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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 - May '18)	-7.1%
Year 18 (May '18 - current)	-5.8%
Cumulative Gain	653%
Av. Annual gain (17 yrs)	17.1%

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# Bioshares

13 July 2018 Edition 752

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies

Extract from Bioshares -

# ResApp to Report Outcomes from Multiple Trials in Coming Months

ResApp Health (RAP:\$0.125) has multiple trial results that are expected to be reported in the coming months. However, the most important will be the results from its US pediatric study with those results likely later next month.

The US study, called SMARTCOUGH-2, is expected to enrol 1,667 children with a range of respiratory conditions and infections, including pneumonia, bronchiolitis and asthma. At the end of May the company announced that it had recruited more than 75% of patients into the study. This study is effectively a repeat of the trial that was completed last year but which failed to achieve endpoints due to a number of shortcomings in the trial process.

The company is commercialising a digital respiratory diagnostic ResAppDx. This smartphone hosted tool seeks to diagnose respiratory illness using recordings received by the smartphone and processed with the company's proprietary algorithms.

#### **Changes for US Study**

Multiple changes have been introduced into the US study to ensure consistency of recording integrity of patient coughs, as well as consistent diagnosis of the condition by a panel of independent doctors.

ResApp has also made changes to the algorithm and it has been able to review a portion of patient recordings to confirm recording quality. It has found only 1% of recordings have been of poor and unacceptable quality.

Each of the disease indication target levels have been met with full recruitment into this study expected by the end of July. Once recruitment has been closed, adjudication of each patient analysis will be required by the independent panel to ensure each patient's condition has been correctly characterised. This will be the main bottleneck with results then expected later next month.

#### **Australian Breathe Easy Study**

Recruitment into the company's Australian pediatric study is expected to be completed also by the end of this month. By the end of last month 603 children had been recruited with all disease targets reached (e.g. asthma, bronchiolitis, pneumonia). Results from this study are likely before the SMARTCOUGH-2 study results are released.

Results from an adult patient study, which had recruited 567 patients at the end of June, should also be reported next month, before the US study results.

The difference between the US trial and the Australian study is that the Australian disease confirmation is conducted by the hospitals conducting the study where the US trial is using an outside team to confirm diagnosis. Once diagnosis has been finalised, an

Continued over

ResApp cont'd

independent group in Australia (Curtin University) and the US (Baim Institute) will run ResApp's algorithm and deliver the final results.

#### Sleep Apnea Trial

The second application of ResApp's technology is for the diagnosis of sleep apnea, also using recordings made by a smart phone, and processed using another of the company's app.

This week ResApp reported that it had recruited 312 patients into the study, with the trial to complete recruitment by the end of September with a target of more than 500 patients. This application will be a direct-to-consumer product with the company likely to seek a licensing deal with one of the major sleep treatment groups, pending positive results.

#### Commercialisation

A positive outcome in the respiratory diagnosis trials will be to achieve accuracy levels in excess of 70%. The greater the accuracy the great product demand that can be accepted and the higher product and deal pricing that may be achieved.

Pending positive Australian and US results, the company will seek to gain regulatory approval in Australia and the US and also secure licensing deals for its product.

Australian hospitals participating in the current studies may be initial adopters, using the product to triage patients arriving with respiratory issues, with annual licenses a possible revenue model.

In April the company signed an agreement (letter of intent) with an undisclosed German hospital network that will begin evaluating ResAppDx once Australian trial results are released.

That agreement will see the group evaluating ResAppDx for 12 months. This will provide information of how the diagnostic could be integrated within the German healthcare system. There would be no revenue generated from this agreement in the first year.

#### Summary

ResApp is approaching a pivotal six-week period, where the results from three prospective, independently assessed trials will detail the accuracy and utility of the ResApp respiratory product.

The outcomes for investors to note are accuracy levels above 70% are the minimum that must be achieved, with accuracy above 80% representing a very useful tool for healthcare providers.

Differentiating between individual conditions – asthma, bronchiolitis, croup, pneumonia – as well as differentiating between upper and lower airway conditions, will be also key outcomes.

ResApp is capitalised at \$82 million and held \$4.3 million in funds at the end of March.

Bioshares recommendation: Speculative Hold 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

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