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Companies covered: **4DX, ARX, AT1, CUV, MDC, NYR, PXS, VHT**

	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)	-35.8%
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 - May '20)	39.5%
Year 20 (May '20 - Current)	23.2%
Cumulative Gain	1241%
Av. Annual gain (19 yrs)	17.3%

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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 –

A Big Six Months Ahead for Pharmaxis

Pharmaxis (PXS: $0.105) has four major milestones ahead in the next six months, which are likely to have a significant impact on the company's share price.

1. FDA Decision on Bronchitol

On 1 November the FDA will deliver a decision on the approval of Pharmaxis' cystic fibrosis drug, Bronchitol.

The drug is currently approved and sold into at least 17 countries around the world, predominantly in Europe and Australia, and should gain US clearance.

The most recent request by the FDA was for Pharmaxis' partner, Chiesi Farmaceutici, to alter its packaging and show that a lung function test for the drug (to ensure hypersensitive patients are not given the inhaled drug) can be easily conducted prior to prescription of the drug.

In FY2020, Bronchitol and Aridol (its lung function test) generated sales of $7.0 million, up 24% over the previous year, with an adjusted EBITDA loss of $4.0 million, down from $5.0 million the previous year.

US approval will bring this business into profitability, with a US$7 million milestone payment to be received following approval and a further US$3 million payment upon launch.

The terms of these payments were recently adjusted to Pharmaxis' favour without penalty.

2. LOXL2 Licensing Deal

Pharmaxis CEO Gary Phillips said that the company still has active partnering discussions underway for its LOXL2 program. A deal was expected as early as last year with the company's share price under pressure until a deal is secured.

Pharmaxis recently completed an additional clinical study around the drug's blood profile based on different treatment regiments.

At this stage no further clinical work is anticipated until a licensing deal is secured.

3. Decision by Boehringer Ingelheim on Diabetic Retinopathy Program

In 2015 Boehringer Ingelheim acquired the compound now termed BI1467335, paying Pharmaxis $83 million to date.

Boehringer has completed 9 clinical studies over the last four years with the compound in over 350 healthy volunteers, and in patients with NASH and diabetic retinopathy.

Cont'd over

One trial, which was looking at the effects of combining BI1467335 with tyramine on blood pressure was terminated, with the NASH program discontinued due to a drug interaction issue (presumably with tyramine, a chemical which can be found in certain cheeses).

Results from Boehringer's second study with BI1467335 in patients with diabetic retinopathy are due this half year. That study is looking at the highest dose of BI1467335 trialed in the NASH study. If there is a clear benefit, then subsequent (Phase II) studies in diabetic retinopathy may be considered at lower doses.

Pharmaxis' next potential milestone payment from this asset is from the commencement of Phase III studies. Results from the Phase IIa diabetic retinopathy trial are currently being assessed by Boehringer.

4. Commencement of Phase II Myelofibrosis Study

Pharmaxis has hired the CRO Parexel to conduct its Phase II study with its pan LOX inhibitor PXS-5505 in patients with myelofibrosis.

A 20,000 page IND submission was made to the FDA last month with clearance to commence the study to be received as early as this month. Pharmaxis has completed multiple trials in animal models and has completed Phase Ia and Phase Ib studies in volunteers showing a good safety profile and inhibition of the lysyl oxidase targets.

This is likely to be an open-label study which will allow data to be generated and reported during the trial. Effects of myelofibrosis included cytopenia and an enlarged spleen, the effects of which can be readily measured.

Once the myelofibrosis study is cleared, Phillips is expecting potential interest from independent investigators in other diseases, including pancreatic cancer (and in conjunction with PD-1 inhibitors) and in liver and oral cancer.

Potential Restructuring

Pharmaxis is in the process of evaluating a potential restructure of its business, which will involve how its mannitol (Bronchitol and Aridol) assets are best utilised and how best to fund its drug development business should Bronchitol receive FDA clearance in November.

This could include divesting of all or parts of the Bronchitol and Aridol business (in Bioshares view) as they move into profitability.

Summary

Pharmaxis is capitalised at $42 million. The company held cash assets of just under $20 million at the end of June, including an R&D tax rebate to be received this half.

Bioshares recommendation: **Speculative Buy Class A**

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, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Cyclopharm, Antisense Therapeutics, Imugene, Exopharm, Immutep, Neuroscientific Biopharmaceuticals, Invex Therapeutics, Anteris Technologies