Soon to enter the 'Phase 3 club'

Share Price: A$0.10

ASX: IMC

Sector: Healthcare

20 March 2024

Immuron (ASX:IMC) took a major step forward and attracted significant investor attention on Thursday 7 March 2024. The company revealed interim topline results from its Phase 2 trial in Travelan. The results were positive and bode well for the company to pursue a Phase 3 clinical trial.

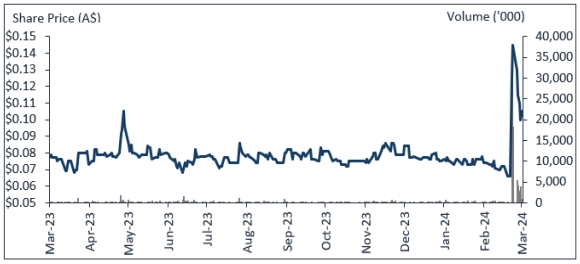
Market cap. (A$m)	22.8
# Shares outstanding (m)	227.8
# Share fully diluted (m)	243.4
Market cap full. dil. (A$m)	24.3
Free float	66.0%
12-months high/low (A$)	0.145 / 0.066
Avg. daily volume ('1000)	388.9
Website	www.immuron.com.au

Source: Company, Refinitiv Eikon, Pitt Street Research

Travelan passes with flying colours

The trial found that a single dose of Travelan is effective In prevention of moderate to severe diarrhea following challenge with enterotoxigenic Escherichia coli (ETEC). Specifically, ETEC induced moderate to severe diarrhoea was reduced by 36.4%, protective efficacy against severe ETEC induced diarrhoea was 66.7% and there was a statistically significant 83.3% reduction of subjects needing early antibiotic treatment post-challenge.

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Immuron is set to join an exclusive club

Although complete results are not due until later this year, the company will now proceed to hold an end of Phase 2 meeting with the FDA to discuss the pivotal Phase 3 registration strategy as well as explore funding for Phase 3. By merely entering Phase 3, Immuron will be among an exclusive list of ASX biotech stocks in Phase 3. We expect this fact alone to lead to continued growth momentum in the months ahead.

Immuron investors have plenty of other catalysts to look forward to including clinical trials with its other assets (which we will outline in this report) and sales growth for Travelan, sold as a general dietary supplement. In the first 8 months of FY23, the company recorded $3.2m in sales, up 168% on the prior corresponding period and well ahead of the $1.8m recorded in the entire 12 months of FY23. This is a testimonial to the strong potential of Immuron's assets. Immuron also recorded a $2.2m gross profit, a 147% gain from the prior corresponding period.

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Valuation range of A$0.25–0.35 per share

We reiterate our valuation of Immuron as first outlined in our initiation report – at A$0.25 per share in a base case scenario and A$0.35 per share in an optimistic (bull) case scenario. Even with the recent re-rate following the results, it is well below the valuation of other ASX companies in Phase 3 and we expect the gap to close in the coming months as the company moves towards Phase 3. Please refer to page 9-10 for more details on our valuation and the key risks to our thesis.

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Recap of Immuron and Travelan

Immuron's commercial and clinical stage assets are designed to treat infectious diseases through oral immunoglobulin-based therapies.

Immuron is an Australia-based biopharmaceutical company developing and commercialising oral immunotherapeutics for the treatment of gut-mediated diseases. **Travelan** and **Protectyn** are Immuron's flagship commercial products. The former is commercially available in three global markets – Australia, Canada, and the US – while the latter is only available in Australia.

Travelan is an orally administered, over-the-counter immune supplement that helps in the reduction of TD and minor gastrointestinal disorders. It is not just a reactive treatment but can be proactively taken before meals to prevent disease. Travelan has been specifically formulated to fight ETEC (Enterotoxigenic E. Coli), stopping it attaching to intestinal walls and thereby neutralising the bacteria's ability to cause diarrhoea, digestive upset, and other associated symptoms.

Independent studies sponsored by the U.S Department of Defense and funded through the Defense Health Agency have demonstrated Travelan to be a much more broad spectrum anti-bacterial strongly suggest Travelan is an effective immunoprophylactic not only for ETEC-mediated TD but the more serious enteric infections caused by Campylobacter spp, Shigella spp,. and pathogenic Vibrio cholera bacteria.

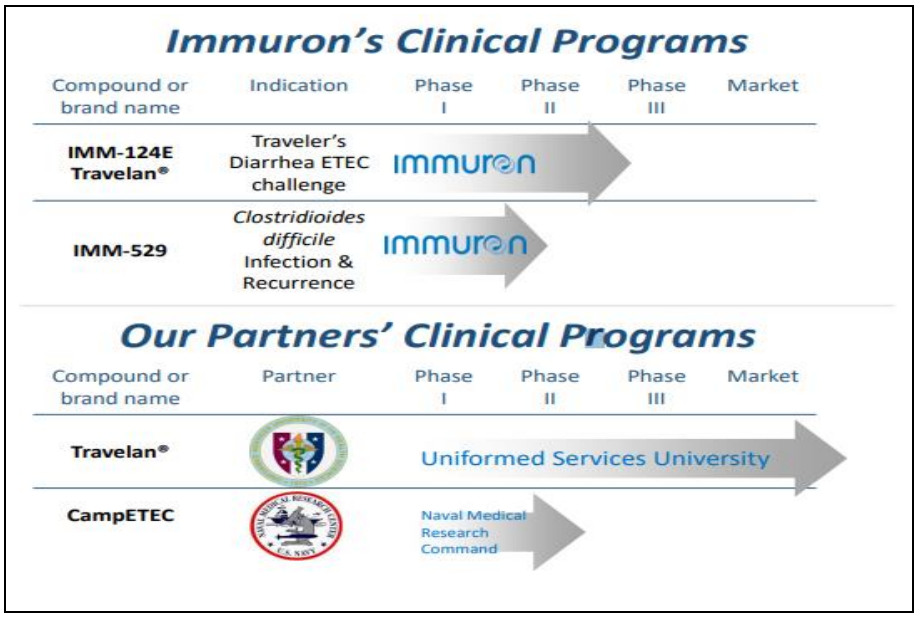
Due to Travelan not being an antibiotic, it comes without any risk of side effects of antibiotics and does not contribute to worldwide concerns about bacterial drug resistance. It also supports a healthy digestive system by providing support to the gut's immune defences whether one is traveling or whether one is at home.

Protectyn is a dietary supplement for gut health, formulated to help maintain a healthy digestive function and support the liver. It is an over-the-counter product targeting lipopolysaccharide (LPS) bacterium in the gut to prevent gut dysbiosis, improve bacterial clearance, reduce chronic inflammation, and improve immune function. Protectyn is scientifically formulated to contain high levels of active antibodies. The antibodies target pathogenic bacteria and the harmful LPS toxins that the bacteria produce in the gut, thereby reducing the bacteria's ability to disrupt the healthy functioning of the gut, liver, and immune system.

Immuron's Clinical Programs

The company's clinical programs are as follows (Figure 1):

Figure 1: Immuron's clinical programs



Source: Company

I. IMM-124E - the API used to manufacture both Travelan and Protectyn. IMM-124E. Travelan is only approved in the US as a general dietary supplement rather than as a preventative treatment for traveller's diarrhea.

II. IMM-529 - an oral formulation intended for patients suffering from recurring Clostridium Difficile Infection (CDI). Immuron has commenced preclinical work on IMM-529 and has demonstrated some positive signs.

III. CampETEC - an oral therapeutic targeting Camptlobacter and ETEC infections. Immuron is collaborating with the US NMRC for this asset. Earlier in 2023, the FDA approved an IND application for CampETEC to test its safety and protective efficacy in a first-in-human study.

IV. Travelan - The US Department of Defense (DoD) Uniformed Services University is running a randomised, placebo-controlled trial in up to 866 participants. Patients have actively been deployed in the military from both the US and the UK. The US DoD has extended the enrolment period and now expects to complete clinical trial enrolment in Q3 2024.

Travelan shows solid data

As noted in previous reports, the FDA has not assessed Travelan for treating TD and Immuron is working to gain the approval. We believe that the approval of Travelan as a preventative treatment of TD would result in a significant increase in commercial opportunities for Travelan in the US.

The company has been conducting a 60-patient Phase 2 clinical trial in the US with Travelan, and interim data was reported in early March 2024. The trial is designed to evaluate the safety and protective efficacy of the new product compared to a placebo in controlled human infection model (CHIM). The primary efficacy outcome is prevention and/or reduction of moderate to severe diarrhoea.

Immuron released interim data which showed strong topline results (Figure 2).

Figure 2: Immuron's clinical trial results

Event post challenge	Travelan® n = 30 n (%)	Placebo n = 30 n (%)	Reduction in AEs or Symptoms (%)	*P value*
Primary Endpoint				
Number (n) of subjects with ETEC-induced moderate-severe diarrhea	7 (23.3%)	11 (36.7%)	NA	0.399
Protective efficacy [%][1] 95% 2-sided Confidence Interval[2]	**36.4%*** **(-79.8%, 79.1%)**			
Secondary Endpoints - Safety and tolerability				
Number of subjects with an adverse event (AE) 95% 2-sided Confidence Interval[2]	4 (13.3%) (-3.8%, 37.1%)	9 (30.0%)	55.6%	0.1172
Number of subjects with (AEs) fever, nausea, anorexia, o abdominal pain/cramps rated as moderate to severe 95% 2-sided Confidence Interval[2]	3 (10.0%) (-5.2%, 31.9%)	7 (23.3%)	57.1%	0.1659
Secondary Endpoints – Degree to which a participant experiences diarrheal symptoms				
Number of subjects who experienced severe diarrhea 95% 2-sided Confidence Interval[2]	1 (3.3%) (-5.8%, 19.2%)	3 (10.0%)	66.7%	0.3006
Number of subjects requiring early antibiotic treatment 95% 2-sided Confidence Interval[2]	1 (3.3%) (1.0%, 32.4%)	6 (20.0%)	83.3%	**0.0444**
Number of subjects requiring IV fluids 95% 2-sided Confidence Interval[2]	0 (-0.7%, 20.7%)	3 (10.0%)	100.0%	0.0756

Source: Company

The results included:

- ETEC-induced moderate to severe diarrhea was reduced by 36.4% in the Travelan group compared to the placebo group
- Protective efficacy of once daily dosing was shown to be 50% as effective as the current recommended three times daily dosing regimen
- 66.7% protective efficacy against ETEC-induced severe diarrhea was observed in the Travelan group compared to the placebo group
- Statistically significant reduction of 83.3% in the subjects in the Travelan group requiring early antibiotic treatment post challenge compared to the placebo

- For subjects requiring intravenous rehydration post challenge, 100% were in the placebo group and none were in the Travelan Group
- A 55.6% reduction in the number of subjects experiencing adverse events post the ETEC challenge was observed in the Travelan group compared to the placebo group

The study is still proceeding – the last patient visits will commence in April and the final report will be in the second half of this year. However, these results are undoubtedly pleasing.

What is next? The Phase 3 club

Immuron is seeking to take Travelan into a pivotal Phase 3 trial (Figure 3). Once Phase 2 is complete and Immuron has the clinical study report - anticipated in the second half of CY24 - the company will have an end of Phase 2 meeting with the FDA to discuss the Phase 3 registration strategy and planned clinical trials, including recommended dosing. This will include making a Biologics License Application (BLA) for Travelan as a prophylactic medicine for Travelers' Diarrhea, that could be used in the US Military. The company is also seeking non-dilutive funding opportunities. As outlined in Phase 3, the company is hoping to initiate it in the second half of 2025. Thereafter, a trial would take ~2 years. Such a trial would enrol a total of 1,200 healthy adult subjects across 2 studies and assess the efficacy and safety of Travelan for the prevention of TD.

Figure 3: Immuron's Phase 3 strategy

Pre	2H 2024	1H 2025	2H 2025	Post
• Phase 1 clinical study (Baltimore, 1996) • Phase 2 clinical study (Poland, 2000) • FDA[1] IND[2] approval (December 2022) • Phase 2 clinical study (Baltimore, 2024)	• Clinical Study Report • End of Phase 2 FDA meeting	• Phase 3 FDA meeting	• Initiate Phase 3	• Trial duration ~ 2 years • End of Phase 3 FDA meeting • BLA[3] submission
• The pivotal registration studies will involve two randomized, double-blind, parallel-group, placebo-controlled Phase 3 clinical studies (drug substance IMM-124E) to assess the efficacy and safety of Travelan® for prevention of traveler's diarrhea (TD)				
• The studies will enroll approximately 1200 healthy adult subjects (600 subjects in two studies) traveling to regions with high TD risk.				
• Subjects will be randomized 1:1 to receive Travelan® or placebo.				
• Dosing will begin 3 days prior to arrival in country and for at least 14 days in country.				
• The primary endpoint will be the development of TD.				

Source: Company

Entering Phase 3 could be a catalyst for a re-rate

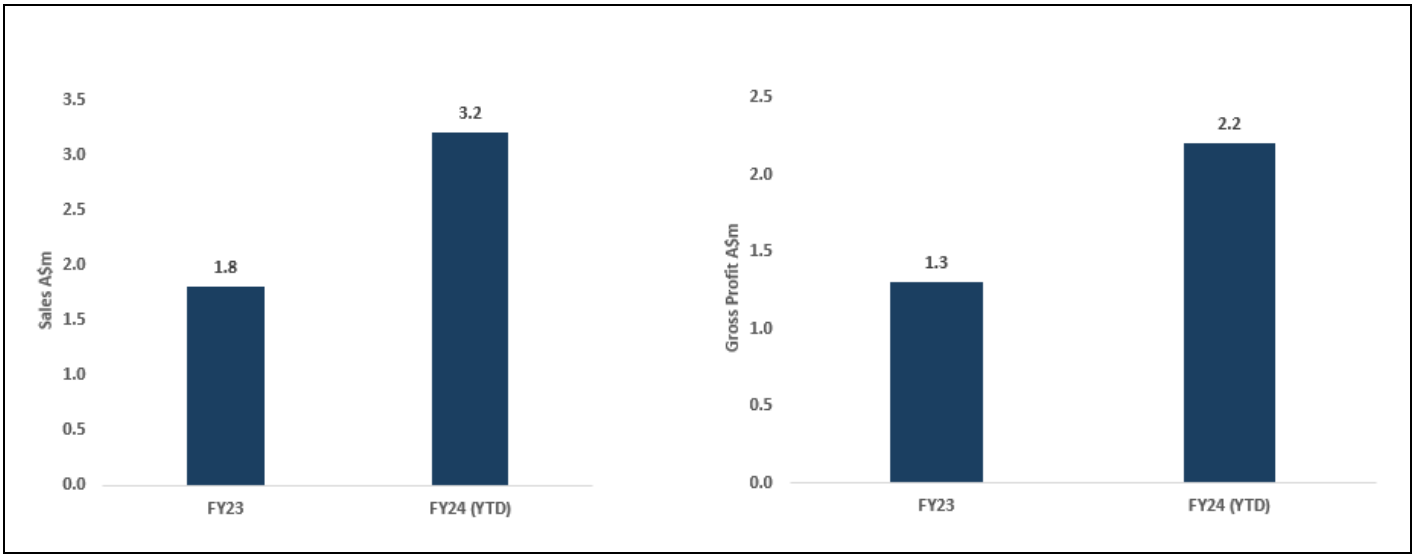
As observed in our recent reports on Prescient Therapeutics (ASX:PTX) and Dimerix (ASX:DXB), there is precedent for companies to re-rate merely by entering Phase 3. Companies such as Opthea (ASX:OPT), Dimerix (ASX:DXB) and Paradigm Biopharmaceuticals (ASX:PAR) have market capitalisations of over $100m, just by being in Phase 3. At less than $30m, we think Immuron is underrated, before you even consider it has products in the market. We think the company can re-rate in the months ahead as it edges closer towards Phase 3.

Other catalysts for the company

Immuron shareholders have plenty of other catalysts to look forward to. These include:

- **Clinical study report for the Travelan study**. These are expected in the second half of 2024 and although these may be a fait accompli, they will still be important to ensuring the company can proceed to Phase 3.
- **Increased sales from Travelan.** As noted in our previous reports on Immuron, Travelan sales have been growing significantly and this trend has continued (Figure 4). Between 1 July 2023 and 29 February 2024, the company made $3.2m in sales revenue, a figure that was up 168% on the prior corresponding period. The company's gross profit grew too, by 147% to $2.2m. The remainder of FY24 could see further growth, driven by the peak spring and summer travel period in the US.
- **Completion of the Campylobacter Challenge**. This is a separate trial for Travelan being conducted with the US Naval Medical Research Command (NMRC). The in-patient stage was completed in December 2023 with the last patient's last visit scheduled for completion in June. Headline results are expected early in the second half of this calendar year, although it is not entirely implausible to think there could be interim data prior to that, and this too could be a catalyst.
- **Progress with IMM-529**. The company has not begun clinical trials for IMM-529 yet but is planning a pre-IND submission to the FDA during 2024. The initial focus remains on the treatment of patients with recurring disease than all sufferers. Granted, it could be a few years before it is commercialised, although clinical trial results in the interim would inevitably help the company's cause.
- **Potentially generating further assets from its technology platform**. The progress of Travelan onto the market as a dietary supplement and into Phase 3 against a specific medical indication bodes well for the company's platform and its potential to generate future assets.

Figure 4: Travelan sales (left side) and gross profit (right side)



Source: Company, Pitt Street Research

Our valuation of Immuron

In our initiating report in October 2023, we had valued Immuron using a Sum of the Parts (SOTP) approach, evaluating Immuron's legacy business, IMM-124E and IMM-529, separately. Our total valuation was A$0.25 per share under our base case projection, while our bull case projection placed the valuation at A$0.35 per share (Figure 5), signifying substantial upside potential when compared with the current market price.

We reiterate our previous valuation range as we remain convinced with the potential of the current key assets of Immuron and the management's plans to expand its applications. The impressive results exhibited by the company for just Travelan, in the latest sales figures, are an indication of the significant untapped potential of the company.

Figure 5: Immuron's SOTP valuation

SOTP valuation	Base Case		Bull Case	
Drugs	**A$m**	**A$ps**	**A$m**	**A$ps**
Legacy business	29.01	0.13	41.21	0.18
IMM-124E	15.70	0.07	23.55	0.10
IMM-529	3.18	0.01	4.32	0.02
rNPV	**47.89**	**0.21**	**69.08**	**0.30**
Cash (close of FY24 - PSR estimate)	9.50	0.04	9.50	0.04
Debt (close of FY24 - PSR estimate)	-	-	-	-
Equity Value	**57.38**	**0.25**	**78.57**	**0.34**
Current Price		0.10		0.10
Upside		150%		250%

Source: Pitt Street Research

Key risks for Immuron

We see the following major risks for our investment thesis on Immuron:

- **Uptake risk:** There is a risk that Immuron may not be able to gain traction in its target markets. There is no guarantee that Immuron and its distributors will secure a higher-than-expected specific number of purchase orders for its existing and new products. If this risk materialises, Immuron will likely report financial results below the forecasts, which could adversely affect its valuation.
- **Clinical risk:** There is a risk that the clinical programmes of IMM-124E and IMM-529, sponsored by Immuron, may not meet their primary or secondary endpoints. The success rate for clinical trials varies significantly across technologies and is typically lower in earlier stages. Although the risk for IMM-124E has reduced somewhat after recent results, it has not entirely been eliminated given more trials will have to be conducted with it.
- **Regulatory risk:** There is a risk that approval in highly regulated markets, such as the US and Europe, takes longer than expected, resulting in a delay in attaining revenue generation status.
- **Timing risk:** There is a risk that Immuron's clinical programmes may take longer to execute than expected, negatively affecting investor sentiment towards the company.
- **Competition risk:** There is a 'what if' scenario in which new and/or existing competitors develop a superior and more affordable product targeting the same market opportunity as Immuron. If this risk materialises, it could hinder the company's market share growth and margins.
- **Forex risk:** When commercialised, Immuron's earnings will be in the local currency of applicable markets. Currency fluctuations can impact the company's total earnings in AUD.

Appendix I – Glossary

Antibiotic – Medicines that inhibit growth of bacteria and fight bacterial infections.

Bovine Colostrum – A milky fluid a cow secretes after giving birth that may help improve immunity, fight germs, and promote gut health. It is extremely nutritious and contains more nutrients than regular milk.

CHIM Study – A well-characterised strain of an infectious agent is given to adult volunteers in order to better understand human diseases, how they spread, and find new ways to prevent and treat them. These studies play a vital role in helping to develop vaccines for infectious diseases.

Clostridioides Difficile – A gram-positive bacterium drumstick-shaped bacillus and a spore-forming obligate anaerobe that produces toxins and is the primary cause most often associated with antibiotic-associated diarrhoea.

Enterotoxigenic Escherichia Coli (ETEC) – The gut bacterium, Escherichia coli produces toxins that stimulate the lining of the intestines, causing excessive fluid secretion and, thus, diarrhoea.

Gut dysbiosis – An imbalance in bacterial composition, changes in bacterial metabolic activities, or changes in bacterial distribution within the gut.

Immunoglobulin – Glycoproteins produced by plasma cells that your immune cells make to fight off bacteria, viruses, and other harmful invaders.

Immunotherapeutic – Immunotherapeutic agents use or modify immune mechanisms.

Lipopolysaccharide bacterium – A cell wall component characteristic of gram-negative bacteria, is a representative pathogen-associated molecular pattern that allows mammalian cells to recognize bacterial invasion and trigger innate immune responses.

Microbiota/Microbiome – Microbiota refers to a community of microorganisms in a specific niche, such as the human gut. The microbiome comprises all the genetic material within a microbiota.

Polyclonal – Represents a mixture of immunoglobulin molecules from different B cells that recognize multiple epitopes on the same antigen.

Prophylaxis – Measures designed to preserve health (as of an individual or of society) and prevent the spread of disease.

Pathogen – A microbe that can cause damage in a host.

Placebo – A medical treatment or procedure designed to deceive the participant of a clinical experiment. It does not contain any active ingredients but often still produces a physical effect on the individual.

Appendix II - Analyst certification

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

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