## **Immur**@n



# INVESTOR PRESENTATION

**FY22 RESULTS & BUSINESS UPDATE** 

31 AUGUST, 2022

**Steven Lydeamore - CEO** 

NASDAQ: IMRN

**ASX: IMC** 

## **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®
- Incorporated in Australia in 1994 and has been listed on the ASX since 1999 and NASDAQ since 2017
- Market capitalisation of \$20.5 million as of 23 August 2022 with cash & cash equivalates balance of \$22.1 million as of 30 July
   2022

## Business Update

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- Refreshed corporate structure including two key hires Steven Lydeamore as CEO and Joanne Casey as R&D Manager
- Flagship product Travelan® once again in demand as global travel rebounded post lockdowns
- Addressable market continues to grow as Immuron expands its distribution capability in FY23
- Capable of producing highly specific orally active immunoglobulins to any enteric pathogen
- Completing an assessment of the entire product portfolio, target markets, competitive advantage and, growth drivers

## FY22 Results & Outlook

- FY22 revenue exceeded budget by 92% driven by an early resurgence in global travel
- Extremely strong balance sheet that will be supporting its refreshed organic growth strategy and new M&A strategy
- Set to file FDA IND and initiate a clinical trial for Travelan® (IMM-124E) this financial year



## **CEO UPDATE & CORPORATE SNAPSHOT**



- Refreshed the executive team, bringing on Steven
   Lydeamore as CEO and Joanne Casey as R&D Manager
- Steven brings over 30 years' of experience in the pharmaceutical industry including over 10 years working for Canada's largest pharma company, Apotex
- Joanne has a BSc Hons in Biomedical Technology and a PhD in Medicine, with experience in antibody development and translation into preclinical and clinical studies
- Strong presence in the Australian retail pharmacy network, where evidence-based OTC products are sold
- In the US, continued relationship with Passport Health, the largest provider
  of travel medicine services with travel clinics in the United States
- Plan to launch Protectyn<sup>®</sup>, a liver and gut health product into our network
- Immuron continues to have a large retail shareholder base in both the US and Australia with BNY Mellon Asset Management (American Depository Shares) having a 35% stake
- The board and management are aligned with our shareholders, currently holding 3%
- Plan to increase market communication with quarterly updates





Financial Snapshot	
Shares on Issue	227,798,346
Total Options	21,303,877
Last Traded Price	\$0.090
52 week High/Low	0.170/0.076
Market Cap	\$20.5m
Cash & Cash Equivalents (as at June 30)	\$22.1m

\*As at 23-Aug-2022

Substantial Shareholders		
Holder	Units	% of CSO
BNY Mellon Asset Management	79,677,424	35.0 %
Management & Board	6,904,554	3.0 %
Authentics Australia Pty. Ltd.	6,000,000	2.6 %
Grandlodge	3,846,712	1.7 %

<sup>\*</sup>As at 23-Aug-2022



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## **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



## **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 2

Isolation of Hyperimmune antibody-rich bovine colostrum



**Oral Antimicrobial therapeutics** without drawbacks of antibiotics



STEP<sub>3</sub>



#### **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

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



## STATUS OF PRODUCT PORTFOLIO AND KEY MILESTONES

- The business is completing an assessment of the entire product portfolio, target markets, competitive advantage and, key growth drivers
- US Department of Defense grant of US\$4.45 million to examine a dosing regimen for Travelan® more suited for use by the military
  - IMM-124E (Travelan®) IND is anticipated to be filed with the FDA in 2H2022
- Market evaluation is being undertaken before initiating further trials of IMM-529 for Clostridioides difficile
- Uniformed Services University is anticipated to commence in 1H2023

   a randomized clinical trial with Travelan® to evaluate the effectiveness
   for prophylaxis during deployment or travel to a high traveler's
   diarrhea risk region
- Naval Medical Research Center is on clinical hold for the proposed trial of CampETEC in campylobacter and enterotoxigenic E.coli (ETEC)

#### **Immuron's Clinical Programs**

Compound or brand name	Indication	Phase I	Phase II	Phase III	Market
IMM-124E Travelan®	Traveler's Diarrhea ETEC challenge	ımmu	ron		
IMM-529	Clostridioides difficile Infection & Recurrance	Immu	Iron		

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

Compound or brand name	Partner	Phase I	Phase II	Phase III	Market
Travelan <sup>®</sup> & Florastor <sup>®</sup>	THE REST OF THE PARTY OF THE PA	Uniformed Se Universi			
CampETEC	THE RESERVED AND A SECOND ASSESSMENT AS A SECOND ASSESSMENT AS A SECOND AS A S	Naval Med Research Ce			

<sup>\*</sup>Further information on the clinical programs can be found on slide 11





## **DISTRIBUTION CAPABILITY**

	Australia	USA	Canada
Retail Pharmacy	<b>©</b>		<b>②</b>
B2B	<b>©</b>	<b>②</b>	
E-commerce	<b>©</b>	<b>©</b>	<b>©</b>

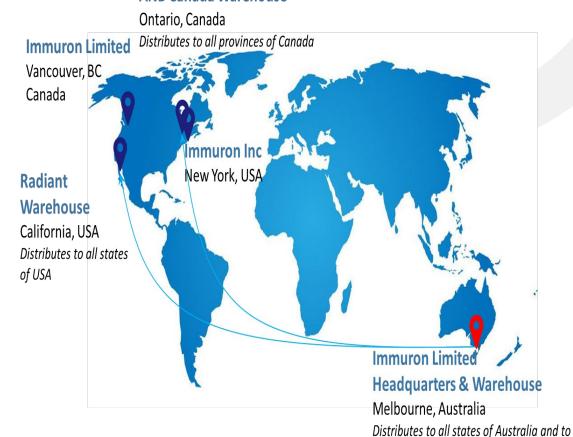




#### **Key Commentary**

- The Australian retail network includes over 3,500 pharmacies
- In the USA, the key B2B customer is Passport Health the largest network of travel clinics
- We are exploring options to expand B2B business in airlines, cruise ships, health & wellness segments
- Immuron's own shopfront on amazon.com will be introduced in the US and Canada during FY23
- Entry into Retail Pharmacy in USA will be explored in FY23

#### **ANB Canada Warehouse**





warehouses in the USA and Canada



## **PROFIT & LOSS**

3				
3	\$000s			
)	Profit & Loss	FY22*	FY21	Var %
	Australian Sales	\$ 201	\$ 40	404%
)	Rest of World Sales	\$ 564	\$ 106	433%
D	Total Revenue	\$ 765	\$ 146	425%
	Cost of Goods	\$ (242)	\$ (51)	373%
2	Gross Profit	\$ 524	\$ 95	453%
)	Gross Profit Margin	68%	65%	5%
3	General Expenses	\$ (3,429)	\$ (3,979)	-14%
)_	Share based payment expenses	\$ (95)	\$ (2,116)	-96%
4	Research and development expenses	\$ (658)	\$ (1,367)	-52%
)	Selling and marketing expenses	\$ (417)	\$ (288)	45%
_	Total Expenses	\$ (4,599)	\$ (7,749)	-41%
	Other Income	\$ 958	\$ 617	55%
)	Other Gains/(losses)	\$ 248	\$ (1,342)	-118%
5	Operating profit/(loss)	\$ (2,870)	\$ (8,380)	-66%

<sup>\*</sup>FY22 - H2 accounts are unaudited

#### **Key Commentary**

- 1 Strong rebound in global sales up 425% on pcp driven by the rebound in international travel
  - Note: total revenue in FY20 was over \$2.5m
- High margin business with Gross Profit margins at 68%
- Realigned cost base for growth with expenses down 14% on pcp, driven by the reduction in employee benefits and general expenses
- Decisions on investments in commercial products and R&D will be made following completing an assessment of the entire product portfolio, target markets, competitive advantage, and key growth drivers
- (\$8.4m) to (\$2.9m)
- FY22 Other Income contains general R&D grants (71%), Australia R&D tax concession (27%) & other (2%)





## **BALANCE SHEET**

\$000s				
<b>Balance Sheet</b>	3	0-Jun-22	3	0-Jun-21
Cash & Cash Equivalents	\$	22,110	\$	25,047
Receivables	\$	663	\$	335
Inventories	\$	327	\$	293
Other Current Assets	\$	572	\$	78
Total Current Assets	\$	23,672	\$	25,753
Property, plant and equipment	\$	227	\$	34
Inventories	\$	957	\$	1,267
<b>Total Non-Current Assets</b>	\$	1,184	\$	1,300
Total Assets		24.056	_	27.052
Total Assets	\$	24,856	\$	27,053
Trade and other payables	<b>\$</b> \$	1,161	<b>\$</b>	758
	•	1,161	•	·
Trade and other payables	\$	1,161	\$	758
Trade and other payables Other current liabilities	; \$	1,161 342	\$ \$	758 363
Trade and other payables Other current liabilities Total Current Liabilities	\$ \$ <b>\$</b>	1,161 342 <b>1,503</b>	\$ \$	758 363 <b>1,122</b>
Trade and other payables Other current liabilities  Total Current Liabilities  Employee benefit obligations	\$ \$ <b>\$</b>	1,161 342 <b>1,503</b>	\$ \$ \$	758 363 <b>1,122</b>
Trade and other payables Other current liabilities  Total Current Liabilities  Employee benefit obligations Other non-current liabilities	\$ \$ <b>\$</b> \$	1,161 342 <b>1,503</b> 0 175	\$ \$ \$ \$	758 363 <b>1,122</b> 36

<sup>\*</sup>FY22 - H2 accounts are unaudited



#### **Key Commentary**

- 1 Immuron is well funded with over \$22.1m in cash & cash equivalents
- Trade and other payables rise with the increased business activity
- No debt the \$175k amount is the recognition of a lease commitments >12 months



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

#### **Organic Growth Strategy**

 Focus on commercialised products and nearterm development extensions, including:

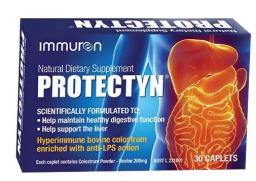
## 1 Travelan®:

- 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

## 2 Protectyn®:

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



## KEY MILESTONES ANTICIPATED TO DRIVE VALUE



		2H 2022		1H 2023			2H 2023			1H 2024		
Travelan®	•		r single dose per day ETEC <sup>2</sup> linical trial	<ul> <li>Initiate ETE CHIM<sup>3</sup> clini</li> </ul>	C IMM-124E cal trial	•	•	llts for IMM- CHIM clinical				
CampETEC	• Submit Complete Response Letter (CRL) to FDA Clinical Hold for CampETEC clinical challenge study'				•	trial Initiate NMI	CHIM clinical RC eter CampETEC	•	Topline resul CampETEC E clinical trial Topline resul CampETEC C CHIM clinical	TEC CHIM ts for NMRC ampylobacter	-	
IMM-529	• IMM-529 cGMP manufacture <sup>5</sup>			•	IMM-529 IN submission <sup>5</sup>		•		O submission <sup>5</sup> -529 phase 2 rial <sup>5</sup>	-		
Travelan® &				Initiate USU	J <sup>6</sup> P3TD IMM-							-

124E field clinical trial



Florastor®

<sup>1.</sup> Investigational New Drug; 2. Enterotoxigenic E.coli; 3. controlled human infection model; 4. Naval Medical Research Center; 5. Pending market evaluation being complete in CY22; 6. Uniformed Health Services University of the Health Sciences





## THANKYOU

## **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 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 antibiot alternative	Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5

