BELL POTTER

Speculative

See Key Risks on Page 10 &11 & Biotechnology Risk warning on Page 13
Speculative securities may not be suitable for Retail clients

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Immutep (IMM)

Creating Value with Phase 3 around the corner

Recommendation
Buy (unchanged)
Price
$0.535
Valuation
$1.00 (previously $0.85)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**86.9%**
Dividend yield	**0.0%**
Total expected return	**86.9%**

Company Data & Ratios	
Enterprise value	**$339.7m**
Market cap	**$400.3m**
Issued capital	**748.2m**
Free float	**97.1%**
Avg. daily val. (52wk)	**$1.41m**
12 month price range	**$0.145-$0.73**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.62	0.44	0.15
Absolute (%)	-13.01	21.59	256.67
Rel market (%)	-13.89	15.68	232.19

Absolute Price

SOURCE: IRESS

Strong clinical data drives development expansion

Updated data from Phase 2 TACTI-002 trial with efti+Keytruda was presented at ASCO conference last month in both non-small cell lung cancer and head and neck cancer. The data continues to be competitive with deep and durable responses (including in those with low PD-L1 expression who typically do not respond to anti-PD-1 monotherapy), while maintaining a favourable safety profile. **The I-O doublet demonstrates clear separation of activity over Keytruda monotherapy with response rates (ORR) notably higher in both the settings.** Both progression free survival and overall survival data are trending favourably in support of the combo when making cross trial comparisons with randomized controlled Keytruda monotherapy trials. Data supports expansion of efti clinical development into later stage settings. Phase 2b TACTI-003 trial in 1L HNSCC will start recruiting patients in 3QCY21.

Balance sheet strengthened to fund expanded development

IMM reported cash balance of $60.6m at the end of 4QFY21, which includes Tranche 1 placement proceeds of $13.7m and warrant exercise of $0.6m. Proforma cash (assuming shareholder approval for Tranche 2 placement and $5m raised under SPP) is $112m, which provides cash runway to end 4QCY23. A new Phase 3 breast cancer trial with efti+chemo combo and Phase 2 trial with triple combo of efti+IO+chemo is expected to start in CY22, which would transition IMM to a late stage developer and materially add to efti's data package and enhance its licensing prospects.

Valuation lifted to $1.00, Retain Buy (spec)

Increased opex related to the new clinical trial programs for efti, manufacturing and personnel and timing of TACTI-003 trial spend have resulted in double digit percentage changes in our FY21-FY23 forecasts. Earning changes and longer term impact of increased market share for efti in 1L NSCLC and 1L HNSCC, partially offset by the dilutive impact of capital raise and conversion of convertible notes into equity, has lifted our valuation for IMM to A$1.00/sh (was A$0.85/sh). We retain Buy (spec). Our hypothetical M&A valuation for IMM is revised to $1.48/sh, which helps ground our DCF valuation. IMM remains one of our key picks in the biotech space for FY22.

Earnings Forecast

Year end 30th June	2019A	2020A	2021E	2022E	2023E
Revenue (A$m)	5.6	13.7	4.8	8.3	75.2
EBITDA (A$m)	-17.3	-13.0	-19.1	-44.0	18.9
NPAT (reported) (A$m)	-18.3	-13.5	-31.0	-46.0	17.0
NPAT (normalised) (A$m)	-18.3	-13.5	-31.0	-46.0	17.0
EPS (reported) (cps)	-5.5	-3.4	-5.3	-5.8	2.0
EPS (normalised) (cps)	-5.5	-3.4	-5.3	-5.8	2.0
EPS growth (%)	N/A	N/A	N/A	N/A	NM
PER (x)	N/A	N/A	N/A	N/A	26.6
EV/EBITDA (x)	-19.6	-26.1	-17.8	-7.7	17.9
Dividend (¢ps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-75.2%	-40.4%	-43.0%	-60.2%	18.1%

NOTE: REVENUE INCLUDES R&D TAX REBATE, MILESTONES FROM EXISTING DEALS AND FY23 REVENUE ALSO INCLUDES RISK ADJUSTED UPFRONT AND MILESTONE FROM POTENTIAL DEAL FOR EFTI. SOURCE: BELL POTTER SECURITIES ESTIMATES

TACTI-002 Trial Data continues to impress

Immutep (IMM) last month reported updated data from its Phase 2 TACTI-002 (KEYNOTE-798) trial exploring the combination of its lead drug efti with Merck's Keytruda in 1st line non-small cell lung cancer patients (1L NSCLC) and 2nd line head and neck cancer patients (2L HNSCC) **at the ASCO 2021 conference**. The data continues to impress us and supports Merck's recent decision to expand the 1L NSCLC cohort with an additional 74 patients and enter into a new collaboration with IMM for a Phase 2b TACTI-003 trial in 1L HNSCC. It also supports IMM's decision to further expand efti development program to now also explore a triple combination of efti+anti-PD-1+chemotherapy.

Key overall takeaways

- **Safety continues to be favourable. No new safety signals observed and the combo is well tolerated.** We note this point is a strong advantage with efti+Keytruda combination vs. the more toxic standard of care (SOC) combination of Keytruda + chemotherapy in NSCLC and chemotherapy regimen in HNSCC.
- **Responses continue to deepen and remain competitive and are durable across both 1L NSCLC and 2L HNSCC**. Durability of response in our view is another advantage of a chemotherapy free combo such as efti+ Keytruda, given chemotherapy either has low or decreased duration of response vs. Keytruda monotherapy.
- **Responses continue to be seen in unselected patient population** i.e. in an all comer trial across various PD-L1 subgroups. This also includes those with low PD-L1 expression who typically do not respond to Keytruda monotherapy.

TACTI-002: Stage 1 & Stage 2 of Part A (1L NSCLC)

In 1L NSCLC, for the ~70% patients who are low PD-L1 expressors, the I-O doublet is likely to be positioned as a chemo free option, with a more favourable safety profile and possibly higher duration of response than the dominant standard of care chemo-IO combo.

IMPROVED OVERALL RESPONSE RATE WITH RESPONSES HIGHER THAN KEYTRUDA MONOTHERAPY ACROSS PD-L1 SUBGROUPS

- 1L NSCLC ORR data presented at ASCO (data cut off 16th April'21) improved since the SITC update (cut off of 8th Oct'20) , climbing from 36.1% (13/36) ORR with 2 CRs and 11 PRs to 41.7% (15/36) ORR with 2 CRs and 13 PRs.
- Responses were seen across all subgroups, including PD-L1 low expressors.
- iORR in ≥1% PD-L1 group was 44% (11/25), which is significantly higher than the 27.3% seen in this group of patients with Keytruda alone in Keynote-042 trial.
- iORR in ≥50% PD-L1 group was 53.8% (7/13), which is also higher than the 44.8% reported for Keytruda alone in Keynote-024 trial and 39% reported in Keynote-042 trial.
- iORR in <50% group of 31.6% (6/19) is also much higher than that seen with Roche's Tecentriq + TIGIT combo which showed almost no benefit in this group vs. Tecentriq alone (16% vs. 18%) in CITYSCAPE trial.
- Median duration of response was not reached but is trending favourably at +13 months.

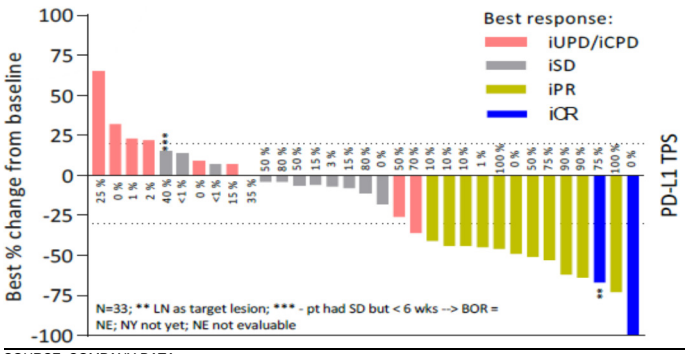
PROGRESSION FREE SURVIVAL HIGHER THAN KEYTRUDA MONO AND COMPARABLE TO DOMINANT CHEMO+KEYTRUDA COMBO

- Median overall PFS (progression free survival) was 8.2 months which is higher than the ~5.4 months PFS in Keynote-042 trial which we note did not include patients with less than 1% PD-L1 expression. Notably, it is similar to the median PFS of 8 to 9 months

seen with the dominant but toxic Keytruda + chemo combination which is standard of care treatment in this population.

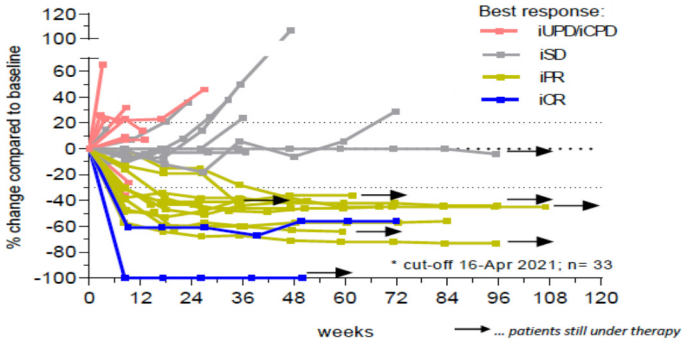
- In the subgroup of ≥50% PD-L1 group median PFS was 11.8 months which is higher than the 7.1 months PFS seen with Keytruda in KEYNOTE-042 trial and 10.3 months in KEYNOTE-024 trial. Median PFS in the <1% PD-L1 subgroup was 4.1 months.
- Overall Survival (OS) data not yet mature, however we note that 7/36 patients are still receiving treatment, with 1 patient for +24 months.

Figure 1 –ORRs at all PD-L1 levels in 1L NSCLC



SOURCE: COMPANY DATA

Figure 2 – Median duration of Response tracking at +13 months - 1L NSCLC



SOURCE: COMPANY DATA

Table 1 - Key Non-Small Cell Lung Cancer Trials – efti+Keytruda combo data continues to be competitive

	Immutep	Merck & Co.					Roche
Clinical Trial Information	Keytruda + efti	Keytruda	Keytruda	Keytruda + chemo	Keytruda + chemo	vibostolimab (TIGIT) + Keytruda (PD-1)	Tiragolumab (TIGIT) + Tecentriq (anti-PD-L1)
Clinical Trial Phase	Phase 2 (TACTI-002/KEYNOTE-798)	Phase 3 (KEYNOTE-042)	(KEYNOTE-024)	(KEYNOTE-407)	Phase 3 (KEYNOTE-189)	Phase 1	Phase 2 (CITYSCAPE)
Patient Number, N (tumour type)	36 1L NSCLC	637 vs. 637 1L NSCLC	154 vs. 151 1L NSCLC	278 vs. 281 1L NSCLC (squamous)	410 vs. 206 1L NSCLC (non-squamous)	41 1L NSCLC	67 1L NSCLC
Type of Patients Recruited	Recruited PD-L1 all comer	Recruited only PD-L1 TPS ≥1%	Recruited only PD-L1 TPS ≥50%	Recruited PD-L1 all comer	Recruited PD-L1 all comer	Recruited patients 73% received ≥1 prior lines of therapy, but PD-1 naive	Recruited only PD-L1 TPS ≥1%
Efficacy Data							
Overall Response Rate (ORR) % (n/N)	**41.7% (15/36)**	**27% (174/637)**	**44.8% (69/154)**	**57.9% (161/278)**	**48% (197/410)**	**29% (12/41)**	**37% (25/67)**
ORR by PD-L1 (TPS) % (n/N)							
≥1% group	44% (11/25)	27% (174/637)	N/A	55.1% (97/176)	55.8% (145/260)	46% (6/13)	37% (25/67)
≥50% group	53.8% (7/13)	39% (118/299)	44.8% (69/154)	60.3% (44/73)	62.1% (82/132)	N/A	66% (19/29)
<50% group	31.6% (6/19)	N/A	N/A	57.1% (113/198)	40.7% (104/255)	N/A	16% (6/38)
ORR in evaluable patients % (n/N)	48.4%	N/A	N/A	N/A	N/A	N/A	N/A
Complete Response (CR) % (n/N)	5.6% (2/36)	0.5% (3/637) in TPS≥1%	3.9% (6/154) in TPS≥50%	2.2% (6/278)	1% (4/410)	2% (1/41)	N/A
Partial Response (PR) % (n/N)	36.1% (13/36)	26.8% (171/637) in TPS≥1%	40.9% (63/154) in TPS≥50%	60.4% (168/278)	47% (193/410)	27% (11/41)	37% (25/67) in TPS≥1%
Stable Disease (SD) % (n/N)	27.8% (10/36)	38.6% (246/637) in TPS≥1%	24.7% (38/154) in TPS≥50%	23.4% (65/278)	36.6% (150/410)	27% (11/41)	N/A
Median PFS (months)	**8.2**	**5.4**	**N/A**	**8.0**	**9.0**	**5.4**	**5.4**
≥1% PD-L1 (TPS) group	N/A	5.4	N/A	8.2	N/A	8.4 (n=13)	5.4
≥50% PD-L1 (TPS) group	11.8	7.1	10.3	8.0	11.1	N/A	N/A
<1% PD-L1 (TPS) group	4.1	N/A	N/A	6.3	6.2	4.1 (n=12)	N/A
Median OS (months) by TPS	N/A	N/A	N/A	17.1	22.0	N/A	N/A
≥1% group PD-L1 (TPS) group	N/A	16.7	N/A	18.9	N/A	N/A	N/A
≥50% PD-L1 (TPS) group	N/A	20	30	N/A	N/A	N/A	N/A

SOURCE: COMPANY DATA, LANCET, NEJM, JOURNAL OF CLINICAL ONCOLOGY AND BELL POTTER SECURITIES

TACTI-002: Stage 1 & Stage 2 of Part C (2L HNSCC)

ORR CONTINUES TO BE 2X VS. HISTORICAL KEYTRUDA MONO RESULTS

- ORR from the entire patient population from Part C was reported for the first time (37 at ASCO vs. 28 at SITC last year).
- 2L HNSCC ORR data presented at ASCO (data cut off 16th April'21) reduced since the SITC update (cut off of 8th Oct'20), falling from 35.7% (10/28) ORR with 3 CRs and 7

PRs to 29.7% (11/37) ORR with 5 CRs and 6 PRs. This is not surprising as ORR tends to erode in many small scale oncology trials when more patients are added and due to the aggressiveness of HNSCC.

- **However, despite the ORR of 29.7% reducing from SITC update, it continues to be 2x or double that of the 14.6% seen with Keytruda alone (based on cross trial comparison to Keynote-040).** ORR in evaluable patients (n=31) was even higher at 35.5%. Response rate in patients with PD-L1 CPS ≥1 (n=24) was higher at 45.8%.
- Median duration of response was not reached but is trending favourably given that all responders were on treatment for +6 months.

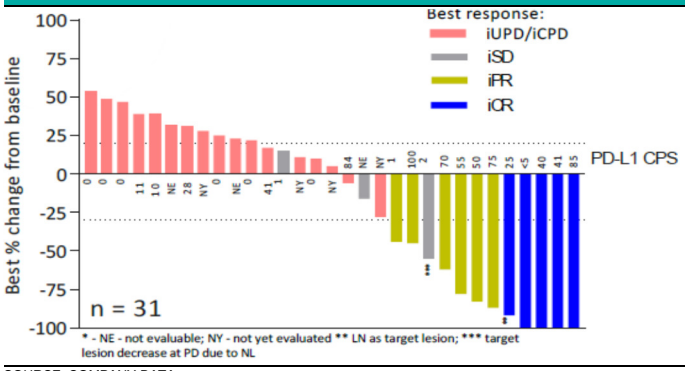
HIGH NUMBER OF COMPLETE RESPONSES

- **Importantly, there were 2 more complete responses** (disappearance of all target lesions) seen since last update at SITC. In total there are now 5 CRs, which is remarkable in this refractory population (having failed previous first line therapies) with extremely poor prognosis.

PROGRESSION FREE SURVIVAL COMPARABLE, OVERALL SURVIVAL LONGER

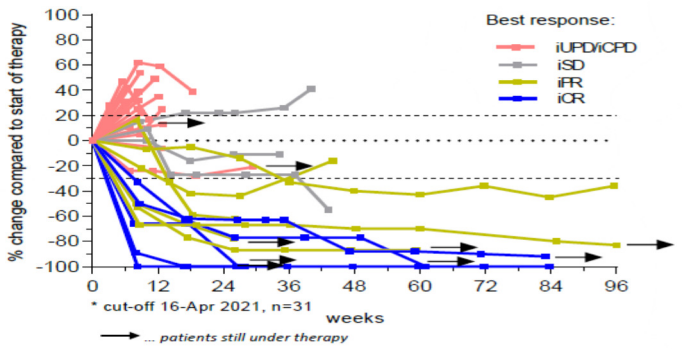
- Median overall PFS (progression free survival) was 2.1 months which is comparable to Keytruda monotherapy as per Keynote-040 trial. However, we note that in subgroup of patients with PD-L1 CPS ≥1 (n=24), median PFS was 4.1 months which was 2x that of Keytruda monotherapy of 2.1 months as per Keynote-040 trial in this population.
- Median Overall Survival (OS) was 12.6 months which is higher than Keytruda monotherapy of 8.4 months as per the Keynote-040 trial. In subgroup of patients with PD-L1 CPS ≥1 (n=24), median OS was 12.6 months which was also higher than Keytruda monotherapy of 8.7 months as per Keynote-040 trial in this population.

Figure 3 –5 complete responses in 2L HNSCC



SOURCE: COMPANY DATA

Figure 4 – Duration of Response trending favourably - 2L HNSCC



SOURCE: COMPANY DATA

Table 2 – Efti combo shows 2x ORR, higher CR and longer OS vs. historical Keytruda results

	Immutep	Merck & Co.
Clinical Trial Information	**Keytruda + efti**	**Keytruda monotherapy**
Clinical Trial Phase	Phase 2 (TACTI-002/KEYNOTE-798)	Phase 3 (KEYNOTE-040)
Patient Number, N (tumour type)	37 2L HNSCC	247 vs 248 2L HNSCC
Efficacy Data		
Overall Response Rate (ORR) % (n/N)	**29.7% (11/37)**	**14.6% (36/247)**
PD-L1 CPS ≥1 group (n/N)	45.8% (11/24)	17.3% (34/196)
ORR in evaluable patients % (n/N)	35.5% (11/31)	N/A
Complete Response (CR) % (n/N)	**13.5% (5/37)**	**1.6% (4/247)**
Partial Response (PR) % (n/N)	16.2% (6/37)	13% (32/247)
Stable Disease (SD) % (n/N)	8.1% (3/37)	22.7% (56/247)
Median PFS (months)	2.1	2.1
PD-L1 CPS ≥1	**4.1**	**2.2**
Median OS (months)	**12.6**	**8.4**
PD-L1 CPS ≥1	12.6	8.7

SOURCE: COMPANY DATA AT ASCO, LANCET PUBLICATION AND BELL POTTER SECURITIES

Funded for expanded Efti clinical program

Immutep (IMM) announced a $60m placement and $5m Share Purchase Plan (SPP) last month to fund the expanded clinical program of its lead drug candidate efti including a Phase 3 registrational trial in metastatic breast cancer and for characterisation and validation of commercial scale manufacturing process.

Tranche 1 of the placement for $13.7m has been completed. Tranche 2 for a further $46.3m is subject to shareholder approval at the upcoming EGM on 26th July'21. We believe it is highly likely that IMM will receive shareholder approval and note that as far as we know, historically the company has not had any knockback on any of its proposals put to vote to shareholders.

Assuming that the SPP raises the maximum $5m and shareholder approval is received for issue of shares under Tranche 2, **we expect IMM to have proforma cash of $112m** (based on 4QFY21 cash balance of $60.6m). This is expected to fund the company's ongoing trials and expanded clinical program for efti through to end of 4QCY23.

Efti – Expansion of Clinical Development Program

Based on the strength of data from IMM's ongoing key trials – Phase 2b AIPAC trial in metastatic breast cancer (mBC) and Phase 2 TACTI-002 trial in 1st line non-small cell lung cancer patients (1L NSCLC) and 2nd line head and neck cancer patients (2L HNSCC), IMM has expanded the clinical development of efti to later stage settings. **The company is expected to start 3 new trials in FY22 which we discuss below:**

PHASE 3 TRIAL IN METASTATIC BREAST CANCER

- This will be a registrational trial with ~500 patients and have overall survival (OS) as the primary endpoint of the trial. The trial is expected to satisfy approval requirements for both US and EU markets.
- It will be based on the Phase 2b AIPAC trial, where interim overall survival data in majority subgroups was very impressive and will likely focus on those subgroups. Recall that in the AIPAC trial, in patients <65 years or with low baseline monocyte count, the combo of efti+ paclitaxel increased OS over chemo alone by +7.1 months and +9.4 months respectively, a clinically and statistically significant outcome.
- Final OS data from AIPAC is expected in 2HCY21. IMM will meet with regulators to finalise Phase 3 trial protocol and we expect the trial to start in 1HCY22.
- Start of this trial will be a key milestone for the company transitioning it into a Phase 3 company on path to first product approval. Being a randomised controlled trial it is also likely to yield immune monitoring data in support of efti's mechanism of action which will be valuable and relevant across efti's clinical development program.
- **HR+/HER2 Metastatic Breast cancer offers an attractive commercial opportunity with relatively less competition given there is no immunotherapy agent approved in this setting.** Endocrine therapies are the backbone treatment and chemotherapy. Efti is targeting the chemotherapy treated patients in the first line to third line setting. Apart from efti and the novel AKT inhibitors we are not aware of any other notable effort to improve outcomes for chemotherapy treated patients.
- As per IMM there are ~350,000 HR+/HER2 mBC patients globally under 65 years of age. We estimate that ~71k of these are in the US and EU5. At peak, we estimate efti's addressable market of 1L-3L chemo treated HR+/HER2 mBC patients under 65 years of age across US and EU at ~34k patients. **We estimate that efti takes 35% market share and forecast in-market peak sales of US$780m in US/EU markets in this setting.**

TACTI-003 – PHASE 2B TRIAL IN 1L HNSCC

- IMM entered into a new clinical trial collaboration with Merck for this trial. Strong data in the second line setting from ongoing Phase 2 TACTI-002 trial led to this additional collaboration with Merck.
- It is expected to be a randomised, controlled trial and recruit up to 154 patients. In cohort A, ~130 patients with PD-L1 positive tumours will be randomised across 2 arms to receive either Keytruda monotherapy or efti+Keytruda combo. There will also be another cohort B of ~24 patients with PD-L1 negative tumours who will receive efti+Keytruda combo. Primary endpoint will be overall response rate (ORR) and key secondary endpoints will be overall survival and progression free survival.
- FDA recently granted Fast track to efti for this indication which was a huge validation of both the data generated in the ongoing Phase 2 TACTI-002 trial and the proposed design of the TACTI-003 trial.
- Patient recruitment is expected to begin in 3QCY21, with first interim data likely to be available in 1HCY22.
- This is an aggressive form of cancer with overall survival in 1L just over 12 months and low response rates. There is a high unmet needs for combination therapies with anti-PD-1 which could improve overall survival, have better safety profile and longer duration of response than chemo-anti-PD-1 combo.
- We estimate addressable market at ~54k recurrent or metastatic HNSCC 1L patients with positive PD-L1 tumours across US and EU at peak **and forecast peak in-market sales for efti at US$981m.**

PHASE 2 TRIPLET COMBO TRIAL WITH ANTI-PD-1 AND CHEMOTHERAPY

- A 20 patient Phase 1 trial called INSIGHT-003 in patients with various solid tumours to test the combination of efti+chemo+ anti-PD-1 is expected to start enrolling patients this quarter i.e. in 3QCY21, with first interim results expected in CY22. The anti-PD-1 being used in this trial has not been disclosed but we expect it to be Keytruda.
- Results of this trial will inform the design for a larger Phase 2 trial with the triplet combo, potentially in NSCLC. The phase 2 trial is expected to have ~80 patients and we expect it to also start in CY22.
- We view this trial as a strategically important piece in efti development given the use of chemotherapy with immunotherapy such as anti-PD-1's across various cancers as standard of care. Keytruda + chemotherapy is the dominant standard of care therapy in NSCLC for the 70% of patients with less than 50% PD-L1 expression. Keytruda + chemo is also used in 1L HNSCC.
- We expect this trial will answer the important question around safety foremost of adding efti to chemo+anti-PD-1 combo. Efficacy results especially in NSCLC along with ongoing extension of TACTI-002 trial in 1L NSCLC will inform the design of a registrational Phase 3 trial in future. **In our view, this will add materially to efti's overall data package and will also be valuable in future partnering discussions for the drug.**

Earnings and Valuation Changes

We have reviewed our assumptions and forecasts for IMM following the interim data released at ASCO 2021 conference from TACTI-002 trial, IMM's placement and SPP announced in June'21 and its 4QFY21 quarterly cash flow statement filed on ASX, which has impacted earnings and valuation.

Key assumption changes

- We have updated our model for the gross $60m capital raise (Tranche 1 $13.7m and Tranche 2 $46.3m assuming shareholder approval) via placement of ~115.4m shares @52cps. Additionally we have also assumed that IMM is able to raise the $5m under its announced SPP by issue of an additional ~9.6m shares at the same price.
- We have updated our model for the conversion of the Ridgeback convertible notes which led to an issue of 47.5m shares. There is now a balance of 3.4m convertible notes outstanding, which we also expect will be converted to equity prior to or on maturity in Aug'25. We have also updated our model for the exercise of warrants and proceeds of ~$0.6m on issue of ~1.9m shares.
- FY21 revenues have declined and FY22 revenues have increased due to shift in timing of US$1m milestone from partner EOC Pharma on start of Phase 2 mBC trial in China, which is now expected in 2HCY21. Launch in China is also pushed back to FY27 (vs. FY26). We have also increased R&D tax rebate expected for FY22 on account of increased clinical trial spend.
- We have reduced our R&D forecast for FY21 by ~$4.9m which was driven primarily by timing with some of the manufacturing and clinical trial costs for Phase 2b TACTI-003 trial moving to FY22, with the trial now expected to start recruiting patients in 3QCY21.
- We have materially increased our R&D forecasts for FY22-FY25 to account for the costs associated with the expanded clinical trial programs for efti for which IMM has raised cash and increased manufacturing cost for efti to support these trials as well as commence manufacturing process characterisation and validation.
- We have also increased our G&A costs by single digit percentages for FY22 and onwards to support an expected increase in personnel and regulatory costs.
- We now assume that efti+Keytruda combo is able to get 50% share of the 1L NSCLC patients with <50% PD-L1 expression (which translates to ~22% of the 1L NSCLC market, up from 12% earlier). We now forecast peak sales (non-risk-adjusted) of US$2.8bn (up from US$1.5bn).
- We have also increased efti's market penetration for 1L HNSCC from 20% to 30% when given in combination with anti-PD-1 Keytruda. We now forecast peak sales (non-risk-adjusted) of US$981m (up from US$654m).

The net result of revisions to our model was a 12% decrease in our FY21 net loss forecast, driven by reduced R&D spend related to TACTI-003 trial which is now expected to start this quarter. Increased opex related to the new clinical trial programs for efti including the Phase 3 mBC trial, manufacturing and personnel and timing of TACTI-003 trial spend have resulted in a large increase in our FY22 net loss forecast and a large decrease in our FY23 NPAT forecast. Earning changes along with longer term impact of increased market share for efti in 1L NSCLC and 1L HNSCC, partially offset by the dilutive impact of the recent capital raise and conversion of convertible notes into equity, has resulted in lifting our valuation for IMM (rounded off) to A$1.00/sh (was A$0.85/sh). We retain our Buy (speculative) recommendation.

Table 3 - Key changes to our FY21-FY23 forecasts

	FY2021E			FY2022E			FY2023E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	5.7	4.8	-16%	4.9	8.3	68%	76.6	75.2	-2%
Interest Income	0.2	0.2	-1%	0.1	0.3	127%	0.2	0.4	118%
R&D	22.3	17.4	-22%	29.0	45.5	57%	19.4	49.7	156%
G&A	6.4	6.4	0%	6.3	6.8	8%	6.0	6.5	8%
EBITDA	-23.1	-19.1	-17%	-30.4	-44.0	45%	51.1	18.9	-63%
EBIT	-25.1	-21.2	-16%	-32.4	-46.0	42%	49.1	17.0	-65%
NPAT (adjusted)	-35.2	-31.0	-12%	-33.7	-46.0	36%	47.8	17.0	-64%
Adjusted Diluted EPS	-6.1	-5.3	-13%	-5.0	-5.8	15%	7.1	2.0	-72%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation is based on a WACC of 13% and a terminal growth rate of 2%. Our diluted valuation takes into account the conversion of convertible note on issue, options, warrants and performance rights and potential cash on the exercise of the options and warrants. **Our diluted valuation also assumes that IMM shareholders approve the issue of Tranche 2 placement shares at the EGM later this month and IMM raises the maximum amount (A$5m) via its proposed SPP and the cash raised as a result.** *Our undiluted valuation (based on current shares on issue) for IMM is $1.11/sh.*

Table 4 - Summary of Valuation

Forecasts	Current (diluted)	Undiluted valuation
Enterprise value from DCF (AUDm)	768.1	768.1
Add: Last reported Cash (AUDm)	60.6	60.6
Add: Potential cash from Tranche 2 placement + SPP	48.8	
Less: Current Debt	0.0	0.0
Equity value (AUDm)	877.5	828.7
Add: Potential cash from exercise of options (AUDm)	0.2	
Add: Potential cash from exercise of warrants (AUDm)	0.7	
Total Equity Value (AUDm)	878.5	828.7
Total shares (million)	886.6	748.2
Value per share (AUD)	**$0.99**	**$1.11**

SOURCE: BELL POTTER SECURITIES ESTIMATES

M&A is a common occurrence in biotech and is one of the key themes in oncology. We see M&A as a probable exit for IMM shareholders. **We apply M&A metrics to arrive at a hypothetical M&A valuation for IMM of $1.48/sh, which helps ground our DCF.**

Table 5 - IMM Sum-of-parts DCF Valuation Summary (diluted)

Asset	Commercial Partner	Stage	First Fiscal Year of sales (Est.)	Peak Market share	Peak Sales (US$m)	Probability of success	Probability adjusted NPV (A$m)	Value per share (A$)	% Mix
Leramilimab (LAG525) - metastatic melanoma	Novartis	Phase 2	2026	15% of previously treated 2L metastatic melanoma patients	$178	35.0%	$12.7	**$0.01**	1.4%
Efti -China - HR+/HER2- mBC (chemo combo)	EOC Pharma	Phase 2	2027	35% of 1L-3L chemo treated mBC patients under 65 years of age	$521	20.0%	$24.5	**$0.03**	2.8%
Efti-cancer peptide vaccine	Cytlimic	Phase 1	NA	NA	NA	8.0%	$0.6	**$0.00**	0.1%
Immuno-oncology diagnostic	LabCorp	NA	NA	NA	NA	NA	$0.0	**$0.00**	0.0%
Efti- HR+/HER2- mBC (chemo combo)	Not yet partnered	Phase 3 in planning	2025	35% of 1L-3L chemo treated mBC patients under 65 years of age	$780	40.0%	$202.6	**$0.23**	23.1%
Efti- mNSCLC (IO combo)	Not yet partnered	Phase 2	2025	50% of <50% PD-L1 mNSCLC patients (PD-1 naiive, molecular test negative)	$2,800	20.0%	$327.5	**$0.37**	37.3%
EFfti - mHNSCC (IO combo)	Not yet partnered	Phase 2b	2024	30% of 1L R/M HNSCC patients with CPS ≥1	$981	34.0%	$265.6	**$0.30**	30.2%
Other Pipeline/Non-allocated	NA	NA	NA	NA	NA	NA	($65.3)	**-$0.07**	-7.4%
Cash (incl. Tranche 1 placement)	NA	NA	NA	NA	NA	NA	$60.6	**$0.07**	6.9%
Potential cash from Tranche 2 placement + SPP	NA	NA	NA	NA	NA	NA	$48.8	**$0.06**	5.6%
Potential cash from exercise of options/warrants	NA	NA	NA	NA	NA	NA	$0.9	**$0.00**	0.1%
Reported Debt	NA	NA	NA	NA	NA	NA	$0.0	**$0.00**	0.0%
Equity Value							**$878.5**	**$0.99**	**100%**

NOTE: IO= IMMUNO-ONCOLOGY, PEAK SALES ARE FOR US AND EU REGIONS ALONE AND FOR EOC PHARMA PARTNERSHIP ARE FOR CHINA ALONE. SOURCE: BELL POTTER SECURITIES ESTIMATES

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. It is listed on the ASX and has its American Depository Receipts (ADR's) listed on NASDAQ. It is based in Sydney, with operations in US, Germany and a R&D lab in Paris. The company's LAG-3 assets come from the acquisition of a private French biotech company in 2014 founded by Dr. Triebel. LAG-3 has the potential to become the third pillar in treatment of cancer, with as broad utility as that seen with previous successful immuno-oncology (IO) approaches targeting PD-1/PD-L1 and CTLA-4, which have yielded blockbuster therapies such as Merck's Keytruda and Bristol Myers' Opdivo. IMM is the global leader in LAG-3. Further validation of its technology is provided by a host of high quality commercial and clinical trial collaborations with Big Pharma. Lead asset efti with its unique mechanism of action as an APC activator is in Phase 2 trials and has blockbuster potential. Partnered assets are also approaching key inflexion points.

INVESTMENT STRATEGY

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

$1.00 Valuation: We value IMM using a risk adjusted DCF at $1.00 which takes into account the potential conversion of convertible notes on issue, options, warrants and performance rights totalling 39.9m and successful closing of Tranche 2 placement and SPP totalling 98.6m shares. The valuation is ~86.9% premium to the current share price of $0.535/sh and therefore supports our Buy (speculative) recommendation.

Hypothetical M&A valuation higher at $1.48/sh helps to ground our DCF valuation: M&A is a common occurrence in biotechnology and is one of the key themes in oncology. We see M&A as a probable exit for IMM shareholders. We apply M&A metrics to arrive at a hypothetical M&A valuation for IMM of $1.48/sh, which helps ground our DCF valuation.

IMM is the leader in LAG-3 drug development: This is the only company with a broad pipeline of LAG-3 assets (4 assets with 3 in the clinic) and the only one exploring the utility of LAG-3 as both an immune stimulator and an immune suppressor. The company has a broad IP portfolio as a result of backing of Dr. Frederic Triebel (IMM's CSO and CMO) who discovered the LAG-3 gene and developed IMM's LAG-3 assets. This leadership position is further underscored by a host of high quality partnerships with Big Pharma.

LAG-3 could become the third IO pillar in treatment of cancer: LAG-3 is a key immune checkpoint and a next generation blockbuster cancer immunotherapy target. **C**linical results in the industry highlight the potential of this target to become the third pillar in treatment of cancer, with as broad utility as that seen with PD-1/PD-L1 and CTLA-4 checkpoint inhibitors. Bristol Myers Squibb is the most advanced with its anti-LAG-3 asset relatlimab. First Phase 3 trial data in 1L Melanoma from relatlimab was recently reported with the trial meeting its primary endpoint of progression free survival. This provides validation for LAG-3 and its interaction with MHC Class II and we expect IMM to benefit from this validation.

Lead in-house product efti is a blockbuster in making: We expect efti with its unique mechanism of action as an APC activator to have broad utility across multiple cancer indications in combination with different treatment modalities (other immuno-oncology agents and chemo therapy). We see it becoming a pipeline in itself with multi-billion dollar sales potential. **We model peak in-market sales of ~US$5.1bn**.

Efti with IO combo has attractive licensing prospects: Efti has the potential to extend the benefits of existing anti-PD-1 therapy to a broader population and improve efficacy over anti-PD-1 monotherapy with no detriment to tolerability. Interim data from Phase 2 TACTI-002 trial from both 1L non-small cell lung cancer (NSCLC) patients and 2L head and neck cancer patients (HNSCC) continue to show responses (ORR) with the efti combo as being much higher than Keytruda monotherapy alone, with a good tolerability profile and in an all comer trial (i.e. irrespective of patients PD-L1 expression). The trial and clinical trial collaboration with Merck has now expanded into the extension phase 'Stage 3' for NSCLC and a new trial in 1st line HNSCC patients called TACTI-003 is expected to start recruiting patients in 3QCY21**.** Key data read outs from TACTI-002 trial and the soon to start TACTI-003 trial is expected over the next 18 months which in our view is critical for the future of the asset. **If positive we believe these data releases will result in significant value uplift for IMM and partnering and/or M&A interest. We forecast a US$1bn deal in FY23.**

Valuable partnerships with NVS and GSK nearing next inflexion points: IMM's LAG525 partnered with Novartis targeting various cancers is currently in 5 Phase 1/2 trials, with progress into Phase 3 expected in FY23. An update is expected on IMM's GSK'781 partnered with GlaxoSmithKline in 2HCY21 as to development path forward, following discontinuation of a phase 2 ulcerative colitis trial recently. Both assets if continue to progress clinically, could potentially be developed for multiple indications with multi-billion dollar sales potential.

Funded through to key inflexion points: Assuming IMM shareholders approve the issue of Tranche 2 placement shares and IMM raises ~A$5m via SPP, the company will have proforma cash (based on end of 4QFY21 balance) of ~A$112m, which funds it through key inflexion points and provides runway through to 4QCY23.

RISKS

The key risks specific to IMM include, but are not limited to, the following:

- **COVID-19 risk:** There is a possibility that COVID-19 disruption could lead to slower recruitment in Immutep's trials as well as delays in regulatory interactions given health authorities are focused on managing COVID-19 outbreak.
- **LAG-3 validated but efti's unique MoA requires further validation:** Research and understanding around LAG-3 as a target is relatively less and in its early years compared to other IO approved targets. There is currently no approved LAG-3 therapy on the market. While BMY's Phase 3 trial meeting its primary endpoint serves as an important validation of the whole class, detailed data on overall survival etc. are yet to come. For IMM's lead product 'efti' however there still remains risk as it is a new approach to targeting LAG-3 as an agonist (pushing the accelerator on immune responses), vs. the more known 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 IO drug class as an APC activator rests solely on IMM's shoulders.
- **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, with the exception of the AIPAC trial, all its other trials to date were early stage trials, were not blinded and had a small number of patients. There is no guarantee that early data will translate to positive outcome in larger trials. Underwhelming result 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 finally reach the market and translate into royalty revenue streams for it

depends on its partners. Delays in timelines will affect near term milestone payments to IMM as well as its long-term revenue flow. Also if the product fails at any stage of clinical development or the partners decide to discontinue the development of the products, IMM's ability to generate revenue from that asset will diminish/or fail totally.

- **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 in part is underpinned by IMM's ability to ultimately 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 much more experience in navigating regulatory channels will be responsible for obtaining approvals, failure to satisfy regulatory requirements could mean that the product will fail to reach the market. There also exists a risk that regulatory agencies may approve a more restricted labelling for IMM's products which could limit the company's use to a smaller patient population and therefore be detrimental for the drugs commercialisation prospects.
- **Commercial risk:** The pharmaceutical market is intensely competitive and in particular the oncology and autoimmune disease space which IMM is targeting has several companies engaged in drug development. IMM's products are not going to be the first to market for the indications its targeting and therefore would not have first mover advantage. Among LAG-3 assets specifically, 'efti' is likely to be first to market from its drug class if approved, however the drug partnered with NVS is unlikely to be the first LAG-3 blocking antibody to reach the market and so will not have the first mover advantage. Also, there is no guarantee that late stage clinical trial results, even if they hit the endpoints of the studies, will be viewed as clinically meaningful by clinicians' vis-à-vis other approved drugs/treatment modalities/combination treatments by then on the market. Even if the drugs do get approved on successful pivotal studies, commercial adoption might still be hampered by the cost of the combination or the competition having much larger impact than the company previously estimated, which would impact market share of IMM's product. We also note that there are several combination approaches in trials with various modalities and the landscape especially in oncology is very dynamic. There is a possibility that by the time IMM or its partners finish all the necessary clinical work and obtain necessary regulatory approvals, other treatment combinations may have become the new SOC and displacing them may be more difficult without additional head-to head comparative trials.
- **Manufacturing risk:** IMM is reliant on third parties for cost effective manufacturing of its products (both for clinical trials and future commercialisation). Disruption or delays at its supplier including problems in scaling up of manufacturing activities are likely to adversely impact timelines for its clinical trials and commercialisation of its products.
- **Funding risk:** IMM has proforma cash of A$112m (based on 30th June'21 cash balance), assuming shareholder approval and issue of shares on Tranche 2 placement and $5m SPP. This should fund IMM's current and expanded clinical programs through to 4QCY23. Although IMM has a high cash balance currently, the company may need to raise additional capital for fully funding its expanded clinical program beyond CY23 and for any additional studies of 'efti'. 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 14 July 2021

Recommendation	Buy, Speculative
Price	$0.535
Valuation	$1.00

Table 6 - Financial summary

Immutep Limited (IMM) — **Share price (A$) $0.535**
As at 14 July 2021 — **Market cap (A$m) 400.3**

Profit and Loss

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Collaboration revenue (Milestones, royalties)	0.1	7.5	0.2	1.5	74.6
Research material sales + grant income	5.5	6.3	4.6	6.8	0.6
Total Revenue	**5.6**	**13.7**	**4.8**	**8.3**	**75.2**
Opex	-23.0	-26.7	-23.9	-52.3	-56.3
EBITDA	**-17.3**	**-13.0**	**-19.1**	**-44.0**	**18.9**
Depreciation & Amortisation	-1.9	-2.1	-2.1	-2.0	-2.0
EBIT	**-19.2**	**-15.1**	**-21.2**	**-46.0**	**17.0**
Net interest & Other Income/(Expense)	0.9	1.6	-9.8	0.0	0.1
Pre-tax profit	-18.3	-13.5	-31.0	-46.0	17.0
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-18.3**	**-13.5**	**-31.0**	**-46.0**	**17.0**
One off items	0.0	0.0	0.0	0.0	0.0
Reported Net profit (loss)	**-18.3**	**-13.5**	**-31.0**	**-46.0**	**17.0**

Cashflow

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Reported NPAT	-18.3	-13.5	-31.0	-46.0	17.0
Non-cash items	3.4	2.5	13.6	3.7	3.3
Net change in Working capital	-0.3	0.1	-0.4	-0.2	1.7
Operating cashflow	**-15.3**	**-10.8**	**-17.8**	**-42.4**	**22.1**
Capex	-0.04	-0.02	-0.02	-0.04	-0.04
Investments	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.04**	**-0.02**	**-0.02**	**-0.04**	**-0.04**
Change in borrowings	0.0	0.0	0.0	0.0	0.0
Equity issued	4.3	20.6	41.2	48.8	0.0
Exercise of Warrants	1.5	0.0	11.2	0.0	0.0
Issue of warrants (net of Finance Cost)	2.2	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	-0.1	0.2	0.0	0.0
Financing cashflow	**8.0**	**20.5**	**52.7**	**48.8**	**0.0**
Net change in cash	**-7.3**	**9.6**	**34.9**	**6.3**	**22.0**
Cash at end of period*	16.6	26.3	60.6	66.9	89.0
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow	**-15.3**	**-10.9**	**-17.8**	**-42.5**	**22.0**

Balance sheet

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Cash	16.6	26.3	60.6	66.9	89.0
Current receivables	5.2	3.3	6.2	6.1	4.5
Inventories	0.0	0.0	0.0	0.0	0.0
Other current assets	1.8	1.5	1.7	1.7	1.7
Current assets	**23.5**	**31.2**	**68.5**	**74.7**	**95.1**
PPE	0.1	0.0	0.0	0.1	0.1
Right-of-Use Assets	0.0	0.2	0.2	0.1	0.1
Non-current receivables	0.0	0.0	0.0	0.0	0.0
Intangible assets	16.9	15.2	12.9	11.0	9.1
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**17.0**	**15.4**	**13.2**	**11.2**	**9.3**
Total assets	**40.5**	**46.6**	**81.7**	**85.9**	**104.4**
Payables	5.1	2.9	5.6	5.6	5.6
Convertible note liability	7.6	8.8	2.2	2.5	2.9
Warrant Liability	3.2	0.9	1.0	1.0	1.0
Provisions	0.3	0.4	0.4	0.5	0.6
Lease Liabilities	0.0	0.3	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.5	0.0	0.0
Total liabilities	**16.2**	**13.3**	**9.7**	**9.6**	**10.0**
Issued Capital	221.1	243.0	313.1	361.9	361.9
Reserves	65.5	66.0	35.6	37.0	38.0
Accumulated (deficit)/Retained Earnings	-262.2	-275.7	-276.6	-322.6	-305.5
Total shareholders Equity	**24.4**	**33.3**	**72.0**	**76.3**	**94.4**
Total funds employed	**40.5**	**46.6**	**81.7**	**85.9**	**104.4**
W/A Diluted shares on issue	334.9	401.0	588.9	797.4	846.7

Valuation data

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Adjusted Net profit (A$m)	-18.3	-13.5	-31.0	-46.0	17.0
EPS (c)	-5.48	-3.36	-5.26	-5.76	2.01
EPS growth (%)	N/A	N/A	N/A	N/A	NM
P/E ratio (x)	N/A	N/A	N/A	N/A	26.6
CFPS (c)	-4.6	-2.7	-3.0	-5.3	2.6
Price/CF (x)	-11.7	-19.8	-17.7	-10.1	20.5
DPS (c)	0.00	0.00	0.00	0.00	0.00
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-19.6	-26.1	-17.8	-7.7	17.9
EV/EBIT	-17.7	-22.5	-16.0	-7.4	20.0

Share price now (A$)	$0.535
Valuation (A$):	$1.00
Premium (discount) to price	86.9%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2019A	2020A	2021E	2022E	2023E
EBITDA/revenue (%)	N/A	N/A	N/A	N/A	25.2%
EBIT/revenue (%)	N/A	N/A	N/A	N/A	22.6%
Return on assets (%)	-45.2%	-28.9%	-37.9%	-53.5%	16.3%
Return on equity (%)	-75.2%	-40.4%	-43.0%	-60.2%	18.1%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Net cash (debt) (A$m)	16.6	26.3	60.6	66.9	89.0
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	4.4	9.3	10.7	12.5	15.7

Interims

Y/e June 30 (A$m)	2H19A	1H20A	2H20A	1H21A	2H21E
Collaboration revenue (Milestones, royalties)	0.1	7.4	0.1	0.0	0.2
Research material sales + grant income	3.2	2.2	4.0	2.2	2.4
Total Revenue	**3.4**	**9.6**	**4.1**	**2.2**	**2.6**
EBITDA	**-8.8**	**-5.4**	**-7.6**	**-9.3**	**-9.7**
Depreciation & Amortisation	-0.9	-1.0	-1.1	-1.1	-1.0
EBIT	**-9.7**	**-6.4**	**-8.7**	**-10.4**	**-10.8**
Net interest & Other Expense	0.0	0.4	1.2	-9.4	-0.4
Pre-tax profit	-9.7	-6.0	-7.5	-19.8	-11.1
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-9.7**	**-6.0**	**-7.5**	**-19.8**	**-11.1**
Reported Net profit (loss)	-9.7	-6.0	-7.5	-19.8	-11.1

Revenue Summary

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
GSK deal -GSK-2831781 - risk adjusted milestones	0.0	7.5	0.0	0.0	0.0
NVS deal -LAG525 - milestones	0.0	0.0	0.0	0.0	2.7
EOC Pharma deal -Efti- milestones	0.0	0.0	0.0	1.4	0.0
Cytlimic deal -Efti- upfront and risk adjusted milestones	0.1	0.0	0.0	0.1	0.0
Potential Efti deal (US/EU) - risk adjusted upfront/milestones	0.0	0.0	0.0	0.0	71.9
Research Material Sales	1.2	0.3	0.4	1.0	0.6
R&D Tax Incentive	4.3	6.0	4.2	5.8	0.0
Total Revenues	**5.6**	**13.7**	**4.6**	**8.3**	**75.2**

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

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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