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

17 November 2023
Edition 948

	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)	-27.3%
Cumulative Gain	1121%
Av. Annual gain (22 yrs)	18.1%

Companies covered: 1AD, CUV, IPD, IMU, NEU, TLX

2023 Top Six Picks: -32%

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Extract from Bioshares –

First Results for Imugene's Oncolytic Virus CF33

In May last year, Imugene (IMU: $0.089) commenced the first study with its novel oncolytic virus, CF33. CF33 was invented by Dr Yuman Fong and his team at City of Hope. It was in-licensed by Imugene in 2019 with the first clinical study having started in May last year.

Last week, the company announced the first results regarding the CF33-hNIS virus Phase I study in patients with a range of solid tumours. So far 34 patients have been treated and results have been released for the first 25 patients who have had their first scan to assess their tumours at six weeks following treatment. All patients had metastatic solid tumours which can be considered very difficult to treat having received extensive prior therapies.

The study has been slowly escalating the virus dose given to the patients. Patients have received the therapy either directly into the tumour or through an IV injection, and some patients having also received a combination therapy with Keytruda. All patients entering the study had received at least two lines of standard-of-care therapy.

Results

The strongest result was a complete response in one patient with bile duct cancer that has been sustained for more than 200 days following treatment (with a mid-level dose of the virus injected directly into the tumour). Another patient with melanoma achieved a partial response (following an IV mid-dose level injection) and 16 patients have achieved stable disease.

The results show some encouraging early data for Imugene with this first-time tested oncolytic virus. The safety profile has been very good with injection site reactions and some flu-like symptoms which can indicate activity of the virus and an immune response.

The study is being conducted across 10 sites in the US and two in Australia. In the monotherapy arm with the therapy injected intratumorally, the study has reached the fourth highest cohort (a 100 times higher dose than the first cohort) with the dose still to be assessed at the highest dose which will be three times higher than the current dose.

In the patients who received monotherapy via IV, the highest dose is now being assessed. This dose is 300 times higher than the dose of the first cohort. In the combination therapy with Keytruda, the second highest dose is currently being investigated intratumorally, and the trial is recruiting at the highest planned dose in the IV arm.

According to Dr Fong, the issue with the first generation of oncolytic viruses is that the dose was too conservative. Of interest will be to see how the patient outcomes change as the highest doses are reached.

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Strong Effect with CF33 in Gastrointestinal Tumours

One of the aims of this study has been to find the recommended Phase II dose. However a strong response has been seen in patients with gastrointestinal cancers, including two with the very difficult to treat bile duct cancer. One of those patients achieved a complete response from monotherapy following three courses of chemotherapy and a low PD-L1 level, which means PD-L1 checkpoint inhibition therapy is unlikely to be effective. A second patient with bile duct cancer has achieved stable disease after five months following combination therapy. Disease control (a partial or full response or stable disease) has been achieved in seven of the eight patients with gastrointestinal cancers from treatment with CF33 alone.

Imugene plans to expand the study with an additional 10 patients with bile duct cancer given these early results. According to the American Cancer Society, the five year survival rate for localised bile duct cancers is 18% which drops to 2% once the cancer metastasises to distant parts of the body. Recent studies have shown a median survival of around 12 months with the latest therapies and once the patients progress, the prognosis is extremely poor.

In expanding to bile duct and other cancers, Imugene will first select the optimum dose which will first be injected directly into the tumour. Bile duct cancers are termed "immunologically cold" according to Imugene's CMO, Dr Paul Woodard, which means that they do not generally respond to immunotherapy treatments.

CF33 works in three ways to treated solid tumours. The first is by directly killing the tumour. The second is by activating immune cells to attack the tumour. And the third is to present parts of destroyed tumour cells to the immune system, effectively priming the immune system according to Dr Woodard.

Imugene is capitalised at $637 million.

Bioshares recommendation: **Speculative Hold 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, Pharmaxis, Dimerix, Patrys, Imugene, Chimeric Therapeutics, Neuren Pharmaceuticals, Aroa Biosurgery, Radiopharm Theranostics, Anteris Technologies, EBR Systems, Immuron, Respiri, Clinuvel Pharmaceuticals