Capital structure

		% of fully diluted	Note
Ordinary shares, ASX Code RAP (million)	649.2[104]	82.8%	
Unlisted options (million)	41.2	5.3%	Average exercise price 9.2 cents, average expiry date 6-Jul-2019
Milestone shares	93.8	12.0%	Issued when annual revenue hits $20m or on acquisition
Fully diluted shares	784.2		

Current market cap:	A$227.2 million (US$170.1 million)
Current share price	$0.35
Twelve-month range	$0.016 - $0.45
Average turnover per day (last three months)	5.7 million

[103] See A method and apparatus for processing patient sounds, WO/2013/142908, priority date 29 March 2012, invented by Udantha Abeynatne, Vinayak Swankar and Yusuf Amrulloh.
[104] 57.2 million escrowed until July 2017.

Appendix IV – ResApp's major shareholders

ResApp currently has only two substantial shareholders[105]

- Freeman Road Pty Ltd, associated with Tee Yen Ng (6.8%)
- Fidelity (5.1%), which went substantial in July 2016.

[105] Uniquest, which obtained its shareholding when it licensed its IP related to the ResApp System, sold below 5% in early July 2016.