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Companies covered: RAP, SPL

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - Current)	-3.9%
Cumulative Gain	**727%**
Av. Annual gain (14 yrs)	**17.3%**

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Bioshares

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Extract from Bioshares –

Learnings for ResApp from US Pediatric Study

ResApp Health (RAP: $0.088) reported results from its US pediatric study of its ResAppDx diagnostic. Top-line results indicate that the trial, called SMARTCOUGH-C, is unlikely to meet the primary endpoints set for the study.

Although the trial outcome was disappointing, there have been considerable learnings for the company with respect to the clinical delivery of this test in the US hospital setting.

The ResAppDx diagnostic uses a smart phone to receive coughing sounds from patients that are processed using a proprietary algorithm.

Study Results

The study recruited 1245 children with respiratory illness symptoms at three hospitals across 12 sites. The trial commenced in December last year with a rapid six month recruitment process. The aim was to provide differential diagnosis of five infections or conditions. These were between upper and lower respiratory disease, whether the cough was due to asthma, or whether the child had croup, bronchiolitis or pneumonia.

In a previous pediatric study, called Breathe-Easy, conducted at two Perth Hospitals in 2015, ResApp had achieved excellent results in assessing the same diseases or conditions.

That study enrolled 1,127 patients. Positive percent agreement (PPA) and the negative percent agreement (NPA) were as follows: for detecting upper respiratory infection, the accuracy was detailed by PPA/NTA was 92%/89%; lower respiratory infection was 90%/92%; asthma detection accuracy was 92%/89%; croup was 100%/96%; bronchiolitis accuracy was at 95%/94%, and detection of pneumonia was at 89% and 79%.

However in this SMARTCOUGH-C trial, the accuracy of ResApp's test was sharply lower. Assessing the cough plus age, gender and symptoms, the accuracy details are summarised below.

Upper respiratory tract infection: 49%/74% (PPA/NPA)
Lower respiratory tract condition: 83%/47% (PPA/NPA)
Asthma: 62%/83% (PPA/NPA)
Bronchiolitis: 80%/95% (PPA/NPA)
Pneumonia: 56%/64% (PPA/NPA)
Croup: Not reported (due to high patient pre-treatment)

The primary endpoint in the trial was the detection of pneumonia with the set target of achieving greater than 75% PPA and 75% NPA.

The one difference between the tests used in these two trials was that the Breathe-Easy

Cont'd over

study was a retrospective study, whereby the algorithm was trained in a 'leave-one-out' process.

The SMARTCOUGH-C study was a prospective study, where there was no change or training of the algorithm. On a large database of over 1,000 subjects, the two approaches should still deliver similar results.
ResApp CEO Tony Keating said that a study continuing in Perth on a prospective basis continues to deliver similar results to the leave-one-out approach and that data from ongoing clinical use should be released by year's end.

Study Issues

Several issues have become apparent from the US SMARTCOUGH-C study which will offer valuable insights into how the test needs to be correctly utilised in a busy clinical setting.

Once the data was unblinded, there were some immediate concerns with the way the study was conducted. Assessing study notes from testing of the patients, Keating said the company became aware of several issues which have potentially been responsible for a lower than expected accuracy result across the study.

One issue was background noise that conflicted data, including a low frequency machine noise, coughing from parents to engage the children to cough, noise from TVs and pre-treatment of patients prior to diagnosis.

The pre-treatment was particularly problematic in detecting asthma where around 30% were pre-treated, and around three quarters of patients were pre-treated for croup.

One of the differences between running a US trial and a trial in Australia is that the researchers involved in the trial worked less interactively with the treating doctors according to Keating.

Utility of ResAppDx test

ResApp may seek FDA clearance for the test for bronchiolitis based on these results. However the in-demand tests are to detect pneumonia, to differentiate between upper and lower respiratory tract conditions, and to be able to quickly assess for an asthma triggered condition.

Asthma and croup can be immediately treated once diagnosed. Bronchiolitis is generally as a result of a viral infection and is not treated with infection specific medication. Pneumonia in children generally as a result of a bacterial infection with antibiotics the main treatment.

Study to be Repeated; US Adults Study to be Run

ResApp intends to repeat the US pediatric study over the next winter season at the end of 2017. The company will also conduct a US study in adults over the same time, which had been previously planned. The company's aim is to have results available from both studies around this time next year.

ResApp is funded to conduct these studies having raised $12.5 million last year and with $8.5 million in funds at the end of June.

There are likely to be some minor changes to the algorithm for the US population said Keating. More important will be changes to the trial protocol. It is likely the pediatric study will be conducted at the same sites, where the hospital staff involved will be aware of the shortcomings of the previous study and the need for improved and more consistent testing conditions.

The algorithm will also be improved to ensure there is less impact from background electrical noise.

While the US clinical setting has shown to be much more challenging to deliver the ResApp test, Keating said that the ongoing prospective study in Perth makes him very confident of the effectiveness of the ResAppDx test.

ResApp's share price fell by 72% this week. The company is now capitalised at $58 million. Taking advantage of the price fall this week was ResApp director Chris Ntoumenopoulos who bought 1 million shares on market.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C
Sell

Corporate Subscribers: Cogstate, Bionomics, Impedimed, Viralytics, Opthea, RHS, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Dimerix, Cyclopharm, Adalta, Immuron, Medibio, Phylogica