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COMPANY NOTE | EQUITY RESEARCH | February 28, 2023

Healthcare: Biotechnology **Company Update**

Imugene Limited | IMU.AX - $0.14 - ASX | *Buy*

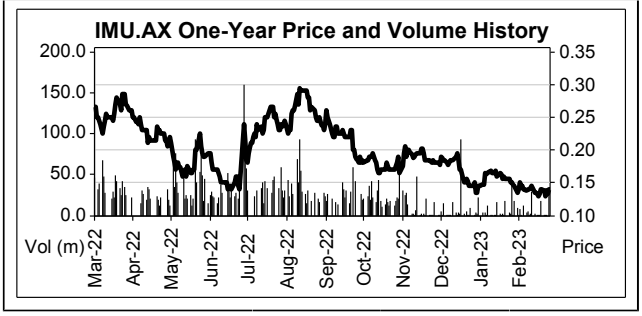
Stock Data	
52-Week Low - High	$0.13 - $0.32
Shares Out. (mil)	6,421.72
Mkt. Cap.(mil)	$899.04
3-Mo. Avg. Vol.	21,045,060
12-Mo.Price Target	AUD0.71
Cash (mil)	AUD161.9
Tot. Debt (mil)	AUD0.0

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 FY1H23: Updating Financial Model Following Release of FY1H23 Financials

IMU already disclosed calendar YE22 cash of $161.9M, and recently released its FY1H23 financials. The cash provides at least three years of funding, as per our projections. Since the start of its FY2023 in July, IMU has presented a substantial amount of results, and we anticipate the announcement pace to remain robust going forward, given the ongoing and upcoming trials. Most recently, the Phase 1 VAXINIA trial is enrolling its first combination therapy cohort, along with higher dose monotherapy cohorts.

- **ASCO GI presentations.** In addition to recently reiterating Phase 2 HERIZON trial results with HER-Vaxx and describing the ongoing Phase 2 nextHERIZON trial with HER-Vaxx (100ug dose) in combination with pembrolizumab or chemotherapy in HER2+ gastric cancer that has previously progressed on trastuzumab, IMU presented two preclinical posters at the 2023 ASCO Gastrointestinal Cancers Symposium. The posters show the utility of IMU's oncolytic viruses CF33, CF33-hNIS14.5, and CF33-hNIS-antiPDL1 in killing gastric cancer cell lines and primary human peritoneal gastric cancer cells. We look forward to clinical results with HER-Vaxx and CF33-hNIS-antiPDL1 from ongoing and planned trials.
- **VAXINIA MAST trial progress.** In December, IMU's Phase 1 MAST (metastatic advanced solid tumors) trial evaluating its CF33-hNIS oncovirus (i.e., VAXINIA) successfully cleared cohort 2 of both the intravenous and intratumoral arms of the monotherapy dose escalation groups, thereby allowing the trial to open cohort 1 of the combination treatment (VAXINIA plus pembrolizumab) group, as well as to open cohort 3 for both monotherapy dose escalation groups. The whole trial aims to enroll up to 100 patients at about 10 U.S. and Australian sites.
- **CHECKvacc.** IMU's ongoing Phase 1 trial (n = 33 to 78) is evaluating intratumorally injected CHECKvacc in metastatic TNBC patients, and results for the first six patients (first two dose cohorts; 1x10^5 pfu and 3x10^5 pfu) were presented. CHECKvacc was well tolerated, with no observed DLTs and no treatment-related AEs reported other than one incidence of injection site discoloration. 99mTc SPECT imaging for virus tracking shows enhancement in 4/6 (67%) patients. Regarding efficacy, albeit at the lowest two doses, there was one SD and 5 PD.
- **ESMO Asia presentation.** Although largely the same final OS HERIZON trial results as were released in early 3Q22 (42% OS benefit versus chemotherapy alone (13.9 versus 8.3 months)), IMU's new results in an oral slide presentation at the recent ESMO Asia Congress consist of duration of response (DoR) data being longer in the HER-Vaxx plus SOC chemotherapy (i.e., cisplatin plus either 5FU or capecitabine; or oxaliplatin plus capecitabine) arm than in the chemotherapy alone control arm (30 versus 19 weeks, respectively). The trial enrolled 36 gastric cancer patients.
(text continued on page 2)

- **PD-1Vaxx.** Last August, IMU presented Phase 1 PD1-Vaxx monotherapy results that demonstrated a CR, PR, and four SD among 14 treatment experienced NSCLC patients taking one of three PD1-Vaxx doses, thus allowing the therapy to proceed to Phase 1b in which it will be given to treatment naive NSCLC patients in combination with atezolizumab. Of note, the CR patient achieved the CR for more than 18 months in the low dose (10ug) group, and we emphasize that PD1-Vaxx is a cancer antigen therapy, not a broadly cytotoxic therapy. Although that one patient was the only responder among the four patients in the 10ug dose cohort, two patients among the six in the 50ug dose cohort achieved SD, and of four patients in the 100ug dose cohort, one achieved PR and two achieved SD. Biomarker results showed that PD1-Vaxx was immunogenic and elicited a sustained and robust antibody response, especially by six weeks at the 100ug dose, which will be the Phase 1b combination therapy dose.
- **SITC presentations.** Three SITC posters describe the clear utility of onCARlytics combination therapy in preclinical animal models. Preclinical data with IMU's onCARlytics (CF33-CD19 oncolytic virus) in combination with partner Celularity's (CELU-NC) placental-derived off-the-shelf allogeneic CYCART-19 T cells was recently presented in a poster at the SITC annual meeting, showing the ability of the therapy to target tumors expressing CD19t. It was shown that onCARlytics can transform triple-negative breast cancer (TNBC) cell line MDA-MB-468 to express CD19t as a CAR T cell target in an oncovirus dose-dependent manner, and that CYCART-19 could target the MDA-MB-468 expressing CD19t as a result of transformation via onCARlytics. Another SITC poster (citation) showed how onCARlytics combined with the CD19 bispecific T cell engaging antibody blinatumomab (a.k.a. Blincyto; binds CD19 on tumor cells and CD3 on T cells) could enhance solid tumor killing. We note that onCARlytics caused a dose dependent increase in T cell activation markers along with IFNγ and IL-2 secretion increase in response to blinatumomab, allowing blinatumomab to initiate T cell-mediated tumor killing in onCARlytics infected solid tumor cells. Preclinical data with IMU's onCARlytics in combination with partner Estrella Biopharma's (private) CD19-Redirected ARTEMIS T cells was also presented in a poster at the SITC annual meeting. When Estrella's CD19-Redirected ARTEMIS T Cells are administered in combination with onCARlytics to cultured tumor cells, enhanced in vitro killing efficacy against MDA-MB-468, HepG2, and Hep3B tumor cells was observed with combination therapy than with onCARlytics monotherapy. We also note an increasing trend in ARTEMIS T cell activation in an onCARlytics MOI-dependent manner.

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 02/28/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**362**	**71.54**	**214**	**59.12**
Neutral [N]	**94**	**18.58**	**28**	**29.79**
Sell [S]	**4**	**0.79**	**1**	**25.00**
Under Review [UR]	**31**	**6.13**	**10**	**32.26**

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.

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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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