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Bioshares

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

Companies covered: **AXP, BNO, MVP, PXS, RAP, UBI, VTI**

Pharmaxis: More Positive Phase I Data from LOXL2 Program

	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 - current)	4.2%
Cumulative Gain	733%
Av. Annual gain (17 yrs)	17.1%

Pharmaxis (PXS: \$0.305) has reported additional positive data from the first of two compounds in its LOXL2 program. This program is one of the short-term drivers for PXS stock, which the company is seeking to transact a major deal around in 1H 2019.

Pharmaxis is developing two candidates within the program. Data from the first compound previously was from a single ascending dose from 10mg to 400mg in healthy volunteers. That part of the trial showed that the drug was safe, had a favourable half-life in the body, of around one day (which means it will be suitable for daily oral dosing), and most importantly, that it inhibited the target enzyme - LOXL2 - in plasma.

LOXL2 is implicated in fibrotic diseases, and inhibiting the enzyme blocks the cross linking in tissue which is necessary for fibrosis, including scarring, to occur. Diseases that the compounds may have applicability to treat include NASH (liver fibrosis), and fibrosis in the lungs, kidneys and heart.

In the Phase I multiple ascending dose trial just completed, which looked at 10mg and 400mg doses of the first compound given daily for 14 days, it was found that the compound remained safe, its plasma concentration increased as expected with dose, and that 80% of the LOXL2 enzyme in the blood was blocked at 400mg after 14 days of dosing. It is also significant that the company has shown target engagement of the compound in animal tissue and is aiming to show this in additional animal models. Inhibition in the tissue is expected to be higher than in the blood.

Additional data that is being generated includes testing from the second compound, which has been completed with results expected this quarter, and three-month animal toxicology work which is expected to be finished by year's end. At that point, the company will be ready for formal commercial discussions with pharmaceutical companies with data to be made available to interested groups.

There are around six potential companies that have maintained interest in Pharmaxis' LOXL2 program. In 2015, Pharmaxis secured a major deal with Boehringer Ingelheim for its SSAO program. That deal was completed at the end of Phase I and included an upfront \$39 million payment to Pharmaxis. To date Pharmaxis has received \$83 million from Boehringer.

Boehringer has two Phase II studies are underway, in NASH and diabetic retinopathy, with results from both studies expected in 1H 2019. Positive progress from those trials is likely to be reflected in Pharmaxis' share price.

We expect the partnering program to be managed with diligence and purpose by Pharmaxis, a company which has developed credible partnering capabilities, especially with the reputation-enhancing deal it struck with Boehringer Ingelheim. Pharmaxis is capitalised at \$120 million.

Bioshares recommendation: **Speculative Buy Class A**

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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, Pharmaxis, Dimerix, Cyclopharm, Adalta, Medibio, Pharmaust, Actinogen Medical, Patrys

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