

## Immuron CEO, Steven Lydeamore to present at Bioshares

Melbourne, Australia, July 24, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to advise our Chief Executive Officer, Steven Lydeamore will be presenting at the 17th Bioshares Biotech Summit in Hobart on July 24<sup>th</sup>.

A copy of the presentation being made at the 17th Bioshares Biotech Summit is included below.

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

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### COMPANY CONTACT:

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### About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting traveller's diarrhoea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tableted preparation of hyperimmune bovine antibodies and other factors, which when taken with meals bind to diarrhoea-causing bacteria and prevent colonisation and the pathology associated with traveller's diarrhoea. 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 Traveller's Diarrhoea, reduce the risk of minor gastrointestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Traveller's Diarrhoea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

### About Traveller's Diarrhoea

Traveller's Diarrhoea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever. Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. *Campylobacter* spp. are also responsible for a significant proportion of cases. The more serious infections with *Salmonella* spp. the bacillary dysentery organisms belonging to *Shigella* spp. and *Vibrio* spp. (the causative agent of cholera) are often confused with Traveller's Diarrhoea as they may be contracted while travelling and initial symptoms are often indistinguishable.

### About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercialising orally delivered targeted polyclonal antibodies for the treatment of infectious diseases.

For more information visit: <http://www.immuron.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.

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# BIOSHARES PRESENTATION

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24 JULY, 2023

Steven Lydeamore - CEO

NASDAQ: IMRN

ASX: IMC



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# 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.

FY2023 results in this presentation are subject to audit review.





# TOPICS

1. Immuron Overview
2. US Department of Defense interest in Immuron Technology
3. Immuron's DoD partnered programs
4. Commercial path forward if Travelan<sup>®</sup> Phase 2 study is successful
5. Partnering with the US Department of Defense





# 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> (Sponsor: Immuron), CampETEC (Sponsor: US Department of Defense), IMM-529 (Sponsor: Immuron), Travelan<sup>®</sup> (Sponsor: US Department of Defense)
- Market capitalisation of A\$17.3m as of 19 Jul 23 with cash & cash equivalents balance of \$18.5 million as of 31 Dec 22



## Business Update

- Flagship product Travelan<sup>®</sup> growing strongly as overseas travel rebounds
- Travelan<sup>®</sup> (IMM-124E) IND filed with and approved by FDA
- Travelan<sup>®</sup> (IMM-124E) Phase 2 clinical trial initiated
- Travelan<sup>®</sup> Uniformed Health Services University P2TD IMM-124E field clinical trial recruited ~300 (>35% of target 868)
- CampETEC IND approved (released from Clinical Hold)



## Results & Outlook

- FY23 sales of A\$1.80 million up 136% on FY22 (subject to audit review)
- Evaluating options to enter Asian and European markets through distributors
- Evaluating options to add to marketed products portfolio in FY24

# 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

amazon.com shopfront launch 1QFY24  
Re-entry into retail pharmacies will be explored in FY24



Evaluating options:

- for entry into Asia and Europe
- to add marketed products to portfolio in FY24

## \$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

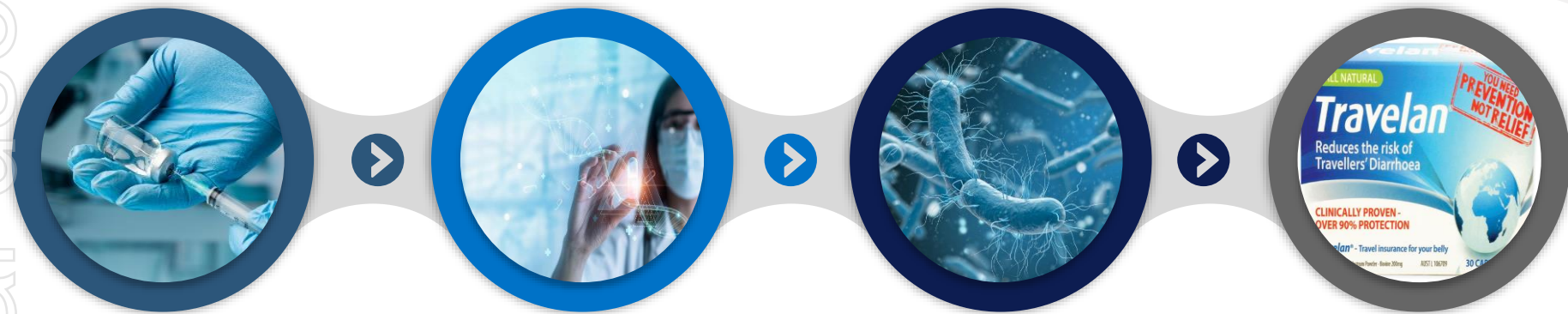
Clostridioides difficile infections (CDIs) to grow to almost \$1.7 billion by 2026, according to GlobalData



# 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)***

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



# US DEPARTMENT OF DEFENSE



- Managed by the Department of Defense collaborating with multiple government agencies
- Focuses on development of medical solutions to protect, treat, and optimize health and performance of U.S. military personnel and civilians



- Focuses on innovative medical solutions to a range of Force Health Protection and Readiness challenges currently facing U.S. Service Members, along with threats anticipated during future operations
- Created a model of vaccine and therapeutic development that is unique, nimble, and responsive to dynamically evolving **infectious disease** threats of military importance



ARMED FORCES  
RESEARCH INSTITUTE  
OF MEDICAL SCIENCES

- Optimize soldier lethality by developing solutions to **infectious diseases** capability gaps through product development and surveillance research in Asia



NAVAL MEDICAL  
RESEARCH  
COMMAND

- NMRC's mission is to conduct health and medical research, development, testing, evaluation, and surveillance to enhance deployment readiness of DoD personnel worldwide
- NRMC focuses on solutions to operational medical problems such as battlefield neurotrauma and wound infections, decompression sickness, naturally occurring **infectious diseases**, and biological threat agents; and is home to the DoD bone marrow registry



UNIFORMED  
SERVICES  
UNIVERSITY

- Coordinates, initiates, and supports research related to military health needs based on a holistic framework of health that includes prevention, resilience, treatment, recovery, rehabilitation, reintegration, and the overall well-being of the warfighter, as well as dual benefit outcomes that will improve civilian health. Our team advances research and collaborations utilizing several mechanisms, to include grants and a variety of cooperative agreements.



## 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.

Bacterial pathogens are the predominant risk, thought to account for the majority of traveler's diarrhea.

76% of Soldiers in OIF and OEF experienced traveler's diarrhea early in their deployment.

The threat of diarrhea will only grow as the effectiveness of antibiotics continues to diminish.

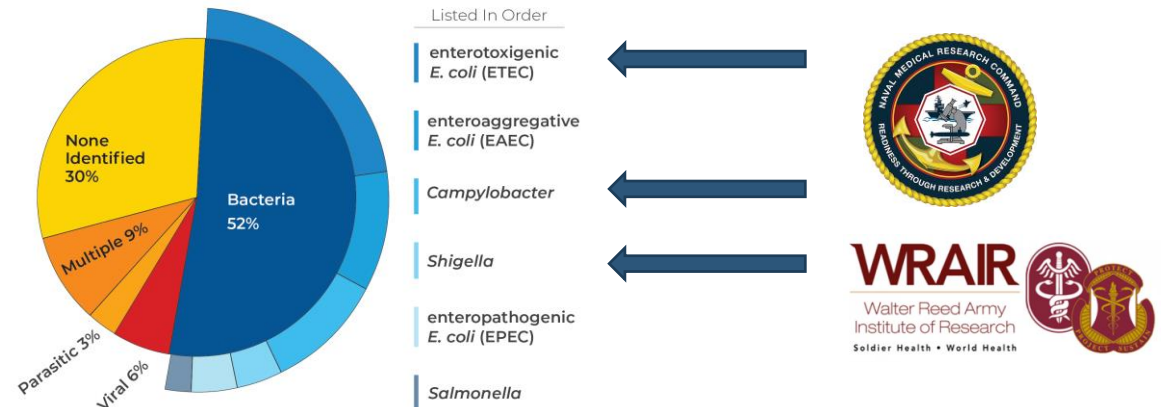
Olson et al. "Tropical Diseases, Travel Medicine and Vaccines, 2019, 5:1-15 Page 3



## Key Commentary

- **US Military Infectious Diseases Research Program (MIDRP)**
- The mission of the MIDRP is to plan, coordinate and oversee for the US DOD requirements-driven medical solutions that **PREVENT, PREDICT, and TREAT** infectious diseases threats
- Diarrheal disease is the leading infectious threat facing deployed U.S. Military
- Effective vaccines are the most suitable preventive measure for infectious diarrheal diseases but there are no licensed products available
- Enteric countermeasure products need to provide protection against military-relevant enteric pathogens
- **The DoD is working with Immuron to develop products with coverage for *Shigella*, *Campylobacter* and multiple ETEC phenotypes and is investigating the possibility of increasing coverage to other pathogens including enteroaggregative *E. coli* (EAEC)**

## Military Infectious Diarrhea Etiological Agents





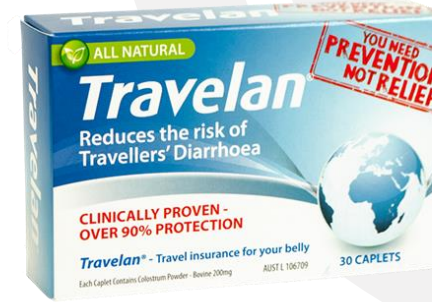
# US DOD R&D COLLABORATION AGREEMENTS



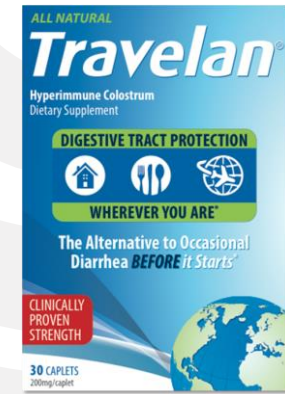
	NMRC	AFRIMS	WRAIR	
Travelan® (ETEC)	✓	✓	✓	✓ Established
Campylobacter	✓			✓ Developing
Shigella	✓		✓	

## Key Commentary

- Immuron partnered with AFRIMS, NMRC & WRAIR to test Travelan® against Campylobacter, ETEC, Shigella and Vibrio cholera
- Walter Reed Army Institute of Research – **June 2016**
- Armed Forces Research Institute of Medical Sciences (AFRIMS) – **June 2016**
- Naval Medical Research Command – **August 2016**
- Travelan® binds 180 pathogenic strains of bacteria from infected personnel deployed in Bhutan, Cambodia, Nepal and Thailand (ETEC, Shigella, Campylobacter)
- Travelan® binds to 71 pathogenic strains of Vibrio cholera from infected personnel in Bangladesh, Cambodia, and Thailand
- Travelan® prevented the development of Shigellosis in 75% of non-human primates receiving therapy



Australian Packaging



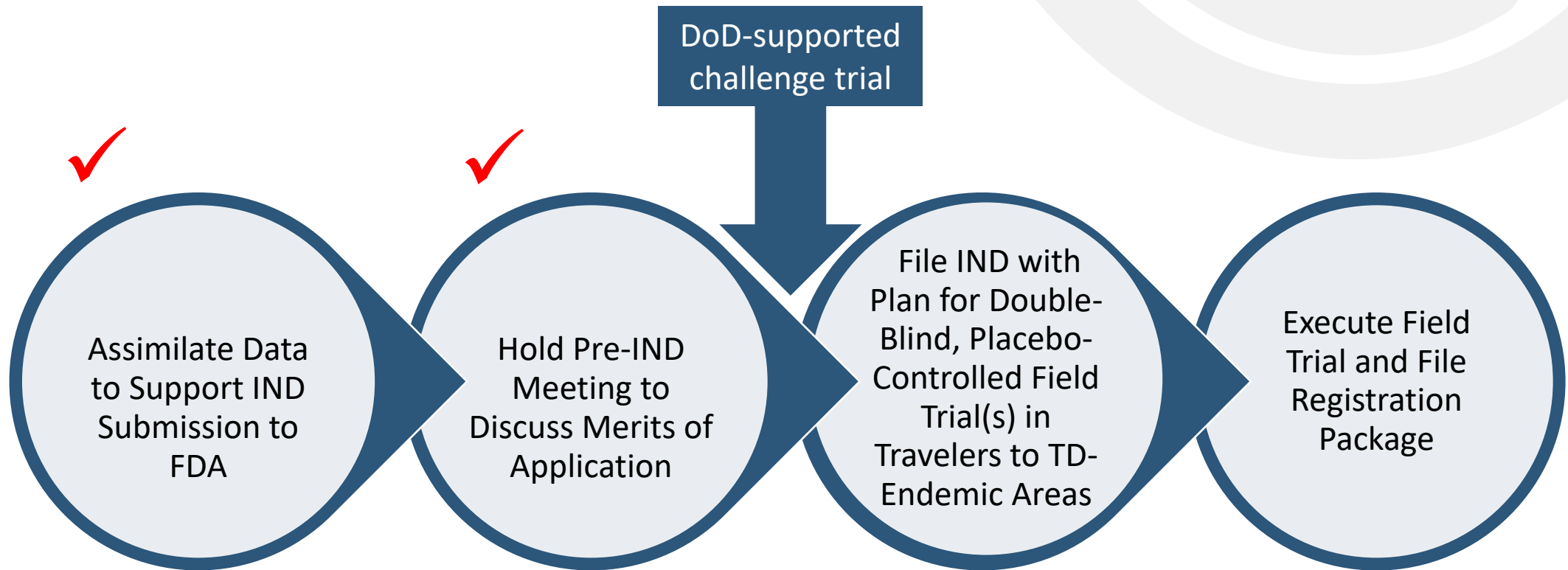
USA Packaging

- ✓ **US Department of Defense grant of US\$4.45 million to examine a dosing regimen for Travelan® more suited for use by the military**
  - IMM-124E (Travelan®) IND was approved by the FDA in December 2022
  - Initiated clinical trial May 2023: [NCT05933525](#)
- ✓ **Travelan® - Uniformed Services University** has recruited more than 35% of 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
  - [NCT04605783](#)
- ✓ **Naval Medical Research Command Clinical Trials of CampETEC** in campylobacter and enterotoxigenic *E.coli* (ETEC)
  - Animal ethics approval for Toxicology study – 22 November 2022
  - Immuron sponsored Toxicology study - completed 20 December 2022
  - FDA removed Clinical Hold on Campylobacter ETEC – 8 May 2023

# TRAVELAN® DRUG DEVELOPMENT PLAN



Travelan® for FDA approval as biologic to reduce the risk of traveller's diarrhoea (TD) in travellers to endemic areas:



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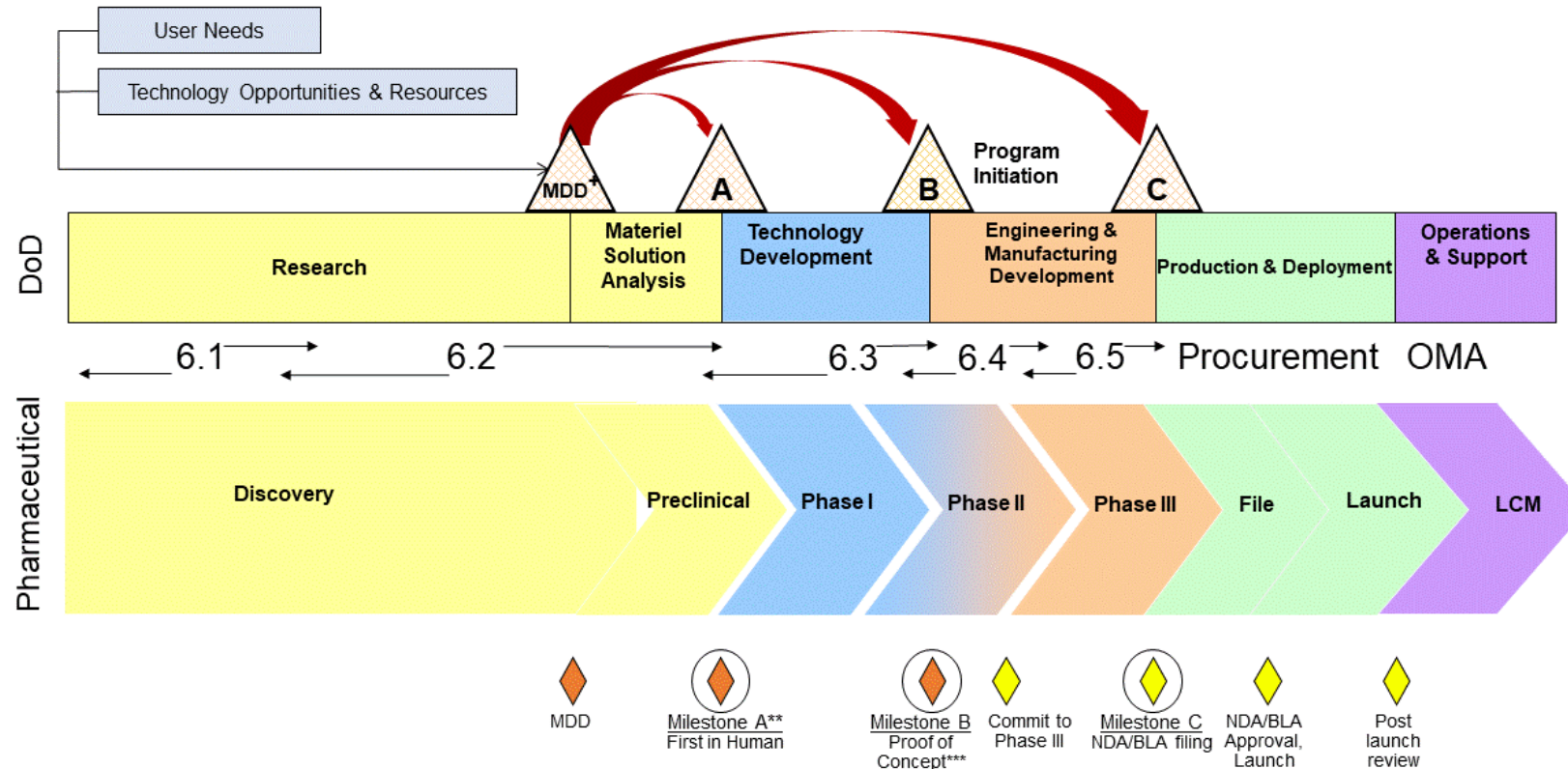




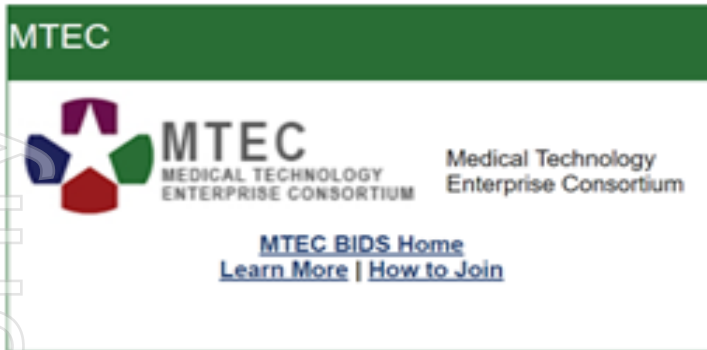
# TRAVELAN<sup>®</sup> DRUG DEVELOPMENT PLAN

Travelan<sup>®</sup> sits around Milestone B. In applying for the MTEC grant, Immuron had a high TRL rating.

## Development Lifecycle - Overview



# PARTNERING WITH US DEPARTMENT OF DEFENSE



## MTEC Membership

**Note: In order to respond to any solicitation on this site, you must be a member of the MTEC Consortium.**

Solicitations include awards from:

- Military Infectious Diseases Research Program (MIDRP)
- Combat Casualty Care Research Program (CCCRP)
- Military Operational Medicine Research Program (MOMRP)
- Clinical and Rehabilitative Medicine Research Program (CRM RP)
- Medical Simulation and Information Sciences Research Program (MSISRP)

- **Join funding consortiums like MTEC** which the U.S. Army Medical Research and Development Command (USAMRDC) and other DoD agencies offer funding opportunities to members through solicitations called Requests for Prototype Proposals (RPPs): <https://mtec-sc.org/how-to-join/>
- **Register on the various U.S. Government / DoD grant funding platforms as a Nontraditional Defense Contractor:** <http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section3014&num=0&edition=prelim>
- **The System for Award Management (SAM.gov) is an official website of the U.S. Government.** <https://sam.gov/content/home>
- There is no cost to use SAM.gov. You can use this site to:
  - Register to do business with the U.S. Government
  - Search for contract opportunities
  - Access publicly available awards
- **Understand the terms and processes, e.g.**
  - Technology Readiness Levels: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>
  - **Grant application and approval process:** <https://research.uga.edu/docs/units/dsc/MTEC-Proposal-Preparation-Guide.pdf>
- **Connect with DoD leadership** at USAMRDC and others like the US Military Infectious Diseases Research Program (MIDRP); key decision-making bodies for future solicitations; membership of MTEC facilitates this



**immuron**

**STEVEN LYDEAMORE  
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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](#)

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](#)

Efficacy of hyperimmune bovine colostrum against shigellosis in rhesus macaque (Macaca mulatta), and bioactivity of HBC against common enteric pathogens

[Islam et al., 2020. Submitted to mSphere, American Society for Microbiology](#)

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

[Rachele Gore, Mitra Mohsenipour, Jennifer L Wood, Gayathri K Balasuriya, Elisa L Hill-Yardin, Ashley E Franks](#)

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/ijy213](#)

## 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](#)





# PARTNERING WITH US DEPARTMENT OF DEFENSE

## LEARN YOUR ACRONYMS

Acronyms	Abbreviations	Acronyms	Abbreviations
ACURO	Animal Care and Use Review Office	NAMD	Naval Advanced Medical Development
ATI	Advanced Technology International	NDC	Nontraditional Defense Contractor
DUNS	Data Universal Numbering System	NMRC	Naval Medical Research Command
HRPO	Human Research Protection Office	OHRO	Office of Human Research Oversight
IACUC	Institutional Animal Care and Use Committee	ROM RPP	Rough Order of Magnitude Request for Project Proposals
KRL	Knowledge readiness level	TRL	Technology readiness level
MTEC	Medical Technology Enterprise Consortium	USAMRDC	U.S. Army Medical Research and Development Command
MIDRP	Military Infectious Diseases Research Program	WRAIR	Walter Reed Army Institute of Research

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