

Speculative

See key risks on Page 5 and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.

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Authorisation

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Recommendation

Buy (unchanged)

Price

\$0.105

Valuation

\$0.15 (previously \$0.105)

Risk

Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return

Capital growth	42.8%
Dividend yield	0.0%
Total expected return	42.8%

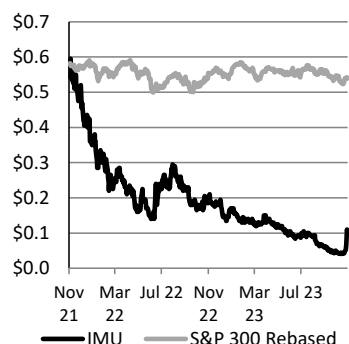
Company Data & Ratios

Enterprise value	\$589.3m
Market cap	\$752.3m
Issued capital	7,165m
Free float	93%
Avg. daily val. (52wk)	\$3.4m
12 month price range	\$0.04 - \$0.21

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.05	0.09	0.20
Absolute (%)	133.33	12.90	-46.15
Rel market (%)	133.18	17.51	-46.42

Absolute Price



SOURCE: IRESS

No Time To Waste – Azer-cel Back In The Clinic

IMU recently in-licensed Azer-cel with the transaction supported by an outstanding dossier of safety and efficacy data. This allogeneic CD19 CAR-T cell therapy program commenced enrolment of a dose escalating phase 1B clinical trial in the US last week. Earlier clinical trials in an identical patient population (to the phase 1B) produced an overall response rate of 83% amongst 18 patients with Diffuse Large B Cell Lymphoma. 55% of patients experienced a duration of response lasting greater than 6 months. This data (albeit in small patient numbers) compares exceptionally well to currently marketed autologous CAR-T therapies approved in earlier lines of therapy.

Interim Data from MAST

IMU recently announced promising interim data from the first 25 patients in the MAST study, investigating the safety and tolerability of CF33 (Vaxinia oncolytic virus) in a variety of solid tumours. As a result the study will expand to include a 10 patient extension in cholangiocarcinoma (bile duct cancer).

IMU has announced a pause of any further acquisitions in addition to a company wide evaluation of all clinical programs for the key purpose of aligning effort with strategic objectives - and (we suspect) shareholder value. In our view this is eminently sensible given the high bar set by equity markets for new capital, particularly for early stage biotechnology assets.

Investment View: Retain Buy (Spec) Valuation \$0.15

Cash as at 30 September was \$163.4m inclusive of the recent \$53m capital raise related to the Azer-cel in license transaction. Operating cash burn for the quarter was \$21.9m. We expect the burn to reduce in subsequent quarters as the R&D program is rationalised. Following this review and the encouraging news flow on Azer-cel and CF33, our valuation increases from \$0.10 to \$0.15. We maintain our Buy (Speculative) recommendation. Next catalysts include further interim data from the MAST study and from Azer-cel.

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenues \$m	11.8	14.0	21.6	44.3
EBIT \$m	-39.7	-42.2	-35.7	-32.0
NPAT (underlying) \$m	-37.9	-40.2	-33.7	-31.5
NPAT (reported) \$m	-37.9	-40.2	-33.7	-31.5
EPS underlying (cps)	-0.6	-0.6	-0.5	-0.4
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 %	-20%	-20%	-20%	-23%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Two Clinical Programs Driving Momentum

Azer-Cel Phase 1B Commences

IMU has confirmed that a first patient has been dosed in the phase 1B trial for Azer-cel. The asset was recently licensed by Imugene from Precision Bioscience in the US. The product is an allogeneic CAR-T CD19 directed cell therapy. The phase 1B trial will enrol 10 to 15 patients with non-hodgkin's lymphoma including Diffuse Large B Cell Lymphoma (DLBCL) with endpoints of safety and tolerability. Investigators will also be assessing durability of response in this heavily pre-treated patient population.

Patients in the trial have relapsed or are refractory for autologous CAR-T therapy. Only about 1/3rd of patients treated with CAR-T have a duration of response greater than 1 year.

Pending the results from this phase 1B study, the company intends to proceed swiftly to an approval study commencing in CY2025. Azer-cel demonstrated clinically meaningful activity in previous clinical studies with an acceptable safety profile including in DLBCL patients who had relapsed following autologous CAR-T therapy.

Trial Design

DOSE-ESCALATION, DOSE-EXPANSION STUDY OF SAFETY OF PBCAR0191 IN PATIENTS WITH R/NHL AND R/R B-CELL ALL (NCT03666000)

This is a multicenter, nonrandomized, open-label, parallel assignment, dose-escalation, and dose-optimization study to evaluate the safety and tolerability, find an appropriate dose to optimize safety and efficacy, and evaluate clinical activity of PBCAR0191 in subjects with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphoma (NHL).

Before initiating PBCAR0191, subjects will be administered lymphodepletion chemotherapy composed of fludarabine and cyclophosphamide. At Day 0 of the Treatment Period, subjects will receive an intravenous (IV) infusion of PBCAR0191. All subjects are monitored during the treatment period through Day 28. All subjects who receive a dose of PBCAR0191 will be followed in a separate long-term follow-up (LTFU) study for up to 15 years after exiting this study.

Market Size

The relapsed/refractory market in DLBCL is estimated at ~11,000 cases annually across the United States and Europe. We expect pricing for Azer-cel will be similar to the market for the autologous products at ~US\$400K/patient (for patients in the US, significantly lower in Europe). US sales are by far the largest sales geography.

Assuming 2,000 patients annually for Azer-cel, peak sales are estimated in the range of US\$700-\$900m annually.

CF-33 MAST Study

The MAST study (Metastatic Advanced Solid Tumours) is a phase 1 clinical trial investigating safety, tolerability and efficacy signals for IMU's oncolytic virus known as Vaxinia or CF33 in various late stage cancers.

Patients are currently enrolling in dose escalation cohorts. 25 patients have reached the first evaluation point with 1 complete response, 16 with stable disease and 8 patients with progressive disease. There have been no unexpected adverse safety events across the patient population which means the dose escalation can continue.

GASTROINTESTINAL CANCERS SHOWING PROMISING EARLY RESPONSE:

The patient group included eight patients with various gastrointestinal cancers where the disease control rate (i.e. complete response, partial response or stable disease) is 75%, (i.e. 6 of 8) hence most patients had some form of response to treatment. We understand each of these patients were dosed via intra tumoural injection.

The responses included one patient with bile duct cancer (aka Cholangiocarcinoma) who had progressed following numerous rounds of chemotherapy and showed a complete response to CF33 – no identifiable tumour. A second patient with bile duct disease achieved stable disease for >4 months.

As a result, IMU is already planning to expand the trial to include an additional 10 patients with bile duct cancers.

As with most cancers, survival is dependent upon the stage of disease at detection. If the cancer is diagnosed at an early stage with disease contained within the bile duct, the 5-year relative survival rate is 17%. If the cancer has spread to the regional lymph nodes, the 5-year relative survival rate is 16%. If the cancer has spread to a distant part of the body, the 5-year relative survival rate is 2%. Most patients are diagnosed with metastatic disease and of those who are candidates for initial curative surgery, the risks are high. Hence the need for new, effective therapies.

There are approximately 12,000 new cases per year in the US. Assuming a therapy cost of ~US\$400K, the TAM in this indication alone is in excess of US\$3bn.

The early success in this hard to treat tumour is very encouraging. We expect to see efficacy on other patients treated via intra tumoural injection particularly in melanoma where access (to the tumour) is straight forward.

INTRAVENOUS DOSING CONTINUES:

The trial included two intravenous (IV) dosing arms with CF33 either as a monotherapy or in combination with the PD-L1 checkpoint inhibitor pembrolizumab. The dose escalation work is continuing, however, the dosing is so far at sub therapeutic levels – hence no interim response data at this time.

The IV dosing is not critical but advantageous. A systemic therapy which attaches to cancer cells preferentially would be highly advantageous for the treatment of metastatic disease. There is no obvious binding mechanism which will preferentially attract the virus to the cancerous cell, hence we wait for results at higher doses.

We conclude that the early signs for safety appear good and we are encouraged by the efficacy signals in GI tumours. Clearly something is going on in the patients showing a response. Imaging (yet to be published) has shown virus contained within target tumours which is suggestive that the virus’s mechanism of action is working as planned.

Figure 1 - Summary of earnings changes

	2024			2025			2026		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	14.0	22.8	-39%	21.6	21.4	1%	44.3	43.5	2%
EBIT	-42.2	-43.4	3%	-35.7	-46.8	24%	-32.0	-24.7	-30%
NPAT	-40.2	-41.4	3%	-33.7	-44.8	25%	-31.5	-24.2	-30%
EPS	-0.6	-0.6	6%	-0.5	-0.6	22%	-0.4	-0.3	-47%

SOURCE: BELL POTTER SECURITIES ESTIMATES

For FY24 we had previously assumed the company may execute an out-license transaction for CF33. It is now clear the data will need more time to mature, hence this assumption is removed.

Following the announcements at the recent 4C regarding prioritisation of the clinical program, we have significantly reduced the assumed R&D spend for FY24 and FY25 resulting in the estimated loss for each financial year being reduced with cash runway now extending well into FY26.

Azer-cel is likely to be the nearest to revenue product. Following commencement of the phase 1B, the risk adjusted revenue model is amended to reflect a modest decrease in risk attached to this asset.

Valuation is amended to \$0.15 from \$0.10 and we maintain our Buy (Speculative) recommendation.

Imugene

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:

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-Vex, PD1-Vaxx, CF33, Azer-cel 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.

Table 1 - Financial summary

Year Ending June	FY22	FY23	FY24e	FY25e	FY26e
R&D incentive	13.0	11.8	14.0	14.0	14.0
Deal revenue (milestones/royalty income)	-	-	-	7.6	30.3
Total Revenue	13.0	11.8	14.0	21.6	44.3
COGS	-	-	-	-	-
Gross profit	13.0	11.8	14.0	21.6	44.3
R&D Expense	-36.6	-30.9	-32.0	-32.0	-50.0
Other expenses	-14.1	-18.2	-22.0	-23.1	-24.1
Total Expenses	-50.9	-51.5	-56.2	-57.3	-76.3
EBIT	-37.9	-39.7	-42.2	-35.7	-32.0
Interest income	0.0	1.9	2.0	2.0	0.5
Pre tax profit	(37.9)	(37.9)	(40.2)	(33.7)	(31.5)
Tax expense	-	-	-	-	-
NPAT- normalised	(37.9)	(37.9)	(40.2)	(33.7)	(31.5)
Reported NPAT	(37.9)	(37.9)	(40.2)	(33.7)	(31.5)
Cashflow (A\$m)	FY22	FY23	FY24e	FY25e	FY26e
Gross cashflow	-30.8	-31.5	-34.8	-33.4	-29.7
Net interest	0.2	1.7	2.0	2.0	0.5
Operating cash flow	-30.6	-29.8	-32.8	-31.4	-29.2
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-30.6	-29.8	-32.8	-31.4	-29.2
Acquisition of intangibles	-0.1	0.0	-12.7	0.0	0.0
Proceeds from issuance	102.7	83.1	50.2	0.0	0.0
Other	-1.4	-0.1	0.0	0.0	0.0
Change in cash held	70.5	53.2	4.7	-31.4	-29.2
Cash at beginning of period	29.5	99.9	153.1	157.7	105.7
FX adjustment	0.1	0.1	0.0	0.0	0.0
Cash at year end	99.9	153.1	157.7	105.7	76.5
Balance Sheet (A\$m)	FY22	FY23	FY24e	FY25e	FY26e
Cash	99.9	153.1	157.7	105.7	76.5
Receivables	12.8	12.1	7.0	7.0	7.0
Other current assets	1.1	0.4	0.4	0.4	0.4
Property, Plant and Equipment	0.9	0.7	0.7	0.7	0.7
Intangibles	32.7	30.5	61.6	59.4	57.2
Other non current assets	0.3	0.2	0.2	0.2	0.2
Total assets	147.6	197.0	227.6	173.4	142.0
Trade payables	5.3	3.5	3.5	3.5	3.5
Lease debt	-	0.2	0.2	0.2	0.2
Provisions	-	0.8	0.9	0.9	1.0
Contingent liability (Azer cel)	-	-	20.6	-	-
Other provisions - non current	3.6	2.9	2.9	2.9	2.9
Total Liabilities	8.9	7.4	28.1	7.5	7.6
Net Assets	138.7	189.5	199.5	165.9	134.4
Share capital	230.8	314.4	364.6	364.6	364.6
Other equity	4.7	4.7	4.7	4.8	4.8
Retained earnings	(103.6)	(141.5)	(181.7)	(215.4)	(246.9)
Reserves	6.8	11.9	11.9	11.9	11.9
Shareholders Equity	138.7	189.5	199.5	165.9	134.4
Market Cap \$m	\$ 752.3				
Share price \$	\$ 0.105				
Enterprise value \$m	\$ 589.3				
Valuation Ratios (A\$m)	FY22	FY23	FY24e	FY25e	FY26e
Reported EPS (cps)	-0.7	-0.6	-0.6	-0.5	-0.4
Normalised EPS (cps)	-0.7	-0.6	-0.6	-0.5	-0.4
EPS growth (%)	nm	nm	nm	nm	nm
PE(x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	nm
PNTA (x)	4.9	4.2	5.5	7.1	9.7
Book Value Per Share (cps)	2.8	3.0	2.8	2.3	1.9
Price/Book (x)	3.8	3.6	3.8	4.5	5.6
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

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