BELL POTTER

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Speculative

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

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Imugene (IMU)

Core Assets Progressing Nicely

Recommendation
Buy (unchanged)
Price
$0.071
Valuation
$0.15 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**111%**
Dividend yield	**0.0%**
Total expected return	**111%**
Company Data & Ratios	
Enterprise value	**$380.7m**
Market cap	**$519.7m**
Issued capital	**7,319.8m**
Free float	**93%**
Avg. daily val. (52wk)	**$3.4m**
12 month price range	**$0.04 - $0.15**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.11	0.11	0.14
Absolute (%)	-33.64	-33.64	-47.86
Rel market (%)	-32.19	-34.69	-50.36

Absolute Price

SOURCE: IRESS

Kincell Partnership Release Key Resources

IMU recently announced a Development Partnership with Kincell in the United States whereby Kincell will take on the manufacturing responsibilities for Azer-cel. Kincell is a privately owned company specialising in the production of CAR-T therapies from its CGMP production facilities in Florida. Under the terms of the Development Partnership, Kincell will assume the lease of Imugene's manufacturing facility in North Carolina and some headcount.

The deal allows Imugene to re-focus on its core competency of research and development for new oncology drugs, rather than the operation of complex production facilities. Kincell is a well established contract manufacturing business in biologics and is ideally suited to the manufacturing operations which Imugene inherited with the Azer-cel acquisition of September 2023.

Inflexion Points Coming

IMU will receive up to US$6m in cash upon certain milestones commencing with deal completion. The reduction in headcount is expected to amount to US$32m in savings to Imugene over three years which is vital to extending the cash runway beyond the period when we expect interim data from the Phase 1b trial with Azer-cel. The deal includes a supply agreement whereby Kincell will manufacture Azer-cell to support ongoing clinical trials. This note also contains a snapshot of the latest progress on the company's three core asset programs. Each of these is moving towards pivotal points in development which should manifest in meaningful clinical data within the next 6 to 12 months.

Investment View: Maintain Buy (Spec) Valuation $0.15

The company remains well funded with cash at 31 December of $139m. The Development Partnership with Kincell will free up crucial management time and resources to concentrate on the clinical programs each of which are moving toward value inflexion points. Retain Buy (Spec) recommendation and valuation $0.15. Earnings revisions have been driven by the recent transaction to acquire Azer-cel.

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenues $m	10.5	16.0	21.6	44.3
EBIT $m	-41.0	-115.9	-63.0	-40.3
NPAT (underlying) $m	-39.1	-95.9	-61.0	-39.8
NPAT (reported) $m	-39.1	-111.9	-61.0	-39.8
EPS underlying (cps)	-0.6	-1.3	-0.9	-0.6
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 %	-21%	-66%	-61%	-66%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Core Assets Progressing Nicely

AZER-CEL

The phase 1b study is a multicentre, nonrandomized, open-label, parallel assignment, dose-escalation, and dose-optimization study to evaluate safety and tolerability. The study will determine the appropriate dose to optimize safety and efficacy, and evaluate clinical activity of Azer cel in subjects with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkins lymphoma (NHL).

The company is targeting 10 to 15 patients that have failed on autologous CAR-T therapy. First patient was enrolled in November 2023. Assuming 1 to 2 enrolments per month we expect enrolment should be approaching completion by mid CY2024.

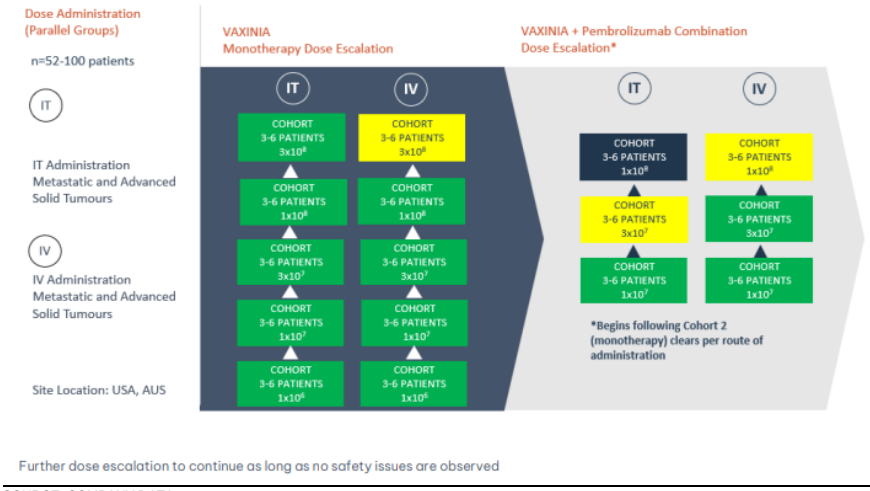
Earlier studies in the same refractory population had shown Azer-cel achieved a complete response of 61% (n=18). Most patients had a duration of response extending > 6 months.

Following completion of the current phase 1b the company intends to move to a phase 2 study which may also support an application for accelerated approval based on unmet need.

CF-33

CF-33 (aka VAXINIA) is the company's proprietary oncolytic virus. The phase 1 MAST study is a multi-arm dose escalation clinical trial that is now approaching completion following 2 years of painstaking dose escalation.

Figure 1 - Latest Snapshot - MAST



SOURCE: COMPANY DATA

The VAXINIA monotherapy cohorts are all but complete and now at the dose where we would expect to see a therapeutic impact.

The fifth and final cohort in the monotherapy section of the trial has now been cleared by the cohort review committee. The combination study with pembrolizumab is now also nearing completion.

IMU has commenced enrolment of an expansion study in 10 patients with bile duct cancers following encouraging early results in this indication as summarised here.

Patient A – three previous lines of therapy, received a mid-dose of CF33 via intratumoural injection and achieved a complete response with duration of response out to at least 430 days; and

Patient B – also failed on multiple lines of therapy, received a mid-dose of CF-33 via IV and achieved stable disease.

The three key points are:

- Both patients had failed on multiple therapies and should be considered as very difficult to treat and unlikely to respond to further lines of conventional therapy;
- Patient B was dosed via IV yet sufficient drug found its way to tumour in order to have a therapeutic effect; and
- The monotherapy response is encouraging. Potential buyers will be encouraged. Future combinations with immuno-oncology drugs are more likely to create a synergistic effect where there are two distinct modes of action.

WHAT WOULD GET PHARMA BUYERS EXCITED

Later this year we expect further updates on efficacy signals from patients dosed at the maximum dose. Some of the points to look for include:

- Analysis of the tumour micro environment demonstrating infiltration of virus, virus replication and increased level of immune check point molecules including PD-L1.
- If the virus is able to replicate within the cancer cells, we would also expect to see an abscopal effect in nearby cancers and this would be an exceptional result – particularly in patients dosed via IV.
- Duration of response – the overall response rate is important, however, duration of response is equally relevant. DoR is a proxy for progression free survival and ultimately overall survival. Among the patients who do respond, the percentage of patients with a DoR >6 months is a relevant benchmark.
- Synergistic effect of the combination study with pembrolizumab in cancer types where pembrolizumab has had minimal effect as a monotherapy.

We expect this detailed analysis to emerge from 2H24 onwards.

ONCARLYTICS

onCARlytics is a CD19-expressing oncolytic virus (CF33-CD19) that enters tumour cells and forces them to express the CD19 protein on the cell surface, presenting a target for CD19 targeted therapies. The OASIS trial commenced patient enrolment in February 2024 and is expected to recruit up to 52 patients with advanced or metastatic tumours.

This ambitious study is a world first and is likely to generate significant interest as the data emerges.

The intratumoural monotherapy section of the trial (with the CF33-CD19 virus alone) is complete and the study is now commencing the combination with the CD-19 targeting therapy Blincyto. The study will be conducted across multiple solid tumour types as investigators assess toxicity and look for early signs of responses.

Data is likely to take several months to emerge.

Figure 2 - Earnings changes

	2024			2025			2026		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	16.0	14.0	14%	21.6	21.6	0%	44.3	44.3	0%
EBIT	-115.9	-42.2	-175%	-63.0	-35.7	-76%	-40.3	-32.0	-26%
NPAT	-111.9	-40.2	-178%	-61.0	-33.7	-81%	-39.8	-31.5	-26%
EPS	-1.3	-0.6	-123%	-0.9	-0.5	-70%	-0.6	-0.4	-39%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The main driver of earnings changes includes the amalgamation of costs associated with the asset purchase from Precision Bioscience. We expect the loss will reduce in FY25 following the divestment of staff costs and as other R&D programs conclude. We maintain our Buy (Speculative) rating and valuation of $0.15.

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 or out license 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 22 April 2024

Recommendation	Buy, Speculative
Price	$0.071
Valuation	$0.15

Table 1 - Financial summary

	FY22	FY23	FY24e	FY25e	FY26e
Year Ending June					
R&D incentive	13.0	10.5	16.0	14.0	14.0
Deal revenue (milestones/royalty income)	-	-	-	7.6	30.3
Total Revenue	**13.0**	**10.5**	**16.0**	**21.6**	**44.3**
Other income	-0.2	-0.2	0.2	0.0	0.0
R&D Expense	-36.6	-30.9	-50.0	-50.0	-50.0
General and admin	-14.1	-20.4	-65.0	-34.6	-34.6
Add back D&A	0.2	2.2	5.0	5.0	5.0
Net expenses	-50.7	-49.3	-109.8	-79.6	-79.6
EBITDA	-37.7	-41.0	-93.8	-58.0	-35.3
Revaluation p'vn movement	0.0	0.0	-17.1	0.0	0.0
D&A	-0.2	-2.2	-5.0	-5.0	-5.0
EBIT	-37.9	-41.0	-115.9	-63.0	-40.3
Interest income	0.1	1.9	4.0	2.0	0.5
Pre tax profit	(37.9)	(39.1)	(111.9)	(61.0)	(39.8)
Tax expense	-	-	-	-	-
NPAT- reported	**(37.9)**	**(39.1)**	**(111.9)**	**(61.0)**	**(39.8)**
Add back abnrmal	0.0	0.0	16.0	0.0	0.0
Reported NPAT	(37.9)	(39.1)	(95.9)	(61.0)	(39.8)

Cashflow (A$m)	FY22	FY23	FY24e	FY25e	FY26e
EBITDA	-37.7	-41.0	-93.8	-58.0	-35.3
Working capital movement	6.9	10.5	4.6	2.3	0.3
Net interest	0.2	1.7	4.0	2.0	0.5
Operating cash flow	-30.6	-28.8	-85.2	-53.6	-34.4
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-30.6	-28.8	-85.2	-53.6	-34.4
Payment for PP&E	-0.3	0.0	-7.7	0.0	0.0
Acquistion of intangibles	-0.1	0.0	-8.7	0.0	0.0
Payment for other assets	0.0	0.0	-4.9	0.0	0.0
Payment - contingent liabilities	0.0	0.0	-2.0	0.0	0.0
Proceeds from issuance	102.7	83.1	50.9	0.0	0.0
Other	-1.4	-0.1	-0.3	0.0	0.0
Change in cash held	70.3	54.2	-57.9	-53.6	-34.4
Cash at beginning of period	29.5	99.9	153.2	95.2	42.1
FX adjustment	0.1	-0.9	0.0	0.0	0.0
Cash at year end	**99.9**	**153.2**	**95.2**	**42.1**	**7.7**

Balance Sheet (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Cash	99.9	153.2	95.2	42.1	7.7
Receivables	12.8	10.8	15.0	15.0	15.0
Other current assets	1.1	0.4	8.0	8.0	8.0
Property, Plant and Equipment	0.9	0.7	23.0	23.0	23.0
Intangibles	32.7	30.5	35.2	30.2	25.2
Other non current assets	0.3	0.2	2.9	2.9	2.9
Total assets	147.6	195.8	179.3	121.2	81.7
Trade payables	5.3	3.5	5.0	7.0	7.0
Provisions	-	0.5	3.9	4.1	4.3
Contract liabilities	-	1.9	16.3	-	-
Other current	-	0.2	2.3	2.4	2.5
Current Liabilities	5.3	6.1	27.5	13.5	13.8
Contract liability (Precision Bioscience)	-	1.0	3.1	3.6	3.6
Other provisions - non current	3.6	0.4	4.4	4.4	4.4
Non current liabilities	3.6	1.4	7.5	8.0	8.0
Total Liabilities	8.9	7.5	35.0	21.5	21.8
Net Assets	138.7	188.3	144.3	99.7	59.9
Share capital	230.8	314.4	365.3	400.1	400.1
Other equity	4.7	4.6	4.7	4.8	4.8
Retained earnings	(103.6)	(142.7)	(254.6)	(315.6)	(355.4)
Reserves	6.8	12.0	29.0	10.4	10.4
Shareholders Equity	138.7	188.3	144.3	99.7	59.9

Market Cap $m	$	519.7
Share price $	$	0.071
Enterprise value $m	$	380.7

Valuation Ratios (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Reported EPS (cps)	-0.7	-0.6	-1.6	-0.9	-0.6
Normalised EPS (cps)	-0.7	-0.6	-1.3	-0.9	-0.6
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)	3.3	2.9	4.7	7.3	14.7
Book Value Per Share (cps)	2.8	2.9	2.0	1.4	0.8
Price/Book (x)	2.5	2.4	3.5	5.1	8.5
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 analysis	1H23	2H23	1H24	2H24e
Revenues	4.8	5.7	8.1	7.9
Net expenses	-21.6	-27.7	-60.1	-49.7
EBITDA	-16.8	-24.2	-52.0	-41.8
Provision adjustment	0.0	0.0	-17.1	0.0
D&A	-1.1	0.0	-1.9	-3.1
EBIT	-17.9	-23.1	-71.0	-44.9

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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