

# Immur@n

# LD MICRO PRESENTATION

#### 6 JUNE, 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.

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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.



## **CEO UPDATE & CORPORATE SNAPSHOT**



Strengthening executive team – New Chief Commercial Officer Flavio Palumbo Flavio brings over 20 year's experience with local and global (Asia, UK) commercial leadership roles with GSK and P&G

Strong sales for Travelan<sup>®</sup> well above pre-pandemic levels, may result in short term stock outages in some wholesalers and pharmacies in June 2023



#### **USA Market:**

Immuron's own shopfront on amazon.com will be introduced during FY23 Re-entry into retail pharmacies will be explored in FY23

> **Canadian Market:** Working towards relaunch into retail pharmacy in FY24



#### Market Expansion:

- Evaluating options to enter Asian and European markets through distributors
- Evaluating options to add to marketed products portfolio in FY24

#### Shareholder Base:

- Large retail shareholder base in US and Australia
- BNY Mellon Asset Management (American Depository 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	IMC: A\$0.084
52 week High/Low	IMC: A\$0.105/0.067 IMRN: \$3.21/1.39
Market Cap	IMC: A\$19.1m
Cash & Cash Equivalents (as at 31 Dec 22)	A\$18.5m

#### Major Shareholders

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

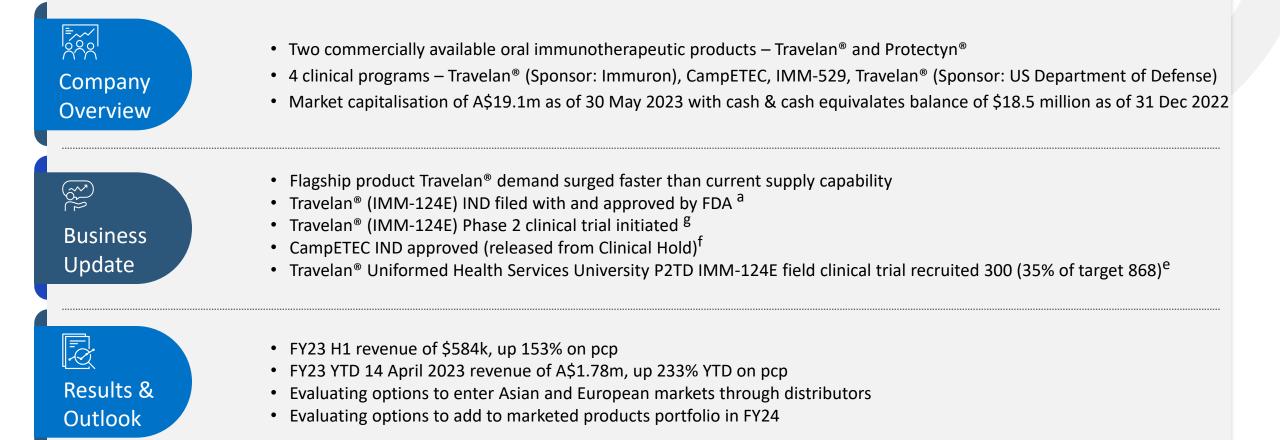
as of 30 May 2023

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## **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

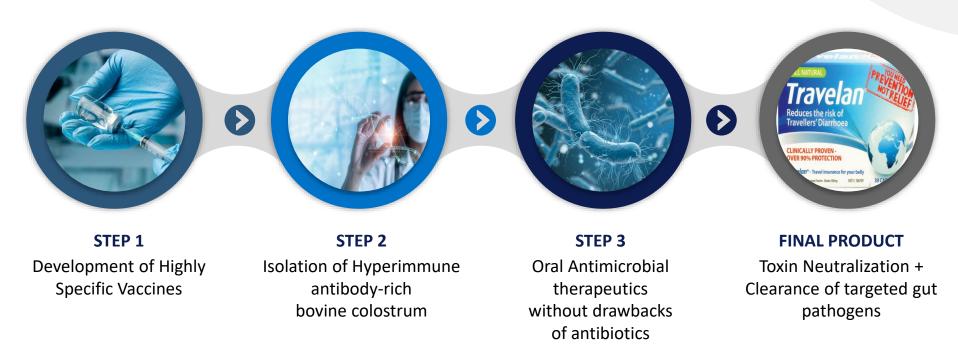


## **TECHNOLOGY PLATFORM**



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.<sup>\*</sup>

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

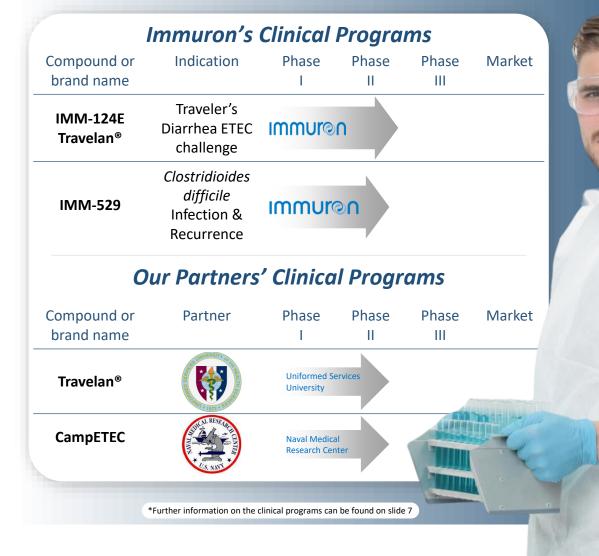
Australian Permitted indications; these statements have not been evaluated by the Food and Drug Administration (FDA)



## STATUS OF PRODUCT PORTFOLIO AND KEY MILESTONES



- US Department of Defense grant of US\$4.45 million to examine a dosing regimen for Travelan<sup>®</sup> more suited for use by the military<sup>b</sup>
  - Market evaluation by <u>Lumanity</u> confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan<sup>®</sup>)<sup>c</sup>
  - IMM-124E (Travelan®) IND was approved by the FDA in 2H2022 a
  - Clinical trial initiated May 2023 g
- Market evaluation by <u>Lumanity</u> 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<sup>®</sup> Uniformed Services University has recruited more than 35% of participants in a randomized clinical trial with Travelan<sup>®</sup> to evaluate the effectiveness for prophylaxis during deployment or travel to a high traveler's diarrhea risk region<sup>e</sup>
  - 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)
  - 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</sup>,b,c,d,e,f,g</sup> ASX Release links in appendix

## **KEY MILESTONES ANTICIPATED TO DRIVE VALUE**



	2Н	2022	1H 2023		2H 2023		1H 2024
Travelan®	•	proved for • dose IMM-124E • <sup>3</sup> clinical trial <sup>a</sup>	IRB Approval <sup>4</sup> Initiated IMM-124E ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial <sup>g</sup>	•	Completion of In-patient phase ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial	•	Topline results for IMM- 124E ETEC <sup>2</sup> clinical trial Clinical Study Report
CampETEC	to FDA Clinic	onsored	Toxicology Study Report FDA IND <sup>1</sup> approved (Clinical Hold released) <sup>f</sup>	•	Initiate NMRC <sup>5</sup> CampETEC ETEC <sup>2</sup> CHIM clinical trial	•	Topline results for NMRC <sup>5</sup> CampETEC ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial Initiate NMRC <sup>5</sup> CampETEC Campylobacter CHIM <sup>3</sup> clinical trial
IMM-529	•	dose active • development	Project strategic planning and budget development	•	IMM-529 cGMP manufacture <sup>6</sup> IMM-529 IND <sup>1</sup> Pre-IND submission <sup>6</sup>	•	IMM-529 IND <sup>1</sup> submission <sup>6</sup> Initiate IMM-529 Phase 2 CDI <sup>8</sup> clinical trial <sup>6</sup>
Travelan <sup>®</sup>	USU <sup>7</sup> P2TD I clinical trial commencer		35% of 868 participants recruited	•	Primary Study Completion	•	Study Completion

Completed; 1. Investigational New Drug; 2. Enterotoxigenic *E.coli*; 3. controlled human infection model; 4. Institutional Review Board; 5. Naval Medical Research Center; 6. Project strategy and budget to be approved by the Immuron Board; 7. Uniformed Health Services University of the Health Sciences; 8. Clostridioides Difficile; <sup>a,e,f,g</sup>ASX Release links in appendix

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### **IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT**



- 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.

>	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 <sup>®</sup>	Traveler's Diarrhea ETEC challenge	IMMUI©U			
IMM-529	Clostridioides difficile Infection & Recurrence	IMMUI©U			

Assessment for IMM-529

Lumanity Opportunity

*Lumanity, a leading lifescience consulting company: https://lumanity.com/company/our-story/* 

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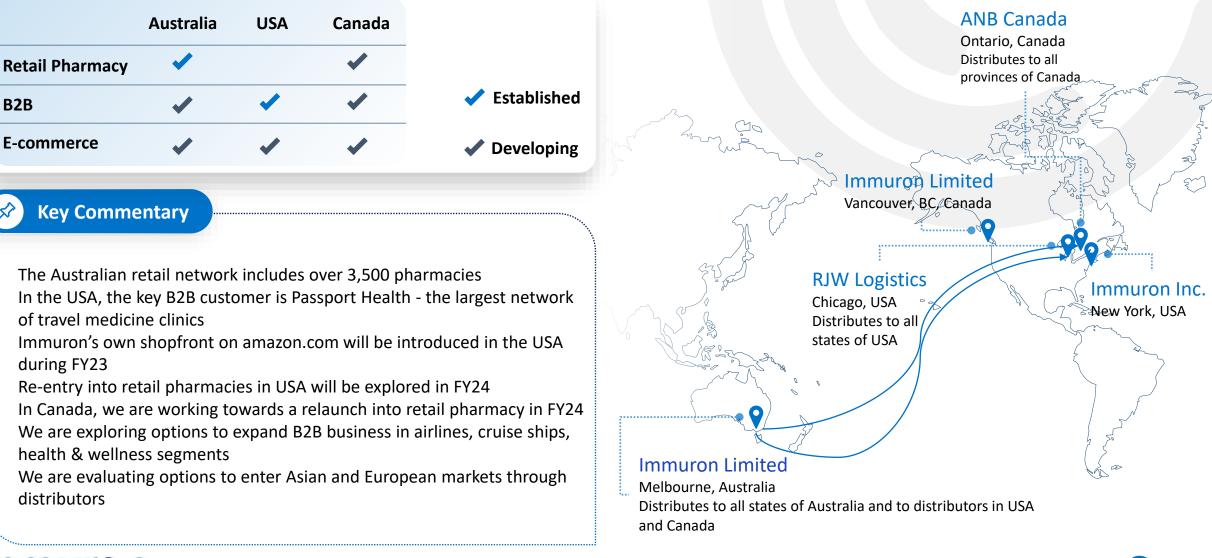
Assessment for IMM-124E

Opportunity

-umanity\*

## **DISTRIBUTION CAPABILITY**





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**B2B** 

## 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 a multibillion-dollar market\*

#### ~7% CAGR

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



Travelan<sup>®</sup> 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

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\* IQVIA Consumer Health Category QuickView MAT Q1 2019 \*\* IMC Company Report - Travelan Market Analysis 2019 \*\*\* Centers for Disease Control and Prevention Yellow Book

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



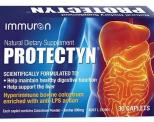


#### **Organic Growth Strategy**

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

#### **01** Travelan<sup>®</sup>:

- 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
  Protectyn<sup>®</sup>:
  - 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
  - 2 Expand existing customer base
- 03 Cost & Earnings Synergies
  - Strength of IP and Management
- *05* Distribution network and sales & marketing by each product

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## **SCIENTIFIC REFERENCES**





#### Travelan<sup>®</sup> (IMM-124E)

Travelan <sup>®</sup> has been shown to reduce both the incidence and severity of ETEC-induced diarrhea in up to 90% of volunteers	<u>Scandinavian Journal of Gastroenterology, 46:7-8, 862-868, DOI:</u> 10.3109/00365521.2011.574726
Travelan as a broad Spectrum anti-bacterial	Immuron Limited, 29 April, 2011
Travelan <sup>®</sup> 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 <sup>®</sup> prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan <sup>®</sup> 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 <sup>®</sup> 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
а	Travelan $^{\circ}$ (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 <sup>®</sup> more suited for use by the military	Immuron awarded A\$6.2 million US DoD funding for Travelan
С	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 <sup>®</sup> - Uniformed Services University has recruited more than 20% of participants in a randomized clinical trial with Travelan <sup>®</sup> 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 <sup>®</sup> Clinical Study	Immuron Initiates Recruitment of Travelan Clinical Study

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