BELL POTTER

19 May 2023

Speculative
See key risks on Page 4 and 5 and Biotechnology Risk Warning on Page 8. Speculative securities may not be suitable for Retail Clients.

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Imugene (IMU)

First In Human Trial For onCARlytics

Recommendation
Buy (unchanged)
Price
$0.12
Valuation
$0.21 (previously $0.35)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

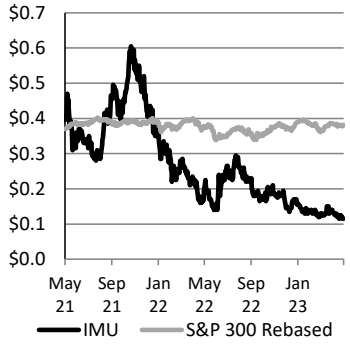
Expected Return	
Capital growth	**75%**
Dividend yield	**0.0%**
Total expected return	**75%**

Company Data & Ratios	
Enterprise value	**$606.8m**
Market cap	**$770.8m**
Issued capital	**6,423m**
Free float	**95%**
Avg. daily val. (52wk)	**$4.6m**
12 month price range	**$0.12 - $0.32**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.14	0.13	0.17
Absolute (%)	-17.86	-11.54	-30.30
Rel market (%)	-16.49	-9.59	-32.48

Absolute Price



SOURCE: IRESS

Mark This Day In The Development Of onCARlytics

The FDA has cleared the Investigational New Drug application to allow commencement of enrolment for a new phase 1 study investigating the combination of Imugene's oncolytic virotherapy candidate CF33-CD19t with Blinatumomab (Blincyto). This phase 1 study will investigate safety and tolerability of the combination in adults with advanced or metastatic solid tumours and will be known as OASIS.

The OASIS trial represents the first human trial for CF33-CD19 (known as onCARlytics) and accordingly this even represents a major milestone in the development of this potential new therapy. Blincyto is a form of T cell therapy approved in the United States for the treatment of Acute Lymphoblastic Leukemia (ALL). It is an off the shelf product, therefore suitable for use in patients who do not have a contra-indication. There are no approved allogeneic CD-19 products.

Pre-clinical data demonstrated that tumours infected with onCARlytics in combination with Blincyto and T-cells show improved tumour cell killing in a xenograft model of TNBC which the investigators described as comparable to CD19-CAR T Cells. Based on this promising data and in view of the ongoing need for new therapies in solid cancer, at the very least this combination is well worth investment in a human trial.

Details of the trial design are scant at this time, however, it will involve multiple patients in multiple treatment arms including a dose expansion cohort. Blincyto is a systemic therapy whereas CF33-CD19 will be administered via both intra-tumoral injection and IV. Blincyto is marketed by Amgen, however, it is not a contributor to the trial.

Investment View: Buy (Speculative) Valuation

IMU has 9 clinical trials underway and approximately $164m in cash representing ~3 years cash burn. The major short term catalyst is the readout from the phase 1 MAST study investigating CF33 in the treatment of solid tumours both as monotherapy and in various combinations with pembrolizumab. Notwithstanding these events, the market cap has continued to shrink in recent months necessitating a reduction our valuation. Valuation is reduced to $0.21 and we maintain our Buy (Speculative).

Earnings Forecast

June Year End	FY22	FY23e	FY24e	FY25e
Revenues $m	13.0	18.0	20.8	46.5
EBIT $m	-37.9	-39.8	-36.2	-10.5
NPAT (underlying) $m	-37.9	-38.8	-35.7	-10.0
NPAT (reported) $m	-37.9	-38.8	-35.7	-10.0
EPS underlying (cps)	-673.0	-0.6	-0.6	-0.2
EPS growth %	nm	nm	nm	nm
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 %	-27%	-22%	-25%	-8%

SOURCE: BELL POTTER SECURITIES ESTIMATES

onCARlytics now in the clinic

The FDA has cleared the Investigational New Drug (IND) application to allow commencement of enrolment for a new phase 1 study investigating the combination of Imugene's oncolytic virotherapy candidate CF33-CD19t with Blinatumomab (Blincyto). This phase 1 study will investigate safety and tolerability of the combination in adults with advanced or metastatic solid tumours and will be known as OASIS.

BLINCYTO is a BiTE (bispecific T-cell engager) immuno-oncology therapy that targets CD19 surface antigens on B cells. BiTE molecules fight cancer by helping the body's immune system detect and target malignant cells by engaging T cells to cancer cells.

Blincyto has two indications in United States being:

- Relapsed or refractory CD-19 positive B Cell precursor Acute Lymphoblastic Leukemia (ALL) in adults and children; and
- CD-19 positive B Cell precursor ALL in first or second complete remission with minimal residual disease (approved under accelerated approval).

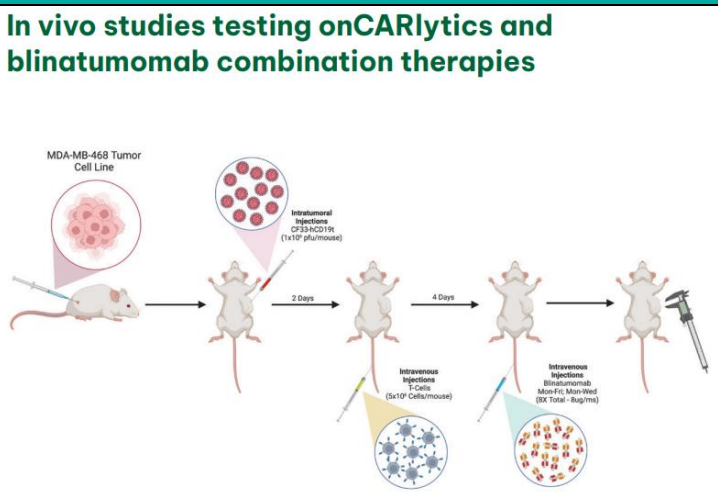
Blincyto is an off the shelf product suitable for any patient without a contraindication. In an ideal world IMU would probably have preferred to investigate a combination with an autologous CD-19 product, however, these are both time and cost prohibitive. The minimum wait period is 28 days and there is no guarantee that product will be available at the conclusion. There are no approved allogenic CD19 products.

Blincyto is marketed by Amgen in the US and Europe, however, the company is not contributing to the cost of the trial. We do expect this to change if the phase 1 results warrant further investigation.

PRE-CLINICAL DATA

Preclinical work for this drug combination was presented at SITC 2022[1]. Mice were engrafted with subcutaneous TNBC (triple negative breast cancer) and were intratumorally injected with onCARlytics. The mice were then intravenously treated with PBMCs ($5x10^6$) followed by BiTE[2].

Figure 1 - Summary trial design in mouse model



SOURCE: COMPANY DATA

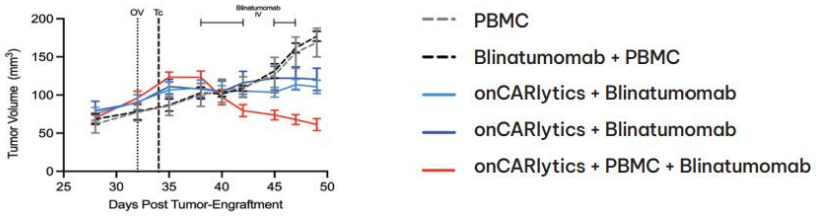
In this model, the mice lack a human immune system, and therefore investigators recreate the immune system by injecting PBMC's . In patients, investigators anticipate there to be

[1] SITC- Society for Immunotherapy of Cancer

[2] PBMT – Peripheral blood mononuclear cells – being lymphocytes (T Cells, B Cells and NK cells) and monocytes. These blood cells are a crucial component of the immune system's capacity to destroy pathogens.

an immune system (and T cells specifically), and thus would only treat with CF33-CD19t and then with Blinatumomab to redirect the patient's own T cells to virus-infected tumor cells.

Figure 2 - Pre-clinical data (onCARlytics+PBMC's+Blincyto) in murine mouse model



SOURCE: COMPANY DATA

The investigators concluded that Blinatumomab treatment following onCARlytics infection and T-Cell treatment showed a significantly higher tumour regression compared to onCARlytics, blinatumomab or T-Cells alone in xenograft models of TNBC.

This data along with the safety data from the MAST study (being the first in human study drug of CF33) were key components on the IND.

The company is yet to select participating sites for this trial, hence enrolments remain some time off but likely to commence in 2023. We expect the study to take two years to complete. The trial is likely to target a range of tumours including breast cancer, colorectal and lung.

VALUATION

IMU has 9 clinical trials underway and approximately $164m in cash representing ~3 years cash burn. The major short term catalyst is the readout from the phase 1 MAST study investigating CF33 in the treatment of solid tumours both as monotherapy and in various combinations with pembrolizumab. Notwithstanding the depth of the clinical trial program, the market cap has continued to shrink over recent months. Fortunately the company has ample capital to continue the trial program to realise value for shareholders.

In our view the market capitalisation is not a fair reflection of the potential within the clinical program. In particular, the oncolytic virus platform is within months of important data readouts. Nevertheless our valuation is limited to 100% upside from the current market price and accordingly valuation is reduced to $0.21 from the previous valuation of $0.35. We maintain our Buy (speculative). As there are no changes to the forecast revenues and expenses, the valuation is lowered by an increase to the discount rate in the DCF model. The model uses a WACC of 21.5%. Part of the increase at least is attributable to recent increases in the base rate.

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 are immense.

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

Imogene'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-Vex, PD1-Vaxx, CF33 and onCARlytics) 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 or license income and no revenues are 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, CF33 and onCARlytics, developed using the Company's technology must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. In addition there are numerous, well funded competitors who may achieve breakthroughs in cancer treatment ahead of IMU which may diminish the value of IMU's assets.

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 19 May 2023

Recommendation	Buy, Speculative
Price	$0.12
Valuation	$0.21

Table 1 - Financial summary

	FY21	FY22	FY23e	FY24e	FY25e
Year Ending June					
R&D incentive	7.3	13.0	18.0	18.0	18.0
Deal revenue (milestones/royalty income)	-	-	-	2.8	28.5
Total Revenue	**7.3**	**13.0**	**18.0**	**20.8**	**46.5**
COGS	-	-	-	-	-
Gross profit	7.3	13.0	18.0	20.8	46.5
R&D Expense	-15.4	-36.6	-40.0	-40.0	-40.0
Other expenses	-10.3	-14.1	-17.0	-17.0	-17.0
Total Expenses	-25.7	-50.9	-57.8	-57.0	-57.0
EBIT	-18.4	-37.9	-39.8	-36.2	-10.5
Interest income	0.0	0.0	1.0	0.5	0.5
Pre tax profit	(18.4)	(37.9)	(38.8)	(35.7)	(10.0)
Tax expense	-	-	-	-	-
NPAT- normalised	**(18.4)**	**(37.9)**	**(38.8)**	**(35.7)**	**(10.0)**
Reported NPAT	(18.4)	(37.9)	(38.8)	(35.7)	(10.0)

Cashflow (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Gross cashflow	-13.3	-30.8	-45.0	-36.2	-10.5
Net interest	0.2	0.2	1.0	0.5	0.5
Operating cash flow	-13.1	-30.6	-44.0	-35.7	-10.0
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-13.1	-30.6	-44.0	-35.7	-10.0
Business acquistions	-5.3	-0.1	0.0	0.0	0.0
Proceeds from issuance	17.9	102.7	78.0	0.0	0.0
Other	0.0	-1.4	0.0	0.0	0.0
Change in cash held	-0.5	70.5	34.0	-35.7	-10.0
Cash at beginning of period	30.1	29.5	99.9	133.6	97.6
FX adjustment	0.0	0.1	0.0	0.0	0.0
Cash at year end	**29.5**	**99.9**	**133.6**	**97.6**	**87.4**

Balance Sheet (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Cash	29.5	99.9	133.6	97.6	87.4
Receivables	6.7	12.8	18.0	18.0	18.0
Other current assets	0.2	1.1	1.1	1.1	1.1
Property, Plant and Equipment	0.5	0.9	0.9	0.9	0.9
Intangibles	34.9	32.7	32.7	32.7	32.7
Other non current assets	-	0.3	-	-	-
Total assets	71.8	147.6	186.3	150.3	140.0
Trade payables	1.3	5.3	5.3	5.3	5.3
Vendor payable	-	-	-	-	-
Other provisions	5.5	3.6	3.6	3.6	3.6
Total Liabilities	6.8	8.9	8.9	8.9	8.9
Net Assets	65.0	138.7	177.4	141.4	131.1
Share capital	113.1	230.8	308.8	308.8	308.8
Other equity	12.1	4.7	4.7	4.7	4.7
Retained earnings	(65.7)	(103.6)	(142.4)	(178.1)	(188.1)
Reserves	5.5	6.8	6.3	6.0	5.7
Shareholders Equity	65.0	138.7	177.4	141.4	131.1

Market Cap $m	$ 770.8
Share price $	$ 0.12
Enterprise value $m	$ 606.8

Valuation Ratios (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Reported EPS (cps)	-0.4	-673.0	-0.6	-0.6	-0.2
Normalised EPS (cps)	-0.4	-673.0	-0.6	-0.6	-0.2
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)	18.6	5.6	5.3	7.0	7.8
Book Value Per Share (cps)	1.4	2.8	2.8	2.2	2.1
Price/Book (x)	8.6	4.3	4.3	5.4	5.8
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

Interim results $m	1H22	2H22	1H23	2H23e
R&D incentive income	5.3	7.7	4.8	13.2
EBIT	-15.2	-22.7	-17.8	-22.0
NPAT	-14.8	-23.1	-17.4	-21.5

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

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