ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | November 16, 2021

Healthcare: Biotechnology

Company Update
Target Price Changed

Imugene Limited | IMU.AX - $0.61 - ASX | *Buy*

Stock Data	
52-Week Low - High	$0.08 - $0.63
Shares Out. (mil)	5,683.42
Mkt. Cap.(mil)	$3,466.89
3-Mo. Avg. Vol.	32,953,710
12-Mo.Price Target	AUD0.71
Cash (mil)	AUD119.5
Tot. Debt (mil)	AUD0.0

Cash (mil): proforma cash includes recent AUD90M equity raise after FYE2021

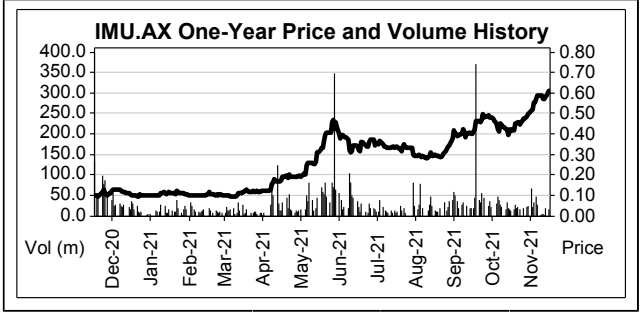
FY ends June 30

Revenue ($AUD millions)

Yr Jun	—2020—	—2021—	—2022E—
		Curr	Curr
1Half	0.0A	0.0A	-
2Half	0.0A	0.0A	-
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	(0.00)A	(0.00)E



IMU.AX: Supply Deal with Merck KGaA & PFE for BAVENCIO/Chemo/HER-Vaxx Ph2 Trial

IMU signed a clinical trial supply agreement with Merck KGaA and Pfizer in order to evaluate IMU's B cell immunotherapy HER-Vaxx in combination with anti-PD-L1 immune checkpoint inhibitor BAVENCIO and standard chemotherapy in HER2+ gastric or gastroesophageal junction adenocarcinomas. Merck KGaA and Pfizer will supply free BAVENCIO to IMU and could potentially take a greater interest in HER-Vaxx if the trial results demonstrate a clear HER-Vaxx benefit. Given the continued HER-Vaxx progress, we raise our PT to AUD0.71 from AUD0.62.

- IMU signed a clinical trial supply agreement with Merck KGaA and Pfizer (the co-commercializers of BAVENCIO) in order to evaluate IMU's B cell immunotherapy HER-Vaxx in combination with anti-PD-L1 immune checkpoint inhibitor BAVENCIO (a.k.a., avelumab) and standard chemotherapy in HER2+ gastric or gastroesophageal junction adenocarcinomas. Merck KGaA and Pfizer will supply BAVENCIO at no cost to IMU and stands to benefit by observing if BAVENCIO adds to HER-Vaxx/chemotherapy in this disease setting. IMU will fund the entire Phase 2 trial (named neoHERIZON), which will evaluate HER-Vaxx/ chemotherapy as background therapy with or without BAVENCIO. The Phase 2 neoHERIZON trial is open-label, multi-center, randomized, takes place in the perioperative setting, and has pathologic CR as its primary endpoint, with secondary endpoints of safety and biomarker evaluation. Although the trial is randomized for the presence or absence of BAVENCIO rather than HER-Vaxx, and therefore will draw more of a conclusion about BAVENCIO's added benefit than HER-Vaxx's added benefit, we note that much larger companies like those donating BAVENCIO for this trial could nonetheless take notice of a potentially highly positive outcome for the triple combination therapy arm and as a result have an increased interest in IMU.
- We note that HER-Vaxx has already delivered encouraging Phase 1b/2 results in gastric cancer. Earlier this year at AACR, IMU reported details from the first 27 (out of 36 total) patients evaluable at an interim analysis of its Phase 1b/2 gastric cancer trial with standard-of-care (SOC) chemotherapy +/- HER-Vaxx, IMU's peptide immunogen designed to elicit a robust polyclonal response against HER2. The ITT analysis showed that eight of 13 SOC control patients died, versus only four of 14 HER-Vaxx/SOC patients, yielding an OS hazard ratio (HR) of 0.418 (two-sided 80% CI: 0.186, 0.942) and a one-sided p-value of 0.083. Regarding PFS, nine SOC patients progressed versus six 6 HER-Vaxx/SOC patients, yielding a PFS HR of 0.532 (two-sided 80% CI 0.267, 1.060) and a one-sided p-value of 0.086. Both treatment groups exhibited highly similar safety, demonstrating that HER-Vaxx does not add appreciable toxicity to chemotherapy, given that the incidence of Grade 3 and higher nonhematological and hematological adverse events were low and balanced between groups. Regarding a particular cardiovascular *(text continued on page 2)*

- *(text continued from page 1)* adverse event, two patients in each treatment group had an asymptomatic LVEF drop, with none of them below an LVEF of 50. By week six, HER2-antibodies were detected in the HER-Vaxx/SOC group and remained high throughout HER-Vaxx treatment.
- After the AACR report, IMU reported additional HER-Vaxx trial information in early September, including that 24 patients had achieved a PFS event and the company awaits enough OS events to conclusively evaluate that highly informative endpoint, which we expect to come in about four months. PFS was designed with a pre-specified one-sided false positive probability of 0.10, and the new data generated a HR of 0.719 with a one-sided p-value of 0.266. There was still no difference in safety between the two treatment arms, showing that HER-Vaxx does not add toxicity to this SOC chemotherapy. Although the p-value missed the 0.10 threshold, this was a small trial, and this HR was comparable to the landmark registrational ToGA trial for Herceptin (n=584 ultimately analyzed; PFS HR of 0.71; p=0.0002), which also tested Herceptin plus SOC chemotherapy versus SOC chemotherapy alone in advanced HER2+ gastric cancer. We believe that IMU can similarly achieve statistical significance in a larger trial.

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 AUD1.48 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 tumors. Our unique platform technologies seek to harness the body's immune system against tumors, 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 tumors. 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	FY1H21A	FY2H21A	FY2021A	FY1H22E	FY2H22E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
Total royalty revenue										
Gross profit										
R&D	3,224	7,612	9,364	7,132	8,223	15,355	9,621	11,353	20,974	27,266
SG&A	2,554	4,777	5,515	3,008	7,303	10,311	5,112	5,368	10,480	11,109
Total operating expenses	**5,778**	**12,389**	**14,879**	**10,141**	**15,526**	**25,667**	**14,733**	**16,721**	**31,454**	**38,375**
Operating income	**(5,778)**	**(12,389)**	**(14,879)**	**(10,141)**	**(15,526)**	**(25,667)**	**(14,733)**	**(16,721)**	**(31,454)**	**(38,375)**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	4,100	3,100	7,200	4,185	4,938	9,124	10,497
Finance income/expense net	94	409	297	(22)	33	11	100	90	190	200
Net income (pretax)	**(3,934)**	**(7,775)**	(10,508)	**(6,063)**	**(12,393)**	**(18,456)**	**(10,448)**	**(11,692)**	**(22,140)**	**(27,678)**
Income tax expense (benefit)										
Net income	**(3,934)**	**(7,775)**	**(10,508)**	**(6,063)**	**(12,393)**	**(18,456)**	**(10,448)**	**(11,692)**	**(22,140)**	**(27,678)**
EPS basic	**(0.0015)**	**(0.0022)**	**(0.0026)**	**(0.0013)**	**(0.0026)**	**(0.0040)**	**(0.0020)**	**(0.0022)**	**(0.0042)**	**(0.0049)**
EPS diluted	**(0.0015)**	**(0.0022)**	**(0.0026)**	**(0.0013)**	**(0.0026)**	**(0.0040)**	**(0.0020)**	**(0.0022)**	**(0.0042)**	**(0.0049)**
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,531,748	4,795,333	4,663,541	5,226,913	5,383,720	5,305,317	5,652,906
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,531,748	4,795,333	4,663,541	5,226,913	5,383,720	5,305,317	5,652,906

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.

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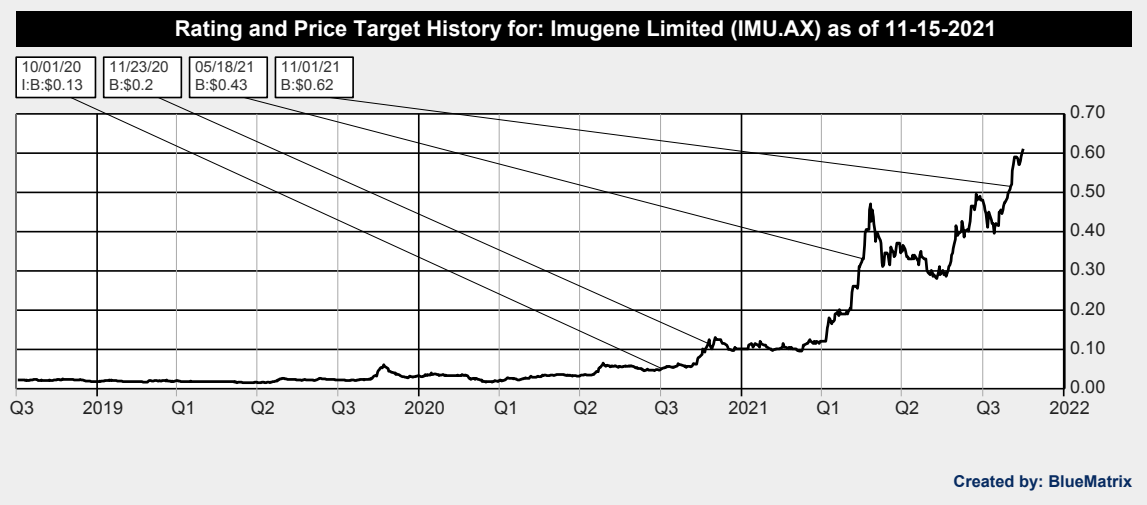

Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of 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 11/16/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**322**	**78.16**	**219**	**68.01**
Neutral [N]	**51**	**12.38**	**29**	**56.86**
Sell [S]	**1**	**0.24**	**0**	**0**
Under Review [UR]	**38**	**9.22**	**25**	**65.79**

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.