

## Imugene Limited

### Recommendation: Speculative Buy

Sector: Pharma & Biotech

Share price target:	\$0.034 - \$0.047
ASX Code:	IMU
Share Price:	\$0.01
52 Week -	
High:	\$0.022
Low:	\$0.008
Current Ordinary Shares:	1,156.6M
Unlisted Options:	50.0M
Cash:	\$2.98M
Market Cap:	\$11.5M

### Major Shareholders (pre-new issue)

Top 20 shareholders:	53.4%
WebInvest	6.6%
Tisia Nominees	6.3%
JK Nominees	6.3%

### Directors

<b>Executive Chairman:</b>	Paul Hopper
<b>CEO:</b>	Charles Walker
<b>Non-Executive Directors:</b>	Dr. Axel Hoos Otto Buttula

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## Imugene is undervalued v ASX, global peers in Immuno-Oncology

- **Imugene Ltd** (ASX:IMU) is an immuno-oncology company developing B-cell based immunotherapies, known as HER-Vaxx for HER-2 positive gastric and breast cancer.
- Immunotherapy has become one of the hottest and most promising areas of study for the treatment of a variety of cancerous tumours, and includes a just announced joint venture between Pfizer and Merck to commence on up to 20 preclinical immuno-oncology programs in 2015.
- From January 2013 to August 2014 an index made up of U.S. immuno-oncology companies increased in value by 262.9%, when compared to a NASDAQ biotechnology index that increased by 102.2%, and the S&P500 that increased by 40.5%.
- HER-Vaxx technology is compelling science that was developed by one of Europe's leading cancer institutes. Approximately \$10 million has already been invested in the technology.
- Imugene's ownership of Her-Vaxx technology is protected by long life patents that do not expire until 2030
- Imugene is focussed on a developmental pathway that will generate multiple catalysts and value inflexion points over the coming 12 months.
- Her-Vaxx has potential to improve upon Roche's blockbuster Herceptin drug that generated annualised sales of \$6.9 billion and targets the same biomarker.
- A current Share Purchase Plan at \$0.01 per share provides shareholders with an ability to acquire shares without brokerage costs.
- Imugene is significantly undervalued when compared with its ASX peers, and even more undervalued when compared against listed global peers and against recent U.S. transactions in the same field (see analysis and valuation).
- **Proactive Investors** initiates a 6- 12 month share price target of \$0.034 - \$0.047. **Speculative Buy.**

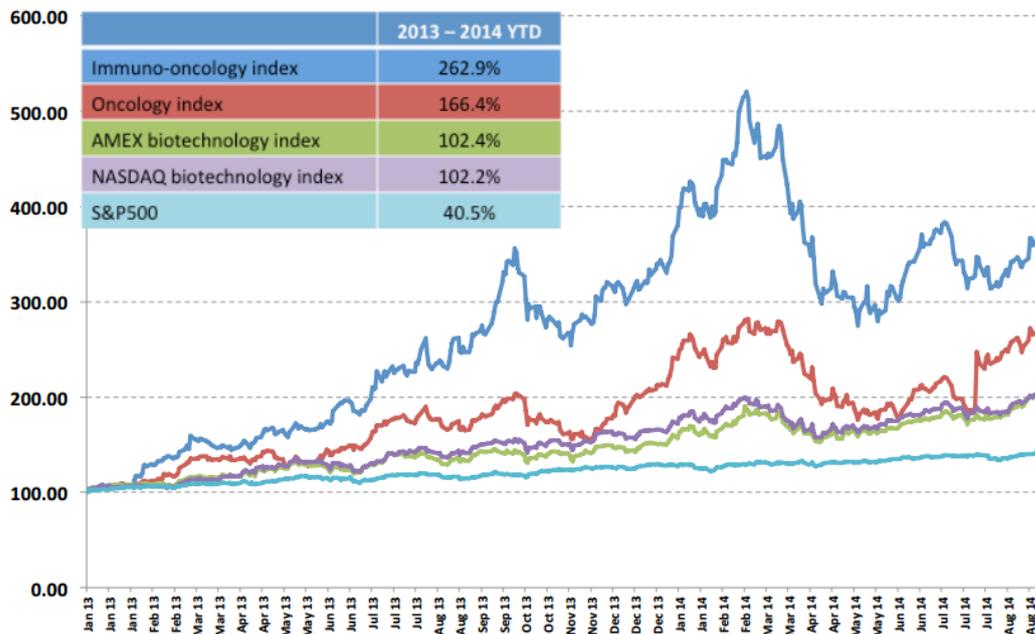


IMAGE ONE: IMMUNE-ONCOLOGY SECTOR EXHIBITS VERY DYNAMIC APPRECIATION

## BACKGROUND

**Imugene Limited** (ASX:IMU) is an ASX listed immuno-oncology focused biopharmaceutical company developing HER-2+ gastric and breast cancer immunotherapies.

In December 2013 the Company completed the purchase of Biolife Science, which owned the rights to an exciting gastric and breast immuno-oncology cancer drug, known as Her-Vaxx. This drug was under development at the Medical University of Vienna in Austria, one of the largest hospital campuses in Europe.

Her-Vaxx shows great promise as a potential treatment for Her-2 positive gastric and breast cancer, and has completed Phase 1 clinical trials in Europe.

Plans are well advanced to take the drug into Phase II trials next year, with Imugene driving an active manufacturing program which is now underway. In July 2014 the Company announced the engagement of Swiss-based Mymetics SA to exclusively develop and manufacture its HER-Vaxx cancer immunotherapy. Mymetics brings specialist experience and expertise to the formulation, manufacture, and quality assurance of virosomes which form the principal delivery mechanism for Imugene's HER-Vaxx.

## MANAGEMENT TEAM BOLSTERED AFTER ACQUISITION OF BIOLIFE SCIENCE

Imugene has assembled a distinguished team at Board and management level, both domestically and globally.

Dr. Axel Hoos of GlaxoSmithKline plc joined the Board in December of 2013. Dr. Hoos is an outstanding scientist that brings a wealth of experience in immuno-oncology to the Company, and was part of the team that developed Yervoy at BMS.

In August 2014 Charles Walker was appointed as Chief Executive Officer. He is a seasoned biotech leader that has executed nearly 50 international fundraisings both as principal and advisor. Most recently he was CEO as well as former CFO of ASX listed biotech Alchemia Ltd (ASX:ACL) where he assisted with the launch and

growth of sales of Alchemia's first product, and the initiation of Phase II and Phase III clinical trials of an anticancer drug candidate, and establishment of collaborations with Astra Zeneca and Merck-Serono.

The Board was also strengthened by the addition of Otto Buttula who has a very successful business track record, and has been an active investor in the biotechnology sector for a number of years.

Dr. Nicholas Ede resigned as Executive Director, and assumed the management of the manufacturing of Her-Vaxx, a role where he has particular expertise as a highly credentialed peptide chemist.

The management team also has the support of a distinguished Scientific Advisory Board from leading institutions that includes Professor Christophe Zelinski who is Director of the Oncology Division, Department of Medicine at the Medical University Vienna, Austria, Professor Ursula Wiedermann who is Professor of Vaccinology at the Medical University of Vienna, and Doctor Neil H. Segal who is an Oncologist at the Memorial Sloan Kettering Cancer Center in New York.

## **INTELLECTUAL PROPERTY**

Imugene has the rights to a family of patents and patent applications and trademarks that protect its core platform technologies via Biolife Science for HER-Vaxx.

The HER-Vaxx immunotherapy platform includes the global rights to three patents:

- 'Vaccine against HER-2/neu Oncogene-associated Cancers', protects specific HER-2 B-cell epitopes and is granted in Australia, Europe, Canada, the USA and Israel
- 'HER-2/neu Multi-peptide Vaccine', further protects specific HER2 B-cell epitopes and is granted in Australia, Europe, Israel and pending in Canada
- 'Multi-epitope Vaccine for HER-2/neu-associated Cancers', claims fusion peptides comprising three noncontiguous B cell epitopes from the extracellular domain of HER-2/neu linked to one another and coupled with a delivery system including a virosome. This patent was acquired from Pevion Biotech (Switzerland), protects "HER-Vaxx" in major markets until at least 2030. The patent is granted in the USA and is pending in Europe

Imugene will also seek patent protection for new intellectual property, including improvements to the platform technologies, and their applications. As a minimum, patent applications will be made in the US, the European Union, Canada, China, Japan, Australia and New Zealand and most other English-speaking countries.

The Company reports that there are no infringement issues or patent disputes with any parties.

## **WHAT IS IMMUNO-ONCOLOGY?**

Immuno-oncology is an emerging therapeutic approach that is being studied for its potential in the fight against cancer and focuses on an understanding of how cancer evades the immune system of a patient.

This approach is different from ways of treating cancer because it uses the natural capability of the patient's own immune system to fight the cancer.

Imugene's technology is being developed to stimulate a patient's immune system to produce its own antibodies to a known and validated target for cancer which is the HER-2 receptor that is expressed on various tumors that include gastric, breast, ovarian, lung, and pancreatic cancers.

HER-Vaxx is a cancer immunotherapy designed to stimulate a patient's own immune system to attack the cancer. HER-Vaxx stimulates a patient's B cells to produce antibodies that target only those cancer cells where HER-2 receptors are present on their surface. Approximately 20% -30% of all patients with gastric, breast, ovarian and pancreatic cancer have this HER-2 molecule, and are known as being HER-2 positive.

The HER-2 molecule stimulates the growth of cancer cells, and an "over expression" of HER-2 is typically associated with a higher chance that the patient's cancer will spread, or produce a greater probability of cancer recurrence.

Roche Holdings Ltd (US\$251.1 billion valuation) owns Herceptin which is an antibody that targets the HER-2 receptor in breast and gastric cancer and reported annualised sales of \$6.9 billion. Roche's newly launched Perjeta also targets the HER-2 receptor.

Imugene believes that the successful development of HER-Vaxx has the potential to improve upon both Herceptin and Perjeta, as the HER-Vaxx P4, P6 and P7 peptides can bind onto the HER-2 receptor at 3 different points, as opposed to two points each for Perjeta or Herceptin.

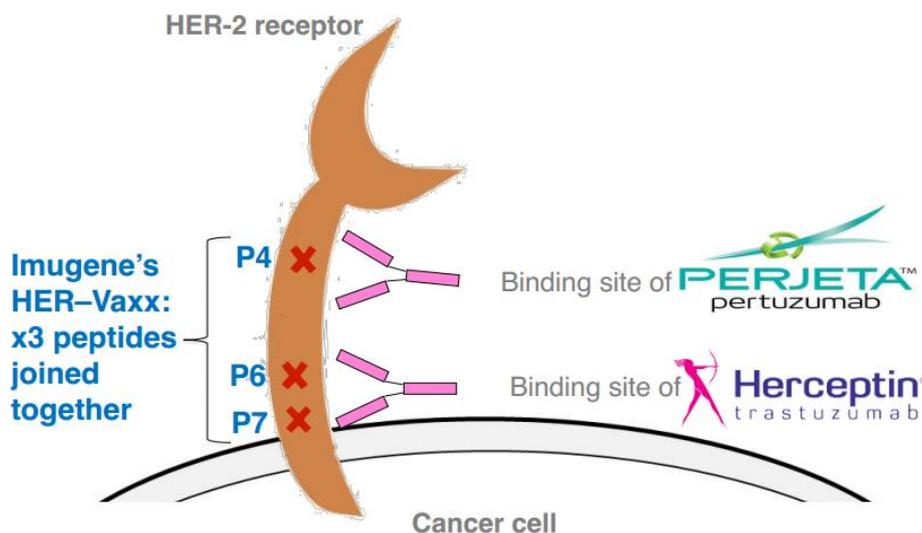


IMAGE TWO: HER-VAXX PEPTIDES BIND TO HER-2 RECEPTOR

### PHASE ONE CLINICAL TRIAL COMPLETED SUCCESSFULLY FOR HER-Vaxx

A Phase I clinical trial was completed at the University of Vienna that included 10 patients, who all had metastatic breast cancer along with over expression of HER-2.

The study confirmed that HER-Vaxx produced negligible toxicity and was tolerated by patients with no side effects. Patients developed anti-HER-2 antibodies, and these antibodies displayed potent anti-tumour activity, showing immune response.

The trial data is encouraging given that it was conducted in a non-target population, with the disease stabilising in 5 patients, and 1 patient going into remission.

### **PROPOSED CLINICAL TRIALS FOR HER-Vaxx – PHASE II FOR GASTRIC CANCER**

A combined Phase Ib and Phase II Trial is now planned to confirm safety, evaluate optimal dosing, and to show efficacy.

Phase Ib will be an open label Trial, in which both the researchers and participants know which treatment is being administered. This will include 18 patients divided into 3 groups of 6.

The endpoints of the trial will establish the HER-Vaxx dosage level for Phase II of the study, evaluate toxicity, measure immunogenicity (immune response), and test a booster schedule that compares 4 weeks of treatment to 8 weeks.

The Phase II Trial will expand to around 68 patients drawn from both Australia and Europe, and be a blinded, placebo controlled trial that evaluates efficacy, safety, and immune response. This means that 34 patients will be treated with HER-Vaxx and chemotherapy, and 34 patients treated only with chemotherapy.

The endpoints of the trial will establish an overall survival rate, and progression to survival. The secondary endpoint will measure immune response.

This robust Phase II trial is focused on attracting a Big Pharma partner to continue development work and commercialisation of HER-Vaxx.

### **GASTRIC CANCER-GLOBAL OVERVIEW**

Gastric cancer is the second leading cause of cancer mortality, and the fourth most common cancer in the world. Approximately 934,000 new cases of gastric cancer are diagnosed each year which produces approximately 700,000 deaths that account for 10.4% of cancer deaths worldwide, each year.

The European Union (27 states) estimated around 83,000 new cases of stomach cancer were diagnosed, and recorded 55,896 deaths in the latest reporting year.

In 2012 the U.S. estimated 21,300 new cases, and 10,540 deaths from stomach cancer.

Australian authorities estimate that there are about 1,900 new cases each year, and China has the largest patient population that makes up 42% of worldwide cases.

The median overall survival rate for advanced gastric cancer is estimated to be less than 12 months.

## HER-Vaxx MANUFACTURING

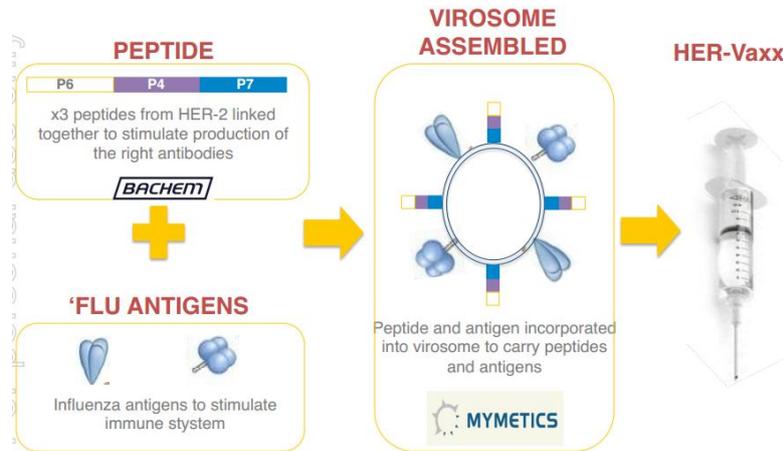


IMAGE THREE: HER-VAXX MANUFACTURE

Imugene has engaged Mymetics SA, based in Switzerland, to exclusively manufacture and develop its cancer immunotherapy HER-Vaxx. Mymetics Corporation (OTC BB: MYMX) is a Swiss-based biotechnology company registered in the US developing next-generation preventative vaccines for infectious diseases.

Mymetics brings specialist experience and know-how in the manufacturing, formulation and quality aspects of all types of virosomes, including influenza-based virosomes, the key delivery component in Imugene's peptide-based immunotherapy HER-Vaxx.

Peptide vaccines have the benefit of being easy to construct and manufacture on a large scale. They are inexpensive and are off the shelf therapy.

Mymetics uses the same vaccine delivery platform for infectious diseases that Imugene is using for the immuno-oncology program. Both companies will work to exploit the potential value of influenza-based virosomes.

## RECENT FUNDRAISING AND SHARE PURCHASE PLAN

On 12 November 2014 Imugene completed a \$2.10 million fundraising (before costs) to sophisticated investors. The Company issued 210 million fully paid ordinary shares at a price of \$0.01 per share, for total issued capital of 1,156.6 million shares.

Otto Buttula who is a Non-Executive Director of the Company subscribed for an additional \$150,000.

A Share Purchase Plan of up to \$15,000 per shareholder issued at \$0.01 per share is also open to shareholders that will close on 28 of November 2014.

## PURPOSE OF FUND RAISING

Funds raised will be applied to the manufacture of HER-Vaxx which is sufficient for initiating clinical trials, initiating Phase 1b/II clinical file in patients with metastatic gastric cancer, preclinical work, corporate costs, intellectual property prosecution, and general corporate purposes.

## FINANCIALS

The net carrying value of the Company's intangible assets of \$6.9 million was predominately due to an increase of \$5.8 million on the previous year, due to the acquisition of Biolife Science.

The September quarter 2014 cash burn was a very lean \$340,000 after accounting for receipt of an R&D tax credit of \$343,000. R&D for the quarter was \$346,000 and administrative costs were an extremely low \$60,000.

Cash held was \$2.98 million, before any funds flow in from the current Share Purchase Plan.

## MULTIPLE PRICE CATALYSTS FOR NEAR TERM VALUATION INCREASE

- Finalise trial protocol 2H 2014
- Appoint CRO to run clinical trial 1H 2015
- US FDA IND granted 1H 2015
- Appoint Principal Investigator 1H 2015
- Announce Preclinical toxicology results 1H 2015
- Announce Preclinical immunologic results 1H 2015
- Recruit and run lead in Phase 1b trial 2H of 2015
- Recruit and run Phase II double-blind randomized placebo-controlled phase II trial 2H 2015
- Report Phase I trial results 2H 2015 to 1H 2016
- Report Phase II results 2H 2017 to 1H 2018

## ANALYSIS & VALUATION

**Imugene** carries a market capitalisation of \$11.5 million, of which \$2.98 million is cash at bank. The Company is advancing into Phase I/II trials and is extremely undervalued when compared with its ASX peer biotechnology companies that are advancing into Phase II trials for a variety of cancers or application of immunotherapies.

ASX listed peers include:

- Oncosil Medical (ASX:OSL) with Market Capitalisation of \$37.3 million – Phase II trial
- Viralytics (ASX:VLA) with Market Cap: \$57.0 million – Phase II trial
- Innate Immuno Therapeutics (ASX:IIL) Market Cap: \$26.1 million – Phase II trial
- Bionomics (ASX:BNO) Market Cap: \$212.0 million - Phase II trial

- Benitec Biopharma (ASX: BLT) Market Cap: \$70.1 million – Phase I trial
- **Imugene (ASX:IMU) Market Cap: \$11.5 million – Phase II trial**

Average market capitalisation of the peer group is \$69 million versus \$11.5 million for Imugene.

Valuations for U.S. based biotechs in Phase I/ II trials range from:

- Tetralogic Pharmaceuticals Corporation (NASDAQ: TLOG) Market Cap: US\$102.7 million to
- Kite Pharma (NASDAQ: KITE) Market Cap: \$1,600 million

Recent Immuno-oncology licensing deals in the U.S. include:

- Newlink Genetics and Genentech for NLG919 in Phase I, with upfront payment of \$150 million, and potential for a total \$1,150 million
- F Star and BMS for FS-102 targeting HER-2 in Phase 1, with upfront payment of ~\$50 million, and potential for a total \$475 million
- Five Prime Therapeutics and BMS for immuno-oncology therapeutics at the discovery stage, with upfront payment of \$20 million and potential for a total \$351 million

This further highlights the potential metrics and upside potential for Imugene.

Successful trial results and progression; partnering with a Big Pharma and/or licensing agreements would add further to this valuation upside. Trial success will be richly rewarded.

Proactive Investors has applied a combination of metrics including: imputed asset value, median valuation and arrived at a valuation for Imugene of between \$39.8 million to \$55.2 million. This translates to a share price valuation of \$0.034 - \$0.047 per share.

A Share Purchase Plan of up to \$15,000 at \$0.01 per share provides shareholders with an ability to acquire further shares without brokerage before 28 of November 2014.

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