



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL  
IMMUNOTHERAPIES – DECEMBER, 2021

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**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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# COMPANY HIGHLIGHTS

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

- Review of Strategic Plan
- Review of R&D Project Pipeline
  - Travelan US Drug Development Plan
  - NMRC Drug Development Plan
  - IMM-529 US Drug Development Plan
  - IMM-124E SARS-COV-2 R&D

# DEVELOPMENT PIPELINE



PRE-CLINICAL    PHASE I    PHASE II    PHASE III    MARKET

1

Commercial Products

Travelan® - commercial product Australia

Protectyn® - commercial product Australia

Travelan® - commercial product Canada

Travelan® - commercial product USA

2

IMM-124E

i) Travelers' Diarrhea FDA drug registration USA

ii) P4TD Travelers' Diarrhea Efficacy Field Trial

iii) COVID-19 research

3

IMM-529

Recurrent *C. difficile* infections

4

Naval Medical Research Center

Moderate to severe *Campylobacteriosis* infections

*ETEC* infections

5

Walter Reed Army Institute of Research

Evaluation of *Shigella* specific therapeutic drug candidates

Personal use only



# TRAVELAN<sup>®</sup>: PLAN FOR EXPANDED USE

## WITH PARTIAL SUPPORT BY US DOD FOR DOSE FINDING

- Immuron is pursuing a regulatory pathway to license Travelan<sup>®</sup> with the FDA via a Biologics License Application (BLA) with a proposed indication to prevent TD induced by ETEC
- We are seeking financial support to fund part of this initiative and develop a dosing regimen acceptable for use by the military

**DRUG CANDIDATE  
IMM-124E**

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

**IND 15675 / IND 17066**

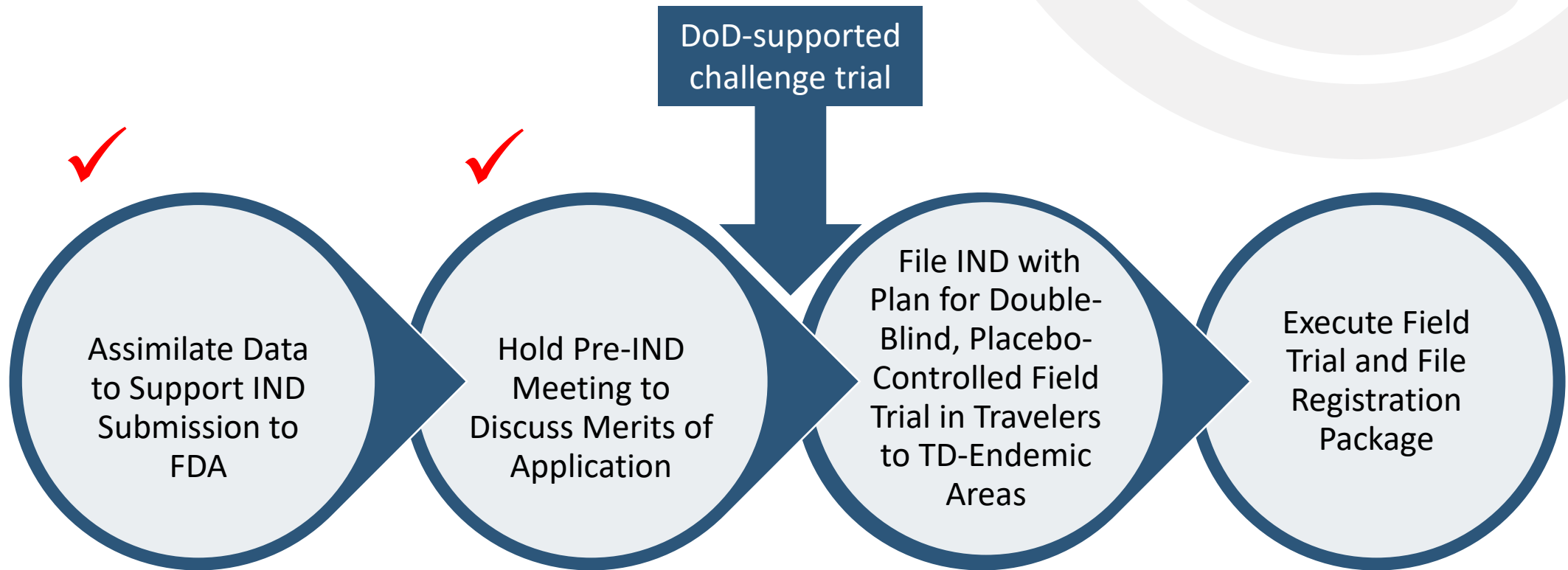


Plan to develop IMM-124E as an approved biologic in the USA targeting travelers' diarrhea



# TRAVELAN® DRUG DEVELOPMENT PLAN

Travelan® for FDA approval as biologic to reduce the risk of travelers' diarrhea (TD) in travelers to endemic areas:





# RATIONALE OF PHASE 2 TO BE SUPPORTED BY US DOD

- Travelan® efficacy studies were performed using two different doses (200 mg and 400 mg) 3 times a day
- Such a regimen is cumbersome for military troops deployed in austere environments and **military field studies have shown that compliance is low with products dosed more than once per day<sup>1</sup>**
- We propose herein to test the efficacy of one large dose per day in a controlled human infection model (CHIM) trial using ETEC H10407 to inform the decision to move forward with a once per day dosing regimen in a Phase 3 study

<sup>1</sup>Srivastava K, Arora A, Kataria A, Cappelleri JC, Sadosky A, Peterson AM. Impact of reducing dosing frequency on adherence to oral therapies: a literature review and meta-analysis. *Patient Prefer Adherence*. 2013;7:419-434 <https://doi.org/10.2147/PPA.S44646>

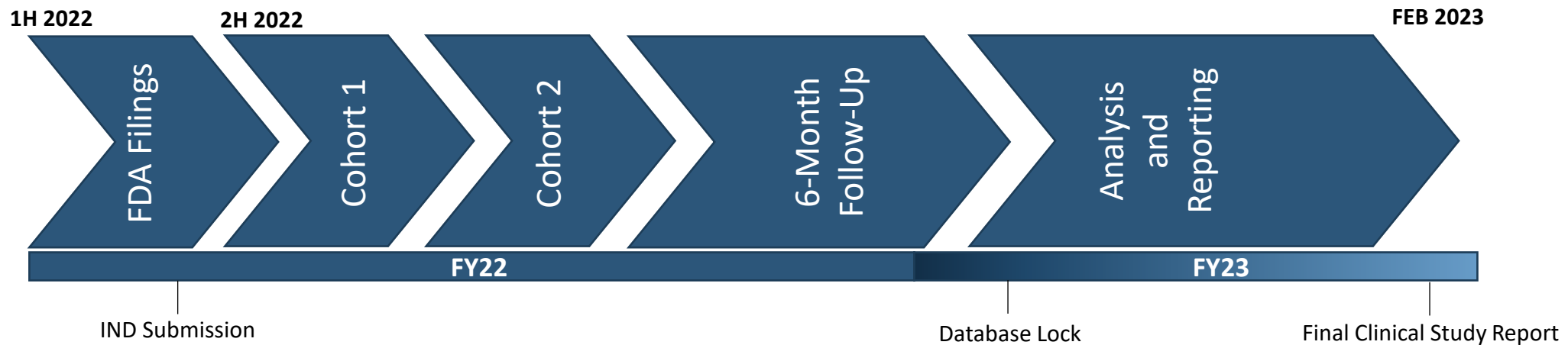


# STUDY DESIGN & TIMELINE OF THE PHASE 2

➤ Randomized (1:1), double-blind, placebo-controlled trial in 60 healthy, adult subjects

- Admission to inpatient facility (two repetitive cohorts)
- Once daily dosing of Travelan®/placebo
- Challenge with  $2 \times 10^7$  CFU of ETEC strain H10407 after two days of dosing
- Follow subjects in an inpatient setting for primary endpoint of moderate-severe diarrhea
- All subjects treated with antibiotics (ciprofloxacin) 5 days post-challenge (or earlier)
- Discharged when symptoms resolved/resolving and no longer shedding challenge organism

Product	N
Travelan® (IMM-124E), one dose (1.2 mg)	30
Placebo	30







# A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL EVALUATING THE EFFICACY OF NON-ANTIBIOTIC OTC PRODUCTS IN TRAVELERS' DIARRHEA (TD) PREVENTION (P4TD)

**CURRENT STATUS – PLAN TO COMMENCE ENROLMENT APRIL 2022**

## *Primary Objective:*

To evaluate the clinical efficacy of Travelan®, Florastor® and Bimuno® vs. placebo for maintenance of GH as measured by the combined endpoint of incidence of GH deficiencies (defined as 3 or more unformed stools in a 24-hour period OR 2 or more unformed stools and one or more associated symptoms in a 24-hour period) or antibiotic treatment for diarrhea per subject report, focusing on a 10 day window of prophylaxis during travel.

## **STUDY DESIGN**

This is a randomized (1:1:1:1 allocation), double-blind, placebo controlled multicenter clinical trial comparing three dietary supplements, Travelan®, Florastor® and Bimuno®, individually against placebo to determine efficacy for maintenance of GH. **A total of 1320 subjects (330/arm)** will be enrolled from the following populations: active duty US and UK military personnel, US DoD beneficiaries and **US civilians** deploying or traveling to intermediate or high GH disruption risk destinations.

# THE EFFICACY OF NON-ANTIBIOTIC OTC PRODUCTS IN TRAVELERS' DIARRHEA (TD) PREVENTION (P4TD)

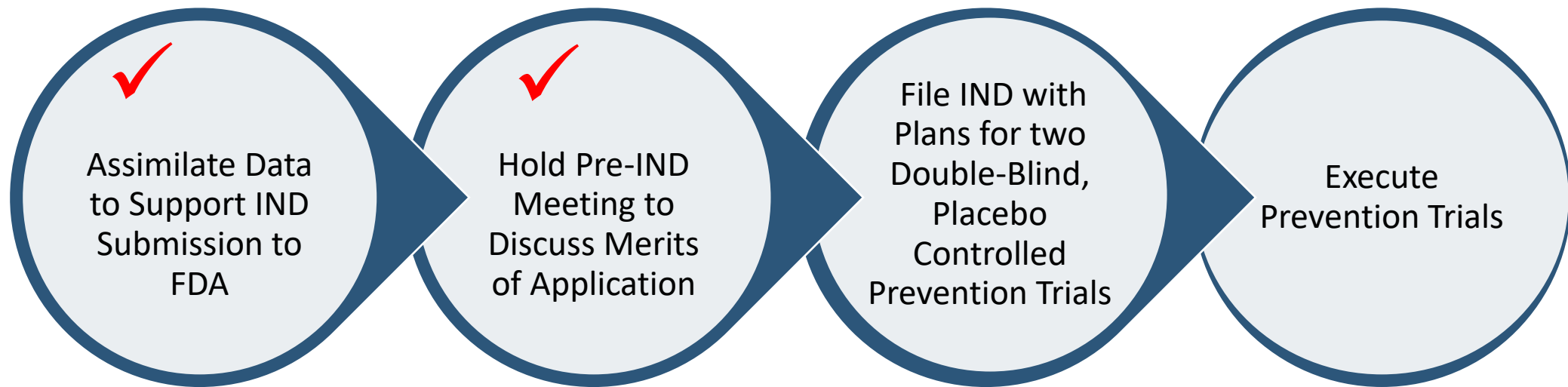


- The study products used in the clinical trial are considered dietary supplements not medicines approved by the FDA
- Clinical Trial Design approved by IRB not FDA
- Each product will be purchased commercially and packaged in sachets similar to placebo – subjects will be instructed to take 1 sachet twice a day with meals.
- Travelers and deployed personnel will be enrolled prior to departure and will begin taking the study product 3 days prior to arrival at destination, continuing for 10 days during travel.
- Enrollment will occur over a 24-month period



# NMRC CAMPETEC DRUG DEVELOPMENT PLAN

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



# NMRC CAMPETEC DRUG DEVELOPMENT PLAN



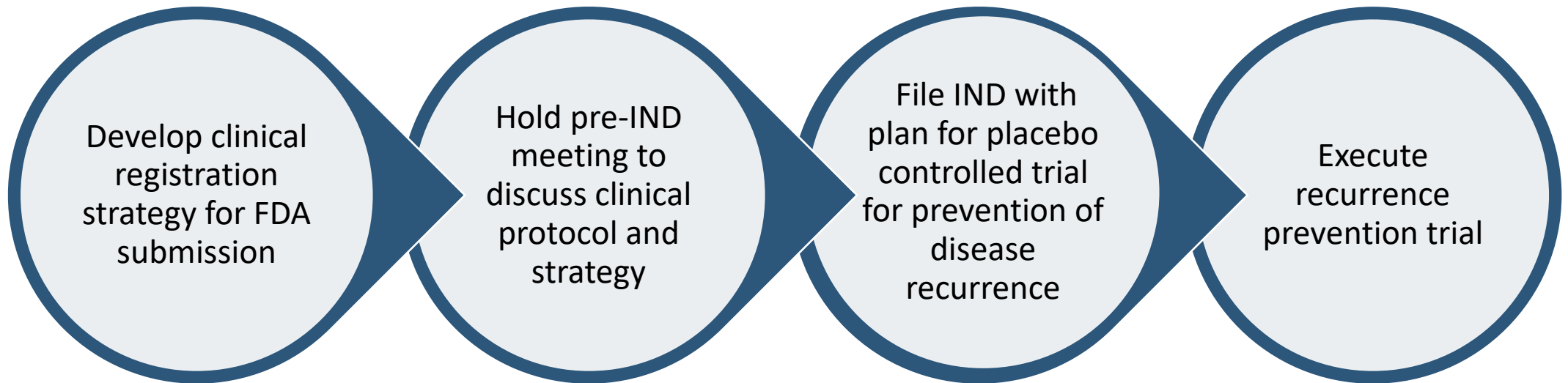
## CURRENT STATUS

- **cGMP DRUG PRODUCT Manufacture**
  - Completed ✓
- **CLINICAL STUDY**
  - IND Application – In progress
  - FDA Review and Approval of IND – Q1 CY22
  - ETEC Study Initiation at John Hopkins – Q2 CY22



# IMM-529 DRUG DEVELOPMENT PLAN

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



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# IMM-529 DRUG DEVELOPMENT PLAN



## CURRENT STATUS

- **COLOSTRUM PRODUCTION**
  - Completed ✓
- **DRUG SUBSTANCE**
  - cGMP manufacture – Q1 CY22
- **DRUG PRODUCT**
  - cGMP manufacture – Q2 CY22
- **CLINICAL DEVELOPMENT**
  - Clinical Protocol - Completed ✓
  - Clinical Sites & Principal Investigators – Identified ✓
  - Engaging with suitable CROs to support Clinical Development – In progress
- **REGULATORY**
  - Pre-IND Meeting on IMM-529 – 2H CY22

# IMM-124E SARS-COV-2 RESEARCH & DEVELOPMENT PROPOSAL



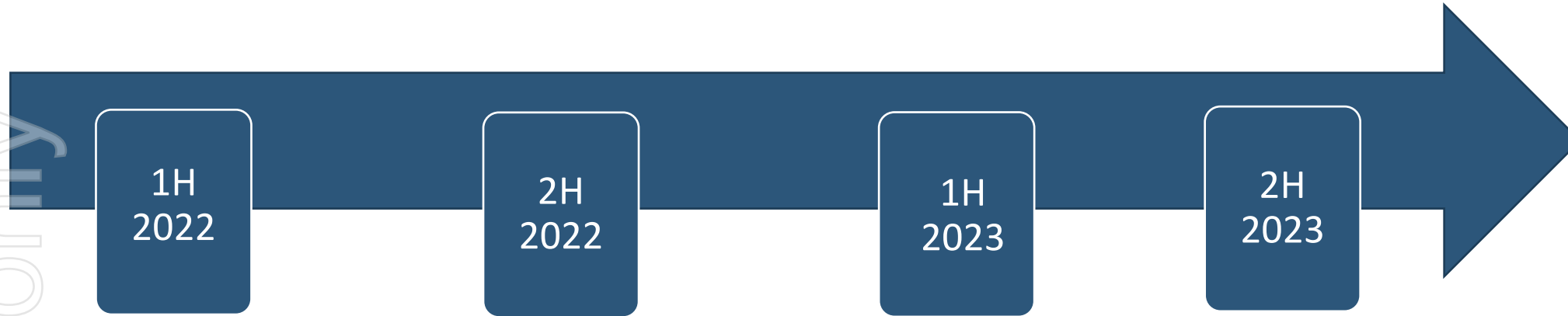
## CURRENT STATUS

### RESEARCH & DEVELOPMENT

- **Monash Research Services Agreement – Completed**
- **Research Agreement with Doherty Institute - Executed**
- The Aims of this work are as follows:
  - Testing of the neutralizing activity of the various fractions isolated by Monash University against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in the cytopathic effect inhibition cell-based assay to be performed by The Doherty Institute – Study initiated December 2021 ✓
  - R&D Work to be expanded to include variants of concern – Draft protocols In progress
  - Murine mouse model for preclinical evaluation – Draft protocols in development



# KEY MILESTONES EXPECTED TO DRIVE VALUE



- NMRC IND Submission (Q1 CY22)
- Initiate NMRC Phase 2 ETEC challenge study (Q2CY22)

- IMM-124E IND Submission
- IMM-529 cGMP Manufacture

- Topline Results NMRC ETEC Study
- Initiate NMRC Phase 2 Campylobacter challenge study
- Initiate IMC Phase 2 ETEC challenge study
- Pre-IND Meeting on IMM-529
- IMM-529 IND Submission

- Topline Results NMRC Campylobacter Study
- Topline Results IMM-124E ETEC Study
- Initiate Phase 2 CDI clinical study

- IMM-124E Infectious diarrhea pivotal field clinical study

Results from  
US Grant application & COVID-19  
Research Program expected YE2021



# 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.