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	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 - May '18)	-7.1%
Year 18 (May '18 - current)	-14.0%
Cumulative Gain	587%
Av. Annual gain (17 yrs)	17.1%

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032
Enquiries for Bioshares
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info[at]bioshares.com.au

David Blake - Editor/Analyst
Ph: (03) 9326 5382
Email: david[at]bioshares.com.au
Mark Pachacz - Editor/Analyst
Ph: 0403 850 425
Email: mark[at]bioshares.com.au

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

Extract from Bioshares –

ResApp Health – Q3 FDA Filing for ResAppDx

ResApp Health (RAP: \$0.093) provided an update last week on the progress of its respiratory diagnostic products in development, which are a smartphone-based app to diagnose respiratory infections and disorders, and an app to diagnose sleep apnea.

SMARTCOUGH-C-2 Results – To File Q3 with FDA

In October, ResApp released results from its US pediatric study of its diagnostic, called the SMARTCOUGH-C-2 study. That study, involving children up to 12 years of age, showed a much improved accuracy compared to the previous US study. In three measures, those being lower respiratory tract infection, upper respiratory tract infection, and asthma, the test achieved over 70% sensitivity and specificity, which in our view is a level that arguably makes for a clinically useful tool.

These are the three specific diagnostics that the company intends to file approval for with the FDA this quarter, under a *de novo* application. These diagnoses alone could serve as a valuable triage tool, with lower airway infection generally more serious than upper airway infection.

The company is also awaiting for the results for a fourth parameter, croup, with recorded samples to be reassessed due to heavily conflicting investigator assessments. Results from croup diagnosis are expected in the current quarter.

For the detection of pneumonia and bronchiolitis, presumably more investigation will be required, with study results using ResApp's algorithm for sensitivity/specificity being 63%/62% and 76%/60% respectively.

However, the assessment of US results was clouded by more disagreement between investigators – agreement from the first two doctors occurred only in 66% of cases. (In the Australian pediatric, prospective study in 585 subjects, the sensitivity and specificity of all the above measures was between 79% - 97%.)

European Path to Market for Pediatric Test

ResApp completed its European regulatory submission for its ResAppDx test in early January for pediatric use. If approved, it will allow the company's test to be used for all of the above mentioned respiratory infections and conditions.

ResApp CEO Tony Keating said that the company has a four step commercialisation process for Europe. This first is to gain acceptance from key opinion leaders. The second is to present its results at conferences and in publications. This will be followed by partnerships with telehealth providers. The company will also seek to secure pilot programs in emergency departments and urgent care clinics.

The company already has a partnership with a German private hospital group, which is expected to initiate a study before the end of February. (The study was previously expected to start in November last year.) The two outcomes from this study will be (a) how

much faster a patient can receive treatment using the ResAppDx product, and (b) what are the cost savings to the hospital in replacing existing diagnostic procedures. That study is likely to involve around 200 patients.

Once European approval is received, it will allow approval to be processed in other regions including Australia and Canada. Based on experiences with other groups, European approval can take up to five months to obtain.

Keating said that the NHS in the UK is highly proactive in its adoption of telehealth, with Switzerland and the Nordic region also very active in adopting this medical modality.

Australian Adult Study in Respiratory Disease

Results from the Australian adult study with the ResAppDx test are expected to be available at the end of March. Some of the key afflictions to diagnose in adults are COPD, asthma, pneumonia and lower respiratory tract infection.

Sleep Apnea Test

ResApp is also developing a test for the diagnosis of sleep apnea. In a study involving 582 subjects, the sensitivity and specificity of the test was found to be between 82% - 84% in detecting mild, moderate or severe sleep apnea. The inclusion of the additional assessment of when the patient is sleeping is expected to improve the accuracy of this test, according to Keating.

Publications

Keating said that principal investigators involved both with the Australian and US pediatric studies have separately submitted results from their respective studies for publication or presentation, with the US study results to be presented at a US industry conference this year.

Commercialisation & Funding

ResApp will maintain its business model of seeking to charge per assessment. Keating said that the company is not lacking in potential suitors to commercialise the technology.

ResApp finished the year with \$6.8 million in cash and a further \$2 million expected from the Commonwealth Government's R&D tax rebate. The company has sufficient funding until towards the end of 2020, when major inflection points should have been reached.

Summary

With positive clinical data generated in several indications in the US and Australia from trials involving over 4,500 subjects, the next step for the company will be to secure regulatory approval in Europe, the US and Australia, with additional clinical data to emerge.

The most important driver for the company over the next 12 - 18 months will be to secure early contracts in the emergency care setting, as well as agreements with telehealth providers.

ResApp is capitalised at \$73 million.

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 Some 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, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys

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To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
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