



## **Immuron CEO, Steven Lydeamore to present at Coffee Microcaps**

Melbourne, Australia, May 2, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company that has developed two commercially available oral immunotherapeutic products for the treatment of gut mediated diseases, is pleased to provide a copy of the presentation being made today in Melbourne at Coffee Microcaps Conference by our Chief Executive Officer, Steven Lydeamore.

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

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### About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. 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 Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

### About Travelers' diarrhea

Travelers' diarrhea 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 travelers' diarrhea 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 commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and 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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# INVESTOR PRESENTATION

COFFEE MICROCAPS

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2 MAY, 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 (ASX:IMC) (NASDAQ:IMRN) 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® (IMM-124E), CampETEC, IMM-529, Travelan® (consumer product)
- Market capitalisation of A\$18.67m as of 20 April 2023 with cash & cash equivalents balance of A\$18.5m as of 31 Dec 2022

## Recent Business Updates








- Travelan® (IMM-124E) - IND filed and received FDA Authorization to proceed under IND 029087<sup>a</sup>
- CampETEC – toxicology study report completed and submitted to FDA
- Travelan® Uniformed Health Services University P2TD IMM-124E field clinical trial recruitment reaches 300
  - 35% of target 868 participants recruited
- Immuron's own shopfront on amazon.com for Travelan® set up for USA market
  - Launch pending establishing necessary safety stock level
- Working towards relaunch of Travelan® into Canadian retail pharmacy in FY24
  - Submitted for range review to major pharmacy chain

## Results & Outlook

- FY23 YTD 14 April 2023 revenue of A\$1.78m, up 233% YTD on pcp – Australian sales contributing A\$1.18m
- Evaluating options to enter Asian and European markets through distributors
- Evaluating options to add to marketed products portfolio in FY24



# DISTRIBUTION CAPABILITY

	Australia	USA	Canada
Retail Pharmacy			
B2B			
E-commerce			



Established



Developing

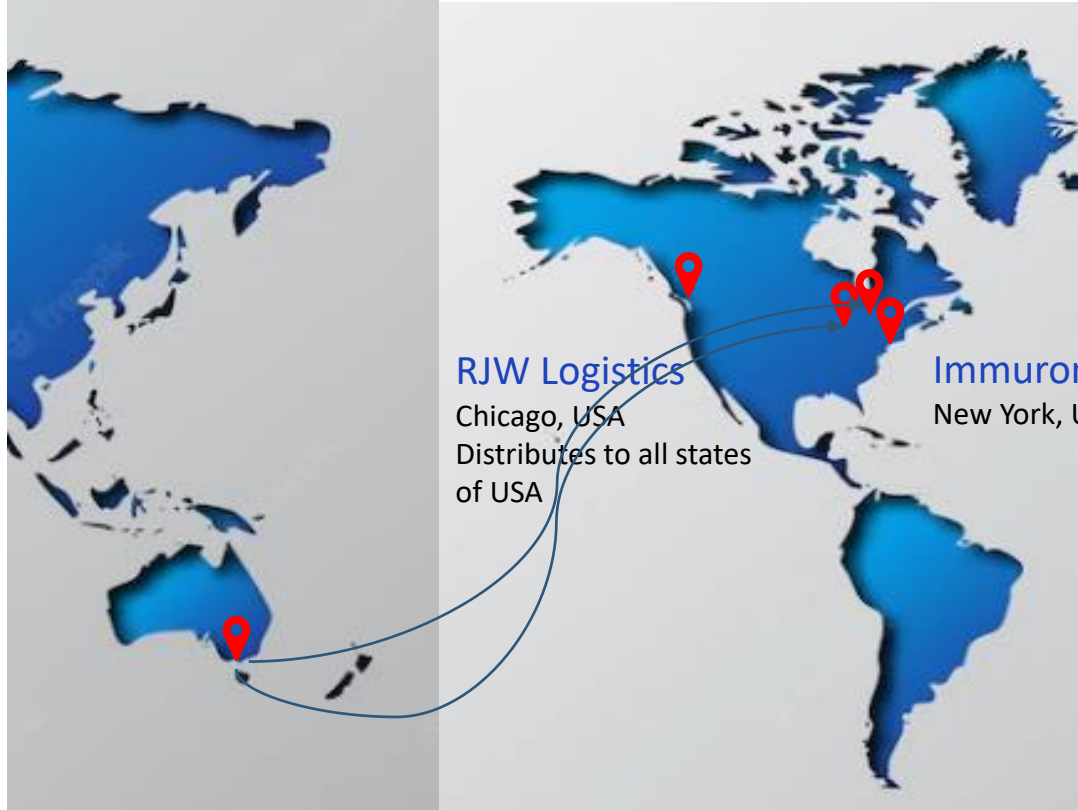
## Key Commentary

- 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’s own shopfront on amazon.com will be introduced in the USA during FY23
- Re-entry into retail pharmacies in USA will be explored in FY24
- In Canada, we are working towards a relaunch into retail pharmacy in FY24
- We are exploring options to expand B2B business in airlines, cruise ships, health & wellness segments
- We are evaluating options to enter Asian and European markets through distributors



Immuron Limited  
Vancouver, BC, Canada

ANB Canada  
Ontario, Canada  
Distributes to all provinces of Canada



RJW Logistics  
Chicago, USA  
Distributes to all states of USA

Immuron Inc.  
New York, USA

Immuron Limited  
Melbourne, Australia  
Distributes to all states of Australia and to distributors in USA and Canada



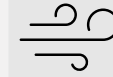


# ADDRESSABLE MARKET & INDUSTRY OVERVIEW



## Billion Dollar Market

Travelers diarrhea 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 traveler's diarrhea\*\*\*



~\$15b+

Immuron's products are a subset of the global digestive health market, which is a multi-billion-dollar market\*

~7% CAGR

Travelers diarrhea treatment market is large and growing at a CAGR of ~7% over 2019-2022\*



Travelan® has large market potential given that acute diarrhea affects millions of travelers each year

\$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

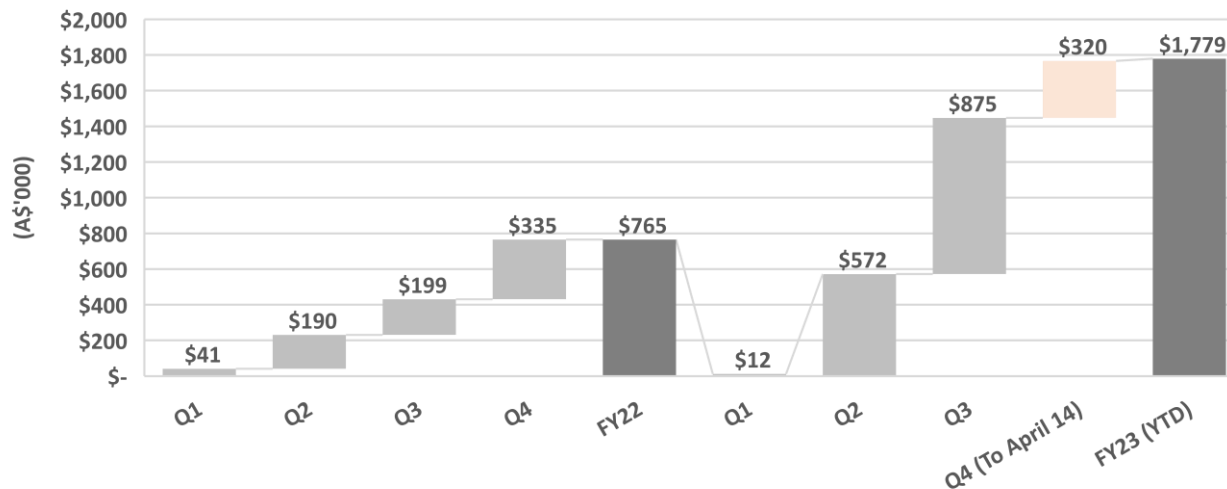
Clostridioides difficile infections (CDIs) to grow to almost \$1.7 billion by 2026, according to GlobalData



## SALES | YEAR TO DATE | 14<sup>TH</sup> APRIL 2023

A\$'000s				
Profit & Loss	FY23 YTD 14 April 2023		FY22 YTD 14 April 2022	
			Var %	
Australian Sales	\$	1,184	\$ 137	764%
Rest of World Sales	\$	595	\$ 397	50%
<b>Total Revenue</b>	<b>\$</b>	<b>1,779</b>	<b>\$ 534</b>	<b>233%</b>

Net Sales | FY22 & FY23



### Key Commentary

- Strong start to Q4 2023 (to 14 April 2023)
  - \$320k Net Sales; up 233% YTD on pcp
- Supply chain capacity addressed by contracting another packaging supplier
- Strong sales for Travelan®, well above pre-pandemic levels, may results in short term stock outages in some wholesalers and pharmacies over the next month
- Building stock to allow accelerated growth in international markets

\*YTD FY2023 results in this presentation are subject to audit review.





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

## Organic Growth Strategy

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

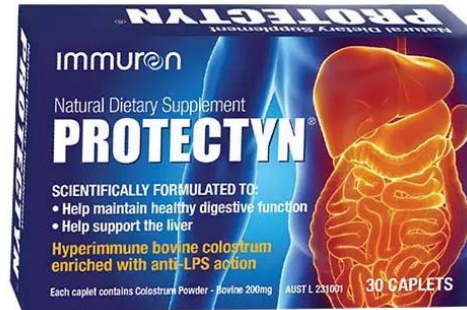
### 1 Travelan®:

- 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



### 2 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:

- 1 Expand market verticals & product offering
- 2 Expand existing customer base
- 3 Cost & Earnings Synergies
- 4 Strength of IP and Management
- 5 Distribution network and sales & marketing by each product



# TECHNOLOGY PLATFORM

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<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 trials anticipated to commence in 1H2023

Market evaluation by [Lumanity](#) confirms the *Clostridioides difficile* market opportunity for IMM-529<sup>d</sup>

- 600mg solid dose active formulation development completed
- Project strategy and budget to be approved by the Immuron Board before initiating clinical trials



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

- Estimated Study Primary Completion Date – 30 July 2023
- Estimated Study Completion Date – 31 December 2023





Naval Medical Research Center Clinical Trials of CampETEC in campylobacter and enterotoxigenic *E.coli* (ETEC)<sup>f</sup>

- Toxicology study submitted to FDA – 8 March 2023
- Written Guidance received from FDA – 10 March 2023
- Response letter submitted – 5 April 2023
- Anticipate FDA feedback in May 2023

## 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 11





# IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT

## Lumanity\* Opportunity Assessment for IMM-124E<sup>b</sup>

- 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<sup>c</sup>

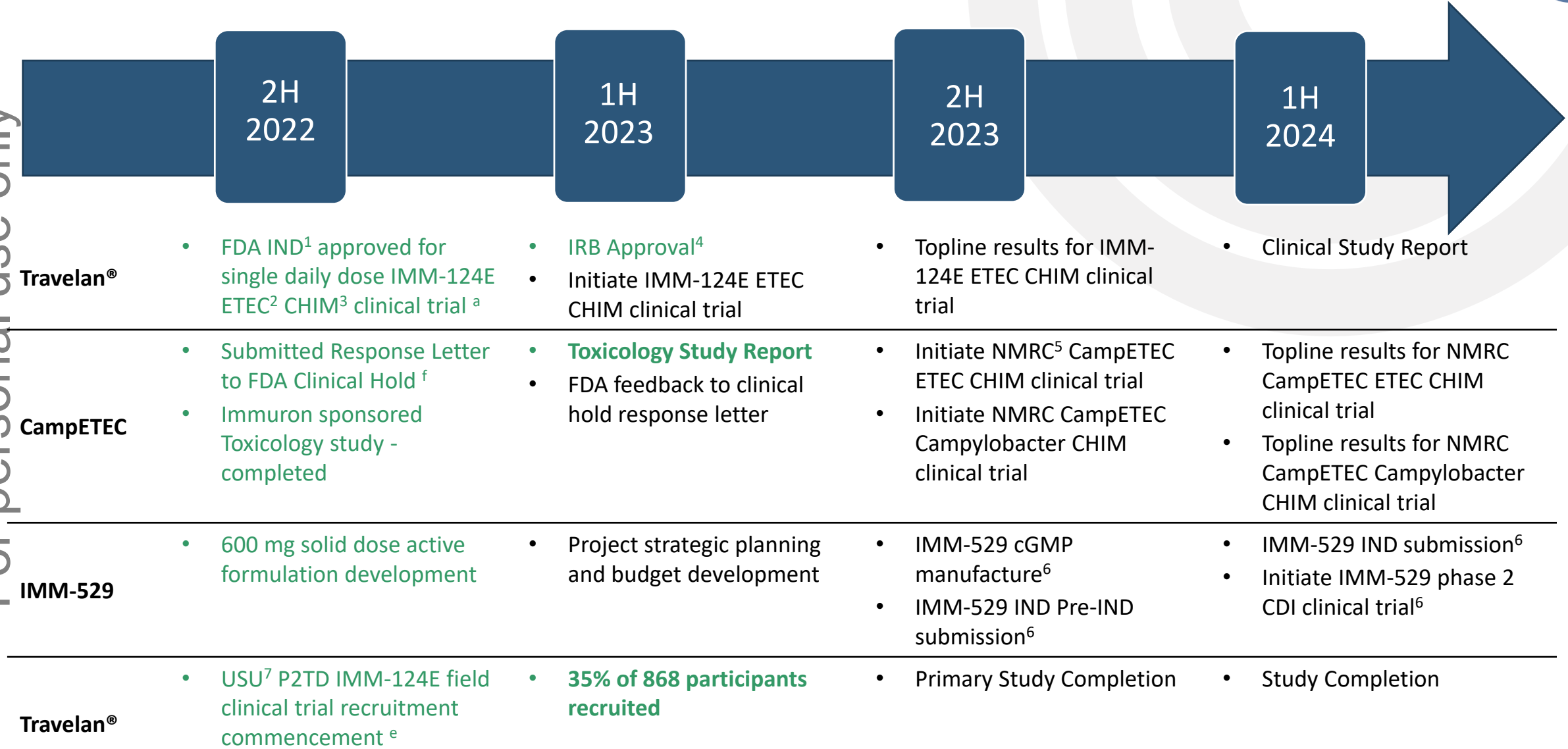
- Infectious disease experts reacted favorably to the IMM-529 MOA, and its unique ability to target three elements of the rCDI infection – the spores, vegetative cells, and Toxin B
- Non-microbiome approaches (such as IMM-529) are still appealing to experts, who noted that clinical trial efficacy (reduction 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 \$93M for the target patient population (limited to 2<sup>nd</sup> recurrence and later based on trial design and payer coverage)
- Positioning IMM-529 at the point of second relapse 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				
IMM-529	<i>Clostridioides difficile</i> Infection & Recurrence				



# KEY MILESTONES ANTICIPATED TO DRIVE VALUE

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**2 May 2023**

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# CORPORATE SNAPSHOT



- **Shareholder Base:**

- Large retail shareholder base in US and Australia
- BNY Mellon Asset Management (American Depositary Shares) holds 34% stake
- Board and management aligned with shareholders, holding 3% stake

## Financial Snapshot

Shares on Issue	227,798,346
Total Options	12,879,720
Last Traded Price	\$0.082
52 week High/Low	0.125/0.067
Market Cap (20 Apr 23)	\$18.67m
Cash & Cash Equivalents (as at 31 Dec 22)	\$18.5m

## Substantial Shareholders\*

Holder	Units	% of CSO
BNY Mellon Asset Management	77,903,505	34.2 %
<b>Management &amp; Board</b>	<b>6,904,554</b>	<b>3.0 %</b>
Authentics Australia Pty. Ltd.	6,000,000	2.6 %
Grandlodge	3,846,712	1.7 %

\*As at 21 April 2023

# 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/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](#)



# 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	Naval Medical Research Center Clinical Trials of CampETEC in campylobacter and enterotoxigenic E.coli (ETEC)	<a href="#">Immuron and US NMRC respond to CampETEC FDA Clinical Hold</a>