

# Q&A WITH STEVEN LYDEAMORE, CEO OF IMMURON LIMITED

Immuron Limited is commercializing and developing a novel class of specifically targeted polyclonal antibodies which are delivered within the gastrointestinal tract and do not cross into the bloodstream.

Products in clinical development have the potential to transform standard of care for moderate to severe Campylobacteriosis, Clostridioides difficile infections, Enterotoxigenic Escherichia coli (ETEC) infections and Traveler's Diarrhea. Immuron markets Travelan® in Australia, Canada and the U.S. In Australia, Travelan® is indicated to reduce the risk of travelers' diarrhea and to reduce the risk of minor gastro-intestinal disorders. In Canada, Travelan® is indicated to reduce the risk of travelers' diarrhea. In the U.S, Travelan® is a dietary supplement for digestive tract protection.

Immuron's clinical programs for IMM-124E and IMM-529 are the first steps in the pathway towards FDA (US Food and Drug Administration) approval in the BLA process (Biologic License Applications).

Lumanity a leading lifescience consulting company conducted an opportunity assessment of IMM-529. Infectious disease experts reacted favourably to the IMM-529 mechanism of action, and its unique ability to target three elements of the CDI infection – the spores, vegetative cells, and Toxin B. Base case yearly revenue in USA for IMM-529 was estimated at US\$92M for the target patient population (limited to second recurrence and later). Positioning IMM-529



Steven Lydeamore

earlier than second recurrence could lead to higher uptake.

C. difficile infection (CDI) can cause life-threatening diarrhoea and is the leading healthcare-related gastrointestinal infection in the world.<sup>1</sup> The global CDI market was estimated to increase to \$1.7B by 2026, according to a report by GlobalData.<sup>2</sup>

1. Australian Commission on Safety and Quality in Health Care
2. GlobalData via Pharmaceutical Technology

## WE'RE ABOUT HALF-WAY THROUGH 2023, WHAT ARE SOME HIGHLIGHTS FOR THE COMPANY FOR THE FIRST HALF OF 2023?

- Global FY23 sales increased by 136% on FY22 to A\$1.8 million
- Two FDA approved INDs: Travelan (IMM-124E) and CampETEC
  - Phase 2 clinical programs for each to commence in collaboration with the Department of Defense
- Travelan randomized placebo controlled field trial being conducted by Uniformed Services University (USU) in active military personnel more than 35% recruited of a targeted 868 participants

## ARE THERE ANY INDUSTRY TAILWINDS TO PUSH FORWARD SOME OF THE COMPANY'S GOALS AND OBJECTIVES FOR 2023?



- International travel continues to rebound following removal of pandemic travel restrictions
  - 2022 travel to Caribbean, Asia, South America, Central America, Africa, Mexico was 83% of the peak 2019 US outbound travel
  - During the March quarter, US outbound travel to these regions was up 6% on 2019
  - In Australia, Australian resident short term departures in April 2023 were 82% of those in April 2019
- Pandemic restrictions impacted our ability to conduct clinical trials, especially for traveler’s diarrhoea
  - We anticipate strong recruitment for our Phase 2 trials (Travelan, CampETEC) and USU’s field trial

- Travelan Phase 2 clinical study
- We anticipate ethics approval and initiation for one of the CampETEC Phase 2 clinical studies (two Phase 2 studies are planned; one in Campylobacter, another in ETEC)
  - We anticipate completion of recruitment for one of the CampETEC Phase 2 clinical studies
  - We anticipate cGMP manufacture of IMM-529 clinical product; IMM-529 has been developed to prevent and treat clostridioides difficile (CDI)
  - We anticipate pre-IND (Investigational New Drug) application to the FDA (US Food and Drug Administration) for IMM-529
  - We anticipate continued strong sales growth for Travelan® in both Australia and USA
    - Currently penetration in USA is low; based on US annual travel numbers and a penetration rate of 15%, USA market potential is estimated at \$83m

**FROM WHAT YOU CAN TELL US, WHAT ARE SOME OF THE COMPANY’S VALUE CATALYSTS FOR THE REST OF 2023?**

- We anticipate completion of recruitment for

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