ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | August 14, 2022

Healthcare: Biotechnology **Company Update**

Imugene Limited | IMU.AX - $0.29 - ASX | *Buy*

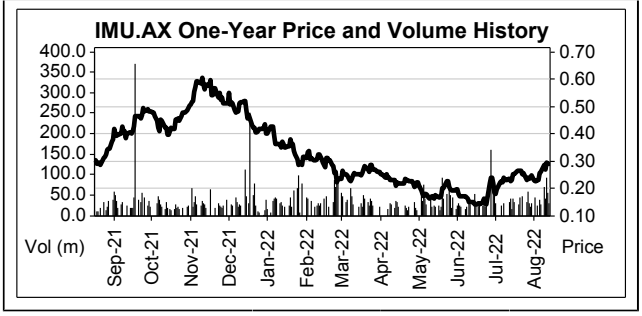
Stock Data	
52-Week Low - High	$0.13 - $0.63
Shares Out. (mil)	5,866.60
Mkt. Cap.(mil)	$1,701.31
3-Mo. Avg. Vol.	37,140,140
12-Mo.Price Target	AUD0.71
Cash (mil)	AUD118.4
Tot. Debt (mil)	AUD0.0

Revenue ($AUD millions)

Yr Jun	—2020—	—2021—	—2022E—
		Curr	Curr
1Half	0.0A	0.0A	0.0E
2Half	0.0A	0.0A	0.0E
YEAR	0.0A	0.0A	0.0E

EPS $AUD

Yr Jun	—2020—	—2021—	—2022E—
		Curr	Curr
1Half	(0.00)A	(0.00)A	0.00E
2Half	(0.00)A	(0.00)A	0.00E
YEAR	(0.00)A	(0.01)A	(0.01)E



IMU: Recent Clinical Highlights from Last Week Underscore Continued Progress

Last week, IMU reported two clinical updates. Phase 1 PD1-Vaxx monotherapy results 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. The third dose cohort of the Phase 1 CHECKvacc monotherapy trial, enrolling at City of Hope, also began dosing TNBC patients.

- **PD1-Vaxx.** Last week, new Phase 1 PD1-Vaxx results in treatment experienced NSCLC patients were presented in a poster titled “Phase 1: IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer” at the IASLC 2022 World Conference on Lung Cancer. The poster contained positive signals with correlative biomarker data in treatment experienced patients, that allowed the program to progress to Phase 1b in treatment naive NSCLC patients. Of note, one patient achieved a 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. Three patients remain on study with the potential to receive further PD1-Vaxx. Biomarker results showed that PD1-Vaxx was immunogenic and elicited a sustained and robust antibody response, especially by six weeks at the 100ug dose. In the Phase 1 portion, PD1-Vaxx monotherapy was given by intramuscular injection four times over the first 64 days, and then once every 63 days thereafter, and the NSCLC patients must have experienced disease progression after prior immune checkpoint inhibitor therapy. The Phase 1b portion will use the 100ug dose in combination with atezolizumab in treatment naive patients. Regarding safety among the 14 enrolled patients, adverse events assessed as related to PD1-Vaxx were overwhelmingly mild injection site reactions, but there were two instances of immune-mediated pneumonitis (one at 50ug and one at 100ug), with one of them being fatal, but with that fatality occurring after the patient withdrew from the trial, and no DLT was identified.
- Another development last week was that City of Hope dosed the first Phase 1 patient in dose cohort 3 of the CHECKvacc dose escalation trial in TNBC patients, evaluating intratumoral injection of this oncolytic virus as a monotherapy. Thus far, oncolytic virus infection and replication is occurring within the injected tumors and no toxicity has been reported. We expect that the final Phase 1 dose tested will be given to an expanded cohort of 12 patients and ultimately be selected as the Phase 2 dose. CHECKvacc is an oncolytic chimeric vaccinia poxvirus that carries the gene to produce an immune checkpoint inhibitor, thereby providing a combination of two therapeutic modalities in one product.

VALUATION

Our 12-month price target of AUD0.71 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 6x multiple of our projected FY2031 operating income of about AUD1.47 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 immunooncology 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	FY1H21A	FY2H21A	FY2021A	FY1H22A	FY2H22E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
Total royalty revenue										
R&D	3,224	7,612	9,364	7,132	8,223	15,355	13,832	15,906	29,738	37,173
SG&A	2,554	4,777	5,515	3,008	7,303	10,311	6,690	7,025	13,715	14,401
Total operating expenses	**5,778**	**12,389**	**14,879**	**10,141**	**15,526**	**25,667**	**20,522**	**22,931**	**43,453**	**51,573**
Operating income	**(5,778)**	**(12,389)**	**(14,879)**	**(10,141)**	**(15,526)**	**(25,667)**	**(20,522)**	**(22,931)**	**(43,453)**	**(51,573)**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	4,100	3,100	7,200	5,313	6,919	12,233	14,312
Finance income/expense net	94	409	297	(22)	33	11	376	(100)	276	290
Net income (pretax)	**(3,934)**	**(7,775)**	(10,508)	**(6,063)**	**(12,393)**	**(18,456)**	**(14,833)**	**(16,112)**	**(30,945)**	**(36,972)**
Income tax expense (benefit)										
Net income	**(3,934)**	**(7,775)**	**(10,508)**	**(6,063)**	**(12,393)**	**(18,456)**	**(14,833)**	**(16,112)**	**(30,945)**	**(36,972)**
EPS basic	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.01)**
EPS diluted	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.00)**	**(0.01)**	**(0.01)**
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,531,748	4,795,333	4,663,541	5,439,587	5,493,983	5,466,785	5,768,682
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,531,748	4,795,333	4,663,541	5,439,587	5,493,983	5,466,785	5,768,682

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 08/14/22	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**334**	**82.67**	**216**	**64.67**
Neutral [N]	**53**	**13.12**	**28**	**52.83**
Sell [S]	**2**	**0.50**	**1**	**50.00**
Under Review [UR]	**15**	**3.71**	**8**	**53.33**

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.