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COMPANY NOTE | EQUITY RESEARCH | August 17, 2023

Healthcare: Biotechnology **Company Update**

Imugene Limited | IMU.AX - $0.09 - ASX | *Buy*

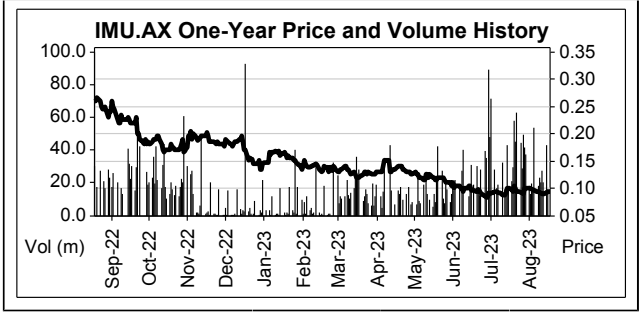
Stock Data	
52-Week Low - High	$0.08 - $0.29
Shares Out. (mil)	6,423.04
Mkt. Cap.(mil)	$603.77
3-Mo. Avg. Vol.	27,144,570
12-Mo.Price Target	AUD0.71
Cash (mil)	AUD152.0
Tot. Debt (mil)	AUD0.0

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: Licenses Clinical Stage Allogeneic CD19 CAR T For Liquid Tumors

IMU licensed azer-cel, an allogeneic CD19 CAR T therapy currently in a Phase 1b trial that is using the RP2D. IMU would conduct another Phase 1b and likely a registrational Phase 2 trial in third- and fourth-line DLBCL could begin in 2024, which would advance IMU closer to commercial stage than it would likely be without azer-cel. There are clear commercial and patient convenience advantages to an allogeneic CAR T approach, and the Phase 2 results will dictate where azer-cel fits in the treatment paradigm.

- IMU licensed exclusive global rights to Precision Biosciences' (DTIL-NC) azercabtagene zarpreleucel (azer-cel) allogeneic CD19 CAR T cell therapy program. The therapy is now in a multi-center Phase 1b and has been tested in more than 84 patients with NHL and ALL, with particularly potency demonstrated in 18 DLBCL patients that had relapsed after autologous CAR T therapy. More specifically, azer-cel delivered an 83% ORR and 61% CR, with a 55% rate of durable response (i.e., >=6 months) in this difficult to treat auto CAR T relapse setting (n=18). A positive FDA meeting was convened in late 2Q23 to discuss going straight into a registrational Phase 2 trial in third- and fourth-line DLBCL, with commercial grade product to be used in the trial.
- Among patients with relapsed/refractory NHL, regardless of prior autologous CAR T cell experience or other prior therapy, azer-cel had an acceptable safety profile, a 58% ORR, and 41% CR rate. There was also no Grade 3 or greater CRS, no ICANS, no infection and no GvHD seen in the most recent cohort that also had been treated with the appropriate lymphodepletion treatment. Azer-cel also delivers in DLBCL patients after relapsing from autologous CAR T therapy, high ORR and molecular remission, not to mention the relative convenience of an allogeneic alternative.
- Under the terms of the agreement, IMU will pay Precision Biosciences $8M cash upfront, $13M deferred for one year in cash or stock, $8M cash or stock upon satisfactory completion of another Phase 1b trial that will soon start and which is being conducted to test the latest manufacturing batch of material (the 1.2 batch), up to $198M in precommercial milestones including FDA and EMA approval in several indications, and nondisclosed royalties. IMU will also acquire the lease to a 32,800 square foot GMP facility in the U.S. along with its 50 employees.
- In unrelated news, IMU's Phase 1 MAST trial evaluating VAXINIA in metastatic or advanced solid tumors who have had at least two prior lines of standard of care treatment, has completed its third intratumoral monotherapy dose cohort. There was no mention of safety or efficacy, but we can at least assume the absence of safety issues significant enough to prevent the trial from advancing to the fourth, and final, intratumoral monotherapy dose cohort. The MAST trial is also dosing intravenous monotherapy dose cohort four, as well as combination therapy (VAXINIA plus pembrolizumab) intravenous dose cohort one. Overall, the trial will recruit up to 100 patients at about 10 sites in the U.S. and Australia.

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)

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	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

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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 08/17/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**350**	**72.61**	**215**	**61.43**
Neutral [N]	**85**	**17.63**	**29**	**34.12**
Sell [S]	**3**	**0.62**	**1**	**33.33**
Under Review [UR]	**42**	**8.71**	**9**	**21.43**

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.