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COMPANY NOTE | EQUITY RESEARCH | November 07, 2023

Healthcare: Biotechnology **Company Update**

Imugene Limited | IMU.AX - $0.07 - ASX | *Buy*

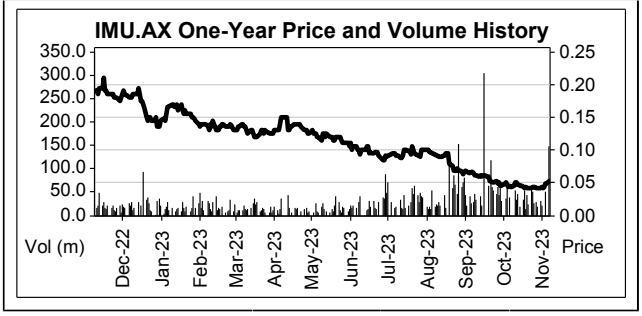
Stock Data	
52-Week Low - High	$0.04 - $0.21
Shares Out. (mil)	7,164.98
Mkt. Cap.(mil)	$372.58
3-Mo. Avg. Vol.	49,679,030
12-Mo.Price Target	AUD0.46
Cash (mil)	AUD163.3
Tot. Debt (mil)	AUD0.0

Revenue ($AUD millions)

Yr Jun	—2023—	—2024E—	—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—	—2024E—	—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: Positive Initial VAXINIA MAST Trial Data, Expanding Bile Duct Tumor Cohort

IMU released initial results from its Phase 1 MAST trial evaluating VAXINIA. Of the 26 evaluable patients, 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.

- IMU recently released initial clinical results from its Phase 1 MAST (Metastatic Advanced Solid Tumors) trial evaluating VAXINIA (oncolytic virus therapy), which is treating cohort 5 of the intravenous monotherapy dose escalation portion and treating cohort 3 of the intravenous combination therapy (VAXINIA plus pembrolizumab) portion. The MAST trial also has cohorts dosing VAXINIA intratumorally, as monotherapy, and along with standard intravenous pembrolizumab dosing. Thus far, 34 heavily pre-treated patients have been dosed with VAXINIA, including 16 intratumorally and 18 intravenously, including both monotherapy and combination therapy cohorts. The 25 efficacy evaluable patients received at least one scan, seven patients have their first scan still pending, and one patient progressed before their first scan. Of the 26 evaluable patients, the best responses were one CR, one PR (melanoma patient taking mid-dose VAXINIA), 16 SD, and eight PD as measured by iRECIST and RECIST criteria.
- Particularly encouraging initial results were seen in gastrointestinal tumor patients (i.e., colorectal, bile duct, pancreatic and liver cancer), where six of eight (75%; all six given VAXINIA monotherapy) such patients (seven monotherapy and one combination therapy) had disease control (i.e., CR, PR or SD). When including just the seven patients taking monotherapy, the disease control rate was 6/7 (86%). Given that one of two bile duct cancer patients achieved the lone CR (so far lasting 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. We note that there have been no adverse safety signals from VAXINIA thus far, and that bile duct cancers are difficult to treat and typically respond poorly to immunotherapy.

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 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)

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	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

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

			IB Serv./Past 12 Mos. as of 11/07/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**357**	**74.53**	**218**	**61.06**
Neutral [N]	**83**	**17.33**	**29**	**34.94**
Sell [S]	**2**	**0.42**	**1**	**50.00**
Under Review [UR]	**31**	**6.47**	**3**	**9.68**

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.