Extract from Bioshares –

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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, IDT, NAN, PXS, RNO,

	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 - current)	26.9%
Cumulative Gain	**835%**
Av. Annual gain (14 yrs)	**19.3%**

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Pharmaxis – All Attention on NASH for Pharmaxis

Pharmaxis (PXS: $0.27) has done well to reduce its net expenditure over the last two years. Its net loss in the September quarter 2014 was $8.3 million. This decreased to $6.2 million for the 2015 September quarter and to $4.1 million for the quarter just passed. The company finished September with $32.4 million in cash.

Bronchitol sales continue to languish, at $0.39 million for the quarter. Whilst this was higher than the June quarter ($0.19 million), it is well below the previous corresponding period ($1.64 million). Italian group Chiesi Farmaceutici is now selling the product into the UK and Germany (since 1 June 2015) and has US rights as well, where a third Phase III trial is being completed.

The quarterly loss on Bronchitol (and Aridol, the asthma diagnostic which uses the same mannitol constituent) has fallen from $3.5 million in 2014 to $1.15 million last year and increased slightly to $1.45 million in the last September quarter. The short-medium term objective for the company is to turn this into a cash generating asset. Russian approval was received during the quarter for Bronchitol and the company expects sales into this market will bring the asset to a breakeven position.

The third Phase III trial with Bronchitol for the treatment of cystic fibrosis in the US completed enrolment in July this year with results due in Q2 2017. Upon launch of the product in the US, Pharmaxis will receive US$10 million from Chiesi.

NASH Developments – Allergan Goes Shopping

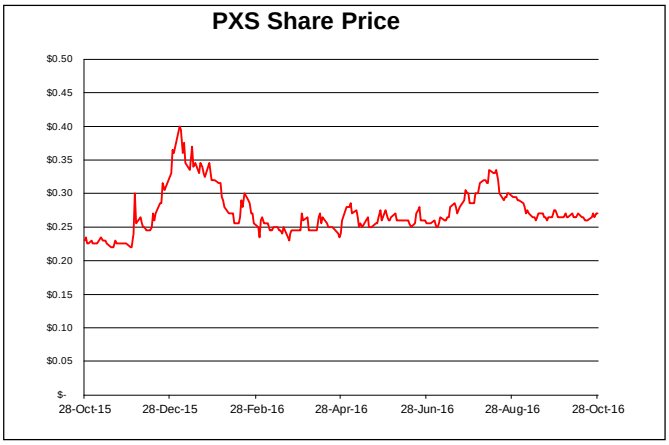
The core focus for Pharmaxis is in its drug development pipeline assets. Pharmaxis licensed its PXS-4728A program to Boehringer Ingelheim last year. It is being development for the treatment of NASH (non-alcoholic steatohepatitis) firstly which is a disease area of very strong interest for pharmaceutical companies. Pharmaxis sold the asset for an upfront fee of $39 million plus milestone payments and an earnout payment based on a percentage of sales.

Last month Allergan announced two acquisitions in the NASH space on the same day, one for Tobira Therapeutics for US$1.7 billion, and the other Arkana Therapeutics for an upfront payment of US$50 million. Tobira had two NASH programs. The lead program was with a compound called cenicriviroc, an immunomodulator and inhibitor of CCR2 and CCR5. This compound failed to meet its primary endpoint in a Phase IIb trial (a two point reduction in the NAFLD score) but did lower liver scarring, a secondary endpoint, which triggered the interest from Allergan. Tobira also has a DPP-4 inhibitor which it planned to develop in combination with cenicriviroc in the treatment of NASH.

Arkana had a preclinical program with a farnesoid X receptor (FXR) inhibitor that is found in the liver. FXR is believed to have a major role in carbohydrate and lipid metabolism.

Cont'd over

Whilst other companies developing NASH treatments responded positively from the announcements, there was little effect on the Pharmaxis share price. Pharmaxis stands to receive around $25 million when the Boehringer program moves into Phase II development, which we expect to occur in 2017. Another milestone payment is due when a Phase II trial begins in other indication and around $55 million is due to be paid to Pharmaxis at the commencement of a Phase III program.



Pharmaxis is also developing its second NASH asset, a LOXL2 inhibitor that disrupts cross linking that occurs to form fibrotic tissue. A Phase I trial is due to start with this program in mid 2017 and be completed by the end of that year. There is the potential for a major licensing opportunity for this program in 2018 should the program pass toxicology testing and deliver appropriate Phase I results.

Pharmaxis is an attractive investment because of it has secured a major pharmaceutical transaction in the NASH space. NASH is a therapeutic area for which there are no effective treatments and an area of drug development that is lacking in credible R&D programs. NASH affects 5% of the US population and is the fastest growing reason for liver cancer and liver transplant.

The US$1.7 billion acquisition of Tobira Therapeutics highlights the continued interest in this filed and the willingness to pay high prices to secure assets that show a hint of efficacy. That Pharmaxis has two assets in this field (one sold to Boehringer with further milestones and earnout fees payable) makes it a stock to consider, particularly given that its technology value is only $54 million.

Upcoming milestones

- Commencement of Phase II trial by Boehringer (1H 2017 likely), triggers $25 million payment to PXS
- Q2 2017 – Results from Phase III trial in CF with Bronchitol in USA
- Mid 2017 – Start Phase I trial with LOXL2 program
- Late 2017/ Early 2018 – Phase I trial results from LOXL2 program
- 2018 – LOXL2 licensing deal
- 2018 – FDA decision on Bronchitol approval
- 2018/2019 Bronchitol launch in USA, triggers US$10 million payment to PXS

Pharmaxis is capitalised at $86 million.

Bioshares recommendation: **Speculative Buy 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 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, Impedimed, LBT Innovations, Viralytics, pSivida, Opthea, Reproductive Health Science, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Antisense Therapeutics, Atcor Medical, Dimerix, Cyclopharm, Adalta