ISSN 1443-850X

BIOSHARES
Australia's Independent Biotech Investment Resource, est.1999

1 May 2023
Edition 937

	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 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Dec '22)	-2.2%
Year 23 (CY2023)	-10.0%
Cumulative Gain	1411%
Av. Annual gain (22 yrs)	18.1%

Companies covered: IMC, PXS, TLX

2023 Top Six Picks: -0.1%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. ACN 085 334 292
PO Box 447
Flinders Lane Vic 8009
AFS Licence No. 258032

Mark Pachacz - Editor/Analyst
Email: mark{at}bioshares.com.au
Ph: 0403 850 425

Edition Number 937 (1 May 2023)

Extract from Bioshares –

Pharmaxis Phase II Trial Results Approaching

Pharmaxis (PXS: $0.061) CEO Gary Phillips said the company is approaching a point when it is about to realise the benefits from the investment that has been made in its clinical programs, with the results from two clinical trials forthcoming. Phillips said it has taken several years to get to this point.

Myelofibrosis Study to Move into Combination Therapy

This is a Phase II study that was seeking to enrol 24 patients as a monotherapy with PXS-5505, in patients who had failed standard-of-care (JAK inhibitor treatment). The life expectancy is only around 12 months for such patients. To date 21 patients have been recruited.

The key information the FDA had wanted to see from this study was the safety profile, which has shown to be very clean. Whilst the company expects to complete recruitment this quarter, the optimal effect is expected to be realised in combination with a JAK inhibitor. The JAK inhibitors work downstream reducing the spleen size but are not curative. PXS-5505 works more upstream in reducing fibrosis in the bone marrow which causes the disease. So a synergistic outcome can be expected.

The FDA has been provided with all the current clinical data, with encouraging signs of efficacy and a good safety profile. Following a meeting with the FDA, the regulator has cleared Pharmaxis to now move into combination therapy with PXS-5505 and a JAK inhibitor. But importantly it will be part of the existing study, with a new treatment arm to be added at existing sites.

A combination arm will likely start with the highest dose explored in the monotherapy trial of 200mg, twice daily, which means a shorter time to reach the best potential therapeutic outcome. The combination arm is expected to start in the second half of this year with available data from the monotherapy study to be released this quarter.

Companies with existing JAK inhibitors would be a logical partner for Pharmaxis to do a licensing deal with, with those companies currently following the progress Pharmaxis is making according to Phillips.

Continued over

Skin Scarring Study

All 50 patients in the scar treatment study completed therapy at the end of March. This is a placebo-controlled study. Results from this study should also be released in the current quarter. Whilst some early beneficial effects have been noticed by Professor Fiona Wood who is coordinating the study, Phillips said that data against the placebo will be key.

Skin biopsies taken from the first eight patients did show physiological changes in the scarred layers of the skin, changing the structure of the scar according to Phillips. The questions that need to be answered however, are which scars will respond best to treatment and for how long will the treatment be required.

Another potential indication will be use of the treatment to prevent scars following surgery with a clinical trial due to commence.

Pharmaxis finished March with $14.7 million in cash. Its market capitalisation is $44 million.

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 of 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, Opthea, Pharmaxis, Dimerix, Patrys, Antisense Therapeutics, Imugene, Chimeric Therapeutics, Neuren Pharmaceuticals, Aroa Biosurgery, Radiopharm Theranostics, Imricor Medical Systems, Anteris Technologies, Bio-Gene Technology, EBR Systems, Immuron