NDF RESEARCH

Providing independent research coverage of
ASX-listed Life Science companies

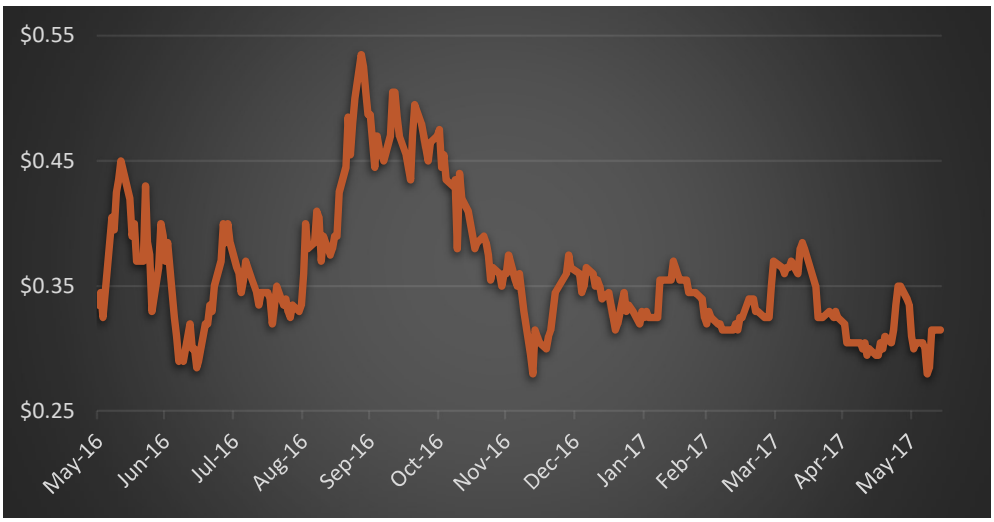
ResApp Health (ASX: RAP)

Update note – Friday 30 June 2017

First major clinical study of ResAppDx reports important data

This note updates our Initiation Report of 25 July 2016 headlined 'The Next Big Thing in Respiratory Diagnostics'. ResApp Health has just reported important data from the first major clinical study of the ResAppDx, a smartphone-based diagnostic for respiratory disease which we have previously called the ResApp System. This Australian study in pediatric patients was not a study for registration purposes but has shown that the ResAppDx works very well as a diagnostic across a broad range of childhood respiratory diseases (including upper respiratory tract infection, croup, bronchiolitis, pneumonia and asthma), each of which provides a clinically-valuable diagnosis. ResApp's US study in pediatric patients, which is being conducted to gain FDA approval, has now completed recruitment and ResApp's investigators will now evaluate the data using the algorithms perfected during the Australian Pediatric Study. Should the US Pediatric Study be successful, we expect a filing shortly for De Novo approval in the second half of 2017, with approval expected in late 2017 or early 2018.

Rating	Risk	Current price	Target price
Buy	Medium	$0.30	$0.85



Stock details

Daily Turnover: $1.09m
Market Cap: A$197.7m
Shares Issued: 659.0m
52-Week High: $0.54
52-Week Low: $0.28

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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	30 June, 2017
Share price	$0.3000
Market capitalisation	$198m
Year end	30 June

Rating	BUY
Price target	$0.850
Upside/downside	183.3%
Valuation	$0.436 / $1.029
Valuation method	Probability-weighted DCF
Risk	Medium

PROFIT AND LOSS (A$m)

Y/e June 30 (A$m)	FY15A	FY16A	FY17E	FY18E	FY19E
Revenue	0.2	0.0	0.0	3.4	9.1
EBITDA	**-0.5**	**-3.3**	**-11.5**	**-5.3**	**-0.5**
D&A	0.0	0.0	-0.2	0.0	0.0
EBIT	**-0.5**	**-3.3**	**-11.8**	**-5.3**	**-0.5**
Net interest	0.0	0.1	0.1	0.0	0.0
Pre-tax profit	**-0.5**	**-3.2**	**-11.7**	**-5.3**	**-0.5**
Tax	0.0	0.0	0.0	0.0	0.0
NPAT	-0.5	-3.2	-11.7	-5.3	-0.5
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit after minorities	-0.5	-3.2	-11.7	-5.3	-0.5

BALANCE SHEET (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Cash	4.1	13.7	8.2	3.1	4.5
Current receivables	0.1	0.1	0.1	0.2	0.4
Inventories	0.0	0.0	0.0	0.1	0.4
Other current assets	0.6	0.0	0.1	0.1	0.1
Current assets	**4.8**	**13.9**	**8.4**	**3.6**	**5.4**
PPE	0.0	0.0	0.0	0.0	0.0
Intangible assets	0.0	2.4	2.2	2.2	2.2
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	0.0	2.4	2.2	2.2	2.2
Total assets	4.8	16.3	10.6	5.8	7.6
Payables	0.5	0.2	0.8	0.9	1.1
Debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	3.8	0.0	0.0	0.0	0.0
Total liabilities	4.3	0.2	0.8	0.9	1.1
Shareholders' equity	0.5	16.0	9.8	4.8	6.5
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	**0.5**	**16.0**	**9.8**	**4.8**	**6.5**
Total funds employed	**4.8**	**16.3**	**10.6**	**5.8**	**7.6**
W/A shares on issue	205	492	659	659	661

CASH FLOW (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
NPAT plus discontinued ops.	-0.5	-3.2	-11.7	-5.3	-0.5
Non-cash items	0.0	0.4	-4.6	0.4	0.4
Working capital	0.1	0.3	10.5	-0.2	-0.3
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**-0.4**	**-2.4**	**-5.8**	**-5.1**	**-0.4**
Capex	0.0	0.0	0.0	0.0	0.0
Investments	-0.2	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.2**	**0.0**	**0.0**	**0.0**	**0.0**
Change in borrowings	0.0	0.0	0.0	0.0	0.0
Equity raised	0.7	12.0	0.3	0.0	1.8
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	4.0	0.0	0.0	0.0	0.0
Financing cashflow	**4.7**	**12.0**	**0.3**	**0.0**	**1.8**
Net change in cash	**4.1**	**9.6**	**-5.5**	**-5.1**	**1.4**
Cash at end of period	4.1	13.7	8.2	3.1	4.5

EARNINGS (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net profit ($m)	-0.5	-3.2	-11.7	-5.3	-0.5
EPS (c)	-0.2	-0.7	-1.8	-0.8	-0.1
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-126.0	-46.0	-17.0	-37.4	-404.4
CFPS (c)	-0.2	-0.5	-0.9	-0.8	-0.1
Price/CF (x)	-157.1	-60.8	-34.3	-38.8	-445.2
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	-378.2	-55.9	-16.4	-36.6	-386.3
EV/EBIT	-378.2	-55.9	-16.1	-36.6	-386.3

PROFITABILITY RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
EBITDA/revenue (%)	-339.1%	N/A	N/A	-156.0%	-5.5%
EBIT/revenue (%)	-339.1%	N/A	N/A	-156.0%	-5.5%
Return on assets (%)	-10.2%	-19.7%	-109.8%	-91.5%	-6.4%
Return on equity (%)	-101.0%	-20.0%	-119.3%	-109.1%	-7.5%
Return on funds empl'd (%)	-101.0%	-20.0%	-119.3%	-109.1%	-7.5%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net debt/(cash) ($m)	-4	-14	-8	-3	-5
Net debt/equity (%)	-846.5%	-85.6%	-84.3%	-64.8%	-69.1%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	1.1	56.6	9.9	3.8	5.0

INTERIMS

Y/e June 30 ($m)	1H16A	2H16A	1H17A	2H17F	1H18F
Revenue	0.0	0.0	0.0	0.0	1.4
EBITDA	**-1.5**	**-1.8**	**-7.4**	**-4.1**	**-2.9**
D&A	**0.0**	**0.0**	**-0.2**	**0.0**	**0.0**
EBIT	**-1.5**	**-1.8**	**-7.6**	**-4.1**	**-2.9**
Net interest	**0.0**	**0.1**	**0.1**	**0.0**	**0.0**
Pre-tax profit	-1.5	-1.7	-7.6	-4.1	-2.9
Tax	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
NPAT	-1.5	-1.7	-7.6	-4.1	-2.9
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Net profit after minorities	-1.5	-1.7	-7.6	-4.1	-2.9

VALUATION

	Base	Optimistic
Value of ResApp technology	340.2	818.7
Value of tax losses	4.3	4.3
Corporate overhead	-19.6	-19.6
Cash now (A$m)	10.4	10.4
Cash to be raised (A$m)	0.0	0.0
Option exercises (A$m)	16.3	16.3
Total value (A$m)	351.6	830.0
Total diluted shares (million)	806.3	806.3
Value per share	$0.436	$1.029
Valuation midpoint	$0.733	
Share price now (A$ per share)	$0.300	
Upside to midpoint	144.2%	

Great data from ResApp's first major clinical study

ResApp's Australian Pediatric Study has now reported major results. In March 2015, ResApp initiated a large study of the ResAppDx in pediatric patients at the Joondalup Health Campus in Perth. Prior to 2015 an early version of the ResAppDx had undergone a proof-of-concept evaluation at Sardjito Hospital in Indonesia, however the Australian Pediatric Study, which was later expanded to a second Perth site at Princess Margaret Hospital, was the first to look at the predictive ability of the diagnostic where a progressively larger sample set gradually improved the sensitivity and specificity of the algorithms through machine learning. ResApp's investigators used the 'leave-one-out cross-validation' approach where the performance of the algorithms was compared to conventional clinical diagnosis by hospital staff[1]. The study initially intended to recruit 150 patients with various respiratory conditions, and these patients had all come on board by July 2015[2]. ResApp raised its recruitment target to 400 in August 2015. The enlargement of the study was designed to further optimise the ResAppDx's diagnostic ability in pneumonia and asthma, but also to add other indications such as bronchiolitis, croup and upper respiratory tract infections[3]. The study represented a step change for the ResAppDx 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. After the 400 subjects had been recruited ResApp's investigators kept adding patients, so that by June 2017 there was more than 1,100 enrolled. ResApp's Australian Pediatric Study has yet to complete, and, indeed, is actually still enrolling, but on 22 June 2017 the company reported major results from 1,127 patients.

The data from the Australian Pediatric Study was excellent. The study has looked at the predictive ability of the diagnostic in six respiratory conditions – Upper Respiratory Tract Infection (URTI), Lower Respiratory Tract Disease (LRTD)[4], croup, asthma, bronchiolitis and pneumonia – and where the dataset and the machine learning algorithms match the design of the currently ongoing SMARTCOUGH-C study for US regulatory approval. While we still don't know the statistical significance of the numbers, the sensitivities and specificities of the ResAppDx were in line with other findings from the Australian Pediatric Study since September 2015, which is to say, generally ~90% or more in each case. ResApp now refers to sensitivity and specificity by the new terms 'positive percent agreement' (PPA) for sensitivity and 'negative percent agreement' (NPA) for specificity as per current FDA usage for many new diagnostics[5]. PPA and NPA are calculated in exactly the same way as sensitivity and specificity, only the terminology has changed.

THE RESAPPDX'S AUSTRALIAN PEDIATRIC STUDY HAS NOW READ OUT DATA

ResAppDx could diagnose all common childhood respiratory conditions in the Australian Pediatric Study. Across five of the six conditions being assayed for – URTI and LRTD, asthma, croup and bronchiolitis – the

[1] Leave-one-out cross-validation is 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.
[2] 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*'.
[3] The diagnosis of each of these diseases has significant clinical usefulness. For example, bronchiolitis is one of the leading causes of hospital admissions in infants and children, while asthma is one of the most prevalent lower respiratory tract diseases to present in Emergency Departments. In a telehealth context, the identification of lower respiratory tract involvement which indicates a more serious condition than an upper respiratory tract infection (i.e. the common cold, etc) significantly improves the ability of the doctor in the telehealth session to provide care.
[4] It's called Lower Respiratory Tract Disease because problems in this part of the respiratory tract may be due to asthma rather than infection.
[5] The thinking is that a new diagnostic test doesn't really have sensitivity or specificity when it is being compared to a measurement that isn't the 'reference standard'. In ResApp's case there is no reference standard for the clinical diagnosis of all of these respiratory diseases. There can only be agreement of the new test with the relevant non-reference standards.

PPA/NPA range was 89%-100%. The condition where the ResAppDx may have initially seemed weak to some was for pneumonia, where the NPA was 89% and the PPA 79%. ResApp explained this as a problem more with the way pneumonia is clinically diagnosed at the moment. There is no gold standard diagnostic method for pneumonia, so the accuracy of current clinical best practice is significantly lower than the numbers achieved. It is also often the case that when a patient presents in hospital with asthma it turns out to also be pneumonia[6]. For ResApp these two reasons made it particularly hard for the new diagnostic to be in agreement with the relevant 'non-reference standards' at the kind of accuracies registered for the other five conditions. In comparison to existing diagnosis methods however, these levels of accuracy should provide significant clinical usefulness to clinicians, the standard against which the FDA reviews diagnostic tests. ResApp also presented data for cough alone, however it is combination of cough and symptoms that ResApp will use in its filings for regulatory approval of the ResAppDx.

ResApp's first US pivotal will read out data soon

ResApp's SMARTCOUGH-C pediatric study has now completed recruitment. After announcing that it would be pursuing FDA approval for the ResAppDx as a Class II medical device via the De Novo pathway[7], ResApp proceeded to design a US pivotal study for the diagnostic in pediatric patients. Initially intended to recruit 1,111 patients aged 29 weeks to 12 years at three prestigious sites – the Cleveland Clinic, Massachusetts General Hospital and Texas Children's Hospital – the SMARTCOUGH-C study initiated in December 2016[8]. The co-primary endpoints of the study were diagnosis of pneumonia compared to clinical diagnosis[9] as well as radiological diagnosis[10]. The diagnosis of other respiratory conditions such as bronchiolitis, asthma, croup, and URTI/LRTD were secondary endpoints. These diseases are the same as reported in ResApp's Australian pediatric study, with URTI being the most common presentation of disease in US Emergency Departments, followed by asthma, and then pneumonia and bronchiolitis. It is also noted the general identification of a lower respiratory tract disease (ie. asthma, pneumonia or bronchiolitis) is in particular an extremely clinically useful measure, particularly in primary care or telehealth, where LRTD signifies a serious infection or disease that requires a high level of care. As with ResApp's two Australian sites, SMARTCOUGH-C recruited quickly. By 10 March 2017 the study had recruited 478 patients[11] for an average of five or six per day. The study had reached 1,157 patients by 25 May, recruiting from March to May an average eight or nine patients per day, and on 19 June ResApp announced that it had completed recruitment at 1,245 patients[12]. We expect that SMARTCOUGH-C will read out data shortly, allowing ResApp to file and gain its first FDA clearance for the device potentially before the end of 2017. If the data from SMARTCOUGH-

IT ONLY TOOK SIX MONTHS OR SO TO GET 1,245 PATIENTS IN RESAPP'S US REGISTRATION STUDY

[6] Specifically, the patient presents with asthma exacerbation, which can be induced by a virus. The patient is then treated using a short-acting Beta2-adrenergic agonist drug such as GSK's Ventolin, and so generally gets better. However, underlying the asthma, the virus can also cause some pneumonia. Because it is viral, antibiotics aren't needed, and the patient recovers without them having to be administered. Basically, the asthma (and the improvement due to treatment of the asthma) masks the pneumonia, which ResAppDx can pick up while the hospital can't because the primary diagnosis in the hospital was asthma.
[7] See the ResApp market release dated 14 March 2016 and headlined '*ResApp completes successful Pre-Submission meeting with the US FDA*'.
[8] See NCT02973282 at www.clinicaltrials.gov.
[9] As there is no gold standard for pneumonia diagnosis, in the US study ResApp is using a clinical adjudication team of three clinicians to attempt to increase the accuracy of the clinical diagnosis that the company is comparing against.
[10] Given the low sensitivity and specificity of chest x-ray (see, for example, Emerg Med J. 2012 Jan;29(1):19-23. Epub 2010 Oct 28) this endpoint seems achievable.
[11] See the ResApp market release dated 15 March 2017 and headlined '*ResApp provides SMARTCOUGH-C study update*'.
[12] See the ResApp market release dated 19 June 2017 and headlined '*ResApp announced completion of enrolment in SMARTCOUGH-C study*'.

C read out as per the recent Australian results for all diseases, it is expected that ResApp will submit for clearance for all six indications.

After pediatric approval comes approval for use in adults. ResApp and its clinical partners are now developing a study of the ResApp study in adults which mirrors the pediatric study. We expect that this study will initiate in the final quarter of 2017[13], with similar study sites and rapid recruitment as per the pediatric study.

A MSF collaboration bodes well for future uptake

ResApp is now collaborating with Médecins Sans Frontières. ResApp announced in September 2016 that a 'leading global humanitarian organisation' would be field testing smartphones loaded with the ResAppDx. ResApp was able to reveal in May 2017 that its collaborator was Médecins Sans Frontières (MSF), known for its work delivering emergency medical care to civilians in war zones as well as places afflicted by epidemics, and natural disasters as well as 'healthcare exclusion' (ie where conventional healthcare as per the First World is unavailable')[14]. That organisation will now proceed to run its own study of the ResAppDx in a Third World setting, where pneumonia is understood to kill in excess of 900,000 children under the age of five globally[15] and where asthma prevalence is also high[16]. We argue that the results of this study are likely to drive rapid uptake of the ResAppDx in markets where it is approved, since it will highlight the ability to work on existing smartphones with no extra specialised hardware required.

The investment case for ResApp Health

- **ResApp is developing a smartphone-based diagnostic for respiratory disease.** The ResApp diagnostic, which the company calls the ResAppDx, was originally developed by Associate Professor Udantha Abeyratne at the University of Queensland (UQ). The ResAppDx is able to detect from patient breathing and coughs with the addition of easily observable symptoms 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 completing a registration study of the technology, ahead of an initial filing for FDA clearance expected in late 2017 or early 2018.

[13] ResApp's goal is to run this study over the next Northern winter. This was a lesson learnt from the US pediatric study – winter is by far the best time to recruit for these kinds of studies.
[14] See the ResApp market release dated 9 May 2017 and headlined '*ResAppDx to be formally evaluated by Doctors Without Borders*'.
[15] See World Health Organisation Fact Sheet No. 31 at www.who.int.
[16] The historical view of asthma being a disease of high-income countries no longer holds: most people affected are in low and middle-income countries and disease prevalence is estimated to be increasing fastest in those countries. Driving this is increased urbanisation, accompanied by more air pollution and widespread construction work. There is particularly high asthma prevalence in Latin America and Africa, much of it underdiagnosed there. See Thorax. 2007 Sep; 62(9): 758–766.

- **What is the technology behind the ResAppDx?** In developing the ResAppDx, 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. ResAppDx 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 RESAPPDX OFTEN 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 ResAppDx 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 >1,100 subjects and the adult study >1,300. Probably the most compelling aspect of ResApp's studies has been the demonstration that pediatric lower respiratory tract involvement initially missed by experienced clinicians using a stethoscope could be detected by the ResAppDx in 97% of cases[17].

- **What is the regulatory path for the ResAppDx?** In December 2016 ResApp's investigators initiated a single US-based study of the ResAppDx in pediatric patients ahead of potential FDA approval. The company expects to be able to complete this study in mid-2017. As with the Australian studies, this study will seek to demonstrate the clinical utility of the ResAppDx 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 the second half of calendar 2017, gaining first approval in late 2017 or early 2018. The company is hoping to be cleared for all conditions in its first submission. We believe the data from this study and the Australian studies will also form the backbone for approvals in Europe and other jurisdictions.

RESAPP CAN POTENTIALLY RECEIVE ITS FIRST FDA APPROVAL IN LATE 2017 OR EARLY 2018

- **What is the market opportunity for the ResAppDx?** In the US, roughly one in ten doctor visits results in diagnosis of a respiratory disorder, which can translate into 125 million diagnoses annually. Asthma (~14% of admitted patients), bronchiolitis (5.8%) and pneumonia (5.6%) are the most common diseases that require hospitalisation following an ED visit in the US[18]. 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 our 25 July 2016 Initiation Report that much of this market is addressable for ResApp given the rapidity, accuracy and hardware-neutral nature of its technology.

[17] See the ResApp market release dated 31 March 2016 and headlined *'ResApp provides updated paediatric clinical study results'.*
[18] Source: PECARN Core Data Project, 2006.

Ten reasons to consider ResApp Health

- **ResApp Health has developed an important breakthrough in respiratory diagnosis**. The ResAppDx 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 FOUR YEARS HAS SEEN THE DIGITAL HEALTH SECTOR BOOM

- **The ResApp technology fits into an ongoing boom in digital health**. The last four 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 ResAppDx has shown in the last three years that it is capable of superior outcomes to existing modalities. For example, in its recently completed study in Australian 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 ResAppDx. With the ResAppDx 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 large studies (ie >1,100 patents each) in pediatric patients in early 2015 and in adults in late 2015 in order to build out the diagnostic capability of its algorithms. A US study in pediatric patents specifically for regulatory approval was initiated in December 2016, with top-line data from this study expected to be available in mid-2017. We believe the recent Australian pediatric results are directly relevant to the US study and provide the best indication of the US results. If this confidence turns out to be justified we believe that ResApp will be in a position to file for its first FDA clearance in the second half of calendar 2017, with that clearance potentially being obtained before the end of 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 ResAppDx. 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, such as Emergency Departments and urgent care clinics 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 ResAppDx 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 ResAppDx 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 the Australian adult clinical study as well SMARTCOUGH-C results in the US, 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 2017 and into 2018.
- **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 $0.44 per share base case and $1.03 per share optimistic case. Our $0.85 target price sits in the upper half of our valuation range and reflects our confidence in US regulatory approval of the ResAppDx in FY18. 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 CAPABLE MANAGEMENT TEAM

Valuing ResApp Health

WE VALUE RESAPP AT $0.44 PER SHARE BASE CASE AND $1.03 PER SHARE OPTIMISTIC CASE

Base case $0.44 / Optimistic case $1.03. On our 25 July 2016 note we valued ResApp Health using a probability-weighted DCF approach at $0.52 per share base case and $1.24 per share optimistic case. Please refer that note for the full thinking that went into that valuation approach. With this note we reduce our valuation slightly to reflect the delay compared to our earlier estimate at completing the first US pivotal study, as well as a slight rise in our discount rate related to an increase in the Australian ten year bond rate from 1.9% to 2.5%. We now value ResApp Health using a probability-weighted DCF approach at $0.44 per share base case and $1.03 per share optimistic case. Our $0.85 target price, which remains unchanged, sits in the upper half of our valuation range and reflects our confidence in US regulatory approval of the ResAppDx in FY18. Our DCF of ResApp was built on the following core assumptions:

- Our WACC was ~10.7%, appropriate in our view for a 'Medium' risk rating[19];
- 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 ResAppDx over the next three years;
- We assumed about A$1m p.a. on R&D related to further development of the ResAppDx;
- 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 ResAppDx, 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 ResAppDx in FY18 (optimistic case) or FY19 (base case) and a European launch in FY19 (optimistic case) or FY20 (base case);
- We modelled steady revenue growth for the first 14 years of the ResAppDx'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 ResAppDx 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 ResAppDx;
- 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

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

[19] For a relevant discount rate, we use WACCs of between 10.7% and 15.1% depending on the risk for Life Science companies. This is derived from a RFR of 2.5%; 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'.

higher sales outcome comes with a heavier investment in the field force for the ResAppDx. 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.

We assume no further capital needs to be raised, with ResApp in a position to fund itself from ResAppDx 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 data both from the pediatric and the adult studies in Australia;
- Data from the US registration study in pediatric patients;
- Filing of Premarketing Submission dossier with the FDA and filing for CE Mark;
- Publications related to the clinical work on the ResAppDx;
- First FDA approval of the ResAppDx in pediatric patients;
- Initiation of US pivotal study of the ResAppDx in adult patients;
- Patent grants covering the ResAppDx.

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 ResAppDx 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 ResAppDx even if ResApp consider the data submitted to the regulators to be adequate.
- **Commercial risk**. There is the risk that the ResAppDx 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 ResAppDx 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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