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	Bioshares Portfolio
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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 - current)	32.3%
Cumulative Gain	633%
Av. Annual gain (14 yrs)	18.7%

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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* –

Opthea's OPT-302 Passes Safety Checkpoint

Opthea (OPT: \$0.465) has released safety data from its Phase Ib trial with its wet AMD drug candidate, OPT-302. Twenty patients have now been treated with the drug candidate, both as a monotherapy (5 patients) and in combination with the eye drug Lucentis (15 patients).

CEO Megan Baldwin said the drug has a very clean safety profile, with the treatment well tolerated and no dose-limiting toxicities observed after 28 days on the highest dose.

Baldwin said that it should not always be assumed that these type of drugs have such a clean safety profile with recent issues with other drugs in this class such as inflammation in the eye.

An Important Milestone

That OPT-302 provides a complete VEGF pathway block with no worrying side effects is an important milestone for the company including no increases in intraocular pressure. Any adverse events were related to the injection procedure and were manageable.

The dosage being evaluated for this drug are 0.3mg, 1.0mg, and 2.0mg, in combination with 0.5mg of Lucentis. One arm of the trial is exploring 2.0mg of OPT-302 as a monotherapy. The highest dose (2mg) is expected to be a therapeutic dose as it is close to the equivalent dose of the eye drug Eylea. In preclinical studies, Eylea and OPT-302 were observed similar in potency assays and are similar in structure.

Eylea and Lucentis both block the VEGF-A pathway involved in new (unwanted) blood vessel formation in the eye. OPT-302 blocks the other two proteins involved in this pathway, VEGF-C and VEGF-D. Last year, Lucentis generated sales of over US\$4.5 billion and Eylea generated sales of over US\$2.6 billion.

However, around half of patients are poor or non-responders to these treatments. The argument is that a more extensive blockage of this pathway will improve treatment outcomes. This includes less frequent injections into the eye, further improvements in visual acuity in all patients, and activity in the poor and non-responder group.

All patients in the last two groups of patients at the highest dose have received at least one dose of treatment. The company will compile data once all patients have received three doses, which is in two months time. Details on safety and efficacy measures will be reported on all 20 patients in Q3 2016.

It had been expected that the company would report on some efficacy measures at this point with selected patients. However, Baldwin said that the company had decided to present pooled, three month data, which in our view is somewhat disappointing given the expectations that were previously set.

Cont'd over

– *Opthea cont'd*

The full data will reveal information on dose dependency, and the effect in treatment-naive patients as well as those who have not previously responded well to Lucentis therapy.

Initiation of Phase IIa Study

Opthea will now start a Phase 2A study, which will be randomised and compare the highest dose of OPT-302 against the combination treatment with Lucentis for three months. There will be 15 patients in each arm with results due at the end of 2016. That trial will use the same 14 sites in the US.

Opthea is capitalised at \$70 million. The company had \$17.7 million in cash at the end of 2015.

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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