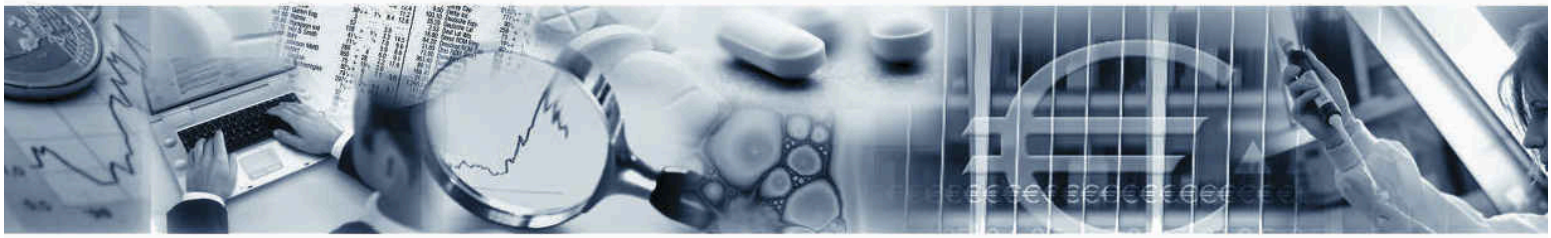

Research Note

Immuron Ltd

Moving to the forefront in NASH

Chief Research Analyst

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Name:	**Immuron Ltd**
Country:	**Australia**
Price:	**AUD 0.285**
ISIN Code:	**AU000000IMC7**
Reuters Code:	**IMC.AX**
Market Cap (AUD m):	**30.11**
EV (AUD m):	**27.82**
Cash & cash eq. (AUD m):	**2.29**
Shares outstanding (m):	**76.95**
Volume:	**60,863**
Free float:	**100%**
52-week Range:	**0.22-0.52**

AUD m (30 June)	2014/15A	2015/16A	2016/17E
Total Revenues	1.959	4.164	4.500
Net (Loss)/Profit	(3.448)	(4.390)	(5.000)
Net loss p.s. (cents)	(4.60)	(5.71)	(6.50)
R&D costs	3.018	3.624	4.000
Cash increase/(decrease)	(3.025)	(0.825)	10.00
Cash and market sec.	3.116	2.29	12.29

Executive Summary

- Immuron Ltd is a publicly listed Australian biopharmaceutical company focused on oral immunotherapy utilizing polyclonal antibody products that target the human gut immune system. Its lead program is IMM-124E which is currently in Phase II for fatty liver-diseases NASH (non-alcoholic steatohepatitis) and ASH (alcoholic steatohepatitis). Its second program, IMM-529, is in development to target the Clostridium *difficile* bacterium. The company is currently preparing its clinical protocol for a phase 1/2 in patients with Clostridium difficile infections (CDI).

- Next to its development pipeline, Immuron markets an OTC product Travelan for the prevention of Travellers' Diarrhea and is sold in several countries (Australia, Canada, US and China). Travelan has been shown to be 90% effective in the prevention of diarrhea in several E-coli challenge placebo controlled studies. Sales for 2016 were AUD 1 million.

- With IMM-124E and IMM-529, the company targets large markets with high unmet medical needs. NASH is a severe type of non-alcoholic fatty liver disease (NAFLD) and is the most common liver disease associated with obesity and type-2 diabetes. 10-20% of people with NAFLD will progress to NASH and has a prevalence of 24 million people in the US alone. The total market for NASH therapies is estimated to be more than USD 35 billion by 2025. CDI is one of top three most urgent antibiotic resistant bacterial threats in the US. It is the most common cause of hospital acquired infection and has overtaken Methicillin-resistant Staphylococcus aureus (MRSA) in prevalence.

- Last year, the company successfully raised AUD 6.3 million from a rights offering. The Company's current cash position is AUD 2.3 million, and we believe that this should be

sufficient to carry out the further development of its pipeline in the coming 12 months. The company also filed a S1 report to the SEC and is targeting a NASDAQ as well as a subsequent US capital raise. We anticipate the listing to be ready in 2017H1. Furthermore, we expect the company to be able to sign a lucrative partnering deal following positive topline Phase II data from IMM-124E given the increased interest from big pharma for NASH assets.

- There are a number of key milestones to focus on in the next 6-12 months which includes the publication of interim and topline results of the IMM-124E Phase II trial in NASH, granting Orphan Indication Status for IMM-529 in CDI and the initiation of a Phase I/II study in CDI.

- **Based on an NPV valuation, we believe that Immuron is substantially undervalued at the current share price of AUD 0.28. Using our valuation model and taking into account potential partnerships in both NASH and CDI, the company's current total value should be AUD 77 million, or AUD 1.00 per share. This represents a substantial upside from the current share price**.

Company Profile & Technology

Immuron Limited is an international biopharmaceutical company with a focus on oral immunotherapy using polyclonal antibody products that target the human gut immune system and gut microbiome. Immuron's technology platform is capable of developing and producing an orally stable therapeutic for various immune mediated and inflammatory disorders among them: non-alcoholic steatohepatitis (NASH) diabetes, colitis, arthritis, inflammatory bowel diseases (IBD), irritable bowel syndrome (IBS), liver fibrosis and other chronic disorders. Its proprietary polyclonal antibody platform produces antibodies potentially suited to treat a wide range of diseases including chronic inflammatory diseases and infectious diseases.

Immuron's platform technology is based on producing antigen targeted, hyper-immune bovine colostrum powder (BCP) suitable for pharmaceutical use. Polyclonal antibodies are derived from the first milking of a cow after calving. Prior to calving, cows are immunized with proprietary vaccines to ensure maximum immunogenicity. The milk is then harvested and purified. This proprietary process ensures that the colostrum contains a high concentration of antibodies and Immunoglobulin G1. The technology is classified as GRAS by the FDA and can be applied to a range of therapies, including infectious diseases and immune mediated disorders. The platform can be used to impact the cell mediated immune system through regulatory T cell populations or it can directly block viruses and bacteria at mucosal surfaces such as the GI tract. Additionally, the dairy origins of Immuron's antibodies enables the company to commercialize the platform through most regulatory pathways, including prescription, medical foods, OTCs and dietary supplements. The GRAS status of our technology platform allow the Company to advance its pre-clinical programs into clinical trials much faster compared to other companies as a result of the platform's proven safety profile.

Business Strategy & Partnerships

Immuron strives to become one of the leading biotech companies in inflammation mediated diseases and anti-infectives. To reach this goal, the company set out a strategy consisting of:

- Rapidly advancing its two lead programs IMM-124E (NASH) and IMM-529 (CDI)
- Leveraging its proprietary technology platform to other indications like ASH, Pediatric NASH and other anti-infectives with the US Army and Navy
- Partnering its fatty-liver programs with commercially strong partners
- Investing in its growing Travelan business worldwide
- Investing in mechanism of action (MOA) studies to potentially identify new opportunities
- Protecting its IP portfolio and patents

Pipeline: Focus on the Gut

With its platform technology that is based on polyclonal antibodies derived from hyper immune bovine colostrum powder (BCP), Immuron currently has two lead programs in development that are targeting high unmet medical needs in diseases that are associated with the human gut. These are (1) IMM-124E targeting NASH, which is currently in Phase II and (2) IMM-529 which is designed to prevent and treat CDI. Currently, the company markets two OTC products for Traveler's Diarrhea (Travelan) and Gut dysbiosis (Protectyn). Travelan is marketed in Australia, US, China and Canada. The company plans to roll out Travelan in additional countries. Last year, Protectyn was launched in Australia targeting the LSP bacteria in the gut to prevent dysbiosis.

Program	MOA	Dosing Form	Indication	Development Status				Notes	Commercial Rights
				Pre-Clinical	Phase 1	Phase 2	Phase 3		
IMM-124E	Anti-LPS	Oral	NASH					Top line results in mid-2017	Worldwide
IMM-124E	Anti-LPS	Oral	ASH					NIH Funded; UVA	Worldwide
IMM-124E	Anti-LPS	Oral	Pediatric NASH					NIH Funded; Emory University	Worldwide
IMM-529	ToxinB antagonist	Oral	C. difficile					Start of Phase 1 in 2017	Worldwide
Several	Shigella vaccine	Oral	Shigella infections					In collaboration with US Army	Worldwide
Several	Campylobacter; ETEC Vaccines	Oral	Campy/ETEC infections					In collaboration with US Navy	Worldwide
TBD	Anti-LPS	Oral	Colitis					In collaboration with Dr Rogler	Worldwide
TBD	Anti-LPS	Oral	Autism					In collaboration with Melbourne University, Murdoch Children's University and La Trobe University	Worldwide

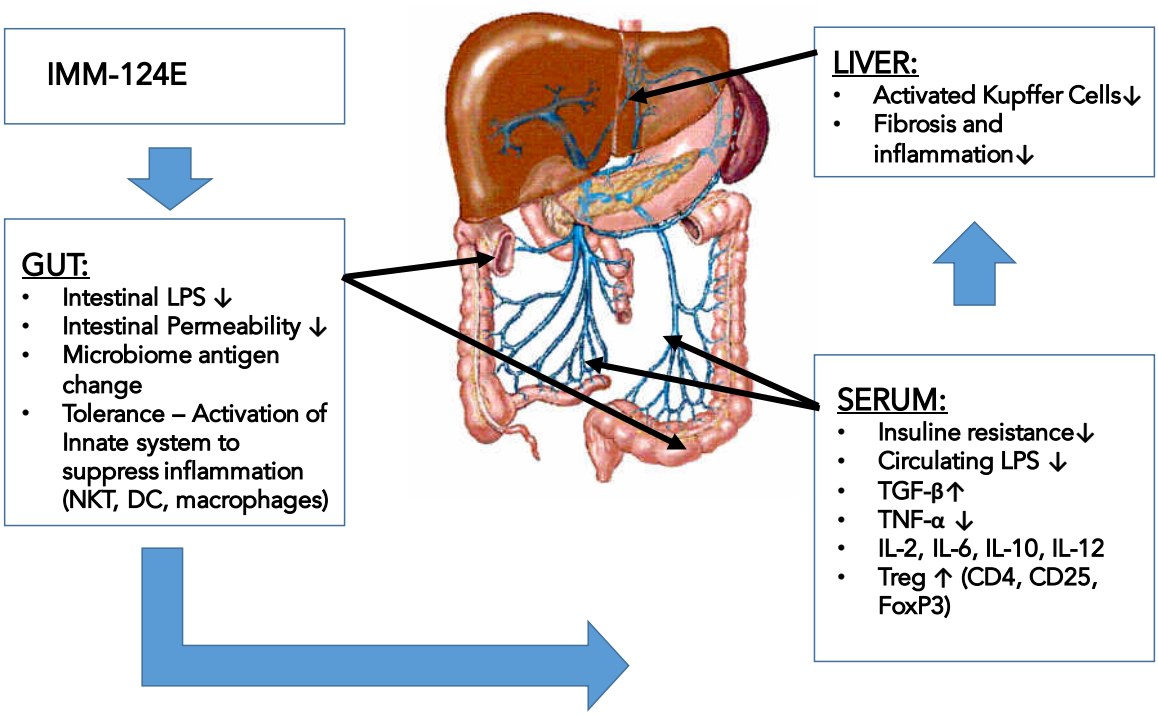
Source: Immuron Ltd

IMM-124E: Phase II study in NASH

In December 2014, Immuron announced the launch of its NASH Phase II multicenter randomized double blind placebo controlled study with IMM-124E for the treatment of NASH. The trial's first

patient was enrolled in February 2015. To date, 104 patients are enrolled out of 120. Top line results are expected to be available in mid-2017.

IMM-124E is made of anti-LPS polyclonal antibodies and manufactured from colostrum which is harvested from dairy cows that have been immunized against bacterial LPS from the most common strains of ETEC. IMM-124E contains at least 40% immunoglobulins composed mainly of IgG1. Studies have shown that these antibodies have high binding affinity to bacterial LPS specific sites. It was also demonstrated that these antibodies cross react with other types of bacteria such as shigella and salmonella.



There is strong support for the clinical benefit of IMM-124E in the treatment of fatty liver diseases. Ingested immunoglobulins are known to interact with the gut immune system to elicit a cell

mediated anti inflammatory response recorded in the serum. This subsequently lowers inflammation throughout the body. In addition, IMM-124E has also been shown to bind to intestinal LPS. This is thought to restore the intestinal barrier function thereby reducing liver LPS related inflammation as well as lowering circulatory LPS levels and bacterial translocation into the liver. Since NASH is associated with changes in the gut microbiota, direct change in the disease associated gut flora is thought to reduce the bacterial strains that are most closely associated with NASH.

In addition to the company-funded Phase II study in NASH, the NIH is funded two fatty-liver disease Phase II trials utilizing IMM-124E as the investigational agent. The first is a Phase II study for the treatment of ASH. The trial is currently enrolling and aims to enrol 66 patients, randomized to the double blinded placebo controlled study. The study is expected to generate safety and preliminary efficacy data and should be completed in 2018. The second study is a Phase II study for the treatment of pediatric NASH. This study aims to enrol 40 pediatric patients for three months treatment and aims to determine safety and efficacy of IMM-124 in these patients.

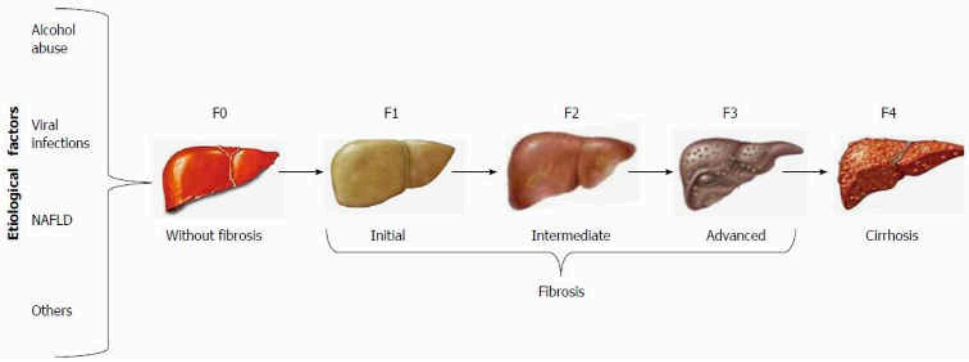
IMM-529: Potential New Revolutionary Treatment for CDI

IMM-529 is an oral biologic that does not destroy the microbiome like antibiotic treatments. This allows the microbiome to return to a healthy state while treating CDI. The antibodies in IMM-529 have been generated against the essential *C. difficile* virulence components, specifically, spores, vegetative cells and toxin B and shown to bind and neutralise a variety of human and animal C. difficile isolates. IMM-529 is in the IND stage and has successfully completed its preclinical program in CDI. Immuron is currently in the process of manufacturing clinical supplies for its Phase I/II and is finalizing the Phase I/II protocol. The company aims to start with the Phase I/II in 2017Q2.

Non Alcoholic Steatohepatitis (NASH): Next holy grail in Biotech?

NASH stands for Non-alcoholic Steatohepatitis. It is often linked with NAFLD, or non-alcoholic fatty liver disease. NAFLD is a condition categorized by excessive fat in the liver of people who drink little to no alcohol. No direct cause has yet to be identified, but it is known that obesity and insulin resistance play strong roles. Most often, NAFLD goes relatively unnoticed, as a liver can remain fatty without disturbing function. However, NAFLD can progress into a far more serious condition known as non-alcoholic steatohepatitis (NASH), a disease characterized by inflammation and irreversible cell death. While most people are unfamiliar with NAFLD, the disease is actually incredibly common. In the US, NAFLD affects around 30% of the population or around 100 million people. Approximately 10-20% of people with NAFLD will progress to NASH. Current estimates place NASH prevalence at 24 million people in the US or 7% of the total population, with similar prevalence in other major developed markets.

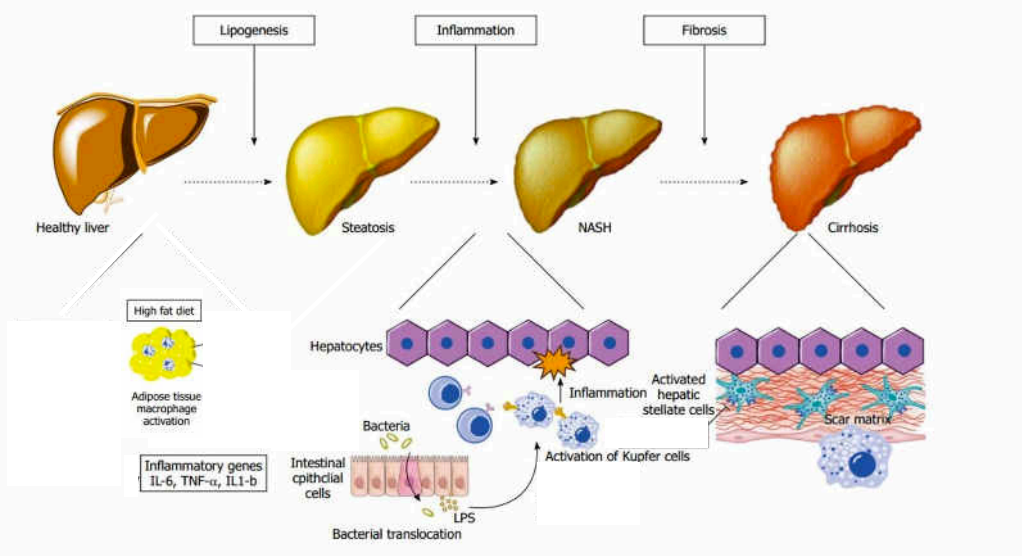
Much in the way a heart condition can worsen as years pass, NASH is a disease that progresses over time. It is estimated that 63% of all NASH patients or around 15 million people have either no scaring on the liver (F0) or mild fibrosis (F1). The other 9 million have either moderate (F2) or severe fibrosis (F3). Over a 10-year period up to 20% of patients with NASH will develop cirrhosis (healthy tissue being replaced with scar tissue) of the liver, and 10% will die from the disease.



Both NASH and NAFLD are becoming more common, possibly because of the greater number of people with obesity. In the past 10 years, the rate of obesity has doubled in adults and tripled in children. Obesity also contributes to diabetes and high blood cholesterol, which can further complicate the health of someone with NASH due to insulin resistance. Diabetes and high blood cholesterol are also becoming more common among Americans. By 2020, NASH is projected to overtake hepatitis C as the leading cause of liver transplants in the U.S.

Pathophysiology of NASH

Inflammation plays a key role in the pathogenesis of NASH as conditions like obesity are all associated with an elevated state of chronic inflammation that cause damage to organs such as the pancreas and the liver. In addition to the elevated state of inflammation suffered by NASH patients, it has also been shown that fatty diets, sugar and obesity are linked to an overgrowth of gram-negative bacteria within the gut. These bacteria produce LSP (LipoPolySaccharides) products that elicit strong innate and cell mediated immune responses in humans, both from within the gut and through circulating endotoxins, particularly via Toll-like Receptor 4 on cells.



The importance of this LPS driven inflammatory process is often overlooked since there are no therapeutics that can effectively block gram-negative bacteria in the gut. Except for broad spectrum antibiotics which are not an option for long term use in NASH patients.

The immune and inflammatory response to liver cell damage is mediated through a well described signalling network of liver and immune cells. Kupffer cells, also known as resident liver macrophages, sense tissue injury and are the first responders to liver cell damage. Activated Kupffer cells initiate an inflammatory response to the liver injury and can activate HSCs(hematopoietic stem cells) to transdifferentiate into myofibroblasts, the primary collagen producing cell type responsible for liver fibrosis. The extent of this fibrosis can vary, and it is described in several stages (F0 to F4).

M&A Activity in NASH underscores big pharma's interest

The field is consolidating, and we would not be surprised to see other big players making plays for smaller promising drug candidates going into 2017. Pharma giant Allergan already brought increased investor attention to the NASH market by buying two treatment developers, Tobira

Therapeutics, Inc. (NASDAQ:TBRA) for a sum of USD 1.7 billion **(a premium of almost 500%)** and private company Akarna Therapeutics Ltd for USD 50 million. Sofar, Intercept Pharmaceuticals is one of the leaders in hoping to be the first to market in NASH, while Gilead Sciences splashed into the space with a USD 470 million deal for a Phase II NASH treatment with Phenex and more recently struck the potentially USD 1.2 billion deal with Nimbus and its early-stage NASH drug. With no treatments currently approved for this chronic disease, the market opportunity is significant. Several companies are working on developing treatments for NASH - the market could be worth billions of dollars and many companies are hoping to cash in on this opportunity. Analysts predict that the market for a NASH drug could reach USD 35 billion or more by 2025.

Company	Partner	Year	Total value	Program
Arresto	Gilead	2010	USD 225m	Phase I asset (LoxL2 antibody) targeting NASH and IPF
Regulus	AstraZeneca	2012	USD 125m	Preclinical
Lumena	Shire	2014	USD 260m	Two Phase II aseets in NASH and cholestatic liver disease
Pharmaxis	Boehringer I.	2015	USD 600m	NASH asset in Phase I
Phenex	Gilead	2015	USD 470m	NASH asset in Phase II
Tobira	Allergan	2016	USD 1.7bn	Total pipeline of the company including Phase IIb asset in NASH
Akarna	Allergan	2016	USD 50m	Licensed preclinical NASH asset
Nimbus	Gilead	2016	USD 1.2bn	Phase I ACC inhibitor
Conatus	Novartis	2016	USD 700m	Worldwide rights to emricasan, a Phase IIb program in NASH Cirrhosis

Source: Van Leeuwenhoeck Inc.

Near Term Milestones

In the past year, Immuron has already reached a number of important milestones with the development of both its lead programs and the increasing sales of Travelan. In the coming 6-12 months we expect a number of important milestones that can drive the stock price upwards. These are:

- Ongoing: OTC Products Travelan and Protectyn: Continued Expansion
- 2017-Jan: NASH Phase II, Fully enrolled
- 2017H2: Nasdaq listing and US Capital Raise
- 2017H2: NASH Phase II Interim Results
- 2017Q2: C. difficile – Manufacturing of Clinical Supplies Completed
- 2017Q2: C. difficile – Initiation of Phase I/II
- 2017H2: NASH Top line data Phase II
- 2017: C. difficile Orphan Indication Granted
- 2018: ASH – Top line data Phase II
- 2018: C. difficile – Phase I/II results

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.