

Company Update

Sales (800) 933-6830, Trading (203) 861-9060

COMPANY NOTE | EQUITY RESEARCH | January 17, 2024

Healthcare: Biotechnology

Imugene Limited | IMU.AX - \$0.08 - ASX | Buy

Stock Data										
Shares (Mkt. Cap 3-Mo. Av	rg. Vol. rice Target il)	\$0.03 - \$0.12 7,169.09 \$576.35 182,733 AUD0.46 AUD163.3 AUD0.0								
Revenue (\$AUD millions)										
Yr Jun	—2023—		—2025E—							
		Curr	Curr							
1Half	0.0A	0.0E	0.0E							
2Half	0.0A	0.0E	0.0E							
YEAR 0.0A 0.0E 0.0E										
EPS \$AUD										
Yr Jun	—2023—		—2025E—							
		Curr	Curr							
1Half	0.00A	0.00E	0.00E							
2Half	0.00A	0.00E	0.00E							
YEAR	(0.01)A	(0.01)E	(0.01)E							
IMU.AX One-Year Price and Volume History 140.0 120.0 100.0 80.0 60.0 40.0 20.0 0.18 0.18 0.18 0.18 0.18 0.18 0.14 0.12 0.10 0.08 0.08 0.014 0.12 0.10 0.00 0.										
Vol (m)	Feb-23 Mar-23 Apr-23 May-23 Jun-23	Jul-23 Aug-23 Sep-23 Oct-23	Dec-23 Jan-24 exit							

IMU: MAST Trial Evaluating VAXINIA Oncolytic Viral Yields More Positive Data

IMU updated its Phase 1 MAST trial evaluating its oncolytic virus CF33-hNIS (VAXINIA) in metastatic advanced solid tumors. With 38 dose escalation phase patients dosed, 31 patients were efficacy evaluable, with about half of the patients having at least disease control (i.e., SD or better), including a CR and two PRs. Particularly positive results in cholangiocarcinoma patients had previously inclined IMU to expand the trial by adding 10-20 such patients. This update follows data released in 4Q23 from 26 efficacy evaluable MAST trial patients.

- IMU updated its Phase 1 MAST trial evaluating its oncolytic virus CF33-hNIS (VAXINIA) in metastatic advanced solid tumors. With 38 dose escalation phase patients dosed (19 dosed intratumorally and 19 dosed intravenously, as either monotherapy or in combination with pembrolizumab), 31 patients (14 intratumoral, 17 intravenous) were efficacy evaluable, having had at least their first scan on day 42. In the 14 intratumoral patients, 7 of 15 (47%) total injected lesions shrunk, with three lesions completely eradicated. Three of 14 had an objective response (21% ORR), with one CR in a cholangiocarcinoma patient and PRs in two melanoma patients (both middose level). Among the 17 intravenous patients, nine (53%) achieved SD. Patients that received prior checkpoint inhibitor therapy derived clinical benefit with both monotherapy and combination therapy. The results in cholangiocarcinoma patients had previously inclined IMU to expand the trial by adding 10-20 such patients.
- Initial data to be presented at ASCO-GI show that seven gastrointestinal cancer patients (3 CRC, 2 biliary tract, 1 pancreatic, 1 liver) responded positively to VAXINIA monotherapy, with a disease control rate of 86% and with changes in tumor burden correlating with systemic anti-tumor immunological changes. Formal poster presentation of the gastrointestinal cancer results will occur on 1-18-24 at ASCO-GI. As can be the case with cholangiocarcinoma, one mid-dose level intratumoral patient had pseudoprogression (an increase in tumor burden followed by a response), with a 49% increase in tumor burden after two cycles of therapy followed by a CR by the fourth cycle, with no known recurrence in over 430 days. The other cholangiocarcinoma patient had SD for more than four months upon receiving intravenous VAXINIA. All therapy was deemed safe and tolerable.
- As a reminder, IMU's last update from this trial on 11-07-23 specified that of the 26 evaluable patients evaluable at that time, the best responses were one CR, one PR, 16 SD, and eight PD. Particularly encouraging initial results were seen in gastrointestinal tumor patients, and given that one of two bile duct cancer patients achieved the lone CR (lasting over 350 days after taking mid-dose VAXINIA), and the second achieved SD for over four months, trial expansion is planned for 10 patients with bile duct cancers taking VAXINIA monotherapy.

VALUATION

Our 12-month price target of AUD0.46 is based on a DCF analysis using a 15% 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.

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 latestage 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 is 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.



Company Note - January 17, 2024

IMUGENE LIMITED

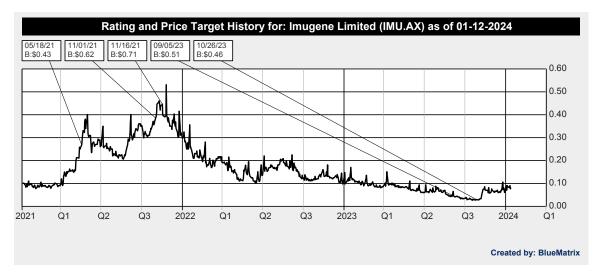
Imugene Limited															Jo	nathan Ascho	off, Ph.D. (64	6) 616-2795
Income Statement																	jaschof	f@roth.com
Fiscal Year ends June																		
(in AUD\$000, except per share items)																		
	FY2018A	FY2019A	FY2020A	FY2021A	FY2022A	FY2023A	FY1H24E	FY2H24E	FY2024E	FY1H25E	FY2H25E	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
CHECKvacc royalty revenue													10,533	72,047	143,126	215,676	286,443	346,566
HER-Vaxx royalty revenue												-	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												-	63,674	311,549	623,478	954,749	1,222,536	1,390,555
R&D	3,224	7,612	9,364	15,355	36,612	30,865	20,035	22,039	42,074	23,141	24,298	47,439	49,811	52,301	52,824	53,353	53,886	54,425
SG&A	2,554	4,777	5,515	10,311	14,061	20,428	11,732	12,318	24,050	12,565	12,816	25,381	26,650	27,982	29,381	30,851	32,393	34,013
Total operating expenses	5,778	12,389	14,879	25,667	50,673	51,293	31,767	34,357	66,125	35,705	37,114	72,820	76,461	80,284	82,206	84,203	86,279	88,438
Operating income	(5,778)	(12,389)	(14,879)	(25,667)	(50,673)	(51,293)	(31,767)	(34,357)	(66,125)	(35,705)	(37,114)	(72,820)	(12,787)	231,265	541,272	870,546	1,136,257	1,302,117
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	7,200	12,684	10,219	5,000	6,000	11,000	8,500	9,500	18,000	19,177	20,136	20,337	20,541	20,746	20,954
Finance income/expense net	94	409	297	11	72	1,852	900	900	1,800	900	900	1,800	2,160	2,808	4,212	6,318	9,477	14,216
Net income (pretax)	(3,934)	(7,775)	(10,508)	(18,456)	(37,917)	(39,222)	(25,867)	(27,457)	(53,325)	(26,305)	(26,714)	(53,020)	8,550	254,209	565,822	897,405	1,166,480	1,337,286
Income tax expense (benefit)													-	50,842	169,747	269,221	349,944	401,186
Net income	(3,934)	(7,775)	(10,508)	(18,456)	(37,917)	(39,222)	(25,867)	(27,457)	(53,325)	(26,305)	(26,714)	(53,020)	8,550	203,367	396,075	628,183	816,536	936,100
EPS basic	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	0.00	0.02	0.04	0.06	0.07	0.08
EPS diluted	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	0.00	0.02	0.04	0.06	0.07	0.08
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,637,197	6,275,676	7,065,301	7,418,566	7,241,934	8,206,195	8,616,504	8,411,350	9,047,330	9,499,696	9,974,681	10,473,415	10,997,086	11,546,940
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,637,197	6,275,676	7,065,301	7,418,566	7,241,934	8,206,195	8,616,504	8,411,350	9,514,045	9,966,412	10,441,397	10,940,131	11,463,801	12,013,656
Source: SEC filings, company press releases, and ROTH	MKM																	

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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**

		_	IB Serv./Past 12 Mos. as of 01/17/24			
Rating	Count	Percent	Count	Percent		
Buy [B]	349	73.47	81	23.21		
Neutral [N]	81	17.05	8	9.88		
Sell [S]	3	0.63	0	0		
Under Review [UR]	40	8.42	3	7.50		

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.

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