BELL POTTER

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Speculative
See key risks on Pages 3 and 4, and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

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Immutep (IMM)

IMM - a very viable big pharma target

Recommendation
Buy (unchanged)
Price
$0.36
Valuation
$0.65 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**80.6%**
Dividend yield	**0.0%**
Total expected return	**80.6%**
Company Data & Ratios	
Enterprise value	**$224.8**
Market cap	**$311.8**
Issued capital	**854.1m**
Free float	**97%**
Avg. daily val. (52wk)	**$0.96m**
12 month price range	**$0.305 - $0.71**

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

TACTI-002: Encouraging data in NSCLC

During an oral presentation at the annual conference of the American Society of Clinical Oncology last week, Immutep provided new data from the Phase 2 trial of their lead check-point inhibitor candidate, efti, + Merck's pembrolizumab (Keytruda®), in patients with 1st line (never been treated) non-small cell lung cancer (NSCLC). The following data was presented:

1. Overall response rate (ORR) was 38.6% - in ALL patients (no restrictions due to PD-L1 levels);
2. Stratification of patients by PD-L1 expression levels indicates that the patient group that displayed the greatest benefit were those with no (<1%) or low (1-49%) PD-L1 levels. These showed an ORR rate of 28.1% and 41.7% respectively; and
3. Median progression-free survival in ALL patients was 6.9 months.

Keytruda® sales reached US$17.2 billion in 2021. This year (2022) it is on target to make Merck US$21 billion – making it the highest grossing pharmaceutical drug globally. Keytruda® will come off patent in approximately 4 years – so Merck is very likely on the hunt for another drug to combine with Keytruda®, giving it another 5 years shelf-life (+5 more for an extension = total 10 years).

In our view, Immutep has an asset in efti that is under very close watch by Merck and other large pharma companies. In March this year, Roche revealed that its Phase III trial of the anti-TIGIT drug, tiragolumab, failed to meet its co-primary endpoints in combination with an immune-checkpoint inhibitor in small cell lung cancer. Meanwhile, BMY last week announced they are acquired the US Biotech, Turning Point, for US$4.1bn off the back of its Phase 1/2 data in NSCLC.

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

Valuation remains unchanged at $0.65 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 presented new data from **patients with 1st line non-small cell lung cancer (NSCLC) taking the combination of efti + Keytruda®** at the American Society of Clinical Oncology (ASCO) Annual Meeting last week.

"*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*"

Results presented were as follows:

1. The overall response rate (ORR) was 38.6% - in ALL patients (no restrictions due to PD-L1 levels). Note that the comparable historical trial of Keytruda® alone (KEYNOTE-001) achieved an ORR of only 19.4% - although there may be some inter-study heterogeneity - i.e., participants may have certain characteristics that affect the results (like age, other co-morbidities, sex, other lifestyle factors) – this new data is encouraging.

   Stratification of patients by PD-L1 expression levels (low, medium or high) indicates the patient groups that showed the greatest benefit from efti were those with no (<1%) or low (1-49%) PD-L1 levels i.e. ORR of 28.1% and 41.7% respectively (these responses were at least 2.5 times better than the historical Keytruda® alone results);

2. Median progression-free survival (PFS) in ALL patients was 6.9 months; and

3. The responses were sufficiently durable (<10% of confirmed partial responses progressed < 6 months) and encouraging to warrant further trials.

COMMERCIAL RELEVANCE OF NEW DATA

The clinical landscape for the treatment of NSCLC has a number of investigational combination therapies – most of which are novel therapeutics in combination with one of the approved anti-PD-1/PD-L1 therapies. Patients with low to no PD-L1 expression have historically shown minimal benefit from the anti-PD-1/PD-L1 therapies alone, and these represent a majority of the patient population (i.e. ~70%) in this indication, thus the unmet patient need.

Earlier this year, the FDA approved the first LAG3-targeted drug (BMY's relatlimab) in combination with the BMY anti-PD-1 antibody therapy – nivolumab (brand name Opdivo®). At this time the combination has a single indication in metastatic melanoma. It is likely that BMY will pursue additional indications for the combination, which would potentially provide it with a competitive advantage over Keytruda therapy alone.

The new data from IMM's TACTI-002 study highlights the benefit of efti in combination with Keytruda® in this low-PD-L1 expressing cohort of NSCLC patients. In our view it is reasonable to assume that multiple pharma companies may have renewed interest in LAG3 assets given the approval of the BMY drug and last week's oral presentation at ASCO. There are multiple indications where a combination may show improved efficacy. Keyruda® and Opdivo® are both approved in multiple indications, either as first or second line therapy.

Also noteworthy is the news that Bristol Myers Squibb (BMY) last week announced it would acquire biotech company, Turning Point, for US$4.1 billion following encouraging results from their Phase 1/2 TRIDENT-1 trial of repotrectinib, in NSCLC patients,. Previously, repotrectinib, a tyrosine kinase inhibitor (TKI) targeting the ROS1 and NTRK oncogenic drivers of NSCLC and other solid tumours, was granted three Breakthrough Therapy Designations from the FDA, despite being a mid-stage candidate.

IMM has been very clear that it intends to partner efti in an approval study and we expect this latest data further strengthens its negotiating position.

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 is 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 reachtheir 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

Immutep
as at 7 June 2022

Recommendation	Buy, Speculative
Price	$0.36
Valuation (Speculative)	$0.65

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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