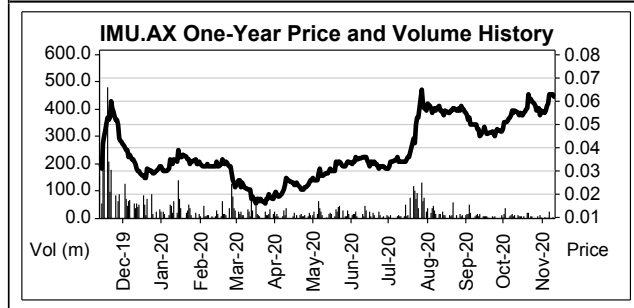


## Healthcare: Biotechnology

# Imugene Limited | IMU.AX - \$0.06 - ASX | Buy

### Company Update

Stock Data			
52-Week Low - High	\$0.02 - \$0.07		
Shares Out. (mil)	4,533.58		
Mkt. Cap.(mil)	\$281.08		
3-Mo. Avg. Vol.	12,184,180		
12-Mo.Price Target	AUD0.13		
Cash (mil)	AUD26.6		
Tot. Debt (mil)	AUD0.0		
FY ends June 30			
EPS \$AUD			
Yr Jun	—2020—	—2021E—	—2022E—
		<b>Curr</b>	<b>Curr</b>
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—
		<b>Curr</b>	<b>Curr</b>
1Half	0.0A	0.0E	-
2Half	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E



## IMU.AX: 1QFY21 Cash Flows, PD1-Vaxx IND Cleared in U.S., U.S. Patent Granted

Imugene reported its 1QFY21 cash flow statement, most importantly ending the quarter with AUD26.6M, which when combined with the highly likely net AUD6.2 million raise from near-term option exercise, is enough to fund operations until mid-FY23, as per our projections. The IND for PD1-Vaxx has recently been approved in the U.S. and the company was granted a U.S. patent for its cancer growth factor immunotherapy platform, specifically covering novel combination treatments targeting the EGFR family and IGF-1R.

- Imugene received FDA clearance of its IND for a Phase 1 trial of its checkpoint immunotherapy drug PD1-Vaxx in non-small cell lung cancer (NSCLC) patients, with Hackensack University Medical Center chosen as the initial site and at which IRB approval has been received. Imugene will open additional U.S. sites at the Mayo Clinic in Phoenix, Arizona, and Ohio State University Medical Center. The PD1-Vaxx monotherapy trial aims to establish safety and optimal biological dose, in addition to assessing efficacy and immune response. This marks the first trial that Imugene is conducting in the U.S. We also note that three ethics approvals were previously received related to the start of Imugene's Australian Phase 1 PD1-Vaxx trial in NSCLC, which is currently screening patients.
- Imugene was also recently granted a method of composition and method of use patent from the USPTO (patent number 10,800,834) covering its cancer growth factor immunotherapy platform, specifically novel combination treatments targeting members of the EGFR family and IGF-1R. The patent provides protection until 2035 in the world's largest pharmaceutical market. In 2Q18, Imugene signed an exclusive, worldwide license to the entire body of cancer vaccine work and intellectual property developed by Professor Pravin Kaumaya of the Ohio State University. The substantial intellectual property estate licensed comprises a broad patent portfolio including six patent families comprising 16 issued patents or pending applications for compositions of matter and/or methods of use of a large range of B cell peptide and cancer vaccines comprising PD-1, HER-1, HER-2, HER3, VEGF, IGF-1R, CD28 peptides and combinations thereof.
- Imugene received guidance from the FDA regarding development of VAXinia in the U.S., which covered both preclinical and clinical work. The pre-IND meeting served to provide Imugene with regulatory guidance and agreement of the preclinical, chemistry, manufacturing, and clinical development plan to be included in the VAXinia IND. The FDA also guided on key aspects of non-clinical investigations and provided feedback on studies required to support the Phase 1 trial, giving Imugene a clear roadmap for a successful future IND submission. Imugene is also pursuing a parallel regulatory pathway in Australia. The single center Phase 1 CHECKvacc trial in TNBC (City of Hope, Los Angeles) is poised to begin once COVID-19 headwinds subside.

## VALUATION

Our 12-month price target of AUD0.13 is based on a DCF analysis using a 35% 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.

<b>Imugene Limited</b>		Jonathan Aschoff, Ph.D. (646) 616-2795								
<b>Income Statement</b>		<a href="mailto:jaschoff@roth.com">jaschoff@roth.com</a>								
Fiscal Year ends June										
(in AUD\$000, except per share items)										
	FY2018A	FY2019A	FY1H20A	FY2H20A	FY2020A	FY1H21E	FY2H21E	FY2021E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
<b>Total royalty revenue</b>										
<b>Gross profit</b>										
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
<b>Total operating expenses</b>	<b>5,778</b>	<b>12,389</b>	<b>7,255</b>	<b>7,624</b>	<b>14,879</b>	<b>8,539</b>	<b>9,508</b>	<b>18,046</b>	<b>24,489</b>	<b>30,344</b>
<b>Operating income</b>	<b>(5,778)</b>	<b>(12,389)</b>	<b>(7,255)</b>	<b>(7,624)</b>	<b>(14,879)</b>	<b>(8,539)</b>	<b>(9,508)</b>	<b>(18,046)</b>	<b>(24,489)</b>	<b>(30,344)</b>
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
<b>Net income (pretax)</b>	<b>(3,934)</b>	<b>(7,775)</b>	<b>(4,791)</b>	<b>(5,717)</b>	<b>(10,508)</b>	<b>(5,879)</b>	<b>(6,578)</b>	<b>(12,457)</b>	<b>(16,236)</b>	<b>(20,879)</b>
Income tax expense (benefit)										
<b>Net income</b>	<b>(3,934)</b>	<b>(7,775)</b>	<b>(4,791)</b>	<b>(5,717)</b>	<b>(10,508)</b>	<b>(5,879)</b>	<b>(6,578)</b>	<b>(12,457)</b>	<b>(16,236)</b>	<b>(20,879)</b>
<b>EPS basic</b>	<b>(0.0015)</b>	<b>(0.0022)</b>	<b>(0.0013)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0013)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0029)</b>	<b>(0.0034)</b>
<b>EPS diluted</b>	<b>(0.0015)</b>	<b>(0.0022)</b>	<b>(0.0013)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0013)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0029)</b>	<b>(0.0034)</b>
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

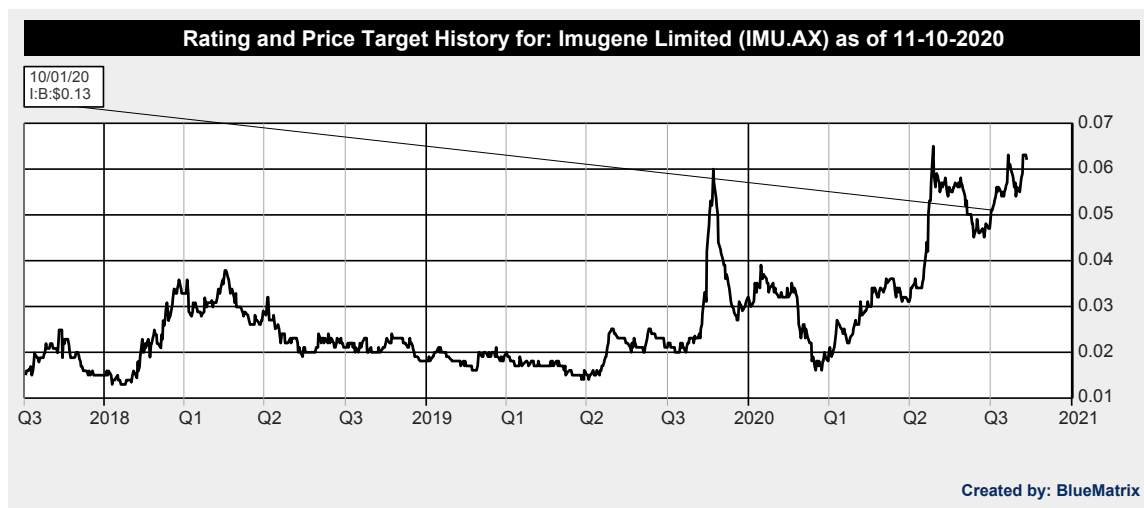
Source: SEC filings, company press releases, and ROTH Capital Partners

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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**

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 11/11/20	
			Count	Percent
Buy [B]	273	73.78	162	59.34
Neutral [N]	57	15.41	21	36.84
Sell [S]	2	0.54	1	50.00
Under Review [UR]	38	10.27	22	57.89

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**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.

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