



FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL IMMUNOTHERAPIES – JUNE 2019

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.

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 commercial and clinical-stage biopharmaceutical company focusing on infectious diseases with oral immunoglobulin-based therapies.

Validated Technology Platform – with One Registered Asset, **Travelan® Generating Revenue**

IMM-124E & IMM-529, in **Clinical Development** for Treatment of Liver Disease and *C. difficile* Infections

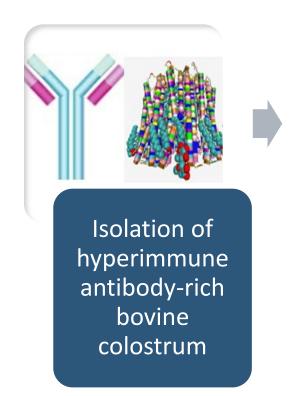
Plan for Accelerated Regulatory Path to Approval for IMM-124E (Travelan®) as Drug to Prevent Travelers' Diarrhea in USA



PLATFORM OVERVIEW: ORAL IMMUNOGLOBULINS











DEVELOPMENT PIPELINE: TWO-PRONGED PLAN



	DEVELOPMENT STAGE				HIGHLIGHTS	
	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
	ANTI-INFLAMMATORY PROGRAMS					
	TGA ARTG Aust L106709 (2004)			Commercial product - Australia		
Travelan®	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		



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







BACKGROUND OF TRAVELAN®: PLAN TO EXPAND USE



COMMERCIAL PRODUCT

Marketed in Australia, USA and Canada





Plan to develop IMM-124E as an approved drug to prevent 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 risk¹.
- Enterotoxigenic *E. coli* (ETEC) are the predominant pathogens^{2,3}:

42% in Latin America 28% in Southeast Asia

 Up to 70% of travelers suffer from travelers' diarrhea⁴.

- 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.



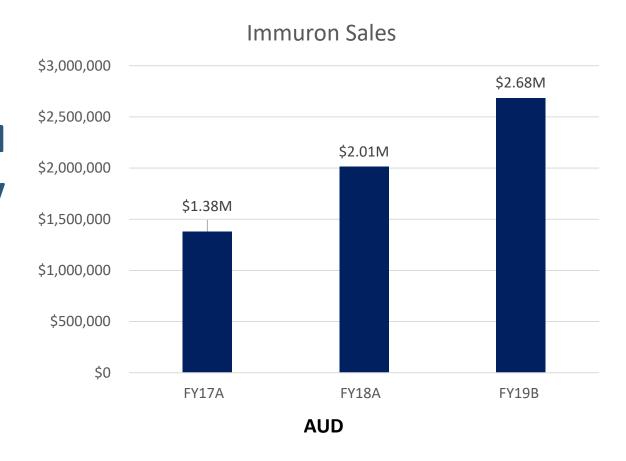


TRAVELAN® COMMERCIAL PROFILE: INCREASING SALES ADDRESSING LARGE MARKETS



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

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, 2017 guidelines for treating Travelers' Diarrhea included¹:

- Antibiotics should <u>NOT</u> be used routinely, except patients at high risk of complications
- Rifaximin recommended when antibiotic prophylaxis is indicated
- Fluoroquinolones not recommended for prophylaxis²
- Insufficient evidence to recommend prebiotics or probiotics

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

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)



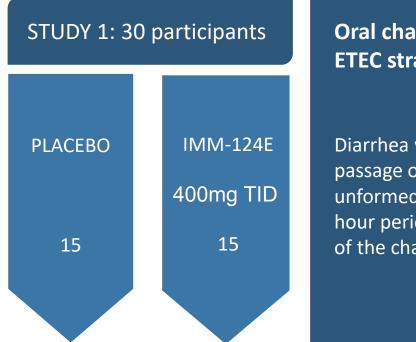
¹ Riddle et al. 2017. Guidelines for the prevention and treatment of travellers' diarrhea: a graded expert panel report. Journal of Travel Medicine 24(1).

TRAVELAN® AS A DRUGTO PREVENT TRAVELERS' DIARRHEA



- 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





Oral challenge with O78 ETEC strain (H10407)

Diarrhea was defined as passage of two or more unformed stools during 48 hour period within 72 hours of the challenge

RESULTS: Travelan® provided over 90% prophylactic efficacy against diarrhea due to infection by the major strain of E.coli that causes TD



SUMMARY OF RESULTS FROM STUDY 1



	meatiment	Стоир	
	Placebo	Colostrum	p
Number of volunteers	15	15	
Number of volunteers with diarrhea	11 (73%)	1 (7%)	0.0005
Number of diarrheal stools/volunteer (mean + SEM)	4.4 ± 0.9	0.4 ± 0.4	0.0004

6 (6)

0 (0%)

12 (80%)

Treatment Group

*Fisher's exact test or Student's t-test (two-tailed) as appropriate.
NS, not significant

6(2-8)

5 (33%)

15 (100%)



diarrhea (mean and range)

Abdominal pain

Mean number of diarrheal stools per volunteer with

ETEC H10407 isolated from feces after challenge

NS

0.04

NS

SUMMARY OF RESULTS FROM STUDY 2



Treatment Group

	Group 1: Placebo tid	Group 2: Colostrum 400 mg tid + buffer	Group 3: Colostrum 200 mg tid	Group 4: Colostrum 400 mg tid	
Number of volunteers	14	14	14	14	
Number of volunteers with diarrhea	12 (86%)	2 (14%), <i>p</i> = 0.0004*	5 (36%), <i>p</i> = 0.02	3 (20%), <i>p</i> = 0.007	
Number of diarrheal stools/volunteer (mean + SEM)	3.9 ± 0.8	0.5 ± 0.3 , $p = 0.0005$	1.8 ± 0.8 , $p = 0.07$	0.9 ± 0.5 , $p = 0.003$	
Mean number of diarrheal stools per volunteer with diarrhea (mean and range)	5 (3–10)	3.5 (3–4)	5 (2–7)	4.7 (2–7)	
Abdominal pain	5 (36%)	0 (0%), <i>p</i> = 0.04	2 (14%), <i>p</i> = 0.04	0 (0%), <i>p</i> = 0.02	
ETEC H10407 isolated from feces after challenge	12 (86%)	14 (100%)	14 (100%)	12 (80%)	



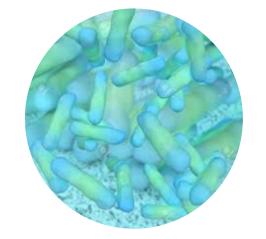
^{*}All tests compared results of active treatment with placebo group; calculation by Fisher's exact test or Student's *t*-test (two-tailed)

TRAVELAN®: ORAL CHALLENGE STUDY PREVENTION OF SHIGELLOSIS (BACILLARY DYSENTERY) IN PRIMATES*



- 12 juvenile rhesus monkeys randomly assigned to Travelan® (n=8) or placebo (high protein milk powder) (n=4) treatment groups
- Travelan® or placebo (500mg) was administered 2x daily for 6-days, starting on day 0
- Each monkey challenged with 2.8 x 10⁹ Shigella flexneri 2a intragastrically on day 3
- Travelan® /placebo treatment stopped on day-6. Monkeys monitored through to day 14
- Faecal samples taken 2 x daily and cultured to establish presence/absence of Shigella flexneri
- Animals continually monitored for clinical signs

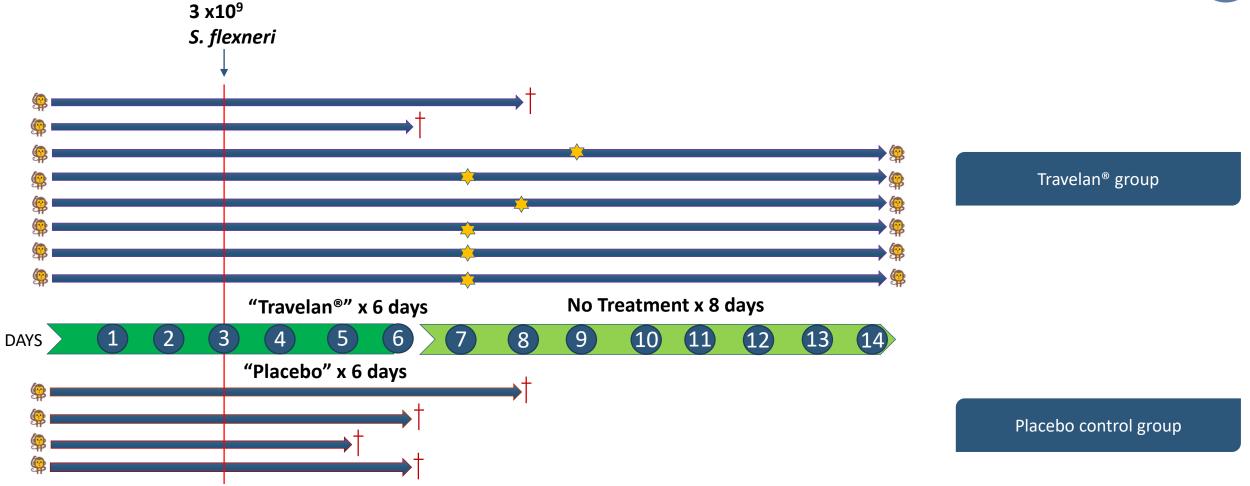
*Collaborative animal model study with AFRIMS & WRAIR





RESULTS OF TRAVELAN® SHIGELLA CHALLENGE STUDY*







*Collaboration with AFRIMS & WRAIR



SUMMARY OF TRAVELAN® SHIGELLA ANIMAL STUDY



Placebo (high protein milk powder) provided no protection against acute shigellosis

All (4/4) Placebo treated monkeys developed severe acute enteric shigellosis.

Travelan® provided 75% protection against acute shigellosis

- 2 of 8 (25%) Travelan®-treated monkeys developed severe acute enteric shigellosis
- 6 of 8 (75%) Travelan®- treated monkeys survived *Shigella flexneri* challenge
- <u>S. flexneri</u> was undetectable in consecutive faecal samples by day-7 in 4 of 6 (67%) survivors and by day 9 in the remaining 2 (33%) survivors



IMM-124E DRUG DEVELOPMENT PLAN



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

Assimilate Data to Support Literature-Based FDA Submission

Hold Pre-IND
Meeting to
Discuss Merits of
505(b)(2)
Application

File IND with
Single DoubleBlind & Placebo
Controlled Trial
for Prevention of
Travelers'
Diarrhea

Execute
Prevention Trial
and File
Registration
Package



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)¹ and obtaining pretravel advice (22.2 million)². Sources of pre-travel advice include primary care provider, travel medicine specialist, company doctors, pharmacist, and travel agencies². 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)				
FDA APPROVED DRUG TREATMENTS FOR DIARRHEA								
PEPTO BISMOL (BSS)	Relief for heartburn, nausea, indigestion, upset stomach and diarrhea.	2 tabs QID	\$20.97 1	82.6 (2013) ²				
IMMODIUM Company Comp	Decrease the frequency of diarrhea in TD, gastroenteritis, inflammatory bowel disease, and short bowel syndrome.	2 tabs (2 mg)	\$17.33 ¹ (48 caplets)	82.5 (2013) ²				
CIPROFLOXACIN (FLUOROQUINOLINE)	Bacterial infections.	500 mg	\$44.52 ³	40.8 (2015) ³				
RIFAXIMIN Sample of the control o	Treatment of Travellers' Diarrhea.	3 caps (200 mg) TID	\$657 ⁴					
PRESENTLY, THERE IS NO FDA APPROVED DRUG TO PREVENT TRAVELERS' DIARRHEA								
TRAVELAN®	Dietary Supplement.	3 caps (200 mg) TID	\$30 – 30 caplets	0.77 (2018) 5				

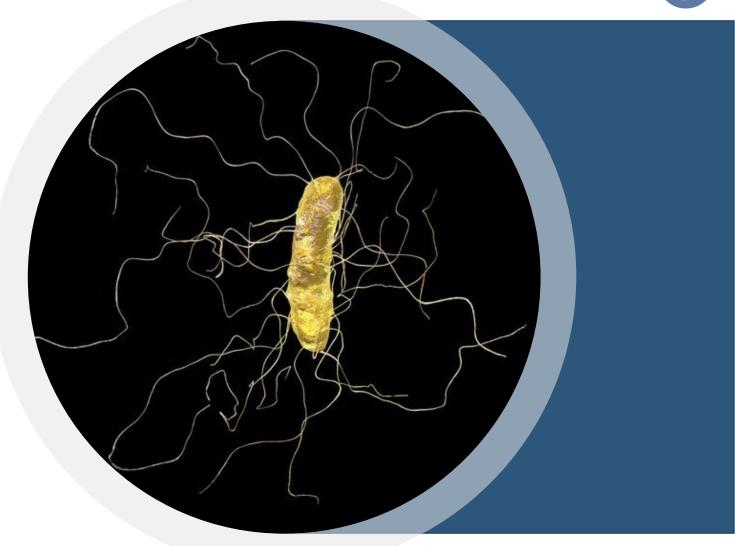
- 1. Amazon.com
- 2. Top 10 OTC brands for digestives by revenue in the USA in 2013
- 3. Almalki et. al., Utilization, spending & price trends for quinolones in the US, Pharmacoecon Open 2017 Jun: 1(2): 123-131
- 4. Drugs.com Xifaxan (rifaximin) price guide. Cost of Xifaxan oral tablet 200 mg ~\$657 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 $2026 CAGR 15\%^1$
- Leading cause of gastroenteritis-associated mortality in U.S.²
- Approx. 44,500 patients³ died in 2014 from C. difficile infections (U.S.)
- Potential orphan disease (7 years market exclusivity and premium pricing)
 - https://www.globaldata.com/global-clostridium-difficle-infectionmarket-approach-2016-2026
 - 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



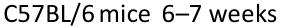
^{*}Isobel Ramsay, Nicholas Brown and David Enoch. Recent Progress for the Effective Prevention and Treatment of Recurrent Clostridium difficile Infection. Infectious Diseases: Research and Treatment Volume 11: 1–4 (2018).

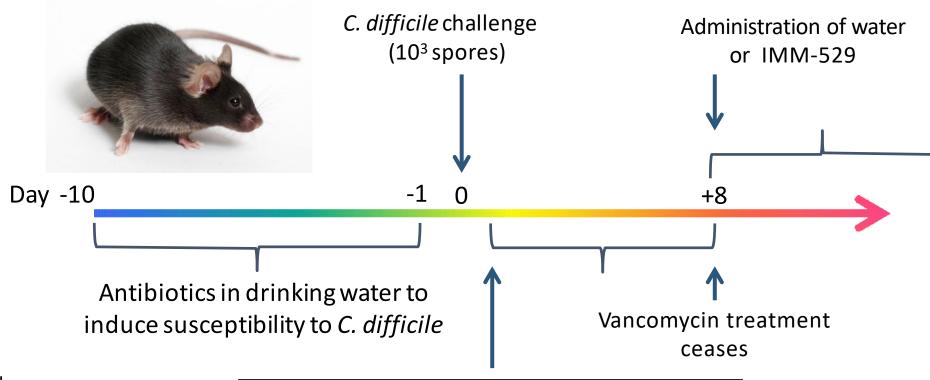


DOI: 10.1177/1178633718758023

THE C. DIFFICILE PREVENTION OF RECURRENT CDI MOUSE MODEL*







Monitor:

Weight loss

Physiological appearance

Activity

Diarrhoea

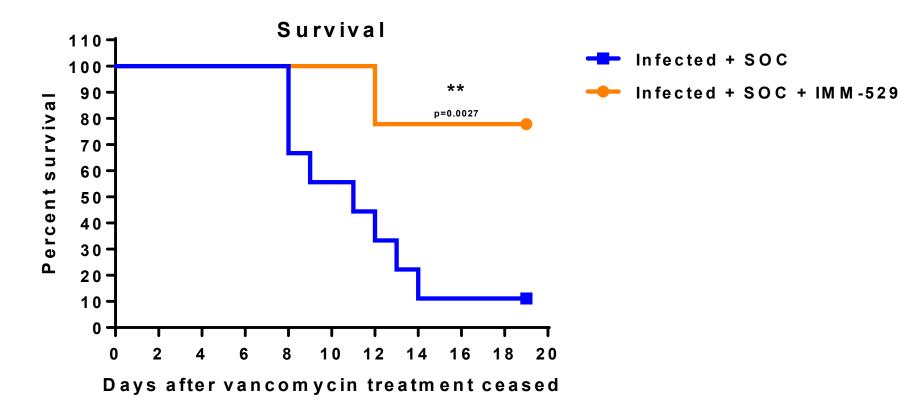
Administration of vancomycin alone or vancomycin + IMM-529 12 hour post infection



IMM-529 ANIMAL MODEL 'RECURRENCE' STUDY



Relapse Study



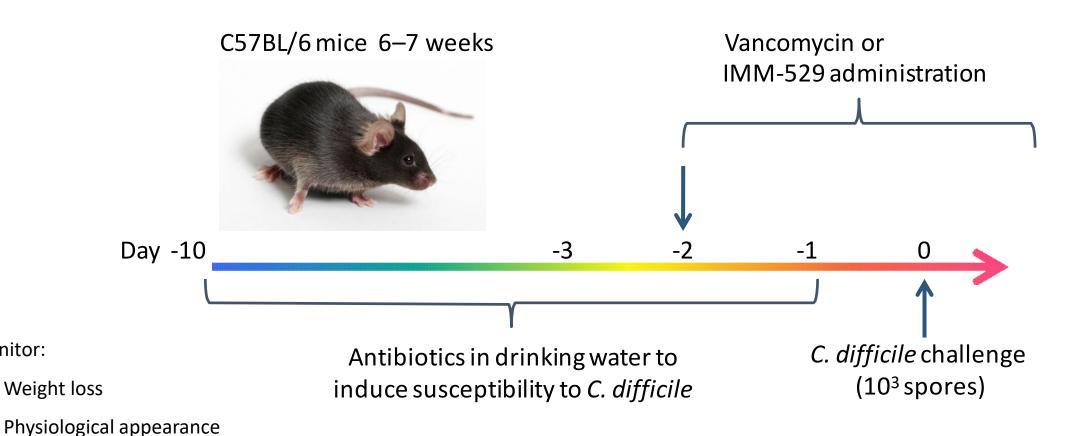
All studies statistically significant

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



THE C. DIFFICILE PREVENTION MOUSE MODEL





Diarrhoea

Activity

Monitor:

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

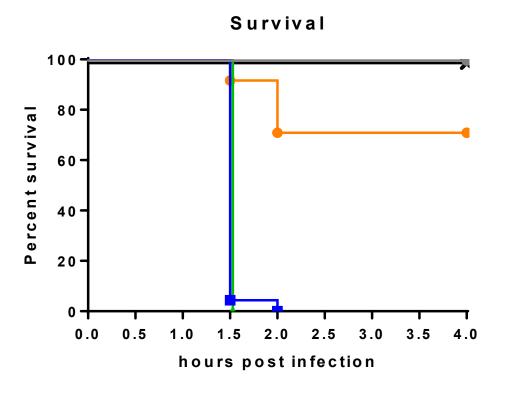


IMM-529 ANIMAL MODEL 'PREVENTION' STUDY



Prevention Study

All studies statistically significant



Uninfected, No treatment

-- Infected, No treatment

★ Infected, Non-immune IgG treatment

Infected, IM M -529 treatment

X Infected, Vancomycin treatment

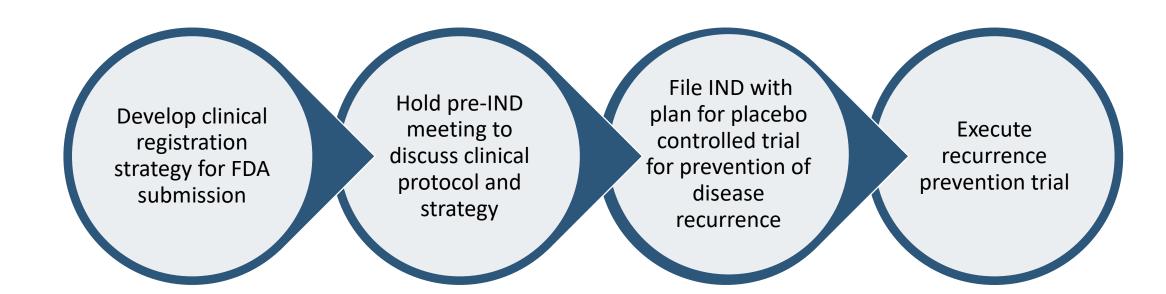
Demonstrated 80% efficacy without use of antibiotics



IMM-529 DRUG DEVELOPMENT PLAN



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





COMMERCIAL & PRODUCT DEVELOPMENT PIPELINE



		DEVELOPMENT STAGE					
PROGRAM	INDICATIONS	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	PROGRAM HIGHLIGHTS
	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 U of Virginia Topline results expected 2H 2019	
IMM-124E	Pediatric NAFLD				NIH Funded; Emory University Topline results expected 1Q 2020		
IMM-529	C. Difficile						Developing to prevent recurrence in C. difficile patients
WRAIR	Shigella						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



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 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 and 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

NON-EXECUTIVE DIRECTORS

- Dr Gary Jacob
- Stephen Anastasiou
- Daniel Pollock
- **Professor Ravi Savarirayan**
- Richard Jay Berman



COMPANY CAPITALIZATION



Immuron Limited	Ordinary Shares	ADS Equivalent ¹
Shares	163,215,706	4,080,393
Options ²	44,823,800	1,120,595
Warrants ³	27,760,000	694,000
Total	235,799,506	5,894,988

Information prepared as at 18 June 2019

- 1. 1 ADS represents 40 ordinary shares
- 2. Options Exercise price range: AUD \$0.468 to \$1.944 (Expiring from 27 Nov 2019 to 15 March 2023)
- 3. Exercise price of USD \$10.00 per ADS (Expiring 13 June 2022)

Share Price (18 June 2019): AUD \$0.135

Market Capitalization: AUD \$22 Million

