

Immuron

Newsletter



Message from the CEO

Dear Shareholders and Investors,

I am pleased to share this Investor update with shareholders in what has been a period of continued growth in all phases of our business.

Since the publication of our last newsletter in August 2015, we have:

1. expanded recruitment of our first-in class Phase II NASH and ASH trials;
2. released extremely promising pre-clinical data in *Clostridium difficile*;
3. further strengthened our pipeline to cover colitis; and
4. expanded our OTC distribution across major markets and launched a new over-the-counter product, Protectyn.

Our portfolio of fatty-liver programs continues to progress with 62 patients now enrolled in our Phase II NASH trial and 29 patients having completed treatment in our NIH-sponsored ASH trial. NASH / ASH is a US\$40B market in which Immuron plays a leading role.

Our recent proof-of-concept program in *Clostridium difficile* (*C.diff.*), yielded unparalleled efficacy results, with statistically significant results in all three animal models including prevention (80% efficacy), treatment of primary disease (80% efficacy) and recurrence of disease (90% efficacy). *C. diff* is potentially a \$billion indication and our first-in-class triple-action oral therapeutic holds the potential to provide a natural option that doesn't destroy the microbiome of the gut and could fundamentally change the current treatment paradigm.

The last quarter has also been incredibly rewarding with the inclusion of CVS and McKesson Corporation amongst our distribution network partners for Travelan in the United States, and the launch of Travelan and Protectyn on JD.com in China. Having our product recognised with leaders in medical distribution and pharmacy retail in the US is indicative of the market opportunity and pathway we are on.

The Immuron Board and Executive team look forward to continuing to work with you and thanks shareholders for their support through the numerous transitions we have made. I also would like to thank the Immuron team for their commitment, hard work and dedication. We are poised towards productive and strong developments for the coming months and we will keep you updated as these opportunities progress.

Thomas Liquard
Chief Executive Officer



Rights Issue Opportunity

****Closing Date Extended to 30th June 2016****

To continue supporting the growth of our products and our programs, we have launched a capital raise that will carry us to our next natural inflection point, which is the *Planned Interim Analysis* of our Phase II program in NASH.

We estimate that the results of this planned interim analysis will be available before the end of the year.

It is our expectation that this inflection point will be supported by other strong clinical and product news that can further build our compelling commercial proposition to both partners and to the market.



Clinical Programs

IMM-124E for Fatty Liver Disease

IMM-124E represents a significant opportunity for Immuron's shareholders. Fatty liver diseases are a key area of investment for large pharmaceutical companies, which is driven by the large size of the market and the lack of approved therapeutics. With 37% of the adult US population, and 27% of the Chinese urban population thought to have fatty-liver disease, the global market for fatty-liver is estimated to be US\$40 billion by 2030 (Deutsche Bank, 2014).

Our goal is to develop the most compelling portfolio of fatty liver programs in the industry.

To this end, we continue to push our NASH and ASH clinical programs forward and in parallel, the team is working on other programs that we believe will allow us to create one of the most compelling portfolio of fatty-liver programs in the industry.

IMM-124E's unique mechanism of action and safety profiles are major differentiators vs. our competitors. As an oral immunotherapy, IMM-124E uses the inherent ability of the gastrointestinal tract's immune system to control unwanted systemic immune response, by inducing systemic regulatory T cells to suppress inflammation. We anticipate no major safety concerns that would limit the long-term use of IMM-124E, as well as the ability to use our therapy in combination with other agents, making it a very attractive therapeutic option for physicians and patients.

IMM-124E is now in a Phase II trial at 28 sites in Australia, US and Israel, under Principal Investigator Dr Arun Sanyal, who is internationally renowned for his work in liver diseases and currently Chair of the Liver Study Section at the National Institutes of Health (NIH). We recently added another four sites to the trial to assist in recruitment. These sites include eStudy Sites in San Francisco and San Diego, as well as the Walter Reed Army Medical Center and the Northwestern Medical Center.

We have also reached the halfway point in recruitment, with 60 patients randomized and we are pleased to report that we have received no significant adverse events in either our NASH or ASH trials. We are targeting to enroll 120 biopsy proven NASH patients and are confident of achieving top-line results in the middle of 2017.

The Company is also planning to perform an interim analysis of the Phase II NASH Trial with a minimum 30 patients. 25 patients have currently completed treatment in the trial. The results of this analysis will be available before the end of the year.

Our Phase II ASH trial targeting serious alcoholic steatohepatitis is also recruiting, with 29 out of the intended 66 subjects currently recruited and randomized. This multi-centre trial is fully funded by the National Institutes of Health and results are anticipated in 2018.

Travelan[®]

The only preventative treatment for Travellers' Diarrhoea

Travelan, our first over-the-counter product for the prevention of travellers' diarrhoea has significantly increased its distribution footprint over the past few months. We were particularly delighted in late April to announce a distribution agreement with McKesson Corporation, the worldwide leader in the distribution of pharmaceutical and medical products to retail pharmacies, hospitals and health systems. It is the largest healthcare distribution company in the world and our relationship opens up the ability to work within McKesson's considerable customer network.

Bi-Mart Corporation, a former subsidiary of Rite Aid, is the first McKesson customer to start stocking Travelan throughout its 75 retail stores and pharmacies. Bi-Mart is the 9th largest discount pharmacy store in the US.

In April, we were also delighted to announce two more significant partnerships, including with CVS and Allocation Inc, a wholesaler of pharmaceutical, medical and surgical products. CVS Pharmacies is one of the largest pharmacy chains in the US and Travelan will be available in 1,016 CVS stores by late May 2016. Several targeted pull-through marketing initiatives are in play to support our introduction into CVS. We are confident that having the support of such big retailers will enhance our efforts to gain uptake amongst travel clinics and specialised distributors.



We are also particularly delighted to establish our entry into the multi-million-dollar e-commerce market in China, for both Travelan and Protectyn. The agreement with QBID, the Australian partner for JD.com, means direct access to China's largest online direct sales company.

Pipeline Update

C. difficile program showing exciting potential

We are particularly excited about our *C.diff.* program, which targets a bacterial infection that is becoming particularly prevalent in hospitals and long-term care facilities and increasingly difficult to treat. With the market expected to grow to over \$1.5 billion by 2024, new treatment modalities are desperately needed. It is estimated that over 28,000 patients die every year in the USA from severe *C. diff.* infections and an additional 100,000 people have relapse phases of the disease.

Our early stage results are extremely encouraging and we are hopeful that this program could achieve orphan drug designation by the FDA.

Our *C. diff.* program, in conjunction with Associate Professor Dena Lyras and her team at Monash University in Melbourne, Australia is unique in that it targets all three infectious cycles (Toxin B, Spores and Vegetative Cells).

We were delighted to report late 2015 that our pre-clinical study with IMM-529 showed statistically significant results – **demonstrating an 80% efficacy in the prevention of C. diff** without antibiotics; **80% efficacy in the treatment of C. diff**; and excitingly a **90% survival rate** vs. 22% in the control group in the relapse studies.

Our IMM-529 antibodies also neutralised a hypervirulent strain that was behind recent worldwide outbreaks.

“It is difficult to obtain such promising outcomes without resorting to antibiotic use and these results are a testament to the strength of the Immuron platform and the potency of these vaccines,” commented Assoc. Professor Lyras, Monash University.

We believe we have a significant opportunity in this market, not only due to the significant unmet need but also because IMM-529 targets toxin B, spores and the vegetative cells that are believed to be the primary cause of relapses and the challenge behind treating the infection. Having a natural product that doesn't destroy the microbiome is of particular interest.

The company is currently preparing its Phase I/II trial protocol and preparing clinical supplies. We are working towards a 10-20 patient dose escalation trial at an Australian facility, to begin 4Q16. If successful, we would continue a phase II under an IND in the US and are hopeful of orphan disease designation.

Travelan update continued...

As the country's largest internet company by revenue, it holds more than 155 million active customer accounts, with over 1.3 billion orders in 2015. We see China as a significant market for our products, as fatty-liver disease has doubled in the past decade due to the rapid rise in obesity and fast food consumption.

Vitamin sales have escalated and as a natural, safe product targeting liver and gut health, we are estimating that this platform will be a strong avenue for both Travelan and Protectyn sales and uptake.

The QBID agreement runs for 2 years initially, with the products due to go live in a few months.

We've recently added digital marketing capabilities to the company to support our OTC product presence in the retail environment. Our Facebook and Instagram presence for Travelan is enjoying strong interest. We invite you to follow us on these sites at #teamtravelan.

In Australia, Protectyn is now being sold to practitioners via the two largest suppliers to the Natural Health Care segment: Osborne Health Supplies and Rener Health Centres.



Immuron's platform technology enables a large range of unmet medical needs to be explored, across infectious diseases and immune mediated disorders.

The versatility and recognised high safety profile of the natural, dairy-derived antibody products opens up multiple regulatory pathways, including prescription (Rx), medical foods, over the counter (OTC) medicines, and dietary supplements.

Pipeline Programs

Diabetes in NASH

Many people with NASH also have type II diabetes. As a significant and rapidly developing market opportunity, we see our unique mode of action as a strong factor in the Company exploring the initiation of a Phase II trial later this year (2016).

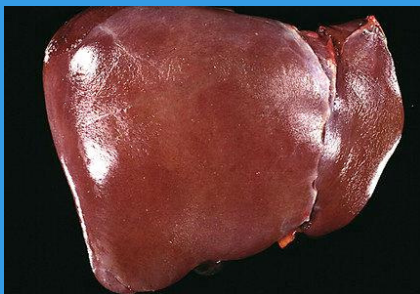
Paediatric NASH

As the growing obesity epidemic continues, fatty liver disease is becoming an increasing problem amongst young children. In line with our NASH program, we are also investigating the potential for a paediatric NASH study, especially given our current safety profile of Immuron's IMM-124E. We look forward to more news in July 2016.

Inflammatory Bowel Disease

Colitis consists of Ulcerative colitis and Crohn's Disease and is a chronic and often debilitating group of Inflammatory Bowel Diseases (IBD), effecting millions of people worldwide. In February 2016, we announced the start of our Colitis program in partnership with leading inflammatory bowel disease researcher, Professor Gerhard Rogler, MD, PhD. and the University of Zurich, Switzerland.

Our pre-clinical program will evaluate the efficacy of IMM-124E within a set of animal models for the treatment of Colitis. The unprecedented level of safety for IMM-124E makes it of high interest. With the current market for IBD set to reach US\$10b by 2021, this is a high market priority area. We are hopeful that this program could be a game-changer for patients and look forward to bringing you results in the first half of 2017.



Images:

A healthy human liver (top) and a liver showing non-alcoholic fatty liver disease (NASH)

(bottom) – which is the subject of Immuron's current NASH Phase II clinical trial using IMM-124E. NASH interim Phase II results are expected H2 2016.

Upcoming Milestones

- Additional US Travelan distribution agreements (ongoing)
- NASH Interim Results (2nd Half of 2016)
- *C. difficile* program to enter Phase I/II (2nd Half of 2016)
- Colitis program to report (1st Half of 2017)
- NASH recruitment completed (2nd Half 2016)
- NASH top-line results expected (Mid-2017)
- ASH results anticipated (2018)

Market Capitalisation of other NASH Comparable Companies...

- Intercept: \$3.5B (Phase III)
- Genfit: \$630M (Phase III)
- Tobira: \$123M (Phase II)
- Galmed: \$60M (Phase II)
- Galectin: \$43M (Phase II)
- Conatus: \$39M (Phase II)

Corporate Update

Expanding our US presence

It has been really pleasing to see our profile expanding in the US media in recent months. We've received good uptake from the travel shows we have attended, with Travelan reviewed on Arizona Midday TV (12 News), and Good Day DC (Fox5).

To view some of the recent videos and print articles, please link through to our investor site at www.immuron.com/investor-centre/

Immuron has made a strong impression exhibiting at Travel related shows in the US, such as 'The International Travel Goods Show 2016', which is the largest travel show in America. This year's event was an excellent opportunity for increasing our exposure amongst the travel community, as well as gaining further customers and leads.

The American Association of Occupational Health Nurses (AAOHN) also held their Annual Meeting in early April, which provided another opportunity for us to build presence amongst an important channel for our products.

Over the period, we were also pleased to have two analyst reports written on the company. In February 2016, US based equities company See Thru Equity LLC, released a full initiation report on Immuron and in January, RedChip Companies Inc. released a research report highlighting our IMM-529 results from the *C. difficile* studies.

RedChip also prepared an initiation report in August 2015 and an additional update on the back of the recent CVS announcement. Both reports have highlighted the significant difference in valuations of companies at similar stages to Immuron. It is particularly worth highlighting the dramatic lift in capitalisation that Intercept Pharmaceuticals received (US\$1.5b to \$6.6 billion), on the back of their Phase II trial results.

A copy of the analyst reports are available on the company website.

In February 2016, we were also pleased to report that the company received a AUD\$1.47m R&D tax concession refund for its Research and Development activities in the 2015 financial year, as well as finalising a funding agreement with a New York based Investment fund to provide AUD\$1.7m, as a mix of equity financing and convertible securities.

To view recent announcements covering product distribution, trial results, and program developments, go to:

www.asx.com.au/asx/statistics/announcements.do?by=asxCode&asxCode=imc&timeframe=D&period=M6

Forward Looking Statements

Any forward looking statements in this document have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations and beliefs about future events are subject to risks, uncertainties and other factors, many of which are outside Immuron Limited's control. Important factors that could cause actual results to differ materially from any assumptions or expectations expressed or implied in this newsletter include known and unknown risks. As actual results may differ materially to any assumptions made in this newsletter, you are urged to view any forward looking statements contained in this newsletter with caution. This newsletter should not be relied on as a recommendation or forecast by Immuron Limited, and should not be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction.



Capital Raising

As announced on 31st May 2016, we are in the process of raising capital through a \$6M non-renounceable Rights Issue.

See the link for details:

www.asx.com.au/asxpdf/20160531/pdf/4371qwnpqcsjx9.pdf

It is intended that net proceeds raised from the Offer will be used to fund the following activities:

1. **NASH: Phase II Results** of Interim Analysis and development of MHRA Protocol / Initiation of Phase II/III Study (Europe)
2. **C-Difficile:** Clinical supplies and initiation of Phase I
3. **OTC:** Marketing and New Market expansion for Travelan and Protection
4. **Colitis:** Completion of pre-clinical studies
5. **Corporate:** Repayment of outstanding Convertible Note Facility
6. **Working Capital:** Other working capital requirements including manufacturing improvements

We are excited by the prospects that are upon us over the next few months, especially in regards to our ongoing NASH trial and related activities. These have the potential to be transformative to the valuation of our business.

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