ROTH Capital Partners

Jonathan Aschoff, Ph.D., (646) 616-2795
jaschoff@roth.com

Sales (800) 933-6830, **Trading** (800) 933-6820

COMPANY NOTE | EQUITY RESEARCH | March 08, 2021

Healthcare: Biotechnology

Company Update

Imugene Limited | IMU.AX - $0.10 - ASX | *Buy*

Stock Data	
52-Week Low - High	$0.02 - $0.14
Shares Out. (mil)	4,759.60
Mkt. Cap.(mil)	$456.92
3-Mo. Avg. Vol.	15,523,790
12-Mo.Price Target	AUD0.20
Cash (mil)	AUD32.8
Tot. Debt (mil)	AUD0.0

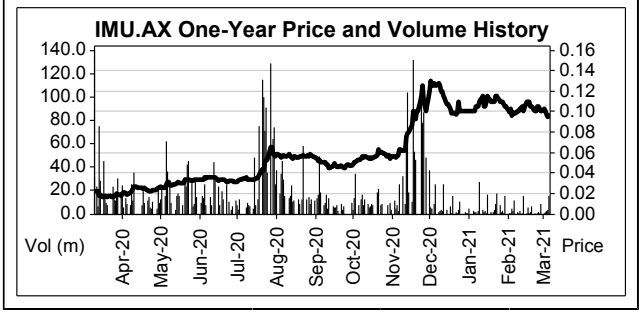
FY ends June 30

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 1H21 Results: Solid HER-Vaxx & PD1-Vaxx Clinical Progress Despite COVID

IMU reported 1HFY21 results, ending calendar 2020 with AUD32.8 million and no debt, enough to fund operations through FY2022 as per our projections, but there are numerous opportunities for the company to add to that cash via exercise of already issued options. We note the continued international clinical progress of HER-Vaxx and PD1-Vaxx despite COVID-19 related enrollment headwinds, and look forward to final HER-Vaxx results and the start of the VAXinia and CHECKvacc clinical programs in the U.S.

- We note recent clinical progress such as the early January completion of patient recruitment of the Phase 2 portion (n=36) of the Phase1b/2 trial of HER-Vaxx in HER2/neu overexpressing advanced/metastatic gastric/GEJ cancer. In this trial, HER-Vaxx plus chemotherapy is being compared to chemotherapy alone, with a primary endpoint of OS and key secondary endpoint of PFS. We remind investors of this trial's interim results that were positive enough to convince the Independent Data Monitoring Committee (IDMC) that Phase 2 enrollment could be reduced to 36 from 68, thereby demonstrating clear proof of concept . Designed for a one-sided false probability of 0.10, a Phase 2 interim analysis based upon the first 27 patients treated delivered a statistically significant p-value of 0.083 along with a highly encouraging OS HR of 0.418 (80% two-sided CI: 0.186, 0.942). Median OS was 14.2 versus 8.8 months for HER-Vaxx versus control. We note the absence of any additional adverse events in the HER-Vaxx/chemotherapy arm versus chemotherapy alone. More specifically, 42.9% of HER-Vaxx patients had at least one Grade 3 TEAE and control patients having at least one TEAE were 30.8% Grade 3, 15.4% Grade 4, and 7.7% Grade 5. The interim results compare favorably to the ToGA trial results with Herceptin/chemotherapy versus chemotherapy in HER2-positive advanced gastric cancer. We therefore remain highly optimistic for similarly positive final trial results.
- IMU has also made clinical progress with PD1-Vaxx, which is currently treating the second dose cohort of its Phase 1 international NSCLC trial. Three different dose cohorts (three to six patients per cohort; 10ug, 50ug, and 100ug doses) are to be tested, and thus we believe that results will be available in . Primary endpoints include safety and determination of optimal biological dose as a monotherapy, with key secondary endpoints of efficacy, tolerability, and immune response. PD1-Vaxx doses are given on days 1, 15, 29, 64, and every 63 days thereafter until disease progression. Tumors are evaluated as per RECIST criteria on day 43 and every 42 days thereafter until disease progression. The trial will be conducted at six sites in Australia and the U.S. We note that there were no safety concerns reported for the 10ug dose cohort.
- IMU's VAXinia and CHECKvacc programs advance toward the clinic and will potentially enroll a broad range of solid tumor patients and be given intravenously or intratumorally (VAXinia), or exclusively given intratumorally to metastatic TNBC patients (CHECKvacc).

VALUATION

Our 12-month price target of AUD0.20 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 almost 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)

Jonathan Aschoff, Ph.D. (646) 616-2795
jaschoff@roth.com

	FY2018A	FY2019A	FY1H20	FY2H20	FY2020A	FY1H21A	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	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

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:

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 03/08/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**311**	**79.13**	**193**	**62.06**
Neutral [N]	**52**	**13.23**	**23**	**44.23**
Sell [S]	**2**	**0.51**	**1**	**50.00**
Under Review [UR]	**28**	**7.12**	**20**	**71.43**

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.

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from