ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | December 11, 2022

Healthcare: Biotechnology **Company Update**

Imugene Limited | IMU.AX - $0.19 - ASX | *Buy*

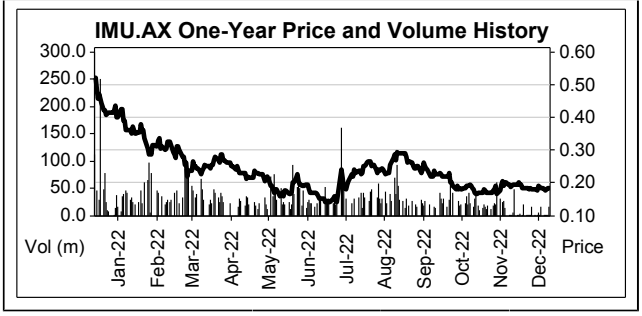
Stock Data	
52-Week Low - High	$0.13 - $0.54
Shares Out. (mil)	6,421.72
Mkt. Cap.(mil)	$1,188.02
3-Mo. Avg. Vol.	23,570,710
12-Mo.Price Target	AUD0.71
Cash (mil)	AUD179.9
Tot. Debt (mil)	AUD0.0

Revenue ($AUD millions)

Yr Jun	—2022—	—2023E—	—2024E—
		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	—2022—	—2023E—	—2024E—
		Curr	Curr
1Half	(0.00)A	0.00E	-
2Half	(0.00)A	0.00E	-
YEAR	(0.01)A	(0.01)E	(0.01)E



IMU: Presents First Two CHECKVacc Dose Cohorts at SABCS, Showing Clean Safety

The 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) 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.

- **Background and preclinical.** IMU's CHECKvacc is a novel chimeric orthopoxvirus that in animal xenografts successfully secretes functional hNIS and single-chain variable fragment against PD-L1. Preclinical studies with intratumorally injected CHECKvacc showed the therapy to be safe and well-tolerated, and CHECKvacc is able to kill triple negative breast cancer (TNBC) xenografts in animal models at doses several magnitudes lower than other oncolytic viruses.

- **Phase 1 trial design.** The ongoing single center, 3+3 design, Phase 1 trial (n = 33 to 78) is evaluating intratumorally injected CHECKvacc in metastatic TNBC patients and results for the six patients from the first two dose cohorts (1x10^5 pfu or 3x10^5 pfu) were presented. Dose cohort 1 patients received a single injection and completed a four-week safety evaluation before the next patient in the cohort was treated. Other patients are to receive injections on days 1 and 15 of each 28-day cycle until disease progression. The trial's primary objective is to evaluate the safety and tolerability of CHECKvacc, with secondary objectives of determining RP2D and response rate by RECIST1.1 and irRECIST. Exploratory objectives are to determine optimal biologic dose, antiviral immune activation as determined by increased expression of PD-1, PD-L1, or CTLA-4, and increased CD8+ cells, and viral kinetics and viral infection using hNIS-based imaging such as technetium scan and viral plaque assays.

- **Initial Phase 1 data.** 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.

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 AUD1.4 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. 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 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. 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
Income Statement
Fiscal Year ends June
(in AUD$000, except per share items)

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	FY2018A	FY2019A	FY2020A	FY2021A	FY1H22	FY2H22	FY2022A	FY1H23E	FY2H23E	FY2023E	FY2024E
CHECKvacc royalty revenue											
HER-Vaxx royalty revenue											
PD1-Vaxx royalty revenue											
Total royalty revenue											
R&D	3,224	7,612	9,364	15,355	13,832	22,780	36,612	24,147	25,596	49,743	57,204
SG&A	2,554	4,777	5,515	10,311	6,690	7,371	14,061	7,740	8,127	15,866	17,135
Total operating expenses	**5,778**	**12,389**	**14,879**	**25,667**	**20,522**	**30,151**	**50,673**	**31,887**	**33,722**	**65,609**	**74,340**
Operating income	**(5,778)**	**(12,389)**	**(14,879)**	**(25,667)**	**(20,522)**	**(30,151)**	**(50,673)**	**(31,887)**	**(33,722)**	**(65,609)**	**(74,340)**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	7,200	5,313	7,371	12,684	6,000	6,000	12,000	22,024
Finance income/expense net	94	409	297	11	376	(304)	72	100	100	200	210
Net income (pretax)	**(3,934)**	**(7,775)**	(10,508)	**(18,456)**	**(14,833)**	**(23,084)**	**(37,917)**	**(25,787)**	**(27,622)**	**(53,409)**	**(52,106)**
Income tax expense (benefit)											
Net income	**(3,934)**	**(7,775)**	**(10,508)**	**(18,456)**	**(14,833)**	**(23,084)**	**(37,917)**	**(25,787)**	**(27,622)**	**(53,409)**	**(52,106)**
EPS basic	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.01)**
EPS diluted	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.01)**
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,439,587	5,834,808	5,637,197	6,584,896	6,979,990	6,782,443	7,121,566
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,663,541	5,439,587	5,834,808	5,637,197	6,584,896	6,979,990	6,782,443	7,588,281

Source: SEC filings, company press releases, and ROTH Capital Partners

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 12/11/22	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**302**	**79.47**	**208**	**68.87**
Neutral [N]	**49**	**12.89**	**25**	**51.02**
Sell [S]	**3**	**0.79**	**2**	**66.67**
Under Review [UR]	**26**	**6.84**	**13**	**50.00**

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 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 does not publish research or have an opinion about this security.