ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | November 23, 2020

Healthcare: Biotechnology

Imugene Limited | IMU.AX - $0.13 - ASX | *Buy*

Company Update

Target Price Changed

Stock Data	
52-Week Low - High	$0.02 - $0.13
Shares Out. (mil)	4,594.45
Mkt. Cap.(mil)	$574.31
3-Mo. Avg. Vol.	18,328,860
12-Mo.Price Target	AUD0.20
Cash (mil)	AUD26.6
Tot. Debt (mil)	AUD0.0

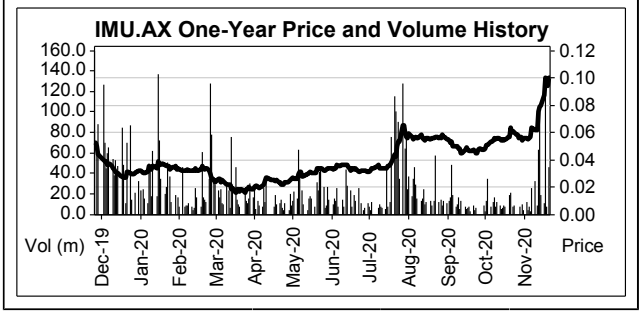
FY ends June 30

EPS $AUD

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

Revenue ($AUD millions)

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



IMU.AX: Interim Phase 2 Data Show HER-Vaxx OS Benefit, Raising PT to $0.20

A second interim analysis of Imugene's Phase 2 HER-Vaxx trial demonstrated a statistically significant OS benefit, specifically median OS of 14.2 versus 8.8 months for HER-Vaxx/chemotherapy versus chemotherapy alone. The robust HR of 0.418 indicates a reduced death risk of 58.2% from including HER-Vaxx. The OS benefit came with no detectable added toxicity, and showed that B cell activating immunotherapies can elicit clinically active antibodies. Additionally, the IDMC recommended enrollment be reduced to 34 from 68, given the robust efficacy.

- Imugene released highly positive second interim Phase 2 results (n=27) for HER-Vaxx, its B cell immunotherapy consisting of HER2 antigens that in this trial is being given to HER2/Neu-positive patients with advanced/metastatic gastric/gastro-esophageal junction cancer. We are raising our price target to $0.20 from $0.13 as a result of the robust efficacy in the absence of any additional safety concerns due to inclusion of HER-Vaxx. The Independent Data Monitoring Committee (IDMC) observed no safety issues, with 42.9% of HER-Vaxx patients having at least one Grade 3 TEAE and rates for control patients having at least one TEAE being 30.8% Grade 3, 15.4% Grade 4, 7.7% Grade 5. The IDMC also and noted the pronounced survival benefit. The prespecified statistical analysis was based upon a one-sided false positive probability of 0.10 and demonstrated that twice as many patients survived in the HER-Vaxx group versus control (10 out of 14 versus 5 out of 13), which translated into an intent-to-treat OS Hazard Ratio (HR) of 0.418 (two-sided 80% CI: 0.186 – 0.942) with a statistically significant one-sided p-value of 0.083. Median OS was 14.2 versus 8.8 months for HER-Vaxx versus control. The longest patient receiving HER-Vaxx remains on therapy and progression-free thus far for 16.3 months after the start of dosing.
- For comparison, with the caveat that it is mature data from a much larger patient dataset (n=584) that was subjected to a more stringent statistical analysis, the ToGA trial with Herceptin/chemotherapy versus chemotherapy in HER2-positive advanced gastric cancer produced median OS of 13.8 versus 11.1 months (HR 0.74 (two-sided 95% CI: 0.60 – 0.91), and median PFS of 6.7 versus 5.5 months (HR 0.71 (two-sided 95% CI: 0.59 – 0.85).
- The currently recruiting Phase 2 portion of the Phase 1b/2 trial is open-label, randomized, controlled, and was originally expected to enroll 68 stage IIIb/IV patients from Eastern Europe and India, but the IDMC has determined at this latest interim analysis that the efficacy is robust enough to require only 34 patients (7 more than the 27 patients upon which the second interim analysis was based) as an adequate *(text continued on page 2)*

- final enrollment. The trial is using the 50µg HER-Vaxx dose (a RP2D selected given the high potency (100% PR rate in three patients) and highly favorable safety profile observed in Phase 1b) in combination with either cisplatin combined with 5-FU or capecitabine, or oxaliplatin combined with capecitabine, versus a chemotherapy only control group.

VALUATION

Our 12-month price target of AUD0.13 is based on a DCF analysis using a 30% 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 AUD1.6 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, products that we project will generate about AUD1.7 billion in global royalty revenue to Imugene in FY2031. Commercial success outside of 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 Limited is a clinical stage immuno-oncology company developing a range of novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumors. The company's 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. Imugene's 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. Imugene is supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies, and their prior work has led to many therapies approved for sale and marketing for global markets. Imugene'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.

Imugene Limited
Income Statement
Fiscal Year ends June
(in AUD$000, except per share items)

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	FY2018A	FY2019A	FY1H20A	FY2H20A	FY2020A	FY1H21E	FY2H21E	FY2021E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
Total royalty evenue										
Gross profit										
R&D	3,224	7,612	4,234	5,131	9,364	5,746	6,436	12,182	18,273	23,755
SG&A	2,554	4,777	3,022	2,493	5,515	2,793	3,072	5,864	6,216	6,589
Total operating expenses	**5,778**	**12,389**	**7,255**	**7,624**	**14,879**	**8,539**	**9,508**	**18,046**	**24,489**	**30,344**
Operating income	**(5,778)**	**(12,389)**	**(7,255)**	**(7,624)**	**(14,879)**	**(8,539)**	**(9,508)**	**(18,046)**	**(24,489)**	**(30,344)**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	2,357	1,717	4,074	2,500	2,800	5,299	7,949	9,146
Finance income/expense net	94	409	107	190	297	160	130	290	305	320
Net income (pretax)	**(3,934)**	**(7,775)**	**(4,791)**	**(5,717)**	(10,508)	**(5,879)**	**(6,578)**	**(12,457)**	**(16,236)**	**(20,879)**
Income tax expense (benefit)										
Net income	**(3,934)**	**(7,775)**	**(4,791)**	**(5,717)**	**(10,508)**	**(5,879)**	**(6,578)**	**(12,457)**	**(16,236)**	**(20,879)**
EPS basic	**(0.0015)**	**(0.0022)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0029)**	**(0.0034)**
EPS diluted	**(0.0015)**	**(0.0022)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0029)**	**(0.0034)**
Basic shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,643,262	5,107,588	4,875,425	5,618,347	6,180,182
Diluted shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,643,262	5,107,588	4,875,425	5,618,347	6,180,182

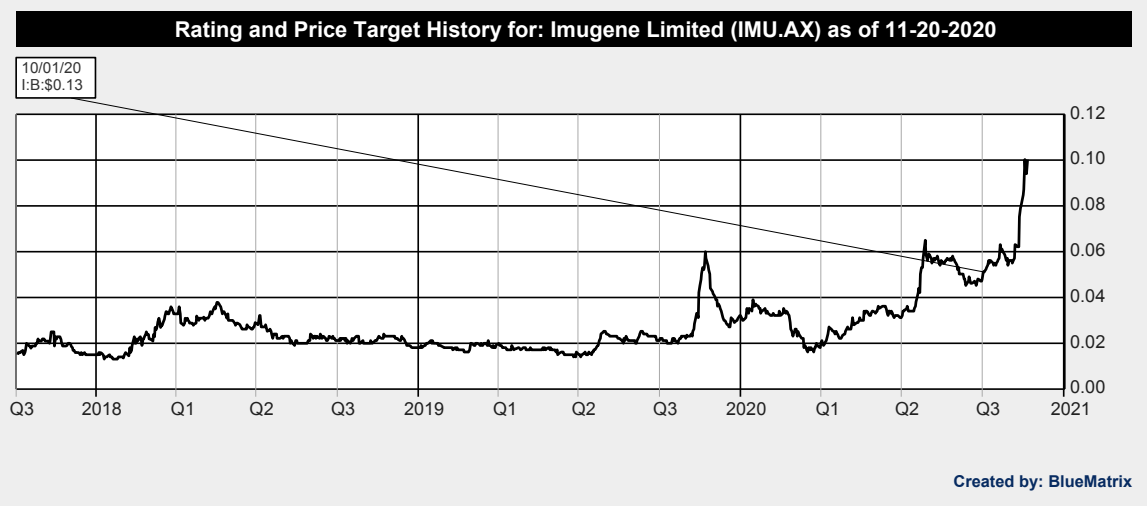
Source: SEC filings, company press releases, and ROTH Capital Partners

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 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 11/23/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**279**	**74.80**	**166**	**59.50**
Neutral [N]	**53**	**14.21**	**20**	**37.74**
Sell [S]	**3**	**0.80**	**2**	**66.67**
Under Review [UR]	**37**	**9.92**	**21**	**56.76**

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.