# Immuron CEO, Steven Lydeamore presentation at Peak Biotech Showcase

Melbourne, Australia, August 21 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN) is pleased to advise our Chief Executive Officer, Steven Lydeamore will be presenting at Peak Biotech Showcase on Wednesday 21st August 2024 at Work Club Olderfleet, 477 Collins Street, Melbourne, Australia.

A copy of the presentation being made is included below.

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

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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
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NASDAQ: IMRN
ASX: IMC

# Biotech Showcase

**Steven Lydeamore**
Chief Executive Officer

21 August 2024

# 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.

YTD FY2024 results in this presentation are subject to audit review.



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# Executive summary

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

## Company Overview

Two commercially available oral immunotherapeutic products – Travelan® and Protectyn®

4 clinical programs: Travelan®(IMC: Phase 2 CHIM trial), Travelan®(USU: Phase 4 field study), CampETEC (NMRC: Phase 2 CHIM trial), IMM-529 (IMC: Protocol development phase, Phase 2 trial)

## Business Update

Flagship product Travelan® growing strongly as overseas travel rebounds

Travelan® (IMM-124E) Phase 2 CHIM trial topline results

Travelan® (IMM-124E) Travelan® Uniformed Services University IMM-124E Phase 4 trial recruited ~77% of 866

CampETEC Phase 2 clinical trial completed inpatient phase

IMM-529 pre-IND filed with FDA

**U.S. Department of Defense Research Award for NMRC and WRAIR to develop an enhanced formulation of Travelan®**

## Results & Outlook

**Sales 1 Jul 23 to 30 June 24 of A$4.9 million up 174% on pcp (unaudited)**

Evaluating options to enter international markets

Evaluating options to add to marketed products portfolio

## Financial Snapshot

| | |
|---|---|
| **Shares on Issue** | 227,998,346 |
| **Total Options** | 15,078,839 |
| **Last Traded Price** | IMC: A$0.10 |
| **52 week High/Low** | IMC: A$0.17/0.065<br>IMRN: $5.96/1.481 |
| **Market Cap** | IMC: A$22.8m |
| **Cash & Cash Equivalents (as at 31 Dec 23)** | A$15.2m |

## Major Shareholders

| Holder | Units | % of CSO |
|---|---|---|
| BNY Mellon Asset Management | 77,828,104 | 34.1 % |
| Authentics Australia Pty. Ltd. | 5,500,000 | 2.4 % |
| Grandlodge | 3,846,712 | 1.7 % |
| **Management & Board** | **1,954,070** | **0.9 %** |

as of 18 August 2024

# Travelan® record sales

## Global

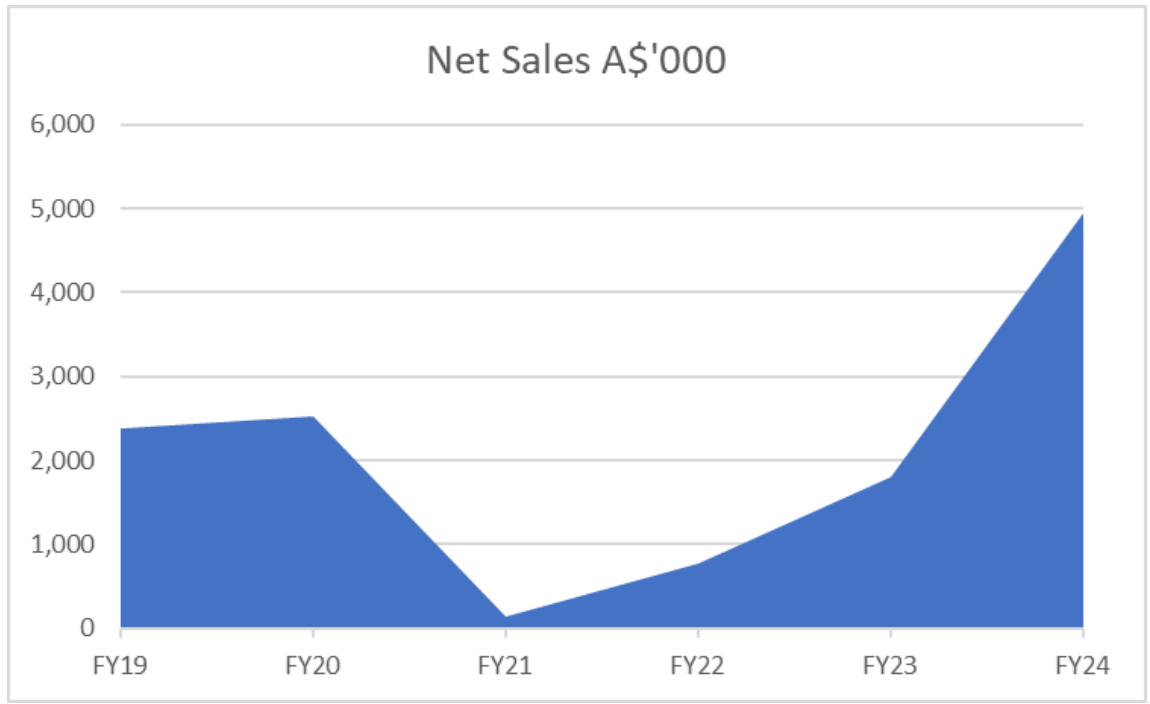
+ Full Year FY2024 AUD$4.9 million up 174% on (prior comparative period) pcp
+ June 2024 Quarter AUD$1.3 million up 253% on pcp and 6% on last quarter

## Australia

+ Full Year 2024 AUD$3.7 million up 223% on pcp
+ June 2024 Quarter AUD$1.0 million up 200% on pcp and 11% on last quarter

## USA

+ **Record annual sales**
+ Full Year 2024 AUD$1.1 million up 74% on pcp
+ June 2024 Quarter AUD$0.3 million up 546% on pcp; down 1% on last quarter



# Addressable market & industry overview


## Billion Dollar Market

Traveller's diarrhoea treatment market is large and growing at a CAGR of ~7%

## Industry tailwinds

Travel picking up significantly following COVID lockdowns

## Frequent Symptom

30% - 70% of travelers experience traveller's diarrhoea**

Chief Commercial Officer has 20+ year's experience with local and global (Asia, UK) commercial leadership roles with GSK and P&G

**USA Market**

FY24: launch on amazon.com and Walmart.com
Planning for increased market penetration in FY25

**Evaluating options**

for entry into international markets

to add marketed products to portfolio in FY25

**$83m**

Based on US annual travel numbers and a penetration rate of 15%, the market potential is estimated at $83m*

**$50m**

Based on EU travel numbers and a penetration rate of 15%, the market potential is estimated at $50m*

**$1.7b**

Clostridioides difficile infections (CDIs) to grow to almost $1.7 billion by 2026, according to GlobalData





** IMC Company Report - Travelan Market Analysis 2019 ** Centers for Disease Control and Prevention Yellow Book*

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# Technology platform

**Immuron's proprietary technology platform combines the natural human nutrition & health benefits of bovine colostrum with a novel class of specifically targeted oral polyclonal antibodies** that offer delivery within the gastrointestinal ("GI") tract and can be used to target viruses or bacteria and neutralize the toxins they produce at mucosal surfaces.

Bovine colostrum is the first milk of cows after calving. It is rich in immunoglobulins, lactoferrin, lysozyme, lactoperoxidase, growth factors and bioactive peptides. Colostrum has higher levels of protein, fat, vitamins, and minerals when compared to milk. This enables full development of the newborn calf in addition to immunity against several pathogens.*

**Step 1**

Development of Highly Specific Vaccines

**Step 2**

Isolation of Hyperimmune antibody-rich bovine colostrum

**Step 3**

Oral Antimicrobial therapeutic without drawbacks of antibiotics


**Final Product**

Toxin Neutralization + Clearance of targeted gut pathogens

- \+ Reduce occurrence and reduce/relieve diarrhoea
- \+ Reduce/relieve abdominal cramping
- \+ Reduce/relieve gastrointestinal pain
- \+ Assists repair of gastrointestinal/gut wall lining
- \+ Enhance/promote immune defence
- \+ Enhance/promote health liver function

**Australian Permitted indications; these statements have not been evaluated by the Food and Drug Administration (FDA)**





** Gomes et. al., NFS Journal, Volume 25, November 2021, pages 1-11, https://doi.org/10.1016/j.nfs.2021.10.001*

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# Travelan® | Mechanism of action

## Pre-Clinical Studies

Broad spectrum antimicrobial

Protects against bacterial adhesion to host cell intestinal epithelia

Binds to surface layer proteins preventing bacterial colonization and motility

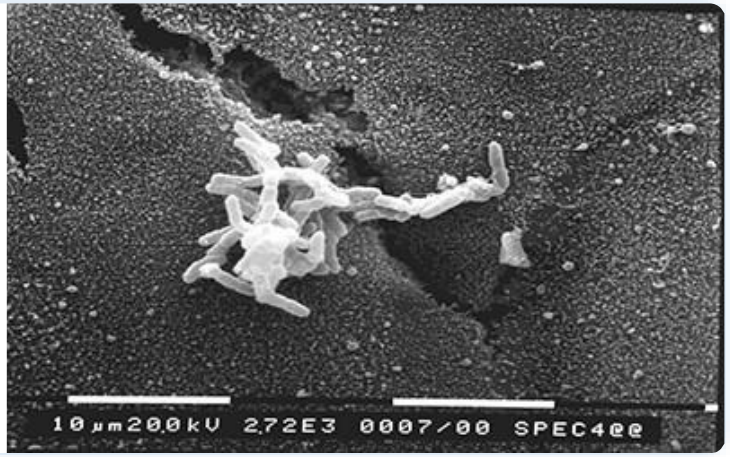
Toxin neutralization and clearance of targeted gut pathogens

### Without Travelan®

Bacteria attach to gut wall and infect


### With Travelan®

Bacteria neutralized by Travelan® antibodies





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# Status of product portfolio and key milestones

**Travelan®**
**MTEC 21-10-013 grant Phase 2**
randomized clinical challenge study to examine a dosing regimen for Travelan® more suited to the military IMM-124E (Travelan®) IND 29087
FDA approval Dec 22

Top-line data 7 March 2024
Clinical Study Report – **September 2024**

**Clostridioides difficile**
**IMM-529**
Prevention of recurrent CDI infections
Vaccine (spores, vegetative cells, and Toxin B)
600mg solid dose active formulation developed

Pre-IND submission to FDA – **1 July 2024**
Clinical protocol and trial preparation in progress

## Collaborative studies

### Travelan® P2TD

**Field study Uniformed Services University**
Phase 2 randomized clinical trial with Travelan® /Placebo to evaluate prophylactic effectiveness during deployment or travel to a high TD risk region
Status **~77%** of participants have been recruited (866 target)
Anticipated topline results – **1Q 2025**

### CampETEC

**NMRC Campylobacter and enterotoxigenic E. coli product**
Manufactured by Immuron
Immuron sponsored GLP Toxicology study completed – Dec 2022
Phase 2 CHIM completion of inpatient phase – December 2023
6 month follow up completed – June 2024
Adjudiction Committee assessment – **23 August 2024**

## Immuron's Clinical Programs

| Compound or brand name | Indication | Phase I | Phase II | Phase III | Market |
|---|---|---|---|---|---|
| IMM-124E Travelan® | Travelers' Diarrhea ETEC challenge | immuron | | | |
| IMM-529 | *Clostridioides difficile* Infection & Recurrence | immuron | | | |

## Our Partners' Clinical Programs

| Compound or brand name | Partner | Phase I | Phase II | Phase III | Market |
|---|---|---|---|---|---|
| Travelan® | | Uniformed Services University | | | |
| CampETEC | | Naval Medical Research Command | | | |





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# WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI

| IMM-529: pre-IND filed with FDA July 2024 | |
|---|---|
| Indication / Target Population | IMM-529 will be indicated for the treatment of recurrent *C. difficile* infection |
| Product Description / Mechanism of Action | • Novel antibody-containing therapeutic which neutralizes C. *difficile* but does not impact the microbiome<br>• Targets not only toxin B but also spores and vegetative cells responsible for recurrence<br>• Potential for use in combination with standard of care (e.g. vancomycin, fidaxomicin)<br>• Targets many isolates |
| Dosage and ROA | • Oral administration, 3 x daily<br>• Trial to test safety 7-day treatment course on top of standard of care (vancomycin, fidaxomicin) |
| Efficacy | 1. Prevention of primary disease (80% P =0.0052)<br>2. Protection of disease recurrence (67%, P <0.01) and<br>3. Treatment of primary disease (78.6%, P<0.0001; TcB HBC). |
| Safety / Tolerability | • To be evaluated in Phase I/IIA study<br>• Equivalent or better than current standard of care |



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# Positive results support Travelan®
## progress to phase 3

### IMM-124E Phase 2

- Healthy volunteers were recruited and randomized to receive a single daily oral dose of 1200 mg of Travelan® or placebo. Dosing commenced 2 days prior to challenge with ETEC strain H10407 and continued for 7 days.
- 60 subjects completed the inpatient challenge component of this current clinical study.
- **36.4% protective efficacy** against Enterotoxigenic Escherichia coli (ETEC) induced moderate to severe diarrhea was observed in the Travelan® group compared to the Placebo group (primary endpoint) even though the attack rate for this study was 37%, much lower than the planned 70%.
- The attack rates on previous Phase 2 (Otto et al. 2011) were 73% and 86% with protective efficacy of 90.9% and 76.7%.
- **43.8% reduction in diarrhea of any severity** in the Travelan® group compared to the Placebo group during the 5-day period post challenge which is ***approaching statistical significance; p=0.066***
- **The number of cumulative adverse events per participant in the Travelan® group (58) *was statistically significantly lower than the Placebo group (109); p<0.05.***
- Phase 2 clinical study data supports the excellent safety and tolerability profile of Travelan®.

**Travelan® topline clinical trial results demonstrate protective efficacy with single daily dose.**

# IMM-124E Phase 3 strategy

| Pre | 2H 2024 | 1H 2025 | 2H 2025 | Post |
|---|---|---|---|---|
| Phase 1 clinical study (Baltimore, 1996) | Additional topline data analysis August 2024 | FDA meeting – Phase 3 clinical protocol | Initiate Phase 3 | Trial duration ~ 2 years |
| Phase 2 clinical study (Poland, 2000) | Clinical Study Report anticipated September 2024 | | | End of Phase 3 FDA meeting |
| FDA[1] IND[2] approval (December 2022) | End of Phase 2 FDA meeting | | | BLA[3] submission |
| Phase 2 clinical study (Baltimore, 2024) | | | | |

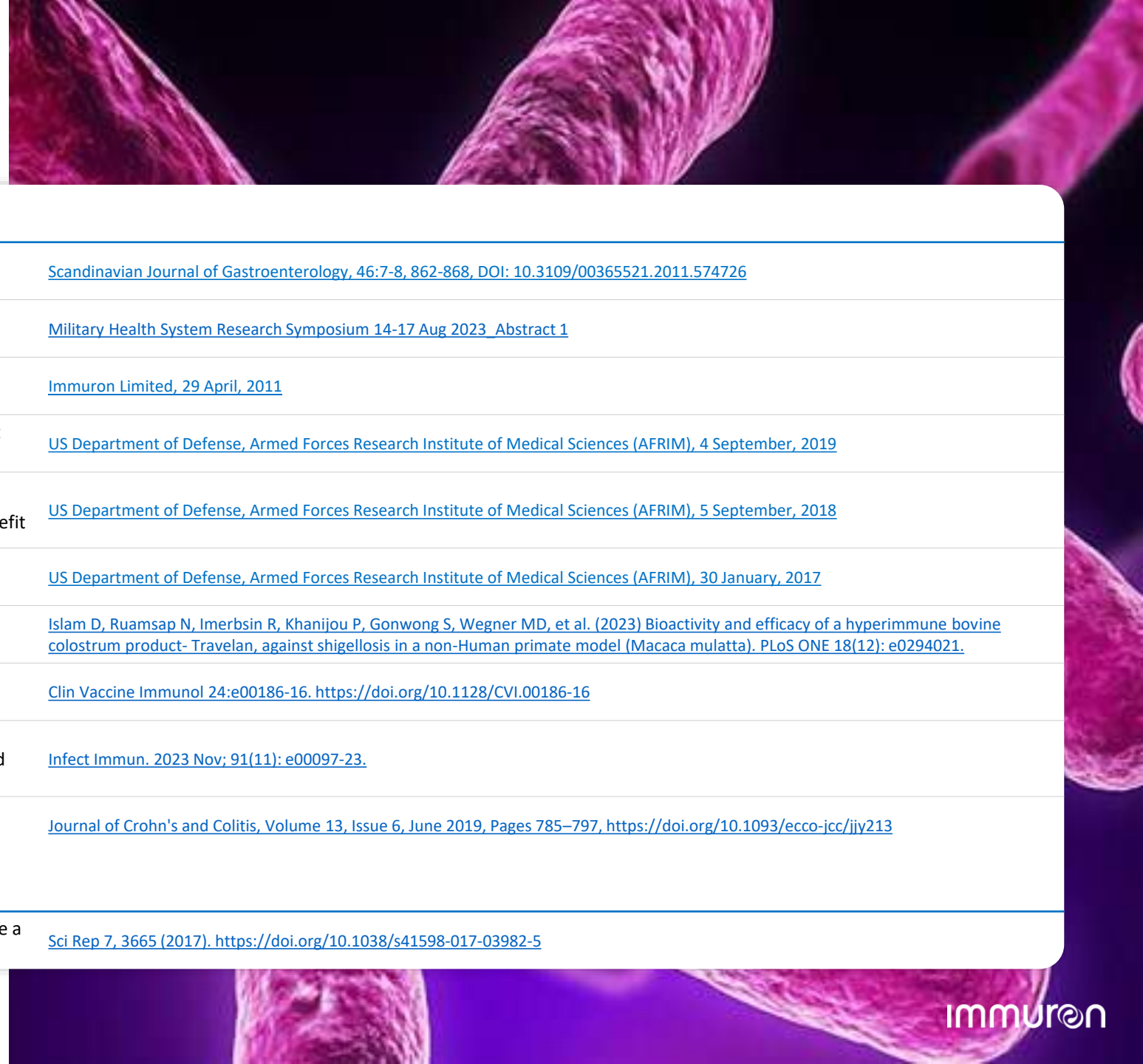
- The pivotal registration studies is anticipated to involve two randomized, double-blind, parallel-group, placebo-controlled Phase 3 clinical studies (drug substance IMM-124E) to assess the efficacy and safety of Travelan® for prevention of traveler's diarrhea (TD)
- Anticipated enrolment of approximately 1200 healthy adult subjects (600 subjects in two studies) traveling to regions with high TD risk.
- Subjects anticipated to be randomized 1:1 to receive Travelan® or placebo.
- Dosing anticipated to begin 3 days prior to arrival in country and for at least 14 days in country.
- The primary endpoint requested will be traveler's diarrhea.





1. U.S. Food and Drug Administration; 2. Investigational New Drug; 3. Biologics License Application

# 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-jcc/jjy213 |

## 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 |





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