



## **H.C. WAINWRIGHT & CO. VIRTUAL PRESENTATION**

11 SEPTEMBER, 2023

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.

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YTD FY2023 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® and Protectyn®
- 4 clinical programs: Travelan® (NMRC: Phase 2 CHIM trial), Travelan® (USU: Phase 4 field study), CampETEC (Phase 2 CHIM trial), IMM-529 (Protocol development phase, Phase 2 trial)



## Business Update

- Flagship product Travelan® growing strongly as overseas travel rebounds
- Travelan® (IMM-124E) IND filed with and approved by FDA
- Travelan® (IMM-124E) Phase 2 clinical trial initiated
- Travelan® Uniformed Health Services University (USU) P2TD IMM-124E field clinical trial recruited 347 (~40% 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 international markets through distributors
- Evaluating options to add to marketed products portfolio in FY24

## Financial Snapshot

Shares on Issue	227,798,346
Total Options	14,568,559
Last Traded Price	IMC: A\$0.075
52 week High/Low	IMC: A\$0.105/0.067 IMRN: \$3.21/1.39
Market Cap	IMC: A\$17.085m
Cash & Cash Equivalents (as at 31 Dec 22)	A\$18.5m

## Major Shareholders

Holder	Units	% of CSO
BNY Mellon Asset Management	78,973,505	34.7 %
<b>Management &amp; Board</b>	<b>6,904,554</b>	<b>3.0 %</b>
Authentic Australia Pty. Ltd.	6,000,000	2.6 %
Grandlodge	3,846,712	1.7 %

as of 21 August 2023



# 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 launched 1QFY24  
Re-entry into retail pharmacies will be explored in FY24



Evaluating options:

- for entry into international markets
- 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

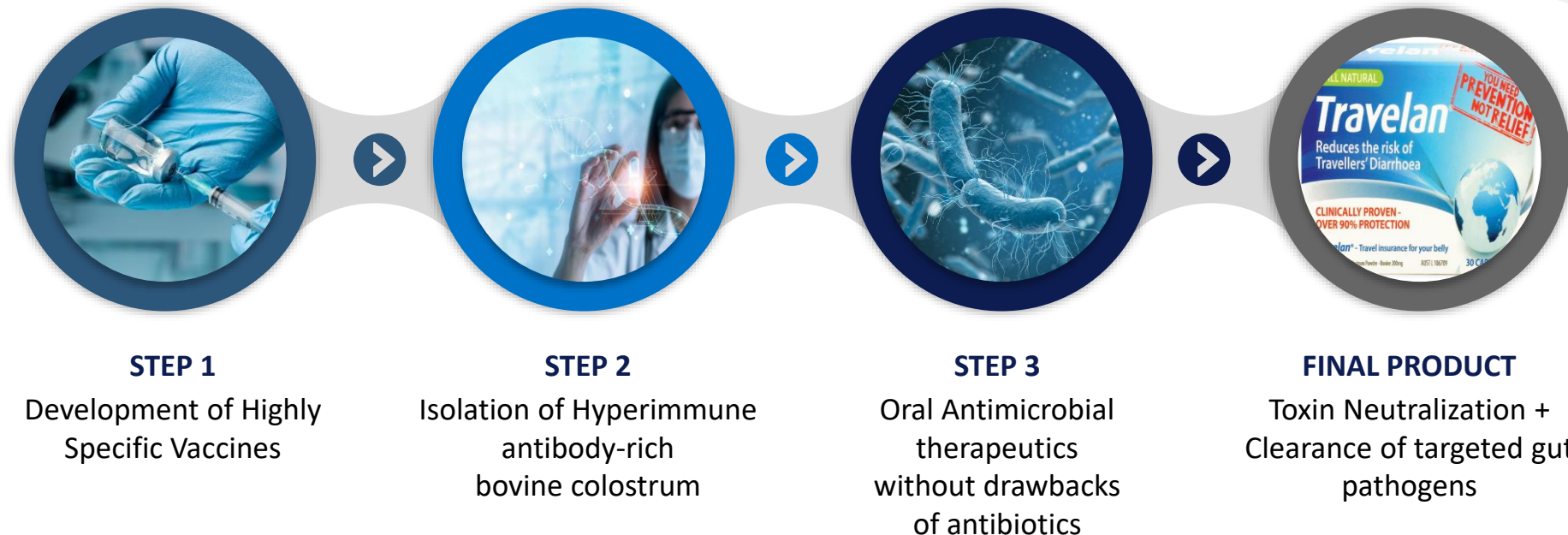
Clostridioides difficile infections (CDIs) to grow to almost \$1.7 billion by 2026, according to GlobalData



# 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.



- ✓ 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)***



# 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<sup>b</sup>
  - Market evaluation by [Lumanity](#) confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)<sup>c</sup>
  - IMM-124E (Travelan®) IND was approved by the FDA in 2H2022<sup>a</sup>
  - Clinical trial initiated May 2023<sup>g</sup>
  - First patients enrolled in July 2023<sup>i</sup>
  - Anticipated clinical study report – 1H 2024
- ✓ Market evaluation by [Lumanity](#) confirms the *Clostridioides difficile* market opportunity for IMM-529<sup>d</sup>
  - 600mg solid dose active formulation development completed
  - Anticipated manufacture of cGMP IMM-529 – 31 December 2023<sup>h</sup>
  - Anticipated pre-IND submission to the FDA – 30 June 2024<sup>h</sup>
- ✓ Travelan® - Uniformed Services University has recruited ~40% 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<sup>e, i</sup>
  - Anticipated completion of enrollment – 31 March 2024
  - Anticipated completion of in-patient phase – 30 June 2024
- ✓ Naval Medical Research Center 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<sup>f</sup>

<sup>a, b, c, d, e, f, g, h, i</sup> ASX Release links in appendix

## 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®					
CampETEC					

\*Further information on the clinical programs can be found on slide 7



# KEY MILESTONES ANTICIPATED TO DRIVE VALUE

	2H 2022	1H 2023	2H 2023	1H 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 <sup>a</sup></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 <sup>g</sup></li> </ul>	<ul style="list-style-type: none"> <li>First patients enrolled <sup>i</sup></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> <li>Clinical Study Report</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)<sup>f</sup></li> </ul>		<ul style="list-style-type: none"> <li>Initiate NMRC<sup>5</sup> CampETEC Campylobacter CHIM<sup>3</sup> clinical trial</li> <li>Completion of In-patient phase 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>Project strategic planning and budget 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>
<b>Travelan®</b>	<ul style="list-style-type: none"> <li>USU<sup>6</sup> P2TD IMM-124E field clinical trial recruitment commencement <sup>e,i</sup></li> </ul>	<ul style="list-style-type: none"> <li>~40% of 868 participants recruited</li> </ul>		<ul style="list-style-type: none"> <li>Completion of enrollment</li> <li>Completion of in-patient phase</li> </ul>

Completed; 1. Investigational New Drug; 2. Enterotoxigenic *E.coli*; 3. controlled human infection model; 4. Institutional Review Board; 5. Naval Medical Research Command;

6. Uniformed Health Services University of the Health Sciences; 7. Clostridioides Difficile; <sup>a,e,f,g,i</sup> ASX Release links in appendix



# 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/>*

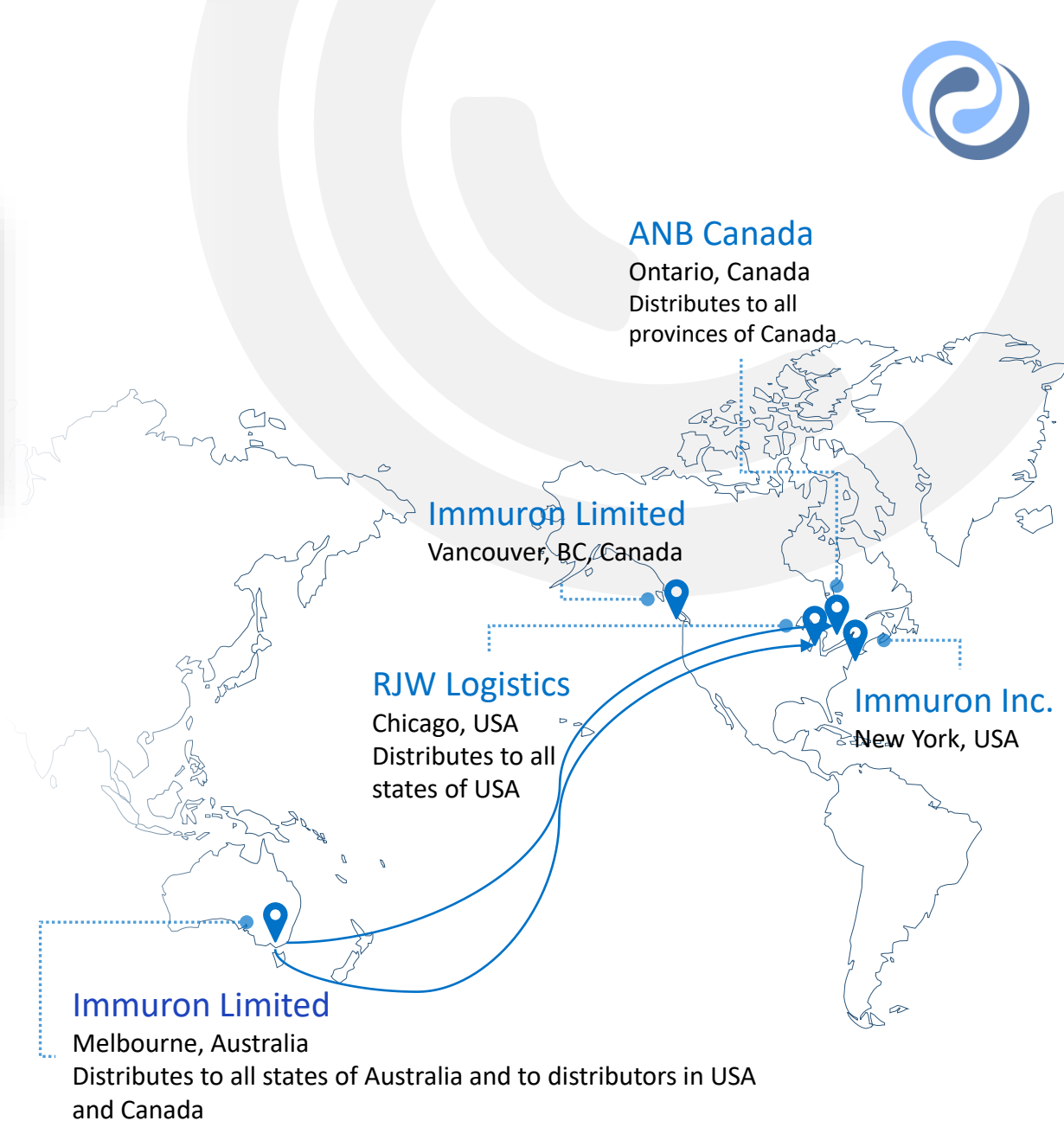


# DISTRIBUTION CAPABILITY

	Australia	USA	Canada	
Retail Pharmacy	✓		✓	✓ Established
B2B	✓	✓	✓	
E-commerce	✓	✓	✓	✓ Developing

## Key Commentary

- The Australian retail network includes over 3,500 pharmacies
- In the USA, the key B2B customer is Passport Health - the largest network of travel medicine clinics
- Immuron launched its own US shopfront on amazon.com in July 23
- Re-entry into retail pharmacies in USA will be explored in FY24
- In Canada, we are working towards a relaunch into retail pharmacy in late FY24
- We are exploring options to expand B2B business in airlines, cruise ships, health & wellness segments
- We are evaluating options to enter international markets through distributors



# BUSINESS POSITIONED FOR ORGANIC GROWTH AND NEW M&A STRATEGY

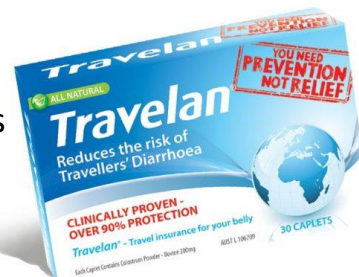


## Organic Growth Strategy

Focus on commercialised products and near-term development extensions, including:

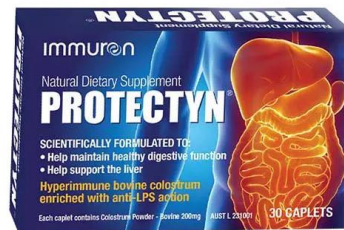
### 01 Travelan®:

- Sales expansion across target geographies
- Growth in distribution network and sales & marketing initiatives
- Product development (new formulations including once daily dosing) e.g. FDA approval



### 02 Protectyn®:

- Sales expansion across target geographies
- Growth in distribution network and sales & marketing initiatives
- Product development and broader applications



## M&A Strategy

By pursuing growth through M&A of a fragmented market, IMC believes that it will be able to increase market geographies, sales channels and penetration driving revenue growth and ultimately shareholder value

### Our M&A Key Criteria focusses on:

- 01 Expand market verticals & product offering
- 02 Expand existing customer base
- 03 Cost & Earnings Synergies
- 04 Strength of IP and Management
- 05 Distribution network and sales & marketing by each product



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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	<a href="#">Scandinavian Journal of Gastroenterology, 46:7-8, 862-868, DOI: 10.3109/00365521.2011.574726</a>
Travelan as a broad Spectrum anti-bacterial	<a href="#">Immuron Limited, 29 April, 2011</a>
Travelan® demonstrates broad reactivity to Vibrio cholera strains from Southeast Asia indicating broad potential for prevention of traveler's diarrhea	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 4 September, 2019</a>
Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 5 September, 2018</a>
Travelan® able to bind and was reactive to 60 clinical isolates of each bacteria, Campylobacter, ETEC, and Shigella	<a href="#">US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 30 January, 2017</a>
Efficacy of hyperimmune bovine colostrum against shigellosis in rhesus macaque (Macaca mulatta), and bioactivity of HBC against common enteric pathogens	<a href="#">Islam et al., 2020. Submitted to mSphere, American Society for Microbiology</a>
Bioactive Immune Components of Travelan®	<a href="#">Clin Vaccine Immunol 24:e00186-16. https://doi.org/10.1128/CVI.00186-16</a>
Hyperimmune bovine colostrum containing lipopolysaccharide antibodies (IMM-124E) has a non-detrimental effect on gut microbial communities in unchallenged mice	<a href="#">Rachele Gore, Mitra Mohsenipour, Jennifer L Wood, Gayathri K Balasuriya, Elisa L Hill-Yardin, Ashley E Franks</a>
Administration of the Hyper-immune Bovine Colostrum Extract IMM-124E Ameliorates Experimental Murine Colitis	<a href="#">Journal of Crohn's and Colitis, Volume 13, Issue 6, June 2019, Pages 785–797, https://doi.org/10.1093/ecco-jcc/ijy213</a>

## IMM-529

Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative	<a href="#">Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5</a>
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# ASX RELEASES REFERENCED



Ref	Slide statement	ASX Release
a	Travelan® (IMM-124E) IND filed with and approved by FDA	<a href="#">Immuron Receives FDA Approval for Travelan IND Application</a>
b	US Department of Defense grant of US\$4.45 million to examine a dosing regimen for Travelan® more suited for use by the military	<a href="#">Immuron awarded A\$6.2 million US DoD funding for Travelan</a>
c	Market evaluation by Lumanity confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)	<a href="#">AGM Presentation</a>
d	Market evaluation by Lumanity confirms the Clostridioides difficile market opportunity for IMM-529	<a href="#">AGM Presentation</a>
e	Travelan® - Uniformed Services University has recruited more than 20% 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	<a href="#">US DOD Travelan Clinical Recruitment Milestone</a>
f	Immuron Announces FDA Removed Clinical Hold on New Campylobacter ETEC Therapeutic Paves Way for Clinical Trial Initiation	<a href="#">FDA Removed Clinical Hold on Campylobacter ETEC Therapeutic</a>
g	Immuron Initiates Recruitment of Travelan® Clinical Study	<a href="#">Immuron Initiates Recruitment of Travelan Clinical Study</a>
h	Immuron Board approves IMM-529 cGMP manufacturing and FDA pre-IND submission	<a href="#">Letter to Shareholders</a>
i	Immuron Announces First Patients Enrolled in Travelan® Clinical Study	<a href="#">Immuron enrolls patients in Travelan clinical study</a>