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Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)

\$470 (Inc.GST)

Edition Number 711 (1 September 2017)

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Bioshare

1 September 2017 Edition 711

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

Extract from Bioshares -

Pharmaxis' Partner Starts Phase II NASH Trial

Boehringer Ingelheim has started a Phase II trial in NASH with the compound it acquired from Pharmaxis (PXS: \$0.265) in 2015. As part of the deal, Pharmaxis will receive \$27 million as a milestone payment. Pharmaxis also expects to receive a further \$15 million towards the end of this year when Boehringer starts a Phase II trial in a second indication.

The Phase II NASH study will seek to recruit 150 patients. It is currently recruiting in three sites in the US, two in Canada and two in the Netherlands. Patients enrolling into the study will have confirmed NASH either through a biopsy or through imaging of the liver. The trial will assess four doses of the compound, BI 1467335, which will also be compared to a placebo.

The primary endpoint will be inhibition of the target enzyme 24 hours after dosing (AOC3) with secondary endpoints being adverse reactions, and changes in liver enzymes after 12 weeks of daily oral treatment with the drug candidate.

The primary completion date of the trial is April next year with results around mid year. If the trial is successful, Boehringer will move onto a Phase IIb study which will likely be a longer study to confirm the outcomes from the Phase IIa. On starting a Phase III trial, Pharmaxis will be eligible to receive the next milestone payment of \$55 million.

Other Programs

Before year's end, Pharmaxis intends to start a Phase I trial with its LOXL-2 anti-fibrotic drug candidate. If results from this Phase I trial are positive, then Pharmaxis will seek to conclude a licensing deal in H2 2018.

Next year Pharmaxis' partner Chiesi Farmaceutici intends to file Bronchitol for approval for the treatment of cystic fibrosis. Pharmaxis is aiming to start two other Phase I trials next year in other programs.

Financials

Pharmaxis finished FY17 with \$21.5 million in cash and will now receive \$27 million from Boehringer Ingelheim from the Phase II NASH milestone payment.

The company's current burn rate is around \$18 million a year. With receipt of a further \$15 million from Boehringer this year, Pharmaxis should end 2018 with around \$54 million.

This will give the company sufficient cash reserves to the end of 2020, excluding any additional licensing revenue or milestones from Boehringer.

Other potential income includes a US\$10 million payment from Chiesi Farmaceutici upon launch of Bronchitol in the US. The company's cash burn may reduce further if its Bronchitol and Aridol products become profitable in the next two years.

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In FY2017, the loss from the Bronchitol and Aridol products was \$7.0 million which included a \$1.5 million contribution to clinical trial costs. We expect losses from this business to fall below \$5 million in FY2018.

With these factors in mind, we have upgraded our recommendation to **Speculative Buy Class A**.

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 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

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