30 January 2023
Company Sponsored Research
Update Note | Sector: Healthcare

Imugene Limited – Initial Clinical Trial Data Encouraging with Strong Financial Position

Imugene Ltd. (ASX: IMU)

Share Price: A$0.15

Valuation: A$0.46

Key Statistics

52 Week Range	A$0.130 - A$0.345
Avg. Volume (3 months)	15.59M
Shares Outstanding	6.42B
Market Capitalization	A$931.15M
EV/Revenue	N/A
Cash Balance*	A$161.91M
Analyst Coverage	5

***Cash balance as of September 2022**

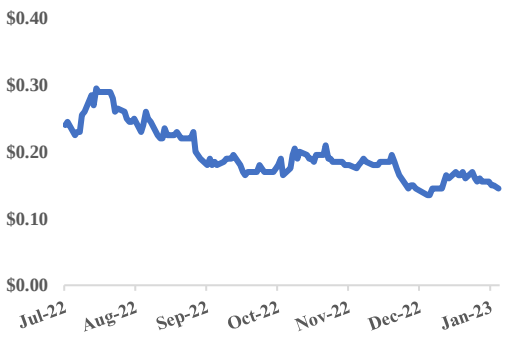
Revenue (in A$mm)

June - FY	2022A	2023E	2024E
1H	n/a	n/a	n/a
2H	n/a	n/a	n/a
FY	n/a	n/a	n/a

EPS (in A$)

June – FY	2022A	2023E	2024E
1H	(0.00)	(0.00)	(0.00)
2H	(0.00)	(0.00)	(0.00)
FY	(0.01)	(0.01)	(0.01)

Stock Price Chart (in A$)



Investment Highlights

- **Q2 FY2023 Cash Flow Update:** Imugene Limited reported a cash balance of A$161.9 million as of the quarter ending December 2022. The operating cash burn, which largely accounted for research and development expenses and administrative costs, amounted to A$8.1 million. Cash R&D expenses for the quarter were reported at A$5.7 million, and staff costs were A$1.76 million. The strong cash position provides runway to support the development of its pipeline candidates and the company's operations over the next few years.

- **Recent Clinical Trials Update:** Imugene Limited announced further details of its HER-Vaxx and CF33 technologies at the Gastrointestinal Cancer Symposium, recently held in San Francisco, and new and initial data from the CHECKVacc trial at the 2022 San Antonia Breast Cancer Symposium held in San Antonio, Texas. During the Oral Abstract session, it was demonstrated that HER-Vaxx (IMU-131) + chemotherapy showed meaningful survival benefits as compared to chemotherapy alone. The poster session concluded that CF33-OVs demonstrated robust infection, replication, functional protein delivery, and killing of Gastro Cancer in vitro. A phase 1 trial investigating the safety and biological activity of the intraperitoneal CF33-hNIS-antiPDL1 for the treatment of GC patients with peritoneal metastases is also planned. At the 2022 San Antonia Breast Cancer Symposium, Imugene announced that the early phase 1 CHECKVacc trial data showed that CHECKVacc administered by intratumoral injection in patients with metastatic Triple Negative Breast Cancer (TNBC) is safe and well tolerated at the dose levels tested.

- **Developments in VAXINIA Intravenous (IV) Cohort 2:** Furthering the developments in IV cohort 2 of the phase 1 trial, the first patient with Metastatic or Advanced Solid Tumours (MAST), was dosed with VAXINIA, a novel cancer-killing virus. Once the lowest doses have been administered and acceptable safety demonstrated, a new combination treatment (VAXINIA with pembrolizumab) would be provided to the new study participants. Overall, the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia, and the trial is anticipated to run for approximately 24 months, funded by existing budgets and resources.

- **Ethics Approval Granted to Start Phase 1 Human Trial of VAXINIA in Australia:** Imugene announced receiving human research ethics approval for the Phase 1 human trial of its anti-cancer oncolytic virotherapy, VAXINIA, in Australia. The trials will commence at Tasman Oncology Research, a comprehensive cancer hospital in Eastwood, South Australia. The trial will determine the safety and optimal biological dosage of VAXINIA both as individual therapy and in combination with immune checkpoint inhibitors. Ethics approval is a confirmation that the necessary pre-clinical safety and efficacy testing of VAXINIA required to commence human clinical trials in Australia have been completed.

- **Valuation:** Rolling over our valuation, we have accounted for updated cash balance, share count, and changes in comparable company analysis. We reiterate our previous valuation of A$0.46, contingent on successful execution by the company.

Company Description

Imugene Limited is an Australian clinical-stage immuno-oncology company developing a range of immunotherapies to activate the immune system of cancer patients to treat and eradicate tumors. The company is developing five unique assets based on three different platform technologies.

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Company Overview

Imugene Limited (ASX: IMU) is an Australia-based clinical-stage biotechnology company focusing on developing immunotherapies for the treatment of various cancers. The company has a diversified pipeline of 5 unique assets developed on a strong research base of 3 platform technologies. The company is targeting ten disease areas with high unmet needs and low survival rates. Imugene's initial focus has been to advance its B-cell peptide vaccines technology, which stimulates the body's immune system to produce antibodies against the normal self-proteins, such as HER2 and PD-1. The two lead therapies within the company's pipeline include HER-Vaxx and PD1-Vaxx, aimed at treating Gastric and Non-Small Cell Lung Cancer, respectively. Expanding its purview, the company acquired the exclusive license to the CF33 Oncolytic Virus technology developed by Professor Yuman Fong at the City of Hope (COH) Cancer Centre in Los Angeles. CF33 is a novel, genetically engineered chimeric orthopoxvirus and has shown promising efficacy in a range of mouse models. Clinical development of CF33 oncolytic virus is being studied in two different constructs, CHECKvacc (CF33+hNIS+anti-PD-LI) and VAXINIA (CF33+hNIS). Both constructs are currently being pursued under phase 1 clinical trial. In addition to B-cell immunotherapy and CF33, Imugene, in May 2021, obtained the worldwide exclusive licenses to the patents covering CF33-CD19, also known as onCARlytics. The CF33-CD19 agent aid CD19-directed CAR T by labeling cancer cells for CAR T cell destruction. CD19 CAR T as a monotherapy faces key challenges in solid tumors largely due to a lack of selectively and highly expressed surface antigens.

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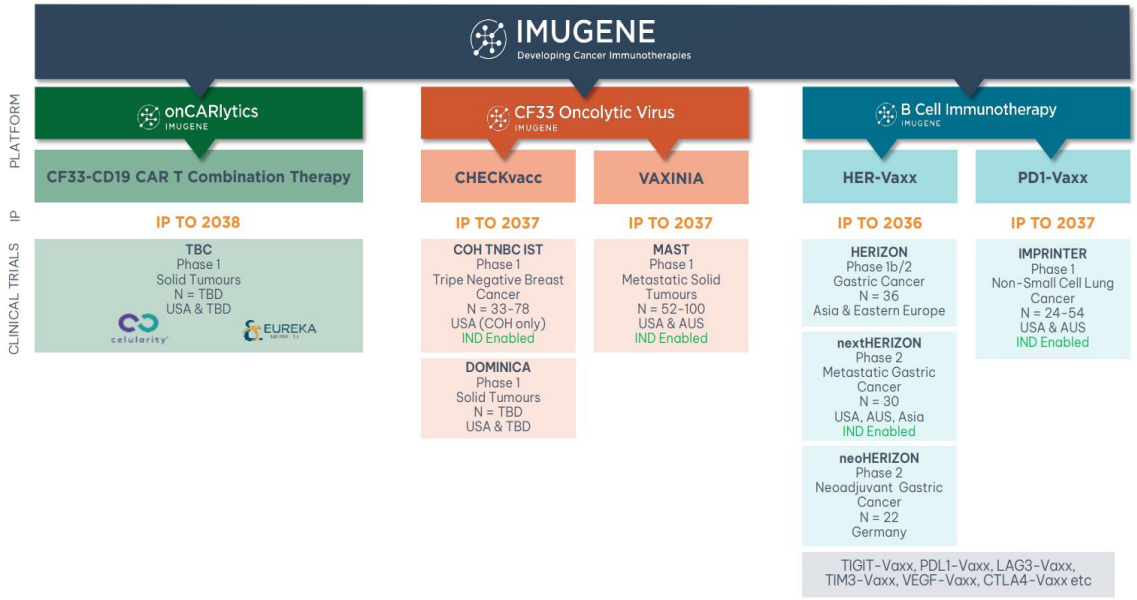

Exhibit 1: Imugene's Three Technology Platforms and Five Unique Assets. Source: Imugene Limited

Imugene's platform technology IP is protected by a set of patents, with a majority of the patent expiration starting post-2035. In order to advance its pipeline through different clinical stages and commercialization, the company has engaged in scientific collaboration with Celularity Inc. (NASDAQ: CELU), Eureka Therapeutics, Inc., and Arovella Therapeutics Ltd. (ASX: ALA). The company has also signed a clinical trial supply agreement with pharmaceutical giants Roche (SWX: ROG), Merck KGaA (ETR: MRK), and Pfizer (NYSE: PFE), adding further validation to its pipeline candidates. The company's pipeline indication represents a multi-billion-dollar market opportunity targeting the highly valuable market of cancer immunotherapy.

B-Cell Peptide Cancer Vaccines - An Effective Active Immunization Approach

In the past decade, there have been considerable advancements in cancer treatment, with targeted therapies and immunotherapies showing great promise for multiple types of cancer. Passive immunization, such as the use of humanized monoclonal antibodies, is proven to have promising therapeutic applications in the treatment of different forms of malignancies but comes with several caveats that limit the usage of these therapies in numerous cases. Toxicity problems and resistance, high costs, sophisticated therapeutic regimen, and long half-life are a few of the significant shortcomings that have raised the need for an efficacious and long-lasting active immunization approach. One such approach that Imugene believes can cause a paradigm shift in cancer research is the advancement of B-cell epitope vaccines. Cancer vaccines based on B-cell peptides are generally composed of an adjuvant and an immunogenic protein containing a B-cell epitope peptide that can induce B cells to create polyclonal antibodies that bind to different parts of the vaccine antigens. The resulting construct of polyclonal antibodies yields a powerful antitumor effect that is long-lasting and inhibits tumor recurrence. Even though humanized mAbs have a somewhat similar mechanism of action, the use of synthetic bodies to treat cancer has been fraught with several concerns. Poor penetration across tissues, large quantities of hmAbs resulting in toxicity, expensive treatment (average cost: US$150,000 per year), and long and frequent infusions. Despite these challenges, hmAbs therapy has become a multi-billion-dollar business.

The use of B-cell immunotherapies to stimulate the patient's immune system to produce polyclonal antibodies may have advantages over synthetic antibodies

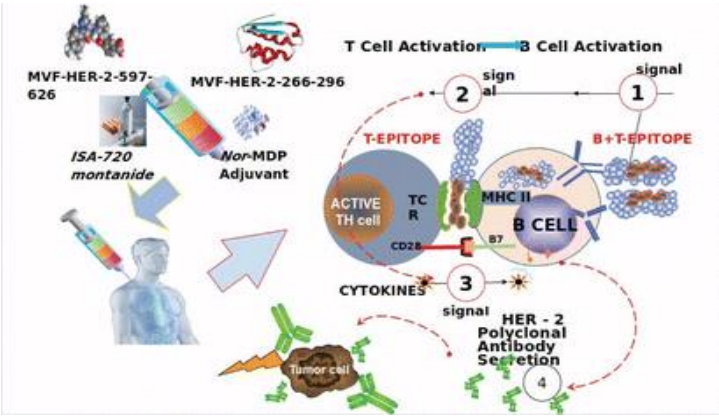

Exhibit 2: B-Cell Epitope Peptide Vaccine Mechanism of Action. Source: Kaumaya et al.

In addition to HER2 and PD-1 cancer vaccines, Imugene has also licensed a number of other B-cell cancer vaccines targeting PDL-1, LAG-3, EGFR, VEGF, and CTLA-4

HER-Vaxx – Cancer Vaccine for Gastric Cancer

HER-Vaxx is B-cell immunotherapy that is designed to treat cancers that overexpresses HER2 protein. Different types of solid tumors such as breast cancer, gastric cancer, ovary, endometrium, bladder, head, and neck cancer have been found with over-expression of the HER2 protein. The amplification/over-expression is often associated with poor prognosis and low survival rates. HER-Vaxx is a B-cell peptide vaccine composed of 3 fused epitopes (p467) derived from the extracellular domain of HER2/neu coupled to CRM197 and adjuvanted with Montanide.[1] The resultant vaccine formulation induces a potent polyclonal antibody response that targets cells with overexpressing HER-2 receptors on their surface. Pre-clinical studies have shown strong anti-tumor activity in-vitro and in-vivo and better growth inhibition of breast cancer cells or HER2 signaling pathway compared with single-agent mAb trastuzumab.

HER-Vaxx has been shown to stimulate a potent polyclonal anti-body response to HER-2/neu, a well-known and validated cancer target

[1] Future Oncology 2020 16:23, 1767-1791

The current vaccine formulation is an enhanced version that replaces virosomes used in previous formulations of HER-Vaxx. The company had previously examined the virosomal formulation in phase 1 clinical trial in end-stage breast cancer patients. While the study showed good immunogenicity as well as an excellent safety profile, several drawbacks of the virosomal formulations, including solubility and limited stability after coupling all the single peptides together to virosomes, were the reasons to reconstruct and improve the multi-peptide vaccine with respect to specificity and clinical applicability. The enhanced formulation has been shown to have a faster production of antibodies and a more rapid immune response.

Competitive Overview

Imugene's lead drug candidate HER-Vaxx faces competition from already approved HER2-directed gastric cancer mAbs and PD-1 binding immune checkpoint inhibitors. Multiple targeted therapies and immunotherapies are currently under clinical trial for advanced or metastatic gastric cancer, indicating fierce competition in this particular disease area. Trastuzumab (Herceptin) and fam-trastuzumab deruxtecan-nxki (Enhertu) are major HER-2-directed therapeutics that are FDA-approved. Even though HER-Vaxx exhibited robust efficacy and safety in the early stages of clinical development, the company's ability to fend off competition depends on its superior safety and comparative efficacy profile at a reasonable cost.

Drug	Patent expiry	Annual Revenue (2021)	Pricing
Trastuzumab	off-patent	$2,694 million	$76,500
nivolumab	2028	$7,523 million	$187,728
fam-trastuzumab deruxtecan-nxki	2024	$426 million	$164,000

Exhibit 3: Major FDA-approved Gastric Cancer Drugs. Source: Diamond Equity Research, Company Filings

PD1 – Vaxx – Therapeutic Vaccine for NSCLC

Immune Checkpoint Inhibitors as potent immunotherapy has already reached consensus, with numerous FDA approvals for several cancer types recording billions of dollars in sales worldwide. Thousands of immunotherapies are currently being tested in clinical trials for different types of malignancies. Even though PD-1/PD-L1 signaling inhibitors have shown great clinical success, the development of primary and secondary resistance has contributed to just a small subset of patients (10–15%) responding to the monotherapy.[2]

Constructed from a single B cell epitope derived from extracellular domain of PD-1, PD-1 Vaxx has shown great potential in pre-clinical and early-stage clinical trials

PD-1 Vaxx is potentially a cost-effective, potent, and novel approach toward inhibiting the PD1/PD-L1 signaling pathway, thus triggering anti-cancer effects similar to those observed in ICI mAbs such as Keytruda® and Opdivo®. Based on the B-cell epitope peptide vaccine platform technology, PD-1 B-cell peptide epitope vaccine (PD-1 Vaxx) is derived from extracellular amino acids 92-110 of PD-1 linked to a measles virus fusion peptide (MVF) amino acid 288-302 via a four amino acid residue (GPSL). The resulting formulation, when injected, elicits a B-cell antibody response, inducing the body to produce polyclonal antibodies. These antibodies block the PD-1 signaling pathway that is crucial for tumor growth and simultaneously promotes T-cell recognition of cancer cell leading to targeted killing. Activation of both T-cell and B-cell

[2] British Journal of Cancer (2021) 125:152–154

functioning encourages immunological response providing a formidable cancer immunotherapy candidate.

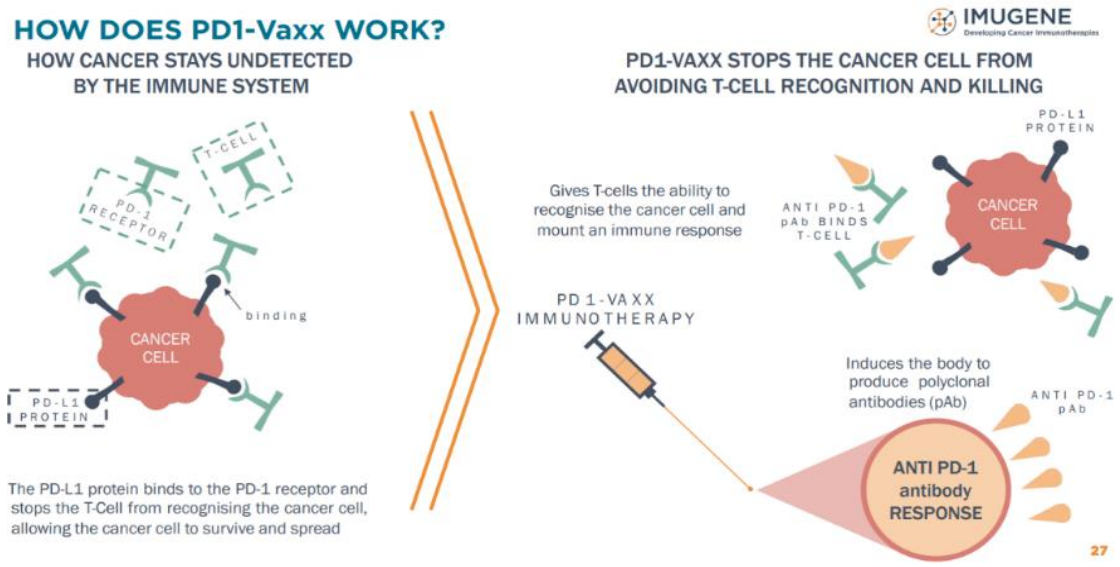

Exhibit 4: PD-1 Vaxx Mechanism of Action. Source: Imugene Limited

Competitive Overview

EGFR inhibitors and ICI mAbs have cornered a large portion of the NSCLC market in dollar terms. Erlotinib (Tarceva), Osimertinib (Tagrisso), Atezolizumab (Tecentriq), Nivolumab (Opdivo), and Pembrolizumab (Keytruda) are a few of the major approved therapeutics for NSCLC. Additionally, thousands of clinical trials are currently underway utilizing different therapeutic approaches for the treatment of NSCLC. By the time PD-1 Vaxx gets FDA approval and is commercialized (estimated: 2028), most of the above-stated drugs would have lost their exclusivity or would be on the verge of losing their exclusivity, leading to the entrance of low-cost biosimilars. A clearer insight into Imugene's competitive positioning within the NSCLC market would be based on its progress in clinical trials, thus providing an idea of its efficacy and safety when compared to other therapeutics in the market. The pricing of PD-1 Vaxx will also play a major role in its ability to capture increased market share.

HER-Vaxx and PD-1 Vaxx have been evaluated as monotherapy in pre-clinical and clinical settings exhibiting anti-tumor properties with tolerable safety profiles. Historically cancer vaccines and immune checkpoint blockades have been limited by low clinical efficacy and development of resistance, respectively. The company's approach to using both in a combination therapy setting in further clinical trials could be a way to improve overall therapeutic outcomes (enhancing the immune response by overcoming the immunosuppressive tumor micro-environment with limited toxicity and resistance). Both these therapies are targeting a sizeable yet competitive market.

Oncolytic Virus - An Emerging Frontier in Cancer Immunotherapy

A virus is an infectious agent that utilizes the host's genetic material to replicate itself, thereby spreading to healthy cells. One such substrate of naturally occurring or genetically modified viruses that act as a potent therapeutic agent and have the ability to infect and kill cancer cells are commonly called Oncolytic viruses. Cancer cells have impaired anti-viral defenses and are

susceptible to infections. Modification in Oncolytic viruses through genetic engineering enhances their ability to deliver therapeutic payload and diminishes the possibility of widespread resistance.

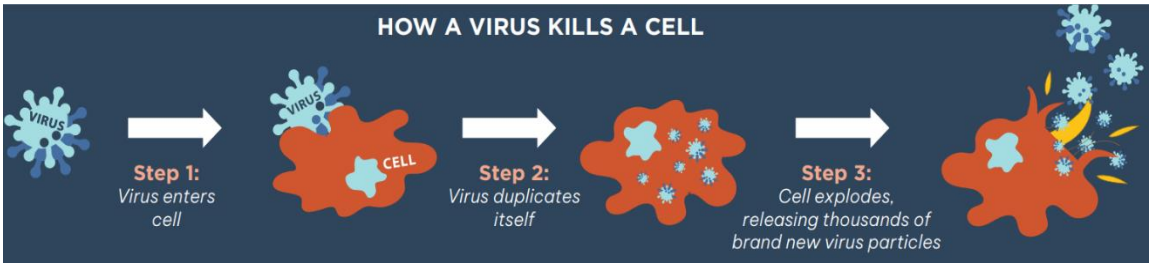

Exhibit 5: Oncolytic Virus Mechanism of Action. Source: Imugene Limited

Although oncolytic viruses are potentially powerful therapeutic agents for cancer treatment, a single type of oncolytic virus is not enough to destroy all the cancer cells due to the heterogeneity of cancer tissues and the complexity of cancer cells. Determining the virus and delivery method are two of the most challenging and crucial parts of the underlying therapy.

Developed at the City of Hope Cancer Center in Los Angeles, California, CF33 is a chimeric vaccinia virus derived from genomic sequencing of multiple strains of vaccinia virus, thus generating a safer and more potent virus that is also immunostimulatory. Nine different "parental" virus strains of orthopoxvirus (cowpox virus, rabbitpox virus, raccoon pox virus) were introduced, grown, and titered in CV-1 cell lines leading to the creation of 100 chimeric orthopoxviruses. These "daughter" virus strains contained different combinations of genes from the parental virus, which were then tested for potency by screening them against the NCI-60 panel. CF33 proved to be the most potent and is chosen further for in vivo and clinical development.

VAXINIA (CF33 + hNIS)

CF33 with Human Sodium-Iodide Symporter (hNIS) gene is currently being evaluated in the phase 1 Mixed Advanced Solid Tumors (MAST) study. Encoding of hNIS gene enables reliable non-imaging of viral replication using positron emission tomography mediating targeted radiotherapy. CF33 encoded hNIS gene has been previously studied in colon cancer xenograft mouse model, demonstrating the synergy of oncolytic viral therapy with radioablation in vivo. The cancer cell lines induced xenografts were implanted into athymic nude female mice and were administered with either intratumoral PBS or CF33-hNIS injections. CF33-hNIS-induced tumor growth abrogation and regression were observed in animals with HCT116-derived xenografts. Abrogation and regression of tumor growth were also observed in HT29-derived tumors in some mice, but the results were not statistically significant. Additionally, the treatment was found synergistic with I-131 Radioisotope, exhibiting an effective and sustained tumor growth inhibition when compared to monotherapy treatment with PBS, CF33-hNIS, or I-131. The use of a more targeted approach (CF33 + hNIS + I-131) would decrease toxicity and enhance efficacy at a lower dosage and cost.

Oncolytic Virus Market and Competitive Overview

Oncolytic virus as a treatment modality has gained a lot of attention after positive results from many clinical trials. The ability to infect cancer cells selectively while allowing for additional genetic modification and stimulating the innate immune system to fight cancer cells offers a novel approach to cancer immunotherapy. The most notable shift in the OV field has been from its application as a direct lytic agent to its development as a multimodal agent involving cell lysis,

immune stimulation, and gene therapy, which further established OV as a strong candidate for cancer therapy.[3]

There are 162 Oncolytic virus therapy currently under active development as of June 2022, of which only four have successfully navigated through clinical development and received regulatory approval. 63% or 103 therapies are in the early stages and haven't even progressed through clinical trials. Of the four OV therapies that have been approved, Imlygic (talimogene laherparepvec) is the most noteworthy, being studied across 50 clinical trials. It was approved for the treatment of melanoma in 2015 by the FDA and EMA. Other OV therapy approval relates to comparatively smaller pharmaceutical markets.

onCARlytics - 'Mark and Kill' Approach

Expanding the Immuno-oncology portfolio, the company licensed the CD19 Oncolytic virus from City of Hope, enabling CD19 CAR-T against solid tumors. CD19-directed CAR T as monotherapy has shown remarkable success in hematological malignancies, but its applicability in solid tumors is accompanied by various challenges which have led to poor outcomes in pre-clinical and clinical studies. Antigen escape, toxicity related to CAR-T cells, antigen heterogeneity, the trafficking of CAR-T cells and tumor infiltration, poor stability, and immunosuppressive microenvironment are among the limitations that impede the ability of CAR-T cell therapy to produce sustained response in patients with solid malignancies (accounts for 90% of all cancer cases worldwide).

Higher generation CAR-T therapy has been shown to have superior ant-tumor activity when compared to first and second generations therapies. However, even with the use of a high later generation of CAR T-cells products, objective responses for trials in solid tumors have been mostly disappointing. Many studies are focusing on enhancing the applicability and usefulness of CAR-T therapies by combining it with other adjuvant therapies. One such combination therapy where Imugene believes that the combination can yield promising results is the use of Oncolytic virotherapy with CD19-directed CAR-T therapy. OVs' ability to selectively replicate themselves while developing adaptive anti-tumor immunity has gained a lot of attention since the FDA approval of T-VEC. OVs can also be engineered in such a way that forces the expression of certain genes in the tumor milieu, that is, activating the targeted transgenic delivery potential, thus augmenting the oncolytic viral treatment.

The company is leveraging the transgenic delivery mechanism of Oncolytic Viruses such as CF33 to infect cancer cells and encourage the selective expression of a CAR-targetable tumor antigen, a truncated non-signalling variant of CD19 (CD19t). These underlying mechanisms of OVs allow endogenous production of T-cells and CAR T-cell infiltration into tumors, eventually exhibiting cancer-killing activities. Imugene obtained the worldwide licenses of the patents covering the cell therapy technology, which includes CF33-CD19, known as onCARlytics™, developed at City of Hope.

Strategic Partnerships

To further the progress of onCARlytics, the company entered into research collaboration agreements with Eureka Therapeutics Inc., Celularity Inc and Arovella Therapeutics Ltd. These partnerships would employ the clinical development expertise of the respective parties in the agreement benefiting Imugene to fast-track the clinical development of onCARlytics. The FDA

[3] Cancers 2021, 13(21), 5452; https://doi.org/10.3390/cancers13215452

IND approval is anticipated by the year-end and the first patient in the phase 1 trial to be dosed in 2023.

The collaboration will explore the use case of Imugene's onCARlytics (CF33-CD19) in combination with Eureka's anti-CD19 ARTEMIS® autologous T-cell therapy, Celularity's allogeneic CAR T-cell therapy (CyCART-19) and Arovella's CAR19-iNKT (ALA-101) cell therapy. The readout from the preclinical studies performed in collaboration with Arovella is expected in H1 2023. These partnerships will allow Imugene to evaluate onCARlyitcs in both allogeneic and autologous therapeutic settings targeting solid tumors. The agreement yields highly complementary oncology therapies that have the ability to force CD19 expression on the surface of tumor cells leading to CAR-T recognition and killing of cancer cells.

Key Risks

- **Clinical Development Risk -** Imugene's market value is tied to its therapeutic products currently in clinical trials. Failure to deliver satisfactory efficacy and safety profile or statistically significant results could negatively impact the company's value.

- **Regulatory Risk -** Post successful completion of clinical trials, the company is required to gain regulatory approval from foreign and or domestic regulatory bodies. Failure to obtain regulatory approval in any of the targeted geographies could negatively impact the company's addressable market and, therefore, the overall value of the company.

- **Foreign Exchange Risk -** The company is exposed to foreign exchange risk, given that clinical trials and other research activities are carried out in foreign geographies. Wide fluctuations in foreign currency could impact the company's cost profile and cash burn.

- **Financing and Dilution Risk -** Imugene is a pre-revenue biotechnology company and relies on external sources of financing to progress its pipeline. Failure or delays in obtaining the required capital would hinder the company's operating and research activities leading to deferment in expected clinical and approval timelines. Financing capital by issuing further equity will dilute the shareholding of existing shareholders.

- **Competitive Risk -** The cancer Immunotherapy market has expanded in the past decade with multiple approvals and thousands of therapeutic products currently in clinical trials. Imugene faces competition from many of the therapeutic products being evaluated in clinical trials, which might affect the company's ability to position and gain market share in its targeted geographies.

These risk factors are not comprehensive. For a full list of risk factors, please read Imugene's latest prospectus and/or annual filings.

Appendix

Income Statement	FY2021 A	FY2022 A	FY2023 E	FY2024 E	FY2025 E
Net sales	-	-	-	-	-
Cost of sales	-	-	-	-	-
Gross profit	**-**	**-**	**-**	**-**	**-**
Operating expenses					
General and Administrative Expenses	(8,348,361.0)	(11,653,985.0)	(14,917,100.8)	(17,154,665.9)	(19,727,865.8)
Marketing Expense	-	-	-	-	-
Research and Development	(15,355,366.0)	(36,611,892.0)	(47,515,041.9)	(51,507,241.5)	(55,620,284.6)
EBITDA	**(23,703,727.0)**	**(48,265,877.0)**	**(62,432,142.7)**	**(68,661,907.4)**	**(75,348,150.4)**
Depreciation and amortization expenses	(1,962,422.0)	(2,407,266.0)	(1,981,978.4)	(2,006,978.4)	(2,031,978.4)
Other income/ (expense)					
Research and development tax incentive	7,231,545.0	12,614,130.0	13,560,189.8	17,598,461.8	19,077,079.3
Other grants	50,000.0	-	-	-	-
Other gains/(losses) - net	(81,268.0)	117,914.0	-	-	-
EBIT	**(18,465,872.0)**	**(37,941,099.0)**	**(50,853,931.4)**	**(53,070,424.0)**	**(58,303,049.5)**
Finance income	126,565.0	192,249.0	499,438.6	665,167.8	449,283.3
Finance expense	(116,056.0)	(120,324.0)	(13,468.6)	(13,468.6)	(13,468.6)
Profit before exceptional items, extraordinary items and tax	**(18,455,363.0)**	**(37,869,174.0)**	**(50,367,961.4)**	**(52,418,724.8)**	**(57,867,234.8)**
Exchange loss (net)	-	-	-	-	-
Employee seperation cost	-	-	-	-	-
Profit before tax from continuing operations	**(18,455,363.0)**	**(37,869,174.0)**	**(50,367,961.4)**	**(52,418,724.8)**	**(57,867,234.8)**
Income tax (expense) benefit	-	-	-	-	-
Net earnings including noncontrolling interests	**(18,455,363.0)**	**(37,869,174.0)**	**(50,367,961.4)**	**(52,418,724.8)**	**(57,867,234.8)**

Exhibit 6: Income Statement (in A$ million). Source: Diamond Equity Research

Disclosures

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