Progressing fast with clinical trials

Share Price: A$0.073

ASX: IMC

Sector: Healthcare

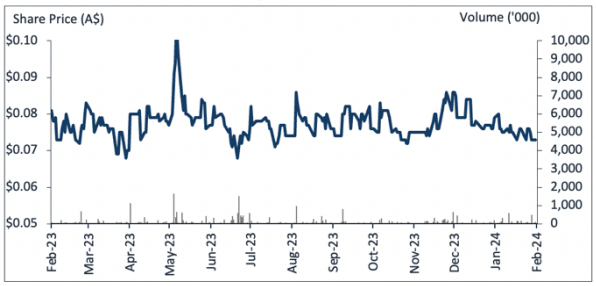
6 February 2024

Immuron (ASX: IMC) is an Australian biotechnology company developing commercial and clinical stage assets that help transform the standard of care for gastrointestinal disorders. Immuron has two flagship commercial products – Travelan and Protectyn – and three clinical stage assets – IMM-529, IMM-124E, and CampETEC.

Market cap. (A$m)	16.6
# Shares outstanding (m)	227.8
# Share fully diluted (m)	243.4
Market cap full. dil. (A$m)	17.7
Free float	66.0%
12-months high/low (A$)	0.105 / 0.067
Avg. daily volume ('1000)	111
Website	www.immuron.com.au

Source: Company, Refinitiv Eikon, Pitt Street Research

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



Source: Refinitiv Eikon, Pitt Street Research

Moving ahead with two key clinical studies

The company has made significant progress in recent months. In October 2023, Immuron announced the second cohort of 34 participants in the clinical trial for evaluation of efficacy of Travelan to prevent moderate to severe diarrhoea. The Phase 2 clinical study is designed to evaluate the protective efficacy of the new product compared to a placebo in a controlled human infection model (CHIM). The readouts of this study will likely be reported by the second half of 2024 and favourable outcomes will position the company well Phase 3.

In addition, in December 2023, the US Naval Medical Research Command (NMRC) completed the in-patient phase of the Campylobacter Challenge clinical study, in collaboration with Immuron. The NMRC has prioritised the clinical development of this study for the evaluation of efficacy of a new therapeutic product to prevent infectious diarrhoea caused by Campylobacter. The headline results from the study are due to be released by mid-2024.

We are pleased with Immuron's top-line growth in H1 FY24. Immuron's sales of Travelan in Australia increased from A$0.3m in H1 FY23 to A$1.9m in H1 FY24. In the US, Travelan's sales grew from A$0.3m in H1 FY23 to A$0.49m in H1 FY24. This is a testimonial to the strong potential of Immuron's assets.

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Clear milestones set for all clinical programmes

Immuron has clear plans for its four clinical stage assets and there are milestones for investors to look forward in the coming months. For IMM-124E, the company is pursuing a regulatory pathway to license Travelan against traveller's diarrhoea. For IMM-529, the company is planning a pre-IND submission to the FDA during 2024. For CampETEC, Immuron is planning to start two Phase 2 trials, one in Campylobacter and another in (ETEC).

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. Please refer to page 9-10 for more details on our valuation and the key risks to our thesis.

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Re-introduction to Immuron

Immuron is an Australia-based biopharmaceutical company developing and commercialising oral immunotherapeutics for the treatment of gut-mediated diseases. The company has both commercialised assets and clinical stage assets with its products designed to treat a range of infectious diseases through oral immunoglobulin-based therapies.

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

Its proprietary technology platform is dedicated to developing and commercialising a novel class of specifically targeted polyclonal antibodies with the potential to address unmet medical needs. These oral polyclonal antibodies are designed for delivery within the gastrointestinal (GI) tract and do not enter the bloodstream, which in turn enhances safety and tolerability without compromising efficacy. Immuron's primary drug candidates have the potential to transform the existing treatment paradigms for moderate to severe cases of Campylobacterosis, Clostridiodes difficile infection (CDI), Enterotoxigenic Escherichia coli (ETEC) infections, and traveller's diarrhoea (TD).

Immuron boasts of a robust intellectual property (IP) portfolio encompassing compositions and methods for the treatment and prevention of enteric bacterial infections in key geographies. The company also has well-established distribution capabilities. In Australia, Immuron's products are available through a retail network of more than 3,500 pharmacies. In the US, its products are available at Passport Health Travel Clinics (the US's largest travel health clinic) and on Amazon.

Travelan and **Protectyn** are Immuron's flagship products. The former is commercially available in three global markets – Australia, Canada, and the US – while the latter is only available in Australia.

Travelan ensures a significantly lower risk of TD

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 and can be proactively taken before meals to prevent disease. It is the #2 Stock Keeping Unit (SKU) and fastest growing product in the antidiarrheal category across all pharmacies in Australia.

Travelan has been specifically formulated to fight ETEC, which is the leading cause of TD. Travelan uses hyperimmune bovine colostrum (BCP) from cows vaccinated against various strains of ETEC to protect against TD. The key benefit of Travelan is that it helps to stop these bacteria from attaching to the intestinal wall and neutralises the bacteria's ability to cause diarrhoea, digestive upset, and other associated symptoms.

FDA approval of Travelan for treating diarrhoea will be a key catalyst for US growth in future.

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.

Travelan is presently marketed in Australia, Canada, and the US. However, it is marketed differently in each of these markets. It is indicated to reduce the risk of TD and gastro-intestinal disorders in Australia. In Canada, Travelan is licensed as a natural health product indicated to reduce the risk of TD. In the US, Travelan is marketed as a dietary supplement for the protection of the digestive tract. Travelan was also successfully launched in the US on Amazon.com, with safety stock established for all products and markets. 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.

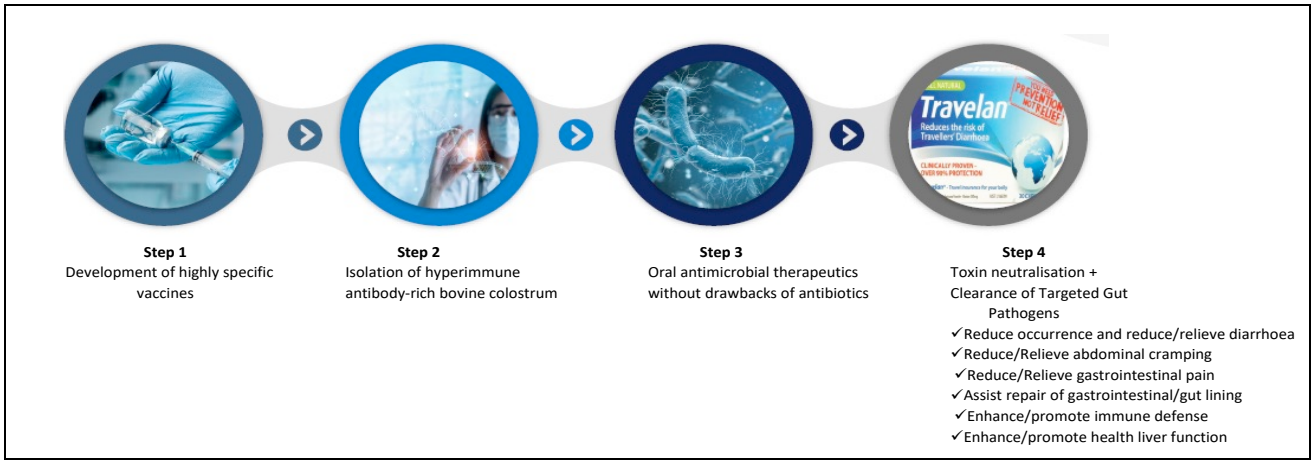
Protectyn helps improve immune function by targeting gut bacteria

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 crucial technology platform boosts its prospects

Immuron's technology platform (Figure 1) combines natural human nutrition and health benefits of bovine colostrum with a novel class of specifically targeted oral polyclonal bodies that provide delivery in the GI tract. The active pharmaceutical ingredient (API) for a particular application is prepared using the first milking colostrum in dairy cows. Bovine colostrum is the first milk a cow gives after a young one is born. Colostrum has higher levels of immunoglobulin G. Immuron's technological platform enables the extraction of polyclonal immunoglobulins from engineered hyper-immune bovine colostrum. The platform helps in targeting viruses and bacteria in the GI tract and neutralising the toxins produced at mucosal surfaces. There are 13 types of ETEC that the cow is vaccinated for. Such an inoculation process helps in the activation of generalised immune response in the host animal to produce antibodies. The hyper immune colostrum which is produced under rigorous dairy industry standards and GMP protocols, is freeze-dried to produce a powder that can be packaged as tablets, capsules, bulk dry powders, or individual sachets for point of care reconstitution, or in combination with other active ingredients.

Figure 1: Immuron's technology platform



Source: Company

Four clinical programmes are underway

The company is actively exploring various research and development avenues to unlock the full potential of its proprietary technology platform and assets. Its four clinical-stage assets are IMM-124E, IMM-529, CampETEC, and Travelan.

I. IMM-124E

IMM-124E is the API used to manufacture both Travelan and Protectyn. IMM-124E has been designed in a way that blocks and reduces bacterial growth without adversely affecting essential microbiota. It is a first-in-class, oral polyclonal antibody therapeutic targeting gram negative ETEC and other cross-reactive pathogenic bacteria in the gut that can lead to blockage of pathologic activities. IMM-124E has recently received FDA Investigational New Drug (IND) approval.

Clinical trials show that IMM-124E has been able to exhibit protective efficacy of up to 84-90% against moderate to severe diarrhoea.

The company has been pursuing antibacterial activities of IMM-124E, thereby focusing on a better understanding of the mechanism of action associated with initial observations. IMM-124E has also undergone clinical testing in randomised, double-blind, placebo-controlled clinical trials. Clinical trials show that IMM-124E confers protective efficacy of up to 84-90% against moderate to severe diarrhoea upon being challenged with ETEC vis-à-vis a placebo. The trials also show a reduction in abdominal cramps and stomach pain compared to those who did not receive Travelan.

II. IMM-529

Immuron is embarking on a new clinical development programme that will focus on the treatment of patients suffering from CDI. IMM-529 is an oral formulation intended for patients suffering from recurring CDI. It contains polyclonal bodies cross-reactive to Toxin B, spores, and vegetative cells of the bacterium. Antibodies of IMM-529 have been demonstrated to bind to and neutralise human and animal C Difficile isolates. IMM-529 has a three-pronged novel approach. This approach has yielded exceptional results in pre-clinical studies, including the prevention of primary disease, treatment of primary disease, and suppression of recurrence.

Immuron has commenced preclinical work on IMM-529 and has demonstrated some positive signs. In the preclinical stage, 80% efficacy was exhibited in treatment studies that did not use antibiotics such as vancomycin. In relapse studies, the survival rate was observed to be 90% versus 22% survival rate in the control group.

III. CampETEC

CampETEC is 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 868 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 Q2 2024.

Immuron's recent achievements

Cohort 2 clinical study commences for Travelan

On October 18, 2023, Immuron announced the second cohort of 34 participants in the clinical trial for evaluation of efficacy of Travelan to prevent infectious diarrhoea caused by ETEC. The first cohort in-patient stage of the study was completed in August 2023. The Phase 2 clinical 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.

The double-blind study was divided into two cohorts of approximately 30 subjects (60 in total) dosed with Travelan or placebo for two days prior to the challenge continuing for seven days. All study participants were challenged with E.Coli, monitored for symptoms, and treated with antibiotics. All study participants are likely to return as outpatients for two weeks, one month, and six months follow-up visits. The final six-month follow up interviews are likely to be initiated in January 2024 and are expected to be completed in April 2024. Headline results of the clinical trial are likely to be reported by the second half of 2024.

Headline results from Phase 2 study for Travelan and Campylobacter Challenge study to be reported by H2 2024.

The Campylobacter Challenge study is underway

On December 4, 2023, the US Naval Medical Research Command (NMRC) initiated the clinical evaluation of a new oral therapeutic targeting Campylobacter and ETEC, in collaboration with Immuron. The NMRC has prioritised the clinical development of the study for the evaluation of efficacy of the new therapeutic product to prevent infectious diarrhoea caused by Campylobacter. The clinical study is being led by Principal Investigator, Dr Kawsar Talaat, MD at John Hopkins University Medical Campus, Baltimore, Maryland.

On December 22, 2023, the US NMRC completed the in-patient challenge phase of the Campylobacter clinical study. A total of 30 participants were enrolled in the study. 27 of the 30 subjects were dosed either with investigational medical product or placebo. All study participants were treated with antibiotics and discharged from the clinic. There is likely to be a return of the study participants as outpatients for subsequent follow-up visits with the last patient's last visit scheduled for completion in June 2024. Headline results from the trial are likely to be reported in the second half of 2024.

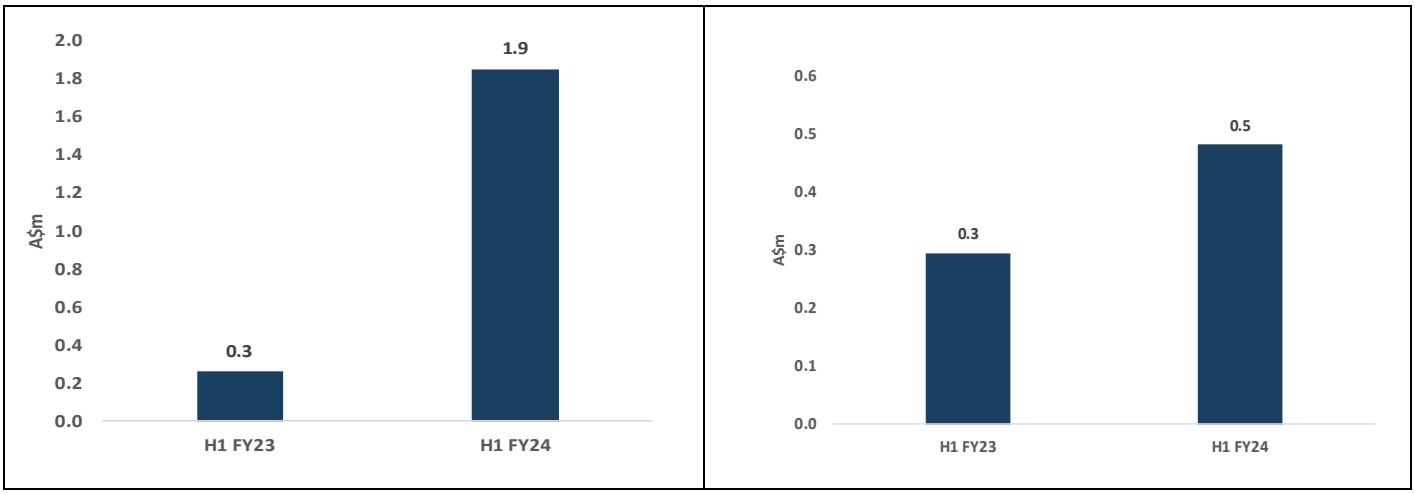
Impressive financial results

Immuron's sales of over-the-counter gastrointestinal and digestive health immune supplement Travelan increased from A$0.03m in Q1 FY23 to A$1.4m in Q1 FY24 in Australia. In the US, Immuron's sales of Travelan increased from A$0.02m in Q1 FY23 to A$0.2m in Q1 FY24.

On a half-yearly basis, Immuron's sales of Travelan increased significantly from A$0.3m in H1 FY23 to A$1.9m in H1 FY24. In the US, Travelan's sales grew from A$0.3m in H1 FY23 to A$0.49m in H1 FY24 (Figure 2).

We believe that Travelan's sales are likely to show further growth closer to the peak spring or summer travel period. Furthermore, Immuron anticipates continued demand for replenishment of Travelan stock with retail pharmacies.

Figure 2: Travelan sales registered strong growth in Australia (ls) and the US (rs)



Source: Company, Pitt Street Research

Immuron's clear plans for clinical programmes

Immuron has a clear plan of action and realistic expectations for its four clinical programmes:

- **IMM 124E** – Primary care physicians are impressed with clinical efficacy endpoint targets demonstrating >80% protection against the development of diarrhoea. Achieving base-case efficacy target is likely to enable the use of IMM-124E by travelers going to highest risk regions such as Central America, Asia, and Africa. The base case yearly revenue in the US for IMM-124E has been projected at US$102m based on the estimated market size and pricing. Top-line results and clinical study report are expected by H1 2024.

  The company is also pursuing a regulatory pathway to license Travelan with the FDA via a biologics license application (BLA) with a proposed indication to prevent TD. Currently, there are no FDA approved drugs for TD. The company is estimating FDA approval in mid-2027 assuming successful completion of the current Phase 2 study and a successful Phase 3 study thereafter.

Immuron is pursuing a regulatory pathway to license Travelan with the US FDA via a BLA with a proposed indication to prevent TD.

- **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. The pathway to the market is not quick by any means, with the asset unlikely to get approval before 2029 at the earliest, accounting for 6-12 months for the investigation of IND (about 18 months for Phase 2, 24 months for Phase 3, and up to 18 months for regulatory approval).

  The base case yearly revenue in the US for IMM-529 has been projected at US$93m for the target patient population based on the estimated market size, anticipated payer restrictions, pricing, and competition. Positioning of IMM-529 earlier than the second recurrence and efficacy targets could lead to a higher uptake.

- **CampETEC** – Immuron is planning to start two Phase 2 trials, one in Campylobacter and another in ETEC. There are certain regulatory processes that the company is likely to undergo for which Phase 2 studies are required. The Institutional Review Board (IRB) is approving a protocol

for CampETEC and the company is planning to start the clinical trial early in 2024. Travelan's Phase 2 clinical trial is expected to report data around mid-2024. Phase 3 studies are also likely to be required before approvals for the drug are secured. Immuron is also moving ahead with a clinical programme to get the status for a prescription biologic drug in Australia.

– **Travelan** – The Travelan USU clinical trial reached 50% of 868 patients in November 2023. Results of the study are likely to provide a good guideline as to how many patients would be needed in the trial for a statistically significant result. Currently, Immuron is undertaking discussions around funding Phase 3 and the CDI programme (Figure 3).

Figure 3: Key progression and milestones of Immuron's clinical assets

	H2 2022	H1 2023	H2 2023	H1 2024
IMM-124E	FDA IND approved for single daily dose IMM-124E ETEC CHIM clinical trial	• IRB approval • Initiated IMM-124E ETEC CHIM clinical trial	• 100% of patients enrolled • Completion of in-patient phase ETEC CHIM clinical trial	• Topline results for IMM-124E ETEC clinical trial • Clinical study report
CampETEC	• Submitted response letter to FDA clinical hold • Immuron sponsored Toxicology study completed	• Toxicology study report • FDA IND approved (clinical hold released)	• Institutional Review Board approval of NMRC CampETEC Campylobacter CHIM clinical trial protocol • FDA approval of IND amendment for change to protocol	• Initiate NMRC CampETEC Camplylobacter CHIM clinical trial • Completion of in-patient phase CampETEC Campylobacter CHIM clinical trial
IMM-529	600mg solid dose active formulation development		IMM-529 cGMP manufacture	IMM-529 (CDI) Pre-IND submission
Travelan	USU P2TD IMM-124E field clinical trial recruitment commencement		50% of 868 participants recruited	• Completion of enrollment • Completion of in-patient phase

Source: Company

Immuron is likely to become a different company from what it is currently and when its existing assets pass trials and attain commercialisation.

In terms of competing over-the-counter products, there are not too many comparable products to that of Immuron. If one takes a conservative estimate of the number of people traveling in US and Europe to high-risk regions, we can see that the market potential is significantly higher than what Immuron is currently doing. In the longer term, Immuron is likely to be a different company from what it is currently and when its existing clinical assets (IMM-124E and IMM-529) pass clinical trials and become commercialised. But in the short to medium term, Immuron expects sales of its current commercial assets to register robust growth. With continued recovery in international travel numbers, the US market could hit the highest sales even in the next financial year or two. The company is also looking at expanding the markets beyond Australia, Canada, and the US by talking to potential marketers in both Europe and Asia.

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 4) 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 half-yearly results, are an indication of the significant untapped potential of the company.

Figure 4: 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		0.08		0.08
Upside		231%		354%

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.
- **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 – 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 of 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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The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation.