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Bioshares

2 February 2018
Edition 730

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

Companies covered: **DVL, OVN, PXS, SRX, RNO, Cash Flow Analysis**

	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 - Current)	-3.3%
Cumulative Gain	732%
Av. Annual gain (14 yrs)	17.3%

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Extract from Bioshares –

A Busy Year for Pharmaxis – Multiple Trial Readouts Ahead

Boehringer Ingelheim has initiated the seventh clinical trial on the anti-inflammatory compound acquired from Pharmaxis (PXS: $0.275) in 2015. To date, Pharmaxis has received $83 million for that compound with more milestones and high single digit earnout payments from sales.

Boehringer is conducting two Phase II studies with the compound acquired (BI 1467335), one in NASH and the second in diabetic retinopathy.

Pharmaxis' busy year will be due to readouts from several trials, expected to occur in 2018.

NASH Phase IIa Trial Readout 2H 2018

The NASH trial is recruiting 147 patients and will be double blinded, including a placebo arm. Primary data from this study is expected in June this year. The primary endpoint is activation of the target enzyme (AOC3, also known as VAP-1 which is part of the SSAO family) which is involved in leucocyte trafficking that contributes to the inflammation process.

This is the same endpoint in the Phase I trial that secured the original deal with Boehringer for this compound, although that trial was in healthy volunteers where 100% inhibition was achieved. In this trial the levels of AOC3 should be significantly higher. There should be a strong chance of meeting the primary endpoint as this endpoint was met in the Phase I study and the comparison with a placebo will be of interest.

Secondary Endpoints – Elevated Liver Enzymes

Of more tangible interest with respect to treating NASH will be any changes in secondary endpoints of elevated liver enzymes due to the disease over the three months of treatment. A meaningful change in these levels will give Boehringer added confidence in the program.

This IIa study is exploring four different doses in patients with moderate-to-severe NASH. The next stage, a Phase IIb trial, will likely look at two doses over a longer period. We estimate a Phase III study may start in 2020, upon which Pharmaxis would receive the next milestone payment of €38 million ($58 million).

Diabetic Retinopathy Phase II trial Readout out mid-2018

At the end of August, Boehringer expects to receive primary data from a 100 patient Phase II study in diabetic retinopathy, looking at improvements in retinal lesions. This study will include a placebo arm and patients will be treated for 12 weeks with a 12 week follow-up period. In recent years it has been shown that chronic, subclinical inflammation is occurring in the retina of patients with diabetic retinopathy.

Continued over

The other five clinical trials (three completed and two ongoing) are investigating pharmacokinetics and pharmacodynamics of the drug candidate in the body of volunteers and patients with kidney damage, as well as comparing a tablet formulation with an oral solution.

Two Phase I Readouts in mid-2018 for LOLX2 programs

Late last year two Phase I trials commenced in Pharmaxis' LOXL2 fibrosis program. One of these trials was started by Pharmaxis' partner Synairgen in the UK.

Pharmaxis and Synairgen started a collaboration in August 2015 to work together with the LOXL2 program in the area of Idiopathic Pulmonary Fibrosis (IPF).

Using Synairgen's tissue biobank assets, specifically lung cells from patients with IPF, Synairgen showed that the Pharmaxis LOXL2 inhibitor was able to reduce cross-linking of collagen fibres in a dose dependent manner, which should result in less stiff lungs.

In December last year the terms of that collaboration were renegotiated, partially as a result of the strong interest Pharmaxis is receiving with this program from potential partners.

Rather than sharing upside equally in the IPF indication, Pharmaxis would take full control of the LOXL2 programs and increase its ownership to 83%.

In return, Synairgen received a payment of £5 million ($9 million) and will benefit similarly across any non-lung licensing deals as well. Another benefit to Pharmaxis is that partnering deals need only being conducted with Pharmaxis.

Results from the two Phase I studies are expected by mid year. A LOXL2 inhibition assay was developed by Pharmaxis (in conjunction with a UK diagnostic group) last quarter which is very important to showing target engagement and thereby securing a major licensing deal, if results are positive, in 2H 2018.

Pharmaxis is conducting three month toxicology testing (it had only 28 day toxicology data on the compound sold to Boehringer) and scale up of manufacture to make the program Phase II ready for a partner.

The company is seeking to secure a licensing deal in the second half of this year pending positive Phase I data.

Bronchitol & Aridol progress

Bronchitol and Aridol sales increased by 34% over the September quarter to $1.4 million with increased sales of Bronchitol to its distributor Chiesi for the German and Italian markets. We expect these products to move into a cashflow positive point in 2019.

In the second half of this year, Chiesi is expected to file Bronchitol for approval in the US. A US market launch will trigger a US$10 million milestone payment to Pharmaxis.

In Australia, which makes up approximately a quarter of Bronchitol sales ($220,000), the Commonwealth government approved the reimbursement of Bronchitol in patients also taking the cystic fibrosis drug Pulmozyme.

Summary

Pharmaxis is capitalised at $88 million and holds approximately $43 million in funds. With multiple, significant milestones ahead for the company over 2018 and a low market capitalisation, the stock remains significantly undervalued. We expect better value recognition of this stock over the course of the year.

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 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, Opthea, RHS, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Dimerix, Cyclopharm, Adalta, Immuron, Medibio, Phylogica, Pharmaust