

Speculative

See key risks on Page 3 and Biotechnology Risk Warning on Page 21. Speculative securities may not be suitable for Retail Clients.

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Imugene (IMU)

Deep Pipeline, Max Potential

Recommendation
Buy (Initiation)
Price
\$0.029
Valuation
\$0.05 (Initiation)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

Capital growth	72.4%
Dividend yield	0.0%
Total expected return	72.4%

Company Data & Ratios

Enterprise value	\$155m
Market cap	\$125m
Issued capital	4,320m
Free float	95%
Avg. daily val. (52wk)	\$931,000
12 month price range	\$0.013 - \$0.063

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.02	0.03	0.02
Absolute (%)	33.3	-12.5	64.7
Rel market (%)	30.8	9.4	78.6



SOURCE: IRESS

The Future Of Cancer Therapy

Imugene is a clinical stage Australian biotechnology company. It has two core technologies both of which have been in-licensed from offshore developers.

HER-Vaxx and PD1-Vaxx are B-Cell cancer immunotherapies. These are an exciting new class of cancer therapy with the potential to become the most significant developments in oncology since the approval of CAR-T therapy. HER-Vaxx is the lead candidate and is currently treating patients in a phase II study in gastric cancer. The drug target cells which over express the HER-2 receptor – being the same target as the blockbuster monoclonal antibody (mAbs) drugs Herceptin and Perjeta. The investigators believe the B cell immunotherapy approach will have significant advantages of over the synthetic mAb's including far higher tumour specificity and safety. The response rates in the dose escalation study were highly encouraging with all patients on the maximum dose seeing a sustained anti-tumour response. The phase 2 study is expected to report in 2H2020.

The second asset is a pre-clinical oncolytic virus (OV). OV's have steadily gained in popularity over the last decade with numerous pharma groups investing in the technology. CF33 is a form of the Vaccinia virus. Versions of the virus have been used for more than 100 years as a platform for vaccines. It is safe for use in humans and the preclinical studies based on human cells lines were encouraging. The virus was developed by scientists at the City Of Hope (COH) in Los Angeles. COH is leading an investigator sponsored study in triple negative breast cancer while the company expects to commence a phase 1 study across a range of solid cancers within the next few months.

Initiate coverage with Buy (Speculative)

The company has numerous data points over the next one to two years. Cash reserves are ~A\$36 representing up to 2 years of cash runway. Valuation is \$0.05 and we commence coverage with a Buy (Speculative) recommendation.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	4.1	3.4	3.7	3.2
EBIT \$m	-8.3	-10.8	-9.4	-12.8
NPAT (underlying) \$m	-7.9	-10.3	-8.9	-12.3
NPAT (reported) \$m	-7.9	-10.3	-8.9	-12.3
EPS underlying (cps)	-0.2	-0.3	-0.2	-0.3
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	-29%	-19%	-20%	-38%

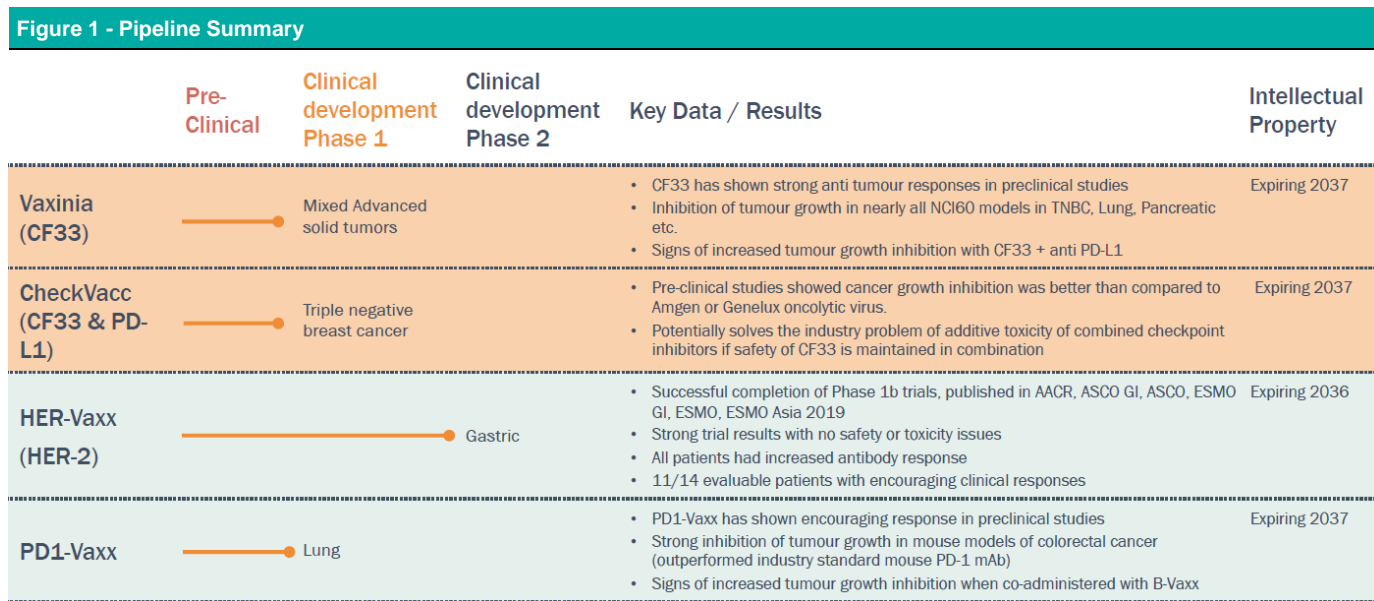
SOURCE: BELL POTTER SECURITIES ESTIMATES

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Investment Thesis

IMU has a pipeline of four potential new drugs which we summarise as follows.



SOURCE: COMPANY DATA

Vaxinia and CheckVacc are oncolytic viruses targeted towards a variety of solid cancers.

HER-Vaxx and PD1-Vaxx are B-cell cancer immunotherapies. These are an exciting new class of cancer therapy with the potential to become the most significant development in oncology since the approval of the first immune checkpoint inhibitor drugs.

The second asset class are oncolytic viruses. IMU acquired the rights to develop this asset from the City Of Hope (COH) hospital in Los Angeles, California. The company paid a token sum for the asset and we understand this was largely because of Chairman Paul Hopper’s influence along with that of world renowned virologist and advisor to the company Dr Len Post. Mr. Hopper’s track record as Chairman of Viralytics (VLA) together with the availability of senior members of the scientific team from that company were important factors in the selection of IMU as a development partner. Not surprisingly the terms of the in-license deal with COH including commitments on timing and R&D budget.

This note focuses on the two most advanced clinical candidates being Vaxinia (CF33) and HER-Vaxx. We provide further detail on the clinical program later in the report, suffice to say we expect the company should be in a position to commence three phase I studies over the course of the next 12 months (from May 2020).

The single asset in the clinic HER-Vax showed a promising response rate in a single phase 1b study. An interim safety readout from the phase II study was announced on 4 May 2020 where the Independent Data Monitoring Committee (IDMC) recommended the study continue without modification.

Over the course of the last 5 years (being the time period over which the company began developing B cell cancer immunotherapies) IMU has raised a total of \$41m, relative to its market capitalisation of \$125m.

As described in figure 1 above, the level of protection over the company’s intellectual property is high. All of the drugs in development are novel and IMU either owns the composition of matter patent or has the exclusive global rights to develop and market the drug.

The company has \$36m in cash which we estimate represents ~2 years of cash runway.

Risk Areas

The key risk include but are not limited to the follow items:

Imugene's ability to achieve profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products (including HER-Vaxx, PD1-Vaxx, CF33) and successfully commercialise those products. There is no guarantee that Imugene's products will be commercially successful.

Imugene does not currently generate revenue from product sales and any such revenue is not anticipated in the short to medium term.

Clinical trial risk

IMU may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct future clinical trials. There is also no assurance that products developed using the Company's technology will prove to be safe and efficacious in clinical trials, or that the regulatory approval to manufacture and market its products will be received. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.

Products, including HER-Vaxx, PD1-Vaxx or CF33, developed using the Company's technology must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing.

The Company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales to fund sufficient revenues for continued operations and growth, may not be achieved.

Arrangements with third-party collaborators

Imugene may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of its products. These collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. There is no assurance that Imugene will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals. If Imugene is unable to find a partner, it would be required to develop and commercialise HER-Vaxx, PD1-Vaxx or CF33 (and other potential products) at its own expense. This may place significant demands on the Company's internal resources and potentially delay the commercialisation of HER-Vaxx, PD1-Vaxx, CF33 (and other products).

Requirement to raise additional funds

The Company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the Company is unsuccessful in obtaining funds when they are required, the Company may need to delay or scale down its operations.

Intellectual property

The Company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights.

B Cell Immunotherapy

HER-Vaxx

The company's lead drug is HER-Vaxx (IMU-131) designed to treat tumours that over express the human epidermal growth factor receptor 2 (HER-2) on the surface of certain cancer cells. Over expression of the HER-2 receptor is a known catalyst for worsening cancer. It is estimated that HER-2 is over expressed in up to 25% of breast cancers as well as approximately 10% – 15% of other cancer types including gastric, ovarian, lung and pancreatic cancers.

The drug is designed to stimulate a B cell response to produce antibodies that target only those cancer cells with the HER-2 receptor on their surface.

The drug has been developed over the course of a decade of research by oncologists, immunologists and vaccinologists in Europe led by Professor Ursula Wiedermann and Professor Christoph Zielinski from The Medical University Vienna, Austria.

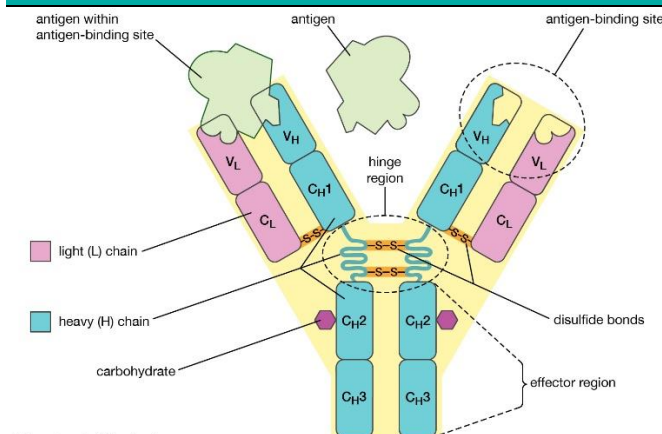
MECHANISM OF ACTION

When a foreign substance enters the body (such as a virus or toxic material such as insect venom) the immune system recognises it as foreign. To eliminate the invader the immune system calls on a number of mechanisms including one of the most important – antibody production. Antibodies (also known as immunoglobulins) are produced by specialised blood cells called B lymphocytes – or B Cells. When an antigen binds to a B cell it normally triggers a B Cell response which results in the secretion of millions of identical clones into the blood stream and lymphatic system where each of the clones attack and neutralise antigens that are identical to the original antigen.

Antibody production may continue for several days and they may remain in the serum for several months providing extended immunity from that particular antigen.

Collectively B Cells may recognise a limitless amount of antigens, however, individually each B cell can only bind to one type of antigen. The differentiation between antibodies is in the antigen receptor which allows different B Cells to recognise different antigens. The section of the antigen responsible for binding the antibody is the epitope – see figure 2.

Figure 2 - B Cell Epitope



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SOURCE: ENCYCLOPAEDIA BRITANNICA

The mechanism of action for IMU131 therefore is to stimulate a B cell response to specific sections of the HER-2 receptor which is over expressed on the cancer cells in patients suffering HER-2 positive cancers (including for gastric cancer, breast, ovarian). The antibodies produced following the vaccination are polyclonal (poly meaning multi) rather than monoclonal, that bind to different parts of the HER-2 receptor.

IMU-131 contains three B cell epitopes called P4, P6 and P7 (collectively p467) conjugated to the carrier protein CRM197 and adjuvanted with Montanide. The addition of these two factors are crucial to boosting the immune response of the antigen. P6 and P7 epitopes target exactly the same region of HER-2 as Herceptin (Trastuzumab), while P4 targets a region also targeted by Perjeta (Pertuzumab).

IMU-131 aims to combine the basic mechanism of action of both Herceptin and Perjeta in one B cell activating immunotherapy. Once bound, the antibody halts the complex HER-2 cell proliferation pathway and leading to cell death. When these polyclonal antibodies bind HER-2, they recruit other arms of the immune system to the tumour microenvironment such as natural killer cells and various regulatory cells that facilitate immune targeting of the cancer cells.

Herceptin and Perjeta are both marketed by Roche Genentech. The fundamental difference between IMU-131 and both Herceptin and Perjeta is that IMU-131 invokes a constant and potent polyclonal antibody response to HER-2 by the patient's own immune system. In theory the immune response may be sustained for many months.

The ability to include more than one B cell epitope from a targeted protein in the immunotherapy means that the immunotherapy can potentially create higher affinity and higher specificity than monoclonal antibody products. The identification of these B cell epitopes and the ability of scientist to mimic their shape with a synthetic peptide were the major obstacles in the development of this drug.

Herceptin and Perjeta are synthetic monoclonal antibodies (mAb's) with relatively short half-lives and therefore require multiple infusions, accordingly, IMU-131 may have a potential cost advantage. The combination of Herceptin and Perjeta has been highly successful in the treatment of HER-2+++ breast cancers with the combination providing a 16 month extension in overall survival. There is no question that HER-2 is a validated target in certain cancers, the key question is whether IMU-131 can outperform the mAb's in controlling these cancers.

The major attractions of the peptide immunotherapeutic approach are:

- A likely sustained anti-tumor effect related to immunological memory that protects against relapsing tumors. This potentially replaces the requirement for multiple infusions of humanized mAbs and their related side effects;
- Tumor specificity and the activation of immune responses against antigens that are selectively expressed by tumor cells. As a result, non-specific toxicity to normal tissues is reduced and anti-tumor responses are more durable and adaptable to cancer control at different stages of disease, including those with early-stage disease and low tumor burdens; and
- Additional benefits of the B cell activating immunotherapeutic approach include the ease of rapid synthesis, safety, lack of toxicity, and cost-effectiveness.

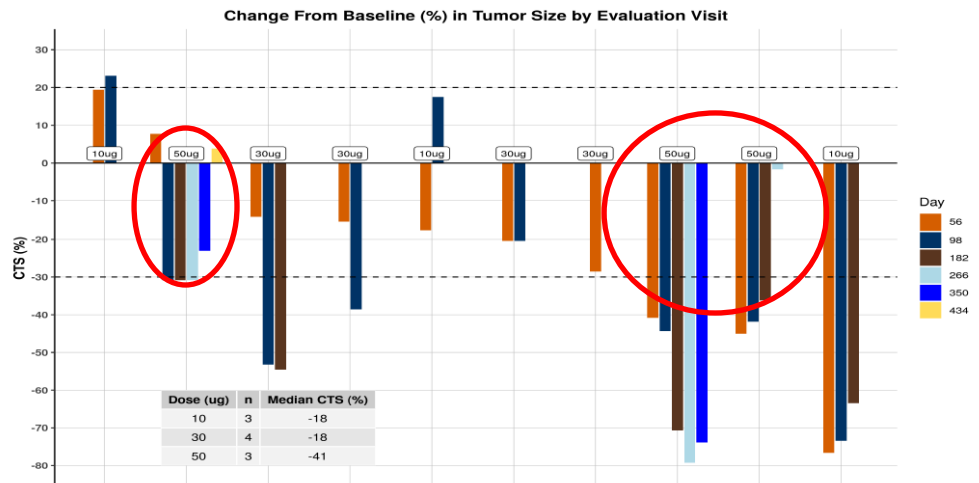
RESULTS FROM PHASE1B CLINICAL STUDY

In an earlier phase Ib study which examined 14 patients (14 sites across 5 countries) with HER-2 positive gastric cancer patients (open label, single arm, dose escalating study) the three patients on the optimal dose (50µg) plus chemotherapy progressed at 266, 355 and 424 days after starting treatment with IMU-131, with a mean progression free survival period of 355 days. There were no safety related issues associated with IMU-131. Tumour response measured according to RECIST1.1.

These patients also showed the highest and most consistent levels of p467 specific antibodies and HER-2 specific antibodies compared to patients on lower doses with the preliminary response data also showing reduction in target tumour size.

Figure 3 - Phas1B study - efficacy data

The circled group indicates those patients on the highest dose. All three achieved greater than 40% reduction in tumour size,



SOURCE: COMPANY DATA

The study yielded 1 complete responder, 5 partial responses and 4 with stable disease. These results are highly encouraging and well worth the investment of a phase II study.

The 50µg dose of IMU-131 is being used in the ongoing phase 2 study.

The key question is the extent to which IMU-131 controls cancer growth and extends overall survival. HER-Vaxx has been shown in pre-clinical studies and now in this phase 1b study to stimulate a potent polyclonal antibody response to HER-2, however, we still don't know if this will lead to a survival benefit. This data will emerge from the randomised phase II study (see study design shown below).

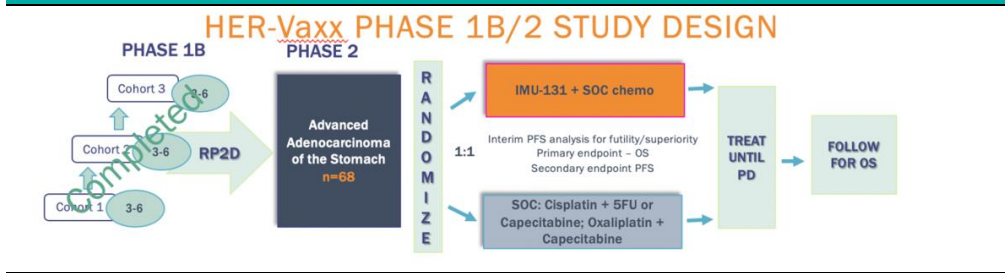
In addition, the preclinical work was highly encouraging with HER-Vaxx antibodies demonstrating an anti-tumour effect in a validated HER-2 gastric cell line. When combined with Herceptin in in-vivo testing of HER-2+ breast cancer cells, the combination showed modestly enhanced inhibition of tumour proliferation.

ONGOING CLINICAL PROGRAM

- Imugene is recruiting a phase 2b trial in HER-2+++ gastric cancer patients testing the combination of IMU131 in conjunction with standard of care chemotherapy;
- This open label, 68 patient trial dosed the first patient in March 2019 and is due to report interim results in mid calendar year 2020; and
- An interim safety readout from the phase II study was announced on 4 May 2020 where the Independent Data Monitoring Committee (IDMC) recommended the study continue without modification.

The trial is recruiting in Eastern Europe and India. Note that the control group does not include Herceptin. Herceptin is approved for gastric cancer in the US but is not widely used (or approved for use) outside of the US. The survival benefit with Herceptin in advanced inoperable gastric cancer is ~2.7 months with overall survival at ~14 months.

Figure 4 - Phase 2 Gastric Cancer Study



The primary endpoint is overall survival with secondary endpoints of progression free survival, safety and immune response.

PD1 - Vaxx

Imugene is licensed this drug candidate from Ohio State University. The PD1-Vaxx is a B-cell immunotherapy, designed to treat tumours such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect similar to Keytruda, Opdivo and the other immune checkpoint inhibitor monoclonal antibodies.

In theory the PD1-Vaxx will invoke a B cell response to produce antibodies targeting a specific section of the PD-1 receptor. This receptor is found on the surface of T cells (killer T cells). When PD1 binds with its ligand (PD-L1) typically found on the surface of cancer cell the T cell becomes inactive against the cancer.

The developers chose a section of PD-1 that is highly immunogenic (i.e. produces an immune response). It also happens to be a section where the blockbuster immune checkpoint inhibitor drugs (ICI's) Keytruda (Merck) and Opdivo (BMS) bind. Both the ICI's and PD1-Vaxx preferentially bind to PD1, hence preventing the T cell from binding to PD-L1 and thereby keeping the T cell active.

Both Keytruda and Opdivo are relatively large molecules requiring constant re-dosing in order to produce an effect. These drugs also produce significant side effects. Conceptually the PD1-Vaxx should have an improved side effect profile over these therapies.

CLINICAL PROGRAM

- IMU plans to commence a phase I clinical trial of PD1-Vaxx in CY2020 targeting non-small cell lung cancer (NSCLC), the most common type of lung cancer, accounting for around 80% of cases;
- This dose escalating study will enrol up to 32 patients across North America and Australia; and
- IMU is expected to file for the IND in the US and ethics approval in Australia within months.

PD1-Vaxx GMP manufacturing, including final sterile fill and finish is done. The final filled and finished vials of PD1-Vaxx have completed non-human primate safety toxicology studies at a US-based contract research organization (CRO). The NHP was chosen due to its target PD1 receptor being 100% identical to human PD1 and hence the study also provided valuable data on the antibody generating potential of PD1-Vaxx in humans.

The three doses tested not only were well tolerated with no adverse events identified, they also generated high levels of PD1-targeting polyclonal antibodies.

This is an important development as it may indicate that PD1-Vaxx will break tolerance in humans, generate antibodies, and may produce an anti-cancer effect similar to Keytruda, and Opdivo. Three doses have been selected for the dose escalation phase of the Phase 1 trial and will combine with ICIs during the expansion of the study.

Oncolytic Virotherapy

CF33 – Vaxinia

Imugene acquired an oncolytic virus (OV) asset in late 2019¹. The Board's interest in OV's stems from the Chairman Paul Hopper's success with Viralytics and that company's OV "Cavatak".

OV's remain an active area of scientific investigation by drug developers around the world. Their predominant use is in combination with immune checkpoint inhibitors. The typical mode of action for an OV being that the virus is introduced to the cancer tumour via intratumoural injection where upon the virus replicates within the cell membrane causing it to burst. The release of tumour antigens drives an immune response which becomes the secondary cause of cell death.

The process of turning cold tumours into hot tumours is now well recognised by drug developers. Oncolytic viruses have been most successful in treating advanced melanoma (where the tumours are most easily accessible). They are preferred by patients and physicians because of their favourable safety profile. In the case of Cavatak (acquired by Merck) the drug showed superior efficacy to Keytruda as a monotherapy, and when used in combination with various checkpoint inhibitors including Keytruda, the efficacy results were vastly superior to either drug as a monotherapy.

OV's are yet to demonstrate meaningful improvement in progression free survival in cancers other than in melanoma. In our opinion this is because it is difficult to get sufficient dose of the virus to the site of the cancers when dosing via IV. The only approved OV on the market is Amgen's T-VEC. T-VEC is not suitable or approved for IV dosing.

Imugene's oncolytic virus is CF33. It was developed by Professor Yuman Fong at the City Of Hope (COH) Hospital in Los Angeles. The virus does not occur in nature, rather it was formed through the pooling of several forms of Orthopoxviruses. These viruses are complex double stranded DNA viruses that replicate in the cytoplasm of the host cell (hence no effect to the host genome, which tends to make these viruses more acceptable for use in humans). Viral populations do not grow through cell division, because they are acellular (incapable of self-division). Instead, they hijack the machinery and metabolism of a host cell to produce multiple copies of themselves, and they assemble inside the cell.

The most famous of this family of viruses is the Vaccinia Virus used to eradicate smallpox.

CF33 was selected to take forward to the clinic as it demonstrated super cell killing ability in the NCI-60 cell line model. The NCI-60 Human Tumour Cell Line Screen has served the global cancer research community for >20 years. The screen utilizes 60 different human tumour cell lines to identify and characterize novel compounds with growth inhibition or killing of tumour cell lines. The operation of this screen utilizes 60 different human tumour cell lines, representing leukaemia, melanoma and cancers of the lung, colon, brain, ovary, breast, prostate, and kidney cancers.

The obvious concern here is safety and the potential for the virus to mutate or replicate in an uncontrolled manner, however, as noted above, the Vaccinia Virus does not affect the host genome. Pre-clinical work in mice showed no viral shedding in blood and urine. In immune competent mice, no virus was detected in other organs at day 7, however the virus was found in the injected tumour.

Various forms of the vaccinia virus have been used as a delivery mechanism (a vector) for presenting antigens to the immune system. Based on this extensive use in humans, it is not unreasonable to conclude that the vaccinia virus is safe in humans².

¹ Mr Hopper was the long serving Chairman of VLA which was acquired by Merck in 2017 for ~\$500m.

CF33 is a chimera (a single virus made up of cells from two or more sets of DNA) of several VV's which were allowed to recombine naturally. The different chimera's (~100 clones in total) were screened to test which one killed most cancer cell lines while causing the least side effects in mice.

Scientists have also modified the genetic code of the virus for the human iodide symporter gene (hNIS) i.e. a tracer. NIS is a well-known target for molecular imaging (in some cases therapy). The gene is responsible for the expression of exogenous iodide allowing for the use of non-invasive imaging of functional NIS expression ^{99m}Tc Technetium - a commonly used, readily available nuclear isotope for nuclear imaging that lights up iodide like a firecracker on 4th of July (under SPECT-CT).

IMU is now targeting the CF33+hNIS for us as an oncolytic agent. The advantages of CF33+hNIS may include but are not limited to:

- The virus replicates quickly – within 6 hours maximising its ability to infect cancerous cells prior to clearance; and
- It has a large viral genome, enabling its acceptance of large foreign DNA inserts of up to 40-kb (such as hNIS and anti-PDL1 inserts).

CF33 DEVELOPMENT

Scientists at City of Hope (COH) generated a pool of natural chimeric orthopoxviruses by coinfecting CV-1 cells (a standard host cell line from monkeys frequently used in oncology drug development) with several different virus strains including the cowpox virus strain Brighton, raccoonpox virus strain Herman, rabbitpox virus strain Utrecht and others (all being members of the orthopoxvirus family). The viruses weren't directly genetically modified, however, genetically these viruses are similar. The combination was allowed to proceed naturally which implies there was an exchange of genetic material between the viruses within the host cell (but not effecting the host cell DNA). As the host cell divides the virus replicates itself with the cell of the host and its progeny.

One of the ways viruses can be released from the host cell is via lysis – a process that kills the cell by bursting its membrane and cell wall. In this case the virus continues to replicate within the cell cytoplasm to the point where it causes the cell to bust open. The company theorises that it is the cell lysis that is responsible for the death of cancer cells.

One hundred chimeric orthopoxvirus plaques were picked from CV-1 cells infected with the chimeric orthopoxvirus pool. CF33 was cherry picked from these chimeric viruses. It is not possible to say what percentage of CF33 derived from which virus. Overall CF33 is more similar to vaccinia.

ARMED VIRUSES AND CHECKVACC

IMU has also developed a so called Armed Virus version of CF33. Known as CheckVacc, this drug proposes to combine CF33+hNIS with a PD-L1 antibody gene insert.

One of the main reasons for immune checkpoint inhibitors (ICI's) fail in cancer therapy is that the area around the tumour is "cold" i.e. devoid of immune cells, hence dosing an ICI is not effective since there is no break on the immune system to turn off or to accelerate.

Oncolytic viruses are engineered to only target cancer cells, infect them, and then in the process of busting them open (lysis), create a chemical signal to invoke an immune response. This turns the area around the cancer into "hot" environment where there are suddenly lots of immune cells responding to various antigen.

² The cowpox virus got its name hundreds of years ago, from a rash that developed in dairymaids that touched the udders of infected cows. Back in 1770, an English farmer discovered that dairymaids that had contracted and recovered from cowpox not only became immune to further cases of cowpox, but also to the more serious viral disease, smallpox. In 1796 English physician, Dr Edward Jenner used the cowpox virus to inoculate a patient to prevent them from contracting smallpox. Hence this was the first successful vaccination performed.

Cancer cells respond by upregulating PD-L1 which binds to the PD-1 receptor on infiltrating T-cells which signals the T-cells to “stand down”. After a while the microenvironment around the cancer will become “cold” again and the cancer will progress.

This cycle led to the concept of “Arming” the virus with an ICI where it’s literally manufactured by the cancer cell as the virus infects means that there is ICI immediately available to stop the cancer turning on the breaks of the incoming immune cells.

This arming process is achieved when the genome of the virus is encoded (modified) to produce specific tumour targeting antibodies (in this case to PD-L1).

This concept of arming viruses is new and has not yet been tested in humans, albeit several papers on this topic have now been published and preclinical data is encouraging.

The leader in this field of research is likely Turnstone Biologics (a private company based in the US). Turnstone recently partnered its technology with the Japanese pharma company Takeda. The two companies will split development costs 50:50 on the RIVAL platform going forward.

As Turnstone describes in a recent release;

“Turnstone’s RIVAL therapeutic pipeline is based on its proprietary vaccinia virus platform, which has been engineered for enhanced immune-stimulation and tumour cell selectivity, potent oncolysis and large transgene carrying capacity. RIVAL-01 is the lead candidate, consisting of the vaccinia virus backbone encoding transgenes for Flt3 ligand, anti-CTLA-4 antibody and IL-12 cytokine. The transgenes are designed to be expressed when the vaccinia virus enters and replicates in cancer cells throughout the body. The resulting local production of these therapeutics at the site of tumours adds to the inherent oncolytic and microenvironment-modifying properties of the virus to form a powerful multi-modal attack on the disease.”

IMU aspires to a similar technology using what appears to be a similar virus platform.

Astellas Pharma in Japan are also working on similar technology to Turnstone. Their work is early and remains in preclinical at this time.

While most of the theory behind oncolytic viruses and their mechanism of action are well understood, important questions remain including why OV’s only seems to affect cancerous cells as opposed to healthy human tissues? One theory is that viruses prefer anti-apoptotic cells (cells not subject to apoptosis – programmed cell death) where cell division is uncontrolled. This could also explain why other strains of orthopoxvirus (vaccina, cow etc) are normally relatively harmless to humans and are adequately dealt with by functioning immune system.

PRECLINICAL DATA

The pre-clinical data in triple negative breast cancer conducted by investigators at the COH was recently published³ where the virus was trialed in combination with an anti-PD-L1 antibody. Neither agent worked particularly well as a monotherapy, but the combination produced a significant anti tumour effect with 50% of mice experiencing complete tumour regression when both agents were injected intra-tumourally. Based on these results COH has commenced an investigator led study which will be partly funded by IMU. The trial is set to recruit its first patient within a year.

³ Shyambabu Chaurasiya, Annie Yang, Seonah Kang, Jianming Lu, Sang-In Kim, Anthony K. Park, Venkatesh Sivanandam, Zhifang Zhang, Yanghee Woo, Susanne G. Warner & Yuman Fong (2020) Oncolytic poxvirus CF33-hNIS-⊗F14.5 favorably modulates tumor immune microenvironment and works synergistically with anti-PD-L1 antibody in a triple-negative breast cancer model, *Oncolimmunology*, 9:1, 1729300, DOI: 10.1080/2162402X.2020.1729300 To link to this article: <https://doi.org/10.1080/2162402X.2020.1729300>

CLINICAL PROGRAM

MAST – PHASE1/2

The company announced the phase 1 MAST study design in April 2020. The trial will be conducted under an IND in the United States and will involve multiple sites in the US including the City of Hope hospital in Los Angeles.

This will be a first in human phase 1 ascending multiple dose safety study of Vaxinia (CF33 + hNIS). Administered intratumorally or intravenously as a monotherapy or in combination with an immune checkpoint inhibitor in adult patients with mixed advanced solid tumours.

Subjects will include non-small cell lung (NSCL), melanoma, bladder, triple negative breast (TNBC), colorectal cancer, renal, head & neck and gastro cancers.

Second primary endpoint is to identify the recommended phase 2 dose either as a combination or monotherapy.

Patients will be followed to assess anti-tumour activity in each cohort.

TRIPLE NEGATIVE BREAST CANCER

The company will also participate in an investigator sponsored study in TNBC. Phase 1 will involve a standard 3+3 dose escalation study using the combination of CF33 + PD-L1. The trial will be conducted at City Of Hope in LA.

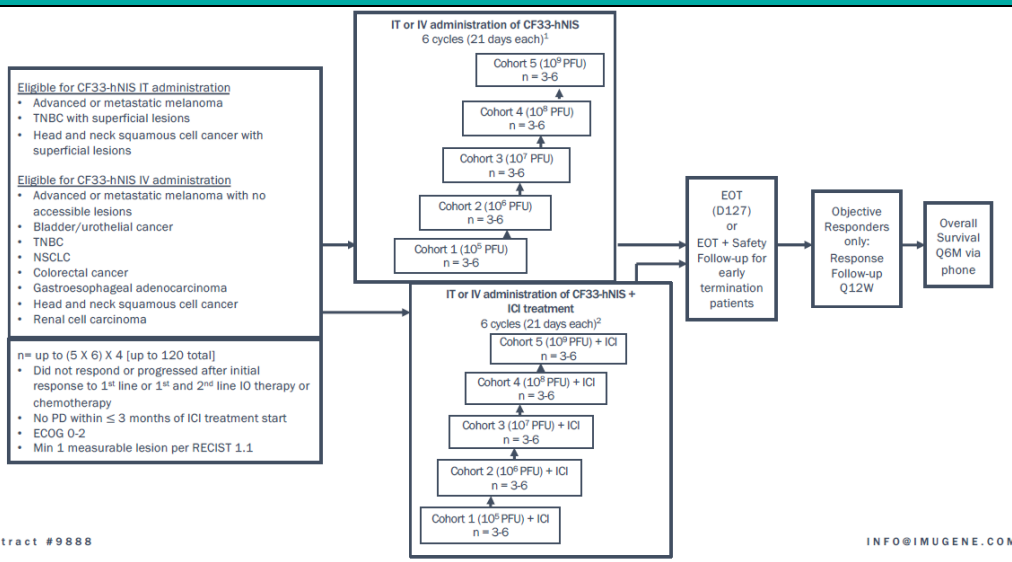
OUR COMMENTS

MAST is a typical trial design for a new oncology agent. Primary endpoints is safety as both a monotherapy and in the combination.

Patients enrolled in phase 1 trials have typically been through multiple rounds of treatment and are close to palliative care. Due to the late stage of disease where often multiple metastases are involved it is not reasonable to expect a significant tumour response in these patients, however, the safety data is important.

The monotherapy data for CF33 data is important. The monotherapy data proves that the virus is having an anti tumoural effect and this cannot be assessed in a combination therapy. Melanoma is the most likely indication to show a response because the tumours can be directly injected with the drug. This is also possible with triple negative breast cancer and head & neck cancers.

Figure 5 - MAST trial design



There will also be significant interest in the intravenous dosing. We understand there is no element of CF33 that attracts it to cancer cells specifically although preclinical data shows

a specific and strong cancer cell targeting ability, hence one of the key barriers will be getting sufficient dose to the cancerous cells. The trial design includes up to five dose escalations in order to determine the MTD. Viralytics attempted a very similar design with Cavatak (the STORM trial) in many of the same indications, however the final results were never reported following acquisition of the company by Merck.

This trial is likely to take a year to recruit and run as there are multiple indications and multiple patients in each cohort.

In relation to the investigator sponsored study, COH is expected to absorb most of the cost of this study. IMU will retain the right the data. In addition to safety, the aim of the trial is to establish the recommended dose for a phase 2 study.

We note that TNBC is included in both the MAST study and the investigator sponsored study. It is likely that each study will use a different ICI. Normally in these trials the cost of the ICI is absorbed by the patient's insurance.

COMPETITIVE LANDSCAPE IN ONCOLYTIC VIRUSES

There are a vast array of small biotech companies developing various candidates for combinations with the ICIs each of which is designed to enhance the efficacy of the ICI. Very few of these candidates have shown efficacy as a monotherapy and therefore the majority will never make it to market.

The leaders in the oncolytic virotherapy field are acutely aware of the requirement to show outstanding results in randomized clinical studies and preferably with at least some data to show efficacy as a monotherapy. There are 10 to 12 biotech companies with development programs in the clinic for oncolytic viruses. We have summarised the leaders in figure 6 below.

Figure 6 - Oncolytic Virus Developers

Company	Code	Market Capitalisation US\$m	OV Portfolio	Stage	n	Backbone	Dosing	Other
Replimune	REPL	662	RP1	Phase 2	30	Herpes Simplex Virus (HSV)	IT	Combo with nivolumab in melanoma
				Phase 2	30	Herpes Simplex Virus (HSV)	IT	Combo with nivolumab in non melanoma skin cancers
				Phase 2	30	Herpes Simplex Virus (HSV)	IT	Combo with nivolumab in bladder cancer
				Phase 2	30	Herpes Simplex Virus (HSV)	IT	Combo with nivolumab in high microsatellite instability colorectal cancer
				Phase 2	125	RP1+anti-PD1	IT	Armed Virus - PD1 refractory melanoma
				Phase 2	240	RP1+cemiplimab vs cemiplimab	IT	Combo therapy in Squamous cell skin cancer
			RP2	Phase 1	20	RP1 + anti CTL-4 gene	IT	Armed Virus, enrolling, indication is not disclosed
	RP3	Preclinical	na	RP1+CTLA-4+CD40L +4-1 BBL	IT	Armed Virus		
Tunstone Biologics	Privately Held		Rival-01			Vaccinia	Unknown	The company has a backbone Vaccinia virus armed with transgenes for FIT3, anti CTLA4 and IL-12. Target are unknown. Reporting dates also unknown.
Genelux	Privately Held	na	GL-ONC1	1b/2	unknown	Vaccinia	IV	Recurrent ovarian cancer - Orlando Florida
			GL-ONC1	1b/2	unknown	Vaccinia	IV	Recurrent ovarian cancer - Newport Beach California
			GL-ONC1	Expanded Access	unknown	Vaccinia	IV	Acute Myeloid Lukemia
			GL-ONC1	1b/2	unknown	Vaccinia	IV	Various solid organ cancers
Merck	MRK	200,000	Various	Stage 1 and 2		Cocksackie Virus and others	IV & IT	Melanoma and various othe solid cancers in combination with Pembrolizumab

Readouts Expected from June 2020

SOURCE: COMPANY DATA, BELL POTTER

In addition to these the privately held French biotech Transgene has partnered with Astra Zeneca to develop and OV program.

Financials and Valuation

Imugene is an early to mid-stage biotechnology company and as such it produces no revenues at this time. The company is reliant on capital from shareholders to fund its operations and acquisitions.

Figure 7 - 5 year history of capital raisings

Fiscal Year	\$m	Shares(m)	Issue Price \$
2015	3,583,500	402	~0.01
2016	3,000,000	383	0.007
2017	6,248,806	59	0.015
2018	8,778,191	490	0.018
2019	20,264,094	754	0.027
2020	24,566,822	683	0.036
	66,441,413		

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

As at 31 December 2019 the company had cash reserves of \$36.7m and for the 6 months then ended the cash burn was \$8.8m. We expect the cash burn to continue at this rate and most likely accelerate as the MAST study commences along with other clinical programs. Accordingly we estimate the company has ~ 2 years of cash reserves.

The HER-Vaxx phase 2 trial is due to report headline results in gastric cancer later this calendar year. In addition the company intends to commence a phase I study with PD1-Vaxx and 2 Phase 1 studies with CF33.

Figure 8 includes our estimate for the R&D expense over the next two to three years based on the clinical program as announced. This schedule is likely to change once the data from the HER-Vaxx trial is known. A clinically meaningful result is likely to warrant further investigation.

Figure 8 - Overview of the timing and cost of the clinical program

Fiscal Year	Current Status	Indication	Stage	N	FY21		FY22		FY23				
					Total \$m	2H20	1H21	2H21	1H22	2H22	1H23	2H23	
B Cell Immunotherapy													
HER Vaxx	Recruiting	Gastric Cancer	Phase 2	68	1.0	1.0	★						
PD1 Vaxx	Not yet recruiting	NSCLC	Phase 1	32	4.3	0.3	0.5	0.5	1.0	1.0	1.0		
Oncolytic Virus													
Vaxinia MAST study	Not yet recruiting	Solid Cancers	Phase 1	~60	20.6	0.3	0.3	5.0	3.0	4.0	4.0	4.0	
Check Vacc	Not yet recruiting	TNBC	Phase 1	32	2.1	0.3	0.3	0.5	0.5	0.5	-	-	
Estimated clinical spend						28.0	1.9	1.1	6.0	4.5	5.5	5.0	4.0

SOURCE: BELL POTTER SECURITIES ESTIMATES ★ LIKELY REPORTING

VAXINIA ACQUISITION

The group acquired 100% of the share capital of Vaxinia Pty Ltd in July 2019. Vaxinia was incorporated in December 2018 for the purpose of securing the right to develop and commercialise CF33.

Figure 9 - Consideration for Vaxinia Acquisition

Vaxinia Acquisition	\$m
Cash paid	1,582,260
Payable to COH	2,938,053
IMU Scrip	6,783,701
Contingent consideration	12,097,335
Total Purchase Consideration	23,401,349

SOURCE: COMPANY DATA

The key financial terms of the purchase include a cash payment of \$97,588 (cash paid in figure 9 includes other components related to the license agreement - see below) and the issue of 128 million IMU shares.

The \$12.1m contingent consideration is represented as other equity in the balance sheet at 31 December 2019. This scrip is to be issued upon the achievement of certain milestone in the development of CF33 which we gather is tied to the achievement of sales milestones.

In addition there is deferred consideration payable should certain milestones be achieved. These are summarized in figure 10.

Figure 10 – Deferred settlement payments Vaxinia

Deferred Acquisition Terms	IMU Shares	Value at Signing
FDA allows IND for CF33	119,354,838	\$ 6,325,806
Dosing 1st patient in Phase 1	134,258,064	\$ 7,115,677
Meeting phase 1 safety endpoint	149,193,548	\$ 7,907,258
	402,806,450	\$ 21,348,741

SOURCE: COMPANY DATA

There is an additional milestone fee payable (related to the Vaxinia acquisition) on meeting the phase 1 safety point \$2.312m (as per note 8 of the 31 December 2020 Financial Statements.). This item is not on the balance sheet at 31 December 2019.

License Agreement for CF33

The group separately signed a License Agreement with the City of Hope (COH) to acquire a worldwide exclusive license to CF33. The completion of the purchase of Vaxinia and the License becoming effective, although each are governed by separate agreement, are contingent on each other, therefore in order for Imugene to gain the benefit of the license and it had to acquire Vaxinia.

The License Agreement makes allowance for the payment by IMU to COH of certain milestone payments as outlined below and a US\$3m upfront payment. We understand this has been paid in part, however the outstanding liability is not on the balance sheet.

The group also has development milestones in respect of the license which are summarized below in figure 11. These are contingent liabilities, not on the balance sheet.

Figure 11 – Development milestones payable in respect of CF33

Deadline	Requirement	US\$m
8-Jul-21	Dose first patient in a phase 1 clinical trial of CF33	150,000
8-Jul-23	Dose first patient in a phase 2 clinical trial of CF33	300,000
8-Jul-26	Dose first patient in a phase 3 clinical trial of CF33	1,000,000
8-Jul-29	US Marketing approval for CF33	300,000
No Deadline	Receive marketing approval for any jurisdiction outside of the US	1,500,000
		3,250,000

SOURCE: COMPANY DATA

The financial statements from 31 December do not set out penalties if the company fails to meet these deadlines. Normally if the license holder is making good progress the deadline could be extended. If there is no progress the drug would simply be handed back.

In addition to development milestones, the company has an obligation for the following items:

- Annual license maintenance fees – US\$50,000 non refundable;
- Sales milestones contingent upon the cumulative value of sales up to US\$1bn plus an ongoing single digit percentage royalty. The sales milestones, if paid, total US\$150m; and
- Development timetable and minimum development spend according to the following schedule.

Figure 12 - Committed Timetable and Development Expenditure for CF33

Deadline	Requirement
8-Jul-21	Dose first patient in phase 1 of CF33 and spend not less than US\$6m on its development
8-Jul-23	Dose first patient in a phase 2 clinical trial and spend not less than US\$9 in addition to the first US\$6m on the development of CF33
8-Jul-26	Dose first patient in phase 3 of CF33
8-Jul-29	US Marketing approval for CF33
No Deadline	Receive marketing approval for any jurisdiction outside of the US

SOURCE: COMPANY DATA

If IMU decides not to pursue the development of the asset, the development timetable becomes redundant along with the financial obligations. If this was the case then we expect IMU would forgoe its investment in the asset.

Valuation

Based on our experience in the biotech sector and oncology drug development specifically, and following our review of the company’s asset portfolio and clinical program we conclude the following:

There continues to be significant international interest in the development of new immunotherapy drugs for the treatment of various cancers. The development of new immunotherapy drugs continues at a significant pace, specifically in the field of immune checkpoint inhibitors;

IMU’s B Cell immunotherapy platform is unique. Unlike various mAb’s for new checkpoint inhibitors, the HER-Vaxx represents a new class of drug which has the potential to supplement current therapies across a range of cancers. The preclinical work and efficacy data from the phase 1b trial were encouraging and definitely warrant the current phase 2 study;

The headline results from the HER-Vaxx study will be a material value inflexion point for the company. While it is likely the drug will invoke some anti-tumoural response, the strength of the signal will guide the future of the clinical programme as well as dictate the terms of any license deal;

We will have a much better idea on the valuation following the phase II results. In the meantime we estimate the company has spent ~\$30m to get the drug to this point. The company has yet to declare its intentions with regard to the future development of HER-Vaxx. Should the phase 2 results warrant further investment, all options remain open including a licensing deal, sale of the asset or internally funding additional clinical trials;

The estimate of valuation for this asset is highly subjective. While the potential patient group that may benefit from the drug at some point in the future is large, the reality is that the drug has several years of clinical trials and many millions of dollars of R&D spend ahead should the result from the current phase 2 study warrant further investment.

In our view there is a very wide range of potential value for the asset, however at this time we believe the value is not more than the cost of development. This is highly likely to change depending on upcoming clinical results.

In our view it is pointless to try to compare the value of this asset with other transactions in the space at this time, so shortly before headline results from a major study and also given the unique nature of this asset. Many well funded pharmaceutical companies have tried and failed with cancer vaccines in the past – admittedly these concentrated on T Cells rather than B Cell immunotherapy.

In relation to CF33, the asset is pre-clinical albeit about to commence a phase 1.

IMU recently acquired the asset for a mere A\$97K in cash plus scrip – the value of which will depend on how the results from the company's various clinical trials plays out. The cash component of the transaction is likely to have been far less than the cost of the development work by COH. While the pre-clinical data is suggestive that the phase 1 study will show an anti-tumoural benefit, the determination of current value is highly speculative.

There are a number of recent transactions in the space which provide an indicator of future value:

The nearest comparable peer valuation is the acquisition by Merck of the Cavatak asset in 2018 for an enterprise value of ~A\$460m (US\$394m). At the time of the acquisition Cavatak had good results from phase II studies in Melanoma.

The second peer is the NASDAQ listed Replimune (REPL) with a market capitalisation of US\$662m (A\$1.03bn) and no debt. Replimune is expecting several results from clinical trials later this year – refer to figure 6.

In the previously discussed deal between the private company Turnstone Biologics and Takeda (from December 2019) for the development of the RIVAL – 01 platform, Takeda will pay up to US\$120m in upfront and near term milestones – most likely attached to the upcoming results from a series of phase 2 clinical studies as outlines in figure 6.

In an older transaction Boehringer Ingelheim (BI) acquired all of shares of Vira Therapeutics for €210m. One of the vendors was BI's Venture Capital Fund and consideration involved an option agreement. The assets of the target company were pre-clinical. This transaction is of limited meaning as it was not arm's length.

Finally Janssen acquired US based BeneVir in 2018 for US\$140m plus development milestones worth another US\$900m. Based on industry journal reports the BeneVir assets were preclinical at the time of the acquisition and based on research from NYU⁴.

Our assessment of value is based on a combination of recent transactions in the Oncolytic virus space plus the estimated development cost (to the company) of HER-Vaxx.

⁴ Endpts.com/playing the long game, 2 May 2018

Figure 13 - Summary valuation

US\$m	High	Low
HER Vax		
- estimated cost of development	26.0	13.2
CF-33	140.0	50.0
Theoretical Enterprise Value	166.0	63.2
Exchange rate A\$/US\$	0.65	0.65
A\$ EV	255.4	97.2
Cash	36.0	36.0
EV A\$m	291.4	133.2
Shares on Issue	4,320.0	4,320.0
Theoretical value per share (cps)	6.7	3.1

SOURCE: BELL POTTER SECURITIES

Our valuation is set of 5.0 cps representing an EV of \$216m. The valuation is supported by a discounted cash flow valuation, however, the vast majority of the value is in the terminal value calculation where the cash flows are long dated and remain highly uncertain.

We initiate coverage with a Buy (Speculative) recommendation.

Board and Management

Paul Hopper – Executive Chairman, Appointed 31 October 2012

Mr Hopper has over 20 years' experience in the management and funding of biotechnology and healthcare companies both as chief executive officer and director in Australia and the United States. Mr Hopper was the Chairman of VLA prior to its acquisition by Merck in 2018. He has an extensive network both in Australia and the United States.

Leslie Chong – CEO and Managing Director, Appointed 28 March 2018

Prior to joining the company Ms Chong was a Senior Clinical Program Lead at the head office of Genetech in San Francisco. She has over 20 years' experience in leading clinical and department development in oncology and specifically in immuno-oncology. Her experience in leading clinical trials is rare and we believe she is a major asset to the company.

Charles Walker – Non Executive Director, Appointed 13 September 2015

Mr Walker has broad and successful experience across the biotechnology and life sciences industry.

Axel Hoos – Non Executive Director, Appointed 20 December 2013

Dr Axel Hoos is Senior Vice President and Therapeutic Area (TA) Head, Oncology R&D at GlaxoSmithKline Pharmaceuticals (GSK). Previously, Dr Hoos was the global medical lead in immunology/oncology at Bristol-Myers Squibb (BMS) where he led the team which developed Yervoy (Ipilimumab), the first life-extending therapy in immuno-oncology.

Leslie Russel – Non Executive Director, Appointed 23 April 2019

Dr Lesley Russell is a haematologist/oncologist and has over 25 years' experience and leadership in the international pharmaceutical field as a chief medical officer. Dr Russell has extensive experience as a director of NASDAQ listed pharmaceutical companies.

Dr Jens Eckstein – Non Executive Director, Appointed 20 May 2019

Dr Eckstein has more than 15 years' venture capital experience in the biopharmaceutical industry and 10 years' operational experience in drug discovery and development. He is also co-founder and managing director of Action Potential Venture Capital (APVC). Previously, he was a general partner at TVM Capital.

Figure 14 - Summary of Director's interest

	Shareholding (m)	Options (m)
Paul Hopper	177.1	25.8
Ms Leslie Chong	4.4	77.1
Mr Charles Walker	28.5	25.4
Dr Axel Hoos	11.4	10.0
Dr Lesley Russell	0.5	25.00
Dr Jens Eckstein	-	-
	221.9	163.35
Shares on issue	4,320	760.3
Free float	95%	

SOURCE: COMPANY DATA

The company has two separate Scientific Advisory Board's, one for Oncolytic Virotherapy and another for Immunology.

Table 1 - Financial summary

Profit & Loss (A\$m)	FY18	FY19	FY20e	FY21e	FY22e
Year Ending June					
R&D incentive	-	4.1	3.4	3.7	3.2
Total Revenue	1.8	4.1	3.4	3.7	3.2
COGS	-	-	-	-	-
Gross profit	1.8	4.1	3.4	3.7	3.2
Expenses Net of R&D	-3.2	-7.6	-8.2	-7.1	-10.0
Other expenses	-2.5	-4.8	-6.0	-6.0	-6.0
Total Expenses	-5.7	-12.4	-14.2	-13.1	-16.0
EBIT	-3.9	-8.3	-10.8	-9.4	-12.8
Interest income	0.1	0.4	0.5	0.5	0.5
Pre tax profit	(3.8)	(7.9)	(10.3)	(8.9)	(12.3)
Tax expense	-	-	-	-	-
NPAT - normalised	(3.8)	(7.9)	(10.3)	(8.9)	(12.3)
Reported NPAT	(3.8)	(7.9)	(10.3)	(8.9)	(12.3)

Cashflow (A\$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-4.5	-7.9	-10.8	-9.4	-12.8
Net interest	0.0	0.4	0.5	0.5	0.5
Operating cash flow	-4.5	-7.5	-10.3	-8.9	-12.3
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-4.5	-7.5	-10.3	-8.9	-12.3
Business acquisitions	-0.6	0.0	-1.5	0.0	0.0
Proceeds from issuance	8.8	20.3	22.8	0.0	0.0
Movement in borrowings	0.0	0.0	0.0	0.0	0.0
Other	-0.7	-1.5	0.0	0.0	0.0
Change in cash held	3.0	11.3	11.0	-8.9	-12.3
Cash at beginning of period	4.8	7.8	19.0	30.0	21.1
FX adjustment	0.0	0.0	0.0	0.0	0.0
Cash at year end	7.8	19.0	30.0	21.1	8.8

Balance Sheet (A\$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	7.8	19.0	30.0	21.1	8.8
Receivables	-	-	-	-	-
Other current assets	2.5	4.4	4.4	4.4	4.4
Property, Plant and Equipment	-	0.3	0.3	0.3	0.3
Intangibles	7.1	7.1	30.5	30.5	30.5
Other non current assets	-	-	-	-	-
Total assets	17.4	30.8	65.2	56.3	44.0
Trade payables	0.4	2.4	2.4	2.4	2.4
Debt - interest bearing	-	-	-	-	-
Vendor payable	-	-	2.9	2.9	2.9
Other provisions	1.0	1.1	1.1	1.1	1.1
Total Liabilities	1.4	3.5	6.4	6.4	6.4
Net Assets	16.0	27.3	58.7	49.8	37.5
Share capital	44.3	63.1	86.8	86.8	86.8
Other equity	-	-	12.1	12.1	12.1
Retained earnings	(29.0)	(36.0)	(46.3)	(55.2)	(67.5)
Reserves	0.3	0.2	0.9	0.9	0.9
Shareholders Equity	15.6	27.3	53.5	44.6	32.3

Valuation Ratios (A\$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-0.1	-0.2	-0.3	-0.2	-0.3
Normalised EPS (cps)	-0.1	-0.2	-0.3	-0.2	-0.3
EPS growth (%)	nm	nm	nm	nm	nm

PE(x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	9.7	5.2	5.6	9.1	69.4
Book Value Per Share (cps)	0.5	0.8	1.2	1.0	0.7
Price/Book (x)	5.3	3.8	2.4	2.9	4.0
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	nm
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

Interim Results	1H20	2H20e	1H21e	2H21e
Revenues	2.4	1.0	1.9	1.9
R&D Expense	-4.2	-4.0	-1.1	-6.0
All Other expenses	-3.0	-3.0	-3.0	-3.0
EBIT	-4.9	-5.9	-2.2	-7.1

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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Biotechnology Risk Warning:

The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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