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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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Bioshares

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

Extract from Bioshares –

Pharmaxis Gains Positive Vote for Bronchitol in USA

Pharmaxis (PXS: $0.27) was originally formed to commercialise Bronchitol for the treatment of cystic fibrosis. Sixteen years after listing on the ASX, it looks like Bronchitol may gain FDA approval after winning a positive FDA advisory committee vote, 9 versus 7 in favour of approval.

The company is expecting a decision from the FDA around mid year, noting that the panel's vote does not require the FDA to approve its New Drug Application (NDA).

If successful, Bronchitol will be marketed in the US by Chiesi Farmaceutici. Pharmaxis will receive a milestone payment of US$10 million upon shipment of the first product to Chiesi in the US.

One of the strong features of this licensing deal is that Pharmaxis maintains manufacturing control. Together with royalties and manufacturing margins, the company should receive over 20% of net sales of Bronchitol.

In Europe, Bronchitol sells for around US$10,000 per patient treated per year, which is very close to the price of the drug Pulmozyme, also used to clear the lungs of people with cystic fibrosis. In the US, Pulmozyme sells for around double that price.

Patient usage is also greater in the US with over 60% of cystic fibrosis patients on the drug. This suggests considerably higher revenue should be achieved in the US from Bronchitol, if it is approved, than in Europe.

The pending approval for Bronchitol will be for the treatment of adults only. In the US there are around 15,000 adults with cystic fibrosis. Experience in Europe has been that patients will switch between Bronchitol with Pulmozyme. Pulmozyme needs to be inhaled

Continued over

through a nebulizer, so is time consuming, compared to Bronchitol which is dosed through a handheld inhaler.

Gaining 20% market penetration in the US would equate to annual sales of US$60 million, or an estimated annual return to Pharmaxis of over US$12 million ($17 million).

The panel vote comes at a time when Bronchitol is nearing a breakeven point for the company. Pharmaxis CEO Gary Phillips expects that Bronchitol, along with the diagnostic Aridol (which is the same material), to be cashflow positive from next financial year, assuming US clearance.

Revenue from Bronchitol and Aridol is tracking at $7.7 million, up 11% over the previous year. This growth rate should accelerate from a relaunch of Aridol in the US in December last year (which was previously generating annualised sales of $0.4 million), an Aridol launch in Canada if approved, and from Bronchitol sales in the US, if approved.

Licensing of LOXL2 Program

Pharmaxis "is progressing" discussions to license its next program, the LOXL2 inhibitor program, said Phillips. Our expectation is that if a favourable deal can be secured, that will occur in coming months. This is the main share price driver for this stock.

In Phase I studies the company has shown that it can achieve 85% target inhibition with no drug toxicity with both of the compounds created. These antifibrotic compounds also show long lasting inhibition according to the company.

To date Pharmaxis has received $83 million from the sale of a drug asset PXS-4728A to Boehringer Ingelheim in 2015. That drug is currently in Phase II studies for the treatment of NASH and diabetic retinopathy. The NASH results are due in September or October this year, and the diabetic retinopathy trial is due to complete in 1H 2020.

LOX Inhibitor for Scar Treatment and Prevention

An interesting program Pharmaxis has underway is a topical pan LOX inhibitor, to treat and reduce scarring. Applying the drug as a topical treatment reduces the potential side effects of a systemic treatment.

Potential applications include prophylactic use following burns or cosmetic procedures, and the treatment of existing scars that continue to remodel as the skin grows. Positive results have been achieved in pig skin, showing that scar sizing can be reduced. Phase I studies are expected to start in 1H 2020 in healthy volunteers, although it could include volunteers with scars.

Pancreatic Cancer Trial

Earlier this year Pharmaxis started a Phase I safety study in healthy volunteers with its systemic pan LOX inhibitor. The company is using its proprietary assay to measure target engagement. Trials in patients with pancreatic cancer are expected to start next year.

Pancreatic tumours are highly fibrotic. They are difficult to treat with existing drugs that struggle to penetrate the stroma (fibrotic tissue). By disrupting this fibrotic network it is thought drugs like Pharmaxis' pan LOX inhibitor may allow traditional therapies to be more effective in penetrating the tumour.

Summary

Pharmaxis has a number of near term milestones ahead. These include, in order of priority, negotiating a LOXL2 licensing agreement, approval and product supply of Bronchitol for cystic fibrosis in the US, and results from the Phase II NASH and diabetic retinopathy studies.

Pharmaxis is capitalised at $106 million and held $35 million in cash at the end of March.

Bioshares recommendation: **Speculative Buy Class A**

Note this is a corrected extract from the original version.

Bioshares

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