

## **Q3 FY23 Business Update Presentation**

Melbourne, Australia, April 19, 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 the Q3 FY23 Investor Presentation for the business update webinar to be held **today at 11:00 am (AEST)**.

The Investor Presentation includes the following material information (unaudited):

- Worldwide sales for the two weeks 1 to 14 April 2023 were A\$320,000. This represents 37% of sales for the whole of Q3 FY23 of A\$875,000.
- Sales FY23 YTD to 14 April 2023 of A\$1,779,000 represents a 233% increase over the corresponding prior period YTD to 14 April 2022 of \$534,000.

Investors are invited to join the webcast and Q&A hosted by Immuron CEO Steven Lydeamore.

To register for the webinar, please click on this link:

https://us02web.zoom.us/webinar/register/WN TpvaXZZ1QDG1FnZdXdtSGA

After registering, you will receive a confirmation email containing information to join the webinar.

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Approved for release by the CEO.

#### **COMPANY CONTACT:**

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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.







# INVESTOR PRESENTATION

**BUSINESS UPDATE** 

19 APRIL, 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 IMM-124E, CampETEC, IMM-529, Travelan®
- Market capitalisation of A\$17.08m as of 17 April 2023 with cash & cash equivalates balance of A\$18.5m as of 31 Dec 2022

## Business Update

- 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 set up for USA market
  - Launch pending establishing necessary safety stock level
- Working towards relaunch 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% 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

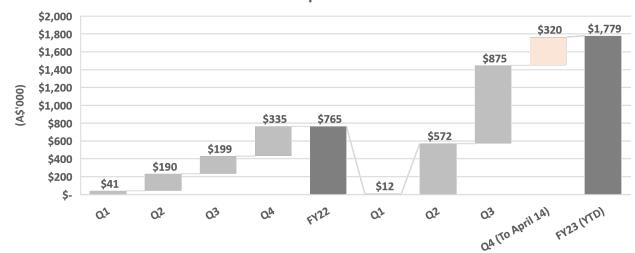




## SALES | YEAR TO DATE | 14<sup>TH</sup> APRIL 2023

A\$000s			
Profit & Loss	FY23 YTD 14 April 2023	FY22YTD 14 April 2022	Var %
Australian Sales	\$ <b>1,184</b> \$	137	764%
Rest of World Sales	\$ <b>595</b> \$	397	50%
Total Revenue	\$ 1,779 \$	534	233%

#### Net Sales | FY22 & FY23



<sup>\*</sup>YTD FY2023 results in this presentation are subject to audit review.

## **Immur**@n

#### **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
- Australian wholesalers and retail pharmacies now fully stocked
- Building stock to allow accelerated growth in international markets

## KEY MILESTONES ANTICIPATED TO DRIVE VALUE



		2H 2022		1H 2023		2H 2023		1H 2024
Travelan <sup>®</sup>	•	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>	•	IRB Approval <sup>4</sup> Initiate IMM-124E ETEC CHIM clinical trial	•	Topline results for IMM- 124E ETEC CHIM clinical trial	•	Clinical Study Report
CampETEC	•	Submitted Response Letter to FDA Clinical Hold <sup>e</sup> Immuron sponsored Toxicology study - completed	•	Toxicology Study Report  FDA feedback to clinical hold response letter	•	Initiate NMRC <sup>5</sup> CampETEC ETEC CHIM clinical trial Initiate NMRC CampETEC Campylobacter CHIM clinical trial	•	Topline results for NMRC CampETEC ETEC CHIM clinical trial Topline results for NMRC CampETEC Campylobacter CHIM clinical trial
IMM-529	•	600 mg solid dose active formulation development	•	Project strategic planning and budget development	•	IMM-529 cGMP manufacture <sup>6</sup> IMM-529 IND Pre-IND submission <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 IMM-124E field clinical trial recruitment commencement <sup>d</sup>	•	35% of 868 participants recruited	•	Primary Study Completion	•	Study Completion





# immuron

Steven Lydeamore Chief Executive Officer Immuron Limited 19 April 2023

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## **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** 

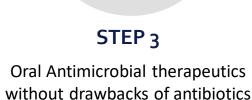




STEP<sub>2</sub>

Isolation of Hyperimmune antibody-rich bovine colostrum









**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)

## **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® 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



<sup>\*</sup> IQVIA Consumer Health Category QuickView MAT Q1 2019



## 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\*\*\*



<sup>\*\*</sup> IMC Company Report - Travelan Market Analysis 2019

<sup>\*\*\*</sup> Centers for Disease Control and Prevention Yellow Book



## IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT

#### Lumanity\* Opportunity Assessment for IMM-124E b

- 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 c

- 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	IMMUron			
IMM-529	Clostridioides difficile Infection & Recurrence	IMMUron			



## **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**

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Ref	Slide statement	ASX Release
а	Travelan® (IMM-124E) IND filed with and approved by FDA	Immuron Receives FDA Approval for Travelan IND Application
b	Market evaluation by Lumanity confirms the Traveler's Diarrhea market opportunity for IMM-124E (Travelan®)	AGM Presentation
С	Market evaluation by Lumanity confirms the Clostridioides difficile market opportunity for IMM-529	AGM Presentation
d	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
е	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

