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Companies covered: AXP, GSS, PAR, RAP, RGS, SDX, VBS

	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 - Current)	-6.3%
Cumulative Gain	**707%**
Av. Annual gain (14 yrs)	**17.2%**

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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 Tightens Up Study Protocol for Repeat US Study

ResApp Health (RAP: $0.072) is planning to repeat its US respiratory study in November although with a number of improvements to the trial protocol to ensure results are more consistent and in line with those previously achieved in Australian and Indonesian studies.

All of the sites involved in the first US study have confirmed that they will participate in the next US study.

There will be a number of changes to the software program in the test, called ResAppDx, which uses a smartphone to listen to patient coughs to help diagnose respiratory illnesses.

One of the important changes will be a sound check that will need to be passed before the cough can be recorded. In the previous trial, a low frequency background noise interfered with some of the recordings. This type of electrical interference will now also be automatically adjusted for in the algorithm.

Other changes include a checklist that will be displayed on the phone that will remind hospital staff to ensure the area is quiet, that TV's are turned off and that only one cough is recorded and not that of parents or carers assisting children in the study.

Also importantly, ResApp will be able to monitor all of the recordings to ensure a high quality of testing is achieved.

In hindsight, one of the problems with the previous US study is that it was the *first* US study conducted. Previous studies had been conducted in Australia and Indonesia, where the algorithm had been developed on a retrospective basis. However, this development also allowed for the procedures to be monitored in the local environments.

Conditions in US hospitals have been found to be starkly different to the less busy Australian hospitals and Indonesian clinics.

With this in mind, the US study recently completed, which did not meet most of its endpoints, has provided very helpful lessons for the company with respect to the clinical use of the product. These learnings will help deliver a more robust diagnostic product.

Another issue with the trial are the differences in disease assessment between the US and Australian hospitals. This is a more difficult issue to address.

Cont'd over

To gain more consistency in the forthcoming US study, ResApp will meet with principal investigators this month to ensure a more standardised approach to clinical diagnosis can be applied to reduce subjectivity in clinical assessments.

Australian Study

The US study was the first major prospective study conducted. Previous trials had been conducted on 'leave-one-out' basis which was used to develop and perfect the algorithm.

ResApp is currently conducting a registration trial for the Australian and European market which is a prospective study being conducted at two hospitals in Perth. That trial started last month with 230 patients already enrolled and tested in the study. This is a double-blind trial with initial results expected by year's end. Trial numbers this year are unlikely to be sufficient for product registration in Australia and Europe (to gain statistical significance), with the trial likely to continue in the 2018 Australian winter season.

Summary

ResApp expects to have strong news flow over the next six to nine months.

Early results from the current, prospective Australian study are expected this year.

The company expects to provide regular updates on trial recruitment in the US study, and the company is aiming to have the US study completed by April next year.

ResApp Health is capitalised at $54 million. The company had $8.5 million in cash at the end of June.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

FDA to be 'Forward-Leaning' to Facilitate Development of Health Apps

According to Mobihealthnews, there were at least 36 mobile health products that received regulatory approval from the FDA last year.

That approval rate can be expected to grow with the appointment of Dr Scott Gothlieb as FDA Commissioner this year, who has signalled the creation of very clear public policies to reduce ambiguity with respect to medical phone apps.

Gothlieb stated that "…it is critical that the FDA be forward-leaning in making sure that we have implemented the right policies and regulatory tools, and communicated them very clearly, to encourage safe and effective innovation."

Some of the changes Gothlieb is considering include the use of post-market data for the regulation of health apps, a third party certification process whereby lower risk digital health products could be marketed without FDA review, and a more streamlined assessment of higher risk products.

Another aspect that needs to made clearer is how the FDA will view iterative changes in software, with the potential for companies to make changes to existing products according to set policies rather than having each seek company FDA feedback for proposed changes to existing products.

A table of FDA approvals of selected digital health and telemedicine technologies is provided in the table on next page.

FDA Approvals of Health Apps and Smartphone Add-ons

Date of Approval	Company	FDA approval
September 2017	Pear Therapeutics	'Reset' app to treat substance abuse.
July 2017	Cogstate	Cognigram digital assessment tool/app for objective cognition measurement
June 2017	Bayer	Companion app for MS drug Betaseron (records all injections and sends data to nurse/doctor)
May 2017	MindMaze	Computer program to re-train patients following stroke or TBI.
April 2017	VitalConnect	Remote monitoring sensors such as ECG, posture, heart rate variations, temperature. Via bluetooth, results sent to app
January 2017	Cambridge Cognition (Cogstate competitor)	Cantab Mobile app test to assess memory issues in older adults. Early warning system of Alzheimer's disease with built-in test for depression.
October 2016	TytoCare	Digital stethoscope
October 2016	Philips	Transducer for smartphone to turn phone into ultrasound
September 2016	AirStrip	Real time interpretation of ECG waves
July 2016	Analytica (Australia)	Approval for OTC (previous prescription only) use of Pericoach pelvic floor muscle trainer and app.
June 2016	Spara Labs	Spirometer connected to smart phone with app to monitor and manage asthma, COPD and Cystic Fibrosis
June 2016	Sandstone Diagnostics	Device and app to measure male fertility at home and to compare results to population averages
March 2016	Qbtech	App to monitor and assess for ADHD by parents
February 2016	iHealth Labs	Smartphone linked to blood pressure device

FDA Approvals in Telemedicine

Date of Approval	Company	FDA approval
April 2016	QServe Group	Dyna-Vision Telemonitoring with in-house devices to monitor cardiac health.
October 2014	Philips	Telemedicine app for use by doctors to prioritise patients at home who need assistance
September 2017	Dictum Health	Telemedicine device for Spirometry (and SpO2, blood pressure, temp and ECG)

FDA Approvals for Wireless Connected Devices

Date of Approval	Company	FDA approval
September 2017	Adherium	Third inhaler monitor
June 2017	iRhythm Zio	Peel-and-stick patch wearable device for ECG nonitoring (not wireless)
May 2017	Oxitone Medical	SpO2 and pulse wrist watch
April 2017	EnsoData	EndoSleep automated analysis of sleep data
April 2017	23andMe	Personal genetic tests direct to consumer for risk of Alzheimer's or Parkinson's diseases (US$199 per test)
December 2016	Masimo Technologies	Forehead sensor to measure SpO2 (oxygen saturation levels in the blood)
December 2016	Clarius Mobile Health	Wireless ultrasound scanner and app
December 2016	Nanowear	Remote cardiac-monitoring undergarments
November 2016	Propeller Health (Adherium competitor)	8th approval for drug inhaler sensor
March 2016	Sensimed	Triggerfish contact lens to monitor for glaucoma progression over 24 hours continuously
March 2016	Medtronic	Wearable sensor and moble patient monitoring system for patients with cardiac illnesses. Data sent to Medtronic server.
March 2016	TaiDoc Technology	Bluetooth enabled pulse oximeter for use in telehealth.
January 2016	Biolight Meditech	Handheld temp sensor, bluetooth connected to app.

Notes

The table above does not include glucose monitoring apps and device approvals of which there have been numerous

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*,Viralytics, Opthea, RHS, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Dimerix, Cyclopharm, Adalta, Immuron, Medibio, Phylogica *LBT was inadvertently deleted from this list from edition 688 onwards