

Leading the LAG-3 Immunotherapy Charge into Immuno-oncology and Autoimmune Disease; Initiating at Buy, \$7.75 PT

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STOCK DATA			
Market Cap (mil)	\$107.9		
52-Week Range	\$1.25 – \$3.92		
3-Month ADTV	103,798		
Shares Outstanding (mil)	30.3		
Short Interest	225,304		
Fiscal Year-End	June		
EARNINGS DATA			
EPS	2018A	2019E	2020E
H1	(0.17)	(0.25)	—
H2	(0.29)	(0.25)	—
FY	(0.44)	(0.49)	(0.53)
Per ADS			
BALANCE SHEET DATA			
	2H18		
Cash & Equivalents	AUD23.5		
Current Assets	AUD28.6		
Total Assets	AUD47.0		
Total Liabilities	AUD13.5		
Total Debt	AUD6.6		
Est. 12 mo. Cash Burn Rate	13.4		
AUD in millions.			

Summary and Recommendation

We are initiating coverage of Immutep Limited with a Buy rating and a 12-month price target of \$7.75 per ADS based on the company's diverse immunotherapy drug candidates targeting the antagonist immune checkpoint protein LAG-3 to address unmet medical needs in cancer and autoimmune diseases. Immutep's lead drug candidate, efitlagimod alpha, is a LAG-3/IgG1 fusion protein and APC agonist being developed as an adjuvant immuno-oncology therapy in multiple clinical trials. The most advanced of these trials are the Phase II AIPAC trial of efitlagimod in combination with paclitaxel to treat metastatic breast cancer and the Phase II TACTI-002 trial of efitlagimod in combination with pembrolizumab to treat recurrent or refractory NSCLC and HNSCC. These trials were enabled by positive preclinical data and early proof-of-concept clinical trials that showed efitlagimod to be well tolerated and to provide strong synergistic effects when combined with chemotherapy or other immuno-oncology drugs. Immutep is also developing IMP761, a first-in-class LAG-3 agonist, in preclinical studies to treat autoimmune diseases. Finally, Immutep has entered into licensing agreements with major pharmaceutical companies such as Novartis and GlaxoSmithKline to develop some of its other anti-LAG-3 drug candidates to treat cancer and autoimmune diseases. In our view, these agreements help to validate LAG-3 as a significant immunotherapeutic target and place Immutep at the forefront of LAG-3 immunotherapy.

Key Points

- **Phase II AIPAC trial in metastatic breast cancer shows promising early results.** Early results for efitlagimod in combination with paclitaxel show an overall response rate (ORR) of 47% and a disease control rate (DCR) of 87%, versus a historical ORR of 31% and a historical DCR of 64% in metastatic breast cancer patients treated with paclitaxel alone. We expect Immutep to complete patient enrollment in this trial in 1Q19, with top-line results expected in 3Q19.
- **Phase II TACTI-002 trial in relapsed or recurrent NSCLC and HNSCC.** We expect this trial of efitlagimod in combination with pembrolizumab to begin enrolling patients in 4Q18, with interim results to be announced in 1H19. TACTI-002 was enabled by the Phase I proof-of-concept trial, TACTI-mel, that was conducted in advanced melanoma patients and showed an ORR of 61%, including two patients with a complete response, with 66% progression-free survival (PFS) at six months. By comparison, advanced melanoma patients treated with pembrolizumab monotherapy had a historical ORR of 33% and six-month PFS of 46%.
- **First-in-class LAG-3 agonist IMP761 in preclinical studies to treat autoimmune diseases.** Immutep is developing a cell-based production platform as part of establishing GMP protocols for IMP761 production in anticipation of entering clinical studies. Preclinical toxicology and pharmacokinetic studies are being conducted in cynomolgus monkeys, with results expected in 1H19.
- **Multiple collaborations expand Immutep's LAG-3 immunotherapy footprint.** Immutep is developing efitlagimod in combination with PD-L1 inhibitor avelumab in collaboration with Merck and Pfizer in a Phase I investigator-sponsored trial called INSIGHT and has licensed rights to efitlagimod to EOC Pharma in China. Immutep has also licensed LAG-3 depleting monoclonal antibody IMP731 to GlaxoSmithKline to treat the autoimmune disease colitis and has licensed anti-LAG-3 monoclonal antibody IMP701 to Novartis as an immuno-oncology adjuvant therapy being developed in combination with Novartis's PD-1 inhibitor spartalizumab.
- **Cash and cash burn.** Immutep finished FY18 with A\$23.5M in cash and cash equivalents and recorded a cash burn of A\$7.8M for the fiscal year. We project a cash burn of \$13.4M for FY19, indicating a cash runway into F2H20.

Analyst certification and important disclosures can be found on pages 28 - 31 of this report.

This document represents an abbreviated discussion of the subject issuer and should not be used as the sole basis for an investment decision. Contact your B. Riley FBR representative for complete research concerning the subject issuers, including research briefs and reports.

Investment Thesis

Initiating Coverage of Immutep Limited at Buy

We are initiating coverage of Immutep Limited with a Buy rating and a 12-month price target of \$7.75 per ADS, which represents 114% potential upside over the closing price of \$3.62 per ADS on September 25, 2018. Immutep is a clinical-stage biotechnology company developing immunotherapy treatments for a variety of cancers and autoimmune diseases with unmet medical needs. Its technological focus is on modulating the activity of the antagonist immune checkpoint protein lymphocyte activation gene-3 (LAG-3). The diversity of its LAG-3 targeting assets, both in mechanism and impact, coupled with its extensive collaborations with leading pharmaceutical companies, has placed Immutep among the global leaders in LAG-3 immunotherapeutics.

Founded in Australia in 1987 as a mining company under the name Prima Resources, the company moved into the biotechnology arena under the name Prima Biomed with the 2001 acquisition of developmental rights to the Austin Research Institute's (Burnet Institute), immunotherapeutic portfolio. This included CVac, a dendritic cell-focused cancer vaccine. In 2014, Prima Biomed acquired French biotechnology company Immutep SA, effectively shifting the company's focus from cancer vaccines to LAG-3 directed immune checkpoint therapies. Prima BioMed subsequently rebranded itself as Immutep Limited. Immutep SA had formed in 2001 with an R&D program focused on the development of LAG-3 targeted immunotherapies. These R&D efforts culminated in the development of efitilagimod alpha (efitilagimod), a LAG-3/IgG1 fusion protein and antigen-presenting cell (APC) agonist, and in the development of anti-LAG-3 monoclonal antibody IMP701, LAG-3 depleting antibody IMP731, and LAG-3 agonist antibody IMP761, as well as related derivative antibody portfolios.

With the out-licensing of IMP731 to GlaxoSmithKline plc (GSK) in 2011 and IMP701 to Novartis AG (NOVN.SWX) in 2012, Immutep has maintained its focus on the development of its lead asset, efitilagimod. Preclinical and early clinical results showed that efitilagimod improved treatment efficacy when given in combination with approved chemotherapy or immuno-oncology treatments. Based on these results, we see great value in efitilagimod as an adjuvant to chemotherapy and other immuno-oncology therapies in the treatment of cancer patients who are poorly served by approved standards of care. Efitilagimod is currently in a Phase II trial called AIPAC in combination with paclitaxel to treat hormone receptor positive, HER2 negative metastatic breast cancer and is expected to start a Phase II trial called TACTI-002 in combination with the anti-PD-1 monoclonal antibody pembrolizumab to treat non-small cell lung cancer (NSCLC) and relapsed or refractory head and neck squamous cell carcinoma (HNSCC). The advancement of efitilagimod in later-phase clinical trials is supported by positive Phase I proof-of-concept data showing efitilagimod to be well tolerated and to improve treatment efficacy when given in combination.

Immutep's second primary focus is on the development of LAG-3 focused immunotherapies for the treatment of autoimmune diseases. These diseases are driven by the overactivation and self-targeting of patients' immune systems. IMP761 is a LAG-3 monoclonal antibody and agonist that is currently in preclinical development. By increasing LAG-3 immune checkpoint signaling, IMP761 aims to reduce T cell sensitivity and immune system activity. In September 2018, Immutep announced that it was commencing with cell line development as the beginning stage in establishing good manufacturing practice (GMP) protocols in anticipation of advancing IMP761 into the clinic. This advancement will also depend on positive results from preclinical toxicology and pharmacokinetic studies being conducted in cynomolgus monkeys. Results from these studies are expected in 1H19.

Since the approval of the first immuno-oncology drug in 2011, immuno-oncology has rapidly expanded within the cancer treatment armament. While a majority of the attention has been given to high-profile targets like PD-1 and PD-L1, other immune checkpoint proteins provide great opportunity to expand and optimize cancer treatment. LAG-3 is an immune checkpoint protein that utilizes unique intracellular signaling and has a differentiated impact on immune system regulation. By focusing not just on immuno-oncology applications, but also on applications in autoimmune disease, Immutep has been able to diversify its portfolio while establishing itself as one of the world's foremost specialists in LAG-3 targeting. Its collaborations with major pharmaceutical companies validate its focus on LAG-3 as an immunotherapy target.

Immutep's Drug Candidate Pipeline

Immutep has four drug candidates in clinical trials in various stages of preclinical and clinical development. Our projections for the progression through clinical trials, regulatory filings and approval, and possible commercial launch of eftilagimod alpha, IMP731, IMP701, and IMP761, assuming later-stage clinical trials are positive, are shown in Exhibit 1. These projections assume that no confounding or complicating issues arise during treatment and follow-up in clinical trials. We project market launches in the U.S. for eftilagimod to treat metastatic breast cancer in 2022 and for eftilagimod to treat NSCLC and HNSCC in 2024. We project that Immutep will advance IMP761 toward the clinic as it completes IND-enabling studies and activities through the end of 2019. IMP731 and IMP701 have been licensed to GSK and Novartis, respectively, so we do not project time lines for their development.

Exhibit 1: Immutep's Product Candidate Pipeline

Product Candidate	Current	2H18E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	Notes
Eftilagimod alpha (LAG-3lg, IMP321)											
AIPAC	II	II	II III	III	III	B M	M	M	M	M	1
TACTI-002	II	II	II	II	III	III	III	B M	M	M	2
TACTI-mel	I	I									3
INSIGHT	I	I	I								4
PD-L1 combination (INSIGHT Expansion)	I	I	I	II	II	II	III	III	III		5
IMP731											
Autoimmune diseases	I	II									6
IMP701 in combination therapy											
Solid tumors and DLBCL	II	II									7
Metastatic TNBC	II	II									8
Solid tumors	I	I									9
Unresectable or metastatic melanoma	I	I									10
IMP761											
Autoimmune diseases	P	P	P	P I	I	I	I	I II	II	II	
Note 1: CT.gov ID: NCT02614833. Eftilagimod alpha in combination with paclitaxel to treat MBC. Note 2: CT.gov ID: NCT03625323. Eftilagimod alpha in combination with pembrolizumab to treat NSCLC and HNSCC. Note 3: CT.gov ID: NCT02676869. Proof-of-concept study; eftilagimod alpha in combination with pembrolizumab to treat metastatic melanoma. Note 4: CT.gov ID: NCT03252938. Investigator-sponsored trial. Note 5: Phase I trial of eftilagimod in combination with avelumab announced on 9/24/18 as expansion arm of INSIGHT. Note 6: CT.gov ID: NCT02195349. Development led by GSK. Note 7: CT.gov ID: NCT03365791. In combination with spartalizumab. Trial led by Novartis. Note 8: CT.gov ID: NCT03499899. In combination with spartalizumab, carboplatin, or both. Trial led by Novartis. Note 9: CT.gov ID: NCT02460224. In combination with spartalizumab. Trial led by Novartis. Note 10: CT.gov ID: NCT03451916. In combination with spartalizumab. Trial led by Novartis.											
Abbreviations: BLA, biologics license application; CT.gov ID, ClinicalTrials.gov identifier; GSK, GlaxoSmithKline plc; HNSCC, head and neck squamous cell carcinoma; MBC, metastatic breast cancer; NSCLC, non-small cell lung cancer; I, Phase I; II, Phase II; III, Phase III; M, market; NIH, National Institutes of Health; P, preclinical; TBD, to be determined; TNBC, triple-negative breast cancer.											

Source: Company reports, ClinicalTrials.gov, and B. Riley FBR Research

Catalysts and Milestones

Immutep has multiple potential catalysts and milestones in the next 12 to 18 months that could have a substantial impact on the equity value of the shares (Exhibit 2). Most significantly, we anticipate completion of enrollment in the AIPAC trial in 4Q18, with top-line data expected in 3Q19. If results are positive, it is possible that Immutep may file for conditional approval in the European market in 2H19, in our view. We expect Immutep to announce interim results from cohort 4 from the Phase I TACTI-mel trial in 4Q18, with top-line results expected in 2Q19. We also expect Immutep to commence the Phase II TACTI-002 trial in 4Q18, with early interim results announced in 2Q19, and to commence the recently announce Phase I trial of eftilagimod in combination with avelumab to treat advanced solid malignancies in 1H19. For IMP761, we expect that Immutep will announce preclinical toxicology and pharmacokinetic results in 1H19 and that it will subsequently establish cGMP protocols in 2H19. We project that Immutep's collaborative partner GSK will advance IMP731 into a Phase II trial in 4Q18 and that Immutep's collaborative partner Novartis will announce updates from the development of IMP701 in 1H19.

Exhibit 2: Catalysts and Milestones Expected for Immuteq in the Next 12 to 18 Months

Drug Candidate	Catalyst or Milestone	Expected	Achieved
Eftilagimod alpha (LAG-3lg, IMP321)			
AIPAC	Complete patient enrollment.	1Q19	
	Announce top-line results.	3Q19	
	Conditional approval in E.U. for combination with Paclitaxel.	4Q19	
TACTI-002	Commence patient enrollment.	4Q18	
	Announce interim results.	2Q19	
TACTI-mel	Announce interim results of cohort 4.	4Q18	
	Announce top-line results of cohort 4.	2Q19	
INSIGHT	Announce interim results at a major medical conference.	4Q18	
PD-L1 Combination	Initiate enrollment in a Phase I dose-escalation trial in combination with avelumab.	1H19	
IMP731			
	Initiate a Phase II trial in psoriasis.	4Q18	
IMP701			
	Announce periodic updates from ongoing clinical trials.	1H19	
IMP761			
	Announce preclinical results from studies in cynomolgus monkeys.	1H19	
	Announce establishment of cGMP procedures.	2H19	

Source: Company reports and B. Riley FBR Research

Investment Rationale

The Immune System Monitors for Foreign Material and Cancerous Cells

The immune system is the critical infrastructure that defends the body from foreign organisms such as viruses and bacteria and plays a vital role in protecting the body from potentially lethal growth irregularities such as cancer. Misregulation of the complex interactions that provide protection from cancerous growth can arise as an adaptive defense by the cancer cells themselves to effectively hide a developing tumor from the immune system, thereby reducing the anti-tumorigenic response. Alternatively, overactivation can cause the immune system to attack healthy tissue, leading to autoimmune diseases whose severity can range from chronic but manageable to progressively debilitating and lethal.

Cells within the body use surface proteins called major histocompatibility complexes (MHCs) to present pieces of protein material from normal and tumor cells and microbes, called epitopes, to immune cells that are monitoring for infection or malfunction. There are three types of MHCs: Class I MHCs (MHCI), Class II MHCs (MHCII), and Class III MHCs (MHCIII). MHCIII will not be discussed here. MHCI is present on the surface of every cell, except red blood cells, and displays epitopes of every protein within the cell on the cell surface for immune surveillance.

MHCII is typically only present on the cell surface of specific types of cells called antigen-presenting cells (APCs) that function within the innate immune system and serve to coordinate the innate immune activity with adaptive immune activity. Important APCs include dendritic cells (DCs), natural killer (NK) cells, and certain types of macrophages and neutrophils. These cells essentially act as scavengers that clean up debris and respond to infection by secreting cytokines and other signaling molecules to help illicit an inflammatory response to promote migration, called chemotaxis, of other immune cells to the site of infection. These cells internalize foreign material through a process called phagocytosis. The foreign material is then broken down, with some of the broken down pieces presented as epitopes on the cell surface by MHCII.

In the case of dendritic cells, this process leads to dendritic cell maturation, with the dendritic cells migrating to lymph nodes where they present the foreign epitopes to immature T cells within the adaptive immune system. The immature T cells then generate antibodies against the epitopes presented by MHCII. These antibodies are incorporated as part of the T cell receptors (TCR), which are present on the cell surface of CD4+ (helper) T cells and CD8+ (killer) T cells. These T cells circulate and monitor MHCII-presenting and MHCI-presenting cells, respectively, and will respond with an immunogenic response when recognizing epitopes interpreted as foreign or mutagenic. CD8+ T cells will act by killing the target cell directly through chemical processes, while the CD4+ T cells respond by secreting cytokines to recruit other cells within the immune system to attack and kill the cells in question.

The interactions between MHCI or MHCII with cells within the adaptive immune system are regulated by sets of regulatory proteins called immune checkpoint proteins. These proteins fall broadly within two roles, immune checkpoint stimulatory or inhibitory proteins. As their roles imply, these groups of proteins serve to throttle up or throttle down, respectively, the activity of T cells as they interact with MHCI- and MHCII-presenting cells and play a prominent role in the maturation of different cell types within the immune system. Prominent proteins within the immune checkpoint stimulatory proteins include OX40, 4-1BB, and certain interleukin receptors, while prominent proteins within the immune checkpoint inhibitory proteins include programmed cell death protein 1 (PD-1), programmed death ligand 1 (PD-L1), cytotoxic T-lymphocyte associated protein 4 (CTLA4), and lymphocyte activation gene-3 (LAG-3).

Misregulation of the immune system can occur through multiple mechanisms. Cancer cells can effectively hide from the immune system by reducing expression of MHCI either through genetic mutation or through alterations of epigenetic regulation of gene transcription. Additionally, T cells within the tumor microenvironment can be deafened to mutagenic signals expressed by cancer cells through MHCI by being induced to express elevated levels of immune checkpoint inhibitory proteins. The creation of such “cold” tumor microenvironments is exacerbated by the recruitment of regulatory T cells (Tregs) that serve to further suppress immune response. In autoimmune diseases, misregulation of immune checkpoint proteins can lead to hypersensitivity within the immune system and can cause the immune system to misinterpret the body’s own cells as foreign.

Since the 2011 approval of ipilimumab (Yervoy), an anti-CTLA-4 monoclonal antibody, the development and approval of novel immune checkpoint targeting drugs in cancer has accelerated significantly. More recently, the approval of anti-PD-1 monoclonal antibody drugs pembrolizumab (Keytruda) and nivolumab (Opdivo) has advanced the field of immuno-oncology (IO). However, while very promising, these drugs have had disappointingly low levels of efficacy in many cancers, leading to the expanded development of IO combinations to improve patient outcomes. New IO combinations include combining IO drugs with each other, with chemotherapy, or with other novel agents to improve efficacy. In our view, such combinations will only be successful if the synergistic improvements in efficacy are not offset by compounded adverse effects of each drug.

Immutep’s Focus on Modulating LAG-3 Function

Lymphocyte activation gene-3 (LAG-3; CD223) is an immune inhibitory checkpoint protein that plays a prominent role in dendritic cell maturation, as well as in T cell maturation and activity. LAG-3 is structurally similar to CD4 and consists of four extracellular immunoglobulin superfamily domains, a transmembrane domain, and a highly conserved intracellular signaling domain. LAG-3 associates with TCRs in receptor rafts on the cell surface and has high binding affinity to MHCII, through which it regulates T cell/MHCII interactions. In CD4+ T cells, this is thought to occur by competing with CD4 for MHCII binding, thereby reducing the stimulatory influence of CD4. LAG-3 also regulates CD8+ T cell activity. It is thought that this regulation occurs indirectly via interactions with molecules secreted by or expressed by Tregs within the tumor microenvironment that promote repression of CD8+ T cell activity.

LAG-3 is expressed on activated T cells and mature APCs and is constitutively expressed by Tregs. Its presence on functionally distinct cells within the immune system highlights its regulatory impact on the immune system. Studies have shown that increased LAG-3 expression in APCs promotes APC activation and migration and has a secondary impact of increasing CD8+ T cell maturation. Conversely, increased expression of LAG-3 within T cells inhibits CD4+ and CD8+ T cell activity while promoting Treg-mediated repression of T cell activity.

Immutep has developed multiple molecules and antibodies that selectively target LAG-3 to toggle its impact during different phases of immune system response. Eftilagimod alpha (IMP31) and IMP701, an antagonist antibody, are being developed as IO drugs that promote immune system responses to cancer. Conversely, IMP731, a depleting antibody targeting LAG-3+ cells, and IMP761, an agonist antibody that enhances LAG-3 sensitivity, are being developed for autoimmune diseases.

Eftilagimod Alpha, an Antigen-Presenting Cell (APC) Fusion Protein and Activator

Eftilagimod, formerly called LAG-3Ig and IMP321, is a fusion protein consisting of four LAG-3 extracellular domains fused to the Fc portion of human IgG1. Eftilagimod was originally developed as an immune antagonist with the goal of disrupting the immune suppressive role of LAG-3 within the immune synapse. However, early research showed that treatment with eftilagimod increased APC activity, resulting in increased dendritic cell maturation and CD8+ T cell activation.¹ Results from a Phase I dose-escalation trial (NCT00351949) conducted in 20 patients with advanced renal cell carcinoma showed that eftilagimod was well tolerated, with no clinically significant adverse events reported.² In addition, eftilagimod when administered biweekly generated a stable disease in a dose-dependent manner, with seven of eight patients who received greater than 6 mg per dose showing stable disease, versus three of 11 showing stable disease when given doses of less than 6 mg. The modest improvement in patient prognosis generated by eftilagimod combined with its impact on APC activation suggested a potential role for eftilagimod as an adjuvant therapy that could be administered in combination with chemotherapy or other immuno-oncology approaches to improve patient responses to treatment.

A 33-patient Phase I dose-escalation trial (NCT00349934) investigated eftilagimod in combination with paclitaxel as a first-line treatment for metastatic breast cancer.³ Eftilagimod was administered to three patient cohorts at 0.25 mg, 1.25 mg, or 6.25 mg per dose on days 2 and 16 of each 28-day cycle of paclitaxel. Two patients were removed from the study due to a paclitaxel-related adverse event (neuropathy), and another was removed due to ineligibility. All other patients received at least six doses of eftilagimod, with no eftilagimod-related adverse events reported. Only three of 30 patients evaluated for efficacy experienced progressive disease six months after treatment began, while 50% of patients experienced a partial response, versus the 25% historical partial response rate for paclitaxel alone. In addition, analysis of blood collected on days 1, 85, and 170 showed a dose- and time-dependent increase in primary APCs (monocytes and dendritic cells) and secondary immune cells (activated CD8+ T cells, NK cells), indicating increased immune system activity. These results formed the basis for proceeding to the ongoing Phase IIb AIPAC trial.

Exhibit 3: Design of an Ongoing Phase IIb Trial of Eftilagimod, in Combination with Paclitaxel, in Metastatic Breast Cancer

This Phase IIb trial is called AIPAC (Active Immunotherapy PAClitaxel).



Source: Immuteq Limited, corporate presentation, July 2014

Ongoing AIPAC Phase IIb Trial of Eftilagimod in Combination with Paclitaxel for Metastatic Breast Cancer

The AIPAC trial (Active Immunotherapy PAClitaxel) Phase IIb trial is being conducted in 241 patients with hormone receptor positive advanced metastatic breast cancer who were divided into two stages (Exhibits 3 and 4). Stage I was a 15-patient open-label, dose-escalation, run-in stage that compared 6 mg doses to 30 mg doses of eftilagimod to determine the recommended Phase II dose (RP2D). Stage II is an ongoing, randomized, double-blind, placebo-controlled trial comparing paclitaxel plus eftilagimod to paclitaxel plus placebo and measuring progression-free survival (PFS) as the primary endpoint.

The Stage I safety run-in portion showed eftilagimod to be well tolerated, even at 30 mg per dose. Consistent with the efficacy results from the Phase I trial, seven of 15 patients (47%) had a partial response, six of 15 patients (40%) had stable disease, and only two of 15 patients (13%) had progressive disease six months after beginning treatment, yielding an overall response rate (ORR) of 47% and a diseases control rate (DCR) of 87% (Exhibit 5). By comparison, historical ORR and DCR in advanced metastatic breast cancer patients treated with paclitaxel was 31% and 64%, respectively.⁴ Based on these results, the RP2D was determined to be 30 mg of eftilagimod given on days 2 and 16 of each 28-day cycle of paclitaxel, which is given at the full recommended dose. The Stage II portion of this trial was initiated in 1Q17, and we expect enrollment to be completed in 4Q18, with PFS monitored for up to three years.

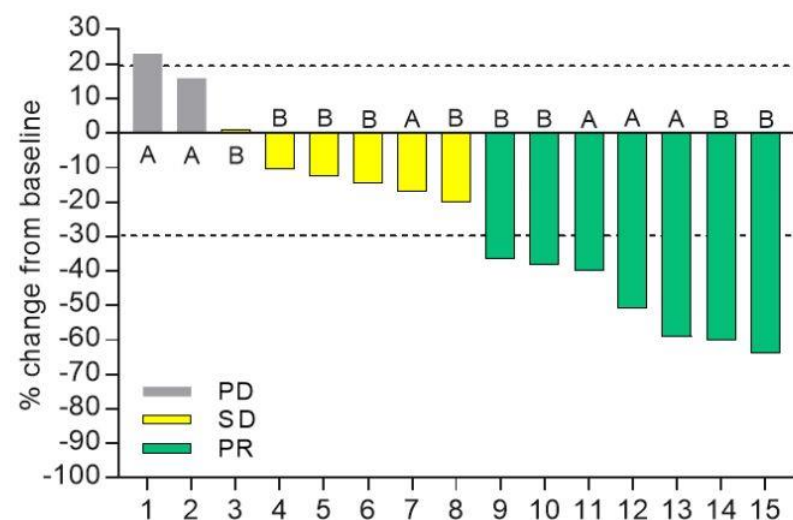
Exhibit 4: AIPAC: An Ongoing Phase IIb Trial of Eftilagimod, in Combination with Paclitaxel, in Metastatic Breast Cancer

Phase:	IIb	Intervention:	Eftilagimod alpha (LAG-3Ig, IMP321), in combination with paclitaxel	Comparator:	Placebo, in combination with paclitaxel
CT.gov ID:	NCT02614833	Current status:	Recruiting	No. subjects:	241
Other ID:	IMP321-P011	Indication:	Metastatic estrogen receptor positive and/or progesterone receptor positive breast adenocarcinoma		
Design:	Stage I: Open-label dose-escalation phase to determine the RP2D for eftilagimod (n=15). Stage II: Randomized (1:1), placebo-controlled, double blind, parallel assignment expansion phase at the RP2D (n=226).				
Start date:	December 2015	Top-line date:	June 2019	Duration of observation:	Three years for PFS; four years for OS
Dosing regimen:	Chemo-immunotherapy phase: six cycles; each cycle is four weeks. Paclitaxel (80 mg/m ²) on Days 1, 8, and 15 by IV injection with adjunctive treatment of placebo or eftilagimod at the RP2D (determined to be 30 mg) on Days 2 and 16 of each cycle by subcutaneous injection. Maintenance phase: Responding or stable patients at the end of the chemo-immunotherapy phase are administered placebo or eftilagimod by subcutaneous injection once every four weeks for up to 12 injections (or about one year).				
Primary endpoint:	RP2D in Stage I. PFS at up to 37 months (about three years) in Stage II.				
Secondary endpoints:	Stage I: Pharmacokinetics and pharmacodynamics of eftilagimod. Stage II: Safety and tolerability at up to 19 months; OS at up to 48 months (four years); change in QoL; time to next treatment; ORR; evaluation of stable disease (last four metrics at up to 37 months). Subset analysis in Stage I: immune response monitoring by changes in levels of circulating immune cells and cytokines.				
Key inclusion criteria:	Previously untreated adult female patients with histologically proven (by biopsy) metastatic estrogen receptor positive and/or progesterone receptor positive breast adenocarcinoma of the primary tumor and/or metastasis who are indicated to receive front-line chemotherapy with paclitaxel; evidence of measurable disease as defined by RECIST version 1.1; laboratory results (hematology and biochemistry) within normal limits for the patient population.				
Key exclusion criteria:	Prior chemotherapy for metastatic breast adenocarcinoma; disease-free interval of less than 12 months from the last dose of adjuvant chemotherapy; inflammatory carcinoma; candidate for trastuzumab (or other Her2/neu targeted agents); systemic chemotherapy, radiation therapy or any other investigational agent within four weeks, endocrine therapy within one week, or CDK4/6 inhibitors within five times the half-life prior to first dose of study treatment and until completion of study treatment; symptomatic known cerebral and/or leptomeningeal metastases; evidence of severe or uncontrolled cardiac disease (NYHA class III-IV) within six months; prior to first dose of study treatment: serious intercurrent infection or active acute or chronic infection, active autoimmune disease requiring immunosuppressive therapy; previous malignancies in prior three years (other than breast carcinoma); prior organ or stem cell transplantation; any condition requiring continuous systemic treatment with corticosteroids or other immunosuppressive medications within four weeks prior to first dose of study treatment.				
Clinical sites:	33 in Europe: Belgium (8), Netherlands (7), Germany (5), Hungary (4), France (3), U.K. (3), and Poland (3).				
Abbreviations:	NYHA, New York Heart Association; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended Phase II dose.				

Source: Immuteq Limited, ClinicalTrials.gov, and B. Riley FBR Research

Exhibit 5: Efficacy Results from the Stage I Run-In of the Phase IIb AIPAC Trial of Eftilagimod, in Combination with Paclitaxel, in Metastatic Breast Cancer

Efficacy results from Stage I of the Phase IIb AIPAC trial: Metastatic breast cancer patients were administered either 6 mg or 30 mg of eftilagimod on days 2 and 16 of the 28-day paclitaxel cycle. Patients were evaluated six months after beginning treatment, with a partial response (PR) occurring in 7/15 patients, stable disease (SD) occurring in 6/15 patients, and progressive disease (PD) occurring in 2/15 patients.



Source: Immuteq Limited, corporate presentation, July 2014

TACTI-mel and TACTI-002 Evaluating Eftilagimod in Combination with Pembrolizumab, a PD-1 Checkpoint Inhibitor

Similar to the adjuvant role that eftilagimod may have in improving the efficacy of chemotherapy, eftilagimod may also provide adjuvant benefits to other immuno-oncology drugs. The PD-1 immune checkpoint inhibitor pembrolizumab has shown encouraging efficacy in many difficult-to-treat cancers, compared with other treatment options. In patients with advanced melanoma, patients taking pembrolizumab had an overall response rate of 33%, versus 12% in patients taking ipilimumab, an anti-CTLA4 monoclonal antibody. Similarly, patients with relapsed melanoma following treatment with first line chemotherapy had ORRs between 21% and 25% for pembrolizumab, versus 4% for ipilimumab.⁵

These results leave room for improvement. A recent study found that the efficacy of anti-PD-1 therapy correlated positively with monocyte concentration prior to treatment.⁶ One-year overall survival for patients receiving anti-PD-1 therapy was about 50% in patients with classical monocyte concentrations below 19% in peripheral blood mononuclear cells (PBMCs), compared with 100% in patients with classical monocyte concentrations above 19%. Recall that eftilagimod increased monocyte activation and durability.

Immuteq initiated TACTI-mel, a Phase I proof-of-concept trial (NCT02676869) of eftilagimod in combination with pembrolizumab in patients with locally advanced or metastatic melanoma, in collaboration with Merck & Co., Inc. (MRK) in 2016 (Exhibit 6). In the first stage of the trial, patients were given pembrolizumab intravenously once every three weeks at 2 mg/kg for up to nine weeks according to the product label. Beginning in cycle 4, patients were evaluated for tumor response to pembrolizumab. Patients who displayed asymptomatic progression or suboptimal response to pembrolizumab were enrolled in the TACTI-mel trial in one of three cohorts and were given eftilagimod in conjunction with pembrolizumab at doses of 1 mg, 6 mg, or 30 mg, depending on their cohort, once every two weeks beginning in cycle 5 of treatment with pembrolizumab. Tumor responses were assessed according to immune-related response criteria, with PFS evaluated every 12 weeks following the end of treatment.

Interim results from the initial 18 patients showed that 50% of patients had tumor reduction, with one patient (6%) showing a complete response, five patients (28%) showing a partial response, six patients (33%) showing stable disease, and six patients (33%) showing disease progression. Additionally, two patients had a complete disappearance of all tumor lesions. This translates to an overall response rate (ORR) of 61%, versus a 31% historical ORR in patients receiving pembrolizumab who were naïve to ipilimumab (anti-CTLA4 monoclonal antibody) and a 21% historical ORR in patients who had previously received ipilimumab treatment. Additionally, 66% of patients were progression free at six months, versus 46% and 34% progression free for historically treated patients who were naïve or previously treated with ipilimumab, respectively.

Exhibit 6: TACTI-mel: An Ongoing Phase I Trial of Eftilagimod, in Combination with Pembrolizumab, in Metastatic Melanoma

Phase:	I	Intervention:	Eftilagimod alpha (LAG-3lg, IMP321), in combination with pembrolizumab		Comparator:	None
CT.gov ID:	NCT02676869	Current status:	Active, not recruiting		No. subjects:	24
Other ID:	IMP321-P012	Indication:	Locally advanced unresectable (Stage III) or metastatic (Stage IV) melanoma			
Design:	Part A: Open-label dose-escalation phase in three cohorts; 1 mg, 6 mg, and 30 mg eftilagimod in Cohorts 1, 2, and 3, respectively, by subcutaneous injection. Part B: Expansion phase at 30 mg eftilagimod by subcutaneous injection.					
Start date:	April 2016	Top-line date:	September 2018	Duration of observation:	12 months	
Dosing regimen:	In Parts A and B, eftilagimod is administered subcutaneously once every two weeks. Pembrolizumab is administered according to its product label.					
Primary endpoint:	Determine the RP2D.					
Secondary endpoints:	ORR by irRC and RECIST 1.1; time to next treatment; PFS; OS (Part B only).					
Key inclusion criteria:	Adult males and females with histologically confirmed locally advanced (unresectable Stage III) or metastatic (Stage IV) melanoma; currently receiving anti-PD-1 therapy with pembrolizumab and after three cycles achieving asymptomatic irPD or sub-optimal irSD or irPR as assessed by imaging within six weeks prior to study start; ECOG performance status 0–1; evidence of measurable disease as defined by RECIST version 1.1; adequate laboratory results (hematology and biochemistry).					
Key exclusion criteria:	More than four prior lines of therapy for advanced or metastatic disease; prior PD-1/PDL-1 targeted therapy; currently treated or less than four weeks since ending treatment with another investigational drug; currently receiving systemic chemotherapy, targeted small molecule therapy, radiotherapy, or biological cancer therapy (other than pembrolizumab) or less than four weeks since completion of these therapies; history of irAEs from ipilimumab of CTCAE Grade 4 requiring steroid treatment; cerebral or leptomeningeal metastases; serious intercurrent infection within four weeks or active acute or chronic infection; history or evidence of interstitial lung disease or active non-infectious pneumonitis; active autoimmune disease requiring immunosuppressive therapy; HIV positive or active hepatitis B or C; continuous systemic treatment with corticosteroids or other immunosuppressive medications within four weeks prior to first dose of study treatment.					
Clinical sites:	Seven in Australia.					
Abbreviations:	CTCAE, Common Terminology Criteria for Adverse Events; ECOG, Eastern Cooperative Cancer Group; irAEs, immune-related adverse events; irPD, immune-related progressive disease; irPR, immune-related partial response; irRC, immune-related response criteria; irSD, immune-related stable disease; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended Phase II dose.					

Source: Immutep Limited, ClinicalTrials.gov, and B. Riley FBR Research

A fourth cohort that recently completed enrollment is being given 30 mg of eftilagimod once every two weeks beginning in cycle 1 of pembrolizumab treatment. We expect Immutep to announce interim results from this cohort in 4Q18.

Phase II TACTI-002 Trial of Eftilagimod in Combination with Pembrolizumab in Non-Small Cell Lung Cancer or Head and Neck Cancer

Based on positive interim results from the TACTI-mel trial, Immutep recently announced a follow-up collaboration with Merck. TACTI-002 (Two ACTIVE Immunotherapeutics), also called Keynote-PN798 (one of many Merck-sponsored “Keynote” trials with pembrolizumab as a monotherapy or in combination with one or more other agents), is a planned Phase II trial of eftilagimod given in combination with pembrolizumab as a first- or second-line treatment of patients with unresectable or metastatic non-small cell lung cancer (NSCLC) or recurrent PD-1 refractory NSCLC or with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) (Exhibit 7). Pembrolizumab is approved by the FDA as a single agent in patients with unresectable or metastatic NSCLC and in recurrent or metastatic HNSCC. In unresectable or metastatic NSCLC, patients taking 2 mg/kg pembrolizumab every three weeks had a median overall survival of 10.4 months, a PFS of 3.9 months, and an ORR of 19%. In patients with recurrent or metastatic HNSCC, patients taking 200 mg of pembrolizumab every three weeks had an ORR of 16%, while the median duration of response was never reached after 27 months, with 23 of 28 patients continuing to respond after six months.

This trial will be a non-comparative, non-randomized, open-label study conducted in 120 patients. Patients will receive 30 mg of eftilagimod every two weeks for eight three-week cycles; they will then switch to receiving eftilagimod once per three-week cycle. They will also receive 200 mg of pembrolizumab every three weeks. The trial will be conducted in two stages. The first stage will be conducted in 20 patients for each indication to evaluate efficacy and will be expanded to an additional 20-patient confirmatory second stage upon achievement of a predefined response criteria. We expect this trial to begin enrolling patients in 4Q18 and to present interim efficacy results in 2Q19.

Exhibit 7: TACTI-002—A Phase II Trial of Eftilagimod in Combination with Pembrolizumab in NSCLC and HNSCC

Phase:	II	Intervention:	Eftilagimod alpha (LAG-3lg, IMP321) in combination with pembrolizumab		Comparator:	None
CT.gov ID:	NCT03625323	Current status:	Not yet recruiting.		No. subjects:	120
Other ID:	TACTI-002; Keynote-PN798	Indication:	Previously untreated unresectable or metastatic NSCLC, or recurrent PD-X refractory NSCLC or with recurrent or metastatic HNSCC.			
Design:	Simon's two-stage, non-comparative, non-randomized, open-label, single-arm, multicenter trial.					
Start date:	November 2018	Top-line date:	June 2020	Duration of observation:	24 months	
Dosing regimen:	Same dosing regimen for NSCLC and HNSCC. Eftilagimod (30 mg) every two weeks for eight three-week cycles, then every three weeks starting with cycle nine by subcutaneous injection. Pembrolizumab (200 mg) every three weeks by IV injection.					
Primary endpoint:	ORR by iRECIST.					
Secondary endpoints:	Frequency, severity, and duration of (serious) adverse events; time to and duration of responses according to iRECIST and RECIST 1.1; response rate according to RECIST 1.1; DCR according to iRECIST and RECIST 1.1; PFS; OS; occurrence of eftilagimod-specific antibodies (ADA); plasma concentration time profile of eftilagimod.					
Key inclusion criteria:	Adults with previously untreated, PD-X naïve histologically or cytologically confirmed diagnosis of NSCLC Stage IIIB not amenable to curative treatment or Stage IV not amenable to EGFR/ALK-based therapy and treatment naïve for systemic therapy given for advanced/metastatic disease (previous palliative radiotherapy for advanced/metastatic disease acceptable) in Part A; previously treated PD-X refractory histologically or cytologically confirmed diagnosis of NSCLC after failure of first-line treatment (for metastatic disease) with at least two cycles of any PD-X containing base therapy alone or in combination with any other immunotherapeutic or chemotherapy in Part B; previously treated, PD-X naïve histologically or cytologically confirmed recurrent HNSCC not amenable to curative treatment with local or systemic therapy or metastatic (disseminated) HNSCC of the oral cavity, oropharynx, hypopharynx, and larynx considered incurable by local therapies after failure of prior platinum-based therapy; submission of formalin-fixed diagnostic tumor tissue; ECOG performance status 0–1; expected survival greater than three months.					
Key exclusion criteria:	For Part A (previously untreated, PD-X naïve NSCLC): NSCLC can be treated with curative intent with either surgical resection and/or chemoradiation and/or radiation; received systemic therapy for the treatment of Stage IV NSCLC, but completion of treatment with chemotherapy and/or radiation as part of neoadjuvant/adjuvant therapy is allowed as long as therapy was completed at least six months prior to diagnosis of metastatic disease; EGFR-sensitizing mutation and/or is EML4 gene/ALK gene fusion positive (ALK translocation). For Part B (previously treated, PD-X refractory NSCLC): symptomatic ascites or pleural effusion; more than one line of chemotherapy for metastatic disease. For Part C (previously treated, PD-X naïve HNSCC): disease is suitable for local therapy administered with curative intent; previously treated with more than one systemic regimen for recurrent and/or metastatic disease. Prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, anti-CTLA-4 antibody, or any other antibody or drug targeting T-cell co-stimulation or checkpoint pathways (Part A and C only); prior therapy with an anti-PD-1, anti-PD-L1, or anti PD L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor and was discontinued due to a Grade 3 or higher irAE (Part B only); received prior chemotherapy, anti-cancer monoclonal antibody, major surgery, or another systemic cancer therapy or has participated in a study of an investigational agent or has used an investigational device within four weeks; known active central nervous system metastasis and/or carcinomatous meningitis; receiving continuous systemic treatment with either corticosteroids or immunosuppressive medications within seven days.					
Clinical sites:	No open sites yet.					
Collaborator:	Merck & Co., Inc.					
Abbreviations:	ADA, anti-drug antibodies; CTCAE, Common Terminology Criteria for Adverse Events; CTLA4, cytotoxic T-lymphocyte-associated antigen-4 DCR, disease control rate; ECOG, Eastern Cooperative Cancer Group; HNSCC, head and neck squamous cell carcinoma; irAEs, immune-related adverse events; irPD, immune-related progressive disease; irPR, immune-related partial response; iRECIST, RECIST for testing immunotherapeutic agents; irRC, immune-related response criteria; irSD, immune-related stable disease; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-X, PD-1 or PD-L1 therapy; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended Phase II dose.					

Source: Immuteq Limited, ClinicalTrials.gov, and B. Riley FBR Research

Phase I INSIGHT Trial of Eftilagimod by Various Routes of Administration in Advanced Solid Tumors

Exhibit 8: INSIGHT: An Ongoing Phase I Trial of Eftilagimod in Combination with Pembrolizumab in Metastatic Melanoma

Phase:	I	Intervention:	Eftilagimod alpha (LAG-3Ig, IMP321)	Comparator:	None
CT.gov ID:	NCT03252938	Current status:	Active, not recruiting.	No. subjects:	38
Other ID:	INSIGHT	Indication:	Locally advanced or metastatic solid tumor.		
Design:	Non-randomized, single group assignment, open-label trial.				
Start date:	August 2017	Top-line date:	February 2019	Duration of observation:	Six months
Dosing regimen:	Arm A, solid tumors: dose-escalating (6 mg, 12 mg, 24 mg, and 30 mg) intratumoral injections of eftilagimod every two weeks. Arm B, solid tumors with intraperitoneal carcinomatosis: dose-escalating (6 mg, 12 mg, 24 mg, and 30 mg) intra-peritoneal injections of eftilagimod every two weeks. Arm C, solid tumors with chemotherapy: subcutaneous injection of 30 mg eftilagimod.				
Primary endpoint:	Feasibility rate defined as rate of patients receiving treatment per protocol without a DLT.				
Secondary endpoints:	Incidence and severity of adverse events according CTCAE; ORR according to RECIST 1.1 and endoscopic response criteria; PFS; OS; immune response in whole blood and tumor tissue; peripheral blood monocyte number and CD8+ T-cell count, associated activation markers, and TILs.				
Key inclusion criteria:	Adult males and females with histologically confirmed locally advanced or metastatic solid tumors; for Arm A, tumor is accessible for repeated injections and biopsies; for Arm B, presence of peritoneal carcinomatosis; for Arms A and B, failure of, refused, or is intolerant of standard therapy; for Arm C, receiving standard-of-care chemotherapy for his/her cancer; ECOG performance status 0–1; adequate hematological, hepatic, renal, and coagulation function parameters.				
Key exclusion criteria:	For Arms A and B, receiving other concurrent antineoplastic treatment, including radiation; for Arm A, presence of bleeding ulcerative tumors; for Arm B, contraindication or refusal of a laparoscopy; history of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins; prior treatment with CD137 agonists, anti-CTLA4, anti-PD-1, or anti-PD-L1 antibodies; clinically significant or active cirrhosis of the liver (Child >Grade A), coronary heart disease, cardiomyopathy or congestive heart failure (NYHA III-IV), brain metastases, chronic inflammatory bowel disease, tuberculosis, infection requiring IV antibiotics, severe pulmonary infection with reduced of pulmonary function; hepatitis B or C (resolved hepatitis B infection is allowed); presence of autoimmune disease requiring immunosuppressive therapy; active or family or personal history or certain arrhythmias or uncontrolled electrolyte disorders that can cause an arrhythmia; HIV-positive; pronounced alcohol abuse with anticipated detoxification; administration of a live, attenuated vaccine within four weeks or anticipation that a live attenuated vaccine will be required during the study; any condition requiring continuous systemic treatment with either corticosteroids or other immunosuppressive agents within two weeks; treatment with systemic immunostimulatory agents (including but not limited to interferons or interleukin-2) within four weeks or five half-lives of the drug, whichever is shorter; previous venous thromboembolism greater than CTCAE Grade 3 within the last 12 months; history of severe allergic episodes and/or Quincke’s edema; prior organ transplantation or stem cell transplantation; participation in another clinical study in a period 30 days prior to start of study treatment and during the study; pregnant or lactating.				
Clinical sites:	Single site in Germany. This is an IST.				
Abbreviations:	CTCAE, Common Terminology Criteria for Adverse Events; DLT, dose-limiting toxicity; ECOG, Eastern Cooperative Cancer Group; IST, investigator-sponsored trial; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TILs, tumor-infiltrating lymphocytes.				

Source: Immutep Limited, ClinicalTrials.gov, and B. Riley FBR Research

INSIGHT is a Phase I investigator-sponsored trial studying intratumoral injections of eftilagimod in 38 patients with locally advanced or metastatic solid tumors (Exhibit 8). This trial consists of three arms. Arm A is a dose-escalation portion testing injections of 6 mg, 12 mg, 24 mg, or 30 mg per injection every two weeks. Arm B is a dose-escalation portion using doses similar to Arm A but given as intraperitoneal injections in solid tumors with intraperitoneal carcinomas. In Arm C, patients with solid tumors previously treated with chemotherapy are given 30 mg subcutaneous injections of eftilagimod every two weeks. This study is measuring dose-limiting toxicities (DLTs) as a primary endpoint, with safety and efficacy, as determined by PFS and OS, monitored as secondary endpoints.

Immutep announced on September 24, 2018, a new collaboration and supply agreement with Merck and Pfizer Inc. (PFE), to initiate a Phase I clinical trial of eftilagimod in combination with PD-L1 inhibitor avelumab in patients with advanced solid malignancies. This trial will be conducted as an extension of the ongoing INSIGHT trial. Given the recent stage of this announcement, no information has yet been made available as to the important details related to this trial. However, we anticipate that this will be a Phase I dose-escalation study that will enroll 10 to 12 patients with advanced solid malignancies and will evaluate safety as a primary endpoint and RP2D and efficacy as secondary endpoints. We project enrollment will begin in 1H19. Due to the early nature of this trial, we are not including it in our valuation of Immutep.

IMP761, a LAG-3 Agonist Antibody

IMP761 is a first-in-class preclinical stage LAG-3 agonist antibody that is being developed to treat autoimmune diseases. This antibody acts by targeting and activating LAG-3 on active T cells, thereby increasing LAG-3 mediated suppression pathways within the target cells. Ideally, this will result in reduced T cell proliferation and activity, thereby reducing overall immune system activity and mitigating the targeting of the body's own tissues.

Immutep announced in early September 2018 that it was advancing toward establishing cGMP protocols for the production of IMP761 for clinical purposes. Immutep is currently conducting preclinical studies of IMP761 in cynomolgus monkeys to determine *in vivo* pharmacokinetics (PK) and toxicology exposure and to provide proof of concept prior to entry into the clinic. We anticipate the announcement of preclinical results beginning in 1H19.

IMP731, a LAG-3 Depleting Antibody

IMP731 (or GSK2831781) is a LAG-3 specific cytotoxic antibody that targets LAG-3+ T cells for elimination. Since LAG-3 is only present within mature T cells, depletion of these cells results in the reduction of autoimmune activity. Immutep licensed global rights to IMP731 and other LAG-3 depleting antibodies to GSK in 2011 following positive preclinical results. In exchange, Immutep is eligible to receive up to A\$118M in developmental milestone payments and mid-single-digit tiered royalties on commercial sales.

GSK completed a Phase I randomized, double-blind, placebo-controlled ascending-dose study of IMP731 in 18 patients with plaque psoriasis. The study assessed multiple safety and tolerability metrics as primary endpoints and measured certain efficacy metrics as secondary endpoints. We anticipate a Phase II trial beginning as early as 4Q18, although no guidance has been given regarding an actual start date.

IMP701 (LAG525), a LAG-3 Antagonist Antibody

IMP701 (or LAG525) is a LAG-3 antagonist antibody that functions by blocking LAG-3-mediated inhibitory effects within the immune synapse. Immutep licensed global rights to IMP701 to CoStim Pharmaceuticals in 2012, which subsequently licensed it to Novartis in 2014. Novartis is developing IMP701 in combination with its anti-PD-1 antibody spartalizumab (PDR001) in multiple trials with or without the addition of chemotherapy agents in multiple cancer indications (Exhibits 9–12). This includes multiple Phase II clinical trials. Similar to the licensing agreement made with GSK for IMP731, Immutep is eligible to receive up to about A\$100M in developmental milestones and is eligible for tiered single-digit percentage royalty payments on commercial sales.

We view the interest that Immutep's depleting (IMP731) and antagonist (IMP701) antibodies have received from major pharmaceutical companies as validating LAG-3 as a therapeutic target. Additionally, because these assets have been licensed out, Immutep has positioned itself to benefit from their further development while insulating itself from the costs and risks associated with conducting clinical trials.

Exhibit 9: Design of an Ongoing Phase III Trial of LAG525 in Combination with Spartalizumab in Certain Solid Tumors and DLBCL

Phase:	II	Intervention:	LAG525 with spartalizumab	Comparator:	None
CT.gov ID:	NCT03365791	Current status:	Recruiting.	No. subjects:	160
Other ID:	CPDR001XUS01	Indications:	Advanced relapsed and/or refractory SCLC, gastric or esophageal adenocarcinoma, CRPC, soft tissue sarcoma, ovarian adenocarcinoma, well-differentiated neuroendocrine tumors, or DLBCL.		
Design:	Single group assignment, non-randomized, open label, parallel cohorts by indication.				
Start date:	January 2018	Top-line date:	January 2020	Duration of observation:	Two years
Dosing regimen:	LAG525 and spartalizumab are administered by IV infusion over a 30-minute period each, with LAG525 administered first, once every three weeks.				
Primary endpoint:	CBR at 24 weeks by tumor type and by local investigator assessment, with solid tumor response assessed by RECIST 1.1 and lymphoma response by Revised Response Criteria for Malignant Lymphoma; PFS up to 24 months (note that trial CBR is compared to historical CBR from the literature).				
Secondary endpoints:	ORR; TTR; DOR; TTP; safety and tolerability.				
Key inclusion criteria:	Adult males and females with confirmed diagnosis of one of the advanced relapsed and/or refractory cancers listed under “Indications” above and with measurable lesions; at least one prior line of therapy and a maximum of five prior lines of therapy (not more than four disease progressions); lesion(s) amenable to biopsy (for expansion cohorts only).				
Key exclusion criteria:	History of severe hypersensitivity reactions to other monoclonal antibodies; impaired cardiac function or clinically significant cardiac disease; active, known, or suspected autoimmune disease or documented history of autoimmune disease within three years (some exceptions); prior immunotherapy treatment with PD-1, PD-L1, CTLA-4, or LAG-3 antibodies (previously treated patients anti-PD-1/PD-L1 antibodies adequately treated for skin rash or with replacement therapy for endocrinopathies are allowed); second primary malignancy within three years of receiving the first dose of study treatment.				
Clinical sites:	22 sites, all in the U.S.				
Abbreviations:	CBR, clinical benefit rate; CRPC, castration resistant prostate cancer; CTCAE, Common Terminology Criteria for Adverse Events; DLBCL, diffuse large B cell lymphoma; DOR, duration of response; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; TTP, time to progression; TTR, time to response.				

Source: Immutep Limited, ClinicalTrials.gov, and B. Riley FBR Research

Exhibit 10: Design of an Ongoing Phase II Trial of LAG525 in Combination with Spartalizumab or Carboplatin or Both in Triple-Negative Breast Cancer

Phase:	II	Intervention:	LAG525 in combination with spartalizumab or carboplatin or both		Comparator:	None	
CT.gov ID:	NCT03499899	Current status:	Recruiting.			No. subjects:	96
Other ID:	CLAG525B2101	Indication:	Loco-regional recurrent or metastatic breast cancer.				
Design:	Randomized, open label, three-arm parallel assignment.						
Start date:	July 2018	Top-line date:	December 2019	Duration of observation:	Two years		
Dosing regimen:	Randomization (1:1:1) into one of three arms: (1) LAG525 (400 mg) and spartalizumab (300 mg) by intravenous infusion every 21 days; (2) LAG525 + spartalizumab as in Arm 1 + carboplatin (AUC=6) every 21 days; and (3) LAG525 and carboplatin as in Arm 2.						
Primary endpoint:	ORR by RECIST 1.1.						
Secondary endpoints:	DOR; OS; TTR; PFS; CBR; pharmacokinetics; ADA for LAG525 and spartalizumab at baseline and throughout the trial until 50 days after the last drug administration.						
Key inclusion criteria:	Histologically and/or cytologically confirmed advanced loco-regional recurrent or metastatic TNBC with measurable lesions by most recent biopsy and standard criteria; disease progression after adjuvant or one prior systemic treatment in the metastatic setting; <i>de novo</i> metastatic disease after one prior line of therapy; prior systemic therapy with a taxane-based chemotherapy for adjuvant or metastatic disease; lesion(s) amenable to biopsy and agree to tumor biopsies at screening and during therapy if medically feasible (archival biopsied tumor tissue allowed at screening if anti-cancer therapy has not been provided since the biopsy was obtained).						
Key exclusion criteria:	Prior treatment with anti-LAG-3, anti-PD-1, anti-PD-L1, or anti-PD-L2 antibody at any line of therapy or platinum agent or mitomycin with recurrence within 12 months after completing platinum-based or mitomycin-containing therapy; major surgery within 14 days or poor recovery (Grade 1 or less) from major surgical side effects; presence of CTCAE ≥Grade 2 toxicity (except alopecia, peripheral neuropathy, and ototoxicity, which are excluded if CTCAE ≥Grade 3) due to prior cancer therapy; radiotherapy within four weeks or poor recovery (Grade 1 or better) from related side effects; known hypersensitivity to other monoclonal antibodies, platinum-containing compounds, or excipients of LAG525, spartalizumab, or carboplatin; history or presence of central nervous system metastases, treated or untreated.						
Clinical sites:	Four sites: one each in Australia, Belgium, Singapore, and Taiwan.						
Abbreviations:	ADA, anti-drug antibodies; AUC=6, area under the curve target to calculate carboplatin dose taking kidney glomerular filtration rate into account; CBR, clinical benefit rate; CTCAE, Common Terminology Criteria for Adverse Events; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TNBC, triple-negative breast cancer; TTR, time to response.						

Source: Immuteq Limited, ClinicalTrials.gov, and B. Riley FBR Research

Exhibit 11: Design of an Ongoing Phase I/II Trial of LAG525 As a Single Agent or in Combination with Spartalizumab in Advanced Malignancies

Phase:	I/II	Intervention:	LAG525 as a single agent or with spartalizumab		Comparator:	None
CT.gov ID:	NCT02460224	Current status:	Recruiting.		No. subjects:	515
Other ID:	CLAG525X2101C	Indications:	Phase I: Advanced solid tumors. Phase II (expansion phase): NSCLC, melanoma, renal cancer, mesothelioma, TNBC.			
Design:	Non-randomized, three-arm parallel assignment, open label.					
Start date:	June 2015	Top-line date:	August 2019	Duration of observation:	Up to 30 months	
Dosing regimen:	Phase I: dose-escalation of LAG525 to identify RP2D as a single agent and in combination with spartalizumab; Phase II: LAG525 dosed at RP2D. Arm 1: LAG525 as a single agent; Arm 2: LAG525 + spartalizumab; Arm 3: LAG525 as a single agent in Japanese patients.					
Primary endpoint:	Phase I: identify MTD and RP2D, incidence of DLTs; Phase II: OS per RECIST 1.1.					
Secondary endpoints:	Pharmacokinetics of LAG525 as a single agent and in combination with spartalizumab (AUC, Cmax, Tmax, t1/2); presence of ADAs to LAG525 and spartalizumab; changes in PD-L1 and LAG-3 expression; ORR, DOR, DCR, and PFS per RECIST and irRC criteria; expression of IFNγ immune-related genes by mRNA profiling; safety (incidence of AEs and SAEs) and tolerability (dose reductions and interruptions).					
Key inclusion criteria:	Phase I: adult male or female patients with relapsed and/or refractory disease with standard therapy or who are intolerant of standard therapy or for whom there is no standard therapy. Phase II: adult male or female patients with advanced/metastatic solid tumors and disease progression following their last prior therapy; diagnosis of any cancer listed in “Indications, Phase II” above; measurable or non-measurable disease as determined by RECIST 1.1; at least one measurable lesion as determined by RECIST 1.1; ECOG performance status 0–1; lesion(s) amenable to biopsy.					
Key exclusion criteria:	History of severe hypersensitivity reactions to study treatment ingredients or other monoclonal antibodies; active, known or suspected autoimmune disease; active infection requiring systemic antibiotic therapy; HIV infection; active HBV or HCV infection; receiving chronic systemic steroid therapy (except for adrenal insufficiency) or systemic immunosuppressive agents; use of live vaccines against infectious disease within four weeks or systemic anti-cancer therapy within two weeks of trial start; presence of symptomatic CNS metastases or CNS metastases requiring local therapy or increasing doses of corticosteroids within the prior two weeks; history of drug-induced pneumonitis or current pneumonitis.					
Clinical sites:	24 sites in 12 countries: U.S. (6), Australia (2), Canada (2), France (2), Germany (2), Italy (2), Singapore (2), Spain (2), Belgium (1), Hong Kong (1), Japan (1), Taiwan (1).					
Abbreviations:	ADAs, anti-drug antibodies; AEs, adverse events; AUC, area under the curve; Cmax, maximum concentration; CNS, central nervous system; DCR, disease control rate; DLTs, dose-limiting toxicities; DOR, duration of response; ECOG, Eastern Cooperative Cancer Group; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IFNγ, interferon gamma; irRC, immune-related RECIST; mRNA, messenger RNA; MTD, maximum tolerated dose; NSCLC, non-small cell lung cancer; ORR, overall response rate; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended Phase II dose; SAEs, serious adverse events; t1/2, half-life; Tmax, time to maximum concentration; TNBC, triple-negative breast cancer.					

Source: Immuteq Limited, ClinicalTrials.gov, and B. Riley FBR Research

Exhibit 12: Design of a Planned Phase II Trial of Spaltalizumab in Combination with LAG525, Capmatinib, or Canakinumab in Unresectable or Metastatic Melanoma

Phase:	II	Intervention:	Spaltalizumab in combination with LAG525, capmatinib, or canakinumab	Comparator:	None
CT.gov ID:	NCT03451916	Current status:	Not yet recruiting.	No. subjects:	135
Other ID:	CPDR001J2201	Indication:	Unresectable or metastatic melanoma.		
Design:	Randomized, three-arm parallel assignment, open label.				
Start date:	Expected in 3Q18	Top-line date:	January 2021	Duration of observation:	Three years
Dosing regimen:	Spaltalizumab (400 mg) in all three arms will be administered by IV infusion once every four weeks. ARM 1: LAG525 by IV infusion; Arm 2: capmatinib (INC280) taken orally; and Arm 3: canakinumab by subcutaneous injection.				
Primary endpoint:	ORR.				
Secondary endpoints:	DOR; OS; PFS; DCR; development or presence of ADA; pFBP defined as changes in number of CD8+ T cells and/or T cell activation marker(s), T cell clonality, and/or gene expression in tumor biopsy samples.				
Key inclusion criteria:	Adult male or female patients with histologically confirmed unresectable or metastatic Stage IIIB/C/D or IV melanoma (by AJCC edition 8 criteria) and previously treated for unresectable or metastatic melanoma; patients with V600BRAF wild-type or mutant disease must have received prior therapy with checkpoint inhibitor therapy (i.e., anti-PD-1/PD-L1 single-agent or in combination with anti-CTLA-4) and must have had objective evidence of disease progression (i.e., RECIST v1.1) while on or after this therapy; patients with V600BRAF mutant disease must also have received prior therapy with a V600BRAF inhibitor, either as a single agent or in combination with a MEK inhibitor; ECOG performance status 0–2; at least one measurable lesion per RECIST v1.1 and suitable for sequential mandatory tumor biopsies (screening and on-treatment); screening tumor biopsy must fulfill predefined tissue quality criteria as assessed by a local pathologist.				
Key exclusion criteria:	Presence of uveal or mucosal melanoma; clinically active or unstable brain metastasis with some exceptions; active infection requiring systemic antibiotic therapy; active, known, or suspected autoimmune disease (or documented history of autoimmune disease) with some exceptions; use of any live vaccines against infectious diseases within three months; systemic chronic steroid therapy or any other immunosuppressive therapy; prior allogeneic bone marrow or solid organ transplant; history of known hypersensitivity to any of the investigational drugs used in this trial; prior systemic therapy for unresectable or metastatic melanoma other than anti-PD-1/PD-L1 single-agent or in combination with anti-CTLA-4, or V600BRAF and MEK inhibitors; medical history or current diagnosis of myocarditis; cardiac TnT level >2 x ULN at screening.				
Clinical sites:	To be determined.				
Abbreviations:	ADAs, anti-drug antibodies; AJCC, American Joint Committee on Cancer; DCR, disease control rate; ECOG, Eastern Cooperative Cancer Group; NYHA, New York Heart Association; OS, overall survival; pFBP, percent favorable biomarker profile; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TnT, troponin T; ULN, upper limit of normal.				

Source: Immutep Limited, ClinicalTrials.gov, and B. Riley FBR Research

Collaborations and Partnerships

EOC Pharma, an Eddingpharm Affiliate

EOC Pharma is a biotechnology company and affiliate of Eddingpharm based out of Shanghai, China. In 2013, Eddingpharm entered into a licensing agreement with Immutep in which Eddingpharm gained the regional developmental and commercial rights to eftilagimod in China, Macau, and Taiwan. Under the agreement, Immutep would provide technical support for the development of eftilagimod and would be eligible to receive developmental milestone payments and an unspecified royalty on all future commercial sales. Eddingpharm transferred these rights to EOC Pharma in 2015. EOC announced in July 2018 its plans to initiate a Phase I trial of eftilagimod in combination with paclitaxel for first- or second-line treatment of metastatic breast cancer in China. In relation to this agreement, Immutep received a \$1M milestone payment in February 2018, following the granting of EOC's IND application for eftilagimod by the Chinese FDA (CFDA).

GlaxoSmithKline (GSK)

Immutep signed a licensing agreement with GSK in 2011 giving GSK full developmental and commercial rights to IMP731. In exchange, Immutep is eligible to receive up to \$100M in developmental milestone payments, as well as tiered single-digit royalty payments on all commercial sales. Since entering into the agreement, GSK has advanced IMP731 from the preclinical to the clinical stage and has completed a Phase I clinical trial in psoriasis. We expect GSK to advance IMP731 into a Phase II trial in 4Q18 or 1H19.

Novartis AG (NOVN.SWX)

Immutep entered into a licensing agreement with CoStim Pharmaceuticals in September 2012 giving CoStim developmental and commercial rights to Immutep's LAG-3 antagonist antibodies, including IMP701. CoStim was subsequently acquired by Novartis in February 2015, which has continued to develop a humanized version of IMP701 in multiple Phase I and Phase II trials under the name LAG-525. The most advanced of these trials are a Phase II trial of IMP701 in combination with chemotherapy in metastatic breast cancer and IMP701 in combination with Novartis's anti-PD-1 monoclonal antibody, PDR001. Immutep is eligible to receive up to about \$100M in developmental milestone payments plus tiered royalties in the mid-single-digit percentages on all commercial sales. Immutep has received two milestone payments, in August 2015 and August 2017, from Novartis under this agreement.

Immutep: Financial Analysis

Immutep's fiscal year ends on June 3, and the company reports financial results semiannually. All financial results are reported in Australian dollars (A\$). Immutep trades on the Australian stock exchange under the symbol IMM and trades ADSs on the NASDAQ exchange under the symbol IMMMP at a ratio of 100 shares per ADS. We note that all financial and valuation results described here are on a per ADS basis. Historical and projected quarterly and annual income statements, balance sheets, and cash flow statements for Immutep are included at the end of this report. We have made projections out to 2027.

2018 Results to Date and Projected Finish to the Year

Immutep reported a net loss of A\$12.7M, or (A\$0.44) per ADS, for FY18, which was greater than the Y/Y net loss of A\$9.4M, or (A\$0.42) per ADS, in FY17. The increase in losses compared to the prior fiscal year can be attributed to an increase in operating losses to A\$12.2M in FY18, up from A\$9.5M in FY17. Immutep earned A\$6.85M in total revenue in FY18, which was comprised of A\$2.6M in license revenue, A\$3.2M in grant revenue, and A\$1.0M in research and development (R&D) related miscellaneous income. By comparison, Immutep earned A\$4.12M in total revenue in FY17, comprised of A\$3.3M in grant revenue and A\$0.8M in miscellaneous revenue.

Immutep reported operating expenses of A\$19.0M, comprised of A\$10.0M in R&D expenses, A\$7.2M in general and administrative (G&A) expenses, and A\$1.8M in depreciation and amortization expenses (D&A). Total operating expenses increased 40% Y/Y from A\$13.6M in FY17. The Y/Y increase in operating expenses was driven by a 33% Y/Y increase in R&D expenses from A\$7.5M, a 67% Y/Y increase in G&A expenses from A\$4.3M, and a 6% Y/Y increase in D&A expenses from A\$1.7M reported in FY17.

We project net losses to increase in FY19 to A\$14.9M, or (A\$0.49) per ADS, driven primarily by an increase in R&D expenses to A\$11.5M, as well as a decrease in total revenue to A\$4.5M due to the projected absence of milestone payments, which were received in 2018 and accounted for as license revenue. This will be slightly offset by a projected decrease in G&A expenses to A\$6.5M and a projected decrease in D&A expenses to A\$1.6M. We project net losses continuing into 2021, when sales of eftilagimod are projected to surpass operating expenses.

Cash and Cash Equivalents, Cash Burn, and Financial Capital Needs

Immutep ended FY18 with A\$23.5M in cash and cash equivalents and had a cash burn of A\$7.8M for the fiscal year. This is in comparison to a cash burn of A\$8.5M in FY17. The lower cash burn in FY18 was due to changes in working capital, as well as to an increase in stock-based compensation. Immutep ended FY18 with A\$6.6M in convertible notes.

We project a cash burn of A\$13.4M in FY19, implying a cash runway into mid FY20. Due to the low share price of A\$0.04 for each share listed on the Australian exchange, versus \$3.62 per ADS as of the close on September 25, 2018, we expect that future cash needs will be met with the issuance of additional ADSs. Alternatively, we think Immutep may continue to raise cash through the issuance of common stock, or it may seek non-dilutive financing in the form of added debt, new collaborations and partnerships, or additional grants.

Valuation Methodology

We base our Buy rating and 12-month price target of \$7.75 per ADS for Immutep on a discounted cash flow (DCF) analysis of revenue and cash flow projected through 2027. Our projections of free cash flow to the firm (FCFF) from eftilagimod sales are adjusted and weighted based on the historical regulatory approval rates of similar treatments at similar stages of development.⁷ Our DCF analysis applies a WACC-calculated 17.8% discount rate and a 2% terminal growth rate yielding an implied enterprise value of A\$308.6M at FY19-end, with an implied market cap of A\$325.4M after adjusting for balance sheet items, or \$231.0M after converting into U.S. dollars using the current exchange rate of 1.41:1 AUD:USD. We also base our price target on our projection that Immutep will have 30.3M ADSs outstanding at FY19-end.

Our model and valuation are based on revenue projections through 2027 for efitilagimod for the treatment of hormone receptor positive/HER2 negative metastatic breast cancer, second-line treatment of non-small cell lung cancer, and second-line treatment of head and neck cancer. Our model projects revenue separately for three major market regions: the U.S.; the top 12 Western European countries by population; and other developed world markets, including Japan, Taiwan, Korea, Canada, Australia, and New Zealand. We do not include milestone or royalty payments from EOC, GSK, or Novartis due to the uncertainty surrounding the development of Immutep's licensed assets. We also do not include IMP761 due to the early stage of development for this asset.

We estimate wholesale acquisition costs (WACs) for efitilagimod based on the WACs of other immuno-oncology drugs on the market. We discount the WAC outside the U.S. to 65% of the U.S. WAC in our base year and adjust WACs upward in subsequent years at the rate of inflation for each market region as projected by the International Monetary Fund. The base-year WAC for efitilagimod in the U.S. was priced at 50% of the average total annual cost of treatment for a cancer patient of \$147,840. This yielded an estimated WAC for efitilagimod of \$59,000 per individual per year in the base year in the U.S. and \$38,350 per individual per year in the base year in European and other developed world markets.

We project a commercial launch of efitilagimod for the treatment of metastatic breast cancer in the U.S. and European markets in 2022 and in other developed world markets in 2023. While we note the possibility that Immutep could receive conditional approval for efitilagimod to treat metastatic breast cancer in the European market in 2020, this potential outcome is not reflected in our valuation model. We project a 2024 launch in the U.S. and European markets for efitilagimod for the treatment of NSCLC and HNSCC in combination with pembrolizumab, with a projected launch date in 2025 in other developed world markets.

For 2027, the final projected year of our model, we project A\$4.2B in total product revenue derived from sales of efitilagimod.

Executive Management⁸

Marc Voigt

Executive Director & CEO

Tenure with the company: six years, four years as CEO and executive director

Mr. Voigt joined Immutep in 2012, initially serving as the company's chief financial officer and chief business officer before being appointed as chief executive officer and executive director in July 2014. Mr. Voigt brings over 18 years of extensive business experience to this position, having served in multiple roles in investment banking, in venture capital, and in private German biotechnology companies. Mr. Voigt began his career working in pension insurances and funds at Allianz Insurance, where he also served as a personal assistant to a member of the executive board. He then moved to net.IPO.AG where he worked in business development and later served as an investment manager in a midsize healthcare venture capital fund. He has also held multiple executive positions within primarily private German biotech companies. Mr. Voigt earned his master's degree in business administration from the Freie Universität of Berlin and is a member of the judging panel of Germany's largest business plan competition.

Frédéric Triebel, M.D., Ph.D.

Founder, Chief Scientific Officer & Chief Medical Officer

Tenure with the company: about 17 years

Dr. Triebel, M.D., Ph.D., helped to found Immutep S.A. in 2001 and has served as its chief scientific officer and chief medical director since 2004. He was appointed to this position at Immutep Limited (formerly Prima BioMed) following the acquisition of Immutep S.A. by Prima BioMed in 2014. Prior to starting Immutep, Dr. Triebel was a professor in immunology at Paris University and worked at Institut Gustave Roussy (IGR) in Paris, where he discovered the LAG-3 gene and subsequently identified its molecular role. While at IGR, Dr. Triebel led a research group and was involved in the follow-up and analysis of patients treated in Phase I/II immunotherapy trials. From 1991 to 1996, Dr. Triebel also served as director of an INSERM Unit. Dr. Triebel trained as a clinical hematologist and later earned his Ph.D. in immunology from Paris University. Dr. Triebel's research has led to 144 publications and 16 patents.

Deanne Miller

COO, General Counsel & Company Secretary

Tenure with the company: six years

Ms. Miller joined Immutep in 2012 and currently serves as the company's chief operating officer, having previously served as Immutep's general counsel and company secretary from October 2012 to November 2016. Prior to joining Immutep, Ms. Miller accumulated diverse commercial experience in her roles as legal counsel at RBC Investor Services, associate director at Westpac Group, legal and compliance manager at Macquarie Group, regulatory compliance analyst at the Australian Securities and Investment Commission, and tax advisor at KPMG. Ms. Miller double majored at the University of Sydney, where she earned her bachelor of laws, with honors, and bachelor of commerce, accounting and finance degrees. She is admitted as a solicitor in NSW and a member of the Law Society of NSW.

Nonexecutive Board Members⁹

Russell Howard, Ph.D.

Chairman of the board since November 2017, director since 2013

Howard Russell, Ph.D., was appointed as nonexecutive director of Immutep in 2013 and has served as chairman of the board since November 2017. Dr. Russell brings extensive leadership experience to this role, having led research groups in both academic and industry settings, including at the Immunoparasitology Laboratory at the Walter & Eliza Hall Institute in Melbourne, Australia, and the National Institutes of Health in Bethesda, Maryland, where he later became tenured. Dr. Howard later joined the DNAX Research Institute of Molecular and Cellular Biology, a part of Schering-Plough, in Palo Alto, California; served as president and scientific director at Affymax, Inc., where he continued to work after its acquisition by GlaxoSmithKline plc in 1995; and was a co-founder and chief executive officer of Maxygen, where he led financial raises totaling over \$250M from an IPO and secondary offerings on NASDAQ. Dr. Howard currently serves as executive chairman of NeuClone Pty Ltd. and served as director of Circadian Technologies Ltd. from 2013 to 2015. Dr. Howard earned his Ph.D. in biochemistry from the University of Melbourne. Dr. Howard is a recognized pioneer in molecular parasitology and was pivotal in the commercialization of DNA shuffling. He holds five patents and has over 150 scientific publications.

Pete Meyers

Vice chairman of the board since November 2017, director since 2014

Mr. Meyers joined the board of directors at Immutep in 2014 and has served as vice chairman of the board since 2017. Mr. Meyers brings extensive experience in healthcare investment banking and executive finance to this role and has overseen multiple IPOs. Mr. Meyers is currently serving as chief financial officer of Eagle Pharmaceuticals, Inc., having previously served as chief financial officer of Motif BioSciences Inc. and as chief financial officer and Treasurer of TetraLogic Pharmaceuticals Corporation. Mr. Meyers also spent over 18 years in healthcare investment banking, including at Dillon, Read & Co. and Credit Suisse First Boston LLC, and served as co-head of global health care investment banking at Deutsche Bank Securities Inc. Mr. Meyers is currently serving chairman and president of The Thomas M. Brennan Memorial Foundation, Inc. He earned his B.S. degree in finance from Boston College and his M.B.A. from Columbia Business School.

Grant Chamberlain

Board member since August 2017

Mr. Chamberlain joined Immutep as a director in 2017, bringing over 20 years of investment banking experience to the position. Mr. Chamberlain is currently serves as a principal of One Ventures, having previously served as head of mergers & acquisitions and financial sponsors, Australia at Bank of America Merrill Lynch. He has also held senior positions at Nomura Australia and Deutsche Bank. Mr. Chamberlain began his career as a corporate lawyer at Freehill Hollingdale & Page. Mr. Chamberlain earned his bachelor of laws, with honors, and his bachelor of commerce from the University of Melbourne.

Income Statement, Semiannual with Projections—Immutep Limited (IMMP)

(Australian \$ thousands, except per share)	1H17A	2H17A	2017A	1H18A	2H18A	2018A	1H19E	2H19E	2019E
Revenue:									
License revenue	-	-	-	2,580	50	2,630	104	69	173
Grant Revenue	1,365	1,952	3,316	1,325	1,889	3,214	1,662	1,910	3,571
Miscellaneous income	225	575	800	332	677	1,009	371	374	745
Product revenue	-	-	-	-	-	-	-	-	-
Total revenue	1,590	2,527	4,117	4,238	2,616	6,854	2,136	2,353	4,489
Operating expenses:									
Cost of goods sold	-	-	-	-	-	-	-	-	-
Research and development and intellectual property	(2,709)	(4,817)	(7,526)	(4,648)	(5,342)	(9,990)	(5,609)	(5,890)	(11,499)
Corporate administrative expense	(2,117)	(2,230)	(4,347)	(3,996)	(3,246)	(7,242)	(3,261)	(3,275)	(6,536)
Depreciation and amortization expenses	(865)	(836)	(1,702)	(895)	(914)	(1,809)	(805)	(770)	(1,575)
Total operating expenses	(5,691)	(7,883)	(13,574)	(9,538)	(9,503)	(19,041)	(9,675)	(9,935)	(19,610)
Profit (Loss) from operations	(4,101)	(5,356)	(9,458)	(5,301)	(6,887)	(12,187)	(7,539)	(7,582)	(15,121)
Other income (expense):									
Net gain on foreign exchange	-	0	0	37	285	323	-	-	-
Interest income	64	41	104	37	140	177	104	69	173
Net loss on fair value movement of warrants	-	-	-	1,333	(1,523)	(190)	-	-	-
Share-based payment to a strategic investor	-	-	-	-	-	-	-	-	-
Loss on foreign exchange	(203)	203	-	-	-	-	-	-	-
Finance costs	-	-	-	-	-	-	-	-	-
Changes in fair value of comparability milestone	-	-	-	-	-	-	-	-	-
Net change in fair value of convertible note liability	(374)	(378)	(752)	(432)	(435)	(867)	-	-	-
Loss on disposal of assets	-	-	-	-	-	-	-	-	-
Total other income (expense)	(513)	(134)	(647)	976	(1,533)	(557)	104	69	173
Profit (Loss) from operations before taxes	(4,615)	(5,490)	(10,105)	(4,325)	(8,419)	(12,744)	(7,435)	(7,513)	(14,948)
Income tax benefit (expense)	552	186	737	0	(2)	(2)	-	-	-
Net profit (loss)	(4,063)	(5,305)	(9,367)	(4,325)	(8,421)	(12,746)	(7,435)	(7,513)	(14,948)
Other Comprehensive gain (loss)	(492)	220	(272)	507	823	1,329	-	-	-
Comprehensive (loss)/income	(4,555)	(5,084)	(9,639)	(3,818)	(7,599)	(11,417)	(7,435)	(7,513)	(14,948)
Basic common shares outstanding (IMM-ASX), thousands	2,061,631	2,079,743	2,284,361	2,284,361	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328
Diluted common shares outstanding (IMM-ASX), thousands	2,061,631	2,079,743	2,284,361	2,284,361	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328
Basic net profit (loss) per share	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)
Diluted net profit (loss) per share	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)
ADRs outstanding (IMMP)	20,616	20,797	22,844	22,844	26,083	26,083	30,261	30,261	30,261
Net profit (loss) per ADR	(0.22)	(0.24)	(0.42)	(0.17)	(0.29)	(0.44)	(0.25)	(0.25)	(0.49)
Common Share to ADR Ratio	100	100	100	100	100	100	100	86	86

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Income Statement, Annual with Projections—Immuteq Limited (IMMP)

(Australian \$ thousands)	2015A	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E
Revenue:													
License revenue	-	175	-	2,630	173	169	283	333	1,011	-	-	-	-
Grant Revenue	1,167	887	3,316	3,214	3,571	4,107	4,928	6,161	8,625	12,506	16,883	19,416	21,357
Miscellaneous income	168	703	800	1,009	745	758	772	786	800	815	829	844	859
Product revenue	-	-	-	-	-	-	-	66,497	193,726	804,025	1,837,512	3,003,759	4,231,379
Total revenue	1,336	1,765	4,117	6,854	4,489	5,034	5,984	73,777	204,162	817,346	1,855,224	3,024,019	4,253,595
Operating expenses:													
Cost of goods sold	-	-	-	-	-	-	-	(13,964)	(36,808)	(136,684)	(312,377)	(480,602)	(634,707)
Research and development and intellectual property	(8,952)	(7,060)	(7,526)	(9,990)	(11,499)	(13,786)	(17,232)	(24,125)	(34,982)	(47,226)	(54,309)	(59,740)	(64,520)
Corporate administrative expense	(5,723)	(6,983)	(4,347)	(7,242)	(6,536)	(7,388)	(7,535)	(7,686)	(8,455)	(9,723)	(11,667)	(13,418)	(15,430)
Depreciation and amortization expenses	(1,341)	(1,993)	(1,702)	(1,809)	(1,575)	(1,466)	(1,339)	(1,223)	(1,117)	(1,021)	(933)	(852)	(779)
Total operating expenses	(16,017)	(16,035)	(13,574)	(19,041)	(19,610)	(22,639)	(26,107)	(46,999)	(81,362)	(194,654)	(379,287)	(554,612)	(715,435)
Profit (Loss) from operations	(14,681)	(14,270)	(9,458)	(12,187)	(15,121)	(17,605)	(20,123)	26,778	122,800	622,692	1,475,938	2,469,408	3,538,160
Other income (expense):													
Net gain on foreign exchange	538	-	0	323	-	-	-	-	-	-	-	-	-
Interest income	219	264	104	177	173	169	283	333	1,011	4,236	12,775	28,986	54,053
Net loss on fair value movement of warrants	-	-	-	(190)	-	-	-	-	-	-	-	-	-
Share-based payment to a strategic investor	-	(47,468)	-	-	-	-	-	-	-	-	-	-	-
Loss on foreign exchange	-	(564)	-	-	-	-	-	-	-	-	-	-	-
Finance costs	(18,365)	(8)	-	-	-	-	-	-	-	-	-	-	-
Changes in fair value of comparability milestone	-	(542)	-	-	-	-	-	-	-	-	-	-	-
Net change in fair value of convertible note liability	-	(608)	(752)	(867)	-	-	-	-	-	-	-	-	-
Loss on disposal of assets	(5)	-	-	-	-	-	-	-	-	-	-	-	-
Total other income (expense)	(17,613)	(48,926)	(647)	(557)	173	169	283	333	1,011	4,236	12,775	28,986	54,053
Profit (Loss) from operations before taxes	(32,294)	(63,196)	(10,105)	(12,744)	(14,948)	(17,436)	(19,840)	27,111	123,811	626,928	1,488,713	2,498,394	3,592,213
Income tax benefit (expense)	142	1,181	737	(2)	-	-	-	-	-	(118,780)	(286,041)	(482,054)	(694,262)
Net profit (loss)	(32,152)	(62,015)	(9,367)	(12,746)	(14,948)	(17,436)	(19,840)	27,111	123,811	508,148	1,202,672	2,016,340	2,897,951
Other Comprehensive gain (loss)	(57)	307	(272)	1,329	-	-	-	-	-	-	-	-	-
Comprehensive (loss)/income	(32,209)	(61,708)	(9,639)	(11,417)	(14,948)	(17,436)	(19,840)	27,111	123,811	508,148	1,202,672	2,016,340	2,897,951
Basic common shares outstanding (IMM-ASX), thousands	1,591,116	2,236,251	2,284,361	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328
Diluted common shares outstanding (IMM-ASX), thousands	1,591,116	2,236,251	2,284,361	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328
Basic net profit (loss) per share	(0.02)	(0.03)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	0.01	0.05	0.19	0.46	0.77	1.11
Diluted net profit (loss) per share	(0.02)	(0.03)	(0.00)	(0.00)	(0.01)	(0.01)	(0.01)	0.01	0.05	0.19	0.46	0.77	1.11
ADRs outstanding (IMMP)	53,037	74,542	22,844	26,083	30,261	32,761	37,344	39,427	39,427	39,427	39,427	39,427	39,427
Net profit (loss) per ADR	(0.61)	(0.83)	(0.42)	(0.44)	(0.49)	(0.53)	(0.53)	0.69	3.14	12.89	30.50	51.14	73.50
Common Share to ADR Ratio	30	30	100	100	86	74	66	66	66	66	66	66	66
Profitability Ratios													
Revenue Growth Rate		32.1%	133.3%	66.5%	-34.5%	12.1%	18.9%	1132.9%	176.7%	300.3%	127.0%	63.0%	40.7%
Gross Profit Margin	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	81.1%	82.0%	83.3%	83.2%	84.1%	85.1%
Operating Profit Margin	-1099.3%	-808.6%	-229.7%	-177.8%	-336.8%	-349.7%	-336.3%	36.3%	60.1%	76.2%	79.6%	81.7%	83.2%
Effective Tax Rate	0.4%	1.9%	7.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	18.9%	19.2%	19.3%	19.3%
Net Profit Margin	-2407.4%	-3513.9%	-227.5%	-186.0%	-333.0%	-346.4%	-331.6%	36.7%	60.6%	62.2%	64.8%	66.7%	68.1%

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Balance Sheet, Semiannual with Projections—Immutep Limited (IMMP)

(Australian \$ thousands)	1H17A	2017A	1H18A	2018A	1H19E	2019E
ASSETS						
Current assets:						
Cash and cash equivalents	16,570	12,237	13,702	23,476	16,556	10,069
Current receivables	1,600	2,194	3,803	3,432	3,096	4,094
Other current assets	492	1,488	820	1,736	732	607
Inventory	-	-	-	-	-	-
Total current assets	18,663	15,919	18,324	28,643	20,384	14,770
Non-current assets:						
Property, plant and equipment, net	24	24	25	26	26	25
Intangibles	19,473	19,020	18,697	18,329	17,533	16,771
Total non-current assets	19,497	19,045	18,722	18,356	17,558	16,796
Total assets	38,159	34,964	37,046	46,999	37,942	31,566
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)						
Current liabilities:						
Trade and other payables	1,245	2,589	2,159	3,664	945	949
Borrowings	-	-	-	-	-	-
Current tax plan	-	-	-	-	-	-
Employee benefits	37	43	96	190	190	190
Total current liabilities	1,282	2,632	2,255	3,853	1,135	1,139
Non-current liabilities:						
Convertible note liability	5,401.0	5,779.0	6,211.2	6,645.8	6,645.8	6,645.8
Warrant liability	-	-	1,422	2,945	2,945	2,945
Employee benefits	50	20	31	32	32	32
Deferred tax liability	171	-	-	-	-	-
Total non-current liabilities	5,623	5,799	7,665	9,623	9,623	9,623
Total liabilities	6,905	8,431	9,920	13,477	10,758	10,762
Stockholders' equity (deficit):						
Contributed equity	195,042	195,353	200,215	213,233	214,329	215,462
Reserves	62,747	63,019	63,076	64,874	64,874	64,874
Accumulated Losses	(226,534)	(231,839)	(236,164)	(244,585)	(252,019)	(259,533)
Total stockholders' equity (deficit)	31,254	26,532	27,127	33,522	27,184	20,804
Total liabilities and stockholders' equity (deficit)	38,159	34,964	37,046	46,999	37,942	31,566
Outstanding shares at end of period (thousands)	2,073,076	2,079,743	2,399,329	3,026,083	3,026,083	2,608,328
Outstanding ADRs at end of period (thousands)	20,731	20,797	23,993	30,261	30,261	30,261
Common share to ADR ratio	100	100	100	100	100	86
SELECTED METRICS (Australian \$ thousands, except per ADR)						
Current ratio	14.6	6.0	8.1	7.4	18.0	13.0
Working capital (in thousands)	17,380	13,287	16,069	24,790	19,249	13,631
Book value per ADS	1.51	1.28	1.13	1.11	0.90	0.69
Cash, cash equivalents and marketable securities per ADS	16,570	12,237	13,702	23,476	16,556	10,069
Debt (in thousands)	5,401	5,779	6,211	6,646	6,646	6,646
Debt to equity ratio	0.17	0.22	0.23	0.20	0.24	0.32

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Balance Sheet, Annual with Projections—Immutep Limited (IMMP)

(Australian \$ thousands)	2015A	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E
ASSETS													
Current assets:													
Cash and cash equivalents	6,760	20,880	12,237	23,476	10,069	22,429	32,156	32,046	162,759	653,552	1,808,489	3,777,844	6,639,299
Current receivables	315	168	2,194	3,432	4,094	2,758	2,160	38,266	45,636	102,168	222,627	362,882	510,431
Other current assets	948	623	1,488	1,736	607	1,328	1,775	1,782	1,914	2,149	2,520	2,854	3,242
Inventory	-	-	-	-	-	-	-	-	-	-	-	-	-
Total current assets	8,023	21,671	15,919	28,643	14,770	26,516	36,090	72,093	210,310	757,869	2,033,636	4,143,580	7,152,972
Non-current assets:													
Property, plant and equipment, net	298	32	24	26	25	25	24	24	24	23	23	22	22
Intangibles	22,662	20,852	19,020	18,329	16,771	15,314	13,983	12,768	11,658	10,645	9,720	8,876	8,104
Total non-current assets	22,960	20,883	19,045	18,356	16,796	15,338	14,007	12,792	11,682	10,668	9,743	8,898	8,126
Total assets	30,983	42,554	34,964	46,999	31,566	41,854	50,097	84,885	221,992	768,538	2,043,379	4,152,478	7,161,099
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)													
Current liabilities:													
Trade and other payables	2,770	1,423	2,589	3,664	949	1,056	1,077	3,095	6,471	20,930	46,324	70,624	92,942
Borrowings	1,508	-	-	-	-	-	-	-	-	-	-	-	-
Current tax plan	21	22	-	-	-	-	-	-	-	-	-	-	-
Employee benefits	80	28	43	190	190	190	190	190	190	190	190	190	190
Total current liabilities	4,380	1,472	2,632	3,853	1,139	1,246	1,267	3,285	6,660	21,119	46,514	70,813	93,131
Non-current liabilities:													
Convertible note liability	-	5,027.2	5,779.0	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8	6,645.8
Warrant liability	-	-	-	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4	2,945.4
Employee benefits	35.7	43.2	20.5	32.3	32.3	32.3	32.3	32.3	32.3	32.3	32.3	32.3	32.3
Deferred tax liability	1,878.3	694.2	-	-	-	-	-	-	-	-	-	-	-
Total non-current liabilities	1,914	5,765	5,799	9,623	9,623	9,623	9,623	9,623	9,623	9,623	9,623	9,623	9,623
Total liabilities	6,294	7,237	8,431	13,477	10,762	10,869	10,890	12,908	16,284	30,743	56,137	80,437	102,755
Stockholders' equity (deficit):													
Contributed equity	179,878	194,531	195,353	213,233	215,462	243,080	271,142	276,801	286,722	310,660	357,435	425,896	514,247
Reserves	5,268	63,258	63,019	64,874	64,874	64,874	64,874	64,874	64,874	64,874	64,874	64,874	64,874
Accumulated Losses	(160,456)	(222,472)	(231,839)	(244,585)	(259,533)	(276,969)	(296,809)	(269,698)	(145,887)	362,260	1,564,932	3,581,272	6,479,223
Total stockholders' equity (deficit)	24,690	35,318	26,532	33,522	20,804	30,985	39,207	71,977	205,709	737,795	1,987,242	4,072,042	7,058,344
Total liabilities and stockholders' equity (deficit)	30,983	42,554	34,964	46,999	31,566	41,854	50,097	84,885	221,992	768,538	2,043,379	4,152,478	7,161,099
Outstanding shares at end of period (thousands)	1,751,495	2,061,631	2,079,743	3,026,083	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328	2,608,328
Outstanding ADRs at end of period (thousands)	58,383	68,721	20,797	30,261	30,261	35,261	39,427	39,427	39,427	39,427	39,427	39,427	39,427
Common share to ADR ratio	30	30	100	100	86	74	66	66	66	66	66	66	66
SELECTED METRICS (Australian \$ thousands, except per ADR)													
Current ratio	1.8	14.7	6.0	7.4	13.0	21.3	28.5	21.9	31.6	35.9	43.7	58.5	76.8
Working capital (in thousands)	3,643	20,199	13,287	24,790	13,631	25,270	34,823	68,809	203,650	736,750	1,987,122	4,072,767	7,059,841
Book value per ADR	0.42	0.51	1.28	1.11	0.69	0.88	0.99	1.83	5.22	18.71	50.40	103.28	179.02
Cash, cash equivalents and marketable securities per ADR	6,760	20,880	12,237	23,476	10,069	22,429	32,156	32,046	162,759	653,552	1,808,489	3,777,844	6,639,299
Debt (in thousands)	-	5,027	5,779	6,646	6,646	6,646	6,646	6,646	6,646	6,646	6,646	6,646	6,646
Debt to equity ratio	-	0.14	0.22	0.20	0.32	0.21	0.17	0.09	0.03	0.01	0.00	0.00	0.00

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Cash Flow Statement, Semiannual with Projections—Immutep Limited (IMMP)

(Australian \$ thousands)	1H17A	2H17A	2017A	1H18A	2H18A	2018A	1H19E	2H19E	2019E
Net loss	(4,063)	(5,305)	(9,367)	(4,325)	(8,421)	(12,746)	(7,435)	(7,513)	(14,948)
Reconciliation of net loss to net cash:									
Depreciation and amortization	865	836	1,702	895	914	1,809	805	770	1,575
Share based payments	1,018	(156)	862	1,288	976	2,264	1,097	1,133	2,230
Changes in fair value of comparability milestone	-	-	-	-	-	-	-	-	-
Changes in fair value of US investor warrant	-	-	-	(1,333)	1,523	190	-	-	-
Non-cash share based payment to a strategic investor	-	-	-	-	-	-	-	-	-
US warrants transaction costs	-	-	-	-	493	493	-	-	-
Unrealized gain on exchange through the profit and loss	(327)	108	(219)	(102)	(299)	(402)	-	-	-
Net change in fair value of convertible note liability	374	378	752	432	435	867	-	-	-
(Gain)/loss on disposal of fixed asset	-	-	-	-	-	-	-	-	-
(Increase) decrease in operating assets and liabilities:									
Inventory	-	-	-	-	-	-	-	-	-
(Increase) in current receivables	(1,432)	(594)	(2,026)	(1,609)	371	(1,238)	336	(998)	(662)
(Increase) in other operating assets	131	(996)	(865)	668	(916)	(247)	1,004	125	1,129
Increase in trade and other payables	(177)	1,555	1,377	(430)	1,505	1,075	(2,719)	4	(2,714)
Increase/ (decrease) in employee benefits	16	(24)	(7)	63	95	158	-	-	-
(Decrease) in income tax payable	-	(22)	(22)	-	-	-	-	-	-
(Decrease) in deferred tax liability	(523)	(171)	(694)	-	-	-	-	-	-
Net cash used in operating activities	(4,118)	(4,389)	(8,507)	(4,452)	(3,325)	(7,777)	(6,911)	(6,479)	(13,390)
Cash Flows from Investing Activities:									
Funds from held-to-maturity investments	-	-	-	-	-	-	-	-	-
Proceeds from disposal of plant and equipment	-	-	-	-	-	-	-	-	-
Payments for purchase of plant and equipment	(1)	(5)	(7)	(5)	(6)	(12)	(8)	(8)	(16)
Payment for acquisition of subsidiary, net of cash acquired	-	-	-	-	-	-	-	-	-
Net cash provided by (used in) investing activities	(1)	(5)	(7)	(5)	(6)	(12)	(8)	(8)	(16)
Cash Flows from Financing Activities:									
Proceeds from issue of shares	-	0	0	3,806	13,162	16,968	-	-	-
Proceeds from issue of convertible notes	-	-	-	-	-	-	-	-	-
Repayment of borrowings	-	-	-	-	-	-	-	-	-
Proceeds from issue of warrants	-	-	-	2,755	-	2,755	-	-	-
Share issue transaction costs	(6)	(2)	(9)	(682)	(144)	(826)	-	-	-
Finance cost of warrants	-	-	-	-	(493)	(493)	-	-	-
Net cash provided by financing activities	(6)	(2)	(9)	5,880	12,525	18,405	-	-	-
Exchange rate adjustments on cash and cash equivalents	(184)	64	(121)	42	581	623	-	-	-
Net increase (decrease) in cash and cash equivalents	(4,309)	(4,333)	(8,643)	1,465	9,774	11,239	(6,919)	(6,487)	(13,406)
Cash and cash equivalents at beginning of period	20,880	16,570	20,880	12,237	13,702	12,237	23,476	16,556	23,476
Cash and cash equivalents at end of period	16,570	12,237	12,237	13,702	23,475	23,476	16,556	10,069	10,069
Cash Burn									
Cash burn: Sum of cash used in OpEx and Property & Equipment	(4,119)	(4,394)	(8,513)	(4,457)	(3,331)	(7,789)	(6,919)	(6,487)	(13,406)
Annual cash burn (Q x 4 or annual)	(8,238)	(8,789)	(8,513)	(8,915)	(6,663)	(7,789)	(6,919)	(12,974)	(13,406)
Years of cash remaining	2.0	1.4	1.4	1.5	3.5	3.0	2.4	0.8	0.8
Months of cash remaining	24.1	16.7	17.2	18.4	42.3	36.2	28.7	9.3	9.0

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Cash Flow Statement, Annual with Projections—Immutep Limited (IMMP)

(Australian \$ thousands)	2015A	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E
Net loss	(32,152)	(62,015)	(9,367)	(12,746)	(14,948)	(17,436)	(19,840)	27,111	123,811	508,148	1,202,672	2,016,340	2,897,951
Reconciliation of net loss to net cash:													
Depreciation and amortization	1,341	1,993	1,702	1,809	1,575	1,466	1,339	1,223	1,117	1,021	933	852	779
Share based payments	739	2,059	862	2,264	2,230	2,618	3,062	5,659	9,920	23,938	46,775	68,460	88,352
Changes in fair value of comparability milestone	-	542	-	-	-	-	-	-	-	-	-	-	-
Changes in fair value of US investor warrant	-	-	-	190	-	-	-	-	-	-	-	-	-
Non-cash share based payment to a strategic investor	18,338	47,468	-	-	-	-	-	-	-	-	-	-	-
US warrants transaction costs	-	-	-	493	-	-	-	-	-	-	-	-	-
Unrealized gain on exchange through the profit and loss	(1,040)	845	(219)	(402)	-	-	-	-	-	-	-	-	-
Net change in fair value of convertible note liability	-	608	752	867	-	-	-	-	-	-	-	-	-
(Gain)/loss on disposal of fixed asset	5	(18)	-	-	-	-	-	-	-	-	-	-	-
(Increase) decrease in operating assets and liabilities:													
Inventory	-	-	-	-	-	-	-	-	-	-	-	-	-
(Increase) in current receivables	5,959	(395)	(2,026)	(1,238)	(662)	1,336	599	(36,106)	(7,371)	(56,532)	(120,459)	(140,255)	(147,549)
(Increase) in other operating assets	351	325	(865)	(247)	1,129	(721)	(447)	(7)	(133)	(234)	(371)	(334)	(388)
Increase in trade and other payables	(1,188)	(1,492)	1,377	1,075	(2,714)	107	21	2,018	3,376	14,459	25,395	24,299	22,318
Increase/ (decrease) in employee benefits	0	(45)	(7)	158	-	-	-	-	-	-	-	-	-
(Decrease) in income tax payable	4	1	(22)	-	-	-	-	-	-	-	-	-	-
(Decrease) in deferred tax liability	(144)	(1,184)	(694)	-	-	-	-	-	-	-	-	-	-
Net cash used in operating activities	(7,786)	(11,310)	(8,507)	(7,777)	(13,390)	(12,632)	(15,266)	(102)	130,721	490,800	1,154,944	1,969,362	2,861,462
Cash Flows from Investing Activities:													
Funds from held-to-maturity investments	9,000	-	-	-	-	-	-	-	-	-	-	-	-
Proceeds from disposal of plant and equipment	-	130	-	-	-	-	-	-	-	-	-	-	-
Payments for purchase of plant and equipment	(48)	(27)	(7)	(12)	(16)	(8)	(8)	(8)	(8)	(7)	(7)	(7)	(7)
Payment for acquisition of subsidiary, net of cash acquired	(20,913)	-	-	-	-	-	-	-	-	-	-	-	-
Net cash provided by (used in) investing activities	(11,961)	103	(7)	(12)	(16)	(8)	(8)	(8)	(8)	(7)	(7)	(7)	(7)
Cash Flows from Financing Activities:													
Proceeds from issue of shares	7,745	13,761	0	16,968	-	25,000	25,000	-	-	-	-	-	-
Proceeds from issue of convertible notes	3,925	13,751	-	-	-	-	-	-	-	-	-	-	-
Repayment of borrowings	(237)	(1,508)	-	-	-	-	-	-	-	-	-	-	-
Proceeds from issue of warrants	-	-	-	2,755	-	-	-	-	-	-	-	-	-
Share issue transaction costs	(164)	(283)	(9)	(826)	-	-	-	-	-	-	-	-	-
Finance cost of warrants	-	-	-	(493)	-	-	-	-	-	-	-	-	-
Net cash provided by financing activities	11,268	25,720	(9)	18,405	-	25,000	25,000	-	-	-	-	-	-
Exchange rate adjustments on cash and cash equivalents	1,040	(393)	(121)	623	-	-	-	-	-	-	-	-	-
Net increase (decrease) in cash and cash equivalents	(7,440)	14,120	(8,643)	11,239	(13,406)	12,360	9,726	(110)	130,714	490,793	1,154,937	1,969,355	2,861,455
Cash and cash equivalents at beginning of period	14,200	6,760	20,880	12,237	23,476	10,069	22,429	32,156	32,046	162,759	653,552	1,808,489	3,777,844
Cash and cash equivalents at end of period	6,760	20,880	12,237	23,476	10,069	22,429	32,156	32,046	162,759	653,552	1,808,489	3,777,844	6,639,299
Cash Burn													
Cash burn: Sum of cash used in OPEX and Property & Equipment	(7,835)	(11,337)	(8,513)	(7,789)	(13,406)	(12,640)	(15,274)	(110)	130,714	490,793	1,154,937	1,969,355	2,861,455
Annual cash burn (Q x 4 or annual)	(7,835)	(11,337)	(8,513)	(7,789)	(13,406)	(12,640)	(15,274)	(110)	130,714	490,793	1,154,937	1,969,355	2,861,455
Years of cash remaining	0.9	1.8	1.4	3.0	0.8	1.8	2.1	292.1	Cash+	Cash+	Cash+	Cash+	Cash+
Months of cash remaining	10.4	22.1	17.2	36.2	9.0	21.3	25.3	3505.1	Cash+	Cash+	Cash+	Cash+	Cash+

Proprietary to B. Riley FBR, Inc. September 27, 2018

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Source: Company reports and B. Riley FBR Research

Discounted Cash Flow (DCF) Analysis—Immutep Limited (IMMP)

(AUD \$ thousands, except where indicated)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	Terminal Value
EBIT	(15,121)	(17,605)	(20,123)	26,778	122,800	622,692	1,475,938	2,469,408	3,538,160	-
Effective Tax Rate	-	-	-	-	-	0	0	0	0	-
Tax	-	-	-	-	-	(118,780)	(286,041)	(482,054)	(694,262)	-
EBIAT	(15,121)	(17,605)	(20,123)	26,778	122,800	503,912	1,189,897	1,987,353	2,843,898	-
ADD: Stock Based Compensation	2,230	2,618	3,062	5,659	9,920	23,938	46,775	68,460	88,352	-
ADD: Depreciation and Amortization	1,575	1,466	1,339	1,223	1,117	1,021	933	852	779	-
ADD: Changes in Working Capital	(2,248)	721	173	(34,095)	(4,128)	(42,307)	(95,435)	(116,290)	(125,619)	-
Less: Capex	(16)	(8)	(8)	(8)	(8)	(7)	(7)	(7)	(7)	-
Free Cash Flow to the Firm (FCFF)	(13,580)	(12,809)	(15,557)	(443)	129,703	486,557	1,142,162	1,940,368	2,807,403	17,768,370
Approval Probability Factor	1	1	1	0	0	0	0.06	0.06	0.06	0.06
Time Period (Years)	1	2	3	4	5	6	7	8	9	9
Discount Factor	0.88	0.75	0.64	0.54	0.46	0.39	0.33	0.28	0.24	0.24
Discounted FCFF	(11,982)	(9,594)	(9,892)	(15)	3,744	11,923	23,760	34,266	42,086	266,366

Terminal Value and NPV Worksheet

Discounted FCFF (2017-2026)	42,210
Terminal value	266,366
Implied Enterprise Value	308,576
Less: Net Debt (Cash)	(16,830)
Add: Investments	-
Implied Market Cap	325,405
Exchange Rate (AUD:USD)	1.41
Implied Market Cap (USD)	231,038
NPV per share (target price, USD)	7.75
Current Market Price	\$3.62
Upside/(Downside)	114%
ADRs Outstanding (est. end of 2018)	30,260.83
Discount Rate	17.8%
Long term growth rate (g)	2.0%

Sensitivity Analysis

		Terminal Growth Rate				
Discount Rate		0.0%	1.0%	2.0%	3.0%	4.0%
	15.8%	8.75	9.25	10.00	10.50	11.25
	16.8%	7.75	8.25	8.75	9.25	9.75
	17.8%	7.00	7.25	7.75	8.00	8.50
	18.8%	6.25	6.50	6.75	7.00	7.50
	19.8%	5.50	5.75	6.00	6.25	6.50

Proprietary to B. Riley FBR, Inc. September 27, 2018
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 Source: Company reports and B. Riley FBR Research

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- ⁸ Company reports and B. Riley FBR Research.
- ⁹ Company reports and B. Riley FBR Research.

Valuation

Our 12-month price target of \$7.75 per ADS is based on a DCF analysis of revenues and adjusted FCFF projected into 2027, with cash flows adjusted based on the probability of gaining regulatory approval. A WACC-calculated 17.8% discount rate and a 2% terminal growth rate were applied to the DCF analysis.

Risks

Developmental risks. Immutep's immunotherapy pipeline is in various stages of clinical development. With no products expected to reach the market in the near term, the time line we project for Immutep assumes that clinical development will proceed with no significant delays in trial initiation or with regard to enrollment or regulatory issues. Since we project that Immutep's leading drug candidate, eftilagimod, will not reach the market until 2022, it may be necessary to make substantial changes to our valuation of the shares if there are any delays or changes in the standard of care that may arise during this period due to new advancements in science or medical approaches or changes in medical care policy.

Transition-related risks. Immutep will face substantial risks associated with the transition from a research and development company to a company manufacturing, marketing, and selling products. Transition-related risks include the ability to establish manufacturing and production systems, including fill-and-finish, sales and distribution networks, and other related commercial processes that the company does not currently have in place. While we recognize some of these risks may be partially mitigated by their relationship with established CMOs, these risks may still require significant financial resources to be properly addressed. Proper and effective training of sales and marketing personnel, as well as treating physicians, could delay or impede the timing of commercial growth and success. These risks apply regardless of whether Immutep decides to build these capabilities internally or to outsource them to third parties.

Clinical risks. Clinical trial results are critical in advancing product candidates toward regulatory agency approval and are highly dependent on the quality of clinical trial design and execution, patient participation, patient follow-up, and data collection and analysis. Positive results from preclinical and early-stage clinical trials do not assure positive results in confirmatory later-stage and registrational clinical studies. Negative or inconclusive results can substantially delay or lead to the discontinuation of the development of product candidates.

Regulatory risks. The FDA, EMA, and other regulatory agencies oversee testing, approval, and monitoring of drugs in development and on the market. Immutep is subject to review by these and other agencies prior to and following market approval to maximize positive impact, minimize health risks, and ensure quality of treatment. Adverse decisions by regulatory agencies can result in delays, financial penalties, and denial of market access for the company's product candidates that would significantly affect our valuation of the company.

Commercial risks. Revenue growth relies on demand for products based on efficacy and safety and the ability to pay for cost of treatment. Treatment cost can be a significant impediment to revenue growth and is dependent on domestic and international medical policies and access to medical care that is not in the control of the company. Additionally, market penetration and adoption is dependent on outreach and marketing to treating doctors. The scope and effectiveness of this outreach is critical to success. Immutep may choose to outsource some outreach activities to third parties and would, therefore, be dependent on their capabilities.

Financial risks. Immutep currently has limited access to additional capital. Actions taken to raise capital as needed could have a significant dilutive effect on current shareholders or present an additional burden if capital is obtained in the form of newly acquired debt.

Manufacturing risks. The establishment of scalable production processes and distribution networks will be pivotal to the transition from a research and development-focused to market-driven company. Options to facilitate this process may include the use of partnerships or agreements with third parties that are not currently built into our company valuation.

Competitive risks. Immutep operates in a highly competitive environment that includes both currently available treatments and treatments still in development. Since available treatments have the advantage of already having an established market presence, they represent substantial headwinds faced by new products in gaining market share. Unanticipated development of alternative treatments and advances in science and medical care cannot be predicted and cannot be accounted for in our company valuation.

Legal and intellectual property risks. The current and ongoing value of the company lies in the security of its intellectual property and the present state of medical care policy. Changes in either matter may have a material impact on the company's business development. If challenged, defending its intellectual property could result in substantial costs.

Market and investment risks. The valuations presented here represent what we believe to be a fair estimate of the market value of the company at the present time. The market and economic influences can cause actual market values to deviate substantially.

Miscellaneous risks. The risks listed here represent a fair assessment of major risks faced by the company and investors in the company, but in no way should this be considered a comprehensive list. Other risks may exist that have not been fully appreciated or accounted for in this report.

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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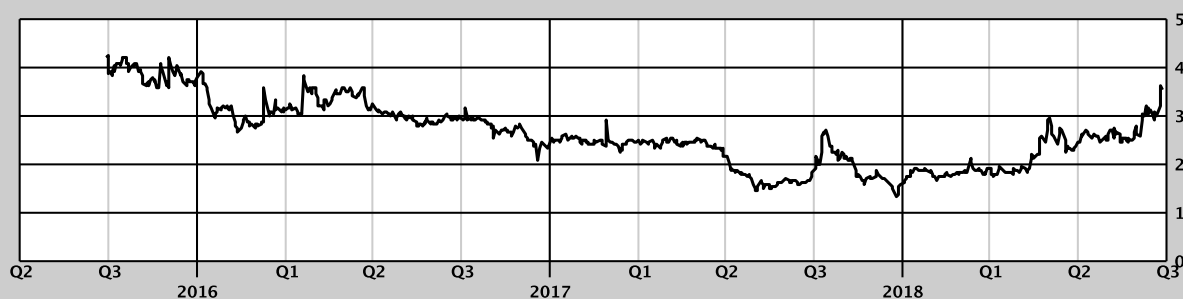
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