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## Immuron Limited (IMRN US - \$3.32 - Buy)

### Oral Immunotherapies for Infectious Diseases | Rating Buy | PT\$6

#### Key Points

On October 14, 2019: Immuron reported 1Q FY2020 sales results for Travelan, a commercial over-the-counter (OTC) GI and digestive health supplement. Sales momentum for the product continued to improve into the first quarter of the fiscal year 2020, benefiting from increasing consumer awareness.

Global Immuron sales in 1Q were AUD 741K, up 54% year-over-year, with continued growth in all geographic markets. Total North American sales for Travelan reached AUD 269K. In the US, Q1 sales grew 81% year-on-year to AUD 232K, with continued expansion at Passport Health Travel Clinics, Medique (Amazon), and Medico Mart. In Canada, Q1 sales reached AUD 38K.

In Q1 FY2020, Travelan sales in Australia grew by 34% year-over-year, to reach AUD 458K. Sales strength reflected the in-pharmacy merchandising program and promotional catalog activity in pharmacy banners.

**OTC Asset – Travelan.** Travelan carries the designation by TGA and Health Canada for the prevention of Traveler's Diarrhea. The product uses hyperimmune BCP from cows vaccinated against various strains of ETEC to protect against and reduce the risk of TD, as well as address minor gastrointestinal disorders. Travelan is commercially available in Australia, U.S.A., and Canada.

**Operational Milestones.** For FY 2019, ended June 30, sales of Travelan in North America reached AUD 1.16M, an increase of 52%. In the United States, Travelan FY19 revenue reached AUD 1.02M. Global Immuron revenue grew by 29% YoY in FY19, reaching AUD 2.6M.

**Platform.** The basis of the company's technology platform enables the development of medicines across a broad range of diseases, and this includes infectious diseases and immune-mediated disorders. The dairy origins of Immuron's antibodies classify the technology, enables commercialization of the platform through multiple regulatory pathways, including prescription, over-the-counter medicines, and dietary supplements.

**FDA registration for clinical development of IMM-124E.** In April 2019, Immuron indicated the clinical development of IMM-124E through an FDA registration pathway as a drug to prevent travelers' diarrhea. This process enhances the commercialization of the Travelan/IMM-124E franchise. The company anticipates a meeting with FDA in second-half 2019 for discussions on a new IND for travelers' diarrhea. A successful clinical program and approval by the FDA of IMM-124E could lead to increases in the marketing of an approved drug with a claim of specifically preventing travelers' diarrhea.

**Product Pipeline - C. difficile infection (CDI).** IMM-529, developed in collaboration with Dr. Dena Lyras at Monash University, targets the virulent Toxin B (spores, and vegetative cells). This multi-pronged approach has yielded positive results in the pre-clinical studies, which includes the prevention of primary disease and suppression of recurrence.

#### Summary

In the short- and medium-term the company sells and licenses Travelan and Protectyn over-the-counter products. In the long-run, the company is researching and developing prescription products, principally for the treatment of NASH and C.difficile.

#### Rating, Price and Target

Symbol	IMRN
Rating	Buy
Price	\$3.32
Price Target	\$6.00

#### Market Data

Market Cap (M)	\$13.50
Shares Outstanding (M)	4.10
Float (M)	2.78
Total Debt (M)	NM
Net Cash/Debt (\$M)	\$3.60
Dividend	NM

FYE Jun	2018A	2019A	2020E
EPS	(2.30)	(3.20)	(3.00)
Revenue (M) <sup>1</sup> (AUD)	1.8	2.4	5.0

<sup>1</sup>Fiscal Year End June 30,

#### Company Description

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a novel and safe technology platform with one commercial asset Travelan generating revenue. Immuron's lead clinical candidate, IMM-124E, is presently being developed as a drug to prevent Travelers' Diarrhea. Immuron's second clinical-stage asset, IMM-529, targets Clostridium difficile Infections (CDI), and is presently in a clinical trial in CDI patients. These products together with the Company's other preclinical immunotherapy pipeline under development targeting immune-relate and infectious diseases are anticipated to meet pressing needs in the global immunotherapy market.

## Overview

Immuron is both a commercial and a clinical-stage biopharmaceutical company with research targeted on the development and productization of a novel class of immunomodulator polyclonal antibodies that can be specifically targeted to treat a variety of gastrointestinal (GI) associated infectious agents.

The company's oral polyclonal antibodies offer precision delivery within the confines of the GI and do not impact the bloodstream. Immuron's lead immunomodulatory product candidates, IMM-124E and IMM-529, are anticipated to improve on the existing treatment paradigms for prevention of traveler's diarrhea, and for *Clostridium difficile* (*C. difficile*), respectively.

The safety profile of Immuron's drug candidates can benefit from the record of safety established from global sales of Travelan, an OTC product that has been on the market since 2004 as a preventative to Traveler's Diarrhea. The available regulatory pathways to commercialize the company's product platform include prescription, over-the-counter medicines, and dietary supplements. The Company markets an

Immuron reported a loss for the year ended June 30, 2019 of AUD 4.6M (2018: AUD 3.0M). Net Assets decreased to AUD 7.4M compared with AUD 8.4M at June 30, 2018, including cash reserves of AUD 5.1M (2018: AUD 4.7M)

As of June 30, 2019, and June 30, 2018, Immuron's accumulated deficit was AUD\$57 million and AUD\$53 million, respectively

## Takeaways

**Recent Financials.** On October 14, 2019: Immuron reported 1Q FY2020 sales results for Travelan, a commercial over-the-counter (OTC) GI and digestive health supplement. Sales momentum for the product continued to improve into the first quarter of the fiscal year 2020, benefiting from increasing consumer awareness.

Global Immuron sales in 1Q were AUD 741K, up 54% year-over-year, with continued growth in all geographic markets. Total North American sales for Travelan reached AUD 269K. In the US, Q1 sales grew 81% year-on-year to AUD 232K, with continued expansion at Passport Health Travel Clinics, Medique (Amazon), and Medico Mart. In Canada, Q1 sales reached AUD 38K.

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**OTC Asset – Travelan.** Travelan carries the designation by TGA and Health Canada for the prevention of Traveler's Diarrhea. The product uses hyperimmune BCP from cows vaccinated against various strains of ETEC to protect against and reduce the risk of TD, as well as address minor gastrointestinal disorders. Travelan is commercially available in Australia, U.S.A., and Canada.

### Figure 1. Immuron Limited - Highlights

IMRN is a commercial and clinical-stage biopharmaceutical company focusing on infectious diseases with oral immunoglobulin-based therapies

- Validated Technology Platform – with One Registered Asset, **Travelan® Generating Revenue**
- IMM-124E & IMM-529, in **Clinical Development** for Treatment of Gastrointestinal Disorders and *C. difficile* Infections
- Plan for Accelerated **Regulatory Path** to Approval for IMM-124E (Travelan®) as Drug to Prevent Travelers' Diarrhea in USA

Company reports and ThinkEquity estimates

**Operational Milestones.** For FY 2019 ended June 30, sales of Travelan in North America reached AUD 1.16M, an increase of 52%. In the United States, Travelan FY19 revenue reached AUD 1.02M. Global Immuron revenue grew by 29% YoY in FY19, reaching AUD 2.6M.

The IMM-124E drug candidate (which contains the same active pharmaceutical ingredient as Travelan) has the potential to prevent travelers' diarrhea. The clinical development of this drug candidate, for the prevention of traveler's diarrhea, is planned to be through an FDA 505(b)(2) pathway.

IMM-124E is also in NIH sponsored Phase 2 clinical trials to treat alcoholic steatohepatitis (SAH) and pediatric nonalcoholic fatty liver disease. The company recently reported results from the SAH trial (see below). The release of top-line data by the NIH, for pediatric NAFLD, is on track for the first quarter of 2020.

The company is evaluating IMM-529, targeting patients with recurrent *C. difficile* infections where current-day standard-of-care antibiotics typically lead to high rates of recurrence. Immuron plans to file an IND with the FDA in 2020 for clinical development of IMM-529, expanding locations for patient enrollment to U.S. sites.

Immuron's lead drug assets target prevalent diseases with a significant unmet need, the prevention of traveler's diarrhea, and *C. difficile*.

**Technology Platform.** The company's technology platform is an antigen targeted hyperimmune bovine colostrum powder (BCP) for pharmaceutical use. Cows, before calving, are immunized with vaccines to ensure immunogenicity. Polyclonal antibodies are collected from the harvested first milk. The end product is colostrum that contains a high level of antibodies and Immunoglobulin G1.

The basis of the company's technology platform enables the development of medicines across a broad range of diseases, and this includes infectious diseases and immune-mediated disorders. The dairy origins of Immuron's antibodies classify the technology, enables commercialization of the platform through multiple regulatory pathways, including prescription, over-the-counter medicines, and dietary supplements.

**FDA registration for clinical development of IMM-124E.** In April 2019, Immuron indicated the clinical development of IMM-124E through an FDA registration pathway as a drug to prevent travelers' diarrhea. This process enhances the commercialization of the Travelan/IMM-124E franchise. The company anticipates a meeting with FDA in second-half 2019 for discussions on a new IND for travelers' diarrhea. A successful clinical program and approval by the FDA of IMM-124E could lead to increases in the marketing of an approved drug with a claim of specifically preventing travelers' diarrhea.

**Clinical Studies IMM-124E.** Additional clinical studies have been conducted with IMM-124E. The first, a Phase II for severe alcoholic hepatitis performed under FDA (IND #015675) and supported by the NIAAA. The second, an NIH funded Phase II for pediatric patients with non-alcoholic fatty liver disease conducted under FDA (IND #017066).

**SAH Trial.** In August 2019, top-line results were released from the severe alcoholic hepatitis trial. Dr. Arun Sanyal of Virginia Commonwealth University was the lead Principal Investigator. The end-point of this study was to evaluate the safety and efficacy of IMM-124E as compared with a placebo in patients with SAH. Results showed that IMM-124E is safe to use in patients with SAH. However it does not reduce circulating lipopolysaccharide levels, mortality, or have an impact on the model for end-stage liver disease score in the study population. Immuron will not continue the clinical development of IMM-124E, specifically to treat SAH.

**Travelers' Diarrhea treatment pathway.** The safety data generated from the SAH patients (n=57), as well as data from the six-month treatment study of IMM-124E in non-alcoholic steatohepatitis under FDA IND #014933 (n=133) were submitted to the FDA to support the clinical development plan for IMM-124E to prevent travelers' diarrhea.

**NAFLD.** The NIH-funded Phase II double-blind, placebo-controlled, randomized clinical trial of IMM-124E in pediatric non-alcoholic fatty liver disease (NAFLD) patients is underway at Emory University, led by Dr. Miriam Vos, a specialist in the treatment of GI disease in children, including NAFLD and obesity. Top-line results for this study are expected in 2020.

**Product Pipeline - *C. difficile* infection (CDI).** IMM-529, developed in collaboration with Dr. Dena Lyras at Monash University, targets the virulent Toxin B (spores, and vegetative cells). This multi-pronged approach has yielded positive results in the pre-clinical studies, which includes the prevention of primary disease and suppression of recurrence.

**Clinical Status of IMM-529.** In March 2019, Immuron provided an update on the status of the IMM-529 clinical trial in patients with CDI. The Phase I/IIa clinical trial, initiated at the end of 2017 at clinics in Israel, for patients with *C. difficile* had not enrolled patients in sufficient numbers. The company is to focus on the

further development of the drug candidate specifically in the treatment of patients suffering from *C. difficile* infections. The company anticipates a meeting with the FDA in 1H2020 to explore further the development of treating patients with CDI.

In March 2019, the United States PTO issued a patent for a method to treat Clostridium difficile with IMM-529. *C. difficile* remains a major medical problem globally with an annual economic burden estimated at USD 10 billion and killing over 40,000 Americans annually alone.

**Market Opportunity – *C. difficile* infection (CDI).** The incidence of *C. difficile* infections has increased dramatically globally over the past two decades. In the US, the estimated rate of *C. difficile* infection in 2011 was 453,000. In 2013, CDC categorized *C. difficile* infection in the highest priority category of antimicrobial resistance threats.

**Business Model.** The IMM-529E neutralizes the disease but does not impact the rest of the microbiome. IMM-529E binds to not only the toxin B but to the spores and vegetative cells – reducing the likelihood of recurrence, which is due to the hardy nature of this Gram-positive bacterium. This pharmacological approach, unlike antibiotics, does not disturb the microbiome.

Immuron has partnered with Dr Dena Lyras, one of the leading experts in *C. difficile*. The strategy is to file an IND with the FDA for IMM-529 to treat *C. difficile* infections and develop a clinical plan that explores the potential for IMM-529 to reduce recurrent *C. difficile* infections.

Immuron will likely retain control of IMM-529 for the treatment of *C. difficile* infections, as there is a lot of value in this asset.

**Other Development Programs — U.S. DoD Travelan Shigellosis Animal Study.** In June 2019, the company provided an update on the cooperative research and development efforts with the United States Department of Defense (DoD). The R&D initiatives with the U.S. Army focus on Shigella research. The company's associates at the Armed Forces Research Institute of Medical Sciences (AFRIMS), a Bangkok-based laboratory of Institute of Research (WRAIR), performed the research.

The company also reported the completed manufacture of three new Shigella-specific bovine colostrum therapeutic products using proprietary vaccines developed by WRAIR. The three Immuron Shigella-specific therapeutic products will go on to evaluation in WRAIR's preclinical models of shigellosis.

**Management Team.** Immuron's senior management team has experience in designing and developing therapeutics, building a stable manufacturing supply chain, and bringing products to the market at large pharma and biotechnology companies. The Advisory Board has thought leaders in their field, Dr. Arun Sanyal in NASH and Professor Dena Lyras in *C. difficile*.

**Market Protection.** Immuron expects that any of their product candidates approved under a Biologics License Application (BLA) could qualify for a twelve-year exclusivity against biosimilar competition.

**Platform with a long runway.** IMM-124E and IMM-529 are the initial drug candidates from Immuron's bovine polyclonal colostrum technology. The company is currently collaborating with the U.S. DoD on the development of additional product candidates utilizing the military's Shigella, Campylobacter and ETEC vaccines.

Shigella kills a million people a year. And Campylobacter is a major cause of acute infectious diarrhea in Southeast Asia. The results from this collaboration with the DoD show potential not only for military applications. Immuron could potentially have a product for those diseases available for civilian purposes that is paid for by the U.S. Army, U.S. Navy or Department of Defense. The Company might have a product ready for commercial launch over the next few years at minimal cost to investors.

**Summary.** In the short- and medium-term the company sells and licenses Travelan and Protectyn over-the-counter products. In the long-run, the company is researching and developing prescription products, principally for the treatment of NASH and *C. difficile*.

## Valuation

Our 12-month price target, based on a forecast enterprise value of USD 25 million, or \$6 per share, uses 160 million shares (4 million ADS) outstanding at the end of fiscal 2020. We performed a discounted cash flow analysis of the projected unlevered free cash flows of Immuron for the fiscal years ending June 30, 2020 through June 30, 2023. We define free cash flow as the cash generated by the Company's existing businesses and future new initiatives that is available either to reinvest, reduce its debts, or to distribute to shareholders.

The discounted cash flow analysis was used to determine the net present value of projected unlevered free cash flows utilizing an appropriate cost of capital for the discount rate, which reflects the relative risk associated with these cash flows as well as the rates of return that security holders could expect to realize on alternative investment opportunities with similar risk profiles to Immuron.

We used a discount rate of 15% to discount the projected unlevered free cash flows related to the Immuron's existing product lines, its future new initiative growth opportunities, and the estimated terminal value.

We believe that this discount rates is consistent with the rate of return that shareholders could expect to realize on alternative investment opportunities with similar risk profiles to the Company's existing and new initiative growth opportunity business.

We calculated the projected unlevered free cash flows by taking Immuron's earnings before interest and taxes (EBIT), subtracting taxes, adding back depreciation and amortization, and subtracting capital expenditures and changes in working capital.

We calculated the terminal value in 2023 using a perpetuity growth formula by capitalizing the normalized fiscal 2023 free cash flow using a 3.0% terminal growth rate and a discount rate of 15%.

We use 5x revenue multiple valuation for terminal value, in line with peer group valuation. Based on these assumptions, the discounted cash flow analysis indicated an estimated enterprise value for Immuron of USD 25 million.

Immuron is well-positioned to address unmet medical needs in large opportunity markets. The company has two clinical assets and is planning to take IMM-124E into a phase III registration trial specifically to prevent travelers' diarrhea. Strategically, licensing deals and M&A provide valuation support.

## Target Markets

The company's primary assets target prevalent diseases with major unmet needs: Travelers Diarrhea and C. difficile.

### Travelers Diarrhea

Travelers' diarrhea is a global problem affecting 10–40% of travelers to low-and-middle-income countries<sup>1</sup>. Although its incidence has declined in the last three decades, likely as a result of better hygienic conditions in destination countries and among travelers, travelers' diarrhea continues to cause significant alterations of travel plans and accounts for one- third of visits to post travel clinics<sup>2</sup>. Its cause was traditionally thought to be largely bacterial. Molecular diagnostic methods have increased the understanding of the role played by viruses, including adenovirus, norovirus, and rotavirus, as well as protozoal pathogens and the difficult-to-culture organisms including C. difficile<sup>3</sup>.

**Figure 2. FDA Approved Multiplex Panels for Gastrointestinal Pathogens**

<u>Assay</u>	<u>Manufacturer</u>	<u>Number of pathogens detected</u>	<u>Time to result (hours)</u>
Verigene EP	Luminex Corp.,Austin, TX	9	<2
Lumine GPP	Luminex Corp.,Austin, TX	14	5
BioFire GIP	BioFire Diagnostics, Salt Lake City, UT	22	1

Sources: FDA, Company Reports and ThinkEquity estimates

New guidelines were published in 2017 by the International Society of Travel Medicine and the Infectious Diseases Society of America. A change from previous guidelines was to introduce a functional classification of severity of travelers' diarrhea; the mild disease is defined as tolerable and not interfering with planned activities, the moderate disease is defined as distressing or interfering with planned activities, and severe disease is defined as diarrhea that is incapacitating or accompanied by bloody stools.

In addition, rapid, multiplex molecular diagnostic techniques have begun to replace conventional stool cultures in many laboratories for the identification of gastrointestinal pathogens. Progress has also been made in the quest for an effective vaccine. Finally, bacterial resistance genes have continued to propagate worldwide, complicating treatment and raising concerns about the implications of asymptomatic carriage<sup>4</sup>.

<sup>1</sup> Connor et al. J Travel Med 2013

<sup>2</sup> Steffen et al. JAMA 2015

<sup>3</sup> Eckbo et al. Infec Dis Clin North Am 2019

<sup>4</sup> Riddle et al. J Travel Med 2017

## Treatment

### Carriage of standby antibiotics

Travelers are commonly provided with antibiotics to be carried on standby with instructions to use them in case of moderate-to-severe travelers' diarrhea, along with rehydration and antidiarrheals. Unfortunately, this strategy may encourage unnecessary antibiotic use. However, carriage of standby antibiotics may avoid travelers acquiring counterfeit medications in Africa or Asia when they do become ill, which has the potential to contribute to antimicrobial resistance because of inadequate dosing, in addition to other risk factors<sup>5</sup>.

**Figure 3. Antibiotics for Treatment of Travelers Diarrhea**

Drug	Some Available Formulations	Adult Dosage	Some Adverse Effects/Pregnancy	Comments	Cost <sup>2</sup>
Azithromycin – generic <i>Zithromax</i> (Pfizer)	250, 500, 600 mg tabs	1000 mg once or divided bid <sup>4</sup> or 500 mg once/day x 3 days	<ul style="list-style-type: none"> <li>▶ GI disturbances</li> <li>▶ Headache, dizziness</li> <li>▶ Vaginitis</li> <li>▶ QT interval prolongation</li> </ul>	<ul style="list-style-type: none"> <li>▶ Active against most invasive and noninvasive bacterial pathogens that cause TD</li> <li>▶ Preferred antibiotic for empiric treatment of moderate or severe TD</li> </ul>	\$8.40 206.00
Ciprofloxacin <sup>3</sup> – generic <i>Cipro</i> (Bayer)	100, 250, 500, 750 mg tabs; 250 mg/5 mL, 500 mg/5 mL PO susp	750 mg once <sup>4</sup> or 500 mg bid x 3 days	<ul style="list-style-type: none"> <li>▶ GI disturbances</li> <li>▶ CNS toxicity (delirium, agitation, nervousness, and disturbances in attention, memory, and orientation)</li> <li>▶ Tendinitis and tendon rupture</li> <li>▶ <i>Clostridium difficile</i> infection</li> <li>▶ Peripheral neuropathy</li> <li>▶ Hypo- and hyperglycemia</li> <li>▶ QT interval prolongation</li> <li>▶ <b>Pregnancy:</b> no adequate studies in pregnant women; observational data suggest that teratogenic effects are unlikely to occur at therapeutic doses</li> </ul>	<ul style="list-style-type: none"> <li>▶ Active against most invasive and noninvasive bacterial pathogens that cause TD</li> <li>▶ Single-dose regimens are preferred over 3-day regimens</li> <li>▶ Should not be used for empiric treatment of TD in South and Southeast Asia due to fluoroquinolone resistance</li> <li>▶ Increases risk for acquisition of multidrug-resistant pathogens such as ESBL-PE</li> <li>▶ Not recommended for use in children</li> </ul>	1.60 34.40
Levofloxacin <sup>3</sup> – generic <i>Levaquin</i> (Janssen)	200, 500, 750 mg tabs; 250 mg/10 mL PO soln	500 mg once <sup>4</sup> or once/day x 3 days	<ul style="list-style-type: none"> <li>▶ Tendinitis and tendon rupture</li> <li>▶ <i>Clostridium difficile</i> infection</li> <li>▶ Peripheral neuropathy</li> <li>▶ Hypo- and hyperglycemia</li> <li>▶ QT interval prolongation</li> <li>▶ <b>Pregnancy:</b> no adequate studies in pregnant women; observational data suggest that teratogenic effects are unlikely to occur at therapeutic doses</li> </ul>	<ul style="list-style-type: none"> <li>▶ Should not be used for empiric treatment of TD in South and Southeast Asia due to fluoroquinolone resistance</li> <li>▶ Increases risk for acquisition of multidrug-resistant pathogens such as ESBL-PE</li> <li>▶ Not recommended for use in children</li> </ul>	1.20 90.10
Ofloxacin <sup>3</sup> – generic	200, 300, 400 mg tabs	400 mg once <sup>4</sup> or once/day x 3 days	<ul style="list-style-type: none"> <li>▶ Hypo- and hyperglycemia</li> <li>▶ QT interval prolongation</li> <li>▶ <b>Pregnancy:</b> no adequate studies in pregnant women; observational data suggest that teratogenic effects are unlikely to occur at therapeutic doses</li> </ul>	<ul style="list-style-type: none"> <li>▶ Increases risk for acquisition of multidrug-resistant pathogens such as ESBL-PE</li> <li>▶ Not recommended for use in children</li> </ul>	49.20
Rifamycin – <i>Aemcolo</i> (Cosmo/Aries)	194 mg tabs	388 mg bid x 3 days	<ul style="list-style-type: none"> <li>▶ Well tolerated in general</li> <li>▶ Most common: constipation, headache</li> <li>▶ Abdominal pain and pyrexia can occur</li> <li>▶ <b>Pregnancy:</b> no data on use in pregnant women; not expected to result in fetal exposure</li> </ul>	<ul style="list-style-type: none"> <li>▶ Minimally absorbed oral antibiotic FDA-approved for treatment of adults with TD</li> <li>▶ Shortened duration of TD caused by noninvasive strains of <i>E. coli</i> by about 1 day</li> <li>▶ Similar in efficacy to ciprofloxacin for TD caused by</li> </ul>	144.00
Rifaximin – <i>Xifaxan</i> (Salix)	200, 550 mg tabs	200 mg tid x 3 days <sup>6</sup>	<ul style="list-style-type: none"> <li>▶ Well tolerated in general</li> <li>▶ Hypersensitivity reactions have been reported</li> <li>▶ <b>Pregnancy:</b> no data on use in pregnant women; teratogenic in animals at doses 2-33 times the usual human oral dose</li> </ul>	<ul style="list-style-type: none"> <li>▶ Minimally absorbed oral antibiotic FDA-approved for treatment of TD in patients ≥12 years old</li> <li>▶ Similar in efficacy to ciprofloxacin for TD caused by noninvasive pathogens</li> <li>▶ Should not be used to treat diarrhea complicated by fever and/or bloody stools</li> </ul>	186.40

ESBL-PE = extended-spectrum beta-lactamase-producing Enterobacteriaceae; soln = solution; susp = suspension; TD = travelers' diarrhea  
 1. Addition of loperamide to antibiotic therapy (4 mg initially, followed by 2 mg after each loose stool [max 16 mg/24 hrs]) results in more rapid improvement of TD symptoms.  
 2. Approximate WAC for 3 days' treatment. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers. Source: AnalySource Monthly. www.fdbhealth.com/policies/drug-pricing-policy.  
 3. Not FDA-approved for treatment of travelers' diarrhea.

Sources: www.fdbhealth.com; AnalySource Monthly; First DataBank; Riddle et al. Clin Infect Dis 2017; The Medical Letter

### Rifamycin SV-MMX: a potential new treatment for travelers' diarrhea

Rifamycin SV-MMX is a poorly absorbed oral rifaximin derivative compounded to optimize drug delivery to the distal small bowel and colon. In an initial randomized trial published in 2014, it was found to be superior to placebo for the endpoint of time to last unformed stool<sup>6</sup>.

Although the potential decreased carriage of resistant bacteria is appealing, the medical community advises caution if invasive bacterial pathogens are suspected, because of Rifamycin SV-MMX's lack of absorption.

### Chemoprophylaxis

Despite strong evidence for the efficacy of prophylactic antibiotics for travelers' diarrhea, they are not recommended for most travellers by the ISTM travelers' diarrhea guidelines, except those at high risk for complications if they acquire travelers' diarrhea, because of concerns over antimicrobial resistance, as well as adverse events of Azithromycin and Ciprofloxacin commonly used as prophylaxis for travelers' diarrhea<sup>7</sup>.

### Summary

Travelers' diarrhea remains a global problem resulting in much morbidity, inconvenience, and health-care utilization by travelers. While there has been diagnostic progress, PCR-based panels have to be carefully interpreted in the clinical context given the limited specificity that has been observed in travelers.

<sup>5</sup> Collins et al. Antimicrob Resis Infect Control 2012

<sup>6</sup> Dupont et al. J Travel Med 2014

<sup>7</sup> Hitch et al. J Travel Med 2018

Antimicrobials must be used judiciously for treating travelers' diarrhea particularly in the context of their unclear efficacy compared with supportive care as well as the continued global emergence of antimicrobial resistance. Immuron's Travelan, an oral immunoglobulin based therapy, could prove to be a cost-effective treatment measure.

### *C. Difficile*

*C. difficile* is a significant cause of healthcare-associated diarrhea and is increasingly present in the community. *C. diff* is implicated in 10-25% of antibiotic-associated-diarrhea<sup>8</sup>. It has been recognized as a significant cause of healthcare-associated diarrhea in adult patients and is responsible for large outbreaks in hospital settings<sup>9</sup>. *C. diff* infection is mediated by toxins —TcdA and TcdB— that disrupt tight junctions destroy the actin cytoskeleton of enterocytes.

The cases of *C.difficile* infection have increased markedly worldwide over the past two decades<sup>10</sup>. In the US, the incidence of *C. difficile* infection in 2011 was 453,000 based on population data across geographic locations. In 2013, CDC assigned *C.difficile* infection in the highest category of anti-microbial resistance threats.

In Europe, the number of cases is estimated at 124,000 per year<sup>11</sup>. Across countries, *C.difficile* infection presents a substantial burden to healthcare facilities in terms of mortality, with longer hospital stays and higher costs<sup>12</sup>.

*C difficile* infection also impacts the community. An estimated quarter of cases of *C difficile* infection are community-acquired<sup>13</sup>. A quick and accurate diagnosis of *C. difficile* infection is a requirement for treatment and to prevent nosocomial transmission.

**Figure 4 Severity Criteria for *C. difficile* Infection**

Category	Signs/symptoms
Physical examination	Fever (core body temperature >38.5°C) Rigors (uncontrollable shaking and a feeling of cold followed by a rise in body temperature) Haemodynamic instability including signs of distributive shock Respiratory failure requiring mechanical ventilation Signs and symptoms of peritonitis Signs and symptoms of colonic ileus. Mixture of blood with stools is rare in <i>C. difficile</i> infection and the correlation with severity of disease is uncertain
Laboratory investigations	Marked leucocytosis (leucocyte count >15 9 10 <sup>9</sup> /L) Marked left shift (band neutrophils >20% of leucocytes) Rise in serum creatinine (>50% above baseline) Elevated serum lactate (≥5 mM) Markedly reduced serum albumin (<30 g/L)
Colonoscopy or sigmoidoscopy	Pseudomembranous colitis Insufficient data is available on the correlation of endoscopic findings compatible with <i>C. difficile</i> infection (eg, edema, erythema, friability, and ulceration) and the severity of disease
Imaging	Distension of large intestine (>6 cm in transverse width of colon) Colonic wall thickening, including low-attenuation mural thickening Pericolonic fat stranding Ascites not explained by other causes. The correlation of haustral or mucosal thickening, including thumbprinting, pseudopolyps and plaques, with severity of disease is unclear

Sources: European Society of Clinical Microbiology and Infection (ESCMID)

The diagnosis of *C.difficile* infection is complex. Currently, the treatment of *C.diff* is reliant on molecules: vancomycin and fidaxomicin for mild and severe forms of the infection. Metronidazole is an inferior treatment for vancomycin and fidaxomicin. Fecal microbiota transplantation is recommended in recurrent disease.

*C. difficile* infection used to be a simple pathology with a simple answer. Now, a better understanding of the pathophysiology has led to improvement of diagnostic techniques and refinement of the definitions unraveling the complexity of the pathology. Metronidazole and Vancomycin have been the backbone of treatment in previous years. New approaches such as fecal microbiota and new molecules like Immuron's IMM-529E could present the next generation of treatments.

<sup>8</sup> Burnham et al. Microbiol Review 2013

<sup>9</sup> Loo et al. NEJM 2005

<sup>10</sup> Lena Et al. NEJM 2015

<sup>11</sup> Zarb et al. Euro Surveill 2012

<sup>12</sup> Hensgens et al. Clin Infec Dis 2013

<sup>13</sup> Khanna et al. Am J Gastroentrol 2012

## Financial Results

On October 14, 2019: Immuron reported 1Q FY2020 sales results for Travelan, a commercial over-the-counter (OTC) GI and digestive health supplement. Sales momentum for the product continued to improve into the first quarter of the fiscal year 2020, benefiting from increasing consumer awareness.

Global Immuron sales in 1Q were AUD 741K, up 54% year-over-year, with continued growth in all geographic markets. Total North American sales for Travelan reached AUD 269K. In the US, Q1 sales grew 81% year-on-year to AUD 232K, with continued expansion at Passport Health Travel Clinics, Medique (Amazon), and Medico Mart. In Canada, Q1 sales reached AUD 38K.

In Q1 FY2020, Travelan sales in Australia grew by 34% year-over-year, to reach AUD 458K. Sales strength reflected the in-pharmacy merchandising program and promotional catalog activity in pharmacy banners.

**Figure 5. Immuron Limited – Overview of Business**

	For the Year ended June 30,				
	2015	2016	2017	2018	2019
	AUD\$	AUD\$	AUD\$	AUD\$	AUD\$
<b>Statement of Operations:</b>					
Total Operating Revenue	\$ 1,002,380	\$ 1,001,077	\$ 1,396,197	\$ 1,842,909	\$ 2,387,426
Total Gross Profit Less Direct Selling Costs	493,079	430,894	515,523	1,424,216	1,720,055
Total operating expenses	(4,775,920)	(9,038,676)	(8,934,050)	(6,356,514)	(6,923,300)
Loss Before Income Tax	(2,691,820)	(5,599,004)	(6,804,154)	(3,010,929)	(4,632,743)
<b>Balance Sheet Data:</b>					
Total assets	\$ 6,018,412	\$ 8,827,484	\$ 8,286,491	\$ 9,242,688	\$ 8,561,647
Total current liabilities	1,207,810	3,886,921	1,711,565	803,338	1,195,531
Total liabilities	1,207,810	3,886,921	1,711,565	803,338	1,210,511
Total stockholders' equity	4,810,602	4,940,563	6,574,926	8,439,350	7,351,136

Sources: Company reports and ThinkEquity estimates

For FY 2019, ended June 30, sales of Travelan, in North America, reached AUD 1.16M, an increase of 52%. In the United States, Travelan FY19 revenue reached AUD 1.02M. Global Immuron revenue grew by 29% YoY in FY19, reaching AUD 2.6M.

Immuron's strategic relationships with its key manufacturing partners for the consumer product Travelan, have enabled the company to maintain gross profit percentage at 70-plus percent. The manufacturing partnerships have given rise to greater efficiencies in the manufacturing processes.

Sales and Marketing Costs increased in the fiscal year 2019 compared fiscal year 2018 from higher marketing in international markets. Freight Costs were relatively flat due to established logistical channels for shipping Travelan from Australia to overseas countries.

Consulting, Employee, and Director expenses increased in fiscal 2019 when compared to fiscal 2018 from options to directors. Director fees and administrative salaries have remained constant.

Corporate Administration expense was flat in fiscal 2019 as compared to fiscal 2018 despite the general increase in the size of the business.

Marketing and Promotion expenses decreased in fiscal 2019 as compared to fiscal 2018 as the Company normalized the promotional efforts of its existing flagship consumer product Travelan.

Total comprehensive loss for fiscal 2019 was AUD\$3.1 million as compared to a loss of AUD\$3.1 million for fiscal 2018.

**Figure 6. Immuron Limited – Balance Sheet Summary**

	Consolidated Statement of Financial Position As at				
	30 Jun 2015	30 Jun 2016	30 Jun 2017	30 Jun 2018	30 Jun 2019
	AUD\$	AUD\$	AUD\$	AUD\$	AUD\$
<b>Assets</b>					
Cash and cash equivalents	\$3,116,074	\$2,290,639	\$3,994,924	\$4,727,430	\$5,119,887
Trade and other receivables	1,691,629	4,387,772	1,768,237	1,683,305	968,926
Total current assets	5,998,898	8,809,421	8,267,654	7,050,437	6,682,444
Property, plant and equipment	19,514	18,063	18,837	20,384	17,140
<b>Total Assets</b>	<b>\$6,018,412</b>	<b>\$8,827,484</b>	<b>\$8,286,491</b>	<b>\$9,242,688</b>	<b>\$8,561,647</b>
<b>Liabilities and Equity</b>					
Total current liabilities	1,207,810	3,886,921	1,711,565	803,338	1,195,531
Total liabilities	1,207,810	3,886,921	1,711,565	803,338	1,195,531
<b>Total stockholders' equity</b>	<b>\$4,810,602</b>	<b>\$4,940,563</b>	<b>\$6,574,926</b>	<b>\$8,439,350</b>	<b>\$7,351,136</b>

Sources: Company Reports and ThinkEquity estimates

### Liquidity and Capital Resources

Immuron has incurred losses inception in 1994. As of June 30, 2019, Immuron had accumulated losses of AUD 56.9 million.

As of June 30, 2019, Immuron had cash and cash equivalents of AUD 5.1 million. The company reported a total of AUD1.0 million in receivables.

On July 19, 2019, the company completed a capital raise comprising 339,130 ADS at US\$4.00 per security. The gross proceeds to the company were USD 1.4 million.

**Figure 7. Immuron Limited – Cash Flow Results**

	For the year ended 30 June*	
	2019	2018
Net cash (outflow) from operating activities	(1,798,579)	(3,504,523)
Net cash (outflow) from investing activities	(2,008)	(5,316)
Net cash inflow from financing activities	2,069,183	4,348,985
Cash and cash equivalents at end of year	5,119,887	4,727,430

\*Financial statements are presented in the Australian currency

Sources: Company Reports and ThinkEquity estimates

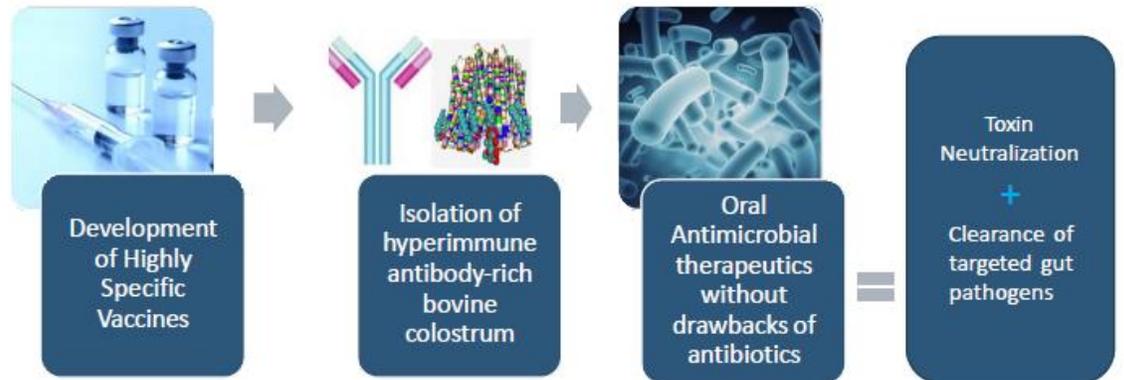
Operating activities. For the fiscal year ended June 30, 2019, and 2018, net cash used in operating activities decreased to AUD 1.8 million from AUD 3.5 million, respectively. The use of cash was from ordinary business operations.

Investing activities. Net cash used in investing activities in fiscal 2019 and 2018 was AUD 2.0k and AUD 5.3k, which is primarily related to purchases of office equipment.

Financing activities. For the fiscal year ended June 30, 2019, net cash provided by financing activities was AUD 2.1 million, which comprised of proceeds from issue of securities and exercise of options.

### Platform Technology

The company's technology platform is an antigen targeted hyperimmune bovine colostrum powder (BCP) for pharmaceutical use. Cows, before calving, are immunized with vaccines to ensure immunogenicity. Polyclonal antibodies are collected from the harvested first milk. The end product is colostrum that contains a high level of antibodies and Immunoglobulin G1.

**Figure 8. Oral Immunoglobulins: Scalable Technology**

Sources: Company Reports and ThinkEquity estimates

The basis of the company's technology platform enables the development of medicines across a broad range of diseases, and this includes infectious diseases and immune-mediated disorders. The dairy origins of Immuron's antibodies classify the technology, enables commercialization of the platform through multiple regulatory pathways, including prescription, over-the-counter medicines, and dietary supplements.

## Pipeline

FDA registration for clinical development of IMM-124E

In April 2019, Immuron indicated the clinical development of IMM-124E through an FDA registration pathway as a drug to prevent travelers' diarrhea. This process enhances the commercialization of the Travelan/IMM-124E franchise. The company anticipates a meeting with the FDA in second-half 2019 for discussions on a new IND for travelers' diarrhea. A successful clinical program and approval by the FDA of IMM-124E could lead to increases in the marketing of an approved drug with a claim of specifically preventing travelers' diarrhea.

Clinical Studies IMM-124E

Additional clinical studies have been conducted with IMM-124E. The first, a Phase II for severe alcoholic hepatitis performed under FDA (IND #015675) and supported by the NIAAA. The second, an NIH funded Phase II for pediatric patients with non-alcoholic fatty liver disease conducted under FDA (IND #017066).

SAH Trial

In August 2019, top-line results were released from the severe alcoholic hepatitis trial. Dr. Arun Sanyal of Virginia Commonwealth University was the lead Principal Investigator. The end-point of this study was to evaluate the safety and efficacy of IMM-124E as compared with a placebo in patients with SAH. Results showed that IMM-124E is safe to use in patients with SAH. However it does not reduce circulating lipopolysaccharide levels, mortality, or have an impact on the model for end-stage liver disease score in the study population. Immuron will not continue the clinical development of IMM-124E, specifically to treat SAH.

**Figure 9. Immuron – Development Pipeline**

	DEVELOPMENT STAGE					HIGHLIGHTS
	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
ANTI-INFLAMMATORY PROGRAMS						
Travelan®	TGA ARTG Aust L106709 (2004)					Commercial product - Australia
	Health Canada NPN 80046016 (2015)					Commercial product - Canada
	Dietary supplement (2015)					Commercial product - USA
IMM-124E (Travelan®)						PLAN TO DEVELOP AS DRUG TO PREVENT TRAVELERS' DIARRHEA IN USA
IMM-529						TO PREVENT RECURRENCE IN C. DIFFICILE PATIENTS

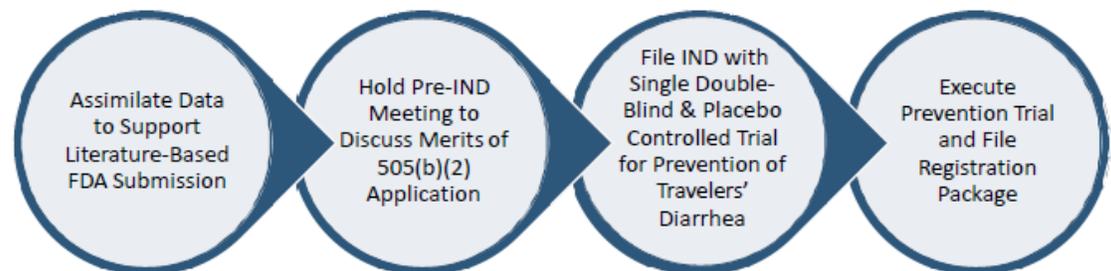
Sources: Company Reports and ThinkEquity estimates

**Travelers' Diarrhea (TD) Treatment Pathway**

The safety data generated from the SAH patients (n=57), as well as data from the six-month treatment study of IMM-124E in non-alcoholic steatohepatitis under FDA IND #014933 (n=133) were submitted to the FDA to support the clinical development plan for IMM-124E to prevent travelers' diarrhea.

**Figure 10. IMM-124E Drug Development Plan**

Revamp Travelan® for FDA approval as drug to prevent Travelers' Diarrhea in travelers to endemic areas:



Sources: Company Reports and ThinkEquity estimates

**NAFLD**

The NIH-funded Phase II double-blind, placebo-controlled, randomized clinical trial of IMM-124E in pediatric non-alcoholic fatty liver disease patients is underway at Emory University, led by Dr. Miriam Vos, a specialist in the treatment of GI disease in children, including NAFLD and obesity. Top-line results for this study are expected in 2020.

**IMM-529 for Treating *C. difficile* Infections**

In March 2019, Immuron provided an update on the status of the IMM-529 clinical trial in patients with CDI. The Phase I/IIa clinical trial, initiated at the end of 2017 at clinics in Israel, for patients with *C. difficile* had not enrolled patients in sufficient numbers. The company is to focus on the further development of the drug candidate specifically in the treatment of patients suffering from *C. difficile* infections. The company anticipates a meeting with FDA in 1H2020 to explore further the development of treating patients with CDI.

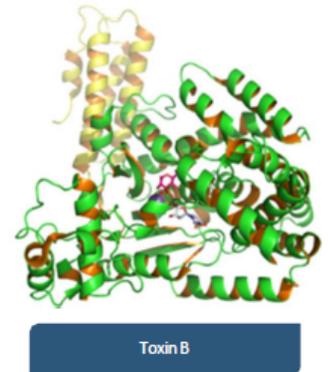
In March 2019, the United States PTO issued a patent for a method to treat *Clostridium difficile* with IMM-529. *C. difficile* remains a major medical problem globally with an annual economic burden estimated at USD \$10 billion and killing over 40,000 Americans annually alone.

### IMM-529 – Value Proposition

Mechanism of Action - IMM-529 targets Toxin B, the major driver in producing CDI infections. The IMM-529 contains antibodies to the spores and the vegetative cells that can lead to recurrence of the CDI infections. It is particularly suitable for patients given front-line treatment with antibiotics such as vancomycin, fidaxomicin, and metronidazole.

#### Figure 11. IMM-529 Opportunity

- IMM-529 highly differentiated – neutralizes *C. difficile* but does not impact microbiome
- Targets not only toxin B but also spores and vegetative cells responsible for recurrence
- Potential use in combination with standard of care
- Targets many isolates



Sources: Company Reports and ThinkEquity estimates

Effective against Virulent Strains - IMM-529 is effective against both normal strains as well as virulent strains of *C. difficile*, providing strong proof-of-concept (POC) that IMM-529 can be effective in treating CDI in the overall battle against difficult-to-treat strains. Moreover, as IMM-529 has a different mechanism of action than standard antibiotics, it has the potential to be used in combination with antibiotics to more effectively reduce the chances of recurrence.

Effective in all Phases of the Disease - IMM-529 has shown that it can be an effective agent in all phases of the disease including prevention of infection, treatment of primary disease and recurrence. This represents a much larger potential use than current drug development programs which primarily target recurrence.

Oral Therapy - IMM-529 is an oral therapy lessening costs on the healthcare system overall.

**Figure 12. IMM-529E Clostridium difficile Infection (CDI)**

*Clostridium difficile* (*C. difficile*) is a bacterium that causes diarrhea and more serious intestinal conditions such as colitis

- Therapeutic market expected to grow from USD \$630 million in 2016 to over \$1.7 billion by 2026 – CAGR 15%<sup>1</sup>
- Leading cause of gastroenteritis-associated mortality in U.S.<sup>2</sup>
- Approx. 44,500 patients<sup>3</sup> died in 2014 from *C. difficile* infections (U.S.)
- Potential orphan disease (7 years market exclusivity and premium pricing)

1. <https://www.globaldata.com/global-clostridium-difficile-infection-market-approach-2016-2026>
2. Jagai, et.al., BMC Gastroenterology, 2014;14:211 Trends in gastroenteritis-associated mortality in the USA.
3. K. Desai, BMC Infect. Dis., 2016,16:303

Sources: Company Reports

### IMM-529 Drug Manufacture

Immuron is focused on biopharmaceutical research and development for an effective and safe non-antibiotic treatment for CDI. This indication accounts for more than 450,000 patients and over 40,000 deaths per year in the United States.

The IMM-529 drug candidate for the clinical trial program has been manufactured utilizing Immuron's patented anti-*C. difficile* vaccine for production of bovine hyperimmune colostrum specific for targeting *C. difficile*. The drug product from this is a first-in-class oral immuno-therapeutic planned for the treatment of CDI.

### Competition

Immuron competitors looking to develop improved treatments for *C. difficile* infections fall into two classes: 1) those looking to develop superior antibiotics that minimize bacterial recurrence. These include Summit and Actelion, and 2) those companies specializing in microbiome approaches to treating CDI, including Seres Therapeutics with its product candidate SER-109, and Kobiolabs which recently announced a planned trial in CDI with its microbiome candidate. Also, Universities and other research institutions can play a role in new approaches to treatment. Some competitors have more financial resources and experience in human clinical trials of new or improved drugs than Immuron.

### Manufacturing Process

Immuron inked a Development and Supply Agreement, effective June 2013, with Synlait Milk. Synlait is a New Zealand company that specializes in the processing of infant formula and special milk powders.

IMM-124E is obtained from Synlait. Immuron's active ingredient is manufactured under cGMP in an Australian TGA-licensed facility. The primary differentiation between milk and Immuron's active ingredient constituents is the presence of antibodies, 35-45% by weight of dry colostrum powder. The classes of immunoglobulins found in the active ingredient are IgG, less so IgM/A.

### Summary

**TD Opportunity.** IMM-124E has potential in preventing travelers' diarrhea. The clinical development of this drug candidate is through an FDA 505(b)(2) pathway, specifically for prevention of travelers' diarrhea.

**Management.** Immuron's senior management team has a proven track record and is spearheading the execution. The Company has thus far executed to plan with accelerated development of the right trials.

**Ecosystem.** Immuron is working with KOLs and leading institutions in the inflammatory and infectious disease space that provide guidance and credibility to the development programs.

**Figure 13. Immuron Limited – Highlights**

- **Global sales reached \$2.39 million for FY 2019**
- **Travelan sales exceeded \$1 million milestone in the United States**
- **Travelan hits the Canadian market**
- **IMM-124E / Travelan US registration strategy - pre-IND meeting request submitted to FDA**
- **SAH study – top line results report**
- **FDA registration strategy for clinical development of IMM-529**
- **U.S. *Clostridium difficile* patent granted**
- **U.S. Department of Defense Travelan *Shigellosis* study results reported**
- **Manufacture of three new *Shigella* products completed**
- **Research and development tax concession refund paid**
- **New director appointed**

Sources: Company Reports and ThinkEquity estimates

**Primary Opportunity**

FDA registration for clinical development of IMM-124E

In April 2019, Immuron announced plans to pursue clinical development of IMM-124E for traveler’s diarrhea through a formal FDA registration pathway. This enhances the commercialization of the Travelan/IMM- 124E franchise. The company is moving forward to develop IMM-124E through the FDA, and in August 2019 submitted an IND application. A successful clinical program, followed by a BLA filing and successful approval by FDA of IMM-124E to specifically prevent TD could lead to increases in the marketing of an approved drug to treat travelers’ diarrhea.

**Figure 14. Immuron Limited - Milestones**



Sources: Company Reports

**Operational Milestones**

The company has effectively redirected further clinical development of IMM-124E to specifically address an unmet medical need, prevention of travelers’ diarrhea. The company has implemented a plan for rapid development of IMM-124E and will be filing a new IND specifically for preventing travelers’ diarrhea. The

company plans to meet with FDA in the Autumn of 2019, and is looking to open a phase 3 trial in the first half of 2020.

Immuron is focusing further clinical development of IMM-529 to establish whether treatment with this drug candidate can reduce recurrence of the disease in *C. difficile* patients, and to design a clinical protocol that specifically evaluates patients with recurrent *C. difficile* infections where the present day standard-of-care antibiotics typically lead to considerable rates of recurrence. The company plans to file an IND with FDA in 2020 for clinical development of IMM-529.

**Summary**, Immuron is a biotech company that has developed novel oral immunotherapies. The Company's lead drug candidates are expected to achieve multiple key milestones over the forecast horizon. The target population for its drug candidates provides a large and growing market potential, with high unmet medical needs.

## Management

### **Gary S. Jacob, PhD** **Chief Executive Officer**

Dr. Jacob has been the CEO of Immuron Limited since November 16, 2018. Dr. Jacob has over 30 years of experience in pharmaceutical and biotechnology - including R&D, operations, business development, and capital financing. Dr. Jacob was the co-founder and founding CEO of Synergy Pharmaceuticals. He was the co-inventor of TRULANCE; an FDA approved drug to treat chronic GI disorders. Dr. Jacob has raised over USD \$500 million of capital in the public markets to support Synergy from founding to approval of TRULANCE® in 2017. Dr Jacob has a Ph.D. in Biochemistry, University of Wisconsin-Madison, and BS in Chemistry from the University of Missouri.

### **Jerry Kanellos, PhD** **Chief Operating Officer**

Dr. Kanellos was the former acting CEO of Immuron Ltd. He has over twenty years' experience in the pharmaceutical and biotechnology industries. Dr. Kanellos was the former Chief Operating Officer of TransBio Ltd. He was responsible for strategic identification, development, and maintenance of global commercial partnerships, along with development, management, and IP portfolio, R&D, and technology transfer. Dr. Kanellos has held leadership roles in business development, project management, IP portfolio management, R&D, senior management. Dr. Kanellos has a PhD in medicine from the University of Melbourne.

## Operational Risks

**Operating Losses.** Immuron has reported losses in every period since they began operations in 1994. The company reported net losses of AUD 6.8 million during the fiscal year ended June 30, 2019. As of June 30, 2019 and June 30, 2018, accumulated deficit was AUD 57 million and AUD 53 million, respectively.

**Commercializing Company-owned IP.** The ability to generate significant revenue from prescription products and reach profitability depends on the ability to successfully develop and obtain regulatory approvals.

**Development Stage Company.** Immuron is a development stage company with a technology platform designed to treat a range of anti-inflammatory indications. Outside of Travelan, the company does not have any product to generate commercial revenues.

**Uncertainties Related to Research and Clinical Trials.** The company's scientific hypotheses and experimental approaches may not lead to a positive outcome. Also, the timeline to obtaining proof of principle may be longer than originally projected.

**Reliance on third parties to conduct trials.** Immuron is dependent on third parties for the clinical trials for IMM-124E and IMM-529. The completion of these trials may differ from original expectations.

**Access to IP Rights.** Immuron may need to acquire or in-license third-party intellectual property rights on terms that are not acceptable.

**Development of pharmaceutical products.** Immuron cannot predict when the development of the current product pipeline will be completed. Immuron may not be able to progress to a stage that will attract a collaborative partner.

**Acceptance in the medical community.** The company may not be able to sustain revenue from sales of the product if it cannot be sold competitively or fails to achieve market acceptance in the medical community.

**Competition.** There are a number of companies working in the field of infectious diseases and C. difficile therapeutics, including Seres, Summit, Actelion, and Kobiolabs for C. difficile.

**Sole Manufacturer.** Synlait, located in New Zealand, is the primary IMM-244E manufacturing partner. The company is also dependent on Catalent Australia to encapsulate the marketed products.

**Orphan Drug.** IMM-529 is only one that would likely qualify for rare disease status is IMM-52

For additional risk considerations, please refer to the company's SEC filings.

Figure 15. Immuron Limited - Income Statement, 2014-2020E

	For the year ended June 30,				For the year ended June 30,		
	2014	2015	2016	2017	2018	2019	2020E
	(Restated)	(Restated)	(Restated)				
	AUD\$	AUD\$	AUD\$	AUD\$	AUD\$	AUD\$	AUD\$
<b>Revenue</b>							
Operating Revenue	981,051	1,002,380	1,001,077	1,396,197	1,842,909	2,387,426	5,000,000
<b>Total Operating Revenue</b>	<b>981,051</b>	<b>1,002,380</b>	<b>1,001,077</b>	<b>1,396,197</b>	<b>1,842,909</b>	<b>2,387,426</b>	<b>5,000,000</b>
Cost of Goods Sold	(277,928)	(316,128)	(301,435)	(337,546)	(418,693)	(667,371)	1,500,000
<b>Gross Profit</b>	<b>703,123</b>	<b>686,252</b>	<b>699,642</b>	<b>1,058,651</b>	<b>1,424,216</b>	<b>1,720,055</b>	<b>3,500,000</b>
	72%	68%	70%	76%	77%	72%	70%
<b>Direct Selling Costs</b>							
Sales and Marketing Costs	(79,796)	(76,794)	(133,781)	(407,751)	(282,241)	(600,000)	(1,200,000)
Freight Costs	(114,278)	(116,379)	(134,967)	(135,377)	(169,458)	(150,000)	(200,000)
<b>Total Gross Profit less Direct Selling Costs</b>	<b>509,049</b>	<b>493,079</b>	<b>430,894</b>	<b>515,523</b>	<b>972,517</b>	<b>970,055</b>	<b>2,100,000</b>
Other Income	804,477	1,591,021	3,008,778	1,614,373	1,850,401	1,200,000	1,000,000
<b>Expenses</b>							
Amortization	(680,587)	-	-	-	-	-	-
Consulting, Employee and Director	(555,487)	(728,140)	(2,840,037)	(1,689,521)	(1,384,298)	(2,000,000)	(2,000,000)
Corporate Administration	(492,465)	(557,422)	(1,320,570)	(1,381,809)	(1,336,516)	(1,500,000)	(1,500,000)
Depreciation	(3,989)	(3,719)	(3,892)	(4,922)	(5,047)	(6,000)	(6,000)
Finance Costs	(463,685)	-	(341,600)	(24,483)	(18,857)	(30,000)	(30,000)
Impairment of Inventory	(50,204)	(35,340)	(4,176)	(136,494)	(163,600)	(30,000)	(30,000)
Marketing and Promotion	(235,176)	(304,687)	(487,591)	(789,608)	(370,699)	(300,000)	(300,000)
Research and Development	(1,289,675)	(3,018,294)	(3,623,961)	(4,630,674)	(2,257,224)	(1,044,528)	(2,000,000)
Travel and Entertainment	(37,327)	(128,318)	(416,849)	(276,539)	(297,606)	(500,000)	(700,000)
Total Expenses	(3,808,595)	(4,775,920)	(9,038,676)	(8,934,050)	(5,833,847)	(5,410,528)	(6,566,000)
<b>Loss Before Income Tax</b>	<b>(2,495,069)</b>	<b>(2,691,820)</b>	<b>(5,599,004)</b>	<b>(6,804,154)</b>	<b>(3,010,929)</b>	<b>(3,240,473)</b>	<b>(3,466,000)</b>
Income Tax Expense	-	-	-	-	-	-	-
<b>Loss for the Period</b>	<b>(2,495,069)</b>	<b>(2,691,820)</b>	<b>(5,599,004)</b>	<b>(6,804,154)</b>	<b>(3,010,929)</b>	<b>(3,240,473)</b>	<b>(3,466,000)</b>
Other Comprehensive Loss	-	(12,581)	8,846	40,017	(79,599)	-	-
<b>Total Comprehensive Loss for the Period</b>	<b>(2,495,069)</b>	<b>(2,704,401)</b>	<b>(5,590,158)</b>	<b>(6,764,137)</b>	<b>(3,090,528)</b>	<b>(3,240,473)</b>	<b>(3,466,000)</b>
Basic/Diluted Loss per Share (cents per share)	5.9	3.6	(7.3)	(6.4)	(2.3)	(3.2)	(3.0)

Sources: Company Reports and ThinkEquity Estimates

**Figure 16. Immuron Limited —Valuation Comparables, Prices as of 10/18/19**

(Amounts listed in AUD. Numbers in millions, except per share data)

Company	Stock Price <sup>(1)</sup>	Market Value of Equity	Enterprise Value <sup>(2)</sup>	Enterprise Value as a Multiple of:							Price as a Multiple of:		Projected EPS Growth	PEG Ratio
				Sales			EBITDA			EBIT	CY+1	CY+2		
				LTM	CY+1	CY+2	LTM	CY+1	CY+2	LTM	EPS	EPS		
Seres Therapeutics, Inc.	5.05 <sup>(3)</sup>	353.3	236.8	4.10x	4.81x	5.52x	NM	NM	NM	NM	NM	NM	0.0%	NM
Kaleido BioSciences, Inc.	7.38 <sup>(3)</sup>	219.8	95.6	NM	4.36	2.62	NM	NM	NM	NM	NM	NM	0.0%	NM
Supernus Pharmaceuticals, Inc.	37.50 <sup>(3)</sup>	1,966.6	2,126.6	3.56	3.51	3.25	9.6	9.1	8.6	10.0	11.5	12.3	0.0%	NM
Assertio Therapeutics, Inc.	1.71 <sup>(3)</sup>	137.8	762.4	2.22	2.21	2.17	4.7	4.2	4.1	60.7	1.3	1.2	20.0%	0.1
VIVUS, Inc.	6.26 <sup>(3)</sup>	66.6	358.2	3.37	3.21	2.48	19.2	NM	NM	NM	NM	NM	0.0%	NM
Lexicon Pharmaceuticals, Inc.	4.67 <sup>(3)</sup>	496.7	702.7	11.20	3.83	4.93	NM	NM	NM	NM	NM	NM	0.0%	NM
Rigel Pharmaceuticals, Inc.	2.39 <sup>(3)</sup>	400.3	280.1	2.92	2.23	2.25	NM	NM	NM	NM	NM	NM	0.0%	NM
SIGA Technologies, Inc.	7.87 <sup>(3)</sup>	638.1	609.8	0.86	NM	NM	1.1	NM	NM	1.1	NM	NM	0.0%	NM
Omeros Corporation	23.17 <sup>(3)</sup>	1,141.8	1,361.2	12.40	8.88	6.19	NM	NM	NM	NM	NM	NM	0.0%	NM
Seres Therapeutics, Inc.	5.05 <sup>(3)</sup>	353.3	236.8	4.10	4.81	5.52	NM	NM	NM	NM	NM	NM	0.0%	NM

<b>High</b>	12.40x	8.88x	6.19x	19.2x	9.1x	8.6x	60.7x	11.5x	12.3x	20.0%	0.1x
<b>Average</b>	4.97	4.21	3.88	8.7	6.7	6.4	24.0	6.4	6.7	2.0%	0.1
<b>Median</b>	3.56	3.83	3.25	7.2	6.7	6.4	10.0	6.4	6.7	0.0%	0.1
<b>Low</b>	0.86	2.21	2.17	1.1	4.2	4.1	1.1	1.3	1.2	0.0%	0.1

<b>Immuron Limited</b>	<b>0.13</b>	<b>22.1</b>	<b>17.0</b>	<b>7.11x</b>	<b>NM</b>	<b>0.0%</b>	<b>NM</b>							
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(1) Financial data provided by Eikon, Google Finance, Company Reports and ThinkEquity as of 10/18/2019

(2) Calculated as Market Value of Equity plus total debt, non-controlling interest and preferred stock, less cash & equivalents.

(3) Converted to AUD from USD at an exchange rate of 1.461.

Sources: Thomson Reuters, Google Finance and ThinkEquity Estimates

## Important Disclosures

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The analyst, Ashok Kumar, responsible for the preparation of this research report attests to the following: (1) that the views and opinions rendered in this research report reflect his or her personal views about the subject companies or issuers; and (2) that no part of the research analyst's compensation was, is, or will be directly related to the specific recommendations or views in this research report.

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### Immuron Limited Rating History as of 10/18/2019

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Think Equity rating definitions are expressed as the total return relative to the expected performance of S&P 500 over a 12-month period.

BUY (B) - Total return expected to exceed S&P 500 by at least 10%

HOLD (H) - Total return expected to be in-line with S&P 500

SELL (S) - Total return expected to underperform S&P 500 by at least 10%

### Current Ratings Distribution

This Equity Ratings Distribution reflects the percentage distribution for rated equity securities for the twelve month period August 26, 2018 through August 26, 2019. Within the twelve month period ended August 26, 2019, Fordham Financial Management, Inc. has provided investment banking services to 53% of companies with equity rated a Buy, 0% of companies with equity rated a Hold and 0% of companies with equity rated a Sell. As of September 30, 2019, ThinkEquity, a Division of Fordham Financial Management, Inc. had sixteen stocks under coverage: Buy 16 (100%), Hold 0 (0%), Sell 0 (0%).