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Companies covered: **MX1, PBT, RAP, Private Company Cap Raisings**

	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)	-9.2%
Cumulative Gain	626%
Av. Annual gain (17 yrs)	17.1%

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Bioshares

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

Extract from Bioshares –

ResApp Reports Updated Results from US Pediatric Study

ResApp Health (RAP: $0.091) has reported the final results from its second US pediatric study with its respiratory diagnostic, ResAppDX. The study was in 1,251 children with respiratory conditions. The final measure reported was for croup, with a sensitivity and specificity of 74% achieved. A full summary of the results from this study, the first US study and the Australian pediatric study are summarised in the table below.

The company now intends to file its diagnostic for regulatory approval with the FDA for three of the six measures – upper respiratory disease, lower respiratory disease, and asthma. These diagnostic assessments will be an important triaging tool either for telemedicine consultations (with its smart phone sound recorder and analytical app effectively replacing the stethoscope) and also in emergency departments. The FDA submission will be made shortly with the documentation having been completed and undergoing a final internal review.

The assessments for pneumonia and bronchiolitis had specificity levels below 70% (meaning more than 30% would have been given an incorrect positive reading), however this was distinctly lower than the results achieved in Australia (81% - 87%) which supports the company's argument that different diagnostic processes in the US contributed to conflicting results.

As earlier reported for the second US study, in 34% of cases the two clinicians could not agree on diagnosis with an assessment from a third doctor required. In the case of croup this was even higher with a third opinion required in 52% of cases.

Croup will not be included in the initial FDA submission. Even through the accuracy level was above 70%, the low incidence of croup in this study (2%) is insufficient to confirm statistically reliable accuracy.

European Submission for ResAppDx-EU

In January this year, ResApp submitted its European regulatory application for ResAppDx-EU. Based on the very strong Australian study results, the company is seeking approval of upper and lower respiratory tract disease, asthma, croup, pneumonia and bronchiolitis. CE Mark clearance can be expected to take up to five months to obtain, which means that a decision should be received by the end of May.

ResApp CEO Tony Keating said that the company has prepared a very solid submission. That submission included very strong clinical data, but also considerable work around usability of the device in clinics and hospitals i.e. whether healthcare workers can easily and appropriately learn to administer the test.

The company has completed recruitment into a prospective adult respiratory disease study in Australia in 956 patients. The top line data is expected to be released this month.

Continued over

If that data is positive, ResApp expects to file a similar submission with the European regulator to extend the application to adults. Approval for adults is also targeted for this year.

Commercial Launch in Europe

The major two initial target markets for the ResApp test are for use within the hospital emergency setting, and for use in telehealth medical consultations. There is a similar level of interest across these two initial applications in Europe, however in the US, telehealth is expected to dominate commercial interest.

In Germany, the company has an agreement with an independent hospital group that is due to begin a pilot study of the diagnostic in around 200 patients. That study will be looking at potential efficiencies that can be gained from incorporating ResAppDx into patient processing, to determine if time and costs can reduced.

In Australia, Keating is optimistic that hospitals that have been involved with its pediatric and adult clinical studies will adopt commercial use of its test once approval has been secured. Around $5-$10 per test is a realistic price for the test.

In the telehealth space, the company has advanced discussions in the UK (there are 5-6 providers) where telehealth has received support from the government, Switzerland (1-2 providers) and in the Nordic states (3-4 providers). In Germany the laws governing restrictions around virtual medical consultations are due to be removed allowing for the wider adoption of telemedicine.

A survey coordinated by Osborne Clarke in Europe showed that 29% of 18-34 year olds would prefer a telemedicine consultation over a visit to the GP, which is more than double for people over 55 years of age (only 14%).

Telemedicine consultations already require patients to complete a short questionnaire prior to the consultation. Inclusion of the ResAppDx test as a pre-consultation preparatory assessment could be usefully streamlined into the telemedicine work flow.

At this point, Keating said that the business development (BD) work so far has been inbound. However that will change once CE Mark clearance is gained, with a full time BD person to be appointed in Europe.

Summary

ResApp Health has an early mover advantage in developing a very useful tool to aid in telemedicine consultations. Countries such as the US, China and the UK have been early adopters and there is evidence of changing regulations in other countries such as Germany that are seeking to streamline the growing healthcare sector that is resulting from an aging and growing population.

Strong Australian pediatric study results and a comprehensive European regulatory submission should position the company well with gaining CE Mark clearance in the next two months, which will be a major driver for the stock.

Results are also expected from the adult Australian prospective study and an at-home sleep study to measure the performance of the company's app in detecting sleep disorders.

ResApp is capitalised $72 million with $6.8 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Updated ResApp Pediatric Study Results - Prospective Trials

Indication	First US Study 2017 SMARTCOUGH-C		Second US Study 2018 SMARTCOUGH-C2		Australian Study 2018 Breath Easy	
	Sensitivity (PPA)	Specificity (NPA)	Sensitivity (PPA)	Specificity (NPA)	Sensitivity (PPA)	Specificity (NPA)
Lower respiratory disease	83%	47%	73%	77%	83%	82%
Upper respiratory disease	49%	74%	76%	70%	79%	80%
Asthma	62%	83%	71%	86%	97%	91%
Croup	INN	INN	74%	74%	88%	86%
Pneumonia	56%	64%	63%	62%	87%	85%
Bonchiolitis	80%	95%	76%	60%	84%	81%
Number of patients	1245		1251		585	

INN - Insufficient numbers *PPA - Positive percent agreement* *NPA - Negative percent agreement*

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, Cyclopharm, Emvision, Antisense Therapeutics