



# **AUSBIOINVEST PRESENTATION**

30 OCTOBER, 2023

Steven Lydeamore - CEO

NASDAQ: IMRN

**ASX: IMC** 

## SAFE HARBOR STATEMENT

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FY2024 results in this presentation are subject to audit review.







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

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\$17.08m				
Cash & Cash Equivalents (30 June 2023)	A\$17.2m				

Major Share	eholders	
Holder	Units	% of CSO
BNY Mellon Asset Management	78,704,665	34.6 %
Management & Board	6,904,554	3.0 %
Authentics Australia Pty. Ltd.	6,000,000	2.6 %
Grandlodge	3,846,712	1.7 %



## TECHNOLOGY PLATFORM FOR GUT MEDIATED DISEASES



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

Toxin Neutralization + Clearance of targeted gut pathogens of antibiotics

**FINAL PRODUCT** 

✓ Reduce occurrence and reduce/relieve diarrhoea

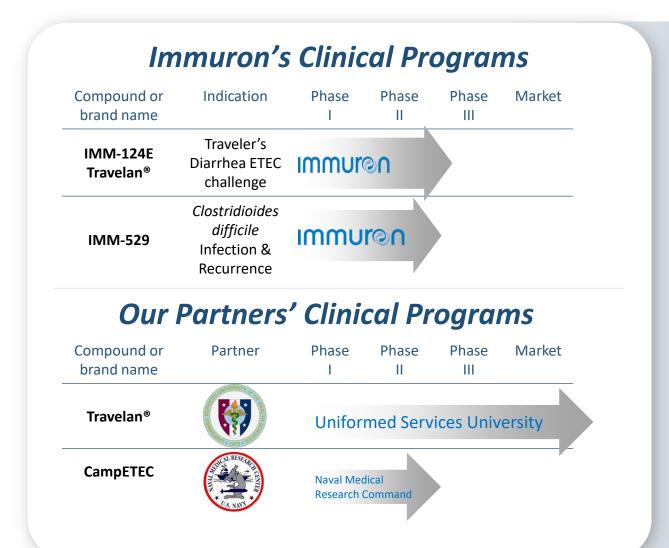
- ✓ Reduce/relieve abdominal cramping
- ✓ Reduce/relieve gastrointestinal pain
- ✓ Assists repair of gastrointestinal/gut wall lining
- ✓ Enhance/promote immune defence
- ✓ Enhance/promote health liver function

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



## STRONG PIPELINE WITH NEAR TERM MILESTONES







# STRONG SALES GROWTH IN ATTRACTIVE MARKET







## **Traveller's Diarrhoea (TD)**

Market is large and growing ~7% 3 CAGR



### **Industry tailwinds**

Travel picking up significantly following COVID lockdowns



### Frequent

30% - 70% of travelers experience TD <sup>4</sup>



#### **Net Sales**

FY23: **A\$1.16 million** 1QFY24: **A\$1.35 million** 229% higher than prepandemic period **1QFY20** 

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#### **Net Sales**

FY23: **A\$0.64 million** 1QFY24: **A\$0.21** million **9%** lower than prepandemic period 1QFY20

#### **Australia**

12 months to July 2023 short term resident returns 77% of those in 2019 <sup>1</sup> **USA** 

**Total departures** June 2023 **99.4%** of June 2019<sup>2</sup>



Chief Commercial Officer has 20+ year's experience with local and global (Asia, UK) commercial leadership roles with GSK and P&G

## \$83m

Based on US annual travel numbers and a penetration rate of 15%, the market potential is estimated at \$83m <sup>5</sup>

## \$50m

Based on EU travel numbers and a penetration rate of 15%, the market potential is estimated at \$50m 5



<sup>2.</sup> https://www.trade.gov/sites/default/files/2023-09/US-Outbound-to-World-Regions.xlsx

<sup>3.</sup> Research Reports World, 28 May 2021: Global Traveler's Diarrhea Therapeutics Industry Research Report, Growth Trends and Competitive Analysis 2021-2027

<sup>4.</sup> Centers for Disease Control and Prevention Yellow Book

<sup>5.</sup> IMC Company Report - Travelan Market Analysis 2019

## VALUABLE SALES POTENTIAL FOR PIPELINE PRODUCTS



# -umanity\* Opportunity Assessment for IMM-124E

- 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® Traveler's Diarrhea ETEC challenge IMMUr⊚∩

IMM-529 Clostridioides difficile Infection & Recurrence Immur⊚∩



Assessment for IMM-529

Lumanity Opportunity

# **NEAR TERM MILESTONES ANTICIPATED TO DRIVE VALUE**



		2H 2022		1H 2023	2H 2023 1H 2024	2H 2023
Travelan®	•	FDA IND <sup>1</sup> approved for single daily dose IMM-124E ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial	•	IRB Approval <sup>4</sup> Initiated IMM-124E ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial	<ul> <li>100% of patients enrolled</li> <li>Completion of In-patient phase ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> <li>Topline results for IMM-124E ETEC<sup>2</sup> clinical trial</li> <li>Clinical Study Report</li> </ul>	Completion of In-patient phase
CampETEC	•	Submitted Response Letter to FDA Clinical Hold Immuron sponsored Toxicology study - completed	•	Toxicology Study Report  FDA IND¹ approved (Clinical Hold released)  •	Institutional Review Board approval of NMRC <sup>5</sup> CampETEC Campylobacter CHIM <sup>3</sup> clinical trial protocol  FDA approval of IND amendment for change to protocol  • Initiate NMRC <sup>5</sup> CampETEC Campylobacter CHIM <sup>3</sup> clinical trial • Completion of In-patient phas CampETEC Campylobacter CHIM <sup>3</sup> clinical trial	approval of NMRC <sup>5</sup> CampETEC Campylobacter CHIM <sup>3</sup> clinical trial protocol FDA approval of IND amendment for change to
IMM-529	•	600 mg solid dose active formulation development		•	IMM-529 cGMP manufacture  • IMM-529 (CDI) <sup>7</sup> Pre-IND <sup>1</sup> submission	IMM-529 cGMP manufacture
Travelan®	•	USU <sup>6</sup> P2TD IMM-124E field clinical trial recruitment commencement		•	<ul> <li>~50% of 868 participants</li> <li>Completion of enrollment</li> <li>Completion of in-patient phase</li> </ul>	· · ·







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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
Clinical Evaluation of Travelan® an Oral Prophylactic for Prevention of Travelers' Diarrhea in Active Duty Military Service Assigned Abroad.	Military Health System Research Symposium 14-17 Aug 2023 Abstract 1
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