



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL  
IMMUNOTHERAPIES – MAY 2019

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**GARY S. JACOB, Ph.D.**  
**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.

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# MANAGEMENT



**Dr Gary Jacob**

*Chief Executive Officer*

- Chief Executive Officer of Immuron Limited since November 16, 2018.
- Over 30 years of experience in pharmaceutical and biotechnology - including R&D, operations, business development and capital financing.
- Co-founder and founding CEO of Synergy Pharmaceuticals.
- Co-inventor of TRULANCE® (plecanatide), an FDA approved drug to treat chronic GI disorders.
- Raised over USD \$500 million of capital in the public markets to support Synergy from founding to approval of TRULANCE® in 2017.
- Ph.D. in Biochemistry; University of Wisconsin-Madison and BS in Chemistry from the University of Missouri.



**Jerry Kanellos**

*Chief Operating Officer*

- Former Acting CEO of Immuron Ltd. 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.

# BOARD OF DIRECTORS – CHAIRMAN & EXECUTIVE VICE CHAIRMAN



## Dr Roger Aston

*CHAIRMAN - B. Sc. (Hons), PhD.*

Dr Aston has more than 20 years experience in the pharmaceutical and biotech industries. He was the Chief Executive Officer of Mayne Pharma Group Limited, after leading HalcyGen's acquisition of Mayne Limited in 2009. He has extensive experience with FDA and EU product registration, clinical trials, global licensing, private placement fundraising and prospectus preparation. Dr Aston has held numerous other board positions in the sector including with Clinuvel Limited, HalyGen Limited and Ascent Pharma Health Limited, recently acquired by Watson.



## Peter Anastasiou

*EXECUTIVE VICE CHAIRMAN - BBSc*

Mr. Anastasiou has extensive business experience in a wide range of organisations. He has been a successful entrepreneur from an early age with his first biotech venture, Neuro Developments Australia, seeded at age 24. Mr. Anastasiou was the founder of Investment Group Grandlodge, and ACS International both of which have generated significant wealth through Investment and Management



# COMPANY HIGHLIGHTS

We are a commercial and clinical-stage 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 Liver Disease and *C. difficile* Infections

Plan for Accelerated **Regulatory Path** to Approval for IMM-124E (Travelan<sup>®</sup>) as Drug to Prevent Travelers' Diarrhea in USA

# PLATFORM OVERVIEW: ORAL IMMUNOGLOBULINS



Development  
of Highly  
Specific  
Vaccines



Isolation of  
hyperimmune  
antibody-rich  
bovine  
colostrum



Oral  
Antimicrobial  
therapeutics  
without  
drawbacks of  
antibiotics



Toxin  
Neutralization  
+  
Clearance of  
targeted gut  
pathogens

# US DOD R&D COLLABORATION AGREEMENTS



## Collaboration on Development of a Shigella-Specific Therapeutic

- 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® binds 180 pathogenic strains of bacteria from infected personnel deployed in Bhutan, Cambodia, Nepal and Thailand



# DEVELOPMENT PIPELINE: TWO-PRONGED PLAN



	DEVELOPMENT STAGE					HIGHLIGHTS
	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
<b>ANTI-INFLAMMATORY PROGRAMS</b>						
Travelan®	TGA ARTG Aust L106709 (2004)					Commercial product - Australia
	Health Canada NPN 80046016 (2015)					Commercial product - Canada
	Dietary supplement (2015)					Commercial product - USA
IMM-124E (Travelan®)	▶					PLAN TO DEVELOP AS DRUG TO PREVENT TRAVELERS' DIARRHEA IN USA
IMM-529	▶					TO PREVENT RECURRENCE IN C. DIFFICILE PATIENTS

# BACKGROUND OF TRAVELAN®: PLAN TO EXPAND USE



## COMMERCIAL PRODUCT

Marketed in Australia, USA and Canada



## DRUG CANDIDATE IMM-124E

Status with FDA:  
IND 14,933\*



\*IMM-124E for treatment of NASH

Plan to develop IMM-124E as an approved drug to prevent Travelers' Diarrhea



# 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 America
  - 28% in 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

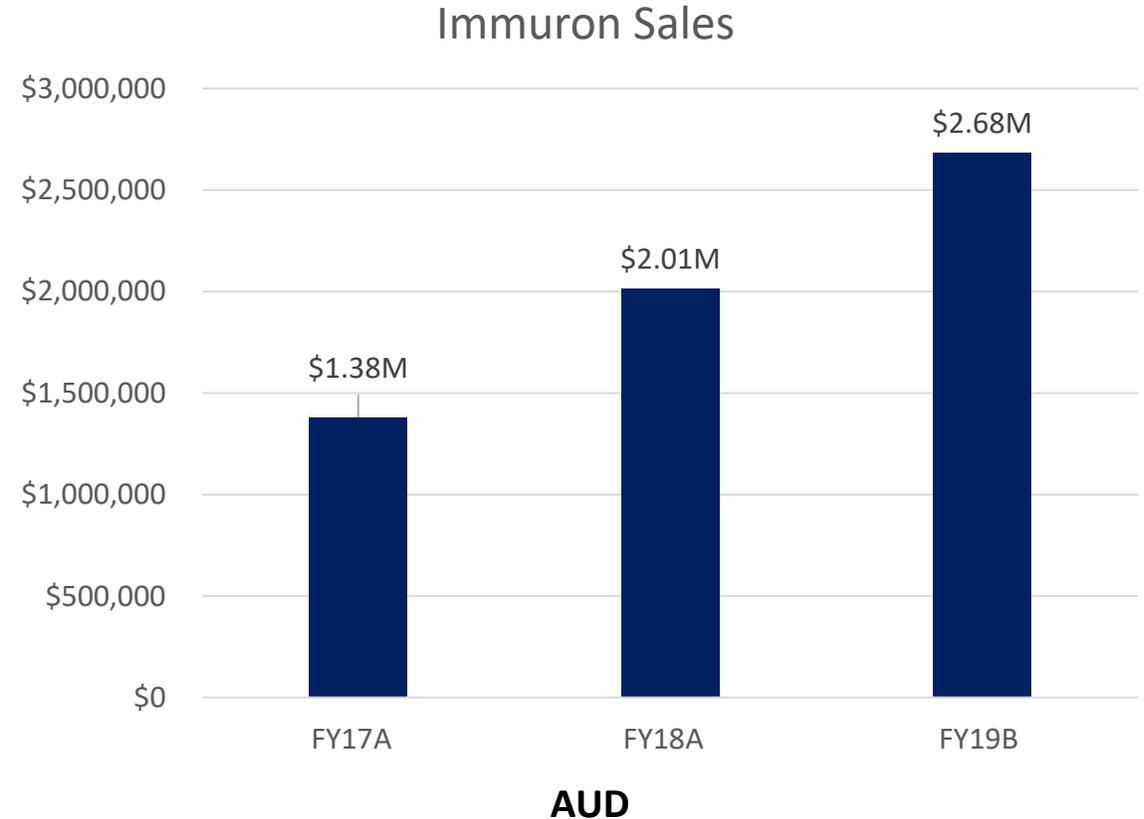
4 – CDC Yellow Book 2018, Chapter 2 Travelers' Diarrhea.

# TRAVELAN® COMMERCIAL PROFILE: INCREASING SALES ADDRESSING LARGE MARKETS



**2019 Global market - US \$630M  
Expected to reach US \$890M by  
2024 at 7% CAGR <sup>1</sup>**

1. <https://www.marketwatch.com/press-release/at-71-cagr-travelers-diarrhea-therapeutics-market-size-to-reach-usd-890-million-by-2024-2019-05-08>



# ANTIBIOTIC RESISTANCE: OPPORTUNITY FOR TRAVELAN®



International Society of Travel Medicine  
Promoting healthy travel worldwide  
Established 1991

International Society of Travel Medicine, 2017 guidelines for treating Travelers' Diarrhea included<sup>1</sup>:

- Antibiotics should **NOT** be used routinely, except patients at high risk of complications
- Rifaximin recommended when antibiotic prophylaxis is indicated
- Fluoroquinolones not recommended for prophylaxis<sup>2</sup>
- Insufficient evidence to recommend prebiotics or probiotics

## The opportunity: Travelan®, the alternative to antibiotic treatment of TD

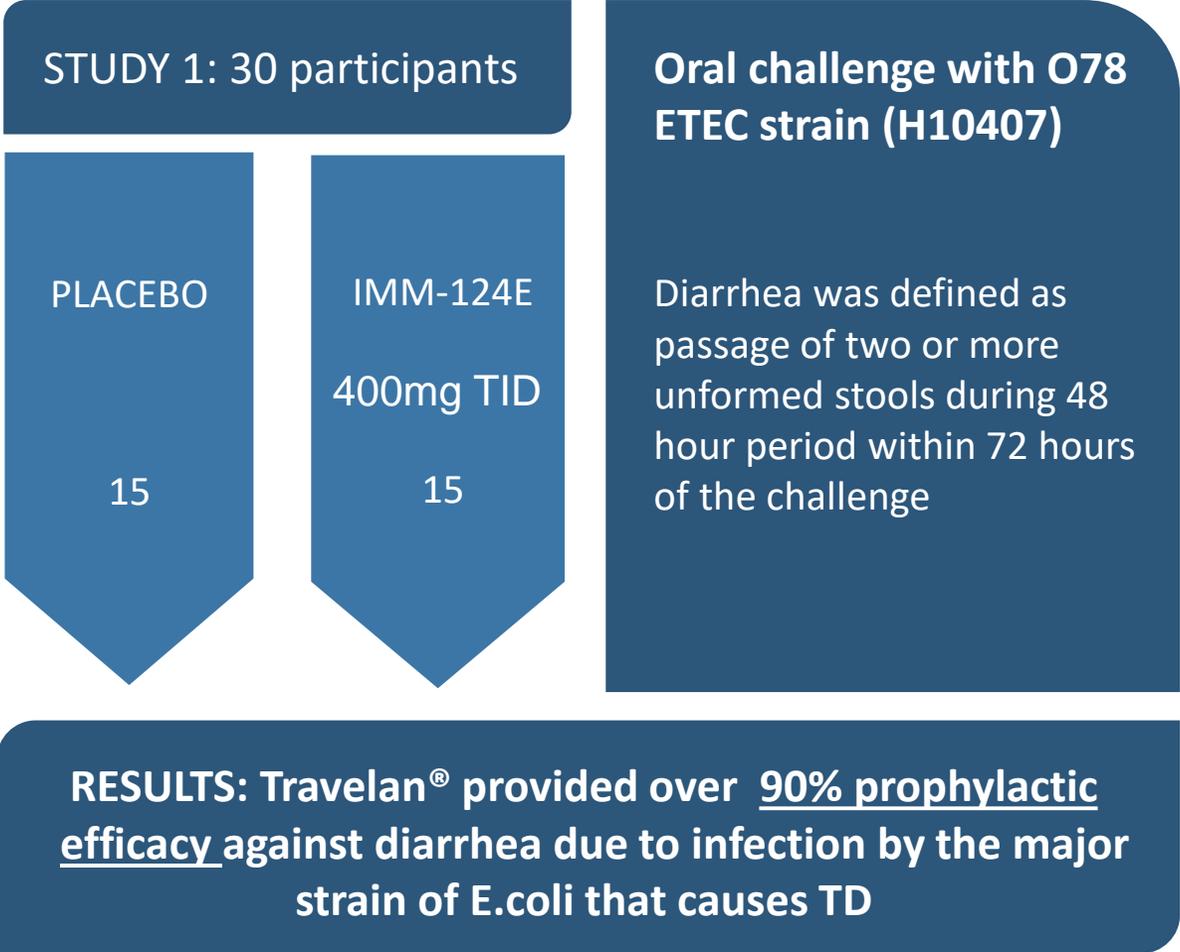
1 Riddle et al. 2017. Guidelines for the prevention and treatment of travellers' diarrhea: a graded expert panel report. Journal of Travel Medicine 24(1).

2 Tribble, D. 2017 Resistant pathogens as causes of traveller's diarrhea globally and impact(s) on treatment failure and recommendations. Journal of Travel Medicine 24(1)

# TRAVELAN® AS A DRUG TO PREVENT TRAVELERS' DIARRRHEA



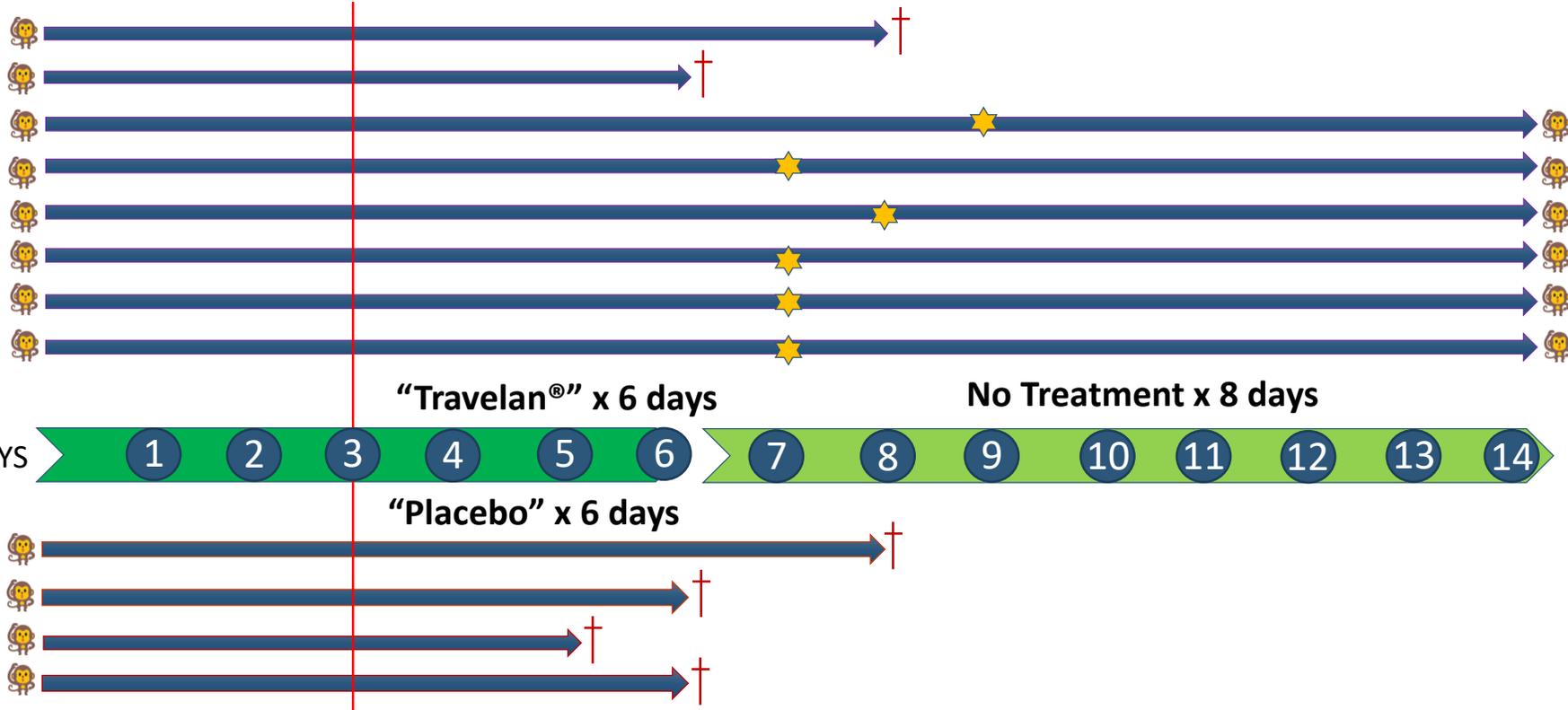
- Travelan® evaluated in two randomised, double-blind, placebo-Controlled Human Infection Model challenge clinical trials
- 90 healthy volunteers in Study 1 & 2
- Published in Scandinavian Journal of Gastroenterology



# RESULTS OF TRAVELAN® SHIGELLA CHALLENGE STUDY\*



$3 \times 10^9$   
*S. flexneri*



Travelan® group

Placebo control group

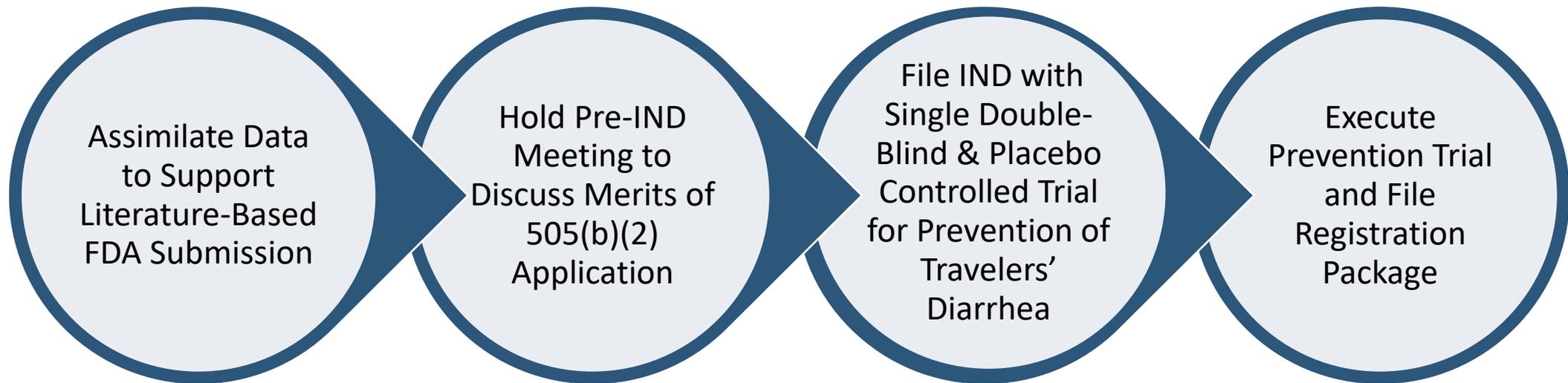
★ = last day of *S. flexneri* consecutive +ve stool culture

\*Collaboration with AFRIMS & WRAIR



# IMM-124E DRUG DEVELOPMENT PLAN

Revamp Travelan® for FDA approval as drug to prevent Travelers' Diarrhea in travelers to endemic areas:



# US SALES FORECAST FOR TRAVELAN®: IF APPROVED AS DRUG TO PREVENT TD



## 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® 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

# COMPETITOR MARKET ANALYSIS – ANTI-DIARRHEAL DRUGS



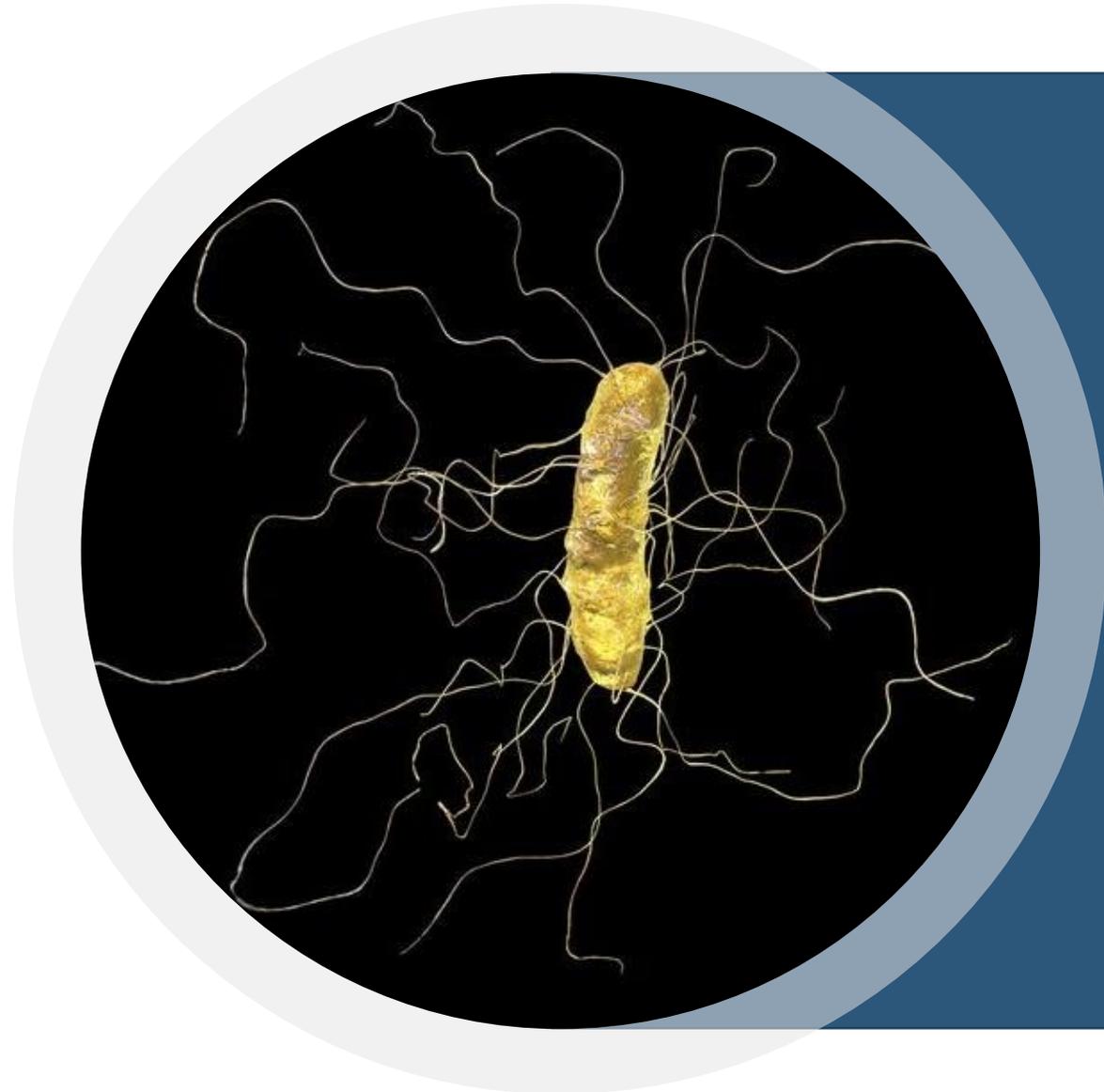
Drug	Indication	Dosing	Ave cost – 2 week trip	Revenue USD Millions (Year)
<b>FDA APPROVED DRUG TREATMENTS FOR DIARRHEA</b>				
PEPTO BISMOL (BSS) 	Relief for heartburn, nausea, indigestion, upset stomach and diarrhea.	2 tabs QID	\$20.97 <sup>1</sup>	82.6 (2013) <sup>2</sup>
IMMIDIUM 	Decrease the frequency of diarrhea in TD, gastroenteritis, inflammatory bowel disease, and short bowel syndrome.	2 tabs (2 mg)	\$17.33 <sup>1</sup> (48 caplets)	82.5 (2013) <sup>2</sup>
CIPROFLOXACIN (FLUOROQUINOLINE) 	Bacterial infections.	500 mg	\$44.52 <sup>3</sup>	40.8 (2015) <sup>3</sup>
RIFAXIMIN 	Treatment of Travellers' Diarrhea.	3 caps (200 mg) TID	\$657 <sup>4</sup>	
<b>PRESENTLY, THERE IS NO FDA APPROVED DRUG TO PREVENT TRAVELERS' DIARRHEA</b>				
TRAVELAN®	Dietary Supplement.	3 caps (200 mg) TID	\$30 – 30 caplets	0.77 (2018) <sup>5</sup>

1. Amazon.com
2. Top 10 OTC brands for digestives by revenue in the USA in 2013
3. Almalki et. al., Utilization, spending & price trends for quinolones in the US, Pharmacoeccon Open 2017 Jun: 1(2): 123-131
4. Drugs.com Xifaxan (rifaximin) price guide. Cost of Xifaxan oral tablet 200 mg ~\$657 for 30 tablets
5. US Sales for Travelan – FY2018



**NEUTRALIZING  
*CLOSTRIDIUM DIFFICILE*,  
WHILE SPARING THE  
MICROBIOME**

**IMM-529**



# CLOSTRIDIUM DIFFICILE MARKET OPPORTUNITY



*Clostridium 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-difficile-infections-market-approach-1-7-billion-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

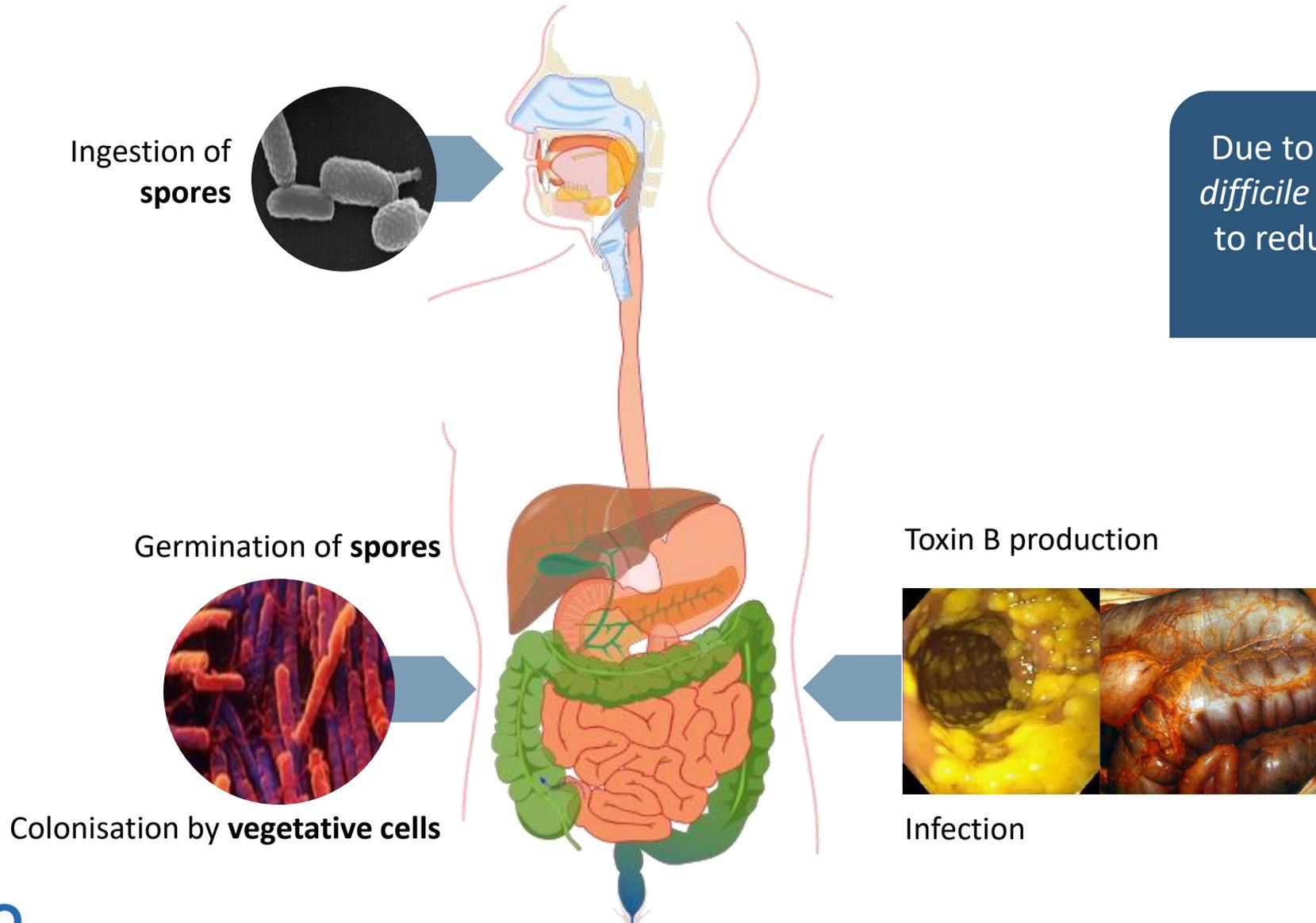
- Current standard of care for *C. difficile* includes vancomycin, metronidazole & fidaxomicin
- Therapies plagued by significant CDI recurrences (\*1st relapse: 25%; 2nd: 40%; 3rd: 60%) underscoring need for new treatments
- Growing resistance to vancomycin treatment
- Some treatments are administered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

# IMM-529 TARGETS

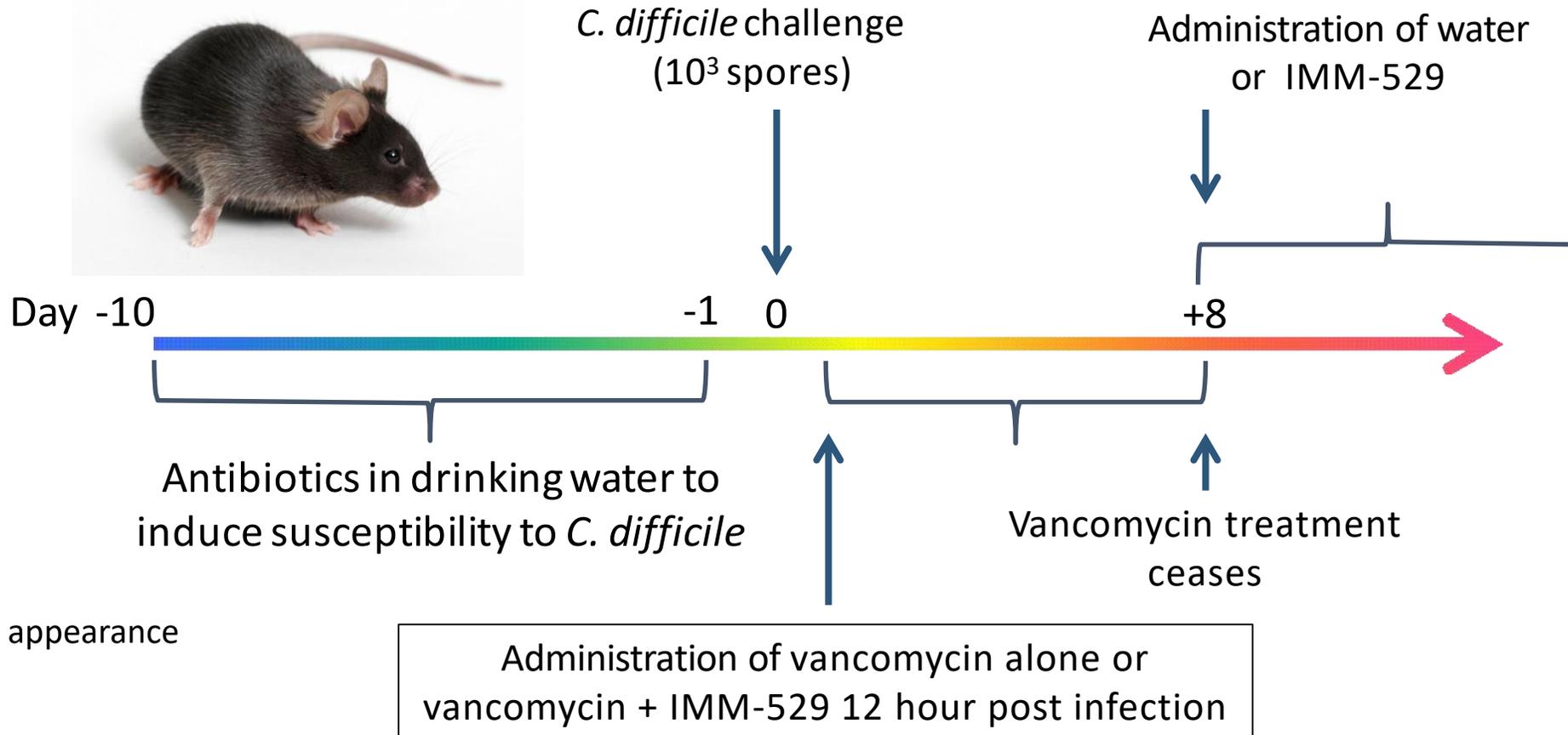


Due to unique character of *C. difficile* bacterium, it is difficult to reduce its recurrence with antibiotics.

# THE *C. DIFFICILE* PREVENTION OF RECURRENT CDI MOUSE MODEL\*



C57BL/6 mice 6–7 weeks



Monitor:

- Weight loss
- Physiological appearance
- Activity
- Diarrhoea

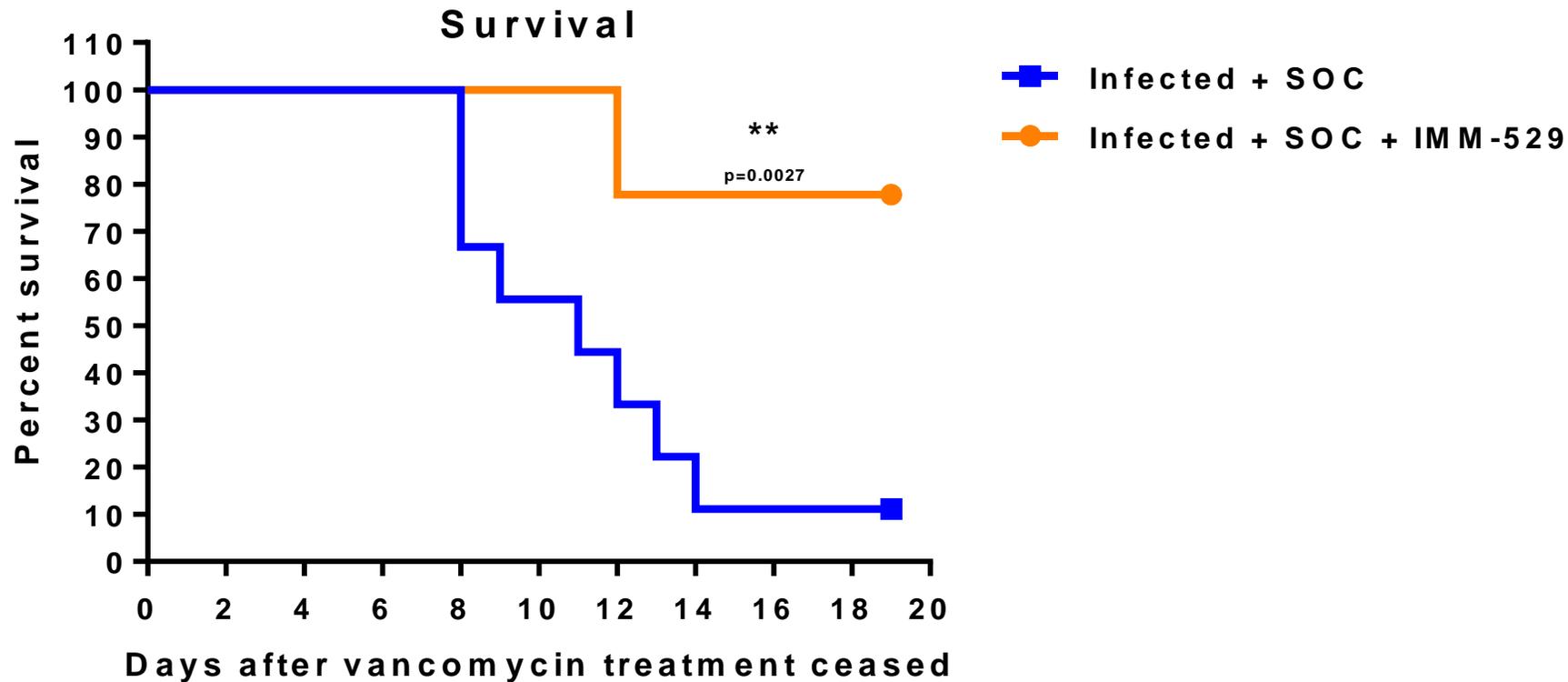
\*Collaboration with Prof. Dena Lyras, Monash University, Australia

# IMM-529 ANIMAL MODEL STUDY



## Relapse Study

All studies statistically significant

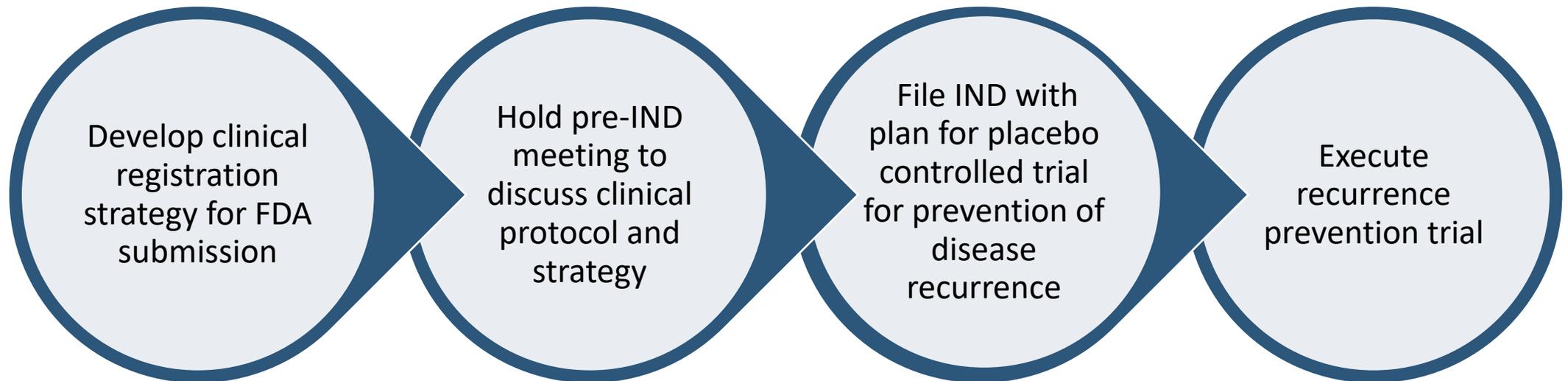


Demonstrated ~80% survival rate (7/9) vs. ~10% survival rate in control group (1/9)



# IMM-529 DRUG DEVELOPMENT PLAN

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



# COMMERCIAL & PRODUCT DEVELOPMENT PIPELINE



PROGRAM	INDICATIONS	DEVELOPMENT STAGE					PROGRAM HIGHLIGHTS
		PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
ANTI-INFLAMMATORY PROGRAMS							
Travelan®	Travelers' Diarrhea	TGA ARTG Aust L106709 (2004)					Commercial product Australia
Travelan®	Travelers' Diarrhea	Health Canada NPN 80046016 (2015)					Commercial product Canada
Travelan®		Dietary supplement (2015)					Commercial product USA
Travelan® (IMM-124E)	Travelers' Diarrhea						Plan for FDA submission
Travelan® (IMM-124E)	NASH						Top Line Results Reported March 2018
IMM-124E	ASH						NIH Funded VCU Topline results expected 2H 2019
IMM-124E	Pediatric NAFLD						NIH Funded; Emory University Topline results expected 1Q 2020
IMM-529	<i>C. Difficile</i>						Developing to prevent recurrence in <i>C. difficile</i> patients
WRAIR	<i>Shigella</i>						Walter Reed Army Institute of Research

# IMM-124E: FATTY-LIVER PORTFOLIO



**Two ongoing NIH funded Phase 2 Programs currently underway: ASH and Pediatric NAFLD**

## **ASH**

- **NIH funded; sponsored by Virginia Commonwealth University**
- Lead Principal Investigator: Arun Sanyal; Former President of AASLD (American Association for the Study of Liver Diseases) and current Chair of the Liver Study Section at the NIH (National Institute of Health)
- **Fully recruited: 56 patients**
- Endpoints: Clinical Safety; Serum endotoxin (LPS) levels
- **Timing: topline results expected in 2H2019**

## **PEDIATRIC NAFLD**

- **NIH funded; sponsored by Emory University**
- Lead Principal Investigator: Miriam Vos;
- **Current enrollment: 23/40 patients**
- Endpoint: ALT; 3 months treatment
- **Timing: topline results in 1H 2020**



# KEY MILESTONES EXPECTED TO DRIVE VALUE



- Pre-IND Meeting to Discuss IMM-124E Literature-Based 505(b)(2)
- IMM-124E ASH Clinical Trial Top Line Results

- Initiate Phase 3 Clinical Trial on IMM-124E TD prevention study
- Pre-IND Meeting on IMM-529 *C. difficile* program
- Pediatric NAFLD Top Line Results

- Phase 3 IMM-124E TD Clinical Data Available
- Initiate U.S. Phase 2 trial on IMM-529 to treat recurrent CDI

- File 505(b)(2) NDA for IMM-124E TD prevention study

Results from US Army trials expected 2019/2020

# COMPANY CAPITALIZATION



Immuron Limited	Ordinary Shares	ADs
Shares	128,565,106	366,265*
Options <sup>1</sup>	44,823,800	N/A
Warrants <sup>2</sup>	N/A	694,000
Total	173,388,906	1,060,265

- 1. Options - Exercise price range: AUD \$0.300 to \$1.944 (Expiring from 28 May 2019 to 15 March 2023)**
- 2. Exercise price of AUD \$10.00 per ADS (1 ADS represents 40 ordinary shares\*) [Expiring 13 June 2022]**

Information prepared as  
at 1 May 2019