



# **THE WATCHLIST INVESTOR PRESENTATION**

23 APRIL 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.

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





# 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<sup>®</sup> and Protectyn<sup>®</sup>
- 4 clinical programs: Travelan<sup>®</sup>(IMC: Phase 2 CHIM trial), Travelan<sup>®</sup>(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<sup>®</sup> growing strongly as overseas travel rebounds
- Travelan<sup>®</sup> (IMM-124E) Phase 2 CHIM trial topline results
- Travelan<sup>®</sup> (IMM-124E) Travelan<sup>®</sup> Uniformed Health Services University (USU) P2TD IMM-124E field clinical trial recruited ~64% of target 866
- CampETEC Phase 2 clinical trial completed inpatient phase



## Results & Outlook

- Sales 1 Jul 23 to 31 Mar 24 of A\$3.6 million up 154% on pcp (unaudited)
- Evaluating options to enter international markets through distributors
- Evaluating options to add to marketed products portfolio

## Financial Snapshot

Shares on Issue	227,998,346
Total Options	15,368,559
Last Traded Price	IMC: A\$0.10
52 week High/Low	IMC: A\$0.17/0.065 IMRN: \$5.96/1.48
Market Cap	IMC: A\$22.79m
Cash & Cash Equivalents (as at 31 Dec 23)	A\$15.2m

## Major Shareholders

Holder	Units	% of CSO
BNY Mellon Asset Management	81,362,005	35.7 %
<b>Management &amp; Board</b>	<b>6,904,554</b>	<b>3.0 %</b>
Authentic Australia Pty. Ltd.	5,500,000	2.4 %
Grandlodge	3,846,712	1.7 %

as of 19 April 2024

# IMM-124E

## BILLION DOLLAR MARKET - HIGH UNMET NEED



### Billion Dollar Market

Traveller's diarrhoea treatment market is large and growing at a CAGR of ~7%<sup>1</sup>



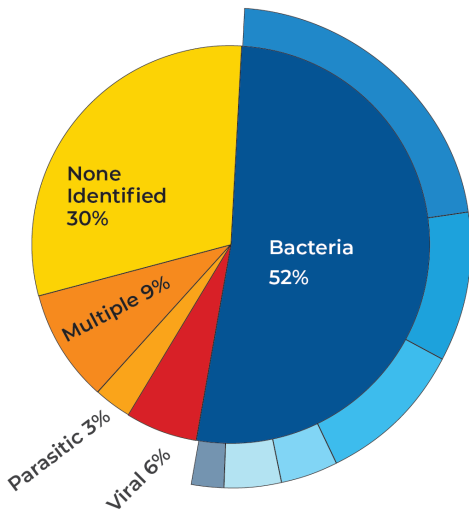
### Industry tailwinds

Travel picking up significantly following COVID lockdowns



### Frequent Symptoms

30% - 70% of travelers experience traveller's diarrhoea<sup>2</sup>



Listed In Order

enterotoxigenic *E. coli* (ETEC)

enteroaggregative *E. coli* (EAEC)

*Campylobacter*

*Shigella*

enteropathogenic *E. coli* (EPEC)

*Salmonella*

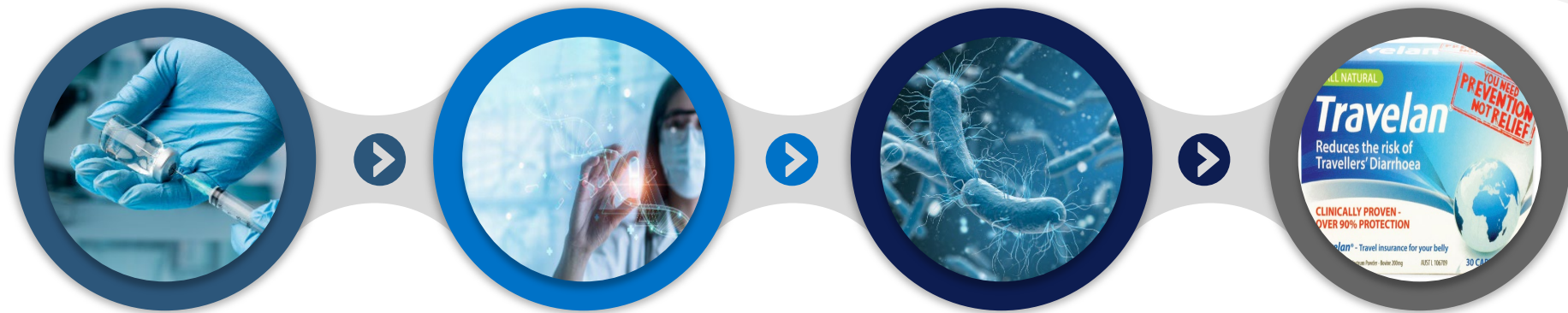
- There are no current reliable vaccines for prevention of Travellers' diarrhoea<sup>2</sup>
- Enterotoxigenic *Escherichia coli* (ETEC) is the leading cause of Travellers' diarrhoea<sup>2</sup>
- Travelan<sup>®</sup> is a hyperimmune bovine colostrum produced by immunization of cows during gestation with a vaccine consisting of antigens derived from 13 different ETEC strains known to cause Travelers' diarrhea
- Travelan<sup>®</sup> is broadly cross-reactive with other ETEC strains not included in the vaccine and other gram-negative bacteria (*Shigella*, *Vibrio cholera*, *Campylobacter spp.*)<sup>3,4</sup>
- Diarrhea ranked 1<sup>st</sup> among 57 infectious disease threats by the 2019 Military Infectious Disease Research Program's Infectious Disease Threat Prioritization Panel based on its impact to readiness<sup>5</sup>
- 76% of Soldiers in OIF and OEF experienced traveler's diarrhea early in their deployment<sup>5</sup>



# TECHNOLOGY PLATFORM

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.\*

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.



**STEP 1**  
Development of Highly Specific Vaccines

**STEP 2**  
Isolation of Hyperimmune antibody-rich bovine colostrum

**STEP 3**  
Oral Antimicrobial therapeutics without drawbacks of antibiotics

**FINAL PRODUCT**  
Toxin Neutralization + Clearance of targeted gut pathogens

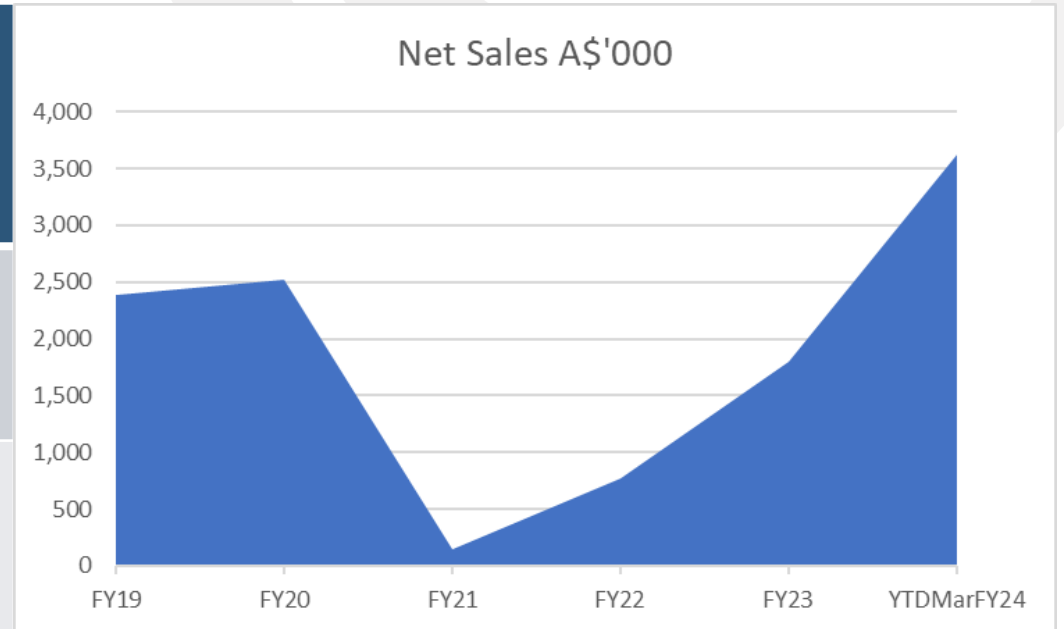
- ✓ Reduce occurrence and reduce/relieve diarrhoea
- ✓ Reduce/relieve abdominal cramping
- ✓ Reduce/relieve gastrointestinal pain
- ✓ Assists repair of gastrointestinal/gut wall lining
- ✓ Enhance/promote immune defence
- ✓ Enhance/promote health liver function

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



# TRAVELAN<sup>®</sup> SALES CONTINUE STRONG GROWTH

<b>Global</b>	<ul style="list-style-type: none"><li>• FYTD Mar 2024 AUD\$3.6 million up 154% on (prior comparative period) pcp</li><li>• Mar 2024 Quarter AUD\$1.3 million up 51% on pcp and 75% on last quarter</li></ul>
<b>Australia</b>	<ul style="list-style-type: none"><li>• FYTD Mar 2024 AUD\$2.8 million up 234% on pcp</li><li>• Mar 2024 Quarter AUD\$0.9 million up 66% on pcp and 99% on last quarter</li></ul>
<b>USA</b>	<ul style="list-style-type: none"><li>• FYTD Mar 2024 AUD\$0.8 million up 35% on pcp</li><li>• Mar 2024 Quarter AUD\$0.3 million up 7% on pcp and 18% on last quarter</li><li>• Sales commenced on Walmart.com</li></ul>



# STATUS OF PRODUCT PORTFOLIO AND KEY MILESTONES



- ✔ US Department of Defense grant of US\$4.45 million to examine a dosing regimen for Travelan® more suited for use by the military
  - Market evaluation by [Lumanity](#) confirms the Traveler’s Diarrhea market opportunity for IMM-124E (Travelan®)
  - IMM-124E (Travelan®) Phase 2 CHIM trial topline results – 7 March 2024
  - Anticipated clinical study report – June/July 2024
  
- ✔ Market evaluation by [Lumanity](#) confirms the *Clostridioides difficile* market opportunity for IMM-529
  - 600mg solid dose active formulation development completed
  - Manufacture of cGMP IMM-529 –December 2023
  - Anticipated pre-IND submission to the FDA – 30 June 2024
  
- ✔ Travelan® - Uniformed Services University has recruited ~64% of 866 participants in a randomized clinical trial with Travelan® to evaluate the effectiveness for prophylaxis during deployment or travel to a high traveler’s diarrhea risk region
  - Anticipated completion of enrollment – July/August 2024
  - Anticipated topline results – December 2024
  
- ✔ Naval Medical Research Center Clinical Trials of CampETEC in campylobacter and enterotoxigenic *E.coli* (ETEC)
  - Animal ethics approval for Toxicology study – November 2022
  - Immuron sponsored Toxicology study completed - December 2022
  - Phase 2 CHIM completion of inpatient phase – December 2023
  - Anticipated topline results – June/July 2024

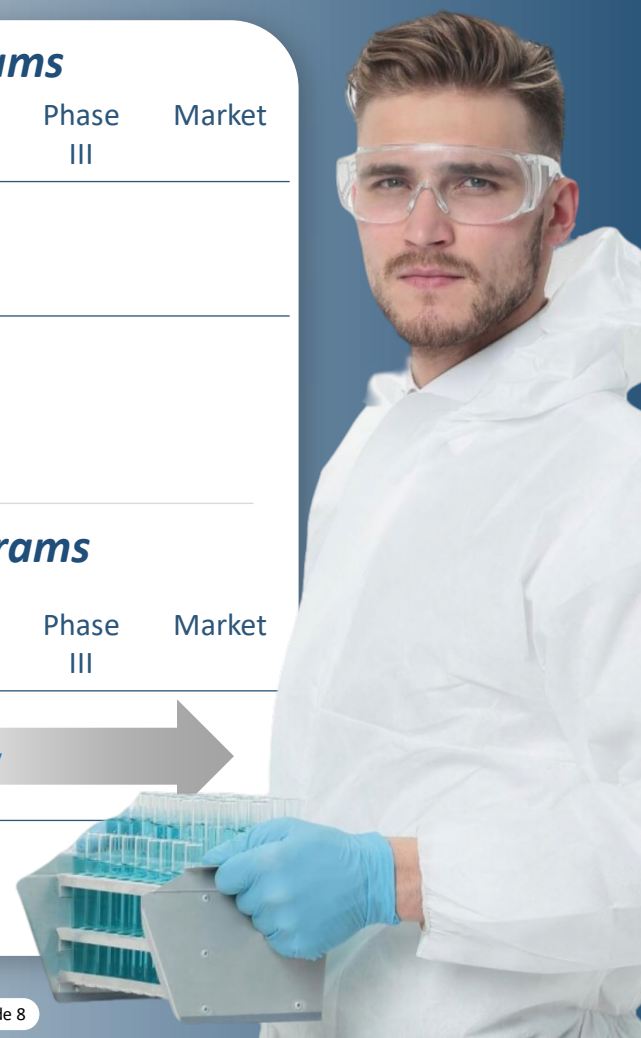
## Immuron’s Clinical Programs

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

## Our Partners’ Clinical Programs

Compound or brand name	Partner	Phase I	Phase II	Phase III	Market
<b>Travelan®</b>					
<b>CampETEC</b>					

\*Further information on the clinical programs can be found on slide 8





# NEAR TERM MILESTONES ANTICIPATED TO DRIVE VALUE

	2H 2022	1H 2023	2H 2023	1H 2024	2H 2024
<b>Travelan®</b>	<ul style="list-style-type: none"> <li>FDA IND<sup>1</sup> approved for single daily dose IMM-124E ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>IRB Approval<sup>4</sup></li> <li>Initiated IMM-124E ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>100% of patients enrolled</li> <li>Completion of In-patient phase ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Topline results for IMM-124E ETEC<sup>2</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Clinical Study Report</li> <li>End of Phase 2 FDA meeting</li> </ul>
<b>CampETEC</b>	<ul style="list-style-type: none"> <li>Submitted Response Letter to FDA Clinical Hold</li> <li>Immuron sponsored Toxicology study - completed</li> </ul>	<ul style="list-style-type: none"> <li>Toxicology Study Report</li> <li>FDA IND<sup>1</sup> approved (Clinical Hold released)</li> </ul>	<ul style="list-style-type: none"> <li>Institutional Review Board approval of NMRC<sup>5</sup> CampETEC Campylobacter CHIM<sup>3</sup> clinical trial protocol</li> <li>Initiated IMM-124E Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Completion of In-patient phase CampETEC Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Topline results for CampETEC Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>
<b>IMM-529</b>	<ul style="list-style-type: none"> <li>600 mg solid dose active formulation development</li> </ul>		<ul style="list-style-type: none"> <li>IMM-529 cGMP manufacture</li> </ul>	<ul style="list-style-type: none"> <li>IMM-529 (CDI)<sup>7</sup> Pre-IND<sup>1</sup> submission</li> </ul>	<ul style="list-style-type: none"> <li>FDA meeting</li> </ul>
<b>Travelan®</b>	<ul style="list-style-type: none"> <li>USU<sup>6</sup> P2TD IMM-124E field clinical trial recruitment commencement</li> </ul>		<ul style="list-style-type: none"> <li>~64% of 868 participants recruited</li> </ul>	<ul style="list-style-type: none"> <li>Completion of enrollment</li> </ul>	<ul style="list-style-type: none"> <li>Topline results</li> </ul>



# 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
- › Non-microbiome approaches (such as IMM-529) are still appealing to experts, who noted that clinical trial efficacy (reduction in relapse rate) and cost/access will be the key drivers of clinical use in recurrent patients, not mechanism of action
- › Based on the estimated market size, anticipated payer restrictions, pricing, and competition, base case yearly revenue in USA for IMM-529 is conservatively projected at **US\$93M** for the target patient population (limited to 2nd recurrence and later based on trial design and payer coverage)
- › Positioning IMM-529 earlier than second recurrence and/or efficacy targets could lead to higher uptake.

Compound or brand name

Indication

Phase I

Phase II

Phase III

Market

IMM-124E - Travelan®

Traveler's Diarrhea ETEC challenge

immuron

IMM-529

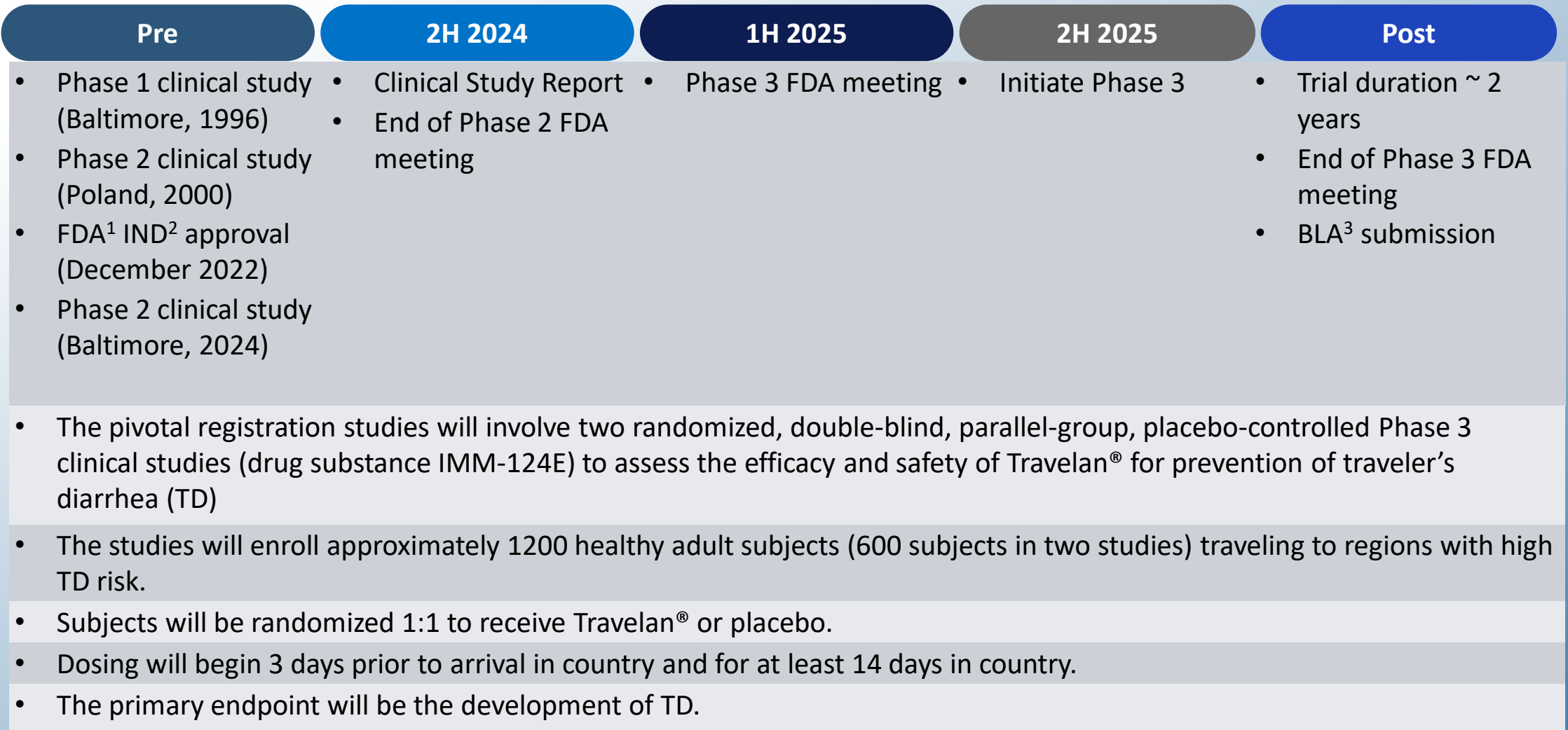
*Clostridioides difficile* Infection & Recurrence

immuron

*Lumantia, a leading lifescience consulting company: <https://lumantia.com/company/our-story/>*



# IMM-124E PHASE 3 STRATEGY



# WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI



## IMM-529

Indication / Target Population	IMM-529 will be indicated for the treatment of recurrent <i>C. difficile</i> infection
Product Description / Mechanism of Action	<ul style="list-style-type: none"><li>• Novel antibody-containing therapeutic which neutralizes <i>C. difficile</i> but does not impact the microbiome</li><li>• Targets not only toxin B but also spores and vegetative cells responsible for recurrence</li><li>• Potential for use in combination with standard of care (e.g. vancomycin, metronidazole, fidaxomicin)</li><li>• Targets many isolates</li></ul>
Dosage and ROA	<ul style="list-style-type: none"><li>• Oral administration, 3 x daily</li><li>• Trial to test safety 7-day treatment course on top of standard of care (vancomycin, metronidazole, fidaxomicin)</li></ul>
Efficacy	<ul style="list-style-type: none"><li>• Mouse data demonstrated ~80% survival rate (7/9) vs. ~10% survival rate in a control group (1/9) in a recurrent CDI mouse model</li></ul>
Safety / Tolerability	<ul style="list-style-type: none"><li>• To be evaluated in Phase I/IIA study</li><li>• Equivalent or better than current standard of care</li></ul>





**immuron**

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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/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>](#)