

Immuron

Newsletter

Message from the Chairman

Dear Shareholders and Investors,

I am pleased to present Immuron's first company newsletter to update you on the status of our clinical trial programs, sales of Travelan (for preventing travellers' diarrhoea) and ongoing developments that will provide us with a strong platform for future growth.

Immuron broadened its global footprint by launching its Travelan business into Canada and the US. In April 2015, we received our first orders for Travelan from the largest travel medicine chain in the US, with over 240 clinics providing travel medicine services worldwide. The US represents a significant market opportunity for Immuron and the volume of initial US orders was higher than anticipated, further bolstering the potential for significant revenue as the US roll-out gains momentum.

In August 2015, we executed our first major non-exclusive sales agreement with a sub-distributor in the US, Traveler's Supply Inc. of Springfield Massachusetts who have contracted to distribute Travelan for a minimum annual purchase of 50,000 units. This is a major endorsement to our distribution strategy in the US market, which maximises margin without the high level of investment required with a direct sales force.

In mid-2014, Immuron also signed a licensing agreement for the sale of Travelan in South Korea, followed by a subsequent agreement in early 2015 for Travelan in China. We are currently awaiting regulatory approval from local authorities before being able to commence sales in these new regions.

The Company has also made significant advances on its other associated pipeline products with the registration and pending launch of our new dietary health supplement in Australia (Protectyn). Protectyn is a hyperimmune colostrum product for gut health, which rebalances the gut flora by targeting inflammatory bacteria and their products. We are looking forward to its launch in the coming months.

Immuron is also making headway with its IMM-124E Phase 2 clinical trial for Non-Alcoholic Steatohepatitis (NASH). We have recruited 33 out of 120 NASH patients in 19 active sites across the US and Australia. We aim to have recruited all 120 NASH patients by the end of 2015. In order to maximise the value of this clinical trial, Immuron is exploring further endpoints now favoured by US Food and Drug Administration (FDA) to determine efficacy and progression of this global disease.

The NASH market has continued to strengthen with global players and deals for NASH products becoming very active. Notably, Boehringer Ingelheim recently acquired Australian-based Pharmaxis' investigational Phase 1 anti-inflammatory



Immuron launches New Product; *Protectyn*

Immuron will be launching Protectyn, a dietary supplement for gut health, scientifically formulated to help maintain a healthy digestive function and support the liver.

Protectyn is enriched with anti-LPS antibodies, which minimises gram negative bacteria in the gut, improving bacterial clearance, reducing chronic inflammation and improving immune function.



drug candidate for NASH. This deal is significant to the Australian biotech sector and we believe Immuron's Phase 2 IMM-124E product is more advanced in its progress to market and therefore well-placed to capitalise on the rising interest in the global market.

Travelan's growing global presence, and the Company's progression of its NASH and Alcoholic Steatohepatitis (ASH) Phase 2 clinical trial programs, makes Immuron well placed to meet significant untapped opportunities in the market.

A key move for the Company has been to appoint Senior Vice President of Innovation, Dr Dan Peres, who is now responsible for leading and managing Immuron's innovation programs, including the Phase 2 clinical trials for NASH, and for the support of US National Institute of Health (NIH) funded Phase 2 clinical trial program for ASH.

To further bolster Immuron's management team, just last week we appointed a new Chief Operating and Scientific Officer, Dr Jerry Kanellos who will act to support and complement Dr Peres in the NASH and ASH clinical trial programs from a drug development and manufacturing perspective as well as to aid the further development of other pipeline programs.

Dr Peres and Dr Kanellos are both important appointments with significant and relevant experience that makes them valuable additions to the Immuron management team.

The Board is committed to establishing the right leadership team to guide Immuron through this next phase of its development. We are highly cognisant that the recent changes in CEO have been less than ideal, and whilst we are disappointed that our recent CEO appointment did not work out, we are absolutely focused on building the right team. We will keep you updated on our recruitment process as further developments occur. In the meantime, we have a strong executive team in place to continue to progress our activity across Travelan sales growth, the NASH and ASH clinical trials, as well as the further development of our other innovation programs.

On behalf of Immuron, I would like to thank you for your support during our period of structural change. We look forward to what we believe will be an exciting year ahead from which we will create a solid position for sustainable development and growth, and I look forward to being able to provide shareholders with updates of this progress over the coming months.

Yours sincerely,

Roger Aston
Chairman

Travelan®

Updates

Travelan® is Immuron's hyperimmune colostrum product for the prevention of Travellers' Diarrhoea (TD). Travelan is unique, clinically proven to reduce the risk of TD by over 90%.

Did you know? Colostrum is the first milk or secretion from mammals after giving birth and is rich in antibodies to promote healthy development of the newborn's immune system. Immuron's hyperimmune technology further enriches bovine colostrum with a high concentration of antibodies.

Travelan is currently awaiting regulatory approval in China and is available for sale over-the-counter (OTC) through pharmacies in Australia, South Korea, Canada and the US.

The US represents a significant market opportunity for Travelan and the Company is excited by the initial success and enthusiasm shown by travel clinics in the US. In April 2015, Immuron received a higher than anticipated volume of first orders for Travelan in the US from the largest travel medicine chain, Passport Health.

Passport Health has over 240 clinics providing travel medicine services across the US. In early August 2015, Immuron has further executed on its first major non-exclusive Travelan sub-distributor agreement with Traveler's Supply Inc. of Springfield Massachusetts.

Traveler's Supply Inc. have contracted for a minimum purchase of 50,000 units of Travelan annually. The company is a leading travel medicine supply company in the US servicing the Travel Clinic market and many other fortune 500 companies such as Citigroup, Barclays and Chevron.

In Australia, Travelan is sold through pharmacies, travel medicine clinics and online channels supported by a national contract sales force to pharmacy, specialist sales representation to travel doctors and the Travelan website.

Accelerating Immuron's business development strategy

With the appointment of Senior Vice President of Innovation, Dr Dan Peres, Chief Operating and Scientific Officer, Dr Jerry Kanellos and other executive roles, Immuron has boosted its business development activities.

The current strategy is focused on expanding Immuron's opportunities to meet its strategic and operational objectives by:

- Reviewing, prioritising and the follow-up of existing Travelan market development activities;
- Securing new distribution partners and/or wholesale customers for Travelan and Protectyn in key marketplaces;
- Increase consumer awareness of Travelan to drive demand through focused advertising and direct marketing campaign via social media, travel booking websites, online ads and at airports around peak holiday seasons. This aims to build brand recognition and educate consumers of the need for Travelan in at-risk destinations to ultimately stimulate purchase.
- Engaging with potential licensing partners for NASH/ASH clinical programs to secure potential licensing partners for IMM-124E for NASH/ASH programs at the end of Phase 2 or 3 milestones.
- Expanding product opportunities for the hyperimmune technology platform; and
- Constant and transparent communication with the investment community.
- Reviewing the product pipeline and recommencing out-licensing and/or research activities in high value project that have been deprioritised over the last few years due to lack of funds.
- In licensing suitably complementary technology.

We are confident that we have the right team to successfully drive Immuron's business development strategy to build shareholder value.

Immuron has recently implemented new sales and marketing initiatives focused on physician detailing, pharmacist education and product promotion to inform product choice, build brand reputation, encourage physician recommendation, increase pharmacy stockists and raise awareness.

To expand its global reach, Immuron has appointed distributors in key marketplaces responsible for gaining product registration, meeting minimal purchase order requirements, supporting marketing and sales, and managing logistics in licensed territories.

Immuron has licensed rights to market, distribute and sell Travelan as a dietary supplement (or equivalent) for TD to Paladin Labs for Canada, Latin America and Africa; Ziwell Pharmaceuticals for Singapore; IntegraMed Asia for Thailand, Cambodia, Vietnam and Hong Kong; and recently Linker Holdings for China, Hong Kong and Macau.

Notably, the license with Paladin Labs has been granted for upfront fees, commercial milestone payments and agreed transfer pricing.

Immuron is now focused on increasing Travelan revenues globally through increasing sales in Australia and internationally, supporting existing distributors to advance product registration and launch in other licensed territories, and market expansion into the major US, Europe and Japan (and India) markets.

The Travelan Market

Travelan is marketed as a dietary supplement which sits in the growing vitamins, minerals and supplements market which produced approximately \$32 billion in revenue in 2012 and is estimated to double to \$60 billion in 2021.

The global traveller's diarrhoea (TD) market is estimated at **US\$600M - \$1.2B**. TD affects 20%-50% of 35 million travellers travelling to high risk destinations where TD is prevalent due the risk of ingesting faecally contaminated food or water.

NASH and ASH Phase II Clinical Trial Progress

NASH is a progressive form of non-alcoholic fatty liver disease (NAFLD) characterised by fat build-up in the liver (steatosis) and chronic inflammation that may progress to cirrhosis, liver failure and even cancer.

A recent Deutsche Bank review of the NASH market suggests a worldwide market for NASH of between \$35-\$40 billion. The high prevalence of Type 2 diabetes and obesity, which lead to NASH and other non-alcoholic fatty liver diseases (NAFLD), boosts the prevalence of NASH and its market growth.

In December 2014 Immuron announced the commencement of patient recruitment for a placebo-controlled, double-blinded and dose-ranging multicentre Phase 2 clinical trial to evaluate the safety and preliminary efficacy of IMM-124E in NASH patients across the US and Australia.

Immuron has so far recruited 33 out of the intended 120 NASH patients across 19 active sites, with 13 sites in the USA and six sites in Australia across New South Wales, Victoria and Queensland. Immuron is looking forward to bringing on three additional sites with two in Israel and a further site in the US, which will bring the total clinical sites to 22 over the coming months.

Immuron is currently working closely with its principle investigators and key opinion leaders to develop initiatives to drive recruitment with the aim of having the trial fully recruited by the end of 2015.

To further bolster its NASH and ASH programs, Immuron has appointed Dr Dan Ruben Peres in a newly created role as Senior Vice President of Innovation to drive the Company's Phase 2 NASH clinical trials and support the US National Institutes of Health-funded Phase 2 ASH trial. Immuron also appointed a new Chief Operating and Scientific Officer, Dr Jerry Kanellos, a seasoned veteran in vaccine development, clinical trial management and regulatory affairs to support Dr Peres from the Company's manufacturing capability perspective.

The primary objectives of the study are to evaluate the safety and preliminary efficacy of IMM-124E. IMM-124E will be compared to placebo in its potential to reduce liver fat and serum liver enzymes.

Patients randomised into the study will be orally administered either 600mg or 1200mg doses of the study drug IMM-124E or placebo three times daily for six months.

The study protocol was prepared in collaboration with a scientific advisory board led by Professor Arun Sanyal of Virginia Commonwealth University in Richmond, Virginia, who is a world-leading NASH specialist. Immuron expects to complete the study in September 2016.

Immuron is now focused on advancing the NASH trial to the end of Phase 2 milestone and initiating business development to secure a R&D partner to complete clinical development and commercialisation of IMM-124E for NASH in key markets.

The Competitive Global NASH market

NASH is one of the most common liver diseases and is currently the third leading cause of liver transplant in the US. Studies show that 5-25% of the growing number of patients with NASH eventually develop cirrhosis (scarring of the liver) within 7 years of follow up.

Many large biopharmaceutical manufacturing companies such as Genfit, Gilead Science, Novo Nordisk, Intercept Pharmaceuticals, Enzo Biochem and Raptor Pharmaceutical Corp have all commenced clinical trials for the development of novel therapeutics for the treatment of NASH in order to gain a competitive edge.

Most recently, Australian-based biotechnology company Pharmaxis' investigational Phase 1 anti-inflammatory drug candidate for NASH have been acquired by pharmaceutical giant, Boehringer Ingelheim. The Immuron NASH product is in a far more advanced stage of development than the Pharmaxis product.

Fighting the war against superbugs: *Immuron's C.Diff Program Progresses*

Immuron's preclinical project on IMM-529 for the prevention and treatment of superbug *Clostridium difficile* infection (CDI) is being developed in collaboration with a prestigious research team at Monash University led by microbiologist Associate Professor Dena Lyras.

CDI is a severe bacterial infection of the colon that often results from eradication of the normal gut flora by antibiotics. The CDI bacterium can cause bloating, constipation, and diarrhoea and has become increasingly deadly over the past decade.

In fact, CDI infection is responsible for epidemics in Australia, Canada, the UK and US where the cost of treating the infection is estimated to be as high as US\$3.2 billion a year.

The Global CDI Market

The public healthcare costs of CDI include increased hospital stays, reduced quality of life and over US\$3.2 billion in direct healthcare expenditure in the US. The global market for CDI is expected to reach US\$500.9 million by 2019, with annual growth of 4.1%.

The current standard of care for CDI is prevention with vaccines, early intervention and aggressive treatment with antibiotics and palliative care. However, current treatment programs are considered suboptimal due to increasing antibiotic resistance and recurrence of CDI in 15-30% of patients.

Immuron's preliminary dose-ranging mouse studies have shown a survival benefit in mice receiving anti-C.Diff colostrum. Immuron expects to complete the mouse studies and provide clinical-enabling data in Q1 2016. Professor Dena Lyras and Dr Melanie Hutton from Monash recently presented at the 5th International *Clostridium difficile* Symposium (ICDS) at Bled, Slovenia on 19-21 May 2015 which resulted in strong pharma interest in the program.

There is a clear need for safe, effective and affordable therapies that are an alternative to antibiotics to treat, prevent or stop recurrence after primary treatment for CDI. In fact, Immuron's IMM-529 preclinical studies have received research funding from both the Australian Research Council and CSIRO.

Immuron aims to submit an IND application for Phase 1/2A clinical studies for the prevention of recurrent CDI infection in hospitalised and immunocompromised patients.

The company may seek to partner this CDI program early with a biopharmaceutical company with existing products and active programs for CDI.

Upcoming Milestones

The following milestones are expected over the coming 6-12 months:

Milestones

Appointment of Chief Executive Officer (CEO)

Appointment of Scientific Advisory Board (SAB)

Securing further distribution or wholesale partners for Travelan in the US and other key marketplaces globally

Subject to Chinese regulatory approval, the launch and first sales of Travelan in China by distribution partner Linker Holdings

Launch of new dietary supplements for gut and liver health – Protectyn

Results from dose-ranging *C. difficile* program pre-clinical study

Complete recruitment of Phase 2 NASH clinical trial

Regulatory application for *C. Diff* program to be approved by TGA or FDA

Results from Phase 2 ASH clinical trial

Secure development partner/s for IMM-124E for NASH/ASH