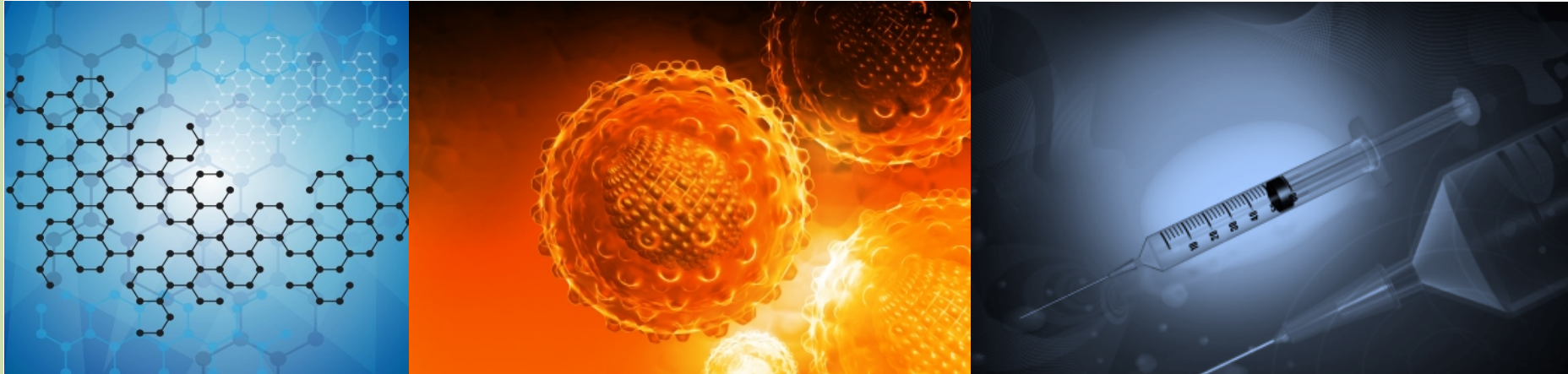


# IMUGENE

ASX: IMU



An Immuno-oncology Company Developing HER-2+ Gastric and Breast Cancer Therapies

Investment Meetings  
January 12-15, San Francisco, USA

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# Corporate Snapshot

- ❖ ASX-listed immuno-oncology company (ASX:IMU)
  - ❖ Market capitalization (Jan 4 2015): USD13.3m
  - ❖ Share price (Jan 4 2015): AUD1.1 cents
  - ❖ Shares outstanding: 1,329,912,516
- ❖ Developing a B-cell based immunotherapy, known as HER-Vaxx, for HER-2 positive gastric & breast cancer
- ❖ Phase I trial completed in patients with HER2+/++ breast cancer
- ❖ Phase I/II trial to begin 2H 2015
- ❖ Technology originates from Medical University of Vienna, one of Europe's leading cancer institutes

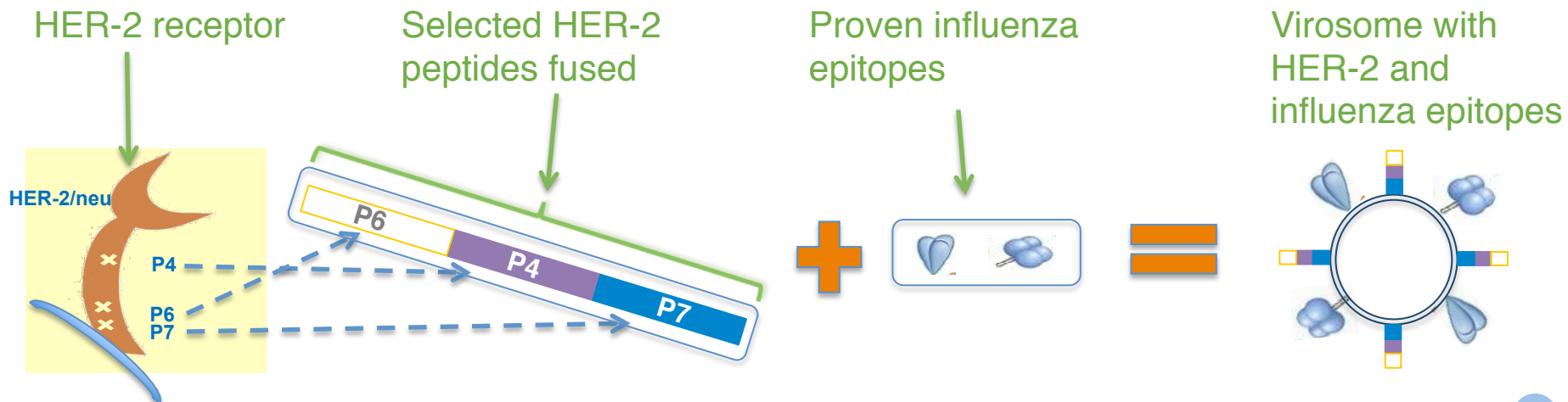


# Investment Highlights

Compelling Science	<ul style="list-style-type: none"><li>• B-cell peptide cancer immunotherapy that induces an antibody response targeting HER-2 over expressing tumors</li></ul>
Management Team	<ul style="list-style-type: none"><li>• Experienced, successful board &amp; management</li></ul>
Investment to Date	<ul style="list-style-type: none"><li>• Approximately \$10m invested to date</li></ul>
News Flow	<ul style="list-style-type: none"><li>• Numerous milestone announcements &amp; valuation inflection points over next 12 months</li></ul>
Robust IP	<ul style="list-style-type: none"><li>• Strong IP with exclusivity until 2030, granted in all major jurisdictions</li></ul>
Strong Upside	<ul style="list-style-type: none"><li>• Targeting improvement over HER-2 antibody, Roche's \$6.4bn Herceptin</li></ul>

# HER-Vaxx: Overview

- ❖ One of the most advanced B-cell vaccines, designed to stimulate a patient's own immune system to repeatedly attack the cancer
- ❖ Stimulates a patient's B cells to produce polyclonal antibodies that target cells with overexpressing HER-2 receptors on their surface
- ❖ About 20% of patients with gastric cancer are "HER-2 positive"
- ❖ HER-Vaxx consists of three peptides from the HER-2 receptor, influenza antigens presented on a virosome



# HER-Vaxx Versus Herceptin®

## Herceptin®

- ❖ Synthetic Ab, with side effects (including ventricular dysfunction, congestive heart failure, anaphylaxis)
- ❖ Monoclonal Ab
- ❖ Half life up to 12 days
- ❖ Requires regular infusion
- ❖ Expensive course of treatment — US \$70,000 per year in the US

## HER-Vaxx

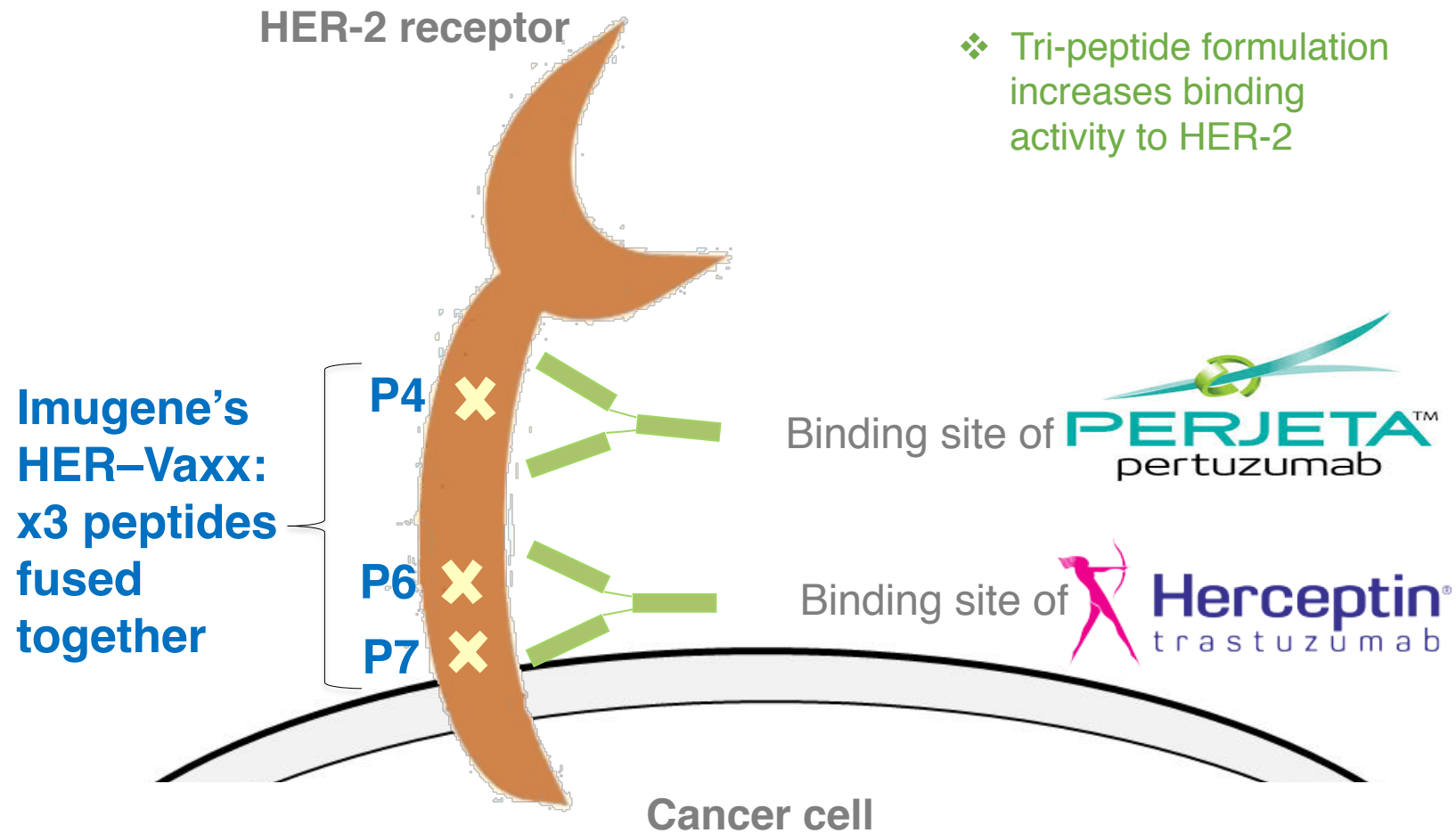
- ❖ Stimulates the immune system to produce natural Abs, therefore could be considerably safer
- ❖ Polyclonal Ab response potentially producing a more powerful anti-tumor effect
- ❖ Antibodies continuously produced — a lasting immune response to inhibit tumor recurrence
- ❖ Potentially low numbers of vaccinations required per year
- ❖ Low cost of production enables greater pricing flexibility & opens up additional markets
- ❖ Potentially applicable in all HER-2 cancers & settings

# HER-Vaxx: Key Differentiators

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- ❖ HER-Vaxx peptide sequences identified through extensive computer modelling of HER-2 receptor
- ❖ Three sequences selected from analysis: all critical to function of HER-2, including the dimerisation loop of the HER-2 receptor
- ❖ Peptides patented worldwide
- ❖ When combined with influenza antigens & a virosome, polyclonal response elicited from B cells targets three key areas of HER-2 receptor
- ❖ Current commercial antibodies – Herceptin and Perjeta – target two or fewer regions of the HER-2 receptor
- ❖ Clinical benefits could include improved efficacy, improved safety, longer administration & lower cost

# HER-2 Target





# Clinical Status: Phase I Completed

## DESIGN

- n=10
- All metastatic breast cancer patients
- HER-2 +/-
- Life expectancy > 4 months
- Conducted at University of Vienna

## OBSERVATIONS

- Patients developed anti-HER-2 antibodies
- Induction of memory T & B cells post vaccination
- Reduction in T reg cells post vaccination, indicating strong vaccine response
- Antibodies induced displayed potent anti-tumor activity

## CLINICAL ENDPOINTS

**1**

Safety and Tolerability

**2**

**Immunogenicity:** antibodies/humoral and cellular responses

# Phase Ib/II Trial Design – Gastric Cancer

**Combined Phase Ib / II clinical trial planned to confirm safety, evaluate optimal dosing and to show efficacy**

## Phase Ib lead in to Phase II Trial

- ❖ Open label
- ❖ 18 patients, x3 groups of 6 patients
- ❖ Endpoints:
  - Dose of HER-Vaxx to use in Phase II part of study
  - Safety: any HER-Vaxx toxicity
  - Immunogenicity (anti-HER2/neu antibody titers)
  - Test booster schedule (q 4 weeks or 8 weeks)

## Phase II Trial

- ❖ ~68 patients from Australia and Europe
- ❖ Efficacy, safety and immune response
- ❖ Randomized, blind, placebo controlled
- ❖ Endpoints:
  - Overall survival
  - Progression-free survival
- ❖ Secondary endpoint:
  - Immune response

# Intellectual Property

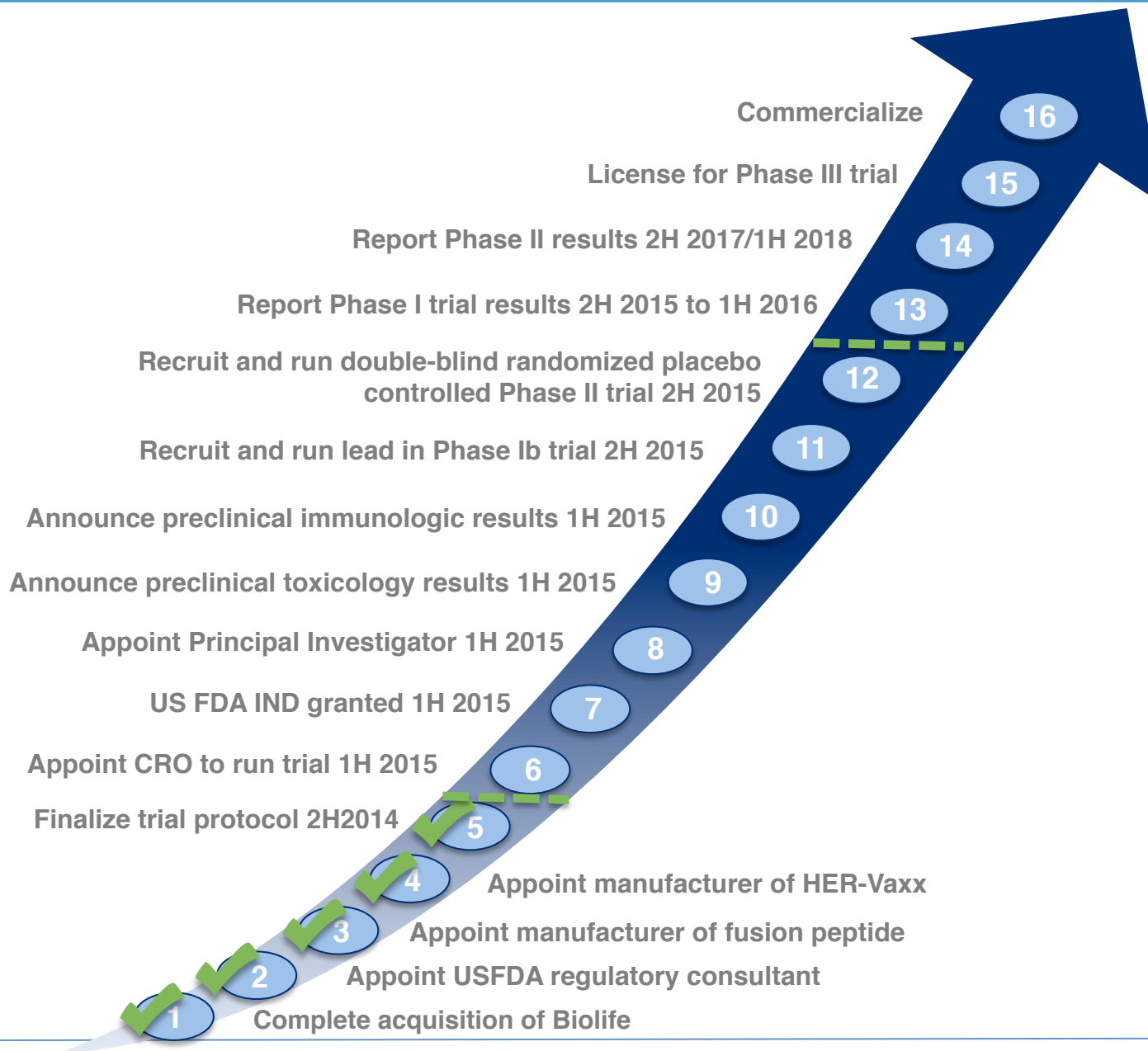
Patent Title	Description	Patent number	Expiry date	Territories
<b>'Vaccine against cancer diseases that are associated with the HER-2/neu Oncogene'</b>	protects specific HER-2 B-cell epitopes	WO02068474	27 Feb 2022	Granted in Australia, Europe, Canada, the USA and Israel
<b>'HER-2/neu Multi-peptide Vaccine'</b>	protects specific HER2 B-cell epitopes	WO2007118660	11 April 2027	Granted in Australia, Europe, Israel and pending in Canada
<b>'Multi-epitope Vaccine for HER-2/neu-associated Cancers'</b>	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	WO2011020604	18 August 2030	Granted in the USA and pending in Europe.
<b>'Lyophilisation of virosomes'</b>	granted through an exclusive global license from Pevion Biotech, is for a patent covering the virosome vaccine delivery platform, used in the manufacture of "HER-Vaxx", in the field of oncology	WO2006/069719	21 December 2025	Granted in EP, US, CN, AU, Eurasia and SA

# Business Development Strategy

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- ❖ Begin awareness campaign for technology with potential partners
- ❖ Initiate robust Phase Ib/II clinical trial
- ❖ Seek data-driven partners for remaining development of HER-Vaxx in gastric cancer
  - ❖ pivotal trial
  - ❖ marketing
- ❖ Seek partners for alternative applications of HER-Vaxx:
  - ❖ additional HER-2 indications
  - ❖ additional settings within indications

# News Flow & Milestones



# Recent Licensing Agreements

Date	Licensor	Licensee	Technology/ Product	Dev Status	Amount (USD)	
					Upfront	Total
28-Oct-14	F-Star	BMS	FS-102 targeting HER-2	Phase I ready	~\$50m	\$475m
20-Oct-14	NewLink Genetics	Genentech	NLG919	Phase I	\$150m	\$1,150m
16-Oct-14	Aduro Biotech	Janssen	Several candidates	Discovery	\$30m	\$847m
19-Aug-14	Emergent Biosolutions	Morphosys	ES414	Preclinical	\$20m	\$183m
18-Jun-14	Collectis	Pfizer	CAR-T therapy program	Preclinical	\$80m	\$299m
27-May-14	CytomX	BMS	Probody platform	Discovery	\$50m	\$348m
17-Mar-14	Five Prime Therapeutics	BMS	Immuno-oncology therapies	Discovery	\$20m	\$351m

**Source:** Oppenheimer & Co., Company news, internet

# Financial Information

❖ Market capitalization (Jan 4 2015):	USD13.3m (AUD16.4m)
❖ Share price (Jan 4 2015):	AUD1.1 cents
❖ Average daily trade:	1.01m shares
❖ Shares outstanding:	1,329,912,516
❖ 2014 loss (June 30 year end):	AUD\$2.1m
❖ <i>Proforma</i> cash at hand (Sept 30 2014):	AUD\$4.4m*
❖ Cash and equivalents (Sept 30 2014):	AUD\$0.9m
❖ Total new funds raised Nov '14, Dec'14:	AUD\$3.5m
❖ Net assets (June 30 2014):	AUD\$6.7m

\* This figure is calculated using the cash position as at 30 September 2014 plus additional funds raised thereafter (gross of expenses) to establish a proforma cash position as though the funds had been raised on 30 September 2014.

# Leadership – Experience and Track Record



**Charles Walker**  
*CEO*

- Former CEO and CFO of ASX-listed Alchemia
- 20+ years in the life science industry, including a decade in specialist corporate finance in London
- Executed ~50 capital markets transactions as principal and advisor



**Paul Hopper**  
*Executive Chairman*

- Extensive international & ASX biotech capital markets experience particularly in cancer vaccines
- Head of Life Sciences Desk & Australia Desk at Los Angeles-based investment bank, Cappello Capital Corp



**Dr Axel Hoos**  
*Non-Executive Director*

- Currently Vice President Oncology R&D at GlaxoSmithKline
- Previously Clinical Lead on Ipilumimab at Bristol-Myers Squibb
- Co-Director of the think-tank Cancer Immunotherapy Consortium; Imugene is his only Board seat worldwide



**Otto Buttula**  
*Non-Executive Director*

- Extensive & successful experience in investment research & financial services management
- Active & substantial investor in the biotechnology sector with a particular focus on oncology
- Several significant positions in ASX-listed companies including Imugene



**Dr Nick Ede**  
*Head of Manufacturing & Operations*

- Former CTO Consegna, CEO Adistem Ltd, CEO Mimotopes P/L, COO EQiTX Ltd (ZingoTX & VacTX)
- VP Chemistry Chiron (now Novartis), Research Fellow CRC Vaccine Technology



# Investment Summary

Quality Science	<ul style="list-style-type: none"> <li>The subject of numerous peer reviewed published journals</li> <li>Medical University of Vienna, one of Europe's leading cancer institutes</li> <li>Technology developed over 10 years</li> </ul>
Differentiation	<ul style="list-style-type: none"> <li>HER-Vaxx directed at validated target, HER-2</li> <li>HER-Vaxx addresses the multiple targets of Herceptin <i>and</i> Perjeta <i>combined</i></li> <li>Herceptin sales of \$6.4bn in 2013</li> </ul>
Robust IP	<ul style="list-style-type: none"> <li>IP portfolio with 2030 horizon</li> </ul>
Leadership	<ul style="list-style-type: none"> <li>Leading clinical &amp; scientific experts; experienced management</li> <li>Board holds significant shares, aligning interests with shareholders</li> </ul>
Best-in-Class Phase II Trial	<ul style="list-style-type: none"> <li>Phase II trial designed to be especially robust &amp; big pharma oriented to support potential future partnerships</li> </ul>
News Flow/Valuation	<ul style="list-style-type: none"> <li>Focused 24 month program to deliver results/value inflection</li> <li>Attractively priced to capitalize on upcoming milestones</li> </ul>

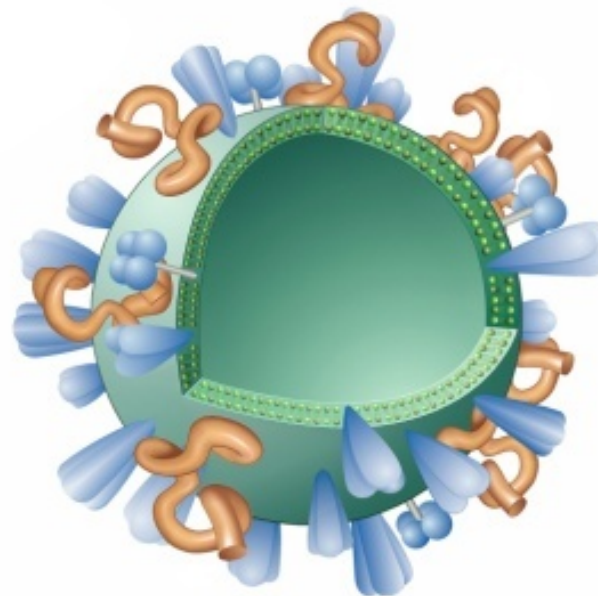
# IMUGENE

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# Appendix

# Preclinical Studies Overview

■ Int. J. Cancer (03)    
 ■ Breast Cancer Res Treat (07)    
 □ Unpublished

## Pep-TT (peptides conjugated to tetanus toxoid)

▪ Immunogenicity screening P1 – P10	mouse	<span style="color: yellow;">■</span>
▪ P4, P6, P7 peptide-specific antibodies	mouse	<span style="color: yellow;">■</span>
▪ HER-2 protein immune precipitation	mouse	<span style="color: yellow;">■</span> <span style="color: blue;">■</span>
▪ HER-2 protein sandwich ELISA	mouse	<span style="color: blue;">■</span>
▪ Antibody characterization IgG1, IgG2a	mouse	<span style="color: yellow;">■</span> <span style="color: blue;">■</span>
▪ IFN $\gamma$ /IL-4 profile <i>in vitro</i>	mouse	<span style="color: blue;">■</span>
▪ SKBR tumor <u>cell line</u> growth inhibition <i>in vitro</i>	mouse	<span style="color: yellow;">■</span> <span style="color: blue;">■</span>
▪ Tumor growth inhibition <i>in vivo</i> spontaneous model	mouse	<span style="color: blue;">■</span>
▪ Effect of IL-12 co-administration	mouse	<span style="color: blue;">■</span>
▪ CDC (complement-dependent cytotoxicity)	mouse	<span style="color: yellow;">■</span>
▪ ADCC (antibody-dependent cellular cytotoxicity)	rabbit	<span style="color: yellow;">■</span>
▪ Repeat dose toxicity study	mouse	<span style="color: white;">□</span>

## Pep-virosome (peptides formulated with virosomes)

▪ P4, P6, P7 peptide-specific antibodies	mouse	<span style="color: white;">□</span>
▪ HER-2 protein sandwich ELISA	mouse	<span style="color: white;">□</span>
▪ SKBR tumor <u>cell line</u> growth inhibition <i>in vitro</i>		<span style="color: white;">□</span> rabbit
▪ Repeat dose toxicity study	rat	<span style="color: white;">□</span>
▪ Immunogenicity & local tolerability study	rabbit	<span style="color: white;">□</span>
▪ Interaction with Herceptin	mouse	<span style="color: white;">□</span>

# Selection of 3 Optimized Peptide Antigens

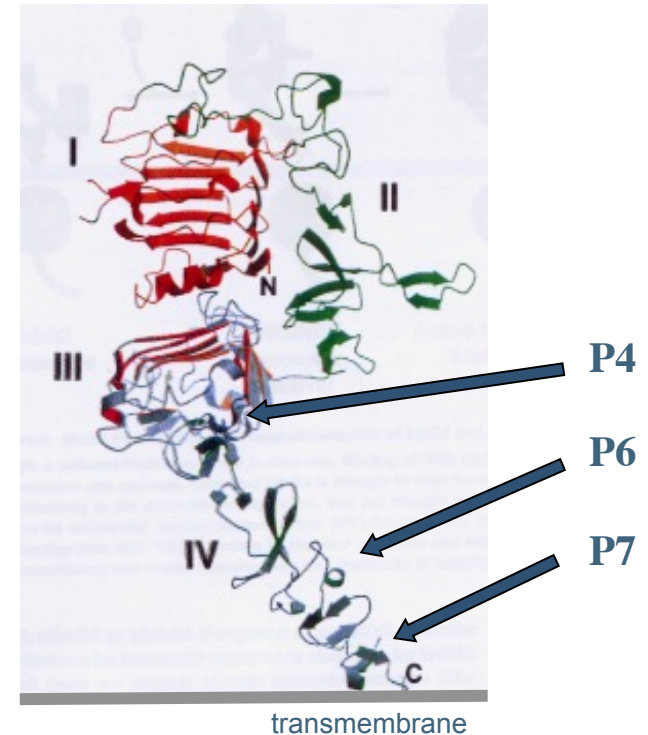
- Antigen identification by computer-aided prediction followed by immunogenicity studies
- Selection of 3 different HER-2 peptide antigens:

P4: PESFDGD PASNTAPLQPGGGGGGC

P6: RVLQGLPREYVNARHC

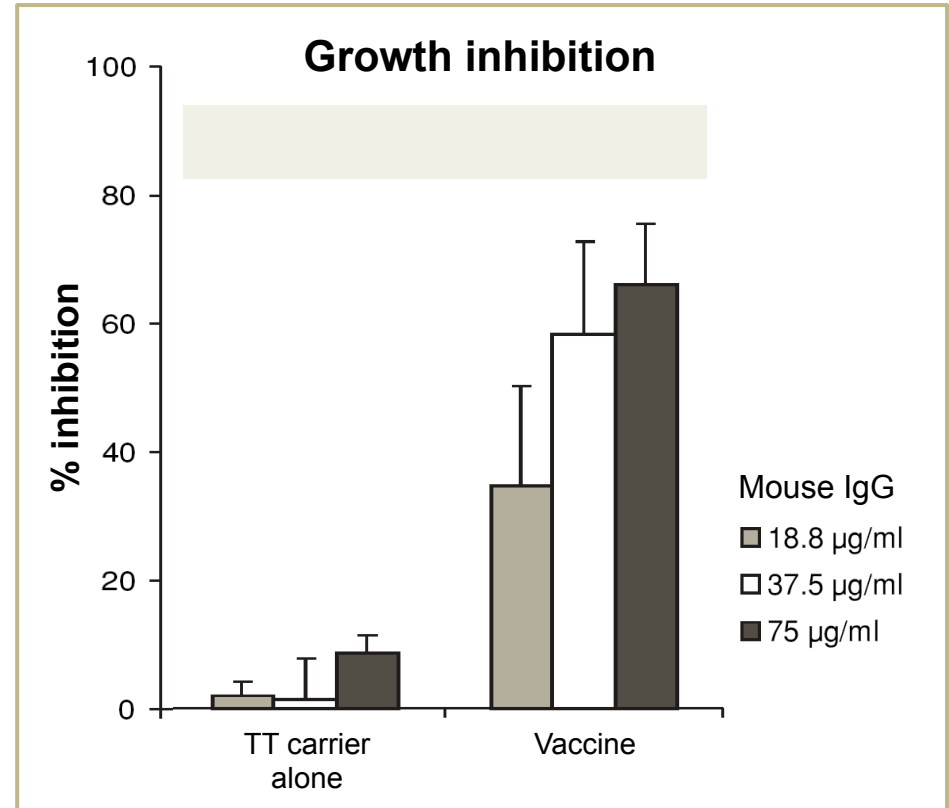
P7: YMPIWKFPDEEGAC

## HER2 protein



# Tumor Cell Line Growth Inhibition *in vitro*

- Immunization of mice with tetanus toxoid-conjugated peptides P4, P6 and P7
- IgG isolated from serum of immunized mice inhibits growth of HER2-expressing tumor cell line SK-BR-3 *in vitro* by up to 70%

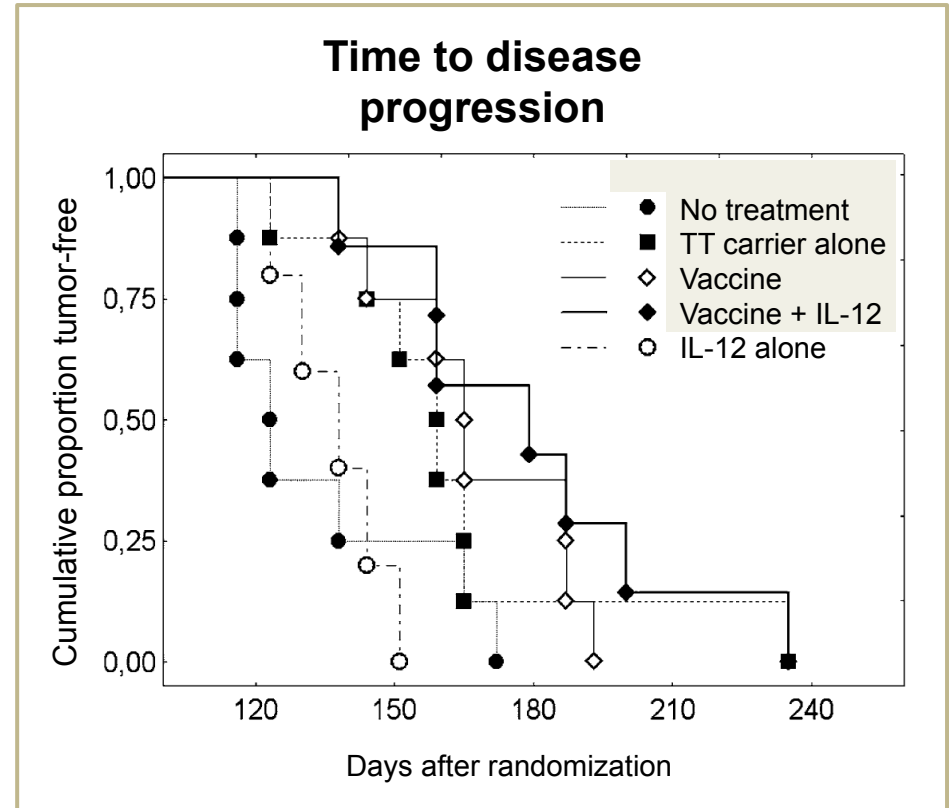


Preclinical study with tetanus toxoid-conjugated peptide antigens

# Tumor Growth Inhibition *in vivo*

## Prolonged time to disease progression

- Immunization of c-neu transgenic mice (recognized HER2 cancer model) with tetanus toxoid-conjugated peptides P4, P6 and P7
- Vaccinated animals show significant delay in tumor onset and reduced growth kinetics
- Co-administration of IL-12 further improves the vaccine performance

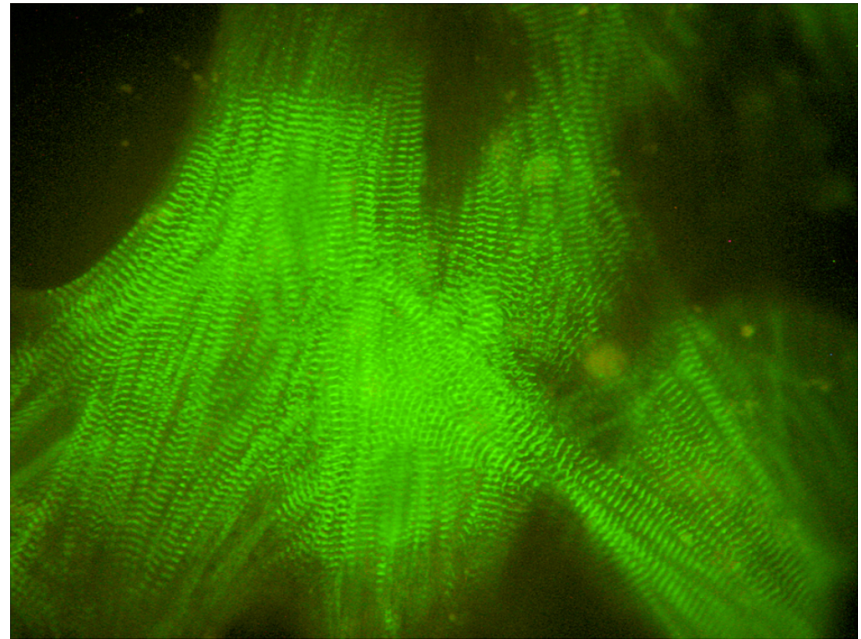


Preclinical study with tetanus toxoid-conjugated peptide antigens

# No Toxicity, in Particular No Cardiotoxicity

- Repeat dose toxicity study with TT-conjugated peptides in mice
- Repeat dose toxicity study with HER-Vaxx in rats
- Local tolerability & immunogenicity study with HER-Vaxx in rabbits
- In vitro toxicity study with purified serum from immunized animals on rat cardiomyocytes

## Rat cardiomyocytes



*In vitro* toxicity study on rat cardiomyocytes



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