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From the Analysts

Several companies have reported clinical trial results recently. This includes LBT Innovations for its APAS system, ResApp Health for its respiratory diagnostic app, and Invion for its Phase II smoking cessation trial.

Dorsavi has signed a significant three year deal with a large physiotherapy network in the UK. We update readers on the progress Minomic is making in introducing a more accurate prostate cancer diagnostic test that may result in substantially fewer biopsies needed for men. And Merck has taken a 4.9% stake in Bionomics.

Companies covered: BNO, DVL, IVX, LBT, RAP, Minomic

	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 14 (May '15 - current)	12.4%
Cumulative Gain	**522%**
Av. Annual gain (14 yrs)	**17.4%**

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– *Extract from Bioshares*

Good Early Data for ResApp

ResApp Health (RAP: $0.035) has generated positive results from its trial with its respiratory diagnostic app. The study is being conducted at two hospitals in Perth, with the aim being to detect two respiratory conditions initially in children, asthma and viral pneumonia.

The trial was started in March this year and to date has enrolled 310 patients with 400 patients expected to be enrolled by year's end. A third hospital, in Queensland, is expected to be added to the study. The company has released initial data on the first 211 children in the study.

Study Design

ResApp's technology is based on analyzing acoustics from patient coughs. The coughs are captured through a smartphone, with the sounds interpreted by a proprietary algorithm. It can be considered as a type of digital stethoscope and is the way that doctors were previously trained to diagnose respiratory conditions.

ResApp first applied the technology as a result of a clinical study in Indonesia that was funded by the Bill and Melinda Gates Foundation. In that study in 91 children, the company was able to achieve a sensitivity of 94% and 100% specificity in detecting bacterial pneumonia and 100% sensitivity and 80% specificity in detecting asthma.

In that study, the company adapted its algorithm to suit the study population in part of the trial from known diagnosis, and then move into a prospective study analysis.

In the current study, ResApp has been refining its algorithm as the trial has progressed. Using what's called a 'leave-one-out' validation, the company sets the algorithm by assessing one sample that has been left out, and refining the algorithm with the remaining positive samples for a particular respiratory condition (e.g. asthma) and the healthy subjects. It then moves through each patient in the population. This allows the algorithm to be refined and then tested using the refined algorithm settings.

It is not a prospective study, with the company using confirmed clinical diagnoses to set its acoustic detection parameters for different respiratory conditions. However, the CEO of ResApp, Tony Keating, said experience from the Indonesian study showed that once the algorithm had been refined (on around 50 patients), there results with the prospective analysis (around 40 patients) were very similar (within 2%).

Study Results

In the current study, the largest confirmed diagnoses were asthma (52 subjects), viral pneumonia (25 subjects) and the healthy group (39 subjects). The study found that the accuracy in separating the asthma patients to the healthy patients was 97% sensitive and 92% specific.

Cont'd over

In diagnosing between the patients with viral pneumonia and the health patients, the accuracy was 91% sensitive and 95% specific. Keating says believes that for its tests to be accepted, it needs to achieve an accuracy in excess of 80%, with the gold standard for diagnosis of pneumonia, x-ray, being 80%-90% accurate.

Additional Forthcoming Data

Other respiratory conditions detected in the trial include croup, bacterial pneumonia, bronchiolitis and upper respiratory tract infection. Work is continuing at the University of Queensland, which pioneered the technology, to build algorithms to detect and differentiate these conditions as the datasets from the trial build.

The current study is focusing on children because the initial clinical work in Indonesia also focused on pediatric respiratory conditions. ResApp intends to start an adult study this year which will seek to enrol a similar number of patients (around 400). That study will start with the pediatric algorithm which will be refined for the adult population. Results from that study are expected by mid 2016.

ResApp is also looking to add additional clinical measures that can be combined with the audio detection of coughing sounds using a smartphone. These include measures such as age, gender, whether the patient has a fever and the breathing rate. Keating believes the company's technology could be better than the gold standard in some cases when these additional parameters are included.

ResApp also intends the current trial to assess the technology as a prospective diagnostic tool.

US Trials and Approval

The company plans to conduct a US trial next year, which will be a prospective trial. That trial is scheduled to start in Q1 next year with the company aiming to gain FDA clearance towards the end of 2016. Keating said there are now more than 100 health apps approved by the FDA. The company will initially be selling the technology for use in telemedicine, where respiratory conditions can be assessed by doctors over the internet.

ResApp plans to file for approval for one respiratory condition at a time with the FDA.

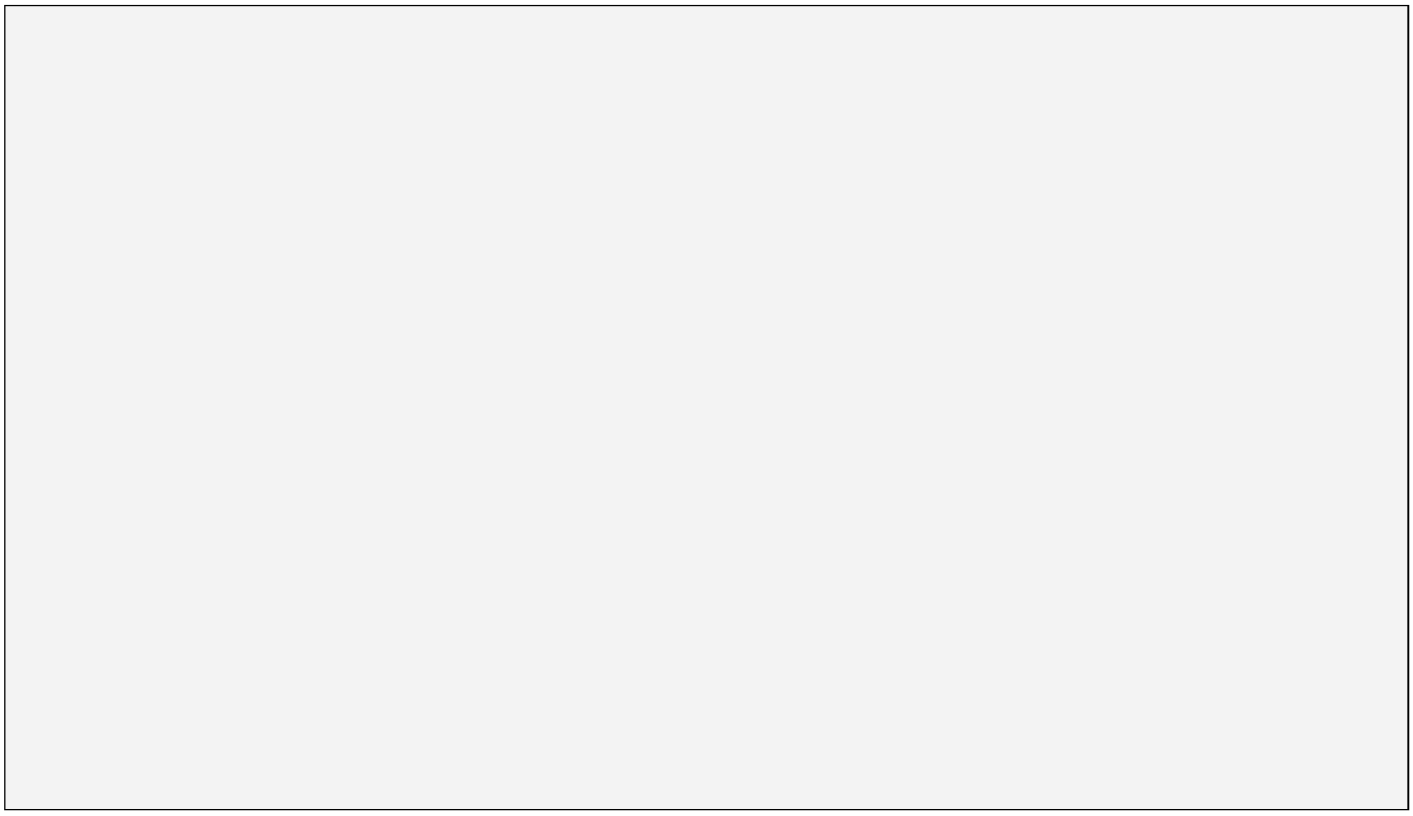
Summary

A high rate of enrollment into this study has been achieved, reflecting the clinical interest in the technology from the participating hospitals. Keating said the hospitals want this technology in their emergency departments, even as a tool to triage patients entering the hospitals.

ResApp has multiple milestones ahead which should see continuous news flow from the company over the next 15 months. Additional data for investors to monitor include recruitment rates into trials, detection of additional conditions, and prospective diagnostic data with detection between conditions.

ResApp is capitalised at $20 million. The company had $4.1 million in cash at June 30, 2015.

Bioshares recommendation: **Speculative Buy Class B**



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, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Benitec BioPharma, Invion, Imugene, Analytica, Circadian Technologies, Reproductive Health Science, Regeneus, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma