



October 2, 2025
ASX Announcement

Letter to Shareholders

Highlights:

- **US Tariffs:** Immuron does not anticipate any material impact from the recently announced US tariffs on pharmaceutical products
- **Travelan® Clinical Study:** Topline results from the Travelan® clinical study conducted by Uniformed Services University are anticipated in October 2025
- **IMM-529 Regulatory Milestone:** Immuron plans to submit an Investigational New Drug (IND) application to the U.S. FDA for IMM-529 (Clostridioides difficile infection) in mid-October 2025
- **ProIBS® Commercial Launch:** The Australian Launch of ProIBS® is on track for Q4 of calendar year 2025
- **IMM-986 Pre-Clinical Progress:** Initial pre-clinical research studies for IMM-986, targeting Vancomycin-resistant *Enterococci* (VRE), are anticipated to be completed by year-end 2025

Dear Shareholder,

I am pleased to provide you with a brief update on progress with a number of projects at Immuron Limited (ASX: IMC; NASDAQ: IMRN).

Sales

As announced on July 17, Immuron achieved record sales up to Financial Year ending June 30, 2025. Immuron is on track to exceed FY24 first quarter sales. First quarter FY25 sales will be reported in **mid-October**. Please note that Travelan® is imported into the United States from Australia as a dietary supplement. It is not a pharmaceutical product and is not anticipated to be impacted by announcements regarding tariffs on pharmaceutical products.

Clinical Trial Update

Immuron has three therapeutic products under development: IMM-124E (Travelan®) for traveler's diarrhea; IMM-529 for Clostridioides difficile infection and IMM-986 for Vancomycin-resistant enterococci.

IMM-124E

Immuron reported on May 30 that we anticipated the final visit of the Last Patient for the Uniformed Services University Travelan® field study would be in July 2025 with topline results to follow in October 2025. The Company continues to anticipate topline results of this trial will be released in **October 2025**.

It is hoped that this trial will enable Travelan® to be recommended in traveler's diarrhea guidelines thereby increasing its market potential as well as enhancing the long standing relationship with the US Department of Defense.



Following these results Immuron will request the end of Phase 2 meeting with the FDA for **IMM-124E** which all act as a precursor to commencement of a Phase 3 clinical program.

Based on [Lumanity](#)'s opportunity assessment prepared for Immuron, the base case yearly revenue in USA for **IMM-124E** is projected at **US\$102 million**.

IMM-529

Immuron is progressing with a new Investigational New Drug (IND) application to the Food and Drug Administration (FDA) to initiate the clinical development of **IMM-529** for the treatment of Clostridioides difficile infection (CDI) and prevention of recurrence of CDI.

Immuron reported on September 16 that we anticipated IND submission to the FDA by the end of September 2025. Immuron now anticipates submission in **mid-October 2025**. Approval of this IND submission by the FDA is a precursor to commencement of a Phase 2 clinical program.

At last year's AGM presentation, we advised Lumanity's assessment that the IMM-529 market in the US can reach peak revenues of **~US\$400 million**.

ProIBS product launch

Immuron reported on September 16 that it anticipated launch of ProIBS in Q1, calendar 2026. Immuron now anticipates a limited launch in **Q4, calendar 2025** with a full launch in Q1, calendar 2026.

[ProIBS®](#) is a European certified medical product for the treatment of symptoms related to Irritable Bowel Syndrome (IBS) such as abdominal pain, bloating and changes in bowel movement (i.e., diarrhea and/or constipation). Immuron has listed ProIBS® in Australia as a listed complementary medicine. Immuron is purchasing the product from [Calmino](#) and anticipates making a gross margin typical for a consumer health product in Australia. The IBS treatment market in Australia is estimated to be a part of the broader "Digestives & Intestinal Remedies" market, generating a revenue of around [A\\$221 million](#) in 2025, with a projected annual growth rate of 3.28%.

Pre-clinical Trial Update

On January 5 Immuron reported a research collaboration with Monash University to develop a new therapeutic against Vancomycin-resistant enterococci (VRE). Immuron has named this drug candidate **IMM-986**. VRE antimicrobial resistance (AMR) poses a significant threat to healthcare systems worldwide. AMR can lead to more severe and harder-to-treat infections in healthcare settings, such as hospitals and nursing homes. These infections often result in longer hospital stays, higher medical costs, and increased mortality rates. In the U.S., the estimated national cost to treat these infections exceeds \$4.6 billion annually ([CDC Antimicrobial Resistance Facts and Stats](#)).

VRE-specific vaccines have been successfully developed and administered to animals. The VRE colostrum harvested from these immunized subjects has been processed into a freeze-dried powder for use in this program. Monash has completed the development of analytical assays to characterize the antibody response in IMM-529. Preliminary analyses have confirmed that IMM-986 exhibits high levels of reactive antibodies targeting vaccine VRE bacterial antigens, as demonstrated through endpoint ELISA and Western Blot assays. These findings indicate a robust antibody response to VRE. Further characterization of the specificity and broad-spectrum cross-reactivity of IMM-986-derived antibodies against other enterococcal strains is currently underway .

Monash are planning initial pre-clinical studies to be performed by the **end of calendar 2025**. Key milestone dates, including the anticipated timing of the initial pre-clinical study results, will be communicated in due course following the receipt of ethics approval.

Thank you for your ongoing support.

A handwritten signature in black ink, appearing to read "S Lydeamore".

Steven Lydeamore
Chief Executive Officer

This release has been authorised by the directors of Immuron Limited.

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FORWARD-LOOKING STATEMENTS:

This document may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition, and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions, or circumstances on which any such statement is based, except as required by law.