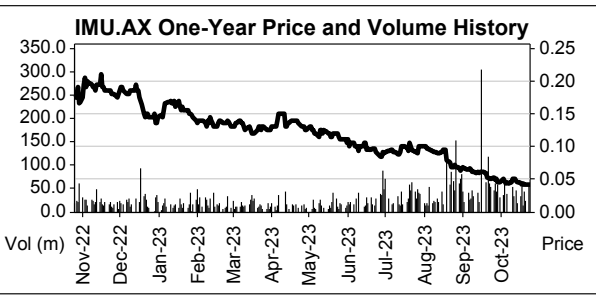


Healthcare: Biotechnology
Company Update
Imugene Limited | IMU.AX - \$0.04 - ASX | Buy

Stock Data			
52-Week Low - High	\$0.04 - \$0.21		
Shares Out. (mil)	7,164.98		
Mkt. Cap.(mil)	\$293.76		
3-Mo. Avg. Vol.	48,138,770		
12-Mo.Price Target	AUD0.51		
Cash (mil)	AUD206.4		
Tot. Debt (mil)	AUD0.0		
Cash (mil): Pro forma cash includes \$53.2M raised after June 30, 2023.			
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	-
2Half	0.00A	0.00E	-
YEAR	(0.01)A	(0.01)E	(0.01)E



IMU: 3 ESMO Posters Highlight HER-Vaxx & Oncolytic Virus CF33-hNIS-antiPD-L1

IMU presented three posters at the current ESMO conference. Among some reiterated survival and antibody response data from its Phase 1b HERIZON trial evaluating HER-Vaxx in gastric cancer, IMU showed that antibodies induced by HER-Vaxx did in fact bind to cancer cells and inhibit phosphorylation of HER-2/neu receptor as well as inhibiting the Akt and MAPK kinases. Another poster showed HER-Vaxx to upregulate PD-L1, inviting the feasibility of co-therapy with checkpoint inhibitors. A third showed IMU's oncolytic virus to activate the immune system around tumors.

- HERIZON trial update.** IMU presented a poster (poster 1536P) at ESMO that included new preclinical and previously released clinical results from its Phase 1b HERIZON trial evaluating standard of care (SOC) chemotherapy +/- HER-Vaxx in patients with Her-2/Neu overexpressing advanced/metastatic gastric/GEJ cancer. Back in 2Q22, IMU reported that final HER-Vaxx OS data from HERIZON demonstrated statistical significance (Hazard Ratio (HR) of 0.558 (80% 2-sided CI: 0.349, 0.895; p=0.054), indicating a 41.5% reduced death risk for HER-Vaxx plus SOC versus SOC alone, with median OS of 14.0 versus 8.3 months in favor of HER-Vaxx. We note that the trial had a pre-specified 1-sided false positive probability of 0.10. There was no added toxicity from HER-Vaxx, and the 100µg HER-Vaxx dose was confirmed for future trials. Other previously released HERIZON trial data included antibody data from 2Q23 showing that HER-Vaxx treatment produced robust (p<0.001) anti-HER-2-IgG and IgG1 antibody responses, and that antibody response correlated with tumor reduction (p=0.001). The tumor reduction correlation may likely be explained by the newly released preclinical findings that the IgG and IgG1 antibodies induced by HER-Vaxx had a dose-dependent functionality in binding to Her-2/neu-expressing cells *in vitro*, and in intracellular phosphorylation inhibition of the receptor and the signaling pathway kinases Akt and MAPK.
- Another poster (poster 472P) was also presented at ESMO in which mouse studies using HER-Vaxx to target HER-2/neu showed HER-Vaxx treatment to upregulate PD-L1 while downregulating HER-2 receptor, resulting in a significantly higher ratio of PD-L1 to HER-2/neu positive metastases in mammary carcinoma cell xenografts. Some clinical data from the Phase 1b HERIZON trial were also shown, demonstrating the same PD-L1 and HER-2 receptor phenomenon in a patient's primary tumor, which could explain that patient's ultimate disease progression. This pair of effects has also been observed in response to Herceptin treatment, and suggest that it is worth investigating the targeting of both HER-2/neu and PD-L1 in this tumor setting.
- A third poster (poster 4581) showed that intratumoral injection of CF33-hNIS-anti-PD-L1 is safe and well-tolerated at dose levels 1 through 3 in patients with metastatic triple negative breast cancer, and that the treatment induces tumor infiltration of cancer fighting CD4+ and CD8+ T cells that indicate the therapy's ability to *(text continued on page 2)*

- *(text continued from page 1)* locally activate the immune system. Significant upregulation of PD-L1 within the tumor microenvironment further substantiates local immune activation, and likely efficacy of anti-PD-L1 therapy, which is contained within the oncolytic virus. SPECT imaging showed local oncolytic viral replication in 75% of treated patients in this ongoing trial, which shows successful tracking of viral replication using non-invasive imaging techniques.

VALUATION

Our 12-month price target of AUD0.51 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. 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 a 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	FY2022A	FY1H23	FY2H23	FY2023A	FY1H24E	FY2H24E	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													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	617,022	944,735	1,209,074	1,373,849
R&D	3,224	7,612	9,364	15,355	36,612	12,651	18,214	30,865	20,035	22,039	42,074	46,282	48,596	51,026	51,536	52,051	52,572	53,098
SG&A	2,554	4,777	5,515	10,311	14,061	9,255	11,173	20,428	11,732	12,318	24,050	25,253	26,515	27,841	29,233	30,695	32,230	33,841
Total operating expenses	5,778	12,389	14,879	25,667	50,673	21,906	29,387	51,293	31,767	34,357	66,125	71,534	75,111	78,867	80,769	82,746	84,801	86,939
Operating income	(5,778)	(12,389)	(14,879)	(25,667)	(50,673)	(21,906)	(29,387)	(51,293)	(31,767)	(34,357)	(66,125)	(71,534)	(11,437)	232,682	536,253	861,989	1,124,272	1,286,910
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	7,200	12,684	4,046	6,173	10,219	5,000	6,000	11,000	17,818	18,709	19,645	19,841	20,040	20,240	20,443
Finance income/expense net	94	409	297	11	72	479	1,373	1,852	900	900	1,800	1,890	2,268	2,948	4,423	6,634	9,951	14,926
Net income (pretax)	(3,934)	(7,775)	(10,508)	(18,456)	(37,917)	(17,380)	(21,841)	(39,222)	(25,867)	(27,457)	(53,325)	(51,826)	9,540	255,275	560,517	888,662	1,154,463	1,322,279
Income tax expense (benefit)													-	76,583	168,155	266,599	346,339	396,684
Net income	(3,934)	(7,775)	(10,508)	(18,456)	(37,917)	(17,380)	(21,841)	(39,222)	(25,867)	(27,457)	(53,325)	(51,826)	9,540	178,693	392,362	622,064	808,124	925,595
EPS basic	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.01)	0.00	0.02	0.04	0.07	0.08	0.09
EPS diluted	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.00)	(0.00)	(0.01)	(0.01)	0.00	0.02	0.04	0.06	0.08	0.08
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,637,197	6,132,017	6,419,335	6,275,676	7,257,881	7,693,354	7,475,618	7,849,399	8,241,869	8,653,962	9,086,660	9,540,993	10,018,043	10,518,945
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,637,197	6,132,017	6,419,335	6,275,676	7,257,881	7,693,354	7,475,618	7,849,399	8,708,584	9,120,678	9,553,376	10,007,709	10,484,758	10,985,661

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

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Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 10/24/23	
			Count	Percent
Buy [B]	362	73.28	218	60.22
Neutral [N]	85	17.21	31	36.47
Sell [S]	2	0.40	1	50.00
Under Review [UR]	42	8.50	9	21.43

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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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