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COMPANY NOTE | EQUITY RESEARCH | April 30, 2024

Healthcare: Biotechnology Company Update

Imugene Limited | IMU.AX-\$0.05-ASX | Buy

Stock Data	
52-Week Low - High	\$0.03-\$0.09
Shares Out. (mil)	7,319.81
Mkt. Cap.(mil)	\$377.40
3-Mo. Avg. Vol.	121,918
12-Mo.Price Target	AUD0.42
Cash (mil)	AUD114.1
Tot. Debt (mil)	AUD0.0

Revenue (\$AOD millions)									
Yr Jun	— 2023—	— 2024E—	— 2025E—						
		Curr	Curr						
1Half	0.0A	0.0A	0.0E						
2Half	0.0A	0.0E	0.0E						
YEAR	0.0A	0.0E	0.0E						

Yr Jun	— 2023—	— 2024E—	— 2025E—
		Curr	Curr
1Half	0.00A	(0.01)A	(0.01)E
2Half	0.00A	(0.01)E	(0.01)E
YEAR	(0.01)A	(0.02)E	(0.01)E



IMU: General Quarterly Business Update, 2H24 To Be Rich In Clinical Data

IMU provided a general business update, most notably regarding its MAST trial in solid tumors, which is evaluating VAXINIA monotherapy and combination therapy with pembrolizumab. As of 04-24-24, 40 of 47 dosed patients are efficacy evaluable, and ORR was 8% (3/40; CR, 2 PRs), with 43% (17/40) achieving SD, thus indicating a 50% overall DCR. There were no additional objective tumor responses from the last update, and we look forward to initial data from the recently opened bile tract cancer expansion cohort (n=10) in 2H24.

- MAST trial. IMU provided an update on all of its clinical programs, in addition to several other business items. Most notable was an update on its MAST trial in solid tumors, which is evaluating IMU's oncolytic virus VAXINIA given intratumorally or intravenously, with or without pembrolizumab. As of a data cutoff of 04-24-24, 40 of 47 dosed patients are efficacy evaluable, and ORR was 8% (3/40; 1 CR and 2 PRs), with 43% (17/40) achieving SD, thus indicating a 50% overall DCR. There were no additional objective tumor responses from the last update, and we look forward to initial data from the recently opened bile tract cancer expansion cohort (n=10) in 2H24. The new MAST trial data compares to the prior MAST update at AACR (data cutoff of 12-19-23), in which 31 of 38 dosed patients were efficacy evaluable, yielding a 21% (3/14) ORR in the 14 intratumoral patients, and a 53% (9/17) DCR (all SD) in the 17 intravenous patients.
- Other clinical programs. Regarding azer-cel (allogeneic CAR T therapy), IMU is enrolling a Phase 1b trial with DLBCL patients who relapsed following an autologous CAR T therapy. At present, 15 U.S. sites are open with plans to open up to five Australian sites and report preliminary data in 2H24. IMU is also conducting preclinical studies with azer-cel/onCARlytics (i.e., IMU's proprietary CF33- CD19 oncolytic virus) combination therapy. Regarding onCARlytics, the Phase 1 OASIS trial is combining onCARlytics with CD19 targeted therapy blinatumomab in patients with acute lymphoblastic leukemia (ALL). Given that the Cohort Review Committee saw no safety issues with onCARlytics monotherapy, the combination therapy arm of the trial is now open at three (growing to possibly 10) U.S. trial sites, which will recruit 40-45 advanced solid tumor patients. We expect to see preliminary combination therapy data in 4Q24. Regarding B cell immunotherapy PD1-Vaxx, Phase 1 will recruit about 44 colorectal cancer patients in Australia and the UK, with preliminary data expected in 2025. PD1-Vaxx will be administered before tumor resection (i.e., the neoadjuvant setting). Regarding HER-Vaxx, which delivered positive results in the Phase 2 HERIZON trial in HER2+ metastatic or advanced gastric/GEJ adenocarcinoma, IMU is currently in business development discussions.

VALUATION

Our 12-month price target of AUD0.42 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. Imagene 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 Imagene products, they may not be well adopted in a competitive marketplace, which would adversely affect Imagene'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. Our 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. Our pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also 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. We are 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. Our 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, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Imugene Limited													Jo	nathan Asch	off, Ph.D. (64	6) 616-2795
Income Statement															jaschoff	f@roth.com
Fiscal Year ends June																
(in AUD\$000, except per share items)																
	FY2020A	FY2021A	FY2022A	FY2023A	FY1H24A	FY2H24E	FY2024E	FY1H25E	FY2H25E	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
CHECKvacc royalty revenue											-	77,986	153,174	229,488	303,968	366,948
HER-Vaxx royalty revenue										-	-	39,382	65,575	93,978	106,912	115,696
PD1-Vaxx royalty revenue											-	199,821	414,303	644,494	828,482	927,547
Total royalty revenue										-	-	317,190	633,053	967,960	1,239,362	1,410,191
R&D	9,364	15,355	36,612	30,865	44,676	28,127	72,803	28,409	28,693	57,102	59,957	62,954	63,584	64,220	64,862	65,511
SG&A	5,515	10,311	14,061	20,428	34,557	29,332	63,890	29,626	29,922	59,548	62,525	65,651	68,934	72,381	76,000	79,800
Total operating expenses	14,879	25,667	50,673	51,293	79,233	57,460	136,693	58,034	58,615	116,649	122,482	128,606	132,518	136,601	140,862	145,310
Operating income	(14,879)	(25,667)	(50,673)	(51,293)	(79,233)	(57,460)	(136,693)	(58,034)	(58,615)	(116,649)	(122,482)	188,584	500,535	831,359	1,098,500	1,264,881
Other income/loss (R&D tax incentive, etc)	4,074	7,200	12,684	10,219	9,230	6,000	15,230	8,500	9,500	18,000	23,083	24,237	24,480	24,725	24,972	25,222
Finance income/expense net	297	11	72	1,852	2,296	900	3,196	900	900	1,800	2,160	2,808	3,650	4,746	6,169	8,020
Net income (pretax)	(10,508)	(18,456)	(37,917)	(39,222)	(67,707)	(50,560)	(118,267)	(48,634)	(48,215)	(96,849)	(97,239)	215,629	528,665	860,829	1,129,641	1,298,122
Income tax expense (benefit)											-	64,689	158,599	258,249	338,892	389,437
Net income	(10,508)	(18,456)	(37,917)	(39,222)	(67,707)	(50,560)	(118,267)	(48,634)	(48,215)	(96,849)	(97,239)	150,940	370,065	602,581	790,749	908,686
EPS basic	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	(0.01)	(0.02)	(0.01)	(0.01)	(0.01)	(0.01)	0.02	0.04	0.06	0.07	0.08
EPS diluted	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	(0.01)	(0.02)	(0.01)	(0.01)	(0.01)	(0.01)	0.02	0.04	0.06	0.07	0.08
Basic shares outstanding	4,074,894	4,663,541	5,637,197	6,275,676	7,169,087	7,384,160	7,276,623	8,096,226	8,501,037	8,298,632	8,926,089	9,372,394	9,841,013	10,333,064	10,849,717	11,392,203
Diluted shares outstanding	4,074,894	4,663,541	5,637,197	6,275,676	7,169,087	7,384,160	7,276,623	8,096,226	8,501,037	8,298,632	8,926,089	9,839,109	10,307,729	10,799,779	11,316,433	11,858,918
Source: SEC filings, company press releases, and ROTH MI	KM															

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Distribution of IB Services Firmwide

IB Serv./Past 12 Mos. as of 04/30/2024

Rating	Count	Percent	Count	Percent
Buy [B]	344	72.27	84	24.42
Neutral [N]	78	16.39	4	5.13
Sell [S]	2	0.42	0	0
Under Review [UR]	52	10.92	1	1.92

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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.

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