

### Biotechnology

**IMMP - NASDAQ**

August 30, 2021

**Intraday Price 8/30/21**

**\$3.71**

Rating:	Buy
12-Month Target Price:	\$8.00
52-Week Range:	\$1.22 - \$7.95
Market Cap (M):	282.7
Shares O/S (M):	76.2
Float:	NA
Avg. Daily Volume (000):	418.3
Debt (M):	\$6.2
Dividend:	\$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	June

#### Total Expenses ('000)

	2021A	2022E	2023E
H1	9,707	9,399	9,948A
H2	7,462	9,799	10,777
FY	17,169	19,198	20,726
Prior	19,146	20,104	21,109



Immutep is listed on the ASX (IMM) and with ADR's traded on NASDAQ (IMMP). 1 ADR= 10 shares of common stock.

**Naureen Quibria, Ph.D.**  
(212) 895-3620  
nquibria@maximgroup.com

## Immutep Limited

**Buy**

**Annual FY Update; AIPAC Final Data Approaching**

### Summary

- **Immutep reported FY21 (Jun) results this morning with a net loss of (~\$22M or A\$29.9M) and ended the period with ~\$44M (A\$60.6M) in cash and cash equivalents on the balance sheet, excluding the second tranche of a two-tranche placement and share purchase plan completed in July (~A\$50M). (See our prior note on [7/16](#) for details.) Post-raise, Immutep should have ~\$80M US (~A\$100M+) and sufficient runway into late CY23.**
- **Near-term catalysts. While multiple operational updates are expected (such as trial initiations and recruitment updates), we are watching for data readouts on: (1) AIPAC final overall survival (OS) data; and (2) TACTI-002.**
- **Conclusion. We believe the significant interest in and validation of LAG-3 as a checkpoint target, following Bristol Myers' (BMY - NR) combination data with an anti-PD-1 (RELATIVITY study), bodes well for Immutep's eftilagimod alpha (efti, soluble LAG-3 protein) studies. In addition, with a bolstered balance sheet, Immutep should be firmly in the driver's seat to execute on the expansion of its pipeline of trials for efti, in our view, including gearing up for potentially two pivotal stage studies (metastatic breast cancer and head and neck), if AIPAC and TACTI-002 are positive. Reiterate Buy.**

### Details

**Phase 2b AIPAC study.** The multi-center, placebo-controlled, randomized trial (N=227) is evaluating eftilagimod alpha (efti) in combination with paclitaxel standard-of-care chemotherapy in patients with HER2-/HR+ metastatic breast cancer. The primary endpoint of the study was progression free survival (PFS), which was missed in March 2020. While the efti combination was numerically greater against SOC, it was not statistically significant. At 6-months, 63% of patients treated with efti +paclitaxel were progression-free vs. 54% of patients that received paclitaxel plus placebo (HR=0.93; p=0.341). Secondary endpoints include overall response rate (ORR) and overall survival (OS). ORR for the study arm was 48.3% vs. 38.4% in the control arm.

At SABCS in December 2020, among the total patient population, a median OS of 20.2 months was reported compared to 17.5 months in the active comparator arm (p=0.14, HR=0.83), which, while not statistically significant, is still meaningful. Interestingly, in a pre-defined subgroup of patients, the delta on mOS widened. In patients under the age of 65, mOS was 21.9 vs. 14.8 months (p=0.012, HR=0.62), a +7.1-month survival benefit; this actually represented 66.7% of the efti treated patients. Among patients with low-starting monocyte counts, mOS was 22.4 months vs. 12.9 months (p=0.02, HR=0.47), a +9.4-month survival benefit. The latter group makes up ~22% of efti treated patients. Among 48.8% of patients with a more aggressive and immunogenic luminal B type of breast cancer, an mOS of 16.3 months was noted compared to 12.6 months in the comparator arm (p=0.077, HR=0.69), a survival trend of +3.8 months. Given the data thus far, the Phase 3 study is likely expected to incorporate OS as the primary endpoint with a focus on one or more of the above subgroup(s). Final OS data is expected in 2H21.

**TACTI-002 (KEYNOTE-798) study.** The ongoing Phase 2 study is evaluating efti with pembrolizumab in 1L non-small-cell lung cancer (NSCLC), 2L in NSCLC in PDX-refractory patients, and 2L head and neck squamous cell carcinoma (HNSCC). Compelling data from prior updates led to an expansion of the Merck (MRK - NR) collaboration; into a program in 1L HNSCC (TACTI-003) and an expansion of the 1L NSCLC arm (addition of 74 more patients). Of note, efti received Fast Track designation for 1L recurrent or metastatic HNSCC by the FDA in April 2021.

- **1L NSCLC.** At ASCO 2021, efti + pembro combination reported an overall response rate (ORR) of 41.7% (CR 5.6%, PR 36.1%, SD 27.8%). Although the patient numbers are still small, the data suggests not only superior activity to

pembro alone but indicates that efti/pembro has activity in low-PD-L1 expressors. Given this initial activity (even in low PD-L1 expressors), the data suggests that the combination could potentially be employed in an “all-comer” setting. Further, if these responses continue to be durable, an efti/pembro combination with its benign safety profile could also be an ideal regimen for “less fit” patients who cannot undergo chemo/pembro treatment.

- **2L HNSCC.** While the numbers are again small, overall response rates with an efti + pembro combination was ~2x (~30%) what has been observed with pembro monotherapy (based on a cross trial comparison with KEYNOTE-040 study, ~15%). And while the ORR reported was slightly lower than prior updates (~36% in Oct. 2020, ~31% in January 2021), the response rates suggest a competitive profile thus far, in our view.

Further updates from the ongoing study are expected in YE21/1H22.

**Prepping for pivotal studies – manufacturing.** Immutep and its manufacturing partner WuXi Biologics have begun scaling up GMP manufacturing of efti (up to 2,000L capacity from 200L) in preparation for potential registration studies and commercial manufacturing.

**Company overview:** *Immutep is a clinical-stage biotechnology company that is focused on developing LAG-3 both as an immune stimulator and an immune suppressor, for cancer and for autoimmune diseases, respectively. The company's lead product candidate is eftilagimod alpha (efti), a soluble LAG-3 fusion protein, that is being evaluated in combination with chemotherapy or immune therapy for multiple advanced cancers. The company also has licensing deals with large pharma for additional LAG-3 products: GSK'781 with GlaxoSmithKline (GSK - NR) and LAG525 with Novartis (NVS - NR).*

Immutep (IMMP) Income Statement (\$'000, USD)			July-Dec	Jan-Jun												
YE June 30	2018A	2019A	2020A	1H-2021A	2H-2021A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
<b>Revenue (000's)</b>																
Eftilagimod Alpha - mBC									-	79,742	246,450	287,746	348,748	395,208	407,143	476,635
Eftilagimod Alpha - NSCLC									-	15,468	164,147	263,529	339,559	480,966	903,965	1,607,020
Eftilagimod Alpha - HNSCC									69,358	119,088	171,758	227,500	260,412	469,844	768,758	
<b>Net Revenue</b>	-	-	-	-	-	-	-	-	69,358	214,297	582,355	778,775	948,719	1,157,865	1,780,952	2,852,413
License revenue	1,947	95	4,492	-	-	-	-	-	-	-	-	-	-	-	-	-
Miscellaneous income	746	785	168	149	79	228	-	-	-	-	-	-	-	-	-	-
Grant Income	2,379	2,953	3,584	1,555	1,037	2,591	-	-	-	-	-	-	-	-	-	-
<b>Milestones and Royalties:</b>																
GSK781 (IMP731) - psoriasis				-	-	-	-	-	-	1,514	2,207	4,390	8,345	11,419	14,943	20,199
LAG525 (IMP701)-mTNBC				-	-	-	-	-	-	-	-	3,058	3,958	4,910	5,916	6,978
Eftilagimod Alpha - mBC (China)				-	-	-	-	-	-	-	-	1,033	1,916	2,412	3,389	6,284
<b>Total Revenues</b>	<b>5,072</b>	<b>3,833</b>	<b>8,244</b>	<b>1,704</b>	<b>1,116</b>	<b>2,819,848</b>	<b>-</b>	<b>-</b>	<b>69,358</b>	<b>215,812</b>	<b>584,562</b>	<b>787,255</b>	<b>962,938</b>	<b>1,176,606</b>	<b>1,805,199</b>	<b>2,885,873</b>
<b>Expenses</b>																
Cost Of Goods Sold									20,807	64,744	175,369	196,814	240,734	294,152	361,040	577,175
Research & Development and intellectual property expenses	7,392	11,282	12,238	6,497	6,086	12,583	14,200	15,478	16,252	17,064	17,918	18,814	19,754	20,742	21,779	22,868
R&D % Rev's																
General & Administrative Expense	5,359	4,329	3,801	2,400	2,186	4,586	4,998	5,248	5,510	5,786	6,075	6,379	6,698	7,033	7,384	7,754
SG&A %																
Depreciation and amortization	1,339	1,278	1,248	811	(811)	-	-	-	-	-	-	-	-	-	-	-
<b>Total expenses</b>	<b>14,090</b>	<b>16,889</b>	<b>17,287</b>	<b>9,707</b>	<b>7,462</b>	<b>17,169</b>	<b>19,198</b>	<b>20,726</b>	<b>42,570</b>	<b>87,594</b>	<b>199,361</b>	<b>222,006</b>	<b>267,187</b>	<b>321,926</b>	<b>390,203</b>	<b>607,796</b>
<b>Oper. Inc. (Loss)</b>	<b>(9,019)</b>	<b>(13,056)</b>	<b>(9,043)</b>	<b>(8,004)</b>	<b>(6,345)</b>	<b>(14,349)</b>	<b>(19,198)</b>	<b>(20,726)</b>	<b>26,788</b>	<b>128,218</b>	<b>385,201</b>	<b>565,249</b>	<b>695,751</b>	<b>854,680</b>	<b>1,414,996</b>	<b>2,278,077</b>
Other income and expenses																
Interest income	131	270	120	37	40	77	-	-	-	-	-	-	-	-	-	-
Loss on foreign exchange	239	336	208	(600)	230	(370)	-	-	-	-	-	-	-	-	-	-
Finance cost			(6)	(3)	(5)	(7)	-	-	-	-	-	-	-	-	-	-
Changes in fair value of comparability milestone																
Net Change in fair value of financial liability	(641.47)	(678)	688	(506)	(349)	(856)	-	-	-	-	-	-	-	-	-	-
Gain/Loss on fair value change of warrants	(141)	654	1,329	(6,204)	(120)	(6,324)	-	-	-	-	-	-	-	-	-	-
Loss on disposal of assets																
Exchange differences on the translation of foreign operations																
<b>Total other income</b>	<b>(412)</b>	<b>582</b>	<b>2,338</b>	<b>(7,276)</b>	<b>(204)</b>	<b>(7,480)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pre-tax income</b>	<b>(9,431)</b>	<b>(12,474)</b>	<b>(6,705)</b>	<b>(15,280)</b>	<b>(6,549)</b>	<b>(21,828.9)</b>	<b>(19,198)</b>	<b>(20,726)</b>	<b>26,788</b>	<b>128,218</b>	<b>385,201</b>	<b>565,249</b>	<b>695,751</b>	<b>854,680</b>	<b>1,414,996</b>	<b>2,278,077</b>
<b>Pretax Margin</b>																
Taxes (or benefits)	(1)		(0)	(0)	0	(0)	-	-	1,339	12,822	38,520	56,525	83,490	102,562	183,949	296,150
<b>Tax Rate</b>									<b>5%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>12%</b>	<b>12%</b>	<b>13%</b>	<b>13%</b>
Exchange differences on the transactions of foreign operations	1,329	558	(100)	(478)	54	(424)	-	-	-	-	-	-	-	-	-	-
<b>GAAP Net Income (loss)</b>	<b>(9,432)</b>	<b>(12,474)</b>	<b>(6,705)</b>	<b>(15,280)</b>	<b>(6,549)</b>	<b>(21,829)</b>	<b>(19,198)</b>	<b>(20,726)</b>	<b>25,449</b>	<b>115,396</b>	<b>346,681</b>	<b>508,724</b>	<b>612,261</b>	<b>752,118</b>	<b>1,231,047</b>	<b>1,981,927</b>
<b>Total Comprehensive Income (loss)</b>	<b>(8,103)</b>	<b>(11,915)</b>	<b>(6,705)</b>	<b>(15,758)</b>	<b>(6,495)</b>	<b>(22,253)</b>	<b>(19,198)</b>	<b>(20,726)</b>	<b>25,449</b>	<b>115,396</b>	<b>346,681</b>	<b>508,724</b>	<b>612,261</b>	<b>752,118</b>	<b>1,231,047</b>	<b>1,981,927</b>
<b>GAAP -EPS</b>	<b>(0.40)</b>	<b>(0.49)</b>	<b>(0.17)</b>	<b>(0.24)</b>	<b>(0.10)</b>	<b>(0.34)</b>	<b>(0.28)</b>	<b>(0.28)</b>	<b>0.35</b>	<b>1.57</b>	<b>4.72</b>	<b>6.91</b>	<b>8.30</b>	<b>10.17</b>	<b>16.62</b>	<b>26.70</b>
Wgt'd Avg Shrs (Bas) - '000s	23,799	25,414	38,899	64,872	64,873	64,873	68,938	73,047	73,193	73,340	73,486	73,633	73,781	73,928	74,076	74,225
Wgt'd Avg Shrs (Dil) - '000s	23,799	25,414	38,899	64,872	64,873	64,873	68,938	73,047	73,193	73,340	73,353	73,352	73,352	73,352	73,352	73,352

Source: Company reports and Maxim

DISCLOSURES

Immutep Limited Rating History as of 08/27/2021

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 08/29/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
<b>Buy</b>	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	86%	54%
<b>Hold</b>	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	14%	41%
<b>Sell</b>	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	0%	0%

\*See valuation section for company specific relevant indices

I, Naureen Quibria, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

**Maxim Group makes a market in Immutep Limited**

**Maxim Group expects to receive or intends to seek compensation for investment banking services from Immutep Limited in the next 3 months.**

**IMMP:** For Immutep, we use the BTK (Biotechnology Index) as the relevant index.

**Valuation Methods**

**IMMP:** We forecast sales for efiti in metastatic breast cancer in 2025 (EU, US) and in 2027 (China), in non-small-cell lung cancer in 2025 (EU, US), and in head and neck in 2024 (EU, US). We assume royalty revenues for LAG525 in 2025 (EU, US) and for GSK'781 in 2027 (EU, US). We use a 30% discount rate and attribute equal weighting to our FCF, discounted EPS and SOTP to derive our price target.

**Price Target and Investment Risks**

**IMMP:** Aside from general market and other economic risks, risks particular to our price target and rating for Immutep include: (1) Development—To date, LAG-3 checkpoint modulators have not been approved; (2) Regulatory—The company's ongoing and future studies may not be sufficient to gain approval; (3) Commercial—The company lacks commercial infrastructure to support a launch if approved; (4) Financial—The company is not

yet profitable and may need to raise additional capital to fund operations; (5) Collaborative—The company has ongoing collaborations with large pharmaceutical companies who could back out of the partnerships, setting back development on product lines and increasing costs; (6) Foreign exchange fluctuations as the company is domiciled in Australia; (7) High volatility of the company's stock price.

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**RISK RATINGS**

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Risk ratings take into account both fundamental criteria and price volatility.

**Speculative – Fundamental Criteria:** This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. **Price Volatility:** Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

**High – Fundamental Criteria:** This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. **Price Volatility:** The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

**Medium – Fundamental Criteria:** This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

**Low – Fundamental Criteria:** This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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**ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST**

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## Corporate Headquarters

New York City  
300 Park Ave., 16<sup>th</sup> Floor  
New York, NY 10022  
Tel: 212-895-3500

Miami Beach  
555 Washington Ave., Suite 320  
Miami Beach, FL 33139  
Tel: 786-864-0880

Capital Markets/Syndicate: 212-895-3695

Corporate Finance: 212-895-3811

Corporate Services: 212-895-3631

Equity/Options Trading: 212-895-3790

Equity Research: 212-895-3736

Fixed Income Trading: 212-895-3875

Global Equity Trading: 212-895-3623

Institutional Sales: 212-895-3873

Institutional Sales Trading: 212-895-3873

Portfolio/Transition Trading: 212-895-3567

Prime Brokerage: 212-895-3723

Wealth Management: 212-895-3624

### Woodbury, Long Island

100 Crossways Park Drive West  
Suite 207  
Woodbury, NY 11797  
Tel: 516-393-8300

### Red Bank, New Jersey

246 Maple Avenue  
Red Bank, NJ 07701  
Tel: 732-784-1900

### West Palm Beach, Florida

105 South Narcissus Avenue  
Suite 222  
West Palm Beach, FL 33401  
Tel: 561-465-2605

### San Rafael, California

4040 Civic Center Drive  
Suite 200  
San Rafael, CA 94903  
Tel: 212-895-3670

### Aventura, Florida

20801 Biscayne Blvd  
Suite 432 / 433  
Aventura, FL 33180  
Tel: 516-396-3120

### Stamford, Connecticut

700 Canal Street  
Stamford, CT 06902