


Healthcare: Biotechnology
Company Update
Imugene Limited | IMU.AX - \$0.10 - ASX | Buy

Stock Data			
52-Week Low - High	\$0.10 - \$0.32		
Shares Out. (mil)	6,423.04		
Mkt. Cap.(mil)	\$642.30		
3-Mo. Avg. Vol.	15,260,630		
12-Mo.Price Target	AUD0.71		
Cash (mil)	AUD161.9		
Tot. Debt (mil)	AUD0.0		
Revenue (\$AUD millions)			
Yr Jun	—2022—	—2023E—	—2024E—
		Curr	Curr
1Half	0.0A	0.0A	0.0E
2Half	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E
EPS \$AUD			
Yr Jun	—2022—	—2023E—	—2024E—
		Curr	Curr
1Half	(0.00)A	0.00A	-
2Half	(0.00)A	0.00E	-
YEAR	(0.01)A	(0.01)E	(0.01)E



IMU: Doses First Combination NSCLC Patient in PD1-Vaxx + Tecentriq Phase 1/1b

Yesterday, IMU dosed the first patient in the combination cohort of its Phase 1/1b trial, named IMPRINTER, which is evaluating IMU's PD1-Vaxx in combination with Roche's anti-PD-L1 immune checkpoint inhibitor Tecentriq in NSCLC. In another IMU development, the FDA recently cleared IMU's onCARlytics IND for a Phase 1 trial evaluating IMU's oncolytic viral therapy onCARlytics in advanced or metastatic solid tumors when administered either intravenously or intratumorally in combination with the anti-CD3 and antiCD19 bispecific monoclonal antibody, Blincyto.

- Yesterday, IMU dosed the first patient in the combination cohort of its Phase 1/1b trial, named IMPRINTER, which is evaluating IMU's PD1-Vaxx in combination with Roche's anti-PD-L1 immune checkpoint inhibitor Tecentriq in NSCLC. The open label, multi-center, dose escalation/expansion IMPRINTER trial is evaluating both PD1-Vaxx alone and in combination with Tecentriq with or without chemotherapy and in NSCLC patients that either have or have not had prior checkpoint inhibitor therapy. The trial will be conducted at U.S. and Australian sites. By contrast to combining two monoclonal antibodies as therapy, PD1-Vaxx induces a polyclonal immune response which may increase response rates for the combination therapy.
- In another IMU development, the FDA recently cleared IMU's onCARlytics IND for a Phase 1 trial evaluating IMU's oncolytic viral therapy onCARlytics in advanced or metastatic solid tumors when administered either intravenously or intratumorally in combination with the anti-CD3 and antiCD19 bispecific monoclonal antibody Blincyto. The onCARlytics therapy is a CD19-expressing oncolytic virus to enable CD19-directed therapies, like Blincyto, to target solid tumors, which are currently otherwise difficult to treat with anti-CD19 therapy alone. City of Hope developed onCARlytics, which was licensed by IMU.

VALUATION

Our 12-month price target of AUD0.71 is based on a DCF analysis using a 10% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected FY2031 operating income of about AUD1.3 billion. We arrive at this valuation by projecting future revenue from CHECKvacc in TNBC, HER-Vaxx in advanced HER2+ gastric cancer, and PD1-Vaxx in NSCLC. Commercial success outside these financially modeled programs would serve as potential upside to our valuation.

Factors that could impede shares of Imugene from achieving our price target include any of its three modeled immuno-oncology products failing to succeed clinically. Also, the FDA and foreign regulatory authorities could fail to approve Imugene's products even if their respective pivotal clinical trials succeed, in the event the agency views the results as not clinically meaningful. Loss of key management personnel could also impede achieving our Imugene price target, as could the significant delay of clinical progress from, for example, lasting COVID-19 headwinds.

RISKS

- **Clinical risk.** Imugene's clinical staged products could fail to deliver statistically significant results in late-stage clinical trials, substantially reducing the value of Imugene's product candidates and therefore our target price.
- **Regulatory risk.** Even if successful in the clinic, Imugene's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce Imugene's value and therefore our target price.
- **Financing risk.** Imugene will need additional capital to fund its operations, and such financing may not occur or it could be substantially dilutive to existing investors.
- **Competitive risk.** For any future approved Imugene products, they may not be well adopted in a competitive marketplace, which would adversely affect Imugene's value and therefore our target price.
- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Its unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Its product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. It is supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets. The company's vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, the company believes Imugene's immuno-oncology therapies will become foundation treatments for cancer. Its goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Imugene Limited																		
Income Statement																		
Fiscal Year ends June																		
(in AUD\$000, except per share items)																		
	FY2018A	FY2019A	FY2020A	FY2021A	FY1H22	FY2H22	FY2022A	FY1H23A	FY2H23E	FY2023E	FY2024E	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
CHECKvacc royalty revenue													10,533	72,047	136,670	205,662	272,981	329,859
HER-Vaxx royalty revenue												1,068	16,663	39,681	66,049	94,579	107,611	116,443
PD1-Vaxx royalty revenue													36,478	199,821	414,303	644,494	828,482	927,547
Total royalty revenue												1,068	63,674	311,549	617,022	944,735	1,209,074	1,373,849
R&D	3,224	7,612	9,364	15,355	13,832	22,780	36,612	12,651	15,181	27,832	32,007	35,207	36,968	38,816	39,204	39,596	39,992	40,392
SG&A	2,554	4,777	5,515	10,311	6,690	7,371	14,061	9,255	10,181	19,436	20,991	22,040	23,142	24,299	25,514	26,790	28,129	29,536
Total operating expenses	5,778	12,389	14,879	25,667	20,522	30,151	50,673	21,906	25,362	47,268	52,997	57,248	60,110	63,115	64,719	66,386	68,122	69,928
Operating income	(5,778)	(12,389)	(14,879)	(25,667)	(20,522)	(30,151)	(50,673)	(21,906)	(25,362)	(47,268)	(52,997)	(56,179)	3,564	248,433	552,304	878,349	1,140,952	1,303,920
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	7,200	5,313	7,371	12,684	4,046	6,000	10,046	12,323	13,555	14,233	14,944	15,094	15,245	15,397	15,551
Finance income/expense net	94	409	297	11	376	(304)	72	479	100	579	608	639	766	996	1,494	2,242	3,362	5,044
Net income (pretax)	(3,934)	(7,775)	(10,508)	(18,456)	(14,833)	(23,084)	(37,917)	(17,380)	(19,262)	(36,642)	(40,067)	(41,986)	18,563	264,374	568,892	895,835	1,159,712	1,324,515
Income tax expense (benefit)														79,312	170,668	268,750	347,913	397,355
Net income	(3,934)	(7,775)	(10,508)	(18,456)	(14,833)	(23,084)	(37,917)	(17,380)	(19,262)	(36,642)	(40,067)	(41,986)	18,563	185,062	398,224	627,084	811,798	927,161
EPS basic	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	0.00	0.02	0.05	0.07	0.09	0.10
EPS diluted	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	0.00	0.02	0.05	0.07	0.09	0.09
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,439,587	5,834,808	5,637,197	6,132,017	6,499,938	6,315,977	6,759,935	7,097,932	7,452,828	7,825,470	8,216,743	8,627,581	9,058,960	9,511,908
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,439,587	5,834,808	5,637,197	6,132,017	6,499,938	6,315,977	6,759,935	7,097,932	7,919,544	8,292,185	8,683,459	9,094,296	9,525,675	9,978,623

Source: SEC filings, company press releases, and ROTH MKM

Jonathan Aschoff, Ph.D. (646) 616-2795
jaschoff@roth.com

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

Within the last twelve months, ROTH Capital Partners, or an affiliate to ROTH Capital Partners, has received compensation for investment banking services from Imugene Limited.

Shares of Imugene Limited may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 06/02/23	
			Count	Percent
Buy [B]	370	75.20	217	58.65
Neutral [N]	98	19.92	32	32.65
Sell [S]	3	0.61	0	0
Under Review [UR]	21	4.27	5	23.81

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH MKM employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH MKM does not publish research or have an opinion about this security.

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from sources believed to be reliable, but are in no way guaranteed to be complete or accurate. This report should not be used as a complete analysis of the company, industry or security discussed in the report. Additional information is available upon request. This is not, however, an offer or solicitation of the securities discussed. Any opinions or estimates in this report are subject to change without notice. An investment in the stock may involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Additionally, an investment in the stock may involve a high degree of risk and may not be suitable for all investors. No part of this report may be reproduced in any form without the express written permission of ROTH. Copyright 2023. Member: FINRA/SIPC.