



# **INVESTOR PRESENTATION COFFEE MICROCAPS**

14 MARCH 2024

Steven Lydeamore - CEO

NASDAQ: IMRN

ASX: IMC

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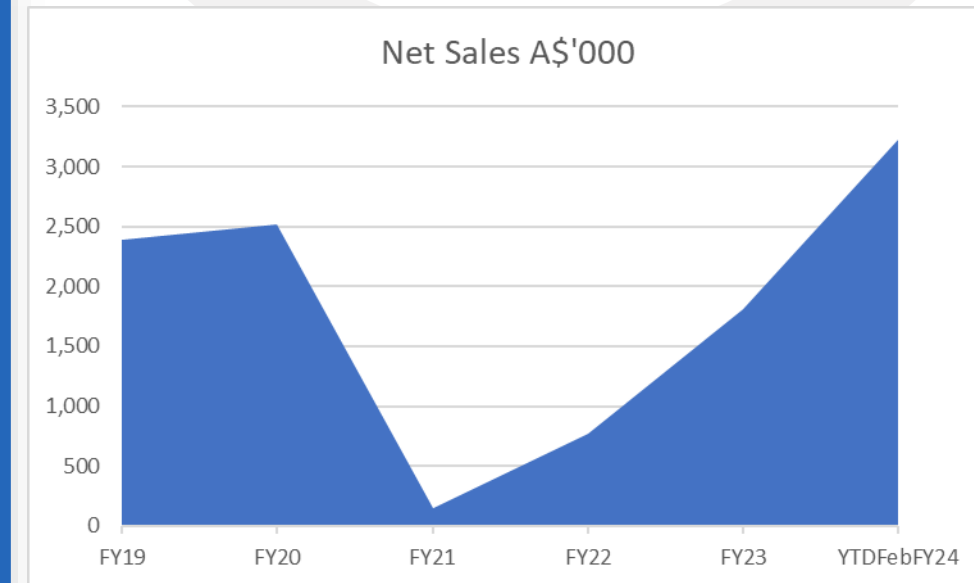


# REVENUE GENERATING WITH STRONG PIPELINE

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

	30-Jun-23 (FY)	7-Mar-24 (FYTD)
Shares on Issue	227,798,346	227,798,346
Total Options	12,879,720	15,568,559
Last Traded Price	IMC: A\$0.075	IMC: A\$0.125
Market Cap.	IMC: A\$17.1m	IMC: A\$28.5m
Cash & Cash Equivalents	A\$17.2m	A\$15.2m (31-Dec-23)
Sales Revenue	FY23 A\$1.8m	A\$3.2m +168% on pcp
Gross Profit	FY23 A\$1.3m	A\$2.2m +147% on pcp





# REVENUE GENERATING WITH STRONG PIPELINE

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

## Pipeline Snapshot

	30-Jun-23	7-Mar-24
Travelan (IMM-124E) - Phase 2 Traveller's Diarrhoea	Initiated IMM-124E ETEC <sup>2</sup> CHIM <sup>3</sup> clinical trial	Topline results for IMM-124E ETEC <sup>2</sup> clinical trial
Travelan® (IMM-124E) – Phase 4 Traveller's Diarrhoea	USU <sup>4</sup> P2TD IMM-124E field clinical trial recruited 35% of 868 participants	Recruited 50% of 868 participants
CampETEC – Phase 2 Campylobacteriosis	FDA IND <sup>1</sup> approved (Clinical Hold released)	Completion of In-patient phase Campylobacter CHIM <sup>3</sup> clinical trial
IMM-529 – Phase 2 Clostridioides Difficile	Completed 600 mg solid dose active formulation development	Completion of IMM-529 drug substance manufacture by CSIRO

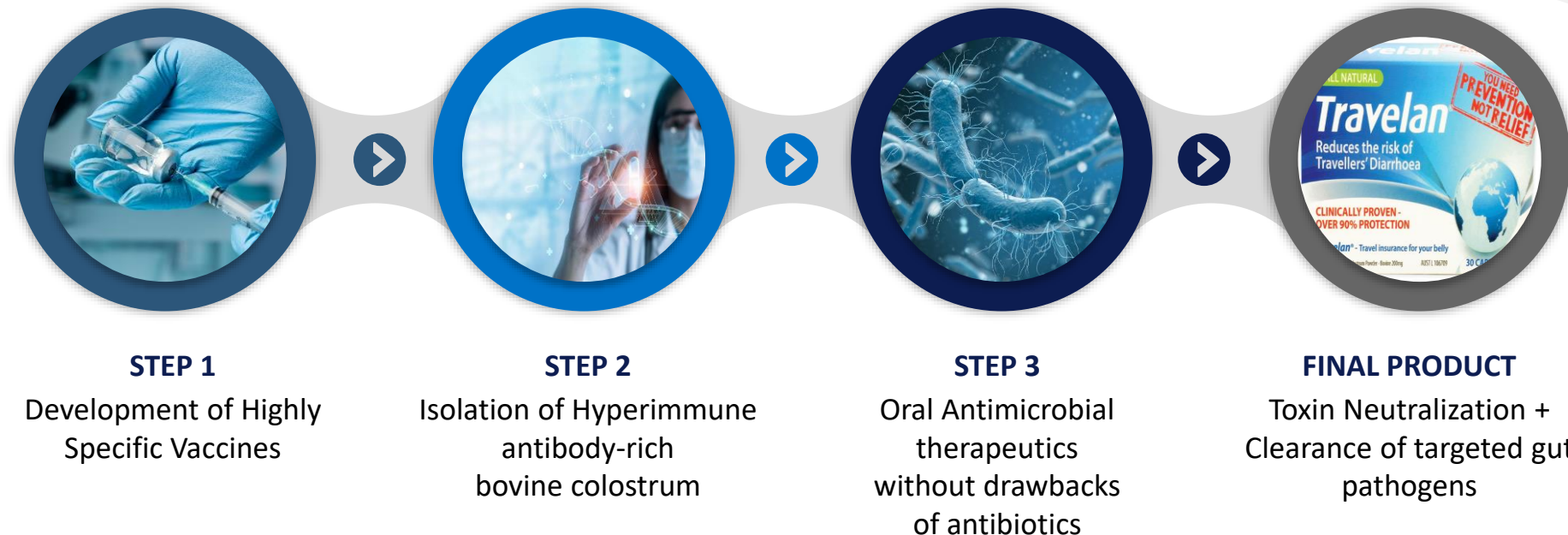




# TECHNOLOGY PLATFORM FOR GUT MEDIATED DISEASES

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.





- ✓ 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



## 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					



# VALUABLE SALES POTENTIAL FOR PIPELINE PRODUCTS



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

- › 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

- › 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

Immuron

**IMM-529**

*Clostridioides difficile* Infection & Recurrence

Immuron



# NEAR TERM MILESTONES ANTICIPATED TO DRIVE VALUE

	2H 2022	1H 2023	2H 2023	1H 2024	2H 2024
Travelan®	<ul style="list-style-type: none"> <li>FDA IND<sup>1</sup> approved for single daily dose IMM-124E ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>IRB Approval<sup>4</sup></li> <li>Initiated IMM-124E ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>100% of patients enrolled</li> <li>Completion of In-patient phase ETEC<sup>2</sup> CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Topline results for IMM-124E ETEC<sup>2</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Clinical Study Report</li> <li>End of Phase 2 FDA meeting</li> </ul>
CampETEC	<ul style="list-style-type: none"> <li>Submitted Response Letter to FDA Clinical Hold</li> <li>Immuron sponsored Toxicology study - completed</li> </ul>	<ul style="list-style-type: none"> <li>Toxicology Study Report</li> <li>FDA IND<sup>1</sup> approved (Clinical Hold released)</li> </ul>	<ul style="list-style-type: none"> <li>Institutional Review Board approval of NMRC<sup>5</sup> CampETEC Campylobacter CHIM<sup>3</sup> clinical trial protocol</li> <li>Initiated IMM-124E Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Completion of In-patient phase CampETEC Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>	<ul style="list-style-type: none"> <li>Topline results for CampETEC Campylobacter CHIM<sup>3</sup> clinical trial</li> </ul>
IMM-529	<ul style="list-style-type: none"> <li>600 mg solid dose active formulation development</li> </ul>		<ul style="list-style-type: none"> <li>IMM-529 cGMP manufacture</li> </ul>	<ul style="list-style-type: none"> <li>IMM-529 (CDI)<sup>7</sup> Pre-IND<sup>1</sup> submission</li> </ul>	<ul style="list-style-type: none"> <li>FDA meeting</li> </ul>
Travelan®	<ul style="list-style-type: none"> <li>USU<sup>6</sup> P2TD IMM-124E field clinical trial recruitment commencement</li> </ul>		<ul style="list-style-type: none"> <li>~50% of 868 participants recruited</li> </ul>	<ul style="list-style-type: none"> <li>Completion of enrollment</li> <li>Completion of in-patient phase</li> </ul>	<ul style="list-style-type: none"> <li>Topline results</li> </ul>



# IMM-124E

## BILLION DOLLAR MARKET

### - HIGH UNMET NEED



## Billion Dollar Market

Traveller's diarrhoea treatment market is large and growing at a CAGR of ~7%



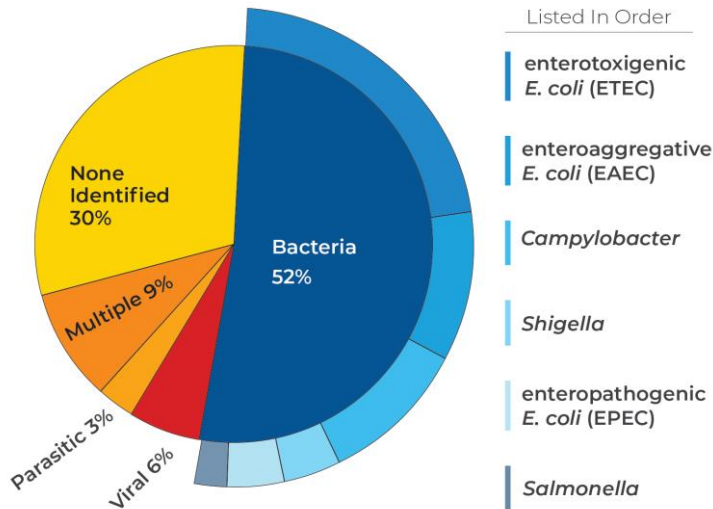
## Industry tailwinds

Travel picking up significantly following COVID lockdowns



## Frequent Symptoms

30% - 70% of travelers experience traveller's diarrhoea<sup>1</sup>



- There are no current reliable vaccines for prevention of Travellers' diarrhoea<sup>1</sup>
- Enterotoxigenic *Escherichia coli* (ETEC) is the leading cause of Travellers' diarrhoea<sup>1</sup>
- Travelan® is a hyperimmune bovine colostrum produced by immunization of cows during gestation with a vaccine consisting of antigens derived from 13 different ETEC strains known to cause Travelers' diarrhea
- Travelan® is broadly cross-reactive with other ETEC strains not included in the vaccine and other gram-negative bacteria (*Shigella*, *Vibrio cholera*, *Campylobacter spp.*)<sup>2,3</sup>
- Diarrhea ranked 1<sup>st</sup> among 57 infectious disease threats by the 2019 Military Infectious Disease Research Program's Infectious Disease Threat Prioritization Panel based on its impact to readiness<sup>4</sup>
- 76% of Soldiers in OIF and OEF experienced traveler's diarrhea early in their deployment<sup>4</sup>



## • Positive Results Support Travelan<sup>®</sup> progress to Phase 3

### • IMM-124E Phase 2

- Healthy volunteers were recruited and randomized to receive a single daily oral dose of 1200 mg of Travelan<sup>®</sup> or placebo. Dosing commenced 2 days prior to challenge with ETEC strain H10407 and continued for 7 days.
- 60 subjects completed the inpatient challenge component of this current clinical study.

### • Travelan<sup>®</sup> topline clinical trial results demonstrate protective efficacy with single daily dose

- **36.4%** protective efficacy against Enterotoxigenic *Escherichia coli* (ETEC) induced **moderate to severe diarrhea** was observed in the Travelan<sup>®</sup> group compared to the placebo group (primary endpoint) even though the attack rate for this study was 37%, much lower than the expected 70%
- The attack rates on previous Phase 2 ([Otto et al. 2011](#)) studies were 73% and 86% with protective efficacy of 90.9% and 76.7%
- **66.7%** protective efficacy against ETEC induced **severe diarrhea** was observed in the Travelan<sup>®</sup> group compared to the placebo group (secondary endpoint)
- **83.3%** statistically significant reduction in the number of subjects in the Travelan<sup>®</sup> group requiring **early antibiotic treatment** post challenge compared to the placebo (secondary endpoint)
- **100%** of the subjects requiring IV fluids post challenge were in the placebo (secondary endpoint)
- **55.6% reduction** in the number of subjects experiencing **adverse events** associated with the ETEC challenge observed in the Travelan<sup>®</sup> group compared to the placebo group (secondary endpoint)
- **Phase 2 clinical study data supports the excellent safety and tolerability profile of Travelan<sup>®</sup>**



# IMM-124E PHASE 3 STRATEGY

Pre	2H 2024	1H 2025	2H 2025	Post
<ul style="list-style-type: none"><li>• Phase 1 clinical study (Baltimore, 1996)</li><li>• Phase 2 clinical study (Poland, 2000)</li><li>• FDA<sup>1</sup> IND<sup>2</sup> approval (December 2022)</li><li>• Phase 2 clinical study (Baltimore, 2024)</li></ul>	<ul style="list-style-type: none"><li>• Clinical Study Report</li><li>• End of Phase 2 FDA meeting</li></ul>	<ul style="list-style-type: none"><li>• Phase 3 FDA meeting</li></ul>	<ul style="list-style-type: none"><li>• Initiate Phase 3</li></ul>	<ul style="list-style-type: none"><li>• Trial duration ~ 2 years</li><li>• End of Phase 3 FDA meeting</li><li>• BLA<sup>3</sup> submission</li></ul>
<ul style="list-style-type: none"><li>• The pivotal registration studies will involve two randomized, double-blind, parallel-group, placebo-controlled Phase 3 clinical studies (drug substance IMM-124E) to assess the efficacy and safety of Travelan<sup>®</sup> for prevention of traveler's diarrhea (TD)</li><li>• The studies will enroll approximately 1200 healthy adult subjects (600 subjects in two studies) traveling to regions with high TD risk.</li><li>• Subjects will be randomized 1:1 to receive Travelan<sup>®</sup> or placebo.</li><li>• Dosing will begin 3 days prior to arrival in country and for at least 14 days in country.</li><li>• The primary endpoint will be the development of TD.</li></ul>				

# WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI



## IMM-529

Indication / Target Population	IMM-529 will be indicated for the treatment of recurrent <i>C. difficile</i> infection
Product Description / Mechanism of Action	<ul style="list-style-type: none"><li>• Novel antibody-containing therapeutic which neutralizes <i>C. difficile</i> but does not impact the microbiome</li><li>• Targets not only toxin B but also spores and vegetative cells responsible for recurrence</li><li>• Potential for use in combination with standard of care (e.g. vancomycin, metronidazole)</li><li>• Targets many isolates</li></ul>
Dosage and ROA	<ul style="list-style-type: none"><li>• Oral administration, 3 x daily</li><li>• Trial to test 28-day treatment course on top of standard of care (vancomycin, metronidazole)</li></ul>
Efficacy	<ul style="list-style-type: none"><li>• Mouse data demonstrated ~80% survival rate (7/9) vs. ~10% survival rate in a control group (1/9) in a recurrent CDI mouse model</li></ul>
Safety / Tolerability	<ul style="list-style-type: none"><li>• To be evaluated in Phase I/IIA study</li><li>• Equivalent or better than current standard of care</li></ul>





# 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](#)

Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta)

[Islam D, Ruamsap N, Imerbsin R, Khanijou P, Gonwong S, Wegner MD, et al. \(2023\) Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model \(Macaca mulatta\). PLoS ONE 18\(12\): e0294021.](#)

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

[Infect Immun. 2023 Nov; 91\(11\): e00097-23.](#)

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/ijy213>](#)

## 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>](#)





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