BELL POTTER

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Speculative
See key risks on Pages 5 and 6, and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.

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Immutep (IMM)

Breast cancer trial data supports mechanism of action

Recommendation
Buy (unchanged)
Price
$0.355
Target (12 months)
$0.65 (previously $0.60)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**83.1%**
Dividend yield	**0**
Total expected return	**83.1%**

Company Data & Ratios	
Enterprise value	**$220.5m**
Market cap	**$307.5m**
Issued capital	**866m**
Free float	**97%**
Avg. daily val. (52wk)	**$0.96m**
12 month price range	**$0.31 - $0.73**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.38	0.37	0.46
Absolute (%)	-6.58	-2.74	-22.83
Rel market (%)	-4.80	-8.16	-27.67

Absolute Price

SOURCE: IRESS

Checking boxes

Immutep have provided final data from the Phase 2 trial of their lead check-point inhibitor candidate, efti, in patients with 2nd line (one previously failed treatment) HER2-negative/HR positive metastatic breast cancer (mBC). While encouraging survival benefit was shown back in November 2021, IMM have now presented data that confirms their 'immune stimulating' drug, efti, is just that – an 'immune stimulator'. All immune system biomarkers that were analysed were statistically increased in the efti+Paclitaxel group compared to control.

Furthermore, a positive correlation was observed between these increased immune biomarkers and overall survival, indicating the stimulation of the immune system is highly likely to be driving the survival benefit seen in a number of patient subgroups.

Regulatory agencies look favourably on data that underpins the mechanism of action of a pharmaceutical agent, and this data is likely to reduce the risk that the FDA in the US, or the EMA in Europe will quash an approval application for efti in not only mBC, but also the other indications efti is being considered for. These other indications include non-small cell lung cancer *and* head and neck squamous cell carcinoma.

Investment view: Valuation $0.65, Retain Buy (Spec.)

Changes to our valuation are mostly driven by a decrease in the risk adjustment we apply to efti being approved by the FDA and EMA by FY24 for use in mBC patients in combination with chemotherapy from 50% to 30%. Valuation is amended to $0.65 from $0.60 and we retain our Buy (Speculative) recommendation.

Earnings Forecast

June Year End	FY21	FY22e	FY23e	FY24e
Revenues	0.0	1.0	10.0	78.6
EBIT $m	-29.9	-35.4	-28.8	49.4
NPAT (underlying) $m	-29.9	-35.3	-28.7	49.5
NPAT (reported) $m	-29.9	-35.3	-28.7	49.5
EPS underlying (cps)	-7.2	-4.1	-3.4	5.8
EPS growth %	nm	nm	nm	-273%
PER (x)	nm	nm	nm	6.1
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	(7.4)	(6.2)	(7.7)	4.5
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	0%	-39%	-47%	45%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Immutep (IMM) release final data from 2nd line metastatic breast cancer patients: phase 2 trial with efti

Immutep (IMM) have released the final data from the Phase 2b trial of their leading immuno-oncology agent eftilagimod alpha (efti) in combination with chemotherapy agent, paclitaxel in 2nd line metastatic breast cancer (mBC) patients.

Specifically, the double blind and randomised AIPAC trial evaluated efti in combination with paclitaxel chemotherapy (efti group) compared to placebo plus paclitaxel (placebo group) in 227 patients with HER2-negative/HR positive mBC.

This final data release shows the effect of the efti combination therapy on the immune response in this population. The overall survival was reported in November 2021, and we described this in our note of March 2022. In summary:

- The efti combination provided an overall survival benefit of +7.5 months in patients <65 years; +4.2 months for Luminal B (aggressive form of hormone receptor-positive BC) patients;
- An impressive +19.6 months for patients with low baseline monocyte levels; and
- Efti also increased progression-free survival in one patient sub-group (low baseline monocyte patients – poor working immune system).

The new data released overnight helps to explain how efti works in these patients:

Efti group had greater increases in all the targeted immune system biomarkers. These include:

- circulating monocytes,
- CD8 T cells and a serum Th1 marker,
- CXCL10, and
- the absolute lymphocyte count (ALC).

(This data indicates the immune systems of patients in the efti group has been stimulated more than placebo group – this is what you would want in a cancer patient fighting the disease).

The data also shows a correlation between improved immune parameters with overall survival.

These results are encouraging because hormone receptor-positive mBC patients have not responded particularly well to modern immunotherapies to date, which explains why chemotherapy remains the standard of care for many of these patients, despite toxicity issues.

AIPAC-003: Planned phase 3 trial

IMM are engaged in ongoing communication with the European Medicines Agency (EMA), following apparently positive feedback, and the FDA to finalize the Phase 3 trial design for efti + paclitaxel in metastatic breast cancer.

Hormone receptor-positive (HR+) breast cancer accounts for around 74% of all breast cancers. There are some 350,000 metastatic HR+ breast cancer patients under the age of 65 globally. The addressable market of 1st to 3rd line chemo-treated patients is approximately 34,000 patients across the US and EU. We estimate efti has the potential to take 35% of this market and reach peak sales of over US$700m. None of this will eventuate without a Phase 3 trial, which may be some time away given the need to harmonize the clinical trial design for AIPAC-003 with various competent authorities globally. This new data that confirms the drug's mechanism of action should be viewed very positively by the regulatory agencies and potential partners.

Next catalysts for IMM

1. Immutep have been awarded an oral presentation to present new data from **patients with 1st line non-small cell lung cancer (NSCLC) taking the combination of efti + Keytruda®** at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting. The abstracts for this conference will be released on 26th May 2022 and the final presentation with full data is to be released at the start of the conference, June 3rd 2022. The title of the presentation is: "*A Phase 2 study (TACTI-002) in 1st line metastatic non-small cell lung carcinoma investigating eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab: updated results from a PD-L1 unselected population*"
2. The Phase 2b TACTI-003 trial design for patients with **1st line (never previously treated) head and neck squamous cell carcinoma (HNSCC)** will be presented in a Trial-in-Progress Poster Presentation at this same ASCO conference. This will be the first trial IMM have run in which the combination of efti + Ketruda® is compared head-to-head with patients taking Keytruda® alone. Note the data off the back of the previous phase 2 trials in 2nd line (previously treated) patients with HNSCC resulted in the FDA awarding efti a fast-tracked review with 5 completed responders (tumour/s disappeared) to the combination treatment. We understand 21 of 154 patients have been recruited onto the trail at this time.

Valuation

The valuation of $0.65 is derived from a discounted cash flow model. The model includes royalties on prospective future sales of efti and milestone income from both EOC Pharma and Novartis who are at various stages of their clinical trials.

EOC have the exclusive rights to efti in China and are currently looking to begin Phase 2 trials in metastatic breast cancer, again in combination with paclitaxel, in CY22. We expect this to trigger a milestone payment of approximately AUD$1m.

Novartis has the global rights to IMM's LAG525 antagonist antibody. The focus and direction of the development pipeline for LAG525 by Novartis is not clear at this stage, although they currently have five ongoing clinical trials registered for LAG525. These trials are focused on multiple indications including blood cancers, breast cancers, solid tumours

and melanoma, with approximately 1,000 patients recruited to date. We are confident that IMM will receive at least one milestone payment from Novartis arising from the recruitment of patients into Phase 3 trials at some point over the next 3 years.

Importantly, our valuation change is mostly driven by a decrease in the risk we have ascribed to the likelihood of efti being approved by the FDA and EMA by FY24 for use in mBC patients in combination with chemotherapy, from 50% risk to 30% risk.

Table 1 - Key changes to our forecasts

	2022			2023			2024		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	1.0	1.0	0%	10.0	10.0	0%	78.6	65.4	20%
EBIT	-35.4	-35.4	0%	-28.8	-28.8	0%	49.4	36.2	37%
NPAT	-35.3	-35.3	0%	-28.7	-28.7	0%	49.5	36.3	36%
EPS	-4.1	-4.1	0%	-3.4	-3.4	0%	5.8	4.3	35%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The WACC is 10% and we have assumed a terminal growth rate of 3%.

Immutep (IMM)

COMPANY DESCRIPTION

Immutep (IMM) is a clinical-stage biopharmaceutical company, focused on the development of novel immunotherapies for the treatment of cancer and autoimmune diseases. Its core technology is based on LAG-3 (lymphocyte activation gene-3) protein, a key mediator of the immune system. IMM is listed on the ASX and has its American Depository Receipts (ADRs) listed on NASDAQ. It is based in Sydney, with operations in US, Germany and France. The company's LAG-3 assets come from the acquisition in 2014 of a private French biotech company founded by Dr. Frederic Triebel (now IMM's CSO and CMO), who first discovered the LAG-3 gene and developed the various LAG-3 assets IMM holds.

IMM have an impressive track record of high quality commercial and clinical trial collaborations with Tier 1 pharmaceutical companies. This is an important history that raises our confidence in the company's future prospects of commercially successful partnerships.

INVESTMENT STRATEGY

We have a Buy (speculative) recommendation on Immutep (IMM). Our investment thesis is based on: $0.65 Valuation.

LAG-3 could become the third major immune checkpoint target, after PD-1/PD-L1 and CTLA-4 checkpoint inhibitors, in the treatment of cancer. Clinical results in the industry highlight its potential. Bristol Myers Squibb new drug, Opdualag™, was approved in March this year (2022) by the FDA for the treatment of adult and paediatric patients >12 years of age with unresectable or metastatic melanoma.

Opdualag™ is a fixed-dose combination of two check-point therapies: nivolumab (PD-1 inhibitor) and relatlimab (a novel LAG-3-blocking antibody), administered as a single intravenous infusion. BMY's relatlimab has thus become the first LAG-3 drug to be approved.

This provides validation for LAG-3 and its interaction with MHC Class II proteins, and we expect IMM to benefit from this approval.

We expect efti to have broad utility across multiple cancer indications in combination with different treatment modalities, including other immuno-oncology agents and chemotherapeutic agents. We view a multi-billion dollar sales potential for the uniquely acting efti. Within that forecast, we model that IMM has the potential to earn peak in-market sales of >$250m p.a. from royalty revenues for efti alone.

KEY RISKS

Key risks we consider to be specific to IMM include, but are not limited to:

Further validation of efficacy of efti required: Research and understanding around LAG-3 as a target is recent and ongoing. Compare this to other approved checkpoint targeting therapies that have a history of successful clinical application. There is currently one approved LAG-3 therapy on the market: BMY's Opdualag™.

For IMM's lead product 'efti', however, there still a risk as it is a new approach to targeting LAG-3 as an agonist (activating the pathway), vs. the more common approach of targeting LAG-3 as an antagonist antibody (releasing the brake on the T cell) such as BMY's relatlimab. Therefore the onus of validating this drug class as an APC activator rests solely on IMM's shoulders and Phase 3 trials should be focussed on this risk.

Clinical risk: There is a risk that one or more of IMM's ongoing clinical trials fail to reach

their endpoints. Though IMM has presented encouraging clinical data to date, some were not blinded and had a small number of patients. There is no guarantee that early data will translate to positive outcomes in larger trials. Underwhelming results from any of IMM's ongoing trials is likely to impact the company's ability to monetise those assets and negatively impact the sentiment around the company and its valuation.

Timing and clinical risk on externally partnered products: For its partnered products LAG525 and GSK2831781, IMM is reliant on Novartis (NVS) and GlaxoSmithKline (GSK) respectively for development timelines. The ability of IMM's products to reach the market and translate into royalty revenue streams depends on these partners.

Reliance on partnerships to unlock value: The success of IMM's business model is underpinned by its ability to ultimately attract valuable partnering deals for its assets, given IMM lacks the commercial infrastructure to support commercialisation. Our valuation is underpinned, in part, by IMM's ability to attract a valuable partnering deal for 'efti' for the US & EU markets. Failure to attract partners or to negotiate attractive deal terms as we have postulated will impact our forecasts.

Regulatory risk: Successful commercialisation of IMM's products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. IMM is likely to partner its products and not look to commercialise them itself. While IMM's partners (current and future), with superior experience in navigating regulatory channels, will be responsible for obtaining approvals. Failure to satisfy regulatory requirements could result in the product failing to reach the market.

Funding risk: IMM had cash reserves of $87.2m as at 31 March 2022 representing approximately 3 years of cash runway based on the forecast cash burn for FY22. The company may require additional capital if the Board decides to expand the clinical program for any additional studies. Additional partnerships may alleviate the need to raise capital, however if IMM needs to raise money, it will be dilutive to shareholders

Table 2 - Financial summary

A$m	FY20	FY21	FY22e	FY23e	FY24e
Year Ending 30 June					
Total Revenue	**7.5**	**-**	**1.0**	**10.0**	**78.6**
Revenue growth	**nm**	**nm**	**nm**	**900.0%**	**686.2%**
COGS	0.0	0.0	0.0	0.0	0.0
Gross profit	7.5	0.0	1.0	10.0	78.6
GP Margin	100%	0%	100%	100%	100%
Employee costs	-20.6	-15.3	-29.6	-30.5	-15.2
Scientific consumables	-6.3	-6.3	-7.8	-9.3	-12.1
Amortisation expense	-1.9	-1.9	-1.9	-1.9	-1.9
Other expenses	-1.1	-10.4	0.0	0.0	0.0
Grant income	9.0	4.0	2.9	2.9	0.0
Total Expenses	-20.9	-29.9	-36.4	-38.8	-29.2
EBIT	-13.5	-29.9	-35.4	-28.8	49.4
Add back D&A	0.0	1.9	1.9	1.9	1.9
EBITDA	-13.5	-28.1	-33.5	-26.9	51.3
Interest expense	0.0	0.0	0.1	0.1	0.1
Other items	0.0	0.0	0.0	0.0	0.0
Pre tax profit	(13.5)	(29.9)	(35.3)	(28.7)	49.5
Tax expense	0.0	0.0	0.0	0.0	0.0
NPAT- reported	**(13.5)**	**(29.9)**	**(35.3)**	**(28.7)**	**49.5**
Add back					
Non recurring items net of tax	-	-	-	-	-
Reported normalised	(13.5)	(29.9)	(35.3)	(28.7)	49.5

Cashflow (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Gross cashflow	-11.0	-17.6	-35.7	-23.6	36.9
Net interest	0.2	0.0	0.1	0.1	0.1
Income tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-10.8	-17.6	-35.6	-23.5	37.0
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised R&D	0.0	0.0	0.0	0.0	0.0
Free cash flow	-10.8	-17.6	-35.6	-23.5	37.0
Purchase of other intangibles	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	20.6	52.9	51.9	0.0	0.0
Movement in borrowings	0.0	-0.2	0.0	0.0	0.0
Redemption of preference shares	0.0	0.0	0.0	0.0	0.0
Dvidends paid (common stock)	0.0	0.0	0.0	0.0	0.0
Change in cash held	9.8	35.1	16.3	-23.5	37.0
Cash at beginning of period	16.6	26.3	60.6	76.9	53.4
FX adjustment	0.1	-0.8	0.0	0.0	0.0
Cash at year end	**26.4**	**60.6**	**76.9**	**53.4**	**90.4**

Balance Sheet (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	26.4	60.6	76.9	53.4	90.4
Receivables	3.3	6.1	5.0	2.0	15.7
Other current assets	1.5	1.7	2.9	2.9	2.9
Inventory	-	-	-	-	-
Property, Plant and Equipment	0.0	0.0	0.0	0.0	0.0
Intangibles	15.2	12.8	11.0	9.1	7.2
Right of use assets	-	0.3	0.5	0.5	0.5
Other non current assets	0.2	0.5	0.5	0.5	0.5
Total assets	46.7	82.1	96.8	68.4	117.3
Trade payables	(2.9)	(4.8)	(2.9)	(3.1)	(2.3)
Other liabilities	(0.3)	(0.4)	(0.4)	(0.4)	(0.4)
Other liabilities	(1.1)	(0.9)	(0.9)	(1.0)	(1.0)
Debt	(8.8)	(2.5)	(2.5)	(2.5)	(2.5)
Lease liabilities	(0.2)	(0.2)	(0.2)	(0.2)	(0.3)
Total Liabilities	-13.3	-8.8	-6.9	-7.2	-6.5
Net Assets	33.3	73.3	89.9	61.2	110.7
Share capital	243.0	313.4	365.3	365.3	365.3
Other equity	-	-	-	-	-
Retained earnings	(275.7)	(274.7)	(310.0)	(338.7)	(289.2)
Reserves	66.0	34.6	34.6	34.6	34.6
Shareholders Equity	33.3	73.3	89.9	61.2	110.7

Valuation Ratios (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Reported EPS (cps)	-2.3	-7.2	-4.1	-3.4	5.8
Normalised EPS (cps)	-2.3	-7.2	-4.1	-3.4	5.8
EPS growth (%)	0%	nm	nm	nm	-273%
PE(x)	**nm**	**nm**	**nm**	**nm**	**6.1**
EV/EBIT (x)	nm	-7.4	-6.2	-7.7	4.5
P/NTA (x)	9.6	4.4	3.8	5.8	2.9
Book Value Per Share (cps)	6.8	9.8	10.5	7.2	13.0
Price/Book (x)	5.2	3.6	3.4	5.0	2.7
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	53%	79%	83%	83%	79%
Net debt/Assets	38%	71%	77%	74%	75%
Gearing	35%	44%	45%	45%	44%
Net debt/EBITDA (x)	Net Cash	Net Cash	Net Cash	Net Cash	1.7
Interest cover (x)	na	na	na	na	na

Revenues Analysis	FY20	FY21	FY22e	FY23e	FY24e
Year End 30 June (AUD$m)					
GSK deal - risk adjusted milestone	-	-	-	-	-
Novartis deal - P3 recruitment milestone	7.5	-	-	10.0	-
EOC Pharma P3 recruitment milestone	-	-	1.0	-	-
Potential efti deal US/EU and sales royalties	-	-	-	-	78.6

InterimResults	1H21	2H21	1H22	2H22e
Revenues	0.0	0.0	0.0	1.0
EBIT	-7.3	-22.6	-17.2	-18.4
NPAT	-7.3	-22.6	-17.2	-18.1

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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The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek U.S. FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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