



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL IMMUNOTHERAPIES – JANUARY, 2021

JERRY KANELLOS, Ph.D. Chief Executive Officer

> 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.

# COMPANY HIGHLIGHTS



We are a <u>commercial</u> and <u>clinical-stage</u> biopharmaceutical company focusing on infectious diseases with oral immunoglobulin-based therapies

- Validated Technology Platform with One Registered Asset, Travelan<sup>®</sup> Generating Revenue
- IMM-124E & IMM-529, in **Clinical Development** for Treatment of Gastrointestinal Disorders and *C. difficile* Infections
- US DoD Research Collaboration New Therapeutic in Clinical Development for Treatment of moderate to severe Campylobacteriosis and Infectious diarrhea caused by ETEC pathogens





#### CAPITAL PROFILE IMMURON LIMITED (ASX:IMC

NASDAQ:IMRN)

**Current Top 10 Shareholders** 

Rank		Holder Name	Current Qty	%
1		HSBC CUSTODY NOM AUST LTD (ADR Program)	104,631,009	46.57%
2	*	GRANDLODGE PTY LTD	11,778,269	5.26%
3		AUTHENTICS AUSTRALIA PTY LTD	7,500,000	3.35%
4		DR RUSSELL HANCOCK	3,000,000	1.34%
5	*	MR STEPHEN ANASTASIOU	2,494,746	1.11%
6		INSYNC INVESTMENTS PTY LTD	2,000,000	0.89%
7		CITICORP NOMINEES PTY LIMITED	1,719,277	0.77%
8		MR ANTHONY FREDERICK WALLACE HYETT	1,350,000	0.60%
9		ANNE PATTISON PTY LTD	1,345,000	0.60%
10		MR WILLIAM DAVID FRANK BIRD	1,300,000	0.58%
		TOTAL TOP 20 SHAREHOLDERS	145,778,865	64.93%
		BALANCE OF SHARES	78,321,141	35.07%
		TOTAL SHARE ON ISSUE	224,100,006	100.00%
	*	Denotes a Director Related Entity (15 October 2020)		

Current Company Market Capitalization AUD\$49.90M ≈ USD\$38.46M (6<sup>th</sup> January 2021)

US\$20 million capital raise with HC Wainwright (24 July 2020)

1 ADS = 40 Ordinary Shares

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#### DEVELOPMENT **PIPELINE** Commer

Institute of Research

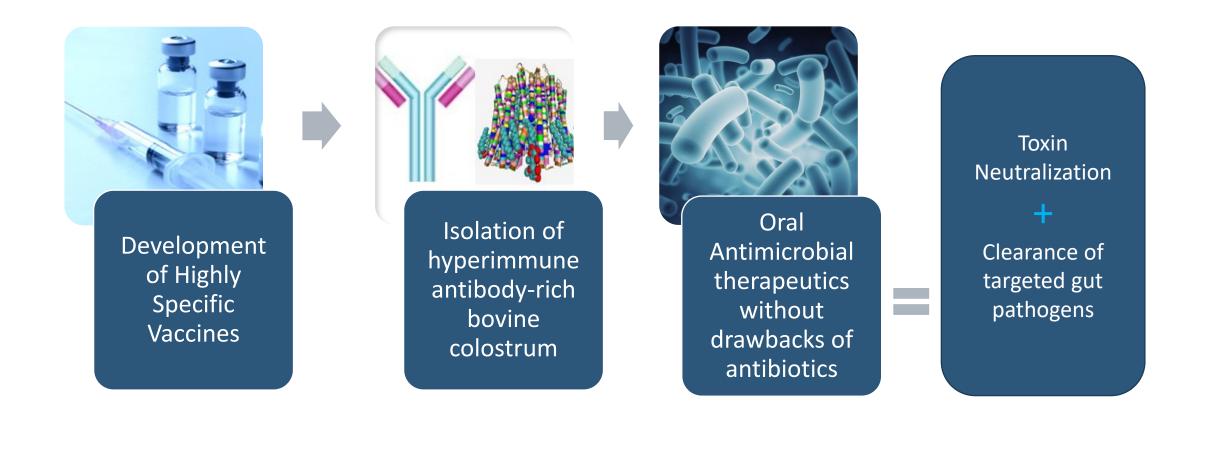
Г	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	MARKET		
	Travelan <sup>®</sup> - commer	cial product Aus	tralia				
Ú							
Commercial	Protectyn <sup>®</sup> - comme	rcial product Au	stralia				
Products							
	Travelan <sup>®</sup> - commer	cial product Can	ada				
	Travelan <sup>®</sup> - commer	cial product USA					
6	i) Travelers' Diarrhea	FDA drug regist	ration USA				
4							
IMM-124E	ii) P4TD Travelers' Di	arrhea Efficacy F	ield Trial				
	iii) COVID-19 researd	h					
	Recurrent C. difficile	infections					
B							
IMM-529							
	Moderate to severe	Campylobacterio	sis infections				
4							
Naval Medical	ETEC infections						
Research Center							
	Evaluation of Shigella specific therapeutic drug candidates						
6							
Walter Reed Army							





# PLATFORM OVERVIEW: ORAL IMMUNOGLOBULINS





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# MECHANISM OF ACTION - TARGETING ENTERIC PATHOGENS (



- Delivers high levels of orally active antibodies to specific enteric pathogenic bacteria which colonize the gastrointestinal tract and cause infection and disease.
- Biological therapeutics which directly target the major pathogenic virulent components;
  - Molecules which facilitate bacterial adhesion to host cell intestinal epithelium Ο
  - Surface layer proteins which contribute to bacterial colonization and motility Ο
  - Endotoxins and enterotoxins that cause disease 0

Without Travelan<sup>®</sup>: Bacteria attach to gut wall and infect



With Travelan<sup>®</sup>: Bacteria neutralized by Travelan<sup>®</sup> antibodies



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**Pre-Clinical** 

Studies

# US DOD R&D COLLABORATION AGREEMENTS



#### **Research Collaborations:**

- Characterisation of Travelan<sup>®</sup>
  Shigella-Specific Target US Army
  Campylobacter-specific Target US Navy
- Armed Forces Research Institute of Medical Sciences (AFRIMS) June 2016
- Naval Medical Research Center (NMRC) August 2016
- Walter Reed Army Institute of Research (WRAIR) June 2016
- Travelan<sup>®</sup> binds 180 pathogenic strains of bacteria from infected personnel deployed in Bhutan, Cambodia, Nepal and Thailand (ETEC, Shigella, Campylobacter).
- Travelan<sup>®</sup> binds to 71 pathogenic strains of Vibrio cholera from infected personnel in Bangladesh, Cambodia, and Thailand.









#### New U.S. Department of Defense Research Collaboration with Immuron to Develop and Clinically evaluate a New Therapeutic against Campylobacter

Key Highlights:

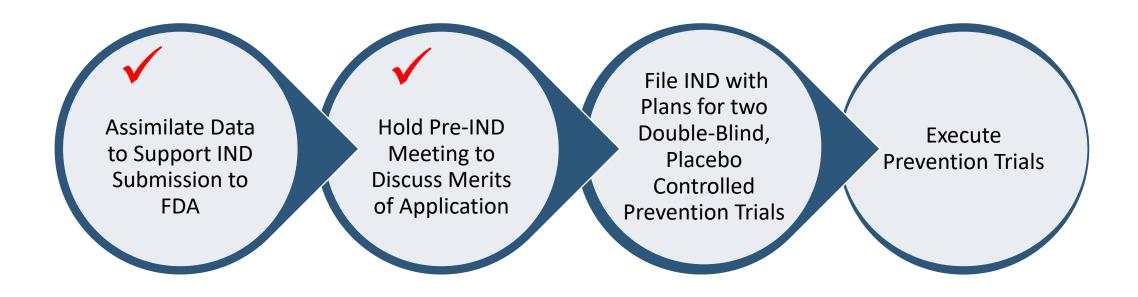
- AU \$5.5 (USD \$3.7) million funding approved by the U.S. Department of Defense to develop and clinically evaluate a new oral therapeutic targeting Campylobacter and ETEC
- Naval Medical Research Center will fund the manufacture and therapeutic evaluation of the new therapeutic to protect against acute infectious diarrhea
- Two human clinical trials to be conducted with new therapeutic under terms of grant

Melbourne, Australia, October 02, 2019: Immuron Limited (ASX: IMC; NASDQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, is pleased to announce the funding of a new research agreement with the Naval Medical Research Center (NMRC), Silver Spring, MD, USA.

# NMRC DRUG DEVELOPMENT PLAN



Two Human Clinical Trials Planned: To evaluate the efficacy of the New Drug in Moderate To Severe Camylobacteriosis and Infectious Diarrhea Caused by ETEC



# **BACKGROUND OF TRAVELAN®: PLAN TO EXPAND USE**

#### **COMMERCIAL PRODUCT**

#### Marketed in Australia, USA and Canada

Plan to develop IMM-124E as an approved drug in the USA targeting Travelers' Diarrhea

**DRUG CANDIDATE IMM-124E** 

#### **Status with FDA:** IND 14,933\*



\*IMM-124E for treatment of NASH







# WHAT IS TRAVELERS' DIARRHEA?



- Caused by consuming food or water infected with pathogens. Three or more unformed stools in 24 hours.
- Bacterial pathogens are the predominant risk<sup>1</sup>.
- Enterotoxigenic *E. coli* (ETEC) are the predominant pathogens<sup>2,3</sup>:

42% in Latin America28% in Southeast Asia

- Up to 70% of travelers suffer from travelers' diarrhea<sup>4</sup>.
- 1 Steffen, R. 2017 Epidemiology of travelers' diarrhea. Journal of Travel Medicine 24(1)
- 2 Leder, K. 2015 Advising Travellers about Management of Travelers' Diarrhea. Australian Family Physician, vol 44 No. 1-2 Jan. Feb 2015
- 3 Castelli et. al., Epidemiology of Travelers' Diarrhea, J. Travel Medicine 2001; 8 (Suppl2) S26-S30
- 4 CDC Yellow Book 2018, Chapter 2 Travelers' Diarrhea.



# US SALES FORECAST FOR TRAVELAN®: IF APPROVED AS DRUG BY THE FDA



#### **MARKET POTENTIAL FOR TRAVELAN® SALES:**

#### USD >\$100 MILLION

#### Market potential figure derived from:

2014 figures of US citizens traveling to high risk destinations for TD (44.3 million)<sup>1</sup> and obtaining pretravel advice (22.2 million)<sup>2</sup>. Sources of pre-travel advice include primary care provider, travel medicine specialist, company doctors, pharmacist, and travel agencies<sup>2</sup>. Our forecast utilizes a very conservative estimate for % of US citizens purchasing Travelan<sup>®</sup> after seeking pre-travel advice.



1. U.S. Department of Commerce, International Trade Administration, National Travel and Tourism Office. U.S. Citizen Traffic to Overseas Regions, Canada & Mexico 2014.

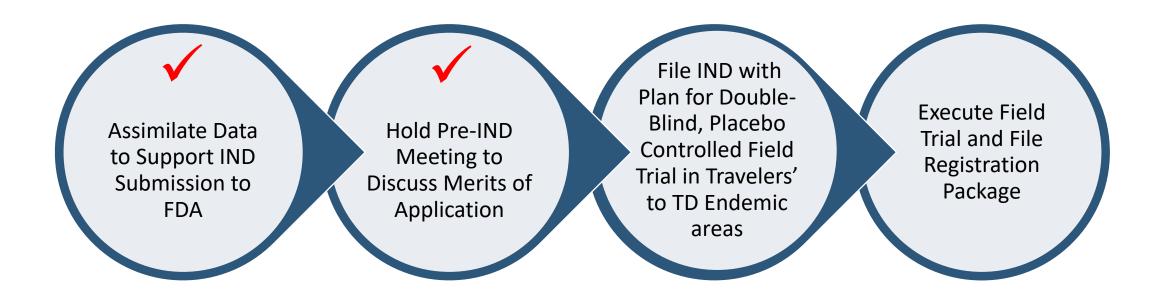
Monthly Statistics, U.S.Outbound Travel by World Regions. 2014. Available at: http://travel.trade.gov/view/m-2014-O-001/index.html. Accessed June 26, 2015.

2. Mathyas Wang , MD , Thomas D. Szucs , MD, MBA, MPH, LLM , and Robert Steffen , MD. Economic Aspects of Travelers ' Diarrhea. Journal of Travel Medicine, Volume 15, Issue 2, 2008, 110–118

# **IMM-124E DRUG DEVELOPMENT PLAN**



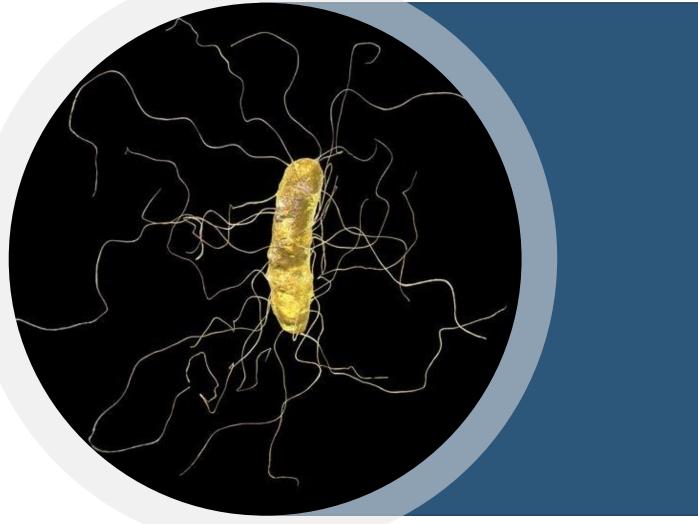
Revamp Travelan<sup>®</sup> for FDA approval as drug to reduce the risk of Travelers' Diarrhea (TD) in travelers to endemic areas:





# NEUTRALIZING *CLOSTRIDIODES DIFFICILE*, WHILE SPARING THE MICROBIOME

IMM-529



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# **CLOSTRIDIUM DIFFICILE MARKET OPPORTUNITY**



*Clostridiodiodes difficile* (*C. difficile*) is a bacterium that causes diarrhea and more serious intestinal conditions such as colitis

- Therapeutic market expected to grow from USD \$630 million in 2016 to over \$1.7 billion by 2026 – CAGR 15%<sup>1</sup>
- Leading cause of gastroenteritis-associated mortality in U.S.<sup>2</sup>
- Approx. 44,500 patients<sup>3</sup> died in 2014 from C. *difficile* infections (U.S.)
- Potential orphan disease (7 years market exclusivity and premium pricing)
  - 1. https//www.globaldata.com/global-clostridium-difficle-infectionmarket-approach-2016-2026
  - 2. Jagai, et.al., BMC Gastroenterology, 2014:14:211 Trends in gastroenteritis-associated mortality in the USA.
  - 3. K. Desai, BMC Infect. Dis., 2016,16:303

# THE UNMET NEED



- Current standard of care for C. difficile includes vancomycin, metronidazole & fidaxomicin
- Therapies plagued by significant CDI recurrences (\*1st relapse: 25%; 2nd: 40%; 3rd: 60%) underscoring need for new treatments
- Growing resistance to vancomycin treatment
- Some treatments are administered intravenously rather than via the gut where C. *difficile* resides



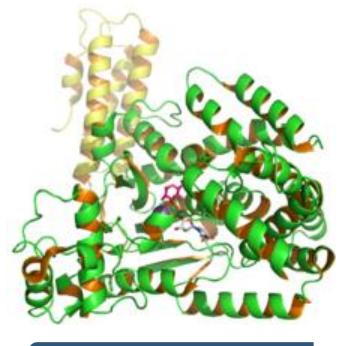
\*Isobel Ramsay, Nicholas Brown and David Enoch. Recent Progress for the Effective Prevention and Treatment of Recurrent Clostridium difficile Infection. Infectious Diseases: Research and Treatment Volume 11: 1–4 (2018). DOI: 10.1177/1178633718758023

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# **IMM-529 OPPORTUNITY**

- IMM-529 highly differentiated neutralizes *C. difficile* but does not impact microbiome
- Targets not only toxin B but also spores and vegetative cells responsible for recurrence
- Potential use in combination with standard of care
- Targets many isolates



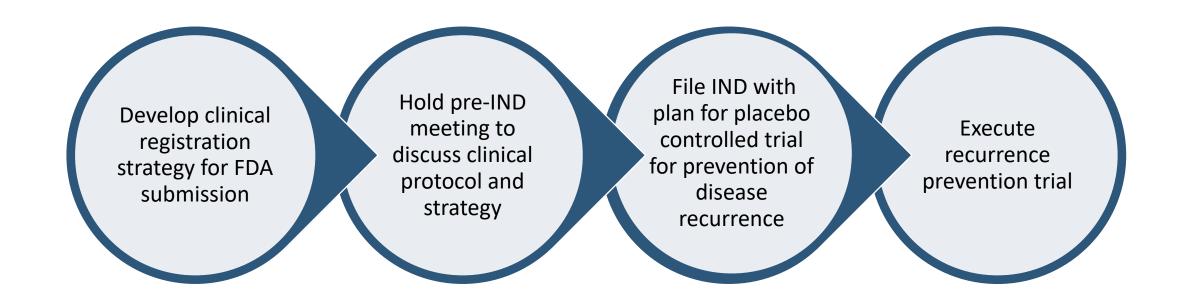




# **IMM-529 DRUG DEVELOPMENT PLAN**



Develop clinical protocol for FDA approval as drug to prevent recurrent *Clostridiodes difficile* Infection:





## **Immuron Reports Neutralizing activity Against SARS-CoV-2**

**Key Points** 

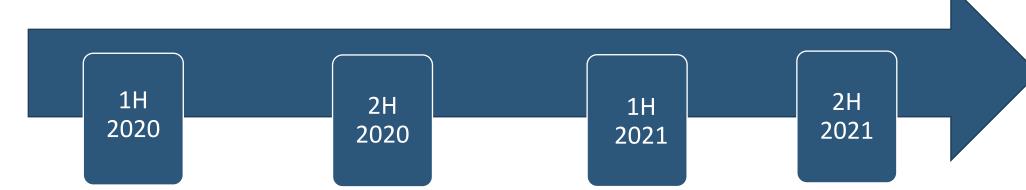
- Immuron's Hyper-immune Bovine Colostrum used to manufacture Travelan<sup>®</sup> and Protectyn<sup>®</sup> demonstrates antiviral activity against the COVID-19 virus in laboratory studies
- Immuron's technology platform offers a potential new oral therapeutic approach to target SARS-CoV-2 in the GI Tract

Melbourne, Australia, July 21, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to announce that the hype-Immune bovine colostrum used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan<sup>®</sup> and Protectyn<sup>®</sup> has demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19.

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# **KEY MILESTONES EXPECTED TO DRIVE VALUE**





- Pre-IND Meeting to Discuss IMM-124E
   Phase 3 Clinical
   Development
- Pre-IND Meeting to Discuss Phase 2 NMRC Clinical Development

- cGMP Manufacture
  Drug Substance
  - Drug SubstanceDrug Product
    - ance Submission Ict • Initiate Phas

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 Initiate Phase 2 Clinical Trials

NMRC IND

- Camylobacteriosis prevention study
- ETEC Infectious diarrhea prevention study
- Phase 2 Clinical Data Available
- IMM-124E IND Submission
- Pre-IND Meeting on IMM-529 *C. difficile* program

Results from US Army Shigella animal studies & COVID-19 Research Program expected in 2021



# **THANK YOU**





#### **Dr Jerry Kanellos – Chief Executive Officer**

- Over twenty years' experience in pharmaceutical and biotechnology industries.
- Former Chief Operating Officer of TransBio Ltd. Responsible for strategic identification, development and maintenance of global commercial partnerships, along with development, management and IP portfolio, R&D and technology transfer.
- Leadership roles in business development, project management, IP portfolio management, R&D, senior management.
- Consultant to academic institutes, private and publicly listed companies and government departments specializing in development and commercialization strategies.
- PhD in medicine from the University of Melbourne.