



# INVESTOR PRESENTATION

**BUSINESS UPDATE** 

28 FEBRUARY, 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.

HY and YTD FY2023 results in this presentation are subject to audit review. The final 2023 Half Year Report will be issued on 28 February 2023.

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### **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	<ul> <li>Two commercially available oral immunotherapeutic products – Travelan<sup>®</sup> and Protectyn<sup>®</sup></li> <li>Incorporated in Australia in 1994 and has been listed on the ASX since 1999 and NASDAQ since 2017</li> <li>Market capitalisation of \$16.6m as of 24 Feb 2023 with cash &amp; cash equivalates balance of \$18.5 million as of 31 Dec 2022</li> </ul>
Business Update	<ul> <li>Refreshed corporate structure including key hire – Flavio Palumbo as Chief Commercial Officer</li> <li>Flagship product Travelan<sup>®</sup> demand surged faster than current supply capability</li> <li>Supply chain capacity addressed by contracting another packaging supplier</li> <li>Capable of producing highly specific orally active immunoglobulins to any enteric pathogen</li> <li>Travelan<sup>®</sup> (IMM-124E) IND filed with and approved by FDA<sup>a</sup></li> </ul>
Results & Outlook	<ul> <li>FY23 H1 revenue of \$584k, up 153% on pcp – Australian sales contributing \$287k</li> <li>FY23 YTD 24 Feb 2023 revenue of \$1.23m, up 234% on pcp – Australian sales contributing \$776k</li> <li>Evaluating launch of Travelan<sup>®</sup> via distributors in international markets (Asia, Europe)</li> <li>Extremely strong balance sheet that will be supporting its refreshed organic growth strategy and new M&amp;A strategy</li> <li>Set to initiate a clinical trial for Travelan<sup>®</sup> (IMM-124E) this financial year</li> </ul>
IMMUr@	<sup>a</sup> ASX Release link in appendix. YTD FY2023 results in this presentation are subject to audit review. The final 2023 Half Year Report will be issued on 28 February 2023.



## YEAR TO DATE SALES – 24<sup>TH</sup> FEBRUARY 2023

\$000s					
	FY	23 YTD	FY2	22YTD	
Profit & Loss	24	Feb 23	24	Feb 22	Var %
Australian Sales	\$	776	\$	67	1058%
<b>Rest of World Sales</b>	\$	457	\$	302	51%
Total Revenue	\$	1,233	\$	369	234%

#### **Key Commentary**

- \$649k sales during January and to 24 February boosting sales YTD
  - Up 234% on pcp
  - Up 111% on FY23 half year
  - Australian sales contributing 63% (up from 18% in pcp)
- Supply chain capacity addressed by contracting another packaging supplier
- Australian wholesalers and retail pharmacies now fully stocked
- Building stock to allow accelerated growth in international markets



## **CEO UPDATE & CORPORATE SNAPSHOT**

- Continued strengthening executive team, bringing on Flavio Palumbo as Chief Commercial Officer
- Flavio brings over 20 year's experience with local and global (Asia, UK) commercial leadership roles with GSK and P&G.
- Travelan<sup>®</sup> is now widely available again following supply challenges in January which have been resolved through the qualification of a new packaging company.
- 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	21,303,877
Last Traded Price	\$0.078
52 week High/Low	0.125/0.07
Market Cap	\$16.6m
Cash & Cash Equivalents (as at 31 Dec 22)	\$18.5m
*As at 24 February 2023	

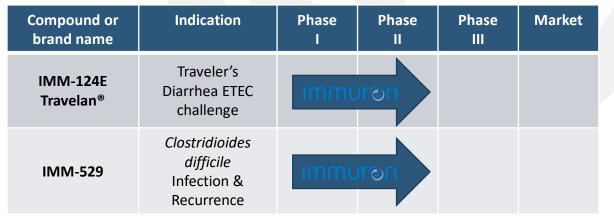
Substantial Shareholders							
Holder	Units	% of CSO					
BNY Mellon Asset Management	77,903,505	34.2 %					
Management & Board	6,904,554	3.0 %					
Authentics Australia Pty. Ltd.	6,000,000	2.6 %					
Grandlodge	3,846,712	1.7 %					
*As at 24 February 2023							



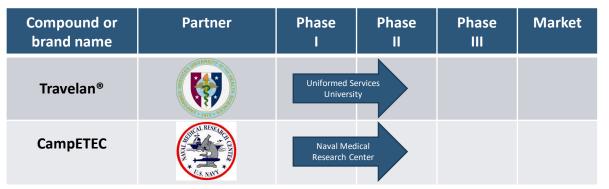
# STATUS OF PRODUCT PORTFOLIO AND KEY MILESTONES

- 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>d</sup>
  - Market evaluation by <u>Lumanity</u> confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan<sup>®</sup>)<sup>e</sup>
  - IMM-124E (Travelan<sup>®</sup>) IND was approved by the FDA in 2H2022<sup>a</sup>
  - o Clinical trials anticipated to commence in 1H2023
- Market evaluation by <u>Lumanity</u> confirms the *Clostridioides difficile* market opportunity for IMM-529<sup>f</sup>
  - o 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 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<sup>g</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)<sup>h</sup>
  - Animal ethics approval for Toxicology study 22 November 2022
  - Immuron sponsored Toxicology study completed 20 December 2022
  - Meeting with FDA to discuss clinical hold 2 December 2022
  - Written Guidance received from FDA 20 December 2022
  - Response letter submitted 25 January 2022
  - Anticipate FDA feedback in March 2023

#### Immuron's Clinical Programs



#### **Our Partners' Clinical Programs**



\*Further information on the clinical programs can be found on slide 11



### **DISTRIBUTION CAPABILITY**

#### Immuron Limited ANB Canada

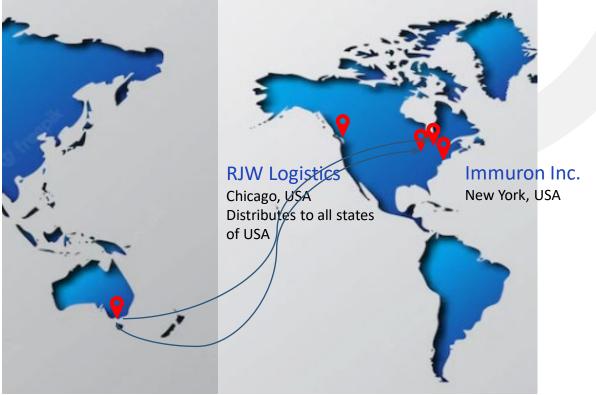
Vancouver, BC, Canada

Ontario, Canada Distributes to all provinces of Canada



#### **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
- We have transitioned to new sales management service and third party logistics providers in the USA
- 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 FY23
- 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**

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



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

Travelar

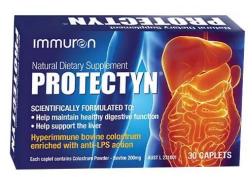
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#### **Organic Growth Strategy**

- Focus on commercialised products and nearterm development extensions, including:
- 1 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



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#### M&A Strategy

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- 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:
    - Expand market verticals & product offering
    - Expand existing customer base
    - Cost & Earnings Synergies
    - A Strength of IP and Management
  - **5** Distribution network and sales & marketing by each product

KEYI	MIL	ESTON	ES ANTIC	IP	ATED T	O DRIVE	VA	LUE			
		2H 2022			1H 2023			2H 2023			1H 2024
<b>Fravelan®</b>	٠		proved for lose IMM-124E <sup>3</sup> clinical trial <sup>a</sup>	•	<ul> <li>IRB Approval<sup>4</sup></li> <li>Initiate IMM-124E ETEC CHIM clinical trial</li> </ul>		•	•	sults for IMM- CHIM clinical	•	Clinical Study Report
CampETEC	•	Submitted R to FDA Clinic Immuron spo Toxicology st completed	onsored	<ul> <li>Toxicology Study Report</li> <li>FDA feedback to clinical hold response letter</li> </ul>			•	ETEC CHIN Initiate NM	/IRC <sup>5</sup> CampETEC 1 clinical trial /IRC CampETEC acter CHIM al	•	Topline results for NMRC CampETEC ETEC CHIM clinical trial Topline results for NMRC CampETEC Campylobacter CHIM clinical trial
IMM-529	٠	600 mg solid formulation	dose active development	<ul> <li>Project strategic planning and budget development</li> </ul>		•	manufacture <sup>6</sup>		•	IMM-529 IND submission <sup>6</sup> Initiate IMM-529 phase 2 CDI clinical trial <sup>6</sup>	
Travelan®	•	USU <sup>7</sup> P2TD I clinical trial i commencem		•	Recruitment Updates		Primary Study Completion		•	Study Completion	

# Immuron

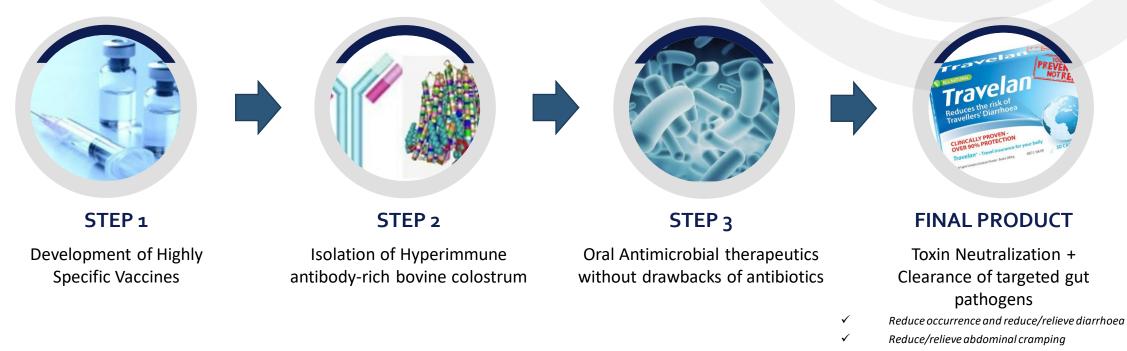
Steven Lydeamore Chief Executive Officer Immuron Limited 28 February 2023

Contact Information: Phone: Australia: +613 8892 4854 Email: steve@immuron.com



### **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.



- ✓ 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)



## **ADDRESSABLE MARKET & INDUSTRY OVERVIEW**

~\$15b+

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

\$50m

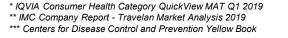
Based on US annual travel numbers and a penetration rate of 15%, the market potential is estimated at \$83m\*\*

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

# IMMUr@n





**Billion Dollar Market** 

Travelers diarrhea treatment market is large and growing at a CAGR of ~7%



# $\stackrel{\square}{\frown}$ Industry tailwinds

Travel picking up significantly following COVID lockdowns



### **Frequent Symptom**

30% - 70% of travelers experience traveler's diarrhea\*\*\*



# 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 <sup>®</sup>	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
Hyperimmune bovine colostrum reduces gastrointestinal carriage of uropathogenic Escherichia coli	Human Vaccines & Immunotherapeutics, 15:2, 508-513, DOI: 10.1080/21645515.2018.1528836
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	<u>Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5</u>

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## ASX RELEASES REFERENCED

Ref	Slide statement	ASX Release				
а	Travelan <sup>®</sup> (IMM-124E) IND filed with and approved by FDA	Immuron Receives FDA Approval for Travelan IND Application				
b	Strategic investment in leading UK based health biotech Ateria Health Limited; an initial 17.5% equity stake; Value of option for further investment in Ateria Health of £1.47m, expiring on 31 July 2023	Immuron completes strategic investment in Ateria Health				
с	Strategic investment in leading UK based health biotech Ateria Health Limited; an initial 17.5% equity stake; Value of option for further investment in Ateria Health of £1.47m, expiring on 31 July 2023	IMC investment in leading gut health biotech Ateria Health				
d	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				
е	Market evaluation by Lumanity confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)	AGM Presentation				
f	Market evaluation by Lumanity confirms the Clostridioides difficile market opportunity for IMM-529	AGM Presentation				
g	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				
h	Naval Medical Research Center Clinical Trials of CampETEC in campylobacter and enterotoxigenic E.coli (ETEC)	Immuron and US NMRC respond to CampETEC FDA Clinical Hold				

