


Healthcare: Biotechnology

Company Update

**Imugene Limited** | IMU.AX - \$0.17 - ASX | *Buy*

Stock Data			
52-Week Low - High	\$0.15 - \$0.63		
Shares Out. (mil)	5,848.80		
Mkt. Cap.(mil)	\$965.05		
3-Mo. Avg. Vol.	34,334,090		
12-Mo.Price Target	AUD0.71		
Cash (mil)	AUD118.4		
Tot. Debt (mil)	AUD0.0		
Revenue (\$AUD millions)			
Yr Jun	—2020—	—2021—	—2022E—
		<b>Curr</b>	<b>Curr</b>
<b>1Half</b>	0.0A	0.0A	0.0E
<b>2Half</b>	0.0A	0.0A	0.0E
<b>YEAR</b>	0.0A	0.0A	0.0E
EPS \$AUD			
Yr Jun	—2020—	—2021—	—2022E—
		<b>Curr</b>	<b>Curr</b>
<b>1Half</b>	(0.00)A	(0.00)A	0.00E
<b>2Half</b>	(0.00)A	(0.00)A	0.00E
<b>YEAR</b>	(0.00)A	(0.01)A	(0.01)E

## IMU: First Phase 1 Advanced Solid Tumor Patient Dosed with CF33-hNIS VAXINIA

IMU dosed the first Phase 1 patient in its CF33-hNIS VAXINIA trial, which is enrolling patients with advanced solid tumors. CF33-hNIS-VAXINIA will either be injected intratumorally or intravenously, to determine if direct tumor injection is necessary. Once the lowest CF33-hNIS-VAXINIA doses are shown to be safe, a portion of the future patients will receive the therapy in combination with pembrolizumab. About 10 trial sites will enroll about 100 patients, and the trial should require about 24 months to complete.

- IMU and City of Hope dosed the first Phase 1 patient in its CF33-hNIS VAXINIA trial, which is enrolling patients with advanced solid tumors. Preclinically, the therapy was shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumors in *in vitro* and *in vivo* models. CF33-hNIS-VAXINIA most likely exerts its effect by stimulating the immune system to both kill cancer cells and be more responsive to co-administered immunotherapies such as checkpoint inhibitors. Checkpoint inhibitors are highly effective in a minority of patients, and adding an oncolytic virus has the potential to render immunologically cold tumors hot by producing large amounts of foreign viral material at the tumor site due to CF33-hNIS-VAXINIA's ability to selectively replicate in tumor cells. Oncolytic virus therapy can even increase the level of PD-L1 in tumors, thereby increasing the effectiveness of anti-PD-L1 therapy.
- The U.S. and Australian multi-center Phase 1 trial will first administer a low dose of oncolytic virus metastatic or advanced solid tumor patients who are rel/ref to at least two prior lines of standard of care treatment. CF33-hNIS-VAXINIA will either be injected intratumorally or intravenously, to determine if direct tumor injection is necessary. Once the lowest CF33-hNIS-VAXINIA doses are shown to be safe, a portion of the future patients will receive the therapy in combination with pembrolizumab. We expect about 100 patients to be enrolled at about 10 trial sites, and we anticipate the trial to require about 24 months to complete.

## 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 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.

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<b>Income Statement</b>										
Fiscal Year ends June										
(in AUD\$000, except per share items)										
	FY2018A	FY2019A	FY2020A	FY1H21A	FY2H21A	FY2021A	FY1H22A	FY2H22E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
<b>Total royalty revenue</b>										
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
<b>Total operating expenses</b>	<b>5,778</b>	<b>12,389</b>	<b>14,879</b>	<b>10,141</b>	<b>15,526</b>	<b>25,667</b>	<b>20,522</b>	<b>22,931</b>	<b>43,453</b>	<b>51,573</b>
<b>Operating income</b>	<b>(5,778)</b>	<b>(12,389)</b>	<b>(14,879)</b>	<b>(10,141)</b>	<b>(15,526)</b>	<b>(25,667)</b>	<b>(20,522)</b>	<b>(22,931)</b>	<b>(43,453)</b>	<b>(51,573)</b>
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
<b>Net income (pretax)</b>	<b>(3,934)</b>	<b>(7,775)</b>	<b>(10,508)</b>	<b>(6,063)</b>	<b>(12,393)</b>	<b>(18,456)</b>	<b>(14,833)</b>	<b>(16,112)</b>	<b>(30,945)</b>	<b>(36,972)</b>
Income tax expense (benefit)										
<b>Net income</b>	<b>(3,934)</b>	<b>(7,775)</b>	<b>(10,508)</b>	<b>(6,063)</b>	<b>(12,393)</b>	<b>(18,456)</b>	<b>(14,833)</b>	<b>(16,112)</b>	<b>(30,945)</b>	<b>(36,972)</b>
<b>EPS basic</b>	<b>(0.0015)</b>	<b>(0.0022)</b>	<b>(0.0026)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0040)</b>	<b>(0.0027)</b>	<b>(0.0029)</b>	<b>(0.0057)</b>	<b>(0.0064)</b>
<b>EPS diluted</b>	<b>(0.0015)</b>	<b>(0.0022)</b>	<b>(0.0026)</b>	<b>(0.0013)</b>	<b>(0.0026)</b>	<b>(0.0040)</b>	<b>(0.0027)</b>	<b>(0.0029)</b>	<b>(0.0057)</b>	<b>(0.0064)</b>
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

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## Disclosures:

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 05/18/22	
			Count	Percent
Buy [B]	353	82.48	235	66.57
Neutral [N]	49	11.45	30	61.22
Sell [S]	2	0.47	1	50.00
Under Review [UR]	24	5.61	15	62.50

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.

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**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.

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