AUSTRALIAN
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

Imugene Limited (ASX: IMU)

Initiating Coverage

July 2019

INDEPENDENT
INVESTMENT RESEARCH

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Imugene Limited (ASX: IMU)

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Investment Profile	
Share price ($) as at 11 July 2019	0.015
Issued capital:	
Ordinary shares (M)	3,609.8
Options (M)	625.3
Fully Diluted (M)	4,235.1
Market capitalisation ($M)	54.1
12-month Share Price Low/High ($)	0.013/0.028

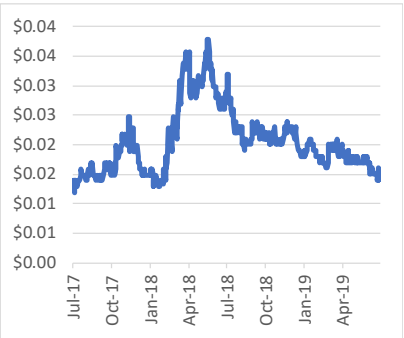
Board and Management

Leslie Chong: Managing Director & CEO
Paul Hopper: Executive Chairman
Dr. Axel Hoos: Non-Executive Director
Charles Walker: Non-Executive Director
Dr. Lesley Russell: Non-Executive Director
Dr. Jens Eckstein: Non-Executive Director
Dr. Mark Marino: Chief Medical Officer
Dr. Nick Ede: Chief Technology Officer
Dr. Anthony Good: Vice President of Clinical Research

Largest Shareholders	%
Private Portfolio Managers	6.2
Platinum Investment Management Limited	3.4
Dr. Nicholas Smith	2.4
Paul Hopper	2.1
Sarah Cameron	1.7
Top 20 Shareholders	**24.3**

Source: IRESS

Share Price



IMU BOOSTS IMMUNOTHERAPY PLATFORM WITH THE ACQUISITION OF ONCOLYTIC VIRUS CF33

Imugene Limited (ASX: IMU) is a clinical stage biotechnology company seeking to develop a range of novel immunotherapies to enhance the efficacy of cancer treatments. The company has announced its intention to acquire the exclusive licence to the oncolytic virus CF33 to add to the existing platform which targets the development of B cell peptide vaccines.

KEY POINTS

Acquisition of Oncolytic Virus CF33: IMU has annonunced the acquisition of Vaxinia Pty Ltd (Vaxinia) and the exclusive licence to the oncolytic virus CF33 from the City of Hope Cancer Centre (COH) in Los Angeles, subject to shareholder approval. CF33 is currently in the pre-clinical phase of development with IMU seeking to commence Phase I trials in 1H'2020. Under the terms of the licence agreement, IMU will acquire the exclusive rights to develop and commercialise CF33, for which it has agreed to pay COH licence fees comprising an upfront fee, annual maintenance fees which are creditable against future royalty payments, performance based consideration linked to the achievement of certain milestones and commercial outcomes, net sales based royalty payments, and sublicencing fees. IMU will also acquire 100% of the shares of Vaxinia. IMU will pay Vaxinia shareholders an upfront cash payment of $462,500 and $1.619m fully paid ordinary IMU shares based on the 7-day VWAP of the share price prior to announcing the deal. The shareholders of Vaxinia will also be eligible for additional share based payments based on the achievement of performance related milestones. The acquisition of CF33 has the potential to add significant value to the company with interest from big pharma being driven by research that highlights the therapeutic benefit of oncolytic viruses when combined with other immunotherapies.

HER-Vaxx Commences Phase II Clinical Trials: The company has commenced a Phase II study of HER-Vaxx targeting patients with HER2-positive metastatic gastric cancer. The study will measure the response of 68 participants who will be randomised into two groups: 1) HER-Vaxx in combination with standard chemotherapy, and; 2) standard chemotherapy alone. The results from the Phase II study are due to be complete in 2020 and will provide a greater insight as to the efficacy of HER-Vaxx in cancer treatments. In early July, the company presented the 266 day results of the continued treatment of subjects from the Phase Ib that were given the highest dose of treatment at the European Society of Medical Oncology (ESMO) conference. Whilst only a small sample, the results presented were positive and provide a level of optimism for the Phase II trials.

PD1-Vaxx to Commence Phase I Clinical Trial: The company is seeking to commence a Phase I clinical trial for PD1-Vaxx in 2020 after encouraging results from the pre-clinical studies. PD1-Vaxx seeks to produce an alternative to the existing commercialised monoclonal antibody immune checkpoint inhibitors. The trial will focus on patients with lung cancer. The company will seek to progress to a Phase II trial in the event the results from the Phase I trial are favourable.

Partnering Opportunities: The immunotherapy market is currently experiencing significant growth with the use of immunotherapies becoming an important addition to the standard of care in oncology. The successful trials of IMU's therapies will provide significant potential partnering opportunities. The opportunities are increased through the potential use of IMU's treatments in combination with existing commercialised immunotherapies to potentially improve response rates without increasing toxicity.

Investment View: IMU is a speculative investment with the ability to generate value for shareholders primarily dependent on the success of the clinical trials and the ability of the company to sell/licence its products to big pharma. The company will be seeking to generate interest from big pharma for its three leading candidates - HER-Vaxx, PD1-Vaxx and CF33 (if the acquisition is approved by shareholders). The company has suffiicient capital for the upfront acquisition costs and announced clinical trials, however, in the event the company does not generate interest in a timely fashion the company will likely have to raise capital which may dilute existing shareholder positions. The acquisition of CF33 would provide the potential for significant value add with a number of deals being done at the early stage of clinical development of oncolytic viruses. One notable deal was the acquisition of Viralytics Limited (ASX: VLA) by Merck & Co. Inc., for a total consideration of AUD$502m ($1.75 per share). This represented a 160% premium to the one month weighted average share price of VLA. This deal is of particular note given the Executive Chairman Paul Hopper was the Chairman of VLA. While we believe there to be significant upside potential from an investment in IMU, there remains significant risks.

SWOT ANALYSIS

STRENGTHS

- The company has a healthy balance sheet with the HER-Vaxx Phase II and PD1-Vaxx Phase 1 clinical trials fully funded.
- The Board and Management team have extensive experience in developing oncology therapies and selling/licensing therapies to big pharma.
- The Vaxinia team that will be joining IMU in the event the acquisition is approved have significant experience in oncolytic virus development, with all the senior members of the team previously working with Viralytics.
- In the event the CF33 acquisition is approved, the company will have three leading immunotherapy candidates that are expected to all be in clinical trials within the next 12 months, providing a number of potential targets for big pharma.
- HER-Vaxx and PD1-Vaxx have patent protection across a number of jurisdictions for a significant number of years. CF33 has a patent pending to secure the worldwide rights to the composition of matter of CF33 and the method of use. The patent has an expected expiration date of 2037.
- The acquisition of Vaxinia is largely going to be IMU script, preserving the cash position of the company.

WEAKNESSES

- Clinical stage biotech companies are a high risk investment proposition. While the early indications support the continued development of the current product pipeline, this can change at any point in the cycle.
- The company is not generating revenue given the nature of its operations with cashflow dependent on capital raisings and/or a licence agreement/sale of the company's products. While the company currently has a healthy cash position with sufficient cash for the upfront acquisition costs and the announced clinical trials for HER-Vaxx, PD1-Vaxx and CF33, the company will likely have to raise capital to further progress the clinical development of products, unless a commercial agreement is entered into.

OPPORTUNITIES

- The immunotherapy market is currently in a significant growth phase providing IMU with a significant opportunity to find a partner/s for their products.
- The acquisition of CF33 provides significant potential to add value to the company. If CF33 successfully completes the Phase I trial and initiates a Phase II trial, there may be a number of suitors to acquire the licence of the oncolytic virus.
- In the event the response rates from the Phase II HER-Vaxx clinical trial are significant, this will enhance the prospect of the company partnering with a pharmaceutical company to further develop the vaccine.

THREATS

- In relation to the immunotherapy B cell vaccine platform, the company is depending to a large degree on the results of the HER-Vaxx Phase II clinical trial to prove the technology platform. In the event the results are not statistically significant it will be difficult for the company to continue with the development of the B cell vaccine product pipeline.
- Growth in the immunotherapy market has resulted in a significant increase in the number of treatments under development. This means increased competition for deals with big pharma.
- In the event a sale/licence transaction is not struck in a timely manner the company will likely have to raise capital. A capital raising may be dilutive to current shareholders.

COMPANY OVERVIEW

- IMU is a clinical stage biotechnology company that focuses on the development of immunotherapies, which are treatments that enable a patient's immune system to recognise and destroy cancer cells.
- The company is focused on targeting B cell peptide vaccines which seek to harness the body's immune system to generate polyclonal antibodies, potentially achieving a similar or greater effect than existing commercialised monoclonal antibody therapies. The company's two lead B cell peptide vaccines are - HER-Vaxx and PD1-Vaxx. HER-Vaxx is the most clinically advanced therapy in the portfolio, targeting cancer cells that have an over expression of HER-2. PD1-Vaxx aims to produce polyclonal antibodies that block PD-1 signaling proteins which stop the immune system from attacking cancer cells.
- The company has announced its intention to expand its product portfolio through the acquisition of the exclusive licence to the oncolytic virus CF33, which was developed by Professor Fong at the City Of Hope Cancer Centre (COH) in Los Angeles. Details of the acquisition are provided in the "Acquisition of Oncolytic Virus CF33" section below. Oncolytic viruses are an emerging form of immunotherapy, the development of which has been driven by advancements in genetic engineering. There is a body of clinical research which suggests the use of oncolytic viruses in combination with checkpoint inhibitors has the potential to improve the efficacy of cancer treatment without increasing toxicity. This has resulted in a growing interest in oncolytic virus treatments from big pharma. The addition of CF33 to the portfolio has the potential to add significant value to the company if clinical trials produce positive results.
- If the acquisition is approved by shareholders, the company will be seeking to commence a Phase I clinical trial for CF33 in 1H'2020.
- In June 2018, the company licensed a B cell immunotherapy portfolio from The Ohio State University Wexner Medical Centre & Mayo Clinic (OSU). The portfolio included PD1-Vaxx and B-Vaxx, a B cell vaccine that targets HER2-positive cancers and is similar to the company's existing HER-Vaxx agent. While B-Vaxx is well advanced we expect the company to focus on the development of HER-Vaxx in the near-term. The licence agreement significantly expanded the B cell vaccine pipeline.

Lead Candidate Clinical Development & IP

	Pre-Clinical	Phase I	Phase II	IP Patents
HER-Vaxx	→	→	→	Patents expire April 2027, August 2030 & April 2036
PD1-Vaxx	→			Patents expire March 2037 & February 2038
CF33	→			Patents expected to expire 2037
CF33 & a PD-L1	→			Patents expected to expire 2037

Note: CF33 is subject to shareholder approval.

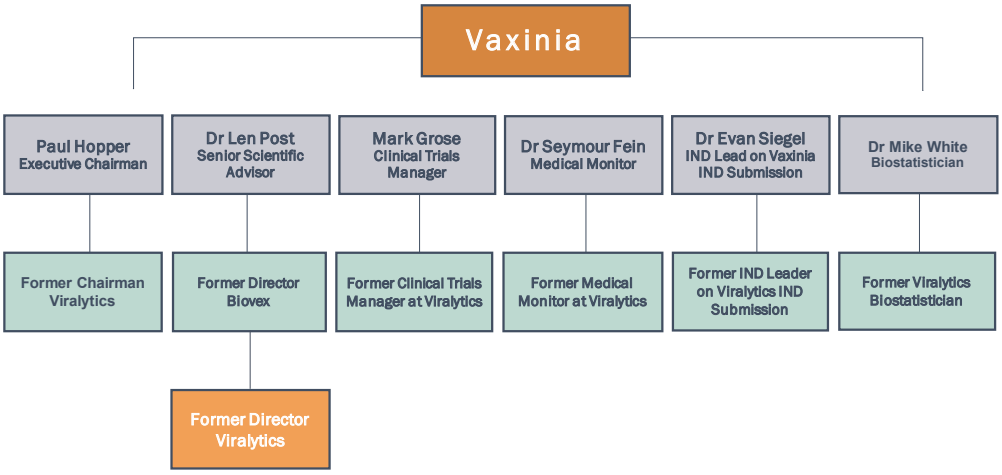
- In addition to the three lead candidates mentioned above, the company has a pipeline of products that it can advance at any time, tabled below. We note that given the interest in the therapeutic value of combining immunotherapy treatments, the company will seek to run trials with the single use of the agents in addition to combinations with commercialised immunotherapies.

Discovery Pipeline

	Pre-Clinical	Phase I	Phase II
Her-1	→		
Her-3	→		
IGF-1R	→		
VEGF	→		
PD-L1	→		
Combination (Various)	→		

ACQUISITION OF ONCOLYTIC VIRUS CF33

- IMU has announced its intention to acquire 100% of the shares in Vaxinia Pty Ltd (Vaxinia) and the exclusive licence of the oncolytic virus CF33. IMU will pay Vaxinia shareholders an upfront cash payment of $462,500 and issue $1.619m in IMU fully paid ordinary shares based on the seven-day VWAP of IMU shares prior to the announcement of the acquisition (107.9m shares based on the share price of $0.015 as at 11 July 2019). Further shares will be provided to Vaxinia shareholders upon the achievement of designated milestones, including the granting of the Investigational New Drug (IND) by the FDA, dosing of the first patient in the Phase I clinical trial and the Phase I clinical trial achieving certain outcomes. All shares issued will be subject to a six-month escrow period.
- Under the terms of the licence agreement, IMU will acquire the exclusive rights to develop and commercialise CF33 from COH, for which it has agreed to pay licence fees comprising an upfront fee, annual maintenance fees which are creditable against future royalty payments, performance based consideration linked to the achievement of certain milestones and commercial outcomes, net sales based royalty payments, and sublicencing fees. IMU is yet to disclose the licence fee payment amount.
- The majority shareholder of Vaxinia is Paul Hopper, the Executive Chairman of IMU. The company has confirmed that the transaction between the two companies has been held at arms length and conflicted parties have been excluded from the decision making process within IMU.
- The key members of the Vaxinia team that will be joining IMU have significant experience in the oncolytic virus market, as detailed below. We note all of the team members were formerly with Viralytics and includes Dr. Len Post who was also a former Director of Biovex, from which Amgen acquired the oncolytic virus T-VEC, now known as Imlygic.



FINANCIAL POSITION

- The company generated a loss of $3.4m for the 1H'19, an increase from the $1.6m loss in 1H'18. The increased loss is largely due to the increased expenditure on research and development activities. Expenditure on research and development activities will continue to increase in the 2H'19 and FY'20 as the company progresses with clinical trials.
- The company had $20.98m at 31 March 2019. The cash position was boosted as a result of a $20.1m capital raising in July 2018.
- The company will pay the upfront acquisition costs from existing cash reserves and is expected to have sufficient capital to complete the Phase II HER-Vaxx, Phase I PD1-Vaxx and Phase I CF33 clinical trials. Therefore, the company is not expecetd to have to raise capital over the coming 12 months, however the company will be required to raise capital to progress products beyond this. At the current share price level we note that any capital raising requirements will result in the issue of a significant number of shares.
- The company will be seeking to secure a sale/licence agreement for the development of its products. The most clinically advanced product is HER-Vaxx, which the company will be hoping to generate interest from big pharma based on the Phase II results. The ability of the company to secure a deal would change the financial position of the company.

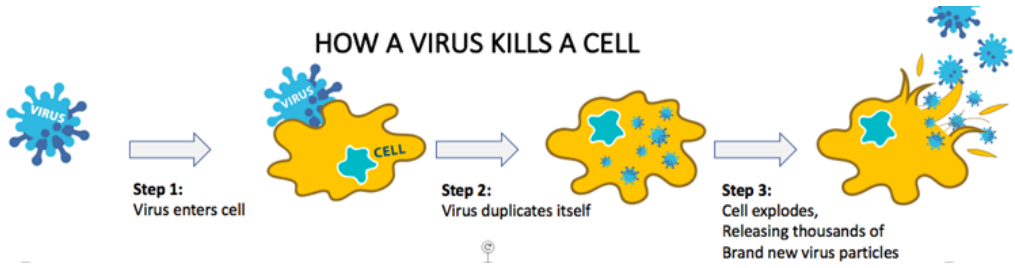
CAPITAL STRUCTURE

- The company currently has 3.6 billion shares on issue and 625.3 million listed and unlisted options on issue with varying exercise prices and exercise dates.
- In the event the acquisition of Vaxinia is approved by shareholders, the company will issue IMU shares equating to $1.619m based on the 7-day VWAP of the IMU share price prior to announcing the deal. This equates to 107.9m shares based on the share price as at 11 July 2019. There will also be a number of performance based shares issued to the shareholders of Vaxinia as part of the acquisition.

Capital Issued	
	Pre-Acquisition
Fully Paid Ordinary Shares	3.609,846,302
Options:	
Options Expiring 30 November 2020 @ $0.026 (Listed)	242,456,487
Options Expiring 30 November 2021 @ 0.04 (Listed)	248,319,200
Unlisted Options with Varying Exercise Dates and Prices	134,500,000
Fully Diluted	**4,235,121,989**

ONCOLYTIC VIRUS CF33

- Oncolytic viruses infect, replicate in and eventually kill cancer cells while leaving healthy cells unharmed.
- According to the National Cancer Institute (NCI), the medical community has been interested in using viruses to treat cancer for more than a century. The use of viruses has gained new levels of enthusiasm with the growing body of research that suggests that oncolytic viruses may work by triggering an immunotherapy response in the body against cancer as opposed to just directly killing cancer cells. Oncolytic viruses have been shown to kill cancer cells and causes the release of 'danger' signals, which generate an immune response.



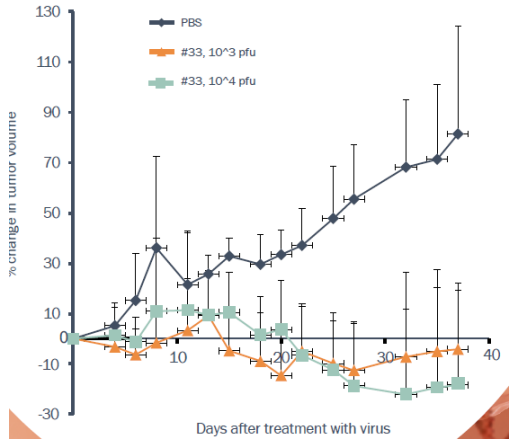
- The basis of CF33 is the vaccinia virus, which is a large enveloped virus that contains a double stranded DNA genome and belongs to the Poxvirus family. The virus was used as a vaccine to eradicate smallpox.
- CF33 was developed by Professor Yuman Fong, the Sangiacomo Family Chair in Surgical Oncology and Chair of the City of Hope Department of Surgery. Professor Fong has led the research effort to employ genetically modified viruses to eliminate cancer cells.
- The CF33 technology has a pending patent application to secure the worldwide rights to the composition of matter of CF33 and the method of use. The patent has an expected expiration date of 2037. COH has also applied for a Provisional Patent for a combination of CF33 with a PD-L1 checkpoint inhibitor.

KEY OUTCOMES OF PRE-CLINICAL STUDIES

- CF33 has proven safe in mice with no viral shedding in blood or urine found. More than 50 mice were treated with CF33 and there were no signs of illness found and the animals ate well and did not suffer weight loss.

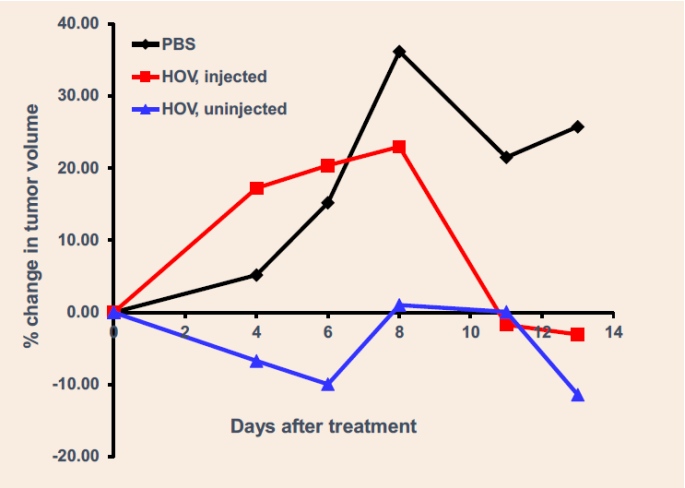
- A key outcome of the studies was that the virus worked at lower doses than competing oncolytic viruses. Reduced dose requirements means CF33 has the potential to reduce the cost and toxicity of treatments.
- CF33 was tested against a range of cancer cell lines. The pre-clinical data demonstrated that the CF33 virus can shrink multiple types of cancer at a low dose and more importantly, there was a reduction in the size of both injected and non-injected tumours.
- The below chart shows the pre-clinical results from the use of CF33 in Triple Negative Breast Cancer (TNBC). Results showed that the tumour reduced in size at both doses.

Effect of CF33 in TNBC



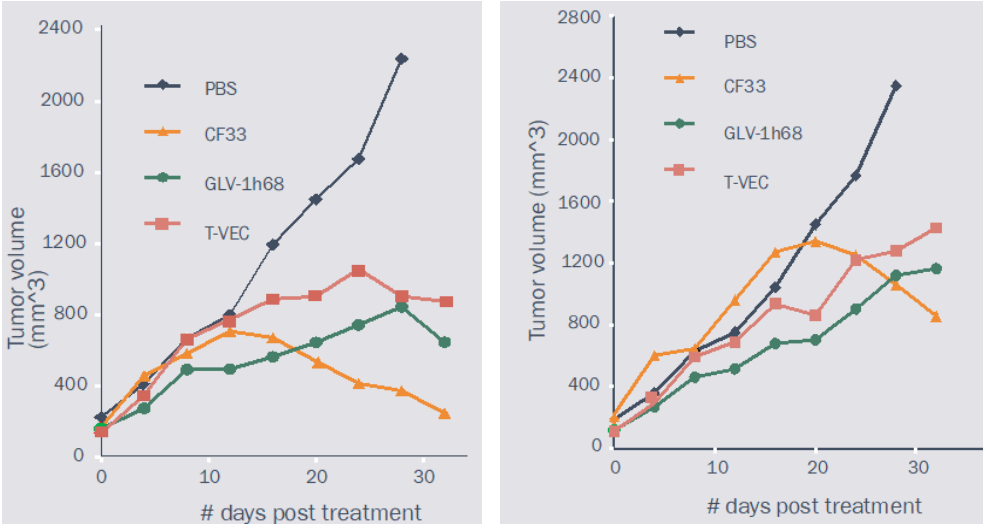
- One of the key outcomes of the pre-clinical studies was the observation of the **abscopal effect,** whereby there is a reduction in the size of non-injected tumours in addition to injected tumours. As shown in the below graphic, there was a reduction in both the injected and non-injected tumours in the 14 days after injection.

Abscopal Effect of CF33



- As part of the pre-clinical trials, CF33 was compared to the Amgen's T-VEC (FDA approved) and Genelux's GL-ONC1 (in Phase II clinical trials) products in killing the Triple Negative Breast Cancer (TNBC) cell line. The below graphic details the outcome. CF33 was shown to be more effective than the other viruses in reducing the tumour size.
- When compared to T-VEC and GL-ONC1, CF33's tumour reduction abilities in non-injected tumours was superior. While T-VEC and GL-ONC1 reduced the rate of growth in non-injected tumours compared to those mice receiving no treatment, CF33 showed a clear reduction in the size of non-injected tumours.

CF33, T-VEC and GL-ONC1 on Injected Tumours | **CF33, T-VEC & GL-ONC1 on Non-Injected Tumours**



Nore: Dose of 10^3 PFU per mouse.
Source: IMU

MANUFACTURING

- IMU intends to continue to use COH for the GMP manufacturing of CF33. COH has a 20,000 square foot multi-product biologics manufacturing facility. IMU has confirmed that the facility has the capacity to produce sufficient amounts of product for Phase I and Phase II clinical trials.
- COH has already commenced production of the CF33 material required for the Phase I trials for both the single agent testing and testing with the immune checkpoint inhibitor.
- The material for the clinical trial will be provided at cost to IMU, resulting in significantly reduced manufacturing costs.

PROPOSED CLINICAL DEVELOPMENT TIMELINE & COST

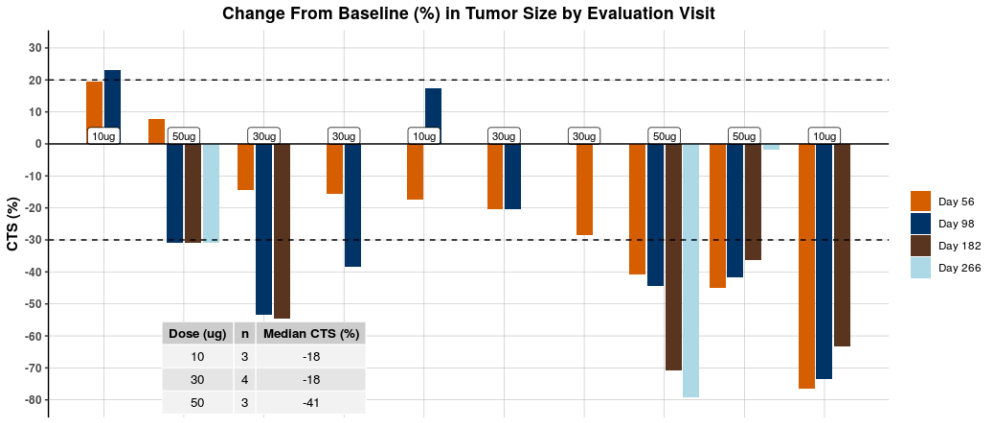
- IMU will seek to commence a Phase I clinical trial in 1H'2020 in which it will seek to assess the safety and efficacy of CF33 across a range of advanced solid cancers including lung, triple negative breast (TNBC), melanoma, bladder and gastric cancers.
- The company will be seeking to assess the use of CF33 as a single agent and in combination with an immune checkpoint inhibitor, which is yet to be selected. The program will be seeking to recruit a total of 30 patients, 15 for each program, with the therapy to be administered intratumorally (directly into a tumour). The Phase I trial is expected to cost USD$4.5m and be completed over an 18-month period.
- In the event the primary end points are met from the Phase I trial, the company will seek to undertake a Phase II trial across four cancer indications to be selected upon the completion of the Phase I trial. The Phase II trial will seek to focus on the use of CF33 in combination with an immune checkpoint inhibitor with an estimated 120 patients. A Phase II trial would be expected to be completed over an 18-month period.
- The Phase II trial is expected to cost USD$18m. The goal of the company would be to find a partner on the basis of the Phase I trials, however in the event this is not the case and the company progresses to a Phase II trial, the company will likely have to raise capital to complete the trial.

HER-VAXX

- HER-Vaxx is the company's most progressed immunotherapy treatment from a clinical perspective with HER-Vaxx commencing Phase II clinical trials in March 2019.
- HER-Vaxx is a B cell vaccine that focuses on cancers that have an over expression of HER-2 (Human Epidermal Growth Factor Receptor). An increase in the incidence of HER-2 in the body is associated with a higher chance of cancer spreading and an increased probability of cancer recurrence. 10% to 30% of gastric, breast, ovarian and pancreatic cancer patients have tested positive for over expression of HER-2.
- HER-Vaxx seeks to stimulate a patients B cells to produce antibodies that target cancer cells with HER-2 on their surface.
- HER-2 is a clinically and commercially validated target for cancer treatment. There are a number of monoclonal antibody therapies that are currently available for use. HER-Vaxx would be the first vaccine to target HER-2. The key difference between HER-Vaxx and monoclonal antibodies is that HER-Vaxx promotes the natural production of antibodies, whereas monoclonal therapies introduce synthetic antibodies to attack cells with HER-2 on their surface.
- Whilst effective, there are a few issues with the use of monoclonal therapies that HER-Vaxx has the potential to address. These include:
  - Patients can develop a resistance to the monoclonal anitbody. The natural production of antibodies reduces the risk of resistance, potentially increasing the efficacy of treatment.
  - Monoclonal therapies require frequent administration and large dose levels. Naturally produced antibodies have the potential to produce a lasting immune response to inhibit tumour recurrence and therefore potentially require a lower number of vaccinations.
  - Monoclonal therapies can have adverse side effects. Lower dose level and frequency requirements of HER-Vaxx has the potential to improve safety.

CLINICAL DEVELOPMENT

- The company completed a Phase Ib clinical trial in 2018. The clinical trial was focused on patients with gastric cancer, the 5th most common cancer and the third leading cause of cancer deaths. After meeting all the endpoints from a Phase Ib study, the company commenced a Phase II clinical trial in March 2019, which is expected to be completed in mid-2020.
- The Phase Ib study showed promising results. The study involved providing 14 patients (10 of which completed the trial and were evaluable) with three different dosage levels - 10, 30 and 50 micrograms. 1 patient showed a complete response, 5 patients showed a partial response (tumour reduced by more than 30%) and 4 patients showed a stable response (less than 20% change in the size of the tumour). There were no safety issues with the trial showing the treatment was well tolerated with no significant reactions and no dose-limiting toxicities were observed. An increased antibody response was shown across all dose levels, with the antibody response shown to be dose dependent.
- The below graphic shows the median change in the tumour throughout the trial for patients that were available for evaluation. Overall, the median tumour size decreased over the trial with the most significant median decline being experienced by those patients receiving the highest dose of HER-Vaxx. While the results are promising, all patients in the trial were also receiving chemotherapy treatment and therefore the impact of HER-Vaxx is not definitive.



Source: IMU

- There were three patients in the Phase Ib trial that received the highest dose administered (50 micrograms) and the dose that will be provided to patients in the Phase II trial. These three patients have continued treatment beyond the completion of the Phase Ib trial. The company has presented the 266 day results of the continued treatment at the European Society of Medical Oncology (ESMO) conference. The results show continued antibody production and reduction in tumour size. Whilst only a small sample, the results presented were positive and provide a level of optimism for the Phase II trials.
- The Phase II study will target patients with HER2-positive metastatic gastric cancer. The study will measure the response of 68 patients who will be randomised into two groups: 1) HER-Vaxx in combination with standard chemotherapy, and; 2) standard chemotherapy alone. The results from the Phase II study will provide a greater insight as to the efficacy of HER-Vaxx in cancer treatments. The phase II participants will be provided with a 50 microgram dose of HER-Vaxx, the highest and most effective dose administered in the Phase Ib trial.
- The trial is being conducted at multiple sites across Asia, Eastern Europe and India. These locations have been selected for the study due to the difficulty in assessing the commercialised monoclonal antibodies and the high prevalence of gastric cancer in these regions. The trial is expected to cost ~$7.5m. The outcomes of the Phase II trial is very important to the progression of the company's B cell vaccine pipeline.

PD1-VAXX

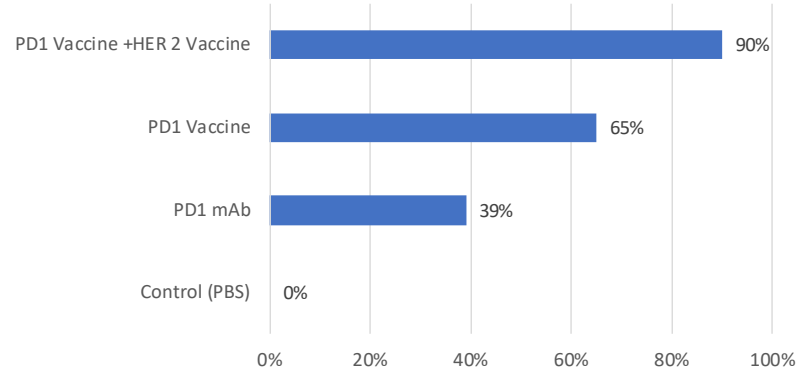
- PD1-Vaxx is a B cell vaccine which seeks to stimulate the body to produce polyclonal antibodies that block PD-1 signaling, producing an anticancer effect similar to other immune checkpoint inhibitor monoclonal antibodies, such as Keytruda and Opdivo.
- Immune checkpoint inhibitors are experiencing significant levels of growth due to the clinical research that has highlighted the improved efficacy of treatment for advanced cancers when checkpoint inhibitors are incorporated into the treatment plan.
- PD1-Vaxx was acquired as part of the licensing agreement from OSU in 2018. OSU had completed pre-clinical studies of PD1-Vaxx with the company looking to progress the PD1-Vaxx to a Phase I trial in 2020.
- The immune checkpoint inhibitor market is one of the fastest growing sectors of the immunotherapy market. As such, there is significant market potential for PD1-Vaxx in the event that the clinical trial results are favourable.

PRE-CLINICAL STUDY PROVIDES VALIDATION FOR PD1-VAXX

- Pre-clinical results provided a proof of concept and validation for PD1-Vaxx. The study showed that the vaccine was able to produce a sustained antibody response to the PD-1 protein.
- The OSU conducted a study of the PD1-Vaxx in a HER2+ colorectal cancer model. The study showed that the PD-1 vaccine inhibited tumour growth to a greater extent than an industry standard PD-1 monoclonal antibody. As shown in the below graphic, the PD-1 vaccine inhibited cancer growth by 65% over a 16 day period after the infusion of cells, compared to the monoclonal antibody of 35%.

- One of the key outcomes of the study was the tumour inhibition that was detected when the PD1-Vaxx was combined with the B-Vaxx agent, which is similar to IMU's HER-Vaxx agent. 90% cancer growth inhibition was realised in the colorectal cancer model, which was far greater than the outcomes from PD-1 agents on their own.

% Cancer Growth Inhibition In Colorectal Cancer



Note: Inhibition of cancer growth 16 days after the infusion of cancer cells.
Source: IMU

CLINICAL DEVELOPMENT

- IMU is seeking to commence a Phase I clinical trial for PD1-Vaxx in 2020 on the back of the encouraging results from the pre-clinical study. The patient sample will be 12-18 and the company will be seeking to determine the optimal dose in addition to determining the safety and response to treatment.
- The trial will be focused on lung cancer of which there are 1.8 million new diagnosis each year. Lung cancer has a very low 5-year survival rate of ~18%, therefore potential advancements in therapeutic treatments are needed.
- The Phase I trial is expected to cost $4m and be completed over an 18-month period.
- A positive outcome from the Phase I trial will see the company progress to a Phase II study, where the company would likely seek to undertake a trial on the use of PD1-Vaxx as a monotherapy as well as the use of PD1-Vaxx with other marketed immunotherapy agents.

IMMUNOTHERAPY MARKET OPPORTUNITY

- Immunotherapy is an emerging market and is at the forefront of cancer innovation. The use of immunotherapies in combination with standard chemotherapy treatment has been shown to improve response rates for cancer treatment. According to BIS Research, the global immunotherapy market was valued at USD$40 billion in 2017 and this is expected to increase to in excess of USD$170 billion over the next decade.
- Oncology has dominated the deal making landscape in recent times. As shown in the below graphic, in 2018 oncology had a significant number more transactions than any other therapy area.

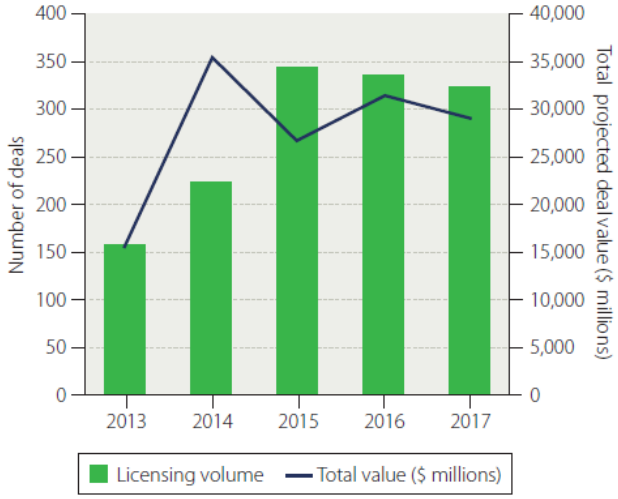
Number of Buy-Side Transactions by Therapy Area for 2018 by Top 30 Pharma Companies

	J&J	Merck	Novartis AG	Roche	Eli Lilly & Co	Takeda	Sanofi	AZ	Novo Nordisk	Pfizer	BI	AbbVie	Gilead	Astellas	Biogen	Merck KGaA	Celgene	Daichi Sankyo	GSK	Amgen	Bayer	BMS	Mylan	Otsuka	Allergan	CSL	Shire	UCB	Teva	TOTAL
Oncology	9	17	8	12	2	3	3	9		6	4	5	5	3		7	1	6	1	2	1	1		3						108
Neuroscience	6	1	3	3	3	3			1	1	1	2		1	7		3		2				1					2		40
Immuno/Inflam	2	1	4	1	1	1	1		2	1	1	1	1	1					1	1		1	1				1			23
Endo/Met	2				3	1			8		1																1			16
Infection	1	1	1		2		5			1	1		2						1							1				16
Diversified			1		3	1	2			3							1		1						1					13
GI	2			1		4								1								1								9
Dermatology	3																								1	1				5
Hematology	1						2		1								1													5
Ophthalm			3	1										1																5
Respiratory	1							1			1										1		1							5
Cardiology						1		2													1									4
Total	27	20	20	18	14	14	13	12	12	12	9	8	8	7	7	7	6	6	6	3	3	3	3	3	2	2	2	2	0	222

Note: Top 30 pharma companies as ranked by 2017 revenues.
Source: Clarivate Analytics

- Growth in the number and value of oncology deals has increased substantially since 2013, as shown in the below graphic. Immunotherapy is driving the growth in oncology transactions. There were 35 deals done that were in excess of $1 billion dollars from 2013 to 2017. Of these, 32 focused on immunotherapies.

Licensing, Joint Venture & Research -Only Oncology Deals from 2013 to 2017



Source: BioPharma Dealmakers

ONCOLYTIC VIRUS MARKET

- Oncolytic viruses are an emerging class of immunotherapy agents for cancer treatments. To date there has been one oncolytic virus that has gained FDA approval, Talimogene laherparepvec (T-VEC or Imlygic®). Imlygic is a treatment for melanoma and was granted FDA approval in 2015. The treatment is injected into tumours and was engineered to produce a protein that stimulates the production of immune cells in the body.
- There are currently a number of clinical trials underway to determine the response rates to a range of oncolytic virus therapies in a range of cancers, including brain, prostate, colorectal, ovarian, lung and breast cancer.
- Amgen acquired Imlygic from Biovex for US$424m, plus milestone payments, however since coming to market has generated meager sales. Despite this, there remains acquisition activity by pharmaceutical companies to gain access to oncolytic virus therapies with the three acquisitions in 2018 receiving upfront payments of in excess of USD$700m. Interest from big pharma is being driven by the growing body of clinical research that suggests improved efficacy when oncolytic viruses are used in combination with other immunotherapy treatments, such as immune checkpoint inhibitors.
- Big pharma companies in particular are interested in potential therapies that will complement their existing product portfolio. For example, the acquisition of Viralytics by Merck & Co in 2018 was driven by the positive clinical results from the use of Viralytics lead therapy CAVATAK in combination with Merck & Co's leading checkpoint inhibitor Keytruda.
- As shown below, the size of deals varies greatly and any deal for CF33 will be dependent on the clinical trial results and the determined value of sales of CF33 with a companies existing drug portfolio.

Oncolytic Virus M&A Activity

Date	Buyer	Target	Value
2011	Amgen	Biovex	USD$424m + USD$575m milestones
November 2013	Sillajen	Jennerex	Not Disclosed
January 2015	Astrazeneca	Omnis	Not Disclosed
June 2015	Targovax	Oncos	Not Disclosed
November 2016	TNK Therapeutics	Virttu Bilogics	USD$5m
December 2016	Britol-Myers Squibb	PsiOxus NG-348	USD$50m + USD$886m milestones
December 2016	Ostuka	Takara Bio	Not Disclosed

Date	Buyer	Target	Value
December 2016	Pfizer	Ignite Immunotherapy	Not Disclosed
October 2017	Abbvie	Turnstone Biologics	Not Disclosed
November 2017	Adlai Nortye	Oncolytics Biotech's Reolysin	USD$21.2m + USD$65.4m
February 2018	Merck & Co	Viralytics	USD$394m
May 2018	Janssen Biotech	BeneVir Biopharm	USD$140m +USD900m in milestones
September 2018	Boehringer Ingelheim	Vira Therapeutics	EUR210m

Source: Vaxinia Pty Ltd

MARKET OPPORTUNITY FOR HER-VAXX AND PD1-VAXX

HER-Vaxx

- HER-Vaxx has the potential to improve on the efficacy of existing commercialised monoclonal antibodies used to treat cancer that over express the HER-2 protein. HER-Vaxx has the potential to replace the monoclonal antibodies as the monotherapy or be used in combination with immunotherapy treatments to improve the efficacy of these treatments without increasing toxicity.
- The company will be embarking on a study of HER-Vaxx with both immune checkpoint inhibitors as well as monoclonal antibodies to determine the potential efficacy of the combined treatment.
- Herceptin and Perjeta are two of the leading monoclonal antibodies used for HER-2 cancer treatment. In 2018, Herceptin generated sales of US$7.1 billion and Perjeta generated sales of US$2.8 billion, so there is a significant market for these products.
- The company will be seeking to undertake a trial of HER-Vaxx with Herceptin, a leading monoclonal antibody to determine the efficacy of the combined treatment. Positive outcomes may provide the potential for partnering opportunities with pharmaceutical companies that have monoclonal antibody products in their portfolio.
- In 2015, the FDA approved the combination of Opdivo (an immune checkpoint inhibitor) with Yervoy (monoclonal antibody) for the treatment of metastatic melanoma. This was the first immunotherapy combination to receive FDA approval and is now approved in over 50 countries. The combination has subsequently been approved for use in the treatment of a number of other advanced cancers, such as kidney and colorectal.
- The ability of pharmaceutical companies to improve sales of their products through combinations that improve efficacy is expected continue to drive interest in novel therapeutic combinations.

PD1-Vaxx

- PD1-Vaxx is an immune checkpoint inhibitor. These treatments have experienced significant growth in recent years with some of the leading immunotherapy treatment sales being checkpoint inhibitors.
- The leading monoclonal antibody immune checkpoint inhibitors are Keytruda, owned by Merck & Co., and Opdivo, which is owned by Bristol-Myers Squibb's. In 2018, Keytruda generated sales of US$7.2 billion and Opdivo generated sales of US$6.7 billion.
- In 2017, the global immune checkpoint inhibitor market was valued at over US$10 billion and is estimated to grow to in excess of USD$56.5 billion by 2025 according to Allied Market Research.
- Given the size and growth potential of the use of immune checkpoint inhibitors for not only single use but as a combination with other immunotherapy treatments for advanced stage cancers, provides a significant opportunity for IMU in the event the clinical trials yield positive results. PD1-Vaxx has the potential to elicit demand from pharmaceutical companies seeking to expand their oncology portfolio to include a checkpoint inhibitor treatment.

INVESTMENT VIEW

- An investment in IMU is speculative given the nature of its operations. The value of the company will be determined by the partnership or sales opportunities generated with big pharma, which in turn will be dependent on the clinical trial outcomes.
- IMU provides exposure to the immunotherapy market, which is a valuable and developing area of cancer treatment. There has been a significant increase in the number and value of transactions and collaborations in the immunotherapy market in recent years as companies seek to improve the efficacy of cancer treatment.
- One of the key factors driving interest from big pharma is the potential for improved efficacy from the use of a combination of immunotherapies. Big pharma are looking for novel therapies that will enhance their existing portfolio of oncology treatments.
- In the event the acquisition is approved, IMU will have three leading candidates that are expected to all be in clinical trials within the next 12 months. Pre-clinical and early stage clinical results have been encouraging. If the trial results are positive, there is the potential for significant value to be generated from these candidates.
- The company has an experienced board and management team that provide confidence in the ability of the company to identify and manage the development and sales process for the company's products.
- While there are a number of positives for the company with respect to the product pipeline and development, there are a number of risks associated with an investment in the company. In addition to the development risks associated with all clinical stage products, there are financial risks. The company currently has a healthy balance sheet and is expected to be able to fund the Phase II clinical trial for HER-Vaxx and the Phase I clinical trials for PD1-Vaxx and CF33, in addition to the Vaxinia and CF33 upfront acquisition costs. However, if a commercial arrangement is not secured on the basis of the results form these trials and the company is required to progress he development in-house, the company will likely have to raise additional capital. Given the current share price this will likely involve the issue of a significant number of shares and will likely be dilutive to existing shareholders.
- We expect positive results from the clinical trials and any potential sale/licence opportunities to be catalysts for the share price, with negative results from the trials likely to have a significant adverse impact.

RISKS

- **Clinical Development Risk:** Clinical trials entail significant risk with treatments in clinical trials having a binary outcome - they either work or they don't. As such, there is the risk that the products in clinical trials will not provide satisfactory outcomes and therefore will not progress. We note that the further into the clinical trial process therapies advance to the less risk there is associated with continued development of the therapy. In addition to the binary outcome, there is also timing risk. While companies will seek to complete trials in the allocated timeframe, there may be delays with patient recruitment that might result in delays to the completion of trials. Furthermore, given the advanced stage of cancer that the patients have may see some of the patient pool not being able to be evaluated, which may impact the outcomes.
- **Dilution Risk:** The Phase 1 PD1-Vaxx, Phase II HER-Vaxx and Phase I CF33 clinical trials are expected to be funded with existing cash reserves. However, in the event the results from the clinical trials are successful and the company does not engage with a pharmaceutical company, IMU will have to raise additional capital to progress the products. Given the current share price, a significant number of new shares will be required to be issued to raise sufficient capital in this event, which may dilute shareholders positions. We note that the capital raised in June 2018 was raised at a 12% discount to the weighted average closing price over the previous five trading days to the raising.
- **Regulatory Risk:** There is always regulatory risk associated with drug development. Developers are heavily reliant on the FDA or other regulatory bodies to determine whether or not a drug can progress through clinical trials and ultimately progress to market.

- **Competition Risk:** There has been an increase in the number of immunotherapy treatments under development due to the growth in the market. As such there will be increased competition for partnering opportunities with big pharma companies.
- **Foreign Exchange Risk:** The company is exposed to foreign currency risk given the clinical trials and product manufacturing is primarily done overseas. Therefore, movements in currencies can impact the Australian dollar cost.
- **Capital Risk:** We do not expect IMU will have to raise capital in the next 12-months, however, in the event the trials are accelereated, unexpected costs are encounctered or there is another acquisition, the company may need to raise capital.

BOARD AND MANAGEMENT

Leslie Chong - Managing Director and CEO: Ms. Chong has over 20 years' experience in oncology clinical development programs. Ms. Chong was previously the Senior Clinical Program Lead at Genentech, a significant player in the global biotech market. Ms. Chong has also worked at the global pharmaceutical companies GSK and Exelixis.

Paul Hopper - Executive Chairman: Mr. Hopper is the founder of IMU. Mr. Hopper has extensive experience in biotech capital markets both domestically and internationally. Mr. Hopper specialises in immuno-oncology and vaccines. Mr. Hopper was formerly the Chairman of Viralytics Limited which was sold to Merck & Co in 2018, and is the Founder and Director of Prescient Therapeutics Limited (ASX: PTX) and Chairman of Suda Pharmaceuticals Ltd (ASX: SUD).

Dr. Axel Hoos - Non-Executive Director: Dr. Hoos is a Senior Vice President and Head of Oncology at GSK. Dr. Hoos is also currently the Chairman of the Sabin Vaccine Institute and Co-Chair of the Cancer Immunotherapy Consortium Think-Tank. Dr. Hoos was formerly the Medical Lead for Yervoy, the first immunotherapy treatment to improve survival.

Charles Walker - Non-Executive Director: Mr. Walker has extensive financial markets experience having executed over 50 cross border transactions. Mr. Walker has held senior executive positions at Alchemcia Limited (ASX: ACL) and Imugene Limited (ASX: IMU). Mr.Walke's clinical experience includes managing a pipeline of drugs in all stages of discovery through to product launch.

Dr. Lesley Russell - Non-Executive Director: Dr. Russell has over 25 years' of senior international operational and leadership experience having worked at Amgen, Eli Lilly, Teva and Cephalon. Dr. Russell has extensive knowledge and experience with new drug development.

Dr. Jens Eckstein – Non-Executive Director: Dr. Eckstein is the Managing Partner of Apollo Ventures, Former president of SR One Ltd., the VC arm of GSK, 15+ years' in VC experience funding early to clinical stage biopharmaceutical companies. Dr. Eckstein has extensive experience as chairman, board of director and founder of several biotechnology and venture capital companies. Creator of OneStart, the world's largest life science accelerator.

Dr. Mark Marino - Chief Medical Officer: Dr. Marino has over 28 years' of experience in drug development. Dr. Marino was formerly the Chief Medical Officer of Cytori, Head of Clinical Pharmacology at Eisai and Roche, Head of Research and Development at Mannkind and Vice President of Clinical Development at Daiichi.

Dr. Nick Ede - Chief Technology Officer: Dr. Ede has over 25 years' experience with peptide vaccines and drug development. Dr. Ede was formerly Vice President of Chemistry Chiron (now Novartis) and Research Fellow CRC Vaccine Technology.

Dr. Anthony Good - Vice President of Clinical Research: Dr. Good has over 20 years' experience in clinical development. Dr. Good has been integral to the development of a number of medicines including Viagra, Revatio, Lipitor and Somavert. Dr. Good previously worked with Pfizer Global Research and Development and Covance Clinical Services.

SCIENTIFIC ADVISORY BOARD

Professor Pravin Kaumaya: Professor Kaumaya is a Professor of the Medicine Department of Obstetric Gynecology at Ohio State University. Professor Kaumaya's research focus is on tumour immunology, mechanisms of tumour sell-immune cells interactions and immune mechanisms. His focus is on the field of vaccines, with a particular focus on peptide vaccines for cancer.

Dr. Michael Caligiuri: Dr. Caligiuri is the President of City Hope National Medical Centre and holds the Deana and Steve Campbell Physician-in-Chief. Dr. Caligiuri was elected President of the American Association for Cancer Research (AACR) in 2017.

Professor Josep Tabermero: Professor Tabermero is President of the European Society for Medical Oncology, President of the Medical Oncology Department at the Vall d'Hebron and Director of the Vall d'Hebron Institute of Oncology.

Professor Tanios Bekail Saab: Professor Bekail Saab is a Professor at the College of Medicine and Science. He is a Program Co-Leader for GI cancer at the Mayo Clinical Cancer Centre and Medical Director at the Cancer Clinical Research Office.

Professor Ursula Wiedermann-Schmidt: Professor Wiedermann-Schmidt is the co-inventor of HER-Vaxx and is a Professor of Vaccinology at the Medical University of Vienna.

Dr. Nigel Segal: Dr. Segal is a Medical Oncologist with expertise in GI, colon and pancreatic cancers. Dr. Segal is an active clinical immuno-oncology researcher and has been the clinical lead in several trials using PD-L1 inhibitors.

Dr. Yelina Janjigian: Dr. Janjigian in a Medical Oncologist with expertise in esophageal and gastric cancer. Dr. Janjigian is active in GI clinical trials testing combinations of Her-2 and checkpoint inhibitor therapies.

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INDEPENDENT
INVESTMENT RESEARCH

Independent Investment Research (Aust.) Pty Limited

SYDNEY OFFICE
Level 1, 350 George Street
Sydney NSW 2000
Phone: +61 2 8001 6693
Main Fax: +61 2 8072 2170
ABN 11 152 172 079

MELBOURNE OFFICE
Level 7, 20–22 Albert Road
South Melbourne VIC 3205
Phone: +61 3 8678 1766
Main Fax: +61 3 8678 1826

DENVER OFFICE
355 S Teller Street
Suite 200
Lakewood 80226
Denver Colorado USA
Phone: +1 161 412 444 724

MAILING ADDRESS
PO Box H297 Australia Square
NSW 1215