

Immuron CEO, Steven Lydeamore to present at H.C. Wainwright

Melbourne, Australia, September 11, 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 virtually at the H.C. Wainwright 25th Annual Global Investment Conference on September 11th.

The webcast to this presentation will be available [here](#) at 7am Eastern Standard Time / 9pm Australian Eastern Standard time on September 11th.

A copy of the presentation being made at the H.C. Wainwright 25th Annual Global Investment Conference is included below.

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

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Chief Executive Officer

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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 tabletised 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.



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.

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 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 %
Management & Board	6,904,554	3.0 %
Authentics 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.



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)

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^b
 - Market evaluation by [Lumanity](#) confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)^c
 - IMM-124E (Travelan®) IND was approved by the FDA in 2H2022^a
 - Clinical trial initiated May 2023^g
 - First patients enrolled in July 2023ⁱ
 - Anticipated clinical study report – 1H 2024



- ✓ Market evaluation by [Lumanity](#) confirms the *Clostridioides difficile* market opportunity for IMM-529^d
 - 600mg solid dose active formulation development completed
 - Anticipated manufacture of cGMP IMM-529 – 31 December 2023^h
 - Anticipated pre-IND submission to the FDA – 30 June 2024^h

- ✓ 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^{e, i}
 - 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^f

^{a, b, c, d, e, f, g, h, i} 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

Travelan®
CampETEC
IMM-529
Travelan®

	2H 2022	1H 2023	2H 2023	1H 2024
Travelan®	<ul style="list-style-type: none"> FDA IND¹ approved for single daily dose IMM-124E ETEC² CHIM³ clinical trial ^a 	<ul style="list-style-type: none"> IRB Approval⁴ Initiated IMM-124E ETEC² CHIM³ clinical trial ^g 	<ul style="list-style-type: none"> First patients enrolled ⁱ Completion of In-patient phase ETEC² CHIM³ clinical trial 	<ul style="list-style-type: none"> Topline results for IMM-124E ETEC² clinical trial Clinical Study Report
CampETEC	<ul style="list-style-type: none"> Submitted Response Letter to FDA Clinical Hold Immuron sponsored Toxicology study - completed 	<ul style="list-style-type: none"> Toxicology Study Report FDA IND¹ approved (Clinical Hold released)^f 		<ul style="list-style-type: none"> Initiate NMRC⁵ CampETEC Campylobacter CHIM³ clinical trial Completion of In-patient phase CampETEC Campylobacter CHIM³ clinical trial
IMM-529	<ul style="list-style-type: none"> 600 mg solid dose active formulation development 	<ul style="list-style-type: none"> Project strategic planning and budget development 	<ul style="list-style-type: none"> IMM-529 cGMP manufacture 	<ul style="list-style-type: none"> IMM-529 (CDI)⁷ Pre-IND¹ submission
Travelan®	<ul style="list-style-type: none"> USU⁶ P2TD IMM-124E field clinical trial recruitment commencement ^{e,i} 	<ul style="list-style-type: none"> ~40% of 868 participants recruited 		<ul style="list-style-type: none"> Completion of enrollment Completion of in-patient phase

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; ^{a,e,f,g,i} 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

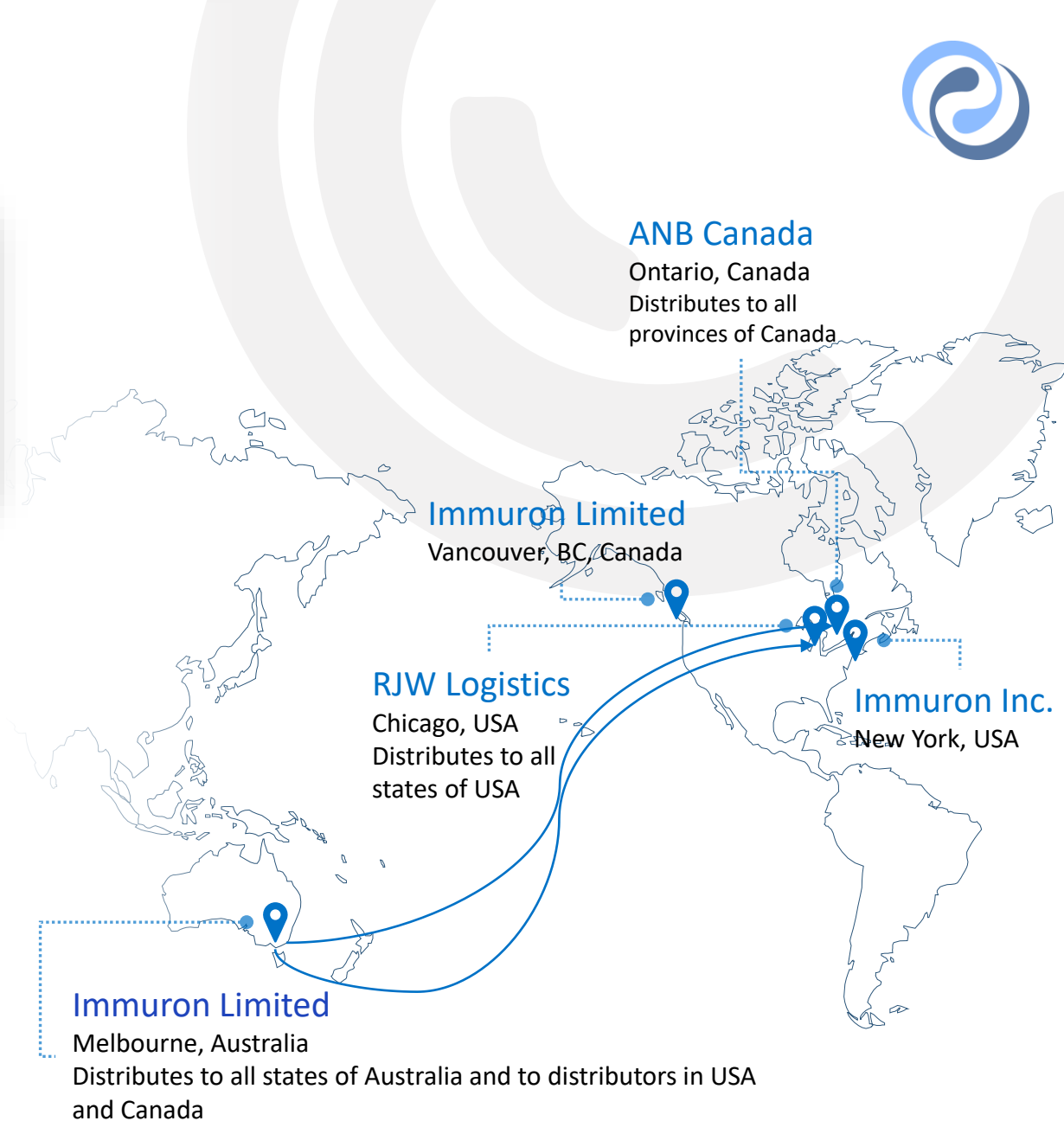
Lumantia, a leading lifescience consulting company: <https://lumantia.com/company/our-story/>

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

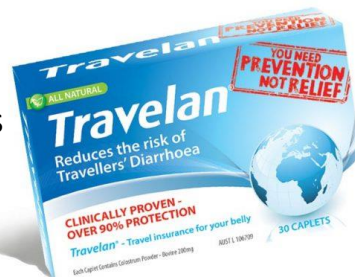


BUSINESS POSITIONED FOR ORGANIC GROWTH AND NEW M&A STRATEGY



Organic Growth Strategy

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

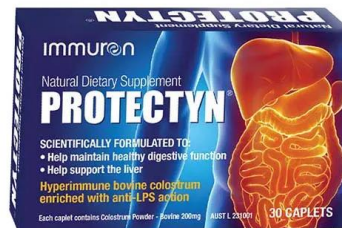


01 Travelan®:

- 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

[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](#)

ASX RELEASES REFERENCED



Ref	Slide statement	ASX Release
a	Travelan® (IMM-124E) IND filed with and approved by FDA	Immuron Receives FDA Approval for Travelan IND Application
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	Immuron awarded A\$6.2 million US DoD funding for Travelan
c	Market evaluation by Lumanity confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)	AGM Presentation
d	Market evaluation by Lumanity confirms the Clostridioides difficile market opportunity for IMM-529	AGM Presentation
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	US DOD Travelan Clinical Recruitment Milestone
f	Immuron Announces FDA Removed Clinical Hold on New Campylobacter ETEC Therapeutic Paves Way for Clinical Trial Initiation	FDA Removed Clinical Hold on Campylobacter ETEC Therapeutic
g	Immuron Initiates Recruitment of Travelan® Clinical Study	Immuron Initiates Recruitment of Travelan Clinical Study
h	Immuron Board approves IMM-529 cGMP manufacturing and FDA pre-IND submission	Letter to Shareholders
i	Immuron Announces First Patients Enrolled in Travelan® Clinical Study	Immuron enrolls patients in Travelan clinical study