



Imugene Ltd. (ASX: IMU)

April 18, 2016**Target Price: A\$0.035****Recent Price: A\$0.011**

Market Data

Fiscal Year	June
Industry	BioTech
Market Cap	A\$17.3M
Price/Earnings (ttm)	N/A
Price/Book (mrq)	1.6x
Price/Sales (ttm)	411x
Top 20 % Ownership	32.9%
Shares Outstanding	1.7B
Equity Float	960.7M
Avg. Volume (3 mo.)	3.1M
As of April 15, 2016	

Income Statement Snapshot

	TTM
Revenue	A\$0.04M
Net Loss	A(\$2.4M)

Balance Sheet Snapshot

	MRQ
Cash	A\$3.7M
Debt	A\$0.0M

Company Website

www.imugene.com/

Company Overview

Imugene (“Imugene,” “IMU,” or the “Company”) is an immune-oncology biopharmaceutical company developing HER2 positive gastric and breast cancer immunotherapies. The Company’s lead product, HER-Vaxx, has successfully completed a Phase I study in patients with breast cancer and the next stage of development will be a Phase Ib/II study in patients with gastric cancer. HER-Vaxx is a proprietary HER2 positive cancer immunotherapy that stimulates a polyclonal antibody response to HER-2/neu. HER-2/neu is a known and validated receptor over-expressed on various tumors including gastric, breast, ovarian, lung, and pancreatic cancers. Imugene’s corporate headquarters are located in Melbourne, Australia with the scientific team in Vienna, Austria.

Valuation

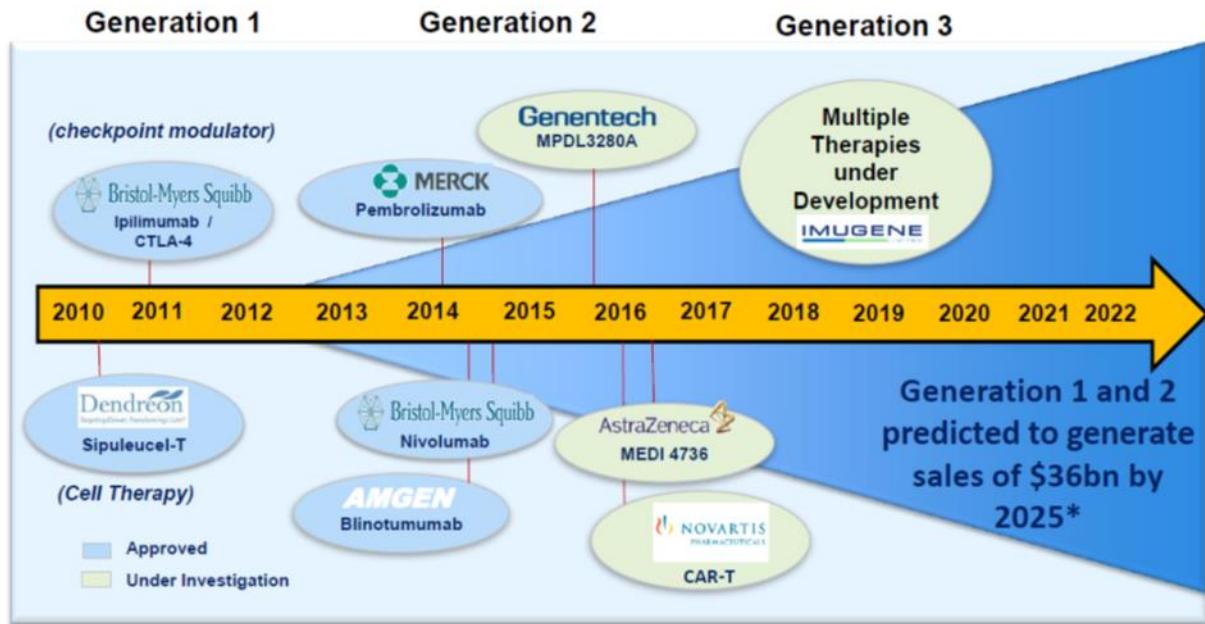
Our valuation of IMU is based on an NPV model for HER-Vaxx in gastric cancer. Our per share valuation is A\$0.035.

Investment Highlights

- HER-Vaxx is a next generation HER-2 cancer immunotherapy using B Cell peptides
- Current T Cell therapies have shown efficacy improvements; however, cost per patient remains high
- HER-Vaxx’s mechanism of action may generate improved efficacy at a lower cost
- HER-Vaxx induces a broad immune system response
- Targets same receptor (plus additional receptors) as Herceptin, Roche’s \$6.9 billion breast cancer drug
- Phase I results displayed a strong antibody and overall immune system response in metastatic breast cancer patients
- Improvements have been made to HER-Vaxx vaccine since Phase I trial; greater antibody (10x) response, lower COGS, and faster immune response
- Positive Phase I results provide the basis for a Phase Ib/II trial in HER2 positive gastric cancer
- Gastric cancer is the second leading cause of cancer death worldwide (738,000 deaths, or 10.4% of cancer cases)
- Preclinical study shows HER-Vaxx improves growth inhibition of breast cancer cells as compared to Herceptin
- Novel mimotope technology platform allows IMU to reverse engineer any antibody and induce a potent antibody response to an identified oncology target
- Strong leadership and experienced management team
- IP with exclusivity until 2030, and further patent life extensions are underway

Investment Highlights

HER-Vaxx is a next generation HER-2 cancer immunotherapy using B Cell peptides. HER-Vaxx is a cancer immunotherapy which induces a patient-generated antibody response. This approach turns a patient's body into an "antibody factory." Other immunotherapies have focused on T Cells, which has often involved manufacturing/reprogramming T Cells outside the body, and then inserting these cells into the patient. The following chart shows an overview of the various generations of immuno-oncology therapies. These therapies include checkpoint modulators and cell therapies:



According to Jill O'Donnell-Tormey, who is the CEO of and director of scientific affairs at the Cancer Research Institute, more than half of current cancer trials focus on immunotherapy, thus validating the viability of this approach. To date, each subsequent generation of immunotherapy development has seen an increase in the median cancer survival rate.

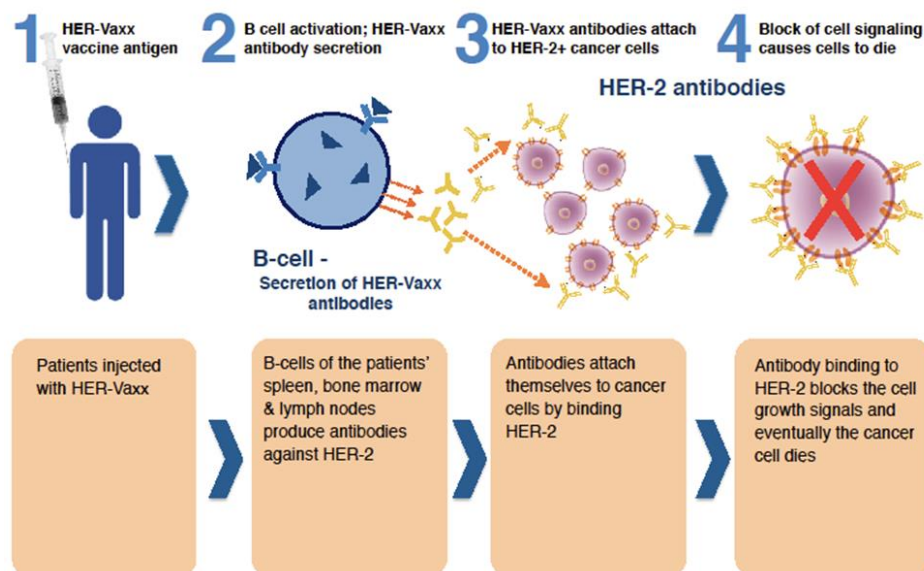
Current T Cell therapies have shown efficacy improvements; however, cost per patient remains high. Checkpoint modulators represent the four most recently approved immunotherapies (blinatumumab combines checkpoint modulator/cell therapy features). These immunotherapies essentially take the "brake" off of the immune system and allow it to work more effectively.

Checkpoint modulators are antibodies, and are easier to make than cell therapies such as Dendreon's Sipuleucel-T. Easier manufacturing has led these therapies to be more economically feasible, although the cost for each of these therapies is still very high. The currently approved checkpoint modulators range from approximately \$103,000-\$178,000 per patient, and higher doses currently being tested could cause the cost of these therapies to skyrocket further. Additionally, while combination therapies have shown efficacy benefits in clinical trials, the cost per patient is exorbitant. According to Dr. Leonard Saltz from Memorial Sloan Kettering Cancer Center, the cost of using ipilimumab and nivolumab as a combination therapy for metastatic melanoma is projected to cost \$295,566 per patient.

Other immunotherapies involve T cells or other immune system cells being manufactured or reprogrammed outside of the body. These manufactured/reprogrammed cells are then inserted into the body. However, due to the complex nature of manufacturing T Cells, it has been difficult to make many of these therapies commercially viable. There are hopes that reducing the needed dosage will bring costs down enough to make these therapies economically feasible, although recent clinical trials have actually experimented with dosage increases.

HER-Vaxx's mechanism of action may generate improved efficacy at a lower cost. HER-Vaxx's B Cell immunotherapy involves teaching B Cells to make antibodies for tumor cells. This turns the patient's body into an "antibody factory."

After injection with HER-Vaxx, B Cells in the patients' spleen, bone marrow, and lymph nodes produce anti-HER-2 antibodies. These antibodies attach themselves to HER-2, blocking cancer cell growth. Eventually, the cancer cell dies.

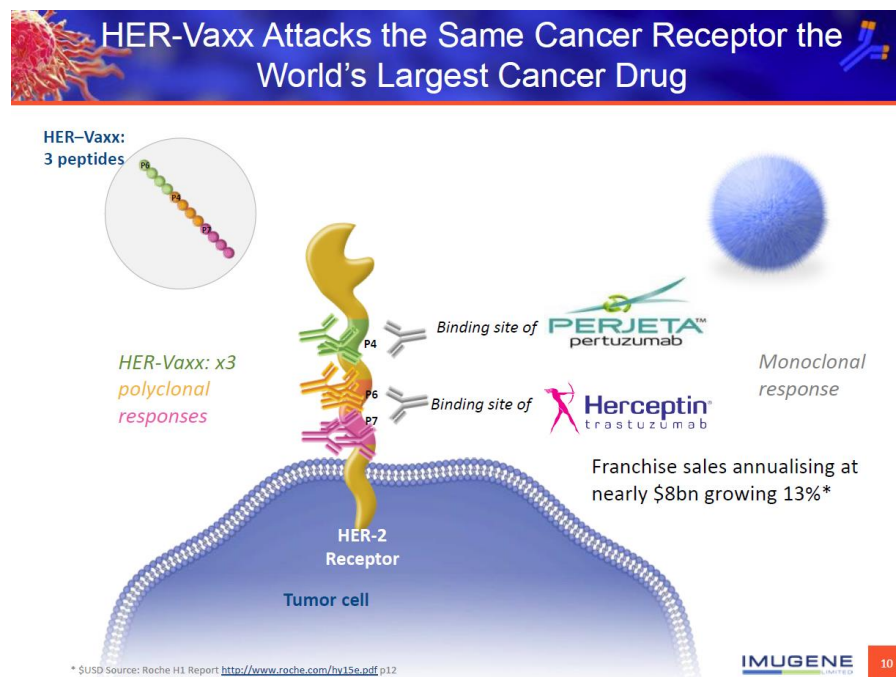


B Cell peptide vaccines may represent the next wave of opportunity in cancer immunotherapy. B Cell vaccines are thought to have a number of advantages over other, mostly T Cell-oriented, immunotherapies as well as monoclonal antibody drugs that represent 'passive' immunotherapy.

- B Cell peptide vaccines have a high chemical stability, helping to ensure that the therapy remains unchanged during storage.
- HER-Vaxx is an active immunization which induces immunological memory over time. Drugs such as Herceptin are passive immunization, whose effectiveness depends upon frequent applications. These frequent applications can drive costs upward significantly.
- Frequent applications can also lead to drug resistance. Active immunotherapy may be able to more effectively circumvent this problem.
- HER-Vaxx also has no HLA restriction, which is an advantage over T Cell-oriented immunotherapy approaches. HLA restrictions may reduce the size of the patient population eligible for T Cell vaccines. HER-Vaxx is a universal vaccine and can be used no matter the patients' HLA haplotypes.

HER-Vaxx induces a broad immune system response. In addition to the antibody response described above, HER-Vaxx causes a broad activation of the humoral and cellular immune response. B Cell vaccines induce T Cell responses and cytokine production, along with potentially cross-presenting to CD8 T Cells. T Cells are a type of white blood cell that is of key importance to the immune system and is at the core of adaptive immunity, the system that tailors the body's immune response to specific pathogens. The T Cells are like soldiers who search out and destroy the targeted invaders. HER-Vaxx may help sicker patients with weaker immune systems rebuild their body's natural defenses over time, due to immune memory. This could be especially useful in patients with late stage cancer.

Targets same receptor (plus additional receptors) as Herceptin, Roche's \$6.9 billion breast cancer drug. The three peptides in HER-Vaxx induce a polyclonal antibody response to the HER-2 receptor, meaning multiple and differing antibodies bind to the target. By contrast the successful and approved HER-2 receptor drugs, such as Herceptin and Perjeta, target only one site with a monoclonal antibody, i.e. single type of antibody.

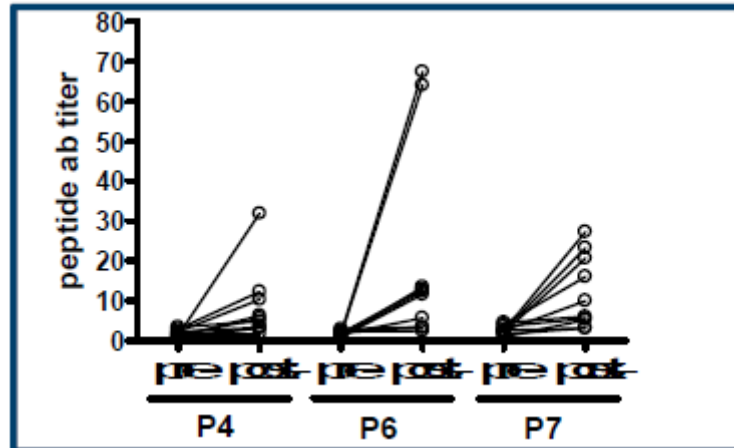


This polyclonal antibody response may cause a superior overall response. Herceptin and Perjeta are currently used in combination for HER-2 breast cancer, as this combination improves survival rates. This is thought to occur because Herceptin and Perjeta bind to different sites of the HER-2 receptor, thus providing a more comprehensive blockade of HER-2 driven signaling pathways. HER-Vaxx binds to both of these sites, along with a third site on the HER-2 receptor. This gives the potential for an even stronger blockade of HER-2 driven signaling pathways.

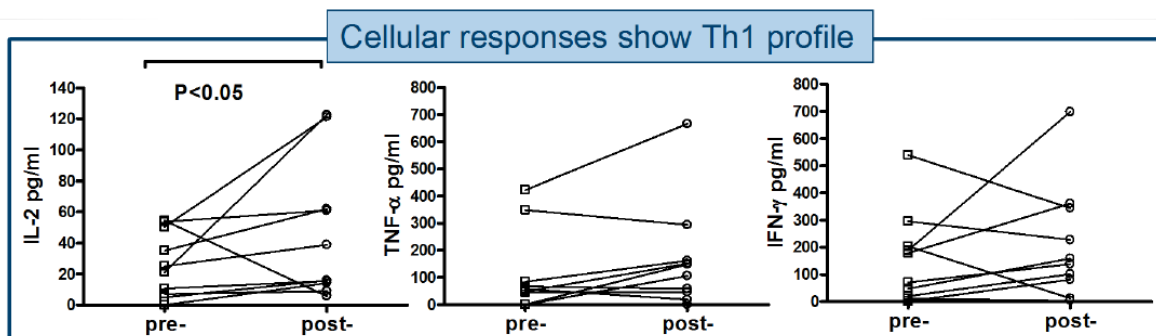
Phase I results displayed a strong antibody and overall immune system response in metastatic breast cancer patients. Imugene performed a Phase I trial for patients who had breast cancer. The trial had 10 metastatic breast cancer patients with a life expectancy of greater than four months. All patients also exhibited the HER-2 +/++ subtype. The clinical endpoints of the trial included safety and tolerability, along

with the development of anti-HER-2 antibodies. Positive results from the Phase I breast cancer study include:

- An anti-HER-2 antibody response in 7/10 patients. The antibodies showed strong anti-tumor activity, with the largest responses from the p7 and p6 sites. The chart below indicates the polyclonal antibody response that was observed:

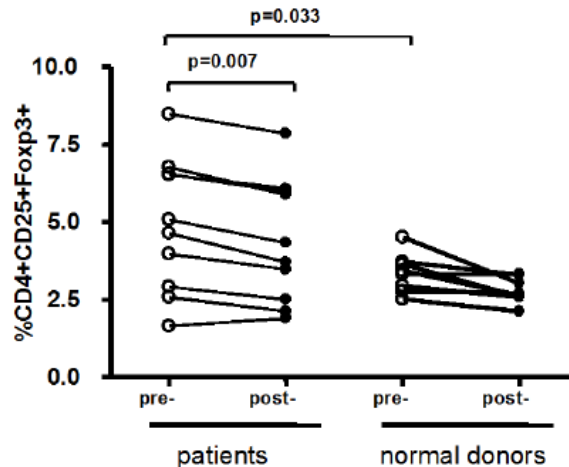


- The majority showed a 4-fold increase in influenza titers. The vaccine used in this study was formulated with influenza ‘virosomes’, that is particles from the influenza virus added in to increase the overall immune response from the vaccine. This fourfold rise in influenza titer suggested that this strategy was successful.
- An increase in T helper (Th1) cytokines, as indicated by increases in IL-2, TNF- α , and IFN- γ . Cytokine therapies have been around for a few decades, and while these therapies have not delivered the benefits to patients that physicians originally hoped for, they do confer benefits and an increase in Th1 cytokines is a positive sign.



HER-Vaxx showed an increase in IFN- γ in most patients (as indicated in the chart on the far-right). Increases in IFN- γ can influence the tumor microenvironment in a positive manner, such as through the reduction of Treg cells, which was seen in the trial results.

- A decrease in Treg cells. Increased Treg cells are correlated with an increase in the presence and severity of cancer. This is because Treg cells enhance tumor evasion mechanisms. Treg cells also can “put the brakes” on the immune system, lowering overall immunotherapy effectiveness. If the Treg cell count can be lowered, the efficacy of cancer treatment should improve. The left-hand portion of the chart below shows the declines in Treg cells pre and post-therapy, and the entire chart shows how Treg cells compare to levels seen in normal donors.



- The therapy was shown to be safe at the dosage used. Only four of the ten patients had grade one local reactions. There were no systemic reactions. Other immunotherapies have had a portion of patients show significant immune related reactions.
- The patients were metastatic breast cancer patients and thus had poorer prognosis than early-stage breast cancer patients. Patients were aged 55-84, and most had metastatic cancer for a fairly extended period of time. Older patients are more likely to show immunosuppression, and thus we find immune system activity in older patients to be a very positive sign.

Overall, HER-Vaxx displayed excellent immunogenicity even at low doses and in patients up to 84 years of age. A strong overall, broad immune response was seen. In our view, it is also promising that both an overall active immune response was seen in conjunction with a decline in T Reg cells. Immune system response is the standard immunotherapy measurement in Phase I trials.

Improvements have been made to HER-Vaxx vaccine since Phase I trial; greater antibody (10x) response, lower COGS, and faster immune response. Following the Phase I trial, IMU conducted preclinical studies which changed its vaccine conjugate from virosomes to CRM₁₉₇. The benefits expected from this are:

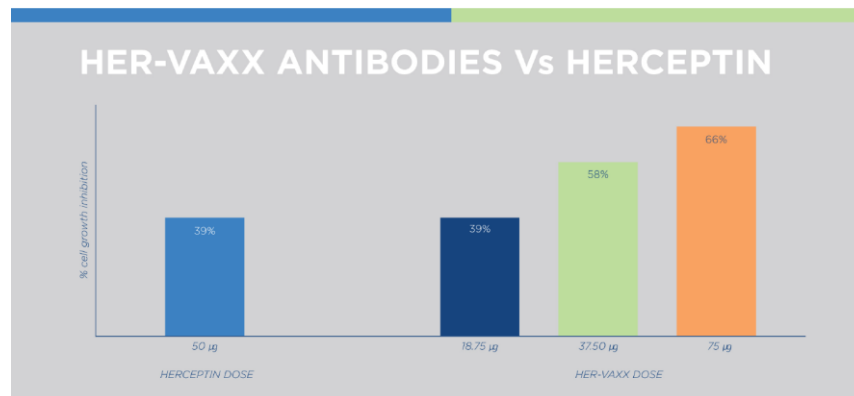
- Earlier antibody titer increase, which is significant after two vaccinations and a peak response was reached after three vaccinations. This will generate a faster immune response, which should improve efficacy, in our view. Immunotherapy normally requires at least weeks of therapy to begin seeing an effect.
- 10x the antibody production of the previous formulation. This will lead to either greater antibody production at the same dose, or the same antibody production at a cheaper dose. This should have a positive effect on both efficacy and the cost of therapy.
- A simpler, lower cost, and less risky manufacturing process. Given the manufacturing and cost difficulties with immunotherapies, this is a significant positive.
- Phase I trial results were positive, and the new formulation should improve results and increase the probability of success of the Company's upcoming Phase Ib/II clinical trial.

Positive Phase I results provide the basis for a Phase Ib/II trial in HER-2 positive gastric cancer. The study will be conducted in two parts. The initial Phase Ib trial is expected to start in the second half of 2016. This will be an open-label dose escalation study designed to evaluate the safety and immunogenicity of the product to select the optimal phase II dose. The larger phase II study will be a randomized controlled

study of HER-Vaxx plus standard-of-care against standard-of-care alone. The trial will take place in Asia, given the higher incidence rates of gastric cancer in Asia.

Gastric cancer is the second leading cause of cancer death worldwide (738,000 deaths, or 10.4% of cancer cases). Gastric cancer is the second most common cause of cancer death and the fourth most commonly diagnosed cancer, with over one million new cases diagnosed each year. Incidence tends to be highest in Asia, South America, and Eastern Europe, and the Company's upcoming clinical trial will take place in Asia. Japan, South Korea, and China have incidence rates of 85, 64, and 30 per 100,000 individuals; these rates are much higher than the average incidence rate of 13.5 per 100,000 individuals. Various analysis of HER-2 expression in gastric cancer indicates that approximately 7%-34% of gastric tumors show overexpression of HER-2. HER-2 overexpression correlates with more aggressive and deadly cancer.

Preclinical study shows HER-Vaxx improves growth inhibition of breast cancer cells as compared to Herceptin. A recent in-vivo study showed that HER-Vaxx improved the growth inhibition of breast cancer cells at comparable doses of Herceptin, and that it showed the same growth inhibition as Herceptin at only one-third of the dose. The following chart shows these results:



While this is a preclinical result, this indicates the potential for HER-Vaxx to potentially be a superior option to Herceptin.

Novel mimotope technology platform allows IMU to reverse engineer any antibody and induce a potent antibody response to an identified oncology target. Imugene also has a mimotope technology platform. The platform allows Imugene to reverse engineer any antibody and produce a peptide mimic of the antibody's target (i.e. epitope). These mimotopes are designed to induce a specific and potent antibody response to an oncology target. Targeted therapy for cancer has become much more important, and new research and insights are consistently developed regarding which genes/pathways should be targeted for cancer treatment. Mimotope technology gives IMU the ability to target these genes/pathways, and generate a B Cell immune response. This greatly expands the Company's potential oncology franchise and pipeline, as this can be used to develop vaccine candidates against various tumors. Four mimotopes candidates are expected to be identified by the end of 2016. Preclinical *in vivo* and *in vitro* results are expected for the Company's 1st mimotope candidate in 2H16.

Strong leadership and experienced management team. Leslie Chong was appointed COO in 2015. Previously, Ms. Chong headed up oncology programs as a senior clinical program lead at Genentech. We note that Genentech also markets Herceptin in the U.S. Professor Ursula Wiedermann is the Chief

Scientific Officer, who co-invented the technology at the Medical University of Vienna. Dr. Axel Hoos is a VP at GSK, and his only board position is at IMU. Dr. Hoos headed the development for Bristol-Myers Squibb's Yervoy, the pioneering CTLA-4 immunotherapy drug ipilimumab. His prior success in immunotherapy should bode well for IMU as they develop their clinical trials, and also speaks to the potential of HER-Vaxx.

IP with exclusivity until 2030, and further patent life extensions are taking place. These patents cover all major potential revenue generating countries. Further, the Company's recent reformulation could potentially extend the patent timeline until 2036. This ensures strong revenue and profit potential for many years following a regulatory approval.

Valuation

As the following peer chart indicates, IMU, based on market cap, exhibits a significant undervaluation as compared to other companies that are developing active cancer immunotherapies that have their lead compounds in either phase I or phase II (GALE is in phase III with a HER-2 peptide vaccine for early-stage, node-positive breast cancer with low-to-intermediate HER-2 expression).

Company Name	Ticker	Price (USD)	Market Cap (USD)	Cash (MRQ)	Debt (MRQ)
TapImmune Inc	TPIV	\$0.62	\$39.9M	\$6.1M	\$0.0M
Trillium Therapeutics Inc	TRIL	\$11.14	\$87.3M	\$62.7M	\$0.2M
Viralytics Ltd	VLA	\$0.51	\$121.4M	N/A	N/A
Affimed NV	AFMD	\$4.50	\$149.7M	\$83.3M	\$5.0M
Northwest Biotherapeutics Inc	NWBO	\$1.60	\$162.3M	\$21.8M	\$22.7M
Galena Biopharma Inc	GALE	\$1.55	\$281.7M	\$29.7M	\$4.7M
Immune Design Corp	IMDZ	\$15.08	\$303.9M	\$112.9M	\$0.0M
Advaxis Inc	ADXS	\$9.66	\$329.4M	\$106.8M	\$0.0M
Adaptimmune Therapeutics PLC	ADAP	\$9.48	\$671.0M	\$247.4M	\$0.0M
NantKwest Inc	NK	\$10.04	\$822.6M	\$294.2M	\$2.5M
Aduro Biotech Inc	ADRO	\$13.20	\$851.6M	\$150.5M	\$0.0M
		Median	\$281.7M	\$95.1M	\$0.1M
		Average	\$347.3M	\$111.5M	\$3.5M
Imugene Ltd	IMU	\$0.01	\$13.3M	\$2.9M	\$0.0M

Source ThomsonReuters, all figures in USD

As of April 15, 2016

We believe that the main reasons behind this undervaluation are the lower visibility of Imugene on the ASX relative to other companies that are listed in the United States, and a lower cash balance relative to peers, which lowers the number of indications that can be currently studied for HER-Vaxx. We believe that the extent of the undervaluation relative to the comp group is unwarranted, given the Company's strong and promising phase I results in HER-2 positive metastatic breast cancer patients, and the support of strong key opinion leaders in cancer immunotherapy.

The above peer chart does not cover the entire universe of cancer immunotherapy companies, but gives a range of potential valuations. Immunotherapy companies with large pipelines of potential drugs/indications are being given higher market valuations; based on our analysis, immunotherapy companies with a deep pipeline are valued at market caps, on the low end, of \$150-\$200 million, and some early-stage immunotherapy companies are receiving market caps of \$1 billion+. IMU's mimotope program has the potential to generate a similarly deep pipeline, and four new mimotopes are expected to be identified by the

end of 2016, with preclinical results available from the 1st mimotope in 2H16. We believe that successful development of the Company's mimotope platform could lead to a significant increase in market cap, potentially into the \$150-\$200 million market cap range.

Our valuation of IMU is based on an NPV model for HER-Vaxx in gastric cancer. Our per share valuation is A\$0.035. Key assumptions of our model are the following:

- Over one million new cases of gastric cancer are diagnosed each year; 29% of these cases are in developed countries, and 7%-34% of gastric cancer patients are estimated to be HER-2 positive. We are assuming that HER-Vaxx will only be sold in developed countries, and we estimate 22% of gastric cancer patients to be HER-2 positive. This gives us an estimated population for HER-Vaxx for HER-2 gastric cancer of 63,800 patients in 2016. We estimate this population to grow at 1% per year.
- Our price per patient for HER-Vaxx is estimated at A\$138,000 (or USD\$100,000). This is slightly below the low end of current prices for cancer immunotherapies.
- We assume that IMU will partner with a large pharma/biotech company to take HER-Vaxx to market. This is due both to the capital needed to run a Phase III trial, and the fact that gastric cancer incidence is mostly in Asia and Europe. This indicates that a pharma with a large worldwide salesforce will be needed to help HER-Vaxx reach its ultimate potential in gastric cancer.
- We assume a license payment in conjunction with a partnership after the conclusion of the Phase II trial. This payment is estimated at A\$104.3 million (or USD\$80 million). Future estimated milestone payments total A\$234.6 million (or USD\$180 million). License/milestone payments in other cancer immunotherapy deals have been higher. Recent immunotherapy deals include Alligator and Janssen (\$700 million in milestones and fees plus royalties), Juno and Celgene (\$1 billion), Innate Pharma and AstraZeneca (\$1.3 billion in milestones and fees plus royalties), Prosvac and Bristol-Myers Squibb (\$975 million in milestones and fees plus royalties), and Flexus and Bristol-Myers Squibb (\$1.25 billion). These deals were completed in various stages of development (from preclinical through Phase III). Our projected milestone payments are lower as we are only assuming rights for gastric cancer in the deal; we believe that rights for all indications would earn fees in line with other immuno-oncology deals completed in 2015/2016.
- We project HER-Vaxx to enter the market in 2026.
- We are projecting a 35% probability of HER-Vaxx passing Phase II trials and a 17.5% probability that HER-Vaxx passes Phase III trials and a NDA. This is slightly above historical rates for overall cancer trial success rates, which we think is reasonable, as targeted therapies have shown higher success rates in cancer than nontargeted therapies.
- We are projecting 2.8 billion in fully diluted shares outstanding, which accounts for an additional capital raise to help fund a Phase II trial in HER-Vaxx.
- Our valuation does not take into account any other potential indications (other HER-2 positive cancers include breast, ovarian, bladder, and non-small-cell lung cancer), nor any platform expansion from the Company's mimotope platform. This provides upside to our target price, and further successful development of IMU's mimotope platform would likely lead to target price increases.

Risks

There is no guarantee that the Company's Phase Ib/II trial for gastric cancer will show statistically significant efficacy. There is no guarantee that the Company will achieve its primary endpoint in either of its current clinical trials. However, the Company has shown very promising efficacy data in previous trials for HER-Vaxx.

IMU's future capital needs are uncertain. IMU is currently in a Phase Ib/II trial for gastric cancer. While near-term capital needs are fairly certain, longer-term capital needs are uncertain, and will be driven by such factors as clinical trial results, potential partnering with other pharma or biotech companies, and initiating clinical trials in new diseases. Depending on how multiple factors occur, the Company's capital raise needs could change significantly.

There is no guarantee that HER-Vaxx will show acceptable safety. Other immunotherapies, including approved immunotherapies, have shown significant adverse events in clinical trials. There is no guarantee that HER-Vaxx will be shown to have proven safety. That said, the Phase I trial in HER-Vaxx showed no significant adverse events.

There may be difficulty in determining acceptable dosage on a patient to patient basis. Prior clinical trials in immunotherapies have shown that some patients may require a larger or smaller dose of an immunotherapy to achieve the best results. Failing to design a clinical trial with the proper dosage could negatively skew either efficacy or safety results.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
HER-2 Gastric Cancer Patients VW (Developed Countries Only)	63,800	64,438	65,082	65,733	66,391	67,054	67,725	68,402	69,086	69,777	70,475	71,180	71,891	72,610	73,336
Price of HER-Vaxx Per Patient	A\$130,000	A\$131,300	A\$132,613	A\$133,939	A\$135,279	A\$136,631	A\$137,998	A\$139,378	A\$140,771	A\$142,179	A\$143,601	A\$145,037	A\$146,487	A\$147,952	A\$149,432
Penetration Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	2%	6%	10%	15%	20%
Total Sales	0	0	0	0	0	0	0	0	0	0	202,405,124	619,420,400	1,053,117,917	1,611,428,381	2,191,757,456
Royalty Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	8%	8%	9%	12%	14%
Royalty Revenue	0	0	0	0	0	0	0	0	0	0	16,192,410	49,553,632	94,780,613	193,371,406	295,887,257
License Payment (assuming successful phase 2 trial)															
Milestone Payment (assuming successful phase 3 trial)															
Milestone Payment (assuming successful NDA)				104,336,496					179,400,000	55,200,000					

Discount Rate	8%
NPV (License Payment)	A\$76.7M
Prob of Success (License Payment)	35%
NPV (Milestone & Royalties)	A\$26.8M
Prob of Success (Milestones & Royalties)	17.5%
	A\$58.8M

Combined NPV	A\$95.6M
Net Debt	-A\$3.7M
Cash from options/warrants	A\$6.8M
Fully Diluted Shares Outstanding (includes additional shares to represent potential future equity raises)	2766.5M
Price Per Share	A\$0.095

Additional Information

Auditor: Grant Thornton Audit Pty Ltd

Transfer Agent: Computershare Investor Services Pty Ltd

[Company Information](#)

[Company Website](#)

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