NASDAQ: IMRN
ASX: IMC

# Coffee Microcaps

**Steven Lydeamore**
Chief Executive Officer

22 October 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 FY2025 results in this presentation are subject to audit review.

immuron

# 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®

3 clinical programs: Travelan®(IMC: Phase 2 CHIM trial), Travelan®(USU: Phase 4 field study), IMM-529 (IMC: preparing IND, Phase 2 trial)

## Business Update

Travelan® (IMM-124E) Phase 2 CHIM trial topline results; **Pharmaron presentation at International Conference**

**Travelan® (IMM-124E) Travelan® Uniformed Services University IMM-124E Phase 4 trial recruited ~85% of 866**

**CampETEC Phase 2 clinical trial topline results announced;**

**NMRC presentation at International Conference**

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

**IMM-529 Immuron completes pre-IND meeting with FDA on the development of IMM-529**

## Results & Outlook

**Sales 1 July 24 to 30 September 24 of A$1.5 million up 13% on prior quarter (unaudited)**

**North American Travelan® sales A$0.5 million up 48% on prior quarter (unaudited)**

Evaluating options to enter international markets

Evaluating options to add to marketed products portfolio

## Financial Snapshot

| | |
|---|---|
| **Shares on Issue** | 229,145,429 |
| **Total Options** | 13,931,756 |
| **Last Traded Price** | IMC: A$0.077 |
| **52 week High/Low** | IMC: A$0.17/0.065<br>IMRN: $5.96/1.481 |
| **Market Cap** | IMC: A$17.4m |
| **Cash & Cash Equivalents (as at 30 June 2024)** | A$11.7m |

## Major Shareholders

| Holder | Units | % of CSO |
|---|---|---|
| BNY Mellon Asset Management | 76,396,824 | 33.3 % |
| Authentics Australia Pty. Ltd. | 5,500,000 | 2.4 % |
| Grandlodge | 3,846,712 | 1.7 % |
| **Management & Board** | **3,101,153** | **1.4 %** |

as of 21 October 2024

# Opportunity to Convert Billion Dollar Traveller's Diarrhoea Market from Relief to Prevention by Travelan®


## Billion Dollar Market

Traveller's diarrhoea treatment market is large and growing at a CAGR of ~7%[1]

## Industry tailwinds

International travel continues to grow
Travel to high-risk destinations from Australia exceeds pre-pandemic levels and still growing

## Frequent Symptom

30% - 70% of travelers experience traveller's diarrhoea[2]

## Proprietary Vaccine

Dairy cows inoculated with proprietary vaccines covering 13 strains of enterotoxigenic E.coli (ETEC)

## Bind and Neutralise to Prevent

According to the Centers for Disease Control and Prevention Traveller's Diarrhoea is a clinical syndrome resulting from microbial contamination of ingested food and water.
Travelan® utilises specific antibodies to bind the bacteria and the toxins they produce effectively neutralising them and inhibiting their attachment to the gastrointestinal tract reducing LPS-related inflammation and bacterial colonisation.

## No White Label Threat

- Colostrum has some antibacterial and immune modulatory properties.
- However, ***Travelan®*** has in addition to the colostrum-derived compounds very high concentration of anti-*E.coli* antibodies.
- ***Travelan®*** utilises specific antibodies to bind the bacteria and the toxins they produce effectively neutralising them and inhibiting their attachment to the gastrointestinal tract reducing LPS-related inflammation and bacterial.
- These antibodies target the major bacteria which cause Traveller's Diarrhoea.
- ***Travelan®*** has a unique synergistic effect between the colostrum-derived products and the high concentration antibodies for suppressing the inflammation and targeting the bacteria which cause Traveller's Diarrhoea in the gastrointestinal system.



[1] https://www.transparencymarketresearch.com/travelers-diarrhea-market.html;*Centers for Disease Control and Prevention CDC.gov 2024*

# Travelan® continued strong sales growth

## Global

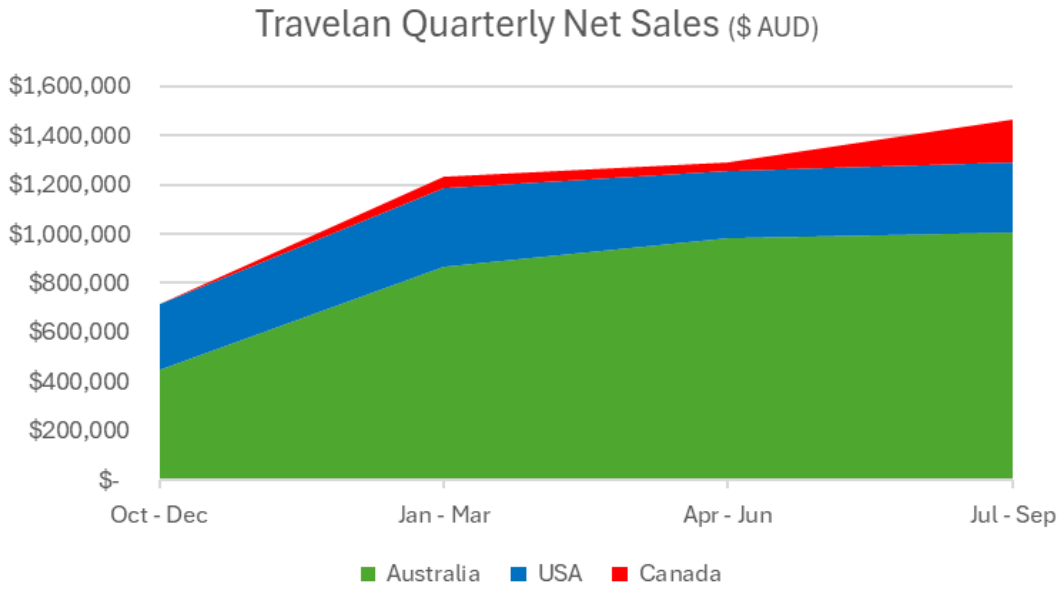
+ Q1 FY2025 AUD$1.5 million up 13% on prior quarter

## Australia

+ Q1 2025 AUD$1.0 million up 3% on prior quarter
+ Secured core ranging in another nine pharmacy banner groups

## North America

+ Q1 2025 AUD$0.5 million up 48% on prior quarter
+ Strongest monthly sales on amazon.com
+ Secured distribution in ten pharmacy/grocery retailers in Canada



# 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 – **October 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
IND, 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 **~85%** of participants have been recruited (866 target)
Anticipated topline results – **April 2025**

### CampETEC

**NMRC Campylobacter and enterotoxigenic E. coli product**
Manufactured by Immuron for NMRC
Top-line data reported **4 October 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 | | | |



immuron

# IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT

## Updated Revenue Estimate for IMM-52 up from US$93 million to ~US$400 million

**Lumanity* 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.

**Lumanity 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 | Indication | Phase I | Phase II | Phase III | Market |
|---|---|---|---|---|---|
| **IMM-124E - Travelan®** | Traveler's Diarrhea ETEC challenge | immuron → | | | |
| **IMM-529** | *Clostridioides difficile* Infection (CDI) & Recurrence | immuron → | | | |

*Lumanity, a leading lifescience consulting company: https://lumanity.com/company/our-story/*

# WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI

| IMM-529: pre-IND filed with FDA July 2024; successful pre-IND meeting | |
|---|---|
| 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 2 study<br>• Equivalent or better than current standard of care |

immuron

# 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**

Phase 1 clinical study (Baltimore, 1996)

Phase 2 clinical study (Poland, 2000)

FDA[1] IND[2] approval (December 2022)

Phase 2 clinical study (Baltimore, 2024)

**2H 2024**

Additional topline data analysis August 2024

**1H 2025**

Clinical Study Report anticipated **October 2024**

End of Phase 2 FDA meeting

FDA meeting – Phase 3 clinical protocol

**2H 2025**

Initiate Phase 3

**Post**

Trial duration ~ 2 years

End of Phase 3 FDA meeting

BLA[3] submission

+ 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

# Upcoming Milestones

## Revenue

+ Continued quarter on quarter growth from growth drivers
+ Secured core ranging in another nine Australian pharmacy banner groups
+ Strongest monthly sales on amazon.com in September 2024
+ Secured distribution in ten pharmacy/grocery retailers in Canada

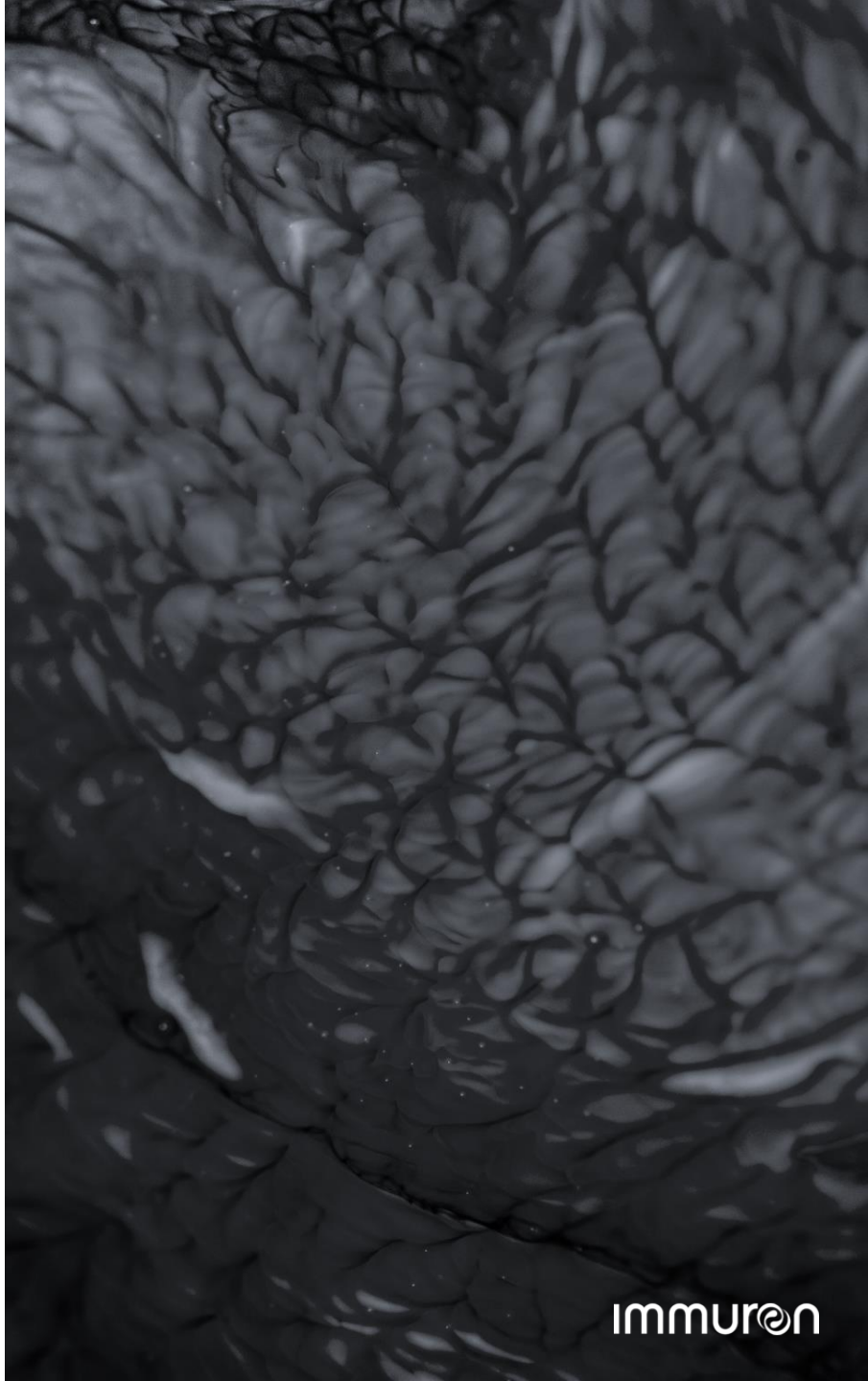
## Clinical

**IMM-124E (Travelan®): Traveller's Diarrhoea**

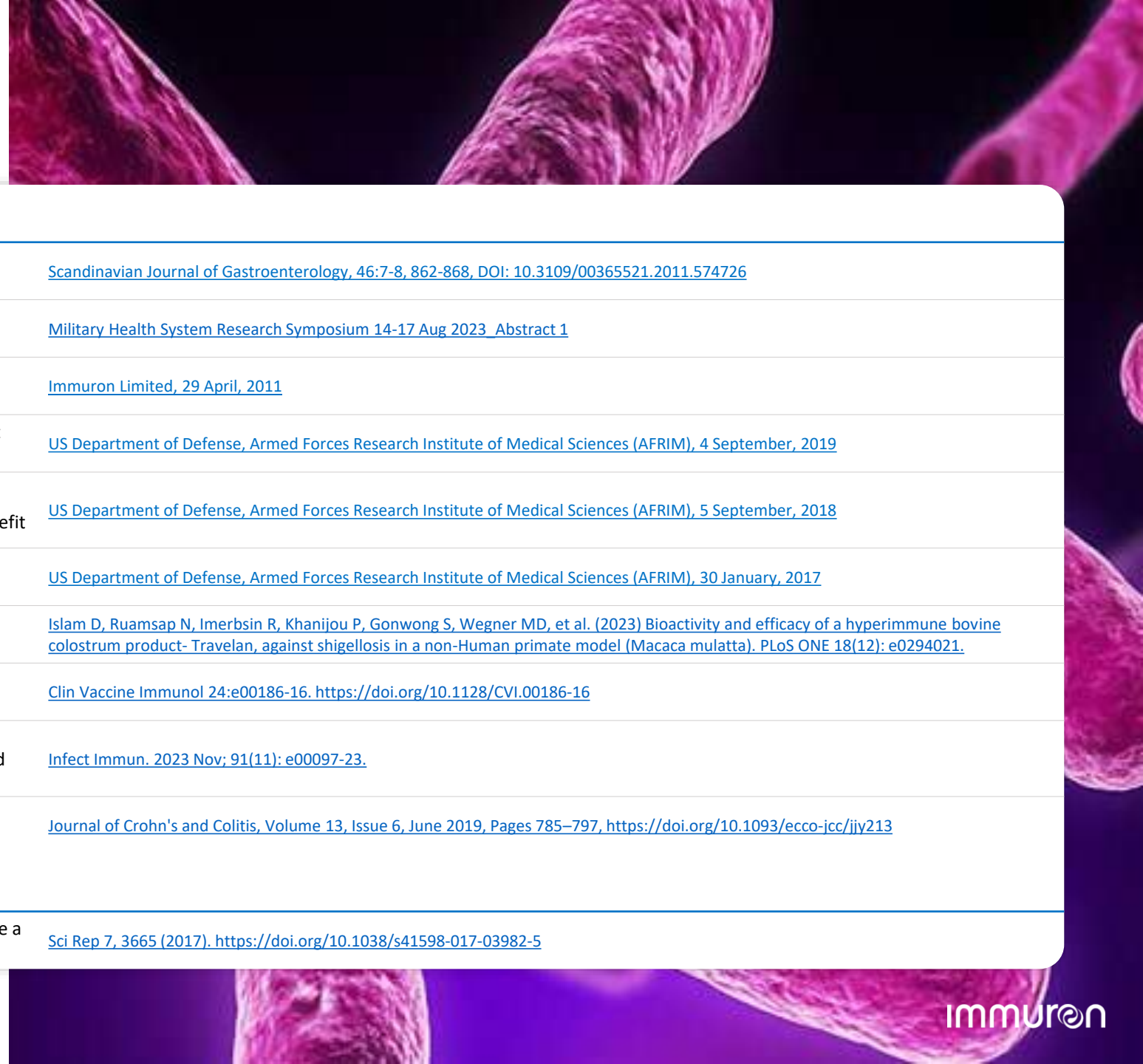
+ end December 2024: 100% recruitment (Phase 4; n=866)
+ IMM-124E: April 2025: Topline data (Phase 4; n=866)
+ IMM-124E: 1H 2025: End of Phase 2 FDA meeting (Phase 2; n=60)
+ IMM-124E: 1H 2025: FDA meeting Phase 3 Clinical Protocol

**IMM-529: Clostridioides difficile infection (C.diff, CDI)**

+ IMM-529: 1H 2025: FDA IND Submission
+ IMM-529: 2H 2025: Initial Phase 2



# 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 |



immuron

## STEVEN LYDEAMORE
## CHIEF EXECUTIVE OFFICER
## IMMURON LIMITED

## CONTACT INFORMATION:


EMAIL: STEVE@IMMURON.COM

PHONE: AUSTRALIA: +61 438 027 172