

Healthcare: Biotechnology
Company Update
 Target Price Changed

Imugene Limited | IMU.AX - \$0.33 - ASX | Buy
Stock Data

52-Week Low - High	\$0.03 - \$0.36
Shares Out. (mil)	4,800.96
Mkt. Cap.(mil)	\$1,584.32
3-Mo. Avg. Vol.	22,535,670
12-Mo.Price Target	AUD0.43
Cash (mil)	AUD29.4
Tot. Debt (mil)	AUD0.0

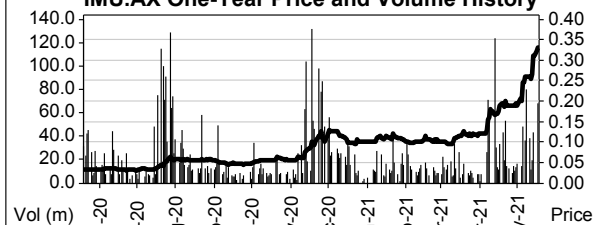
FY ends June 30

Revenue (\$AUD millions)

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

EPS \$AUD

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

IMU.AX One-Year Price and Volume History


IMU: Licenses Oncolytic Virus That Enables CAR T Therapy to Target Solid Tumors

IMU took a exclusive, global development and commercial license from City of Hope for CF33-CD19, an oncolytic virus that infects solid tumor cells and is administered along with standard CD19 CAR T therapy. CF33-CD19 is intended to increase the immunogenicity of the tumor in general, as well as force tumor surface expression of CD19, thereby allowing CD19-directed CAR T therapy to recognize and destroy tumor cells. Phase 1 should begin in 2022, and we are raising our PT to \$0.43.

- Given the approvals of CAR T therapy in hematological indications, (Yescarta: anti-CD19 for B-cell lymphoma, Kymriah: anti-CD19 for DLBCL and ALL, Tecartus: anti-CD19 for MCL, Breyanzi: anti-CD19 for B-cell lymphoma, and Abecma: anti-BCMA for MM), solid tumors clearly remain more difficult to target with CAR T. City of Hope therefore developed CF33-CD19, an oncolytic virus that preferentially replicates in tumor cells, turning immunologically cold tumors hot while forcing expression of CD19 on the tumor cell surface. Although CF33-CD19 will likely originally be developed in conjunction with a CD19 CAR T, we note that it should also work with any CD19-directed therapy such as bispecific antibodies and antibody-drug conjugates. The patent for CF33-CD19 expires in 2038. IMU has already licensed backbone virus CF33, and the closely related checkpoint inhibitor-expressing antitumor virus CHECKvacc, from City of Hope, both of which should soon enter the clinic.
- In vitro* and *in vivo* preclinical work evaluating CF33-CD19 and CD19-directed CAR T combination therapy in TNBC, pancreatic, prostate, ovarian, brain, and head and neck cancers demonstrated the combination is more potent against solid tumors than either component alone, and the work was recently featured on the front page of *Science Translational Medicine*. More specifically, CF33-CD19 expresses a nonsignaling, truncated CD19 for tumor-selective delivery, thus producing CD19 at the cell surface prior to also directing virus-mediated tumor lysis. Cocultured CD19-CAR T cells secreted cytokines and exhibited potent cytolytic activity against the infected tumor cells. Subsequently, several mouse tumor models, the combination therapy reduced tumor burden and viral CD19 induced local immunity characterized by tumor infiltration of both endogenous and adoptively transferred T cells. CAR T cell-mediated tumor killing also induced release of virus from dying tumor cells, which propagated tumor expression of CD19.
- In exchange for global rights to the technology, IMU will pay City of Hope a non-disclosed upfront payment, annual maintenance fees that are creditable against potential future royalties, developmental and commercial milestones, any sublicensing fees, and single-digit royalties on any net sales. IMU and City of Hope have also entered into a four-year sponsored research agreement to further develop the technology. IMU is currently in the clinic with two promising antigen therapies (HERVaxx and PD1vaxx), with HERVaxx having shown high efficacy and low toxicity in Phase 2 in gastric cancer, and the first oncolytic virus program about to enter the clinic.

VALUATION

Our 12-month price target of AUD0.43 is based on a DCF analysis using a 20% 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 about 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 almost AUD1.7 billion in global royalty revenue to Imugene in FY2031. 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 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.

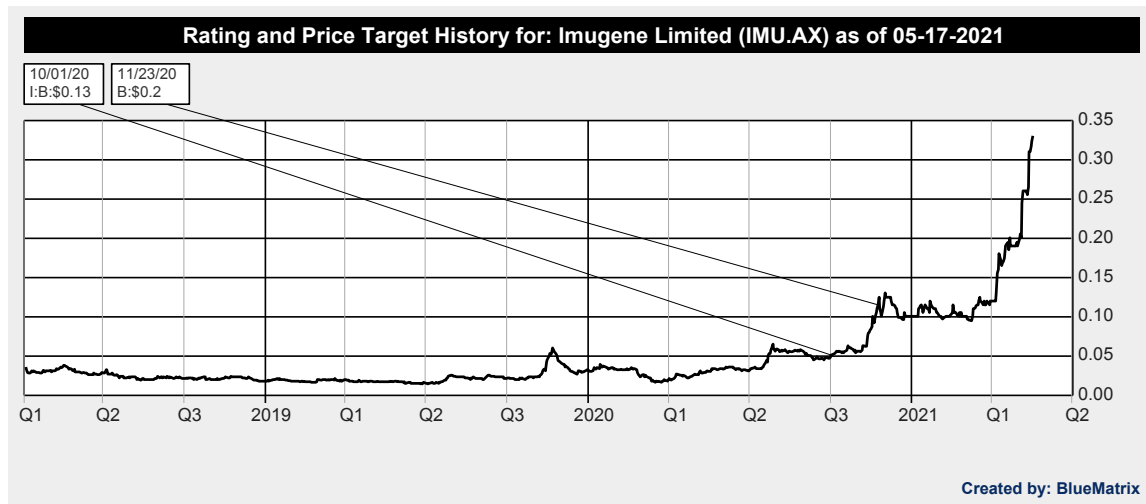
Imugene Limited		Jonathan Aschoff, Ph.D. (646) 616-2795								
Income Statement		jaschoff@roth.com								
Fiscal Year ends June										
(in AUD\$000, except per share items)										
	FY2018A	FY2019A	FY1H20	FY2H20	FY2020A	FY1H21A	FY2H21E	FY2021E	FY2022E	FY2023E
CHECKvacc royalty revenue										
HER-Vaxx royalty revenue										
PD1-Vaxx royalty revenue										
Total royalty revenue										
Gross profit										
R&D	3,224	7,612	4,234	5,131	9,364	7,132	7,846	14,978	20,220	26,286
SG&A	2,554	4,777	3,022	2,493	5,515	3,008	3,309	6,317	6,759	7,165
Total operating expenses	5,778	12,389	7,255	7,624	14,879	10,141	11,155	21,295	26,979	33,451
Operating income	(5,778)	(12,389)	(7,255)	(7,624)	(14,879)	(10,141)	(11,155)	(21,295)	(26,979)	(33,451)
Other income/loss (R&D tax incentive, etc)	1,750	4,205	2,357	1,717	4,074	4,100	3,413	7,513	8,796	10,120
Finance income/expense net	94	409	107	190	297	(22)	130	108	113	119
Net income (pretax)	(3,934)	(7,775)	(4,791)	(5,717)	(10,508)	(6,063)	(7,612)	(13,674)	(18,071)	(23,212)
Income tax expense (benefit)										
Net income	(3,934)	(7,775)	(4,791)	(5,717)	(10,508)	(6,063)	(7,612)	(13,674)	(18,071)	(23,212)
EPS basic	(0.0015)	(0.0022)	(0.0013)	(0.0013)	(0.0026)	(0.0013)	(0.0015)	(0.0028)	(0.0033)	(0.0039)
EPS diluted	(0.0015)	(0.0022)	(0.0013)	(0.0013)	(0.0026)	(0.0013)	(0.0015)	(0.0028)	(0.0033)	(0.0039)
Basic shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,740,920	4,977,966	4,859,443	5,475,763	6,023,339
Diluted shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,740,920	4,977,966	4,859,443	5,475,763	6,023,339

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 05/18/21	
			Count	Percent
Buy [B]	298	76.41	190	63.76
Neutral [N]	51	13.08	26	50.98
Sell [S]	1	0.26	1	100.00
Under Review [UR]	39	10.00	27	69.23

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:

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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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