BELL POTTER

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Speculative

See key risks on Page 6 and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.

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Imugene (IMU)

HER-vaxx Program To Expand

Recommendation
Buy (Hold)
Price
$0.40
Valuation
$0.52 (previously $0.25)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**30%**
Dividend yield	**0%**
Total expected return	**30%**

Company Data & Ratios	
Enterprise value	**$2,002.4m**
Market cap	**$2,132.4m**
Issued capital	**5,331m**
Free float	**94%**
Avg. daily val. (52wk)	**$5.4m**
12 month price range	**$0.05 - $0.50**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.30	0.43	0.06
Absolute (%)	31.67	-7.06	581.03
Rel market (%)	30.07	-13.22	557.60

Absolute Price

SOURCE: IRESS

Capital Raise Accelerates Development Program

Imugene has announced the initiation of the next leg of its clinical program for the development of HER-vaxx. The company will initiate 3 separate studies, each in gastric cancer to study the efficacy of the drug in early, mid and late stage disease. As previously speculated, these studies will involve combinations with both PD1 and PD-L1 I/O drugs. These multinational phase 2 trials will target specific populations of patients either before or after treatment with trastuzumab (being the standard of care drug in the US). We were pleased to see that the company is not planning a head to head study vs trastuzumab in first line therapy as we consider that such a trial would have carried extraordinarily high risk. Such a trial would have taken many years and required tens of millions of dollars of investment.

Imugene also announced the hazard ratio on the secondary endpoint of progression free survival (PFS) in its phase 2 gastric cancer trial. The HR of ~0.72 was equivalent to that produced by Herceptin (trastuzumab) in earlier studies, albeit the result was not statistically significant. PFS is not thought to be a precursor to overall survival (OS) in this indication. Earlier OS data from interim results had indicated a 5½ month survival benefit. Final OS data is due in CY2021 or early CY2022. The clinical program outlined here provides IMU with more options for development of HER-vaxx and may attract interest from partners.

Investment View: Upgrade to Buy (Spec), Valuation raised

The key changes to earnings include the 6% dilution to shares on issue from the recent $90m capital raise. The company now has c. $130m in cash. We have increased the clinical trial spend in the period FY22 – FY25 and now expect IMU will spend at least $30m annually on development. The long dated years of the DCF have been amended to include potential future revenues from the onCARlytics program, now expected to commence clinical trials in FY23. Valuation is raised to $0.52 from $0.25 and we upgrade to Buy (Spec). The potential of these new therapies may be attractive to future development partners.

Earnings Forecast

June Year End	FY21	FY22e	FY23e	FY24e
Revenues $m	7.3	13.5	15.8	18.6
EBIT $m	-18.4	-27.5	-30.3	-27.5
NPAT (underlying) $m	-18.4	-27.0	-29.8	-27.0
NPAT (reported) $m	-18.4	-27.0	-29.8	-27.0
EPS underlying (cps)	-0.4	-0.5	-0.6	-0.5
EPS growth %	nm	nm	10%	-9%
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	-28%	-21%	-30%	-37%

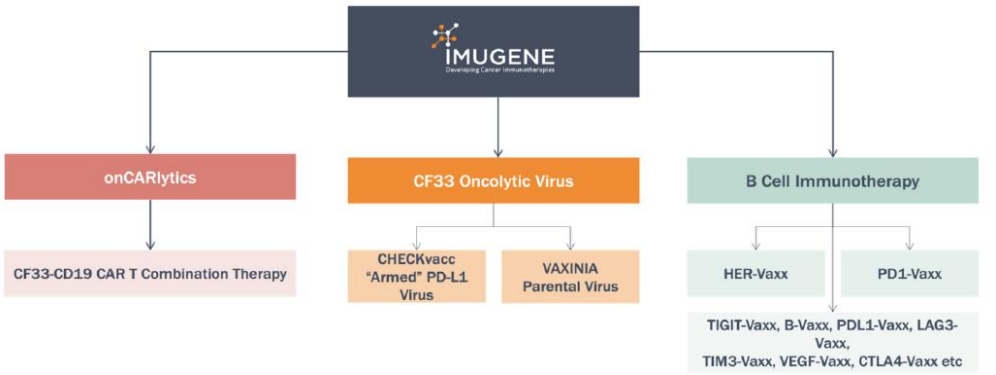
SOURCE: BELL POTTER SECURITIES ESTIMATES

Clinical Program To Expand

IMU continues to aggressively pursue new therapies for the treatment of various cancers and over the course of the next 12 months the clinical program is set to ramp up with numerous trials either commencing or reporting.

The recent funding round was extremely well supported by institutions both in Australia and Asia.

Figure 1 - Overview of development pipeline



SOURCE: COMPANY DATA

HER Vaxx Update

The company had previously reported interim data from the phase 2 trial investigating the use of IMU-131 in the treatment of gastric cancer. The interim results are strongly suggestive of an overall survival benefit vs chemotherapy alone.

Earlier data also indicates:

- Treatment with HER-Vaxx clearly demonstrates patients develop high levels of HER2-specific antibodies early in the treatment protocol and are maintained during treatment and maintenance phase with only a few booster injections. In our view there is a reasonable hypothesis that patients treated with HER Vaxx may benefit from a reduced side effect profile compared to mAb's providing a similar therapeutic effect;
- Tumour response is correlated with the amount of antibody levels. Patients with antibody levels higher than 1050ng/ml received greater than 50% tumour reduction. Antibody levels may serve as a potential biomarker;
- In contrast to patients on chemotherapy alone, the reduction of tumour size was substantially higher in patients that received HER-Vaxx + chemotherapy.

NEW DATA

The data announced today concerned the secondary endpoint of progression free survival (PFS). IMU did not provide the PFS statistic (normally measured in months), however, it did provide the hazard ratio (HR) of 0.719 with a one sided p value of 0.266. The p value indicates the outcome was not statistically significant while the hazard ratio indicates a 28.1% reduced chance of death compared to the standard of care. The HR was very similar to the HR produced in the approval study for Herceptin and at this point in development it is conceivable that two drugs produce a similar survival benefit. They both target the same cancer receptor.

There was no difference in safety between the two arms of the trial.

The Primary endpoint of the trial is overall survival. Earlier interim data indicated 5½ month overall survival benefit with a HR of 41%. The absence of a statistically significant

difference on the secondary endpoint is interesting, however the OS data is of far greater relevance. Final OS data is likely to be available within the next 6 months.

UPDATE ON CLINICAL PROGRAM

IMU will now commence three new HER-vaxx trials:

- Next*HERIZON*
- Neo*HERIZON*
- Neu*HERIZON*

These trials will encompass early and late stage gastric cancers including combinations with PD-1 and PD-L1 checkpoint inhibitors. The trials will be conducted in the US, Australia and South Korea.

The trial names provide a strong hint of the likely patient group. NeoHERIZON for example suggests that HER-vaxx will be administered prior to a main therapy (most likely still Herceptin). NextHERIZON is suggestive of a patients who have failed on standard of care.

Details regarding collaborations (if any), participant numbers, endpoints and timing are yet to be confirmed.

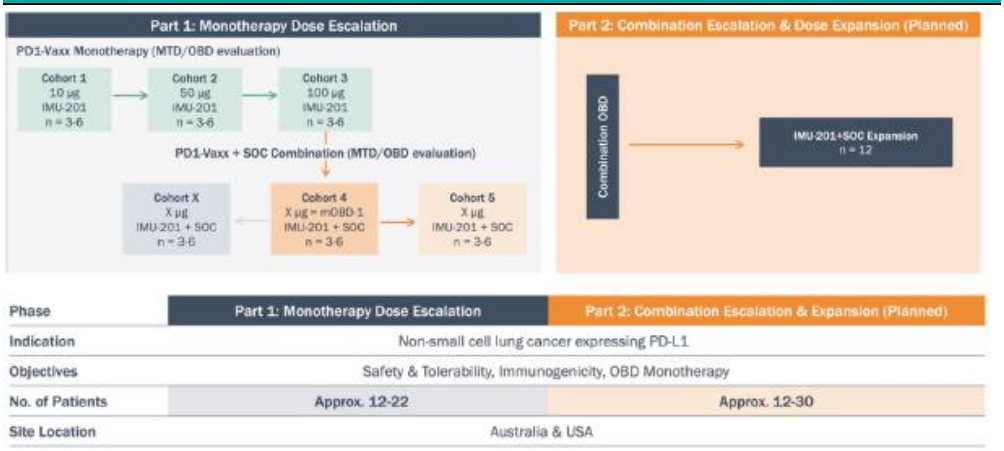
The standard of care for gastric cancer in the US is trastuzumab (Herceptin) in combination with chemotherapy. The clinical plan for HER-vaxx does not include a head to head trial which is clever. Head to head trials are rare because the risk of failure is too high. Drug developers generally find a path to market that avoids such is high risk approach as is the case here. The three studies discussed above will be phase II.

PD1-Vaxx

The company's PD1-Vaxx is a B-cell immunotherapy, peptide cancer vaccine designed to treat tumours such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect similar to pembrolizumab and nivolumab. The hypothesis is that a polyclonal-induced B-cell antibody response will be more effective or as effective with improved safety over current monoclonal antibody therapy.

The dose escalation study is proceeding will with participants now on cohort 3, being the highest dose. Provided the safety data is supportive, we expect the trial will shortly move to cohort 4 being the first combination with chemotherapy.

Figure 2 - PD1-Vaxx Phase 1 trial design



SOURCE: COMPANY DATA

onCARlytics

CAR-T therapy has enjoyed enormous success in the treatment of blood based cancers since approval in 2017. IMU has now in-licensed a program to investigate a novel approach for the use of CAR-T therapy in the treatment of a range of solid tumour cancers.

OnCARlytics is a novel combination immunotherapy utilizing the CF33 oncolytic virus to deliver and present cell surface CD19 antigen, promoting CD19 CAR T cell anti-tumour responses against solid tumours.

Scientists at City of Hope (COH) engineered CF33 to infect solid tumour cells and insert the CD19 transgene to enable presentation of CD19 over the tumour cells during tumour cell infection. onCARlytics (CF33-CD19) is planning to use autologous (being the currently approved drugs) or allogeneic CD19 CAR Ts to then create the anti-tumour effect. The mouse models have showed encouraging efficacy as has been reported by IMU in previous market releases.

IMU recently announced an exclusive strategic partnership with Celularity (NASDAQ: CELU) to explore the therapeutic potential of the combination of CF33-CD19 and Celularity's CD19 targeting chimeric antigen receptor (CAR) placental - derived investigational T-cell therapy, CyCART-19:

- Pre clinical in vitro and in vivo combination studies to commence in 2021. Once the first indication is identified, IMU intends to apply for an IND to commence a human trial;
- We expect further research collaborations of this nature with a variety of CAR-T products including autologous versions of CAR-T.

The research collaboration agreement with Celularity is effective now and has an initial term of twelve months. In the event new IP is generated from the research collaboration the companies will negotiate an agreement for commercialisation of the benefits to flow from the new IP.

Celularity's IP is the development of allogeneic placental T cells derived from the postpartum human placenta. Placental T cells are engineered with CAR expression, and knockout of endogenous T cell receptors (TCR) termed P CAR-T. Unlike adult peripheral blood mononuclear cell derived T cells, placental-derived CAR T cells are mostly naïve (CD45RA+), expand readily ex vivo, express markers of stem cell memory, and have lower expression of effector or exhaustion markers, allowing for greater proliferative potential of these cells in vivo.

The proof of concept work to be conducted over the course of the next year (in vitro/ in vivo) and will be instructive for the future of this development therapy.

The onCARlytics program is still early stage but with immense potential and we look forward to its progress in preclinical work over the next 12 months.

VALUATION AND CHANGES TO EARNINGS

Figure 3 - Summary of earnings changes

	2022			2023			2024		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	13.5	6.3	114%	15.8	4.5	250%	18.6	5.5	237%
EBIT	-27.5	-9.7	-184%	-30.3	-7.5	-303%	-27.5	-10.5	-161%
NPAT	-27.0	-9.2	-193%	-29.8	-7.0	-325%	-27.0	-10.0	-170%
EPS	-0.5	-0.2	-157%	-0.6	-0.1	-465%	-0.5	-0.2	-156%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Following the recent capital raise the company has approximately $130m in cash which it will spend on an extensive clinical programs over the coming years. Changes to earnings reflect our expectation of a large increase in clinical trial spend, most particularly in the

three new HER vaxx trials announced today and the development work on the onCARlytics program.

Future revenues (beyond the short term forecast period) now include heavily discounted revenues from development of a future onCARlytics drug. It is worthwhile to re-enforce that development work in onCARlytics remains pre-clinical. The company does yet have a product to take into the clinic, albeit this may change over the ensuing 12 months. The potential market for a CAR-T effective in solid tumours is conservatively estimated as a multi blockbuster drug.

Our valuation is revised upwards to $0.52 and we upgrade to Buy (Speculative). The key changes to earnings includes the dilution from the recent capital raise, a significant reduction in the risk rating attached to the HER-vaxx program and inclusion of long dated revenues from the onCARlytics program inclusive of modest assumption around pricing, effect size and share of IP rights. We also made large increases to the clinical trial spend in the period FY22 – FY25.

The OnCARlytics program is likely to take several years of development from this point before there is a clear signal of efficacy in humans, hence it carries a large discount for risk. Nevertheless, any sign off efficacy is likely to generate immense interest in this asset and we are mindful of the US$11.9bn paid by Gilead in 2017 for Kite Pharma with the key assets being Kite's Lead CAR T Therapy Candidate, Axicabtagene Ciloleucel, which at the time was under Priority Review in the U.S. and Expedited Review in the EU. Others including Novartis invested not dissimilar amounts for late stage CAR-T assets.

Figure 4 - Imugene Clinical Program

	Current Status	Indication	Stage	IP Expiry	N	FY21 2H20	1H21	2H21	FY22 1H22	2H22	FY23 1H23	2H23
B Cell Immunotherapy												
HER Vaxx (HER2)	Completed recruitment	Gastric Cancer	Phase 2	2036	34							
NextHERIZON	Planning	Gastric Cancer	Phase 2									
NeoHERIZON	Planning	Gastric Cancer	Phase 2									
NeuHERIZON	Planning	Gastric Cancer	Phase 2									
PD1 Vaxx	Dose escalation	NSCLC	Phase 1	2037	32							
Oncolytic Virus												
Vaxinia (CF33-hNIS)	Recruiting	Solid Cancers	Phase 1	2037	~60							
Checkvacc (VF33-nHIS-aPD-L1)	IND approved	Triple Neg BC	Phase 1	2037	32							
onCARlytics												
CF33 - CD19 (onCARlytics)	Pre clinical	Not specified	Phase 1	2038	Four year sponsored research agreement with City of Hope to develop the technology (commencing from June 2021)							
Estimated clinical spend												

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Risk Areas

Imugene is a drug developer specialising in the development of new agents for various cancer indications. The company has a history of in-licensing early stage assets, typically pre clinical or with phase 1 data, and progressing their development. Consequently the risk of failure is probably high, however the future financial benefit from development of a new chemical entity for the treatment of disease can be very attractive.

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

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

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

Clinical trial risk

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

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

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

Arrangements with third-party collaborators

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

Requirement to raise additional funds

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

Intellectual property

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

Imugene
as at 2 September 2021

Recommendation	Buy, Speculative
Price	$0.40
Valuation	$0.52

Table 1 - Financial summary

	FY20	FY21	FY22e	FY23e	FY24e
Year Ending June					
R&D incentive	4.2	7.3	13.5	15.8	15.8
Total Revenue	**4.2**	**7.3**	**13.5**	**15.8**	**18.6**
COGS	-	-	-	-	-
Gross profit	4.2	7.3	13.5	15.8	18.6
R&D Expense	-9.4	-15.4	-30.0	-35.0	-35.0
Other expenses	-5.6	-10.3	-11.0	-11.0	-11.0
Total Expenses	-15.0	-25.7	-41.0	-46.0	-46.0
EBIT	-10.8	-18.4	-27.5	-30.3	-27.5
Interest income	0.3	0.0	0.5	0.5	0.5
Pre tax profit	(10.5)	(18.4)	(27.0)	(29.8)	(27.0)
Tax expense	-	-	-	-	-
NPAT- normalised	**(10.5)**	**(18.4)**	**(27.0)**	**(29.8)**	**(27.0)**
Reported NPAT	(10.5)	(18.4)	(27.0)	(29.8)	(27.0)

Cashflow (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Gross cashflow	-10.4	-13.3	-27.5	-30.3	-27.5
Net interest	0.3	0.2	0.5	0.5	0.5
Operating cash flow	-10.1	-13.1	-27.0	-29.8	-27.0
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-10.1	-13.1	-27.0	-29.8	-27.0
Business acquistions	-1.5	-5.3	0.0	0.0	0.0
Proceeds from issuance	22.7	17.9	90.0	0.0	0.0
Movement in borrowings	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Change in cash held	11.1	-0.5	63.0	-29.8	-27.0
Cash at beginning of period	19.0	30.1	29.5	92.4	62.6
FX adjustment	0.0	0.0	0.0	0.0	0.0
Cash at year end	**30.1**	**29.5**	**92.4**	**62.6**	**35.5**

Balance Sheet (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	30.1	29.5	92.4	62.6	35.5
Receivables	4.2	6.7	6.7	6.7	6.7
Other current assets	0.2	0.2	0.2	0.2	0.2
Property, Plant and Equipment	0.2	0.5	0.5	0.5	0.5
Intangibles	30.5	34.9	34.9	34.9	34.9
Other non current assets	-	-	-	-	-
Total assets	65.2	71.8	134.7	104.9	77.8
Trade payables	1.4	1.3	1.3	1.3	1.3
Debt - inerest bearing	-	-	-	-	-
Vendor payable	-	-	-	-	-
Other provisions	4.0	5.5	4.0	4.0	4.0
Total Liabilities	5.4	6.8	5.3	5.3	5.3
Net Assets	59.8	65.0	129.4	99.6	72.5
Share capital	92.8	113.1	203.1	203.1	203.1
Other equity	12.1	12.1	12.1	12.1	12.1
Retained earnings	(47.3)	(65.7)	(92.7)	(122.5)	(149.5)
Reserves	2.2	5.5	6.9	6.9	6.8
Shareholders Equity	59.8	65.0	129.4	99.6	72.5

Valuation Ratios (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Reported EPS (cps)	-0.3	-0.4	-0.5	-0.6	-0.5
Normalised EPS (cps)	-0.3	-0.4	-0.5	-0.6	-0.5
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBIT (x)	nm	nm	nm	nm	nm
P/NTA (x)	60.4	62.0	21.0	32.6	56.0
Book Value Per Share (cps)	1.4	1.4	2.6	1.9	1.4
Price/Book (x)	29.6	28.7	15.3	21.1	29.0
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	nm
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

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

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

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

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

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

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