

Immuron 2024 AGM Presentation

Highlights:

- Global sales increased 172% in FY24 to \$4.90m; Record Travelan® sales of \$4.86m
- Record monthly sales in October 2024 of \$1.49m
- Completed and reported topline results for Travelan® Phase 2 and NMRC's Campylobacter clinical trial; planning 2H2025 Phase 3 initiation for Travelan®
- Positive feedback from the FDA to IMM-529 pre-IND filing; planning 2H2025 Phase 2 initiation
- Updated US\$400m peak sales US forecast by [Luminity](#) for IMM-529

Melbourne, Australia, November 18, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to release its AGM Presentation ahead of today's Annual General Meeting which is being held at the office of K&L Gates, Level 25, Rialto South Tower, 525 Collins Street Melbourne, Victoria, Australia at 11am Australian EST and virtually at <https://bit.ly/IMCAGM2024>.

This release has been authorised by the directors of Immuron Limited.

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About Immuron

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 infectious diseases.

About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

Travelers' diarrhea (TD)

TD is generally defined as the passage of ≥ 3 unformed stools per 24 hours plus at least one additional symptom (such as nausea, vomiting, abdominal cramps, fever, blood/mucus in the stools, or fecal urgency) that develop while abroad or within

10 days of returning from any resource-limited destinations ([Leung et al., 2006](#)). Diarrhea continues to be the most frequent health problem among travelers to destinations in lower- and middle-income regions ([Steffen, 2017](#)). Deployed US military personnel, essentially representing a long-term traveller population, are particularly affected given their population dynamics and the context in which they seek care and treatment ([Connor et al., 2012](#)). Diarrhea is the leading infectious disease threat to the overall health and preparedness of deployed US armed forces, with diarrheagenic *E. coli*, *Campylobacter* spp., and *Shigella* spp. among the most commonly reported etiologies ([Riddle et al., 2006](#)).

Immuron Platform Technology

Immuron's proprietary technology is based on polyclonal immunoglobulins (IgG) derived from engineered hyper-immune bovine colostrum. Immuron has the capability of producing highly specific immunoglobulins to any enteric pathogen and our products are orally active. Bovine IgG can withstand the acidic environment of the stomach and is resistant to proteolysis by the digestive enzymes found in the Gastrointestinal (GI) tract. Bovine IgG also possesses this unique ability to remain active in the human GI tract delivering its full benefits directly to the bacteria found there. The underlying nature of Immuron's platform technology enables the development of medicines across a large range of infectious diseases. The platform can be used to block viruses or bacteria at mucosal surfaces such as the Gastrointestinal tract and neutralize the toxins they produce.

IMM-124E (Travelan®)

IMM-124E was developed using Immuron's platform technology. IMM-124E is produced from the colostrum of birthing cattle that have been immunised during pregnancy with a vaccine containing the outer antigens of multiple human derived ETEC. A total of 13 ETEC strains are used in the vaccine to produce high levels of antibodies against selected surface antigens from the most common strains of ETEC.

The resultant hyperimmune colostrum IMM-124E from ETEC vaccinated cows contains significant levels of polyclonal antibodies specific for ETEC antigens LPS, CFA-I and Flagellin ([Sears et al., 2017](#)).

The antibodies produced in IMM-124E have been found to have a stronger binding and neutralizing activity (than the antibodies of unvaccinated cattle) against a wide range of LPS antigens including both the variable O-polysaccharide region and the preserved oligosaccharide core 'R' region of LPS from the 13 serotypes used in the ETEC vaccine.

IMM-124E is manufactured into a tablet form referred to as Travelan®.

IMM-529

Immuron is developing IMM-529 as an adjunctive therapy in combination with standard of care antibiotics for the prevention and/or treatment of recurrent *Clostridioides difficile* infection (CDI). IMM-529 antibodies targeting *Clostridioides difficile* (*C. diff*) may help to clear CDI infection and promote a quicker re-establishment of normal gut flora, providing an attractive oral preventative for recurrent CDI.

Immuron is collaborating with Dr. Dena Lyras and her team at Monash University, Australia to develop vaccines to produce bovine colostrum-derived antibodies. Dairy cows were immunised to generate hyperimmune bovine colostrum (HBC) that contains antibodies targeting three essential *C. diff* virulence components. IMM-529 targets Toxin B (TcB), the spores and the surface layer proteins of the vegetative cells.

This unique 3-target approach has yielded promising results in pre-clinical infection and relapse models, including (1) Prevention of primary disease (80% $P = 0.0052$); (2) Protection of disease recurrence (67%, $P < 0.01$) and (3) Treatment of primary disease (78.6%, $P < 0.0001$; TcB HBC). Importantly IMM-529 antibodies cross-react with whole cell lysates of many different human strains of *C. diff* including hypervirulent strains.

To our knowledge, IMM-529 is, to date, the only investigational drug that has shown therapeutic potential in all three phases of the disease ([Hutton et al., 2017](#)).

References

Connor P, Porter CK, Swierczewski B and Riddle MS. Diarrhea during military deployment: current concepts and future directions. *Curr Opin Infect Dis.* 25(5): 546-54; 2012.

Hutton, M.L., Cunningham, B.A., Mackin, K.E. et al. Bovine antibodies targeting primary and recurrent *Clostridium difficile* disease are a potent antibiotic alternative. *Sci Rep* 7, 3665 (2017). <https://doi.org/10.1038/s41598-017-03982-5>

Leung AK, Robson WL, Davies HD. Travelers' diarrhea. *Adv Ther.* Jul-Aug; 23(4): 519-27; 2006

Otto W, Najnigier B, Stelmasiak T and Robins-Browne RM. Randomized control trials using a tablet formulation of hyperimmune bovine colostrum to prevent diarrhea caused by enterotoxigenic *Escherichia coli* in volunteers *Scandinavian Journal of Gastroenterology* 46: 862–868; 2011.

Riddle MS, Sanders JW, Putnam SD, and Tribble DR. Incidence, etiology, and impact of diarrhea among long-term travelers' (US military and similar populations): A systematic review. *American Journal of Tropical Medicine and Hygiene.* 74(5): 891-900; 2006.

Sears KT, Tennant SM, Reymann MK, Simon R, Konstantopolos N, Blackwelder WC, Barry EM and Pasetti MF. Bioactive Immune Components of Anti-Diarrheagenic Enterotoxigenic *Escherichia coli* Hyperimmune Bovine Colostrum products. *Clinical and Vaccine Immunology.* 24 (8) 1-14; 2017.

Steffen R. Epidemiology of travelers' diarrhea. *J Travel Med.* 24(suppl_1): S2-S5; 2017.

For more information visit: <https://www.immuron.com.au/> and <https://www.travelan.com>

FORWARD-LOOKING STATEMENTS:

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition, and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions, or circumstances on which any such statement is based, except as required by law.



AGM PRESENTATION

18 NOVEMBER, 2024

Steven Lydeamore - CEO

NASDAQ: IMRN

ASX: IMC

SAFE HARBOR STATEMENT

Certain statements made in this presentation are forward-looking statements and are based on Immuron's current expectations, estimates and projections. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements.

Although Immuron believes the forward-looking statements are based on reasonable assumptions, they are subject to certain risks and uncertainties, some of which are beyond Immuron's control, including those risks or uncertainties inherent in the process of both developing and commercializing technology. As a result, actual results could materially differ from those expressed or forecasted in the forward-looking statements.

The forward-looking statements made in this presentation relate only to events as of the date on which the statements are made. Immuron will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

FY2025 results in this presentation are subject to audit review.





EXECUTIVE SUMMARY

Immuron Ltd (ASX:IMC) (NASDAQ:IMRN) is a globally integrated biopharmaceutical company focused on developing, and commercialising, oral immunotherapeutics for the treatment of gut mediated diseases

Company Overview

- Platform Technology: capable of producing highly specific orally active immunoglobulins to any enteric pathogen
- Two commercially available oral immunotherapeutic products – Travelan® and Protectyn®
- Two pipeline assets in three clinical programs
- Market capitalisation of \$17.6 million as of 25 October 2024 with cash and cash equivalents balance of \$11.7 million as of 30 June 2024

Business Update

- The FY24 sales and marketing strategy of distribution, awareness, education and visibility via consumer media and the trade is working
- Travel continues its momentum and Travelan is increasing market share of the antidiarrheal category
- Global sales increased 172% in FY24 to \$4.90 million; Record Travelan® sales of \$4.86 million
- Travelan® was the #1 SKU in the Antidiarrheal category across Chemist Warehouse pharmacy in Australia¹
- Record monthly sales in October 2024 of \$1.49 million
- Completed and reported topline results for Travelan® Phase 2 and NMRC's Campylobacter clinical trial; planning 2H2025 Phase 3 initiation for Travelan®
- Positive feedback from the FDA to IMM-529 pre-IND filing; planning 2H2025 Phase 2 initiation

NAVAL MEDICAL RESEARCH COMMAND TRIAL





NMRC experimental campylobacter/ETEC vaccine

- The trial was funded by the Naval Medical Research Command (NMRC). Immuron's produced a hyperimmune bovine colostrum (HBC) trial product using the NMRC vaccine which was tested in a controlled human infection model study. The results of this clinical trial are unrelated to Travelan® and do not impact Immuron's plans to hold an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). Nor does this NMRC trial impact on Immuron's commercialization strategy for Travelan®.
- Trial Conclusions:
 - CampETEC was well-tolerated
 - No moderate or severe adverse events were reported
 - CampETEC did not significantly prevent campylobacteriosis
 - Regimen dose of CampETEC not enough / too many bacteria in the inoculum
 - Targeting the polysaccharide capsule may not prevent epithelial cell invasion
- Future Direction:
 - NMRC to evaluate:
 - New vaccine candidates which target Campylobacter (e.g. whole cells and Surface layer proteins of the flagellum, a whip-like appendage that enables bacterial motility) for the development of HBC
 - USD \$2.3 million funding for NMRC and Walter Reed Army Institute of Research (WRAIR) approved by the U.S. Department of Defense
 - This work will utilize the extensive experience of the US Department of Defense human infectious disease vaccine programs, and one part of this program will target key protective antigens of the enteric bacterial pathogen campylobacter

STRONG PIPELINE WITH NEAR TERM MILESTONES



Immuron's Clinical Programs

Compound or brand name	Indication	Phase I	Phase II	Phase III	Market
IMM-124E Travelan®	Traveler's Diarrhea ETEC challenge				
IMM-529	<i>Clostridioides difficile</i> Infection & Recurrence				

Our Partners' Clinical Programs

Compound or brand name	Partner	Phase I	Phase II	Phase III	Market
Travelan®	 Uniformed Services University				



TRAVELAN® PROGRESSES TOWARDS PHASE 3



Travelan® (IMM-124E) Phase 2

- Travelan® IND Approval – **December 2022**
- Study Initiation – **May 2023**
- First cohort recruitment completed – **July 2023**
- Presentations at Military Health System Research Symposium – **August 2023**
- Second cohort recruitment completed – **October 2023**
- Completion of In-patient phase – **October 2023**
- Topline Results – **March 2024**
- Anticipated Clinical Study Report – **December 2024**
- Anticipated End of Phase 2 FDA meeting – **1H 2025**
- Anticipated initiation of Phase 3 clinical study – **2H 2025**



US Uniformed Services University Traveller's Diarrhoea Clinical Field Trial

- USU's Infectious Diseases Clinical Research Program (IDCRP) are conducting a randomized clinical trial to evaluate the efficacy of Travelan® against placebo for Traveller's Diarrhoea
- 866 study participants (433 per arm)
- 50% recruitment milestone – **October 2023**
- 85% recruitment milestone – **September 2024**
- Anticipated completion of recruitment – **December 2024**
- Anticipated topline results – **April 2025**



IMM-529 PROGRESSION TO PHASE 2

IMM-529 Clinical Development for Treatment of *C. difficile* Infections

- Opportunity Assessment completed by  Lumarity
- *C. difficile* infection (CDI) affects just over ~400,000 people in the US annually
- Sizable number of patients who experience at least one recurrence (~20-25%),
- Many patients experience multiple recurrences, creating persistent unmet need for novel therapies to address recurrences
- Infectious disease experts reacted favorably to the IMM-529 MOA, and its ability to target three elements of the CDI infection –the spores, vegetative cells, and Toxin B
- Non-antibiotic treatments (such as IMM-529) are appealing to experts
- 600mg solid dose active formulation development – February 2023
- cGMP manufacture – **December 2023**
- FDA pre-IND submission – **July 2024**
- Positive FDA feedback to pre-IND submission – **September 2024**
- Updated peak sales US forecast by  Lumarity for IMM-529: from US\$93 million to **US\$400 million**
- Anticipated initiation of Phase 2 clinical trial – **2H 2025**

IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT



Lumantia* Opportunity Assessment for IMM-124E

- › Immuron's development of **IMM-124E** (hyperimmune bovine colostrum) as a prescription medication has the potential to address this unmet need
- › Primary care physicians (PCP)s impressed with clinical efficacy endpoint targets demonstrating > 80% protection against the development of diarrhea.
- › If base case efficacy targets are reached, IMM-124E would mostly be used by travelers going to the highest risk areas (e.g., rural Central America/Asia/Africa).
- › Based on the estimated market size and pricing, the base case yearly revenue in USA for IMM-124E is projected at **US\$102M**.
- › Reaching higher efficacy goals could broaden use.

Lumantia* Opportunity Assessment for IMM-529

- › Infectious disease experts reacted favorably to the **IMM-529** MOA, and its unique ability to target three elements of the rCDI infection – the spores, vegetative cells, and Toxin B
- › If IMM-529 can achieve a significant reduction in recurrences among patients with CDI, it can reach peak revenues of **~US\$400** million in USA
- › Based on new information about the overall CDI market and IMM-529's potential to be used earlier in the treatment algorithm (based on approvals for treatment and prevention of recurrence)
- › Derived wholly from secondary research, price target increased to Vowst level, as a second mover IMM-529 is projected to reach a 30% share of the advanced treatment market

Compound or brand name

IMM-124E - Travelan®

IMM-529

Indication

Traveler's Diarrhea ETEC challenge

Clostridioides difficile Infection (CDI) & Recurrence

Phase I

Immuron

Phase II

Immuron

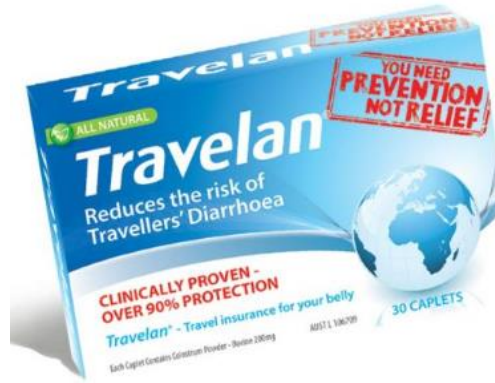
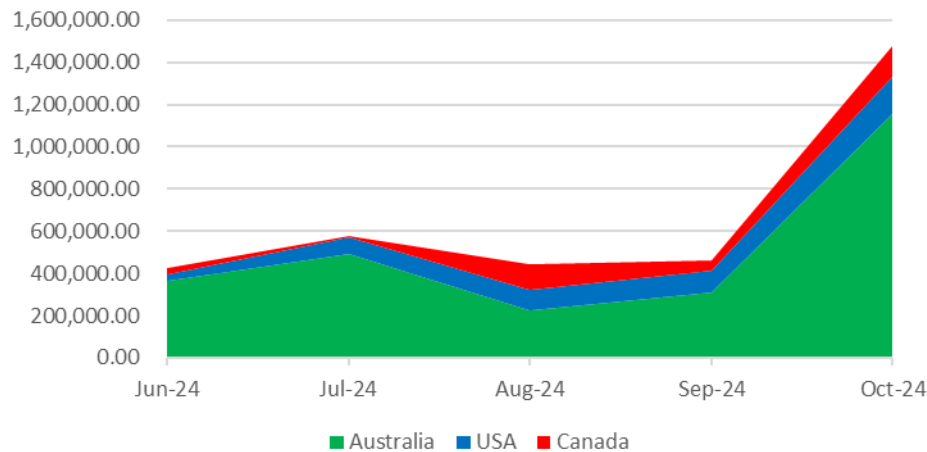
Phase III

Market

CONTINUED STRONG SALES GROWTH



A\$ Net Sales

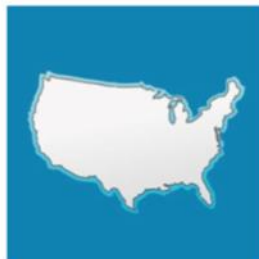


- **Global** sales increased by 172% in the 2024 fiscal year to a **record** A\$4.90 million compared to A\$1.80 million in FY23
 - **Record** monthly sales in October 2024 of \$1.49 million
- **Australia**
 - FY24: a **record** A\$3.75 million; up 223%
 - Q1, FY25: A\$1.01 million
 - October 2024: A\$1.16 million
 - Travelan® was the **#1** SKU in the Antidiarrheal category across Chemist Warehouse in Australia¹
- **USA**
 - FY24: a **record** A\$1.08 million; up 67%
 - Q1, FY25: A\$0.28 million
 - October 2024: A\$0.17 million
- **Canada**
 - FY24: A\$0.08 million
 - Q1, FY25: A\$0.17 million
 - October 2024: a monthly **record** A\$0.15 million



EXPANSION OF TRAVELAN® DISTRIBUTION

WHERE TO BUY TRAVELAN

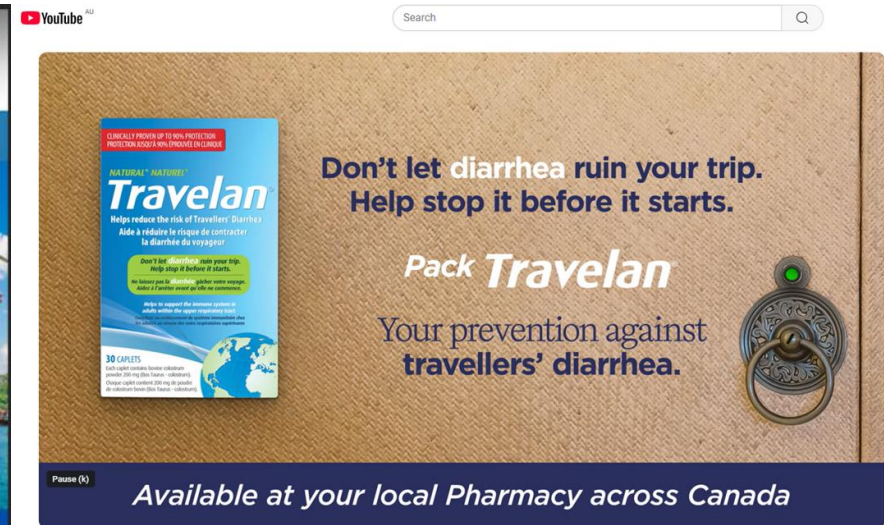


CONSUMER MARKETING ACTIVITY DRIVING TRAVELAN® SALES GROWTH



We continue to drive awareness, consideration and engagement

- Ranging across major retailers (Australia, Canada)
- In-store positioning and promotion
- Retailer catalogues
- Search and social media marketing
- Social competitions
- User generated content
- Influencer program
- HCP user generated activity
- Amazon Prime sales promotions
- Amazon sponsored brand ads





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Scientific references

Travelan® (IMM-124E)	
Travelan® has been shown to reduce both the incidence and severity of ETEC-induced diarrhea in up to 90% of volunteers	Scandinavian Journal of Gastroenterology, 46:7-8, 862-868, DOI: 10.3109/00365521.2011.574726
Clinical Evaluation of Travelan® an Oral Prophylactic for Prevention of Travelers' Diarrhea in Active Duty Military Service Assigned Abroad.	Military Health System Research Symposium 14-17 Aug 2023 Abstract 1
Travelan as a broad Spectrum anti-bacterial	Immuron Limited, 29 April, 2011
Travelan® demonstrates broad reactivity to Vibrio cholera strains from Southeast Asia indicating broad potential for prevention of traveler's diarrhea	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 4 September, 2019
Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 5 September, 2018
Travelan® able to bind and was reactive to 60 clinical isolates of each bacteria, Campylobacter, ETEC, and Shigella	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 30 January, 2017
Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta)	Islam D, Ruamsap N, Imerbsin R, Khanijou P, Gonwong S, Wegner MD, et al. (2023) Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta). PLoS ONE 18(12): e0294021.
Bioactive Immune Components of Travelan®	Clin Vaccine Immunol 24:e00186-16. https://doi.org/10.1128/CVI.00186-16
Hyperimmune bovine colostrum containing lipopolysaccharide antibodies (IMM-124E) has a non-detrimental effect on gut microbial communities in unchallenged mice	Infect Immun. 2023 Nov; 91(11): e00097-23.
Administration of the Hyper-immune Bovine Colostrum Extract IMM-124E Ameliorates Experimental Murine Colitis	Journal of Crohn's and Colitis, Volume 13, Issue 6, June 2019, Pages 785–797, https://doi.org/10.1093/ecco-icc/jiy213
IMM-529	
Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative	Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5