ISSN 1443-850X

Bioshares

11 August 2021
Edition 899

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

Companies covered: **ACR, CUV, IMU, NEU, 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)	-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 - Current)	1.6%
Cumulative Gain	1968%
Av. Annual gain (20 yrs)	20.7%

Individual Subscriptions (24 issues/year)
$550 (Inc.GST)
Edition Number 899 (11 August 2021)

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence No. 258032

Mark Pachacz - Editor/Analyst
Email: mark[at]bioshares.com.au
Ph: 0403 850 425

Extract from Bioshares –

Imugene Secures $90 Million Transformational Capital Raise

Immuno-oncology company Imugene (IMU: $0.295) has raised $90 million at $0.30 a share from local and international investors. It's a transformational capital raise that will fund the company's multiple cancer R&D technology platforms into 2025.

The company is also conducting a Share Purchase Plan (SPP) to raise up to $5 million at the same price, with a free option, exercisable at $0.45, for every two shares issued in the capital raise.

Last week Imugene announced an R&D partnership with Cellularity Inc. to combine Imugene's novel oncolytic virus with Cellularity's off-the shelf (allogenic) CAR-T technology. It's initially a 12-month partnership, with the aim being to use Imugene's oncolytic virus to prime the solid tumours for destruction with the T-cells (from Cellularity). This will be by initially driving CD19 expression on the tumour as the virus (from Imugene) infects the tumours.

Imugene's Current Programs

Imugene is now more appropriately funded to commercialise its suite of novel platform technologies in the oncology space.

1. CF33 Oncolytic Virus with anti-PDL1 (CHECKvacc)

In 2019 Imugene licensed a novel cancer killing virus, CF33, from the City of Hope. The virus was selected from 100 evolved variants of different strains of the pox virus for its ability to kill cancer cells at very low doses (much lower than other oncolytic viruses) with no major evidence of toxicity. Another feature is that it shrinks not only injected tumours but also distant tumours (an abscopal effect).

The feature of pox viruses is that they infect many different types of tumours, but also being bigger DNA viruses, they are amenable to genetic engineering.

The challenge with introducing a novel virus into the therapeutic domain was in gaining regulatory clearance. Last month the FDA cleared Imugene's first program with this virus, that being using CF33 that also promotes the expression of anti-PD-L1 proteins. This effectively combines a lysing effect of an oncolytic virus with checkpoint inhibitor action in the one therapy, called CHECKvacc. (Plus hNIS protein expression that allows imaging of the therapy by PET or SPECT as well as allowing the addition of radioisotopes that can kill surrounding tissue of infected cells.)

Continued over

The first study with this therapy will be in women with triple negative breast cancer and is due to begin shortly at the City of Hope cancer centre. Following a dose escalation phase, 12 women will be treated with the therapy at the determined optimal dose.

2. CF33 Oncolytic Virus (Vaxinia)
Imugene is seeking to move the CF33 virus (with hNIS) without the PD-L1 protein expression feature into a Phase I study in patients with various solid tumours. Prior to that trial commencing, FDA clearance is required.

3. CF33 Oncolytic Virus Expressing CD19 with CAR-T (onCARlytics) - Autologous therapy
In May this year Imugene licensed additional technology from the City of Hope that uses the same CF33 oncolytic virus but that expresses CD19. This will be used in combination with CAR-T cell therapy, which directs the cell therapy to the virus infected tumour expressing CD19. This will be an autologous therapy using a patient's own reprogrammed cells.

Following toxicology studies and FDA clearance, Imugene intends to move this into Phase I studies as a monotherapy.

4. onCARlytics with Cellularity - Allogenic therapy
The collaboration with Cellularity is seeking to make Imugene's onCARlytics therapy available as an off-the-shelf (allogenic) therapy using the placental-derived cells from Cellularity that do not require any matching between donors. Cellularity's cells do not elicit a GvHD response.

5. HER-Vaxx Gastric Cancer Study
The HER-Vaxx technology is a B-cell vaccine that seeks to have patients produce specific antibodies against the HER2 protein expressed on certain gastric and breast cancer tumours. It is an alternative approach to injecting engineered antibodies, such as Herceptin, against the same target.

In a completed Phase Ib study in 11 (evaluable) patients with gastric cancer, the best clinical response and antibody generation response was seen, not surprisingly, in the highest dose cohort. All three patients in that cohort achieved a partial response in their tumours to therapy, with two showing more than a 40% reduction in tumour volume up to eight weeks.

A Phase II, open label study in 36 patients is underway comparing HER-Vaxx plus chemotherapy against standard-of-care (chemotherapy). Recruitment was completed in January this year. Interim results have shown a benefit in both overall survival (HR=0.418 i.e. chance of death reduced by 58.2%) and in progression-free survival (HR=0.532 i.e. chance of disease progression reduced by 46.8%), although results at this point are not statistically significant. Final results from the study are expected this year. Results to date show a high adaptive immune response to the vaccine without added toxicity to treatment.

6. PD1-Vaxx Phase I Lung Cancer Study
In November last year Imugene started a Phase I study with PD1-Vaxx in patients with non-small cell lung cancer. Similar to the HER-Vaxx technology, this therapy is seeking to have patients generate their own PD1 inhibition proteins to generate a similar effect to injected antibody treatments such as Keytruda and Opdivo. The third patient cohort in the Phase I study is currently receiving treatment.

Summary

Imugene is well placed to execute on its multiple novel oncology programs following its significant capital raise. The company is now capitalised at $1.56 billion.

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, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Antisense Therapeutics, Imugene, Exopharm, Immutep, Neuroscientific Biopharmaceuticals, Invex Therapeutics, Anteris Technologies, Chimeric Therapeutics, Neuren Pharmaceuticals