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Bioshares

26 August 2019
Edition 806

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

Companies covered: **RAP, SOM, Clinical Trials Survey**

	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 - May '19)	-2.3%
Year 19 (May '19 - Current)	32.1%
Cumulative Gain	931%
Av. Annual gain (18 yrs)	16.0%

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Extract from Bioshares –

ResApp Gains First Regulatory Clearance for Pediatric Diagnostic

ResApp Health (RAP: $0.20) has gained European regulatory approval for its smartphone-based respiratory test in children. Following clinical studies in over 6000 patients, this will be the first commercially available smartphone-executed respiratory test worldwide.

In clinical studies in Australia (Breath Easy), the ResAppDx test achieved sensitivity of between 79% - 97% for detecting lower and upper respiratory disease, asthma, croup, pneumonia and bronchiolitis. The specificity levels for these diseases were between 81% - 91%. We see this performance as sufficient for gaining commercial adoption.

ResApp's test will be positioned for use in telemedicine, effectively replacing the stethoscope used in regular general practice consultations.

Growth in Telemedicine

In the field of telemedicine, consultations are gaining traction through companies such as Teladoc Health, which has been in operation since 2002. It operates in 130 countries, with 36 million members or paid users in the US.

The number of telemedicine consultations increased by 70% in the last year for Teladoc, now tracking at 3.6 million a year, with 73% of those visits in the US. Its revenue is tracking at US$520 million a year, up 38%.

Telemedicine visits offer time and cost savings to the patient, with a telemedicine visit costing US$45 in the US, compared to US$60 for a clinical consultation. Last year, leading managed care group Kaiser Permanente, which has 12 million members in the US, used telemedicine kiosks for 52% of its members' interactions.

In the UK, the NHS is targeting telemedicine to reduce the 400 million medical consultations by GPs and in hospital outpatient services. It expects to save over £1 billion a year, with every patient to be offered online GP consultations. In China, telemedicine consultations are expected to reach four billion by 2026.

With around 30% of GP visits related to respiratory ailments, ResApps' now approved test in Europe offers telemedicine providers a means to extend the range of telemedicine visits through ResApp's 'digital stethoscope' with its inbuilt diagnostic algorithms.

Next Steps for ResApp

A next step for ResApp will be securing sales and distribution arrangements with third parties. The company expects the test will cost the user between $5 - $10 per test in telemedicine or clinical visits.

The company is awaiting approval in the US from the FDA for its pediatric respiratory disease diagnostic. A submission was made in April this year.

Continued over

The results from the US study were not as strong as those obtained from the Australian Breath Easy study, with less conformity between doctors in the US in diagnosing respiratory ailments. (In 34% of cases doctors could not agree on the initial diagnosis in its Smartcough-2 study.)

ResApp expects to shortly file its adult respiratory diagnostic test for approval in Europe. In its Australian study in 979 adult subjects, sensitivity of between 83%-89% was achieved in detecting lower respiratory disease, pneumonia, asthma exacerbations, COPD and COPD exacerbations. The specificity was similarly strong, at between 84%-91%.

ResApp is also planning a US adult study for is ResAppDx test, although this may depend on the FDA decision for its pediatric test submission.

First Deal Anticipated in the Next Six Months

Tony Keating, ResApp's CEO, is aiming for the company's first commercial deal in Europe within the next six months.

Likely initial customers will be hospitals, looking to use the product as a triage tool in the emergency care setting, hospitals with telemedicine offerings, and telemedicine groups.

Keating said that many of the companies ResApp has been in discussions with were all waiting for ResApp to gain regulatory approval, which has now occurred. This may translate into deals very quickly according to Keating.

ResApp will seek to first sign on high quality hospitals, with access to be provided on a non-exclusive basis. The UK is a high priority target market for the company.

In Europe, ResApp's test has been approved for six indications, which is the number of indications the company applied for.

In the US, the number of indications initially applied for is three, those being lower respiratory tract infection, upper respiratory tract infection, and asthma, all in children at this stage.

ResApp is capitalised at $130 million, with $5.5 million cash at the end of June.

Bioshares recommendation: **Speculative Hold Class B**

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ResApp Health - Select Milestones

At-home Sleep Study (250 pts)	Q3 2019
ResAppDX (Adult) CE Mark Submission	CY 2019
Complementary Hardware Devices • ruggedised hand held • wearable monitor Prototypes CE MARK	 end CY2019 2020
FDA De Novo Clearance *(our estimate, based on 360 days of direct and indirect FDA review days)*	Q2 2020

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, Heramed, Imugene, Exopharm