



# Immuron Limited

*Developing Unique Oral Immunotherapies  
that Fundamentally Change the Paradigms  
of Care*

May 2017

# Forward Looking 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.

# Free Writing Prospectus Statements

Immuron Limited (ASX:IMC)



This presentation contains a “free writing prospectus,” or a portion thereof, required to be filed by us with the Commission or retained by us pursuant to Rule 433 under the Securities Act of 1933, as amended, or the Act.

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all the information you should consider before investing.

We have filed a registration statement (including a prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the SEC website at <http://www.sec.gov>. The preliminary prospectus, dated May 5, 2017, is available on the SEC website at <http://www.sec.gov>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Joseph Gunnar & Co., LLC. Attention: Prospectus Department, 30 Broad Street, 11th Floor, New York, NY 10004. Telephone: 888-248-6627, E-mail: [prospectus@jgunnar.com](mailto:prospectus@jgunnar.com).

# Offering Summary

Immuron Limited (ASX:IMC)



## Offering Size

US\$8,750,000 of American Depository Shares (ADSs) and Warrants

## Exchange/Ticker

Ordinary Shares are listed on the ASX under the symbol IMC  
Applied to list the ADSs and Warrants on the NASDAQ Capital Market under the symbols “IMRN” and “IMRNW”, respectively

## Warrants Offered

50% Warrant coverage. Each Warrant will have an estimated per ADS exercise price of 125% of the per ADS public offering price, will be exercisable immediately and will expire five years from the date of issuance.

## Use of Proceeds

Clinical development of IMM-124E (fatty liver), IMM-529 (*C. difficile*) and other general corporate purposes

## Joint Book-Runners

Joseph Gunnar & Co. and Rodman & Renshaw, a unit of H.C. Wainwright & Co.

## Co-Manager

WallachBeth Capital, LLC

# Investment Highlights



- **Clinical stage biopharmaceutical** company targeting inflammatory-mediated and infectious diseases with **oral immunotherapies**
- **Lead program, IMM-124E, in Phase 2 development** for the treatment of multiple high value indications, including **NASH, ASH** and **Pediatric NAFLD**
  - NASH Phase 2 interim data expected 3Q 2017 with topline results expected 4Q 2017
  - National Institutes of Health (NIH) funding Phase 2 studies in ASH and pediatric NAFLD
- **IMM-529**, biologic with unique triple mechanism of action for treatment of ***C. difficile*** expected to commence **Phase 1/2 study in 2Q 2017**
- Well positioned to address high unmet medical need in **multiple blockbuster markets**
- **High-value peer licensing deals and M&A underscore potential upside**
- **Company plans to uplist to NASDAQ in 2Q 2017**
- **Experienced Management Team and strong support** from leading **KOLs and institutions (NIH, DoD)**

# Experienced Management Team



## **Thomas Liquard**

*Chief Executive Officer*

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Mr. Liquard spent the majority of his career at Pfizer in New York in various commercial leadership positions, and was also COO, then CEO, of Alchemia Limited, an oncology ASX biotech company.

## **Dan Peres, MD**

*Chief Medical Officer*

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Dr. Peres, a surgeon by training, has deep experience in liver diseases and clinical development, including NASH, having worked for leading Medical Devices and Pharma companies since 2008.

## **Jerry Kanellos, PhD**

*COO & Scientific Officer*

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Dr. Kanellos has over 20 years of experience in the pharmaceutical and biotech industries including CMC, operations and BD. He has held senior roles at CSL and Transbio Limited.

## **Reza Moussakhani**

*Manufacturing Quality Director*

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Mr. Moussakhani has extensive experience in implementation of project/quality and process improvements, including with Hospira and Sigma Pharmaceuticals.

# Prominent Scientific Advisory Board and Leading Research Partners



## Advisory Board

**Dr. Arun Sanyal (MD)**  
*University of Virginia*

Former President of the AASLD. Current Chair of the Liver Study Section at the NIH. IMM-124E lead PI.

**Dr. Stephen Harrison (MD)**  
*San Antonio Military Medical Center  
Brooke US Army Medical Center*

Internationally renowned expert in NASH. Lead PI of Galectin's GR-MD-02's Phase 2 trial.

**Dr. Manal Abdelmalek (MD)**  
*Duke University Medical Center*

Dr. Abdelmalek is a leading investigator in the field of NASH.

**Dr. Gerhard Rogler (MD, PhD)**  
*Zurich University*

Professor Rogler is a leader in the field of colitis and has authored more than 200 original peer-reviewed articles.

**Dr. Miriam Vos (MD)**  
*Emory University*

Dr. Vos specializes in the treatment of gastrointestinal disease in children, as well as fatty liver disease and obesity.

**Dr. Dena Lyras (PhD)**  
*Monash University*

Dr. Lyras is one of the world's leading experts in *C. difficile*.

## Organizations



**Universität  
Zürich** UZH

# Oral Immunotherapy: Scalable, Disruptive Technology



1

## Vaccines Are Developed



2

## Antibodies Are Harvested from Colostrum



Antigen Specific Antibodies (IgG and IgG1) + Adjuvants

3

## Broad Therapeutic Effect

Induction of regulatory T-cells  
+  
Clearance of Targeted GUT Pathogens

- Reduced gut and blood pathogens responsible for initiating inflammation
- Reduces systemic inflammation
- Lowers organ injury
- Not associated with general immune suppression
- Generally Regarded as Safe (GRAS)

## Competitive Advantage

- **Platform capable of spawning multiple drugs** → Long-term value creation
- **Regulated as biologics by the FDA** → 12 years exclusivity in the US for each approval
- **Significant hurdles to generic biosimilar entry** → No pharmacokinetic baseline; Mixture (e.g., Copaxone)
- **Safety established** → Generally Regarded As Safe (GRAS)

# Immuron's Clinical Programs

## Multiple Near-Term Inflection Points



Program	Indications	Development Stage				Program Highlights
		Pre-Clinical	Phase 1	Phase 2	Phase 3	
<b>Anti-Inflammatory Programs</b>						
IMM-124E	NASH					<ul style="list-style-type: none"> <li>- Interim data expected 3Q 2017</li> <li>- Topline results expected 4Q 2017</li> </ul>
IMM-124E	ASH					<ul style="list-style-type: none"> <li>- NIH Funded; UVA</li> <li>- Topline results expected 2018</li> </ul>
IMM-124E	Pediatric NAFLD					<ul style="list-style-type: none"> <li>- NIH Funded; Emory University</li> <li>- Topline results expected 1H 2018</li> </ul>
IMM-124E	Colitis					Collaboration Univ. of Zurich; Pre-clinical acute studies positive (04/17)
IMM-124E	Autism					Childrens Research Institute, La Trobe & RMIT Universities
<b>Anti-Infective Programs</b>						
IMM-529	<i>C. difficile</i>					Phase 1/2 Expected to start 2Q 2017
IMM-124E / Shigella Vaccine	Shigella Infections					Collaboration with US Army
IMM-124E	Campylobacter; ETEC Infections					Collaboration with US Navy

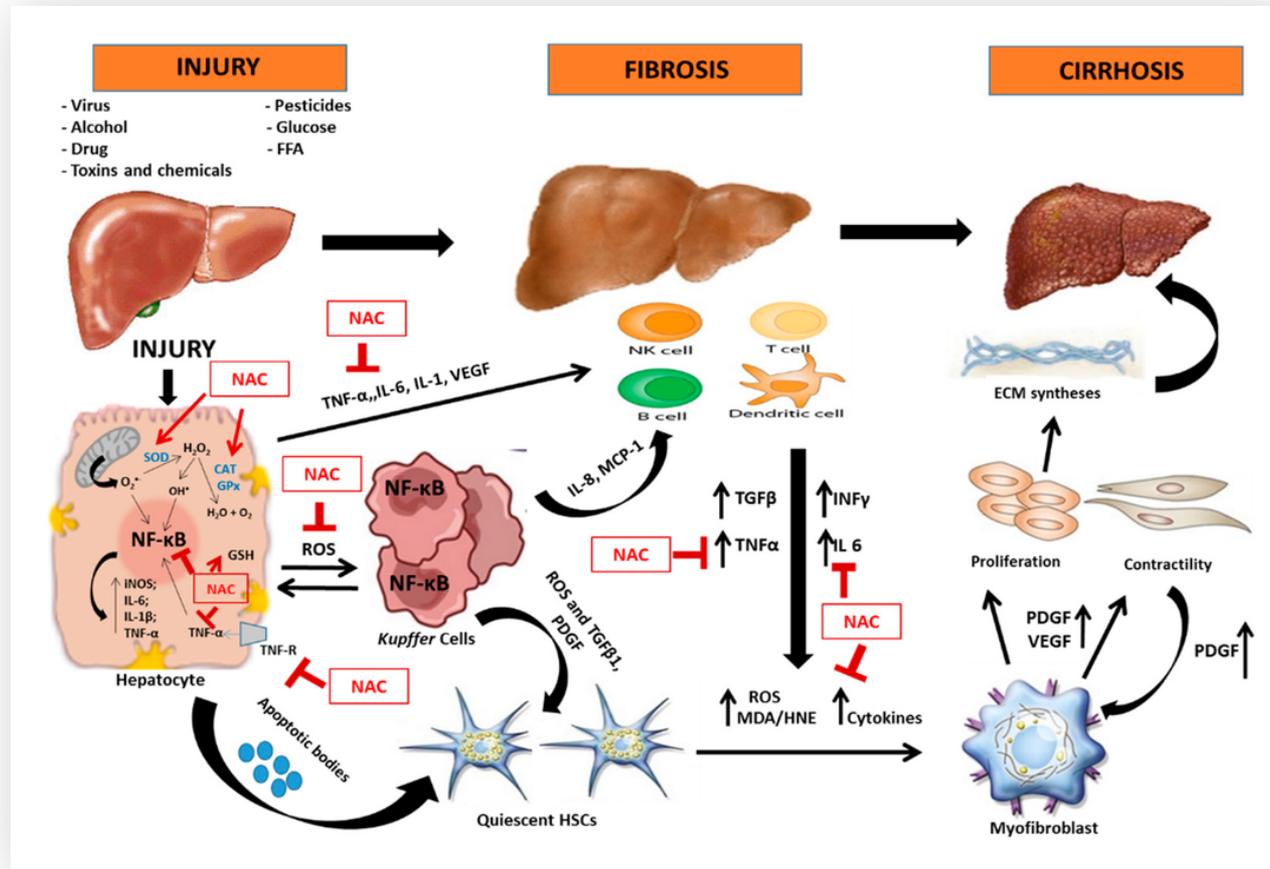
# IMM-124E

Revolutionary Treatment for NASH

# NASH (Non-Alcoholic Fatty Liver) Pathophysiology



## NASH – Pathophysiology



- Blood derived antigens (including circulating LPS) determines tolerance vs. inflammation
- Kupffer cells play a key role in liver inflammation and fibrosis
- Tregs hold a key role in tolerance (homeostasis)
- Much like hepatic tolerance the gut immune system can promote anti-inflammatory effect

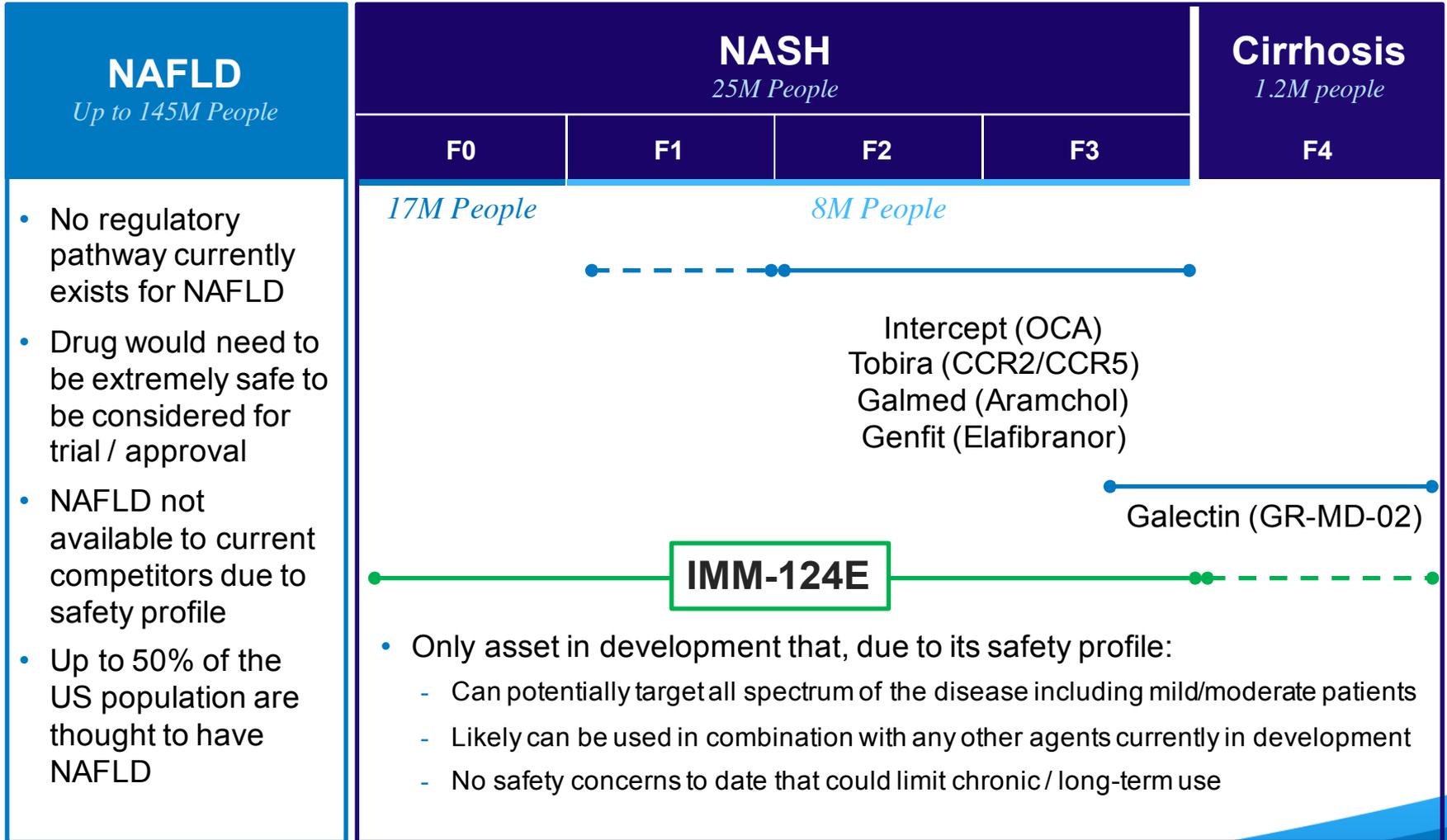
Source: Adapted from Cohen-Neftaly; Scott L. Friedman, 2011

# IMM-124E in NASH (Non-Alcoholic Fatty Liver)



- **Broad anti-inflammatory mechanism of action**
  - Targeted LPS antibodies
  - Upstream Effect: **LPS-TLR4 pathway**
  - Downstream: **Anti-inflammatory through both innate and adaptive immune systems** (e.g., the induction of regulatory T-cells to control and inhibit excess inflammation)
- Strong **anti-fibrotic effect** demonstrated with CCl4 model
- **Unique competitive profile due to safety/MOA:**
  - Addresses **multi-factorial** nature of NASH
  - Potential for **broad combination use**
  - Safety profile supporting of **long-term chronic use**
  - Potential to **expand to mild/moderate** populations
- **Market exclusivity** (biologics; high barriers to generic biosimilar entry)

# IMM-124E – Uniquely Positioned to Address Large Unmet Need of \$35B Market (2030)



# IMM-124E: Fatty-Liver Portfolio – 3 Phase 2 Trials



## Three Ongoing Phase 2 Programs: NASH, ASH and Pediatric NAFLD

### NASH

- 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)
- Multi-center, double-blinded, placebo controlled trial; 25 sites running in US, Australia and Israel
- Fully recruited: 134 patients with biopsy proven NASH
- Primary endpoint: changes in liver fat content confirmed by MRI; changes in ALT (liver enzymes)
- 3 arms: placebo, high dose and low dose
- Timing: topline results expected by 4Q 2017

### ASH

- NIH funded; sponsored by University of Virginia
- Expected enrollment: 66 patients
- Endpoint: ALT
- Timing: topline results expected in 2018

### Pediatric NAFLD

- NIH funded; sponsored by Emory University
- Expected enrollment: 40 patients
- Endpoint: ALT; 3 months treatment
- Timing: topline results expected in 1H 2018

# IMM-124E – Summary of Data

Prevention of Fibrosis and Improvement in Metabolic/Inflammatory Markers



## CCI4 Fibrosis Studies

- **Carbon-Tetrachloride (CCI4) a non-disease related fibrosis model**
- **Aim:** To demonstrate effects of IMM-124E on Fibrosis caused by Intraperitoneal CCI4
- **Results:**
  - Marked **reduction in Liver Fibrosis and Inflammation** on Histology
  - Marked reduction on Liver Damage markers (i.e. ALT, Bilirubin etc.)
  - Marked **reduction in Liver Activated Macrophages (F4/80 high)**

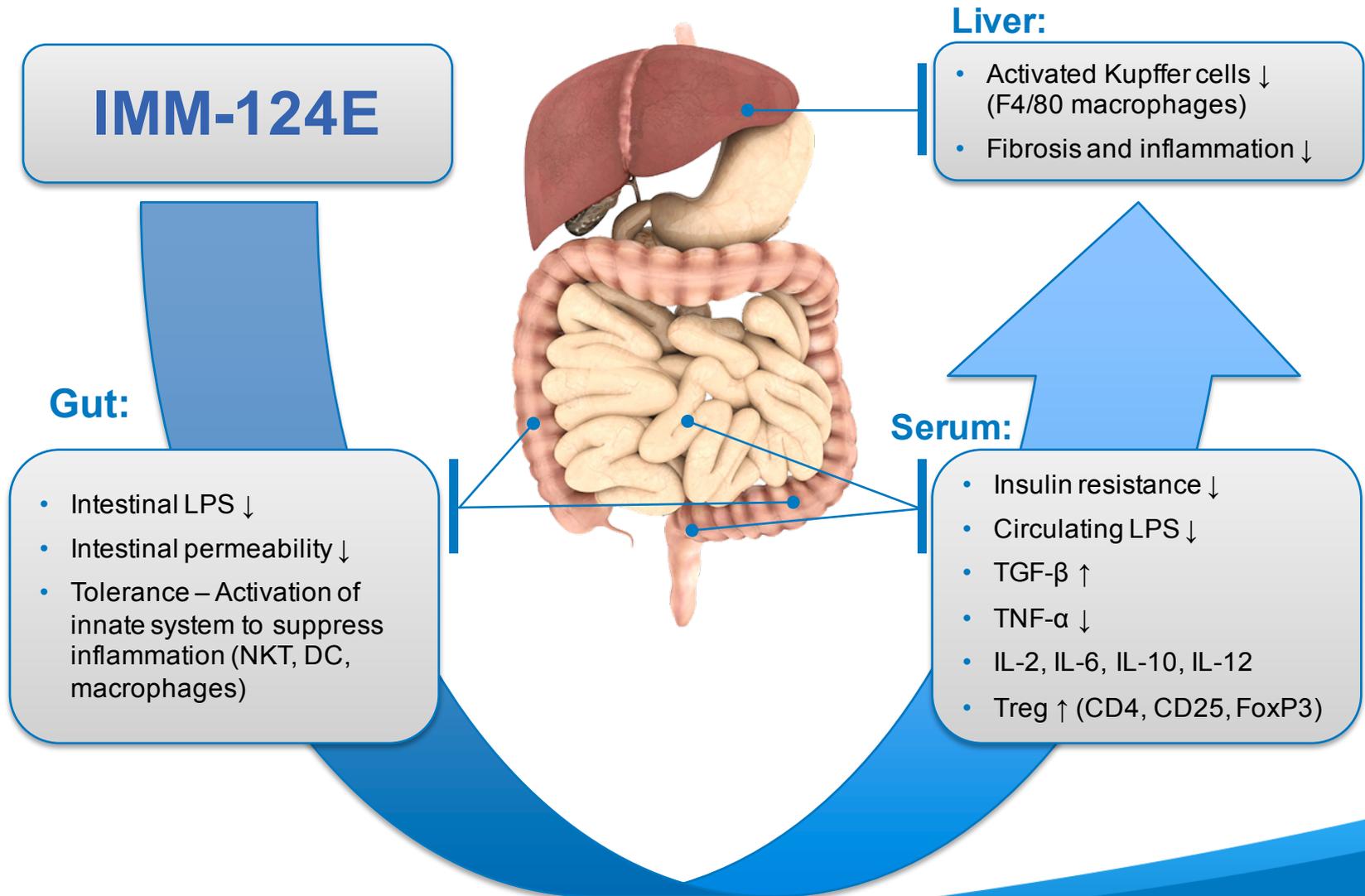
## Ob-Ob Mice

- **Model represents the Metabolic syndrome**
- **Aim:** To demonstrate the effect of IMM-124E or **anti-LPS IgG** (derived from IMM-124E)
- **Results:**
  - Anti-LPS IgG considerable reduces ALT level
  - Improved metabolic status for IG and IMM-124E treated mice (i.e. TG, Fasting Glucose and OGTT)
  - **Anti-inflammatory shift: Decreased TNF- $\alpha$  and increase splenic NKT cells**

## Phase 1/2 Clinical Studies

- **Aim: To show safety and efficacy of IMM-124E Biopsy Proven NASH Patients**
- **Population:** 10 subjects with biopsy proven NASH and Type 2 Diabetes
- **Results:**
  - Improved Metabolic status (e.g. HbA1c, HOMA OGTT) GLP1 and Adiponectin
  - Improved Liver status (e.g. ALT)
  - **Proof of concept: increase in Circulatory Regulatory T-Cell**

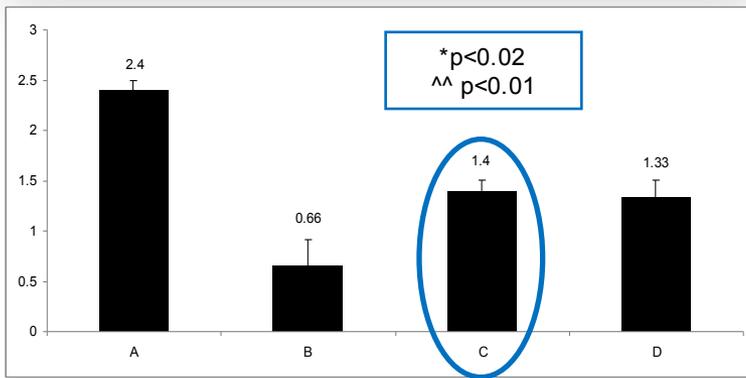
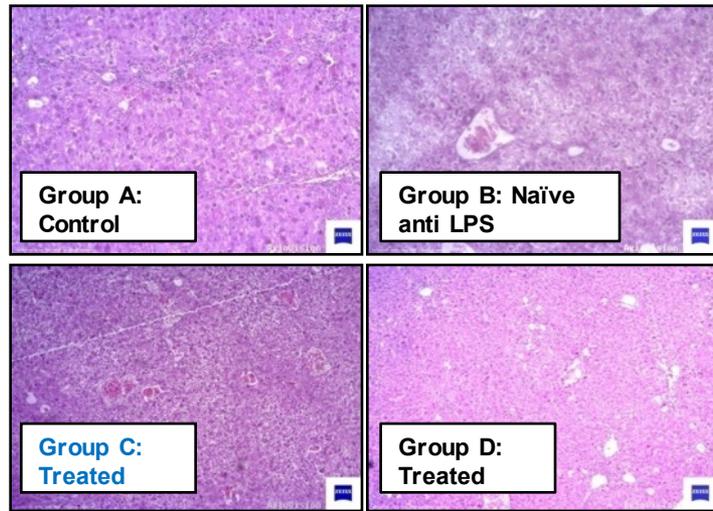
# IMM-124E in NASH (Non-Alcoholic Fatty Liver)



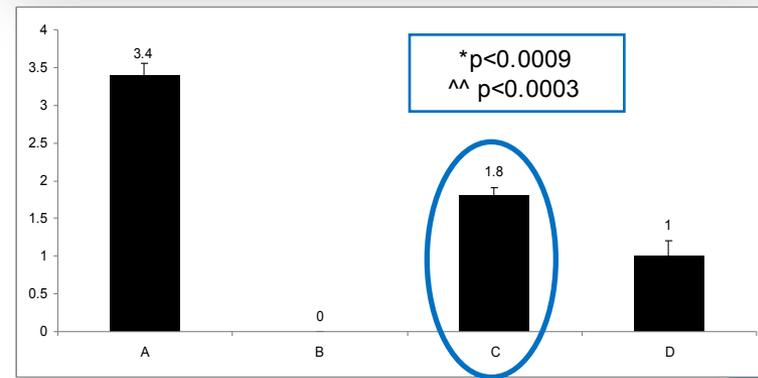
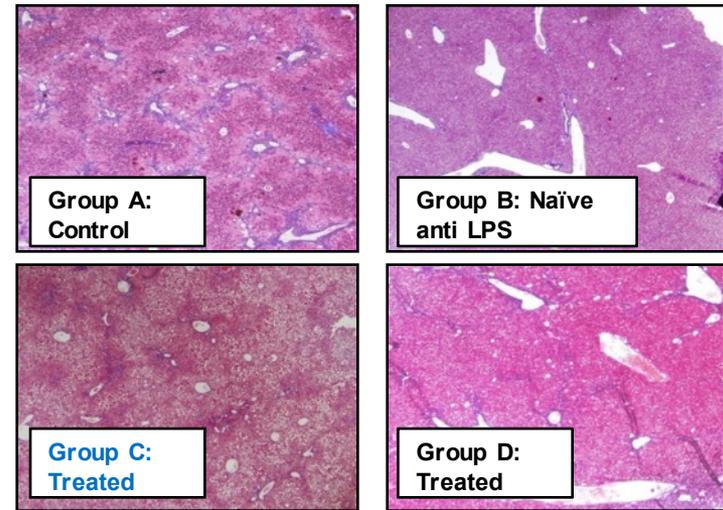
# Animal Models: IMM-124E Improves Fibrosis and Inflammatory Markers



## Decrease Portal Inflammation



## Improved Metavir Fibrosis Score



# Animal Models: Macroscopy – Prevents Fibrosis



## Fibrotic Liver

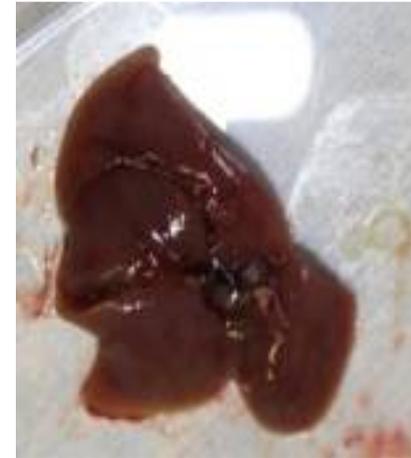
*CCl4 (carbon tetrachloride)*



**IMM-124E**

## IMM-124E Treated Liver

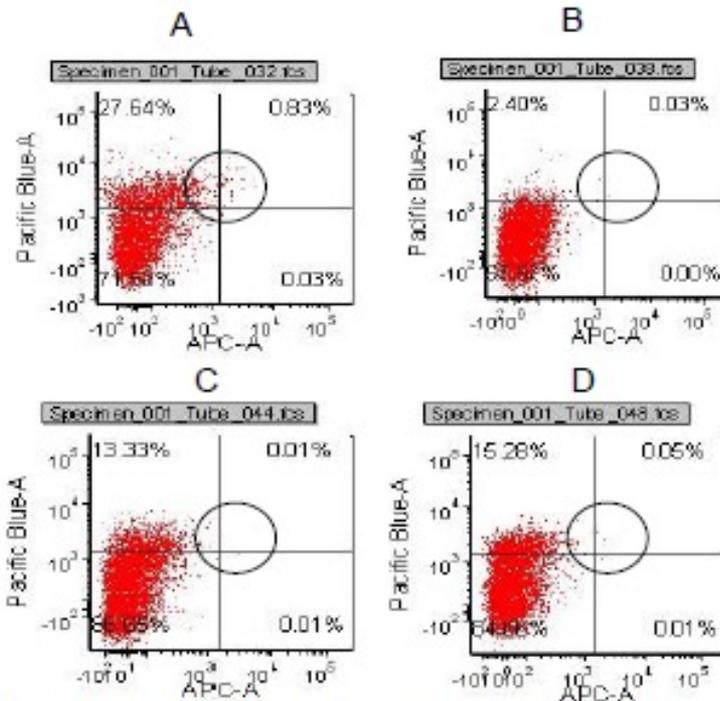
*CCl4 (carbon tetrachloride)*



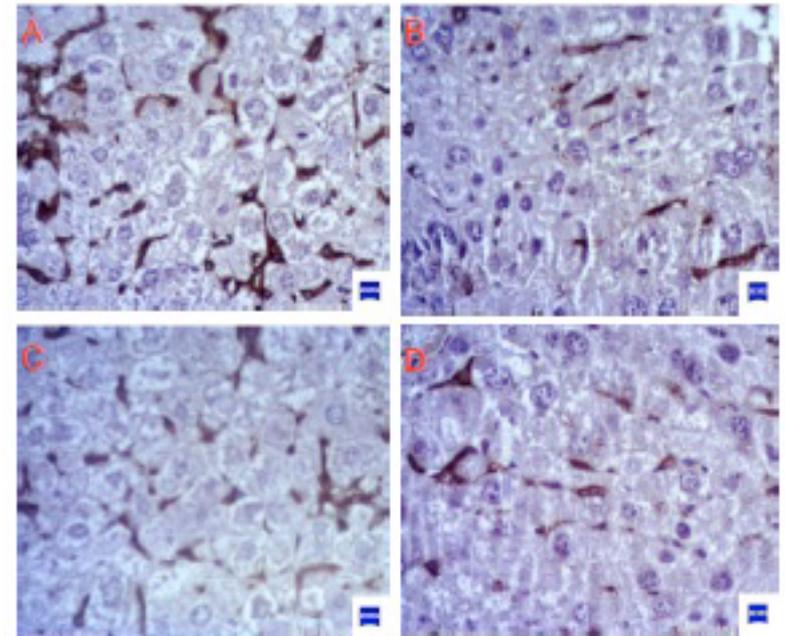
**Treatment with IMM-124E Prevents Fibrosis and Inflammation**

*Mizrahi M. 2013, AASLD; Hepatology 751A*

# Suppression of F4/80High Macrophages



Kupffer cells 4/80 Flow cytometry (FACS analysis) for F cells in group A vs. group C 4/80 showed higher F 0.05P<



Kupffer cells showed 4/80 Immunohistochemical staining for F 0.05 cells in group A vs. group C P<4/80 F rehgh

**Marked Reduction in Liver Activated Macrophages (F4/80 high)**

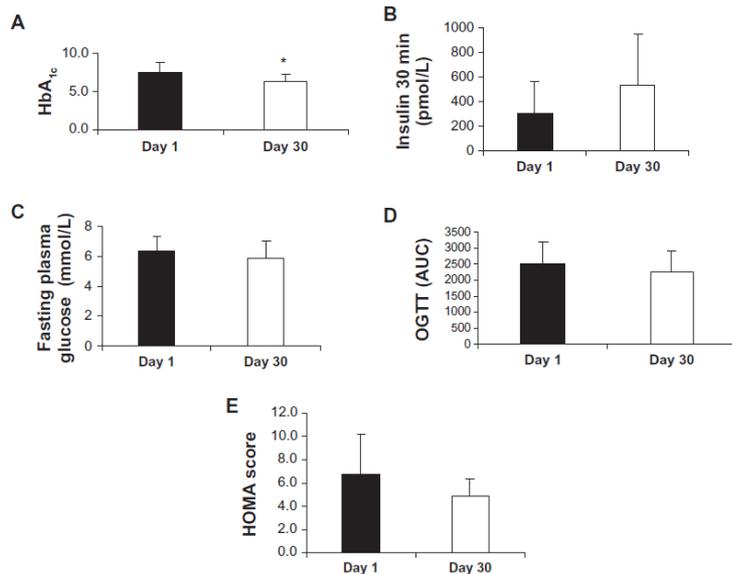
# Phase 1/2: Improves Liver Function and Reduces Insulin Resistance



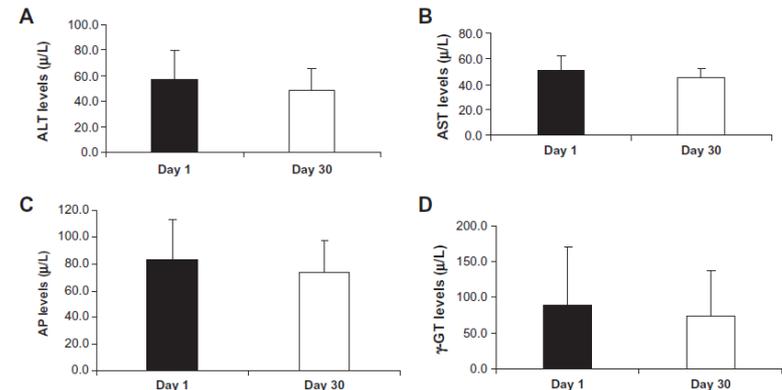
## Results of a Phase 1/2a clinical trial; N=10

30 Days Treatment Endpoint Met; NO SAFETY ISSUES REPORTED

### Improved HBA1C, OGTT and HOMA



### Improved Liver Enzymes

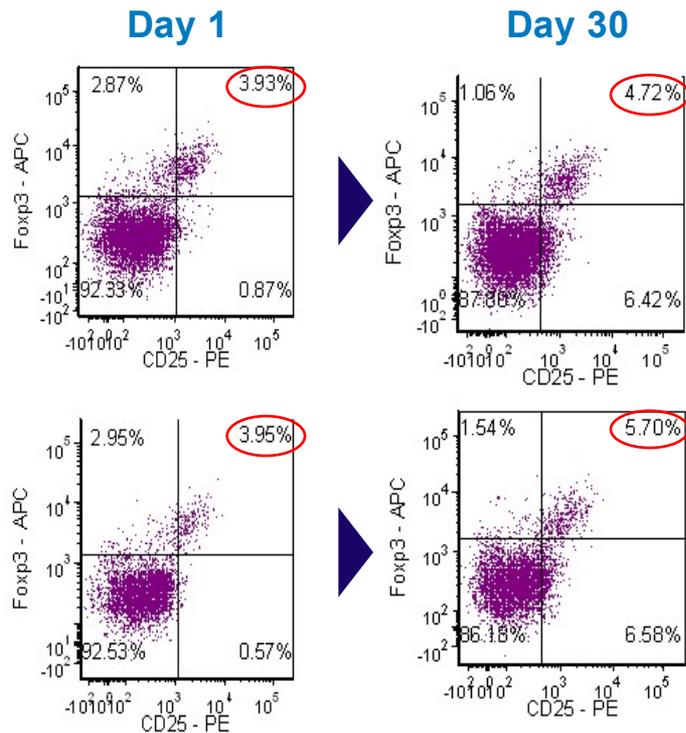


Improved Metabolic Status (e.g. HbA<sub>1c</sub>, HOMA OGTT) GLP1, and Adiponectin and Liver Function (e.g. ALT)

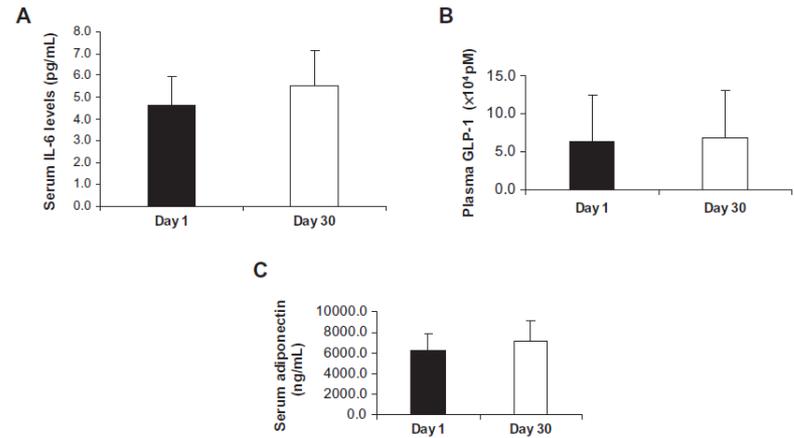
# Phase 1/2: Improves Inflammatory Biomarkers



## Increased CD4+CD25+FOXP3+ TREGS



## Increased GLP1 and Adiponectin



Proof of Concept:

Increase in Circulatory  
Regulatory T-Cell

# IMM-124E Key Milestones



3Q  
2017

- NASH Phase 2 interim analysis
- Results of MOA studies:
  - SanyalBio

4Q  
2017

- NASH Phase 2 Topline Results
- Results of MOA studies:
  - Duke

2018

- Results of colitis pre-clinical studies:  
2017/2018

- NASH-centric transaction after NASH Phase 2
- Pediatric NAFLD Phase 2 topline results
- ASH Phase 2 topline results

# IMM-529

Neutralizing *Clostridium difficile*, but Sparing the  
Microbiome

# IMM-529 in Clostridium *difficile* Infection (CDI)



- **Biologic with unique triple mechanism of action**
  - Antibodies neutralize the toxin B, the spores and the vegetative cells
- **Potential to redefine the standard-of-care (SOC) therapy for CDI**
  - Current antibiotic treatments exacerbate recurrence
  - **IMM-529 stops virulence, without impacting the microbiome**
  - Compelling data in all three phases of the disease including (1) prevention of primary disease, (2) treatment of primary disease and (3) prevention of recurrence
  - Orally administered, safe
- **>70% survival rate in CDI mice treated with IMM-529 vs. <7% survival rate in control groups**
- **Potential orphan disease designation; potential breakthrough / fast track designations**
- **Market exclusivity** (biologics; high barriers to generic biosimilar entry)

# IMM-529 for the Treatment of CDI



## Market Opportunity

- Therapeutic market is expected to grow from \$356.3 million in 2014 to over \$1.5 billion by 2024 – CAGR 15%
- Nearly 30,000 patients die each year from *C. difficile* infections (US)
- Potential orphan disease (7 years market exclusivity and premium pricing)

## Unmet Need

- Vancomycin and metronidazole are the current standard of care, accounting for 80% of patient share (US)
- However, therapies are plagued by significant CDI recurrences (1st relapse: 25%; 2nd: 40%; 3rd: 50%) underscoring need for new treatments
- There is also growing resistance to vancomycin treatment

## IMM-529 Positioning

- Highly differentiated – Neutralizes *C. difficile* but does not impact microbiome
- Only asset that targets not only toxin B but also the spores and the vegetative cells responsible for recurrence
- Can be used in combination with standard of care
- Targets many isolates

# Triple Action MOA

## Neutralizing *C. difficile*; Sparing the Microbiome



### Spores – Infectious Particles

**IMM-529** antibodies bind to multiple epitopes on surface antigens on spores and prevent adherence to host cells and limit germination.

Heat, ethanol and UV resistant. Survive gastric acid, adhere to cells in the colon and germinate.

### Vegetative Cells

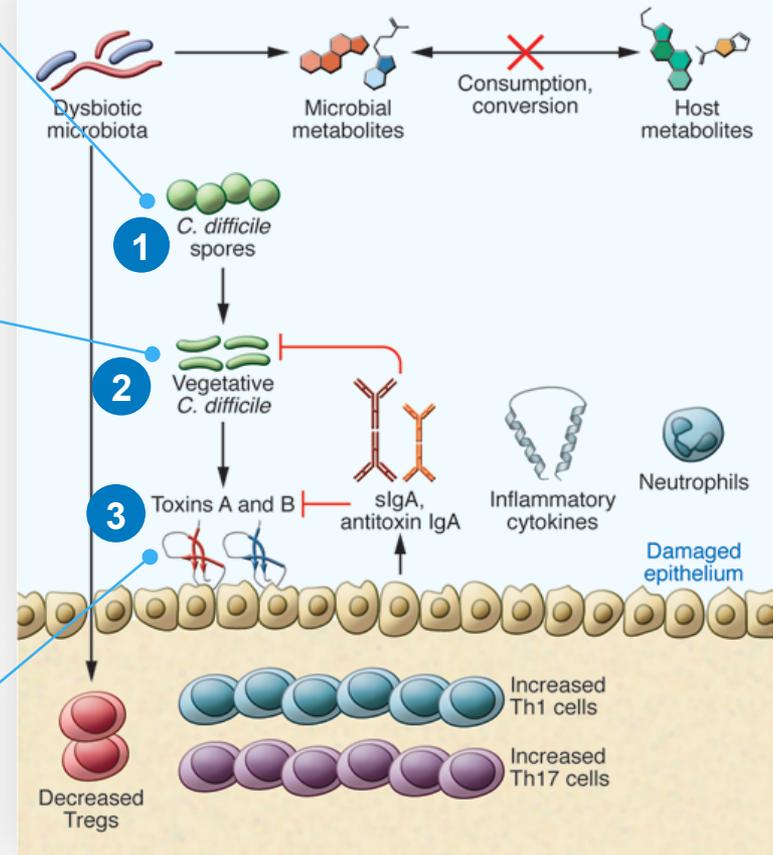
**IMM-529** antibodies bind to multiple epitopes on the surface layer proteins (SLP) on vegetative cells and limit colonization.

Fimbriae and other surface layer proteins (SLP) contribute to bacterial colonization. Fimbriae are used to adhere to other bacteria and to host cells and is one of the primary mechanisms of virulence

### Toxin B

**IMM-529** antibodies bind to multiple epitopes effectively neutralize toxin B, inhibiting toxin mediated epithelial cell apoptosis and limit toxin translocation into the systemic circulation and inflammatory cascades.

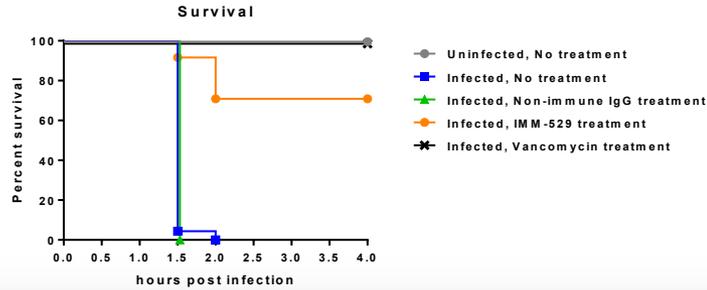
Toxin B is essential for virulence. Toxin B disrupt the cytoskeleton and tight junctions of intestinal epithelial cells.



# Results of Pre-Clinical Studies

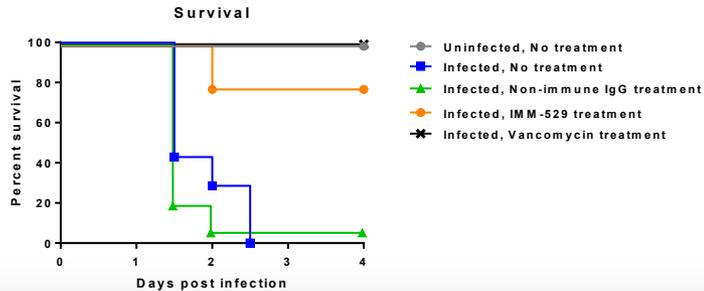


## Prevention Studies



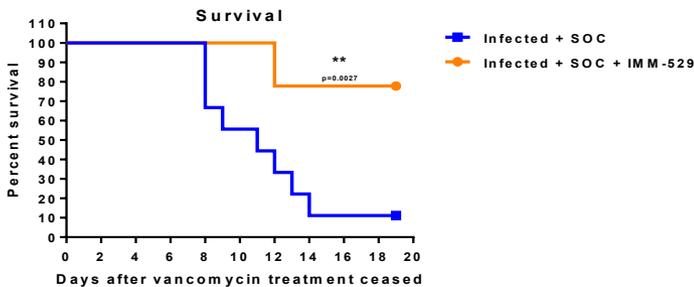
Demonstrated ~70% survival rate without use of antibiotics vs. 0% for control group ( $P < 0.0001$ )

## Treatment Studies



Demonstrated ~80% survival rate without use of antibiotics vs. <7% in control group ( $P < 0.0001$ )

## Relapse Studies



Demonstrated ~80% survival rate vs. ~11% survival rate in control group ( $P < 0.0027$ )

All studies statistically significant

Potentially only therapeutic (approved or in development) that can treat all phases of the disease:

1. Prophylaxis
2. Treatment
3. Recurrence

# Phase 1/2 Study Design



## Phase 1/2 Study in CDI Expected to Commence 2Q 2017

- **Phase 1/2, randomized, double blind, placebo-controlled clinical study of IMM-529 for the treatment of CDI**
- **60 subjects** to be enrolled up to 3 weeks of definitive diagnosis of CDI (at least 20 subjects to be enrolled within the first 72 hours)
- **Subjects randomized to IMM-529 or placebo in a 2:1 ratio**
- **Treatment duration:** 28 days on top of SOC (vancomycin / metronidazole)
- **Follow-up:** 3 months
- **Primary objective:** To evaluate the safety and tolerability of IMM-529 together with standard of care (SOC) in patients with CDI
- **Secondary objective:** To evaluate the effectiveness of IMM-529 together with SOC to treat patients with CDI

# IMM-529 Key Milestones



2Q  
2017

- **Clinical supplies manufacturing**
- **Initiation of Phase 1/2 Trial in CDI**

2018

- **Topline results expected from Phase 1/2 study in CDI**

# Corporate and Financial Overview

# Robust IP and Extended Market Protection



## Strong Patent Portfolio

- 6 patent families offering composition and/or method of treatment claims
- Approved / pending in major geographies including US, Europe, Japan and China
- Granted patent terms ending between 2024 and 2030 with possible extensions

## Extended Market Exclusivity

- Immuron's drugs are considered "biologics" by the FDA
- In the US, this is expected to confer Immuron's new drugs 12 years of market exclusivity, offering investors a long revenue tail

## Generic Protection

- Immuron's drug not absorbed in the blood
- No baseline for PK studies
- This results in lengthy process for biosimilar manufacturers

# Recent High-Value NASH LM&A Highlights

## Potential for Significant Upside



- Focused on advancing IMM-124E and IMM-529 through key clinical inflection points while pursuing partnering opportunities
- Recent licensing and M&A partnerships in NASH **underscores potential of IMM-124E**



- 2016: Licensed preclinical NASH asset
- ~\$50M upfront + other undisclosed milestones



- 2016: Acquired Tobira
- ~\$530M (5x market cap at time of announcement), in a deal valued at up to \$1.7B



- 2015: Acquired Phenex
- NASH asset in Phase 2
- Total deal value \$470M



- 2014: Acquired Nimbus
- Preclinical assets and platform
- \$400M upfront in a deal valued at \$1.2B



- 2015: Acquired Pharmaxis
- NASH asset in Phase 1
- \$39M upfront – Total deal value \$600M



- 2014: Acquired Lumena
- 2 Phase 2 assets for NASH and cholestatic liver disease
- Total deal value \$260M

# NASH and *C. difficile* Comps Indicate Potential for Substantial Growth



Company	Ticker	Program	Development Stage	Market Cap*
Program in NASH				
 Intercept	ICPT	Obeticholic acid	Phase 3	US\$2.9B
 GENFIT TOWARDS BETTER MEDICINE	GNFT	Elafibranor	Phase 3	US\$1.1B
 Conatus Pharmaceuticals	CNAT	ENCORE-LF	Phase 2	US\$195M
Program in <i>C. Difficile</i>				
 SERES THERAPEUTICS™	MCRB	SER-109; SER-262	Phase 2	US\$423M
 summit	SMMT	SMT19969	Phase 1	US\$143M
 assembly biosciences	ASMB	ABI-M101	Preclinical	US\$419M

\*As of May 4, 2017

# Company Capitalization – Pre-Offering



Immuron Limited	Pre-Offering Ordinary Shares	Pre-Offering “ADSs Equivalent” <sup>1</sup>
Shares	103,641,417	2,591,035
Options <sup>2</sup>	33,177,523	829,438
Warrants	0	0
Total	136,818,940	3,420,473

1. Each ADS is equal to 40 ordinary shares
2. Options - Weighted average exercise price: AUD\$0.544

# Use of Funds – Net of Raise Fees



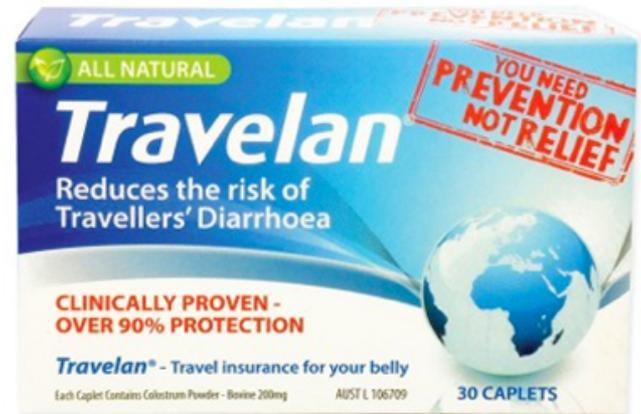
Programs	Use of Funds
<b>IMM-124E</b> – Advance the clinical development of IMM-124E for the treatment of fatty-liver diseases. Funds sufficient to complete our Phase 2 clinical programs in NASH, ASH and Pediatric NASH	\$3,000,000
<b>IMM-529</b> – Advance development of IMM-529 and complete our Phase 1/ 2 in patients suffering from recurrent CDI	\$1,100,000
<b>Other Clinical</b> – Support other programs including colitis pre-clinical program and collaboration with the US Army and US Navy	\$1,000,000
<b>Corporate Activities</b> – Fund manufacturing costs of clinical supplies and Travelan, current and future R&D activities, Business Development activities, marketing initiatives for Travelan in the United States and Australia, for working capital and other general corporate purposes	\$2,138,000
Total	\$7,238,000 (net of fees)

# Travelan OTC/Business

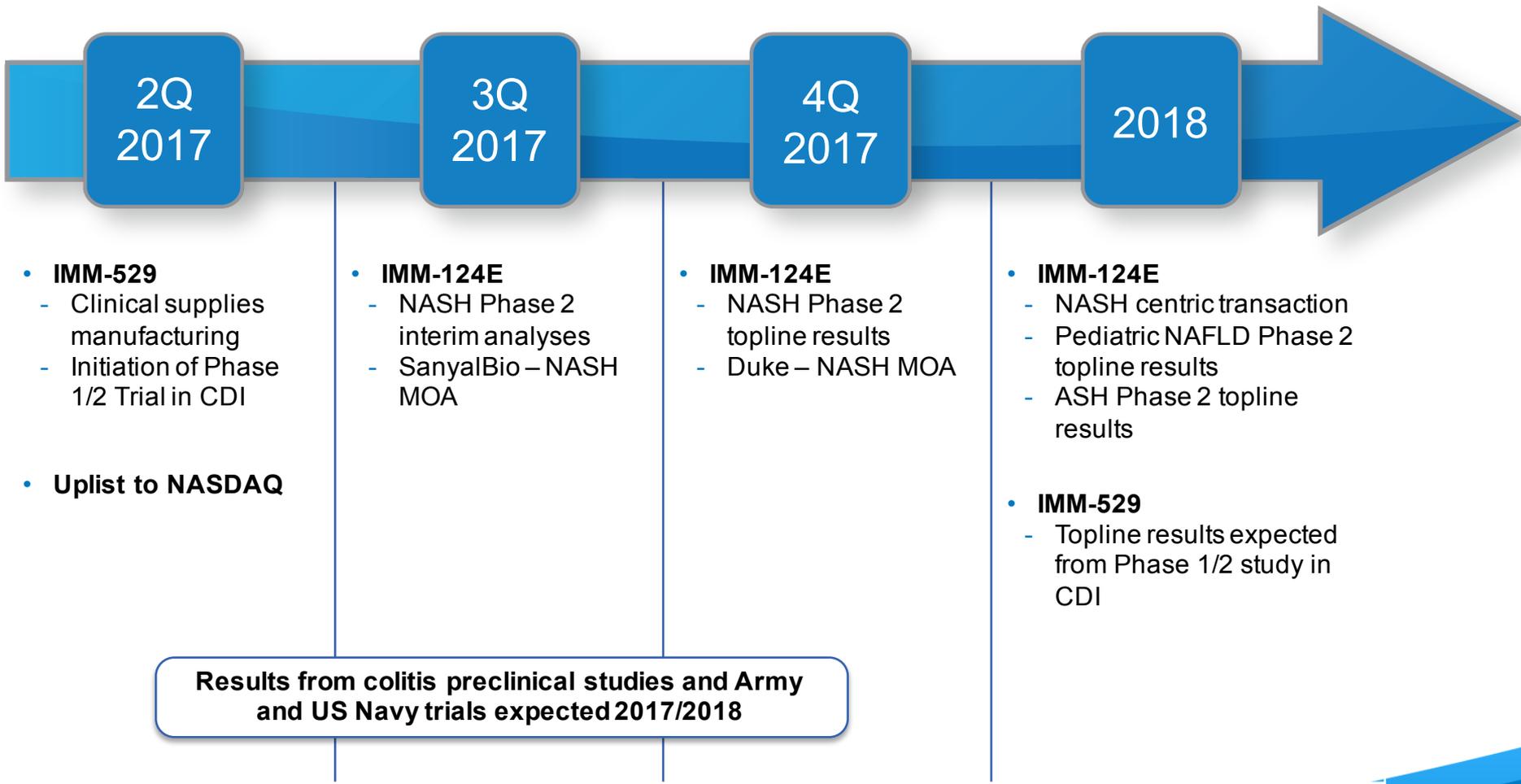
A unique Preventative Treatment for Traveler's Diarrhea



- **Travelan/OTC: unique value proposition that is valued by consumers and customers**
  - Up to 90% effective in preventing traveler's diarrhea
  - Significantly reduces the motility of ETEC strains
  - Binds to multiple epitopes and antigens on both the bacterial surface and flagella
  - Has substantially greater reactivity against purified ETEC flagella antigen than IgG purified from non-immune colostrum powder
- **Annual Revenues of AU\$1M+; Cash flow positive**
  - Net revenues: 1H2017 +41% vs 1H2016
  - Pursuing new geographies
  - Potential WW peak sales: \$20M+
  - Global traveler's diarrhea market estimated at \$600M
- **Multiple ways to keep growing OTC business:**
  - Continued penetration of current markets
  - Geographic expansions
  - New products / new formulations (e.g., shigella)



# Key Milestones Expected to Drive Value



# Investment Highlights

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- ✓ Targeting inflammatory-mediated and infectious diseases with oral immunotherapies
- ✓ Lead program, IMM-124E, in Phase 2 with key data readouts before year end
- ✓ Phase 1/2 study IMM-529 for treatment of CDI expected to commence 2Q 2017
- ✓ Well positioned to address high unmet medical need in multiple blockbuster markets
- ✓ High-value peer licensing deals and M&A underscore potential upside
- ✓ Plans to uplist to NASDAQ in 2Q 2017
- ✓ Experienced Management Team with strong support from leading KOLs and institutions

**Thank You**