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Bioshares

13 May 2019
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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies

Companies covered: **ACW, AXP, LBT, PXS, OSP, RHT**

	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)	-2.6%
Cumulative Gain	660%
Av. Annual gain (18 yrs)	16.0%

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Extract from Bioshares –

LBT Innovations Resets Expectations

LBT Innovations (LBT: $0.072) is resetting expectations with investors regarding the sale process for its automated plate processing instrument, called APAS Independence. The focus at this point is on completing its module validations and premarketing of its product in the US to make contact with its target customers.

LBT, through its 50% owned joint venture, Clever Culture Systems AG, is commercialising APAS in Europe and the US, with LBT functioning as the distributor in Australia. At this point, LBT is also selling the product directly into Europe and the US until distribution agreements are secured.

Early Challenges to Overcome

LBT has a number of challenges with selling APAS, which are contributing to early sales expectations not being met.

The company is seeking to appoint distributors in its target regions, that will not only sell the product, but also assist with installation and after sales support. However, to gain the interest from major distributors, it would benefit from early product acceptance by customers.

For customers to adopt the product, reference sites and feedback from early users is very helpful, as is local product support to address any technical challenges.

The company also needs to complete module validation for each of the regions before samples (e.g. urine samples, MRSA infection, sputum, wound swabs etc) can be processed in its instrument. It is not a 'plug and play' system, with the instrument needing to be integrated into the Laboratory Information System at each laboratory.

In the US the company also requires additional regulatory approval for the instrument. This is expected soon.

Continued over

ralian Market Progress

The first APAS instrument was sold to St Vincent's Hospital in Melbourne in August last year. LBT estimates that the total market in Australia is between 20 - 40 instruments, with 19 of the 26 potential customers being public hospitals. There are currently no public tenders that include its instrument with the company progressing discussions with one of the major private pathology groups.

The APAS instrument needs to be validated for each type of specimen, as well as for the different agar (media) plates that are used by the pathology groups. Although this involves considerable work, it will also function as an obstacle to competitors that will seek to follow LBT. LBT has hired an additional 10 staff, largely to assist with module validation, with a total staff count of 27.

One of the future features of the APAS product may be if it can direct use by pathology groups for a particular type of agar plate, which would make the APAS product valuable to plate manufacturers.

Currently in Australia the instrument is approved for sale, the urine sample module has been completed, and modules for MRSA (golden staph) testing are expected to be completed in Q3 this calendar year.

European Progress

LBT is aiming to get European clearance for its MRSA analysis module in Q3 this year, and urine modules completed in Q4, with product launch later this year. It will have urine and MRSA module validation available for the particular plates that are most common in Europe, which make up close to 70% of all samples analysed on an agar plate. Germany is the lead target market, where it has a product installed at a reference site. There are over 300 suitable laboratories that it will target (that process more than 400 samples a day). The company has a local sales person in Germany with a pipeline of labs the company is targeting.

US Progress

LBT filed its automated instrument for approval with the FDA late last year with approval expected this year. (Approval had previously been received for a system that was not fully automated.)

A urine analysis module is expected to be cleared by the regulator this year with the MRSA module to be cleared in early 2020. At this point the company is building its data base of suitable labs and making initial contacts with lab managers. LBT CEO Brent Barnes said that the early conversations with the US lab managers has been “fantastic”, with no competitors on the market.

The sales process generally involves the laboratories signing a formal evaluation document which will then facilitate a four week evaluation of the instrument on site. In the US there are 1,500 relevant laboratories with the company to target initially the top 150 early adopters.

Reducing Module Development Times

The first two modules, for urine samples, took the company 18 months to complete. This validation period has been halved, with the next four modules, for MRSA, expected to take only nine months to complete. For Australia and Europe, it is a self-validation process, and the US the process is assessed by the FDA.

Reference Sites

LBT has made progress in having its instrument installed in three reference sites around the world; one at St Vincent's in Melbourne (which was a commercial sale), one in Germany at Labor Dr Wisplinghoff, and one placed at Hennepin Health in Minneapolis (under Dr Glen Hansen).

The site in Germany has been validating the MRSA module (on two European plates) with additional validation on other plates being conducted in Adelaide by LBT. Dr Wisplinghoff has analysed 17,000 samples with the APAS system, and validated its accuracy with a sensitivity of 100% and specificity of 98%.

The US reference site will conduct the module validation necessary for the US agar plates used more commonly in that region. For the US, there are eight plates alone that are commonly used to analyse urine samples, that LBT is validating.

Summary

While not providing sales forecasts for the year ahead, Barnes expects the company to make instrument sales in each of the three regions it is active in, that being Australia, Europe and the US.

The sales process for LBT with the APAS Independent product is a long period, at over 12 months. However it is a very large global market with around 13,000 labs worldwide that would benefit from such a system. According to the company, selling 1,500 instruments would generate revenue of around $600 million for the joint venture and annual licensing income to LBT approaching $60 million.

However, the immediate challenge for the company is to secure multiple early product sales in its three key regions.

LBT is capitalised at $15 million with $4.2 million in cash at the end of March. It also has access to a government loan for $4 million, repayable over five years, with the first $1 million recently drawn down.

Bioshares recommendation: **Speculative Hold Class B**

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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