PITT STREET RESEARCH

Immuron Ltd.

Immunity for the gut

Share Price: A$0.072

ASX: IMC

Sector: Biotechnology

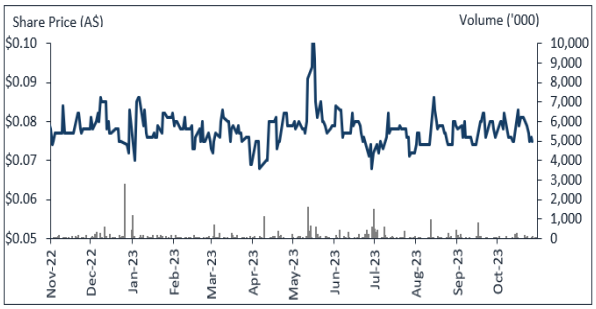
1 November 2023

Immuron (NDQ: IMRN, ASX: IMC) is an Australian biotech company developing commercial assets that help transform the standard of care for gastrointestinal disorders. Through its proprietary technology platform, IMC creates pharmaceuticals to treat gut-mediated diseases through oral immunoglobulin-based therapies. IMC has 2 flagship commercial products – Travelan and Protectyn – and 3 clinical-stage assets – IMM-529, IMM-124E and CampETEC.

Market Cap. (A$ m)	16.4
# shares outstanding (m)	227.8
# share fully diluted (m)	242.4
Market Cap Ful. Dil. (A$ m)	17.5
Free Float	100%
12-months high/low (A$)	0.105 / 0.068
Avg. 12M daily volume ('1000)	122.3
Website	www.immuron.com.au

Source: Company, Pitt Street Research

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



Source: Refintiv Eikon, Pitt Street Research

Travelan and Protectyn are attractive amid concerns related to antibiotic resistance

Travelan is Immuron's flagship oral immunotherapeutic product, commercially available in three international markets – Australia, Canada, and the US. Travelan is an immune supplement that helps reduce the risk of traveller's diarrhoea (TD) and minor gastrointestinal disorders. It is superior because it is both a proactive and reactive treatment. Protectyn is Immuron's other oral immunotherapeutic product, only available in Australia at present. It is a dietary supplement for gut health that has been formulated to help maintain a healthy digestive function and support the liver. Both are likely to remain attractive amid concerns related to antibiotic resistance. Immuron's sales have increased by 136% in FY23 to reach A$1.8m (compared to A$0.8m in FY22).

Immuron's clinical assets offer further upside

IMM-124E is the drug substance and the active pharmaceutical ingredient in Travelan. In the U.S., Travelan® is marketed as a dietary supplement for digestive tract protection and as such the company cannot make any claims about the therapeutic benefits against Travellers' diarrhoea. But the company is pursuing a regulatory pathway to license Travelan against travellers' diarrhoea (Travelan Rx), an indication for which there are no FDA approved drugs for. IMC has just initiated a Phase 2 clinical trial in the US with IMM-124E. As for IMM-529 and CampETEC, these are oral formulations intended for patients suffering from recurring Clostridioides Difficile infection and moderate to severe campylobacteriosis respectively. Shareholders can look forward to continued progress with these assets too.

Valuation range of A$0.25–0.35 per share

Using a Sum of the Parts (SOTP) valuation, we value Immuron at A$0.25 per share under a base case projection and A$0.35 per share in an optimistic (or bull) case scenario. We see the key value-creating catalysts as the advancement of the company's clinical-stage assets with the end goal of bringing these assets to market. Please see p.20 for the key risks.

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Introducing Immuron

Immuron (NASDAQ: IMRN, ASX: IMC) is an Australian-based biopharmaceutical company focused on the development and commercialisation of oral immunotherapeutics for the treatment of gut-mediated diseases. It is a diversified company from an investor perspective because it has both commercialised assets and clinical stage assets. The company's assets are based on its proprietary technology platform which is based on polyclonal immunoglobulins (IgG) derived from engineered hyper-immune bovine colostrum.

Commercial product portfolio recorded high uplift in sales

Travelan is superior because it is both a proactive and reactive treatment

Travelan and Protectyn are Immuron's flagship products. The former is commercially available in three global markets – Australia, Canada, and the United States – while the latter is only available in Australia. **Travelan** is an orally administered, over-the-counter immune supplement that helps in reducing the risk of traveller's diarrhoea (TD) and the risk of minor gastrointestinal disorders. It is not just a reactive treatment and can be proactively taken before meals to prevent disease.

Immuron's other oral immunotherapeutic product is **Protectyn**. It is a dietary supplement for gut health, formulated to help maintain a healthy digestive function and support the liver. Global sales of Travelan and Protectyn increased by 136% in FY23 to A$1.8m (compared to A$0.8m in FY22). This growth was attributable to increasing sales in both Australian pharmacies and in Passport Health travel clinics in the US, as travel numbers return to pre-COVID levels.

Four clinical programs are underway

The company is actively exploring various research and development avenues to unlock the full potential of its proprietary technology platform and its assets (both those commercialised and those in a clinical phase). The company's three clinical-stage assets are:

- IMM-124E,
- IMM-529, and
- Camp-ETEC

IMM-124E is the drug substance and the active pharmaceutical ingredient in Travelan. In the U.S., Travelan® is marketed as a dietary supplement for digestive tract protection and as such the company cannot make any claims about the therapeutic benefits against Travellers' diarrhoea. But the company is pursuing a regulatory pathway to license Travelan with the Food and Drug Administration (FDA) via a Biologics License Application (BLA) with a proposed indication to prevent travelers' diarrhoea (TravelanRx). Currently there are no FDA approved drugs for the prevention of travellers' diarrhoea.. The company plans to change that and has just initiated a Phase 2 clinical trial in the US.

IMM-529 is an oral formulation intended for patients suffering from recurring Clostridioides Difficile infection. The company has not begun clinical trials just yet, but is planning a pre-IND submission to the US FDA during FY24.

CampETEC is an oral therapeutic targeting *Campylobacter* and Enterotoxigenic *Escherichia coli (*ETEC) infections. Immuron is collaborating with the U.S Naval Medical Research Command (NMRC) with this asset. Earlier this year, the FDA approved the Investigational New Drug (IND) application to test the safety and protective efficacy in a first-in man study.

Two human infection model clinical studies involving challenge with ETEC and Campylobacter are planned, with the first study due to commence in 2023.

In addition to the current CampETEC and IMM-124E trials, there are two other clinical programs with Travelan, making a total of four. Two of Immuron's clinical programs (one with CampETEC and one with Travelan) are sponsored by the US Department of Defense (US DoD). The US DoD has gotten on board because gastrointestinal diseases are a significant problem when US soldiers are abroad, and the Department is searching for solutions that can make a difference.

A significant market opportunity exists for Immuron's assets

Immuron's clinical programs have the potential to transform the existing treatment paradigms for moderate to severe Campylobacteriosis, recurrent *Clostridioides difficile* infections (CDIs), Enterotoxigenic *Escherichia coli* (ETEC) infections, Shigellosis, and TD. And there are significant market opportunities ahead of the company. According to GlobalData, the global market for CDIs is expected to grow to almost $1.7bn by 2026. The market potential in the US for Travelan is estimated at US$83m, and the EU market is estimated at US$50m. The US is an important market, not just because of the size of the market but also because Travelan is underpenetrated there. In our view, given the size of the global market, there is significant potential upside Immuron.

Eight key reasons to look at Immuron

1) **Immuron has both commercial and clinical stage assets** – Immuron is a rare company, offering both stable revenues due to existing products on the market and growth potential with assets in the clinic. The company's clinical programs - IMM-124E, IMM-529 and CampETEC - have the potential to transform the existing treatment paradigms for several gut-mediated diseases.
2) **IMM-124E has a unique path to market** – IMM-124E is an existing compound in Travelan. The reason Immuron is conducting a clinical trial in the US is because Travelan is only approved as a general dietary supplement and not specifically for traveller's diarrhoea, although it is so approved in Australia and Canada with specific therapeutic claims as a preventative treatment to travellers' diarrhoea. This a unique path to market in that Immuron is testing a clinical asset with comprehensive data supportive of its cause and when it eventually gets market approval as a therapeutic drug in the USA, it will potentially transform the existing Travelan business.
3) **Significant partnerships will help advance the company's ambitions** – These include a notable partnership with the US Department of Defense that has led to two clinical trials (for Travelan and CampETEC) that are currently underway. The company also has well-established distribution capabilities including retail network of more than 3,500 pharmacies in Australia as, in the US, that country's largest travel health clinic network (Passport Health) as well as Amazon.
4) **Immuron's strong Intellectual Property (IP) portfolio –** Immuron's technology platform can potentially transform the GI disorders treatment landscape. The company owns several patent families for the hyper-

immune colostrum. Immuron continued to expand its patent portfolio during FY23 and was granted patents for compositions and methods for the treatment and/or prophylaxis of *Clostridioides difficile* associated disease in Australia, New Zealand, the US, and several European countries. It also has patent families for enteric bacterial infections in key geographies.

5) **There's substantial market potential for Immuron's assets –** According to GlobalData, the global market for CDIs is expected to grow to almost $1.7bn by 2026. The market potential in the US for Travelan is estimated at US$83m, and the EU market is estimated at US$50m. Given the size of both the global TD and CDI market, there is significant potential upside for the company. As we will outline later in the report, independent third-party data from Lumanity suggests that IMM-124E and IMM-529 could each reach ~US$100m in annual sales in the United States with both being conservative estimates with IMM-529 only accounting for second recurrence of CDI.
6) **Immuron is well-funded for the next few years** – The company has sufficient cash for the next couple of years. Immuron ensures prudent cash flow management by bolstering its commercial operations and advancing clinical trials. Most funding has come from grants provided by the US DoD, with Phase 2 studies funded by the US military.
7) **Seasoned leadership team in place** – Immuron has a seasoned leadership team with significant expertise in the pharmaceutical and biotechnology industries. The CEO, Steven Lydeamore, has over 30 years of international pharmaceutical experience. He was last appointed as the CEO of Anatara Lifesciences Ltd. During his tenure, Anatara successfully transitioned from a preclinical to a clinical company, following the development of a gastrointestinal tract delivery technology (from which two products have commenced human clinical trials).
8) **The company is undervalued at the current price** – We have Immuron at A$0.25-$0.35 per share. We foresee the company being re-rated as it continues to grow Travelan's sales and advances its clinical programs. We see the two most important catalysts being the company's 1HY24 results (due in February next year) and the obtaining of IND status from the FDA for IMM-529.

Immuron is a leading biopharmaceutical company

Immuron's proprietary technology platform focuses on the commercialisation of a novel class of specifically targeted polyclonal antibodies

Immuron is a biotechnology company focused on advancing commercial assets that have the ability to transform the standard of care for gastrointestinal disorders. The company operates in both commercial and clinical stages with its pharmaceutical products designed to treat a range of infectious diseases through oral immunoglobulin-based therapies. The company's 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. This enhances safety and tolerability without compromising efficacy. Immuron's primary drug candidates (currently being developed clinically) have the potential to transform the existing treatment paradigms for moderate to severe cases of Campylobacteriosis, *Clostridioides difficile* infection (CDI), Enterotoxigenic Escherichia coli (ETEC) infections and TD.

Immuron's clinical assets are considered as biologics by the US FDA with 12 years of market exclusivity being conferred from date of approval in the US. 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, including Australia, the US, New Zealand, India, Canada, and several European countries, most of which are set to expire on March 4, 2024. Furthermore, it has also been granted the IP portfolio for methods and compositions for the treatment and prophylaxis of *Clostridiodes difficile* associated disease across the above-mentioned geographies, expiring on April 17, 2034.

To push its flagship products, Immuron has established a strong presence within the Australian retail pharmacy network, where evidence-based OTC products are sold (Figure 1).

Figure 1: Immuron's distribution network

	Australia	US	Canada
Retail Pharmacy	✓		✓
B2B	✓	✓	
E-commerce	✓	✓	✓

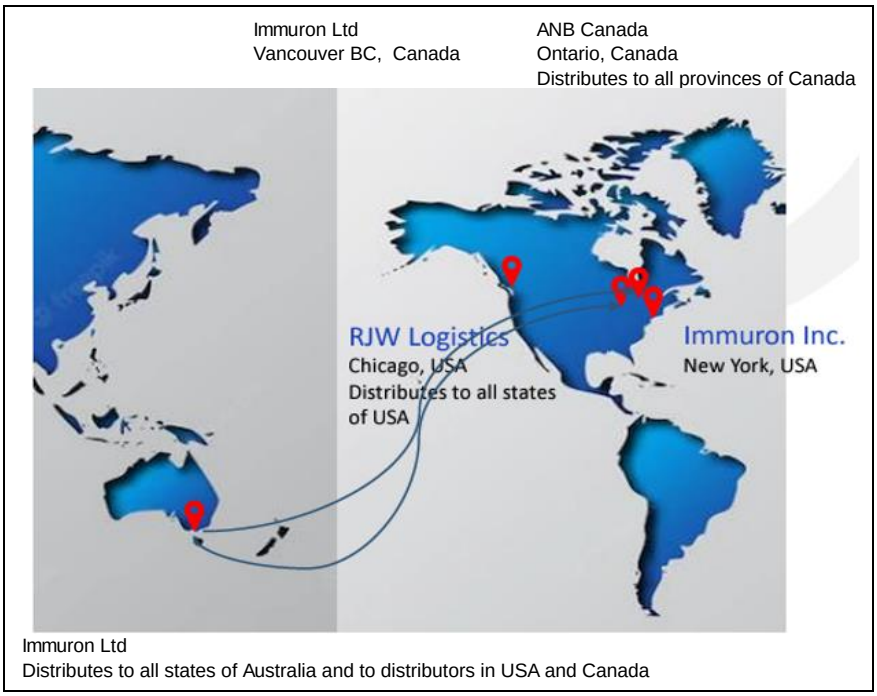
✓ Established

✓ Developing

Source: Company, Pitt Street Research

Immuron is currently pursuing organic growth and M&A to expand the sales of commercial products within existing and new geographies and to increase product offerings. Immuron launched its own shopfront on Amazon.com in the US during July 2023. Immuron also plans to relaunch into retail pharmacy in FY2024 for which it has submitted the review to a major retail chain (Figure 2).

Figure 2: Immuron's region wise distribution



Source: Company

History of the company

Immuron was incorporated in 1994 and has been listed on the ASX since April 30, 1999. It successfully completed an initial public offering on the NASDAQ in June 2017. Immuron has been marketing Travelan since 2004, when it received the initial approval in Australia. Subsequently, Travelan was also licensed for sale in Canada through Immuron's partnership with Paladin Labs in 2013. The authorisation for Travelan's sale in Canada came with a Product License secured by Paladin Labs from Health Canada. Immuron also secured a partnership with the US-based provider of travel medicine services, Passport Health, for the sale of Travelan throughout its clinic network in late 2015. Passport Health, with its more than 250 travel clinic locations, is committed to delivering first class medical care and maintaining a highly trained medical staff. It has leveraged its expertise in travel medicine to service the vaccination, wellness, examination, and records management needs of corporations, government agencies, and other large organisations.

The likely gamechanger for treatment of Traveller's Diarrhoea

It is unusual for a small cap biotech stock to have a commercial product on the market. Immuron has been actively engaged in pursuing opportunities to develop and commercialise its proprietary oral immunotherapeutic products. Immuron's products are not absorbed by the body and do not have resistance factors that produce the same outcome as antibiotics. Immuron's products are a subset of the global digestive health market, a multi-billion-dollar market.

Immuron has two commercial products - Travelan and Protectyn. Both the products are listed medicines on the Australian Register for Therapeutic Goods (ARTG).

Immuron's flagship asset Travelan ensures a significantly lowered risk of TD

Travelan is an orally administered, over-the-counter immune supplement that helps in reducing the risk of traveller's diarrhoea (TD) and the risk of minor gastrointestinal disorders. 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.

Since Travelan is not an antibiotic, it comes with no risk of the side effects of antibiotics and thus does not contribute to worldwide concerns about bacterial drug resistance.

Since Travelan is not an antibiotic, it comes with no risk of the side effects of antibiotics (such as rashes, dizziness and, ironically, diarrhoea itself) and thus 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 travelling or at home. It is designed to target and neutralise pathogenic bacteria and the toxins the bacteria produces in one's GI tract before one gets sick. It also provides assistance in maintaining the delicate balance of gut microbiota during stress or weakened immunity by eliminating invading pathogens.

How does Travelan work?

Pathogenic bacteria in contaminated food or water attack the intestines and release diarrhoea causing toxins. Travelan contains high levels of antibody specific to against 13 strains of ETEC, which is the most common cause of TD. Travelan directly targets the pathogens in the gut and prevents them attaching to the intestinal wall. Consequently, it prevents infection and its resulting symptoms from occurring.

Travelan's active ingredient is hyperimmune BCP, a natural and rich source of antibodies that bind to ETEC and other diarrhoea and cause bacteria in the GI tract. 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.

Where is Travelan marketed?

Travelan is marketed in Australia, Canada, and the US. However, it is marketed differently in each of these markets. In Australia, it is indicated to reduce the risk of TD and gastro-intestinal disorders. In August 2023, Immuron executed a new packaging and supply agreement with a new Contract Manufacturing Organization and received a GMP clearance from the

TGA, allowing the company to recommence selling to retail pharmacy wholesalers and other customers. 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 digestive tract support**. *Travelan has not yet been assessed by the FDA for treating diarrhoea*** and Immuron is working to gain that approval. Its IND was cleared in December 2022. We believe that the approval of Travelan as a preventative treatment for TD is likely to result in a significant increase in commercial opportunities for Travelan in the US.

Immuron's focus is two-fold:

- First, on expanding the sales of Travelan across multiple geographies through growth in the distribution network and sales and marketing initiatives.
- Second, on conducting clinical work with IMM-124E (a key compound in the existing Travelan product) with the hope this new Rx may significantly expand the commercial opportunities of the product in the USA but still serve the same market need. Immuron is alluding to the eventual product as TravelanRx but we will use Travelan interchangeably in this section to allude to the existing and new product.

How can Travelan be purchased and consumed?

Travelan is available for purchase from pharmacies in Australia and Canada. In Australia, Travelan is sold in chemists for A$33-A$37 in packs of 30, dependent on the individual pharmacy. In the US, it is sold through Amazon and Passport Health travel medicine clinics for similar pricing. Travelan can be taken not just as a reactive antibiotic but also before meals to prevent disease. One caplet of Travelan needs to be taken before every meal. Additional caplets might be taken when increased protection is required. This is especially likely to be the case while travelling abroad to high-risk destinations for TD such as Southeast Asia, Central and South America. Travelan can also be taken at home when one is at greater risk of stomach upset and diarrhoea.

Why is Traveller's Diarrhoea a problem?

The morbidity and discomfort associated with Traveller's Diarrhoea decreases daily performance, affects judgement, decreases personal morale and, for military personnel, operational readiness. Traveller's Diarrhoea has become an increasing problem in the last decade because several enteric pathogens have demonstrated increasing resistance to commonly prescribed antibiotics. Also, Traveller's Diarrhoea is now recognized by the medical community to result in a post-infectious sequela, including post-infectious irritable bowel syndrome (IBS) and several post-infectious autoimmune diseases.

Traveller's Diarrhoea is a particular problem for the US Department of Defense. Indeed, when troops are deployed abroad, diarrhoea is ranked 1st among 57 infectious disease threats by the 2019 Military Infectious Disease Research Program's Infectious Disease Threat Prioritisation Panel. 76% of soldiers in the US Navy experienced this early in their deployment. This is why the Department is collaborating with Immuron in two clinical trials which we outline later in this report.

What is the market potential for Travelan?

We believe that Travelan (both the existing product on the market today and the future Rx product that will come on the US market when Immuron's clinical efforts with IMM-124E succeed) has a significant market potential given the Traveller's Diarrhoea that affects millions of travellers each year. Data from Lumanity[1] suggests that 56 million Americans each year travel to high-risk countries[2] and roughly half of them (28 million) seek professional advice prior to travel. Of the latter, 6 million (or 22%) travel to the 'highest risk countries' for bacteria-related diarrhoea risk. Lumanity has estimated that if Travelan penetrated just 22.6% of the latter figure it could reach sales of US$102m[3].

This may still be a conservative estimate. The figures above only account for direct flights, so smaller countries that require connecting flights may be underrepresented. Also, there is potential that physicians may opt to prescribe (and patients may opt to take) IMM-124E at their own discretion to prevent a case of Traveller's Diarrhoea in countries with under a 70% risk but where risk is nonetheless high (examples may include Caribbean and Eastern European countries).

Protectyn helps in improving immune function by targeting gut bacteria

Protectyn is an oral biopharmaceutical product for the GI tract and liver health. It is a dietary supplement for gut health formulated to help maintain a healthy digestive function and support the liver. Protectyn is an OTC product targeting lipopolysaccharide (LPS) bacterium in the gut to prevent gut dysbiosis, improve bacterial clearance, reduce chronic inflammation, and improve immune function. Protectyn was launched in FY2016.

Protectyn is scientifically formulated to contain high levels of active antibodies. These antibodies target pathogenic bacteria and the harmful LPS toxins that those bacteria produce in the gut, reducing the bacteria's ability to disrupt the healthy functioning of the gut, liver and immune system. The bacteria and LPS toxins are associated with several diseases, including leaky gut syndrome, bacterial translocation, IBS, fatty liver, metabolic syndrome and gut dysbiosis. Removing harmful bacteria and LPS toxins to restore normal bacterial balance in the body is an important part of the treatment of the disease. Protectyn is not an antibiotic and thus does not promote resistance to antibiotics. Antibodies in Protectyn aid in maintaining the delicate balance of the gut microbiota in times of stress or weakened immunity by eliminating invading pathogens.

How does Protectyn work?

Bacteria and LPS toxins disrupt the normal functioning of the gut. Bacteria and toxins enter the bloodstream. This can lead to inflammation. Protectyn contains BCP, which is sourced from dairy cows that have been specifically "hyper-immunised" with patented Immuron vaccines by experienced and qualified veterinarians. These vaccines illicit a strong immune response, which allows the cow to produce very high levels of specific antibodies against pathogenic bacteria and harmful LPS toxins. These anti-LPS antibodies

[1] Data from Luminty and trade.gov that was provided to Pitt Street Research by Immuron. The information is unclassified.
[2] High risk country means a potential attack rate of over 50% of travellers per year who consume non-approved local food, water or ice and do not take countermeasures to prevent infection.
[3] Assuming the sale of 1.36m packages of Travelan Rx at US$75 each

bind to the pathogenic bacteria and the toxins produced, effectively neutralising and allowing the bacteria to be eliminated from the GI tract before they can leak into the bloodstream, disrupting the digestive system. Once bounded by the antibodies in Protectyn, the harmful elements can be removed safely from the body. Thus, Protectyn helps in restoring gut balance, maintaining healthy digestive function, and supporting liver health. Protectyn also contains other components that occur naturally in the colostrum. These compounds are known for reducing inflammation in the body and providing benefits related to digestive and liver health.

Clinical studies have shown protection of up to 90% from ETEC in those taking Protectyn. Immuron is focused on sales expansion of Protectyn across target geographies through growth in the distribution network as well as sales and marketing initiatives. The focus is on product development and broader applications. Protectyn is currently only marketed in Australia as an immune supplement to help maintain a healthy digestive function and a healthy liver. It is sold online and in health practitioner clinics.

Immuron's crucial technology platform

Immuron's technology platform 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 technology platform allows polyclonal immunoglobulins to be extracted 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. (Figure 3).

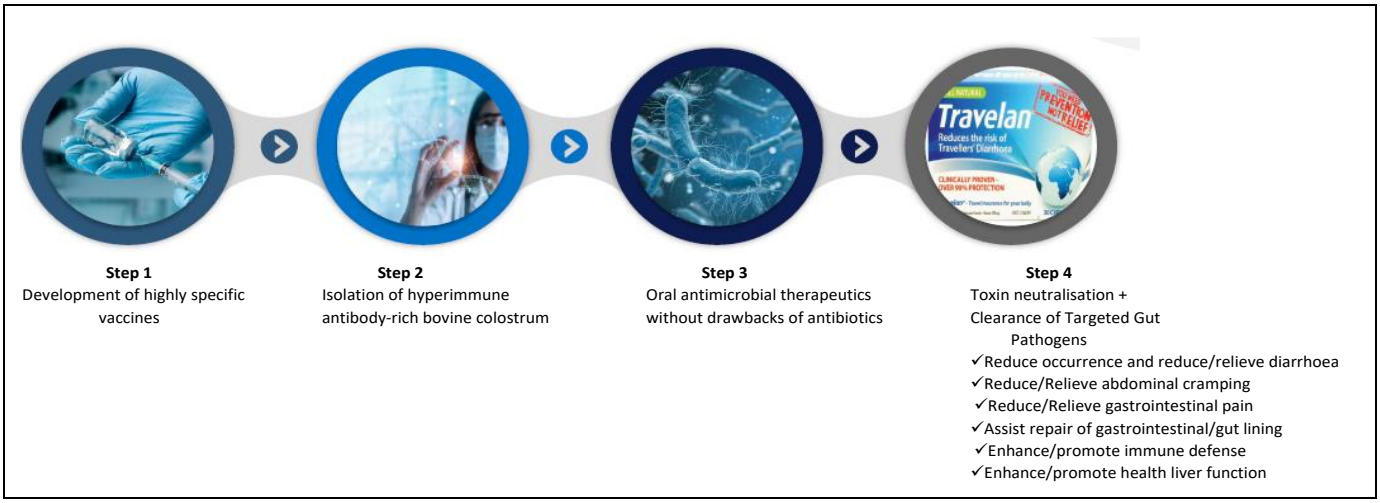
How are polyclonal immunoglobulins obtained from bovine colostrum?

The inoculation of dairy cows with vaccines activates a generalized immune response in the host to produce antibodies.

The active pharmaceutical ingredient (API) for a particular application is prepared using the first milking colostrum in dairy cows. Prior to calving, pregnant cows are immunised with proprietary vaccines to ensure maximum immunogenicity. Immunity doesn't pass from mother to child through the placental wall. Instead, it passes through the colostrum. Bovine colostrum is the first milk a cow gives after a young one is born. It is different from breast milk, which comes a few weeks after birth. Colostrum has higher levels of immunoglobulin G. Unlike humans, who receive most immunity across the placenta, this milk product provides all the immunoglobulin for the first week of the calf's life. Immuron can obtain polyclonal immunoglobulins from bovine colostrum. There are 13 different types of ETEC that the cow is vaccinated for. Such an inoculation process helps in the activation of a generalised immune response in the host animal to produce antibodies. The dairy origins of the antibodies also help in the commercialisation of the company's technology platform through regulatory pathways such as prescriptions, medical foods, over the counter (OTC) medicines and dietary supplements.

After calving, bovine colostrum is harvested and processed to produce a hyper immune bovine colostrum powder. 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, caplets, capsules, bulk dry powders, or individual sachets for point of care reconstitution, or in combination with other active ingredients. Immuron's robust technology process results in an export-grade certified dairy ingredient product that is registered by DairySafe Victoria for domestic and export use.

Figure 3: Immuron's technology platform



Source: Company, Pitt Street Research

Immuron's existing business has solid growth prospects

At present, Immuron derives revenue from the sale of its hyperimmune products, Travelan and Protectyn. In FY23 (the 12 months to June 30, 2023), sales of Travelan and Protectyn increased from A$765k in FY22 by 135.8% to A$1.8m in FY23. The sales increase was mainly due to recovery in sales in the Australian and North American markets for Travelan. In Australia, sales of Travelan for FY23 increased by 667.7% from A$0.14m in FY22 to A$1.1m in FY23, while that of Protectyn increased marginally by 4.4% from A$57k to A$60k over the same period. In the US, Travelan's sales increased by 28.2% from A$501K in FY22 to A$643k in FY23, led by higher sales in both Passport Health Travel Clinics and distributor sales (Figure 4 and Figure 5). Overall, Travelan's sales in all regions increased by 146.5% (from A$0.7m in FY22 to A$1.74m in FY23).

Immuron announced record monthly sales Travelan in September 2023

In September 2023, Immuron announced record monthly sales of Travelan. The sales of Travelan increased from A$14.6k in August 2022 to A$1.2m in August 2023. This increase partially reflects 3 months of backorders accrued while awaiting GMP Clearance from the TGA. But the broad recovery over the last 3 years also reflects the bottoming out of traveller numbers during the pandemic and the gradual recovery since CY20.

In the longer term, Immuron will be a different company to what it is now, if and when its existing clinical assets (IMM-124E and IMM-529) pass clinical trials and become commercialised. But in the short-to-mid-term, Immuron expects sales of its current commercial assets to register robust growth. With the continued recovery in international numbers and the expected surpassing of pre-COVID levels next calendar year, the US market could hit the highest sales even in the next financial year or two.

Figure 4: Sales from Travelan and Protectyn have registered a strong increase from FY2021 to FY2023

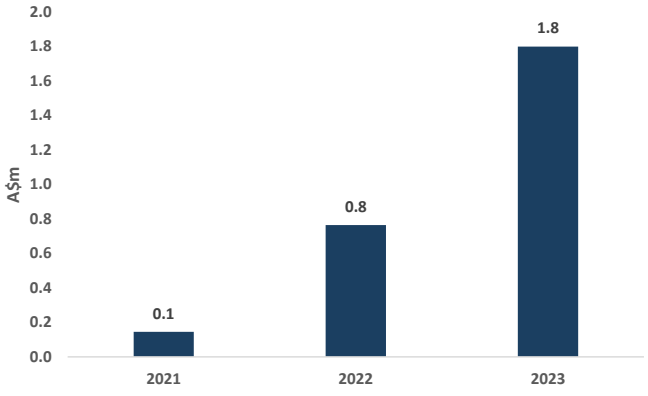
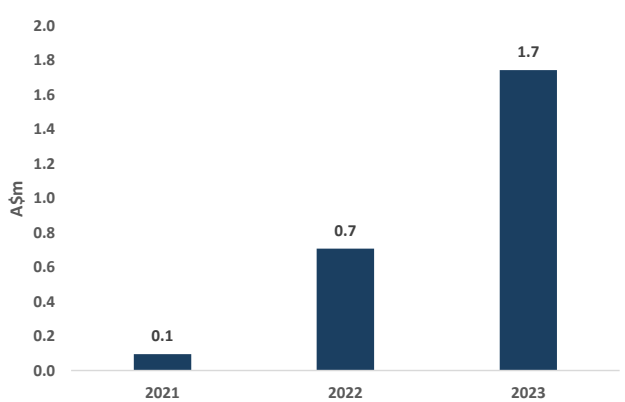


Figure 5: Travelan sales have increased considerably from FY2021 to FY2023



Source: Company, Pitt Street Research

Immuron's clinical programs underway

Immuron has three lead drug candidates that are entering the clinical development phase. The clinical programs being conducted by Immuron have been summarised below.

IMM-124E

IMM-124E is the API used to manufacture both Travelan and Protectyn. The way IMM-124E has been designed is to block and reduce 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 lead to blockage of pathologic activities.

Clinical testing in randomised, double-blind, placebo-controlled clinical trials for IMM-124E showed protective efficacy of 84-90% against moderate to severe diarrhoea

Market evaluation done by Lumanity (as outlined on pages 9-10 of this report) confirms IMM-124E's opportunity for TD. The company has been pursuing antibacterial activities of IMM-124E, focussing on a better understanding of the mechanism of action associated with initial observations. For previous preclinical studies, please refer to the Appendix section. IMM-124E has also undergone clinical testing in randomised, double-blind, placebo-controlled clinical trials. Clinical trials show that Travelan confers protective efficacy of up to 84-90% against moderate to severe diarrhoea upon being challenged with ETEC vis-à-vis a placebo. In addition, these trials showed a significant reduction in abdominal cramps and stomach pain compared to those who did not receive Travelan.

So why is IMM-124E in a clinical trial all over again? Because Travelan is only approved as a general dietary supplement in the US, not against Traveller's Diarrhoea. The company will give itself the best chance of eventual regulatory approval if it does a clinical trial in the US. If IMM-124E is bought to market, it will be a more premium product compared to the existing Travelan on the market today.

The IMM-124E IND was granted by the FDA at the end of 2022. Currently, the product is in a Phase 2 study that will ultimately enrol 60 patients. The patients in the study will begin a regimen of either six IMM-124E tablets over 7 days or the placebo before being exposed to an ETEC strain. The primary

endpoint is the number of subjects that ultimately encounter moderate to severe diarrhoea. Each patients stool sample will be graded by how 'watery' it is. **Headline results are expected in the first half of 2024**. 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.

IMM-529

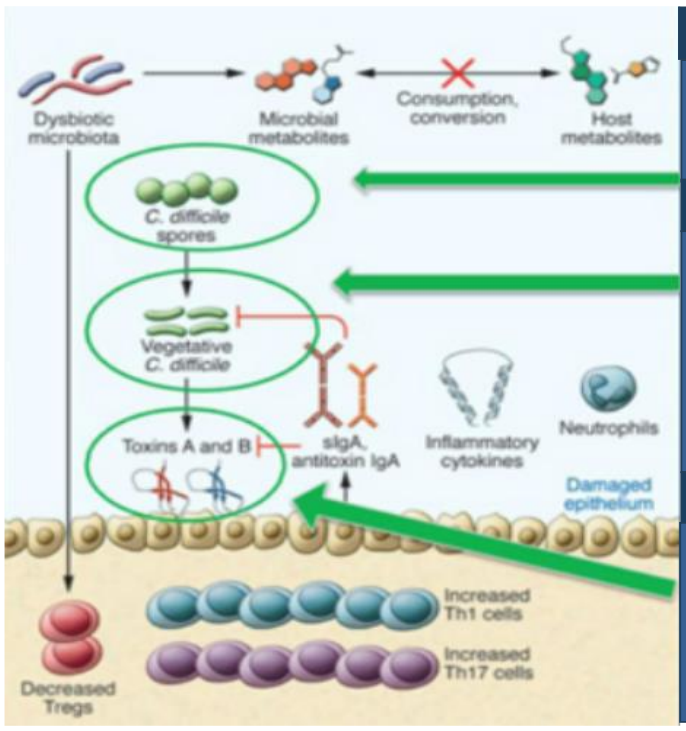
Immuron is embarking on a new clinical development program that will focus on the treatment of patients suffering from CDI. *Clostridioides difficile* is a gram-positive, toxin-producing, spore-forming bacterium that generally causes severe and persistent diarrhoea in infected individuals, but can also lead to more severe outcomes, including in the most serious cases, death. It has a recurrence rate of 15%–20% and a mortality rate of 5%

IMM-529 is an oral biologic that targets the *Clostridioides difficile* bacterium and contains polyclonal bodies cross-reactive to Toxin B, spores and vegetative cells of the bacterium. Transmission of *Clostridioides difficile* occurs by ingestion of spores either through person-to-person contact, animal-to-person contact or environment-to-person contact.

It does not destroy the microbiome (like antibiotic treatments do). Rather, it allows the microbiome to return to a healthy state while effectively treating virulent *Clostridioides difficile* simultaneously. Experts in the field of infectious diseases have reacted favourably to IMM-529's ability to target three elements of the CDI infection - spores, vegetative cells, and toxin B.

The antibodies in IMM-529 have been demonstrated to bind to and neutralise human and animal *Clostridioides 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 (Figure 6).

Figure 6: IMM-529's Novel Triple Action revolutionises the treatment for CDI



Spores - infectious particles	
IMM-529 antibodies bind to surface antigens on spores and prevent adheres to host cells and limit germination	Heat, ethanol and UV resistant. Survive gastric acid, adhere to cells in the colon and germinate
Vegetative cells	
IMM-529 antibodies bind to SLP on vegetative cells and limit colonisation	Fimbrae and other surface layer proteins (SLPs) contribute to bacterial colonisation. Fimbrae are used to adhere to other bacteria and to host cells and is one of the primary mechanisms of virulence
Toxin B	
IMM-529 antibodies neutralise toxin B, inhibiting toxin mediated epithelial cell apoptosis and limit toxin translocation into the systemic circulation and inflammatory cascades	Toxin B is essential for virulence. Toxin B disrupts the cytoskeleton and tight junctions of intestinal epithelial cells

Source: Company, Pitt Street Research

Immuron has conducted preclinical work on IMM-529 and has shown positive signs.

The company is at a far earlier stage with this asset. The next step is to file an IND with the FDA before the end of FY24. The initial focus on treating patients with recurrent disease rather than all sufferers. The pathway to market isn't quick by any means, with the asset unlikely to get FDA approval before CY29 at the earliest, accounting for 6-12 months for the IND to be investigated, ~18 months for Phase II, ~24 months for Phase III and up to 18 months for regulatory approval.

Nonetheless, Immuron has conducted preclinical work on IMM-529 and it has shown positive signs. In the preclinical stage, 80% efficacy was demonstrated 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).

CampETEC

CampETEC is a new therapeutic targeting Campylobacter and ETEC infections on which Immuron has been collaborating with the Naval Medical Research Command (NMRC) since October 2019.

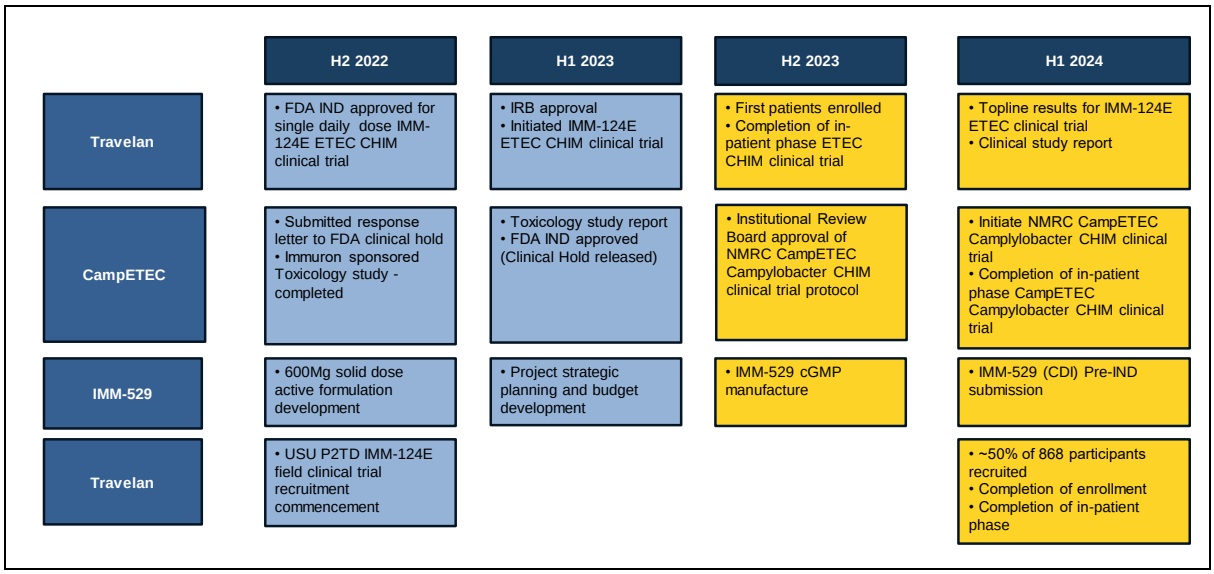
After nearly four years of hard work and some setbacks (most notably a brief FDA Clinical Hold), the US FDA approved an IND application to test the safety and protective efficacy of CampETEC in a first-in human study. Safety and protective efficacy of the product is likely to be tested using two CHIM clinical trials with one focussed on the hyperimmune product's ability to protect volunteers against ETEC infections and the other focussed on moderate to severe campylobacteriosis. A total of 60 volunteers divided into 2 inpatient cohorts, will be enrolled in the randomised, placebo-controlled trials, and will be assigned to Cohort 1 ETEC or Cohort 2 *C. Jejuni* controlled human infection models randomly. Separately, the company also sponsored a toxicology study that was completed in December 2022.

Going forward, Immuron is planning to start two Phase 2 trials, one in Campylobacter and another in ETEC. There are some regulatory processes that the company is likely to go through for which Phase 2 studies are required. Phase 3 studies are also likely to be required before approvals for the drug are secured. Immuron is also moving ahead with a clinical program to get the status for prescription biologic drug in Australia.

Travelan

The US Department of Defense (USU) is running a randomised, placebo-controlled trial in up to 868 participants. Patients were actively deployed in the military from both the US and UK. The USU has successfully enrolled 347 participants into the clinical study following the initiation of enrolment and approximately 260 have completed the study. The USU has extended the enrolment period and now expects to complete clinical trial enrolment in Q2 2024 (Figure 7).

Figure 7: Key milestones anticipated to drive value



Source: Company, Pitt Street Research

Immuron is well-positioned

Immuron has secured funding from key agencies

In recent years, Immuron has entered research collaborations with various agencies to enable the investigation of therapeutic indications including campylobacter, ETEC, Shigella and CDI.

Figure 8: Funding agreements secured, and collaborations entered into by Immuron

Key funding received	Key collaborations
• In January 2022, Immuron was awarded A$6.2m for a new research agreement with the US DoD - a Biologics License Application (BLA)[4] of a therapeutic Bovine immunoglobulin supplement targeting TD caused by ETEC. Of this, A$4.8m was awarded for testing the efficacy of a large daily dose regimen of Travelan in a controlled human infection model (CHIM) clinical study using the ETEC strain H110407. The dose regimen is more conducive for use in military populations. • Immuron has benefited from non-dilutive grant funding from the US DoD and new patents. A second application for additional funding has been considered eligible for the award after securing funding from the US DoD MTEC for progressing Travelan with the US FDA. Additionally, Immuron received a European patent titled Methods and Compositions for treatment and prophylaxis of *C. difficile*	• **US DoD** - Immuron is collaborating with the US DoD involving programs with the Walter Reed Army Institute of Research for development of three Shigella specific therapeutic products. With Travelan, the US DoD has done studies showing a broad-spectrum antibiotic activity for 180 different pathogens. ***We believe that Immuron's collaboration with the US DoD is a validation of the potential of the former's technology platform to develop novel anti-infectives.*** • **Armed Forces Research Institute of Medical Sciences (AFRIMS)** - In June 2020, AFRIMS completed the histopathological analysis which provides a comprehensive review of the clinical disease and its effect on the gut. The results showed that Travelan is functionally cross-reactive and may have prophylactic activity against Shigellosis. • **US Department of Defense Uniformed Services University (USU)** - In May 2022, Immuron provided a key update on a planned clinical field trial sponsored by USU for the evaluation of Travelan's efficacy in TD. P4TD study is a

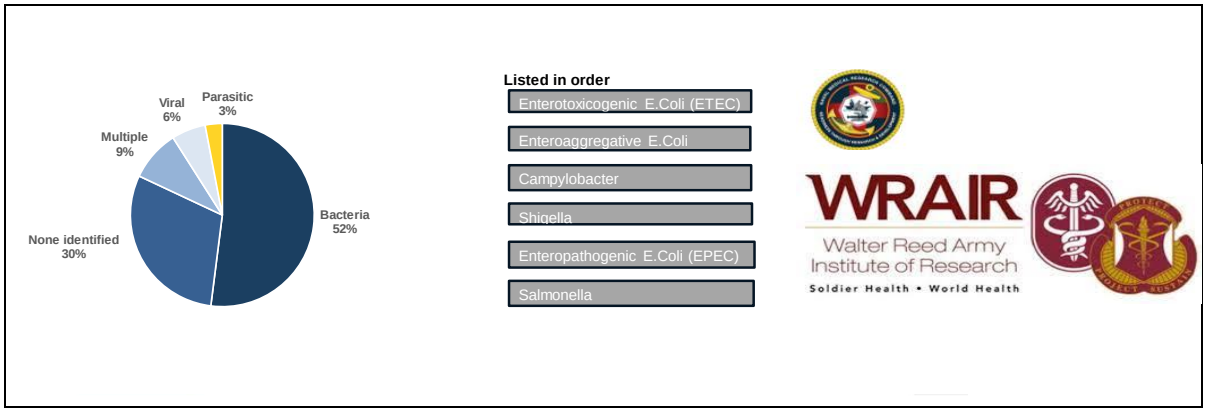
[4] BLA is the FDA term for prescription biological drug

associated disease from the European Patent Office (EPO). • The company also received funding from the Naval Medical Research Command (NMRC) for CampETEC. The NMRC was awarded A$1.4m in a separate grant to provide immunological support for Immuron's clinical program.	randomised, double-blind, placebo controlled multicenter clinical trial. Initially it was designed to evaluate the effectiveness of 2 nutraceuticals – IMM-124E and Florastor (another probiotic supplement) versus a placebo for prophylaxis to assess the ability to maintain normal gut function during travel to high-risk destinations for TD. Florastor has since been dropped from this study and it is now Travelan vs placebo only. ***Topline results for the ETEC clinical trial are expected by H1 2024.*** • **US Department of Defense** is providing grant money for two programs. Both the programs are proceeding towards an active phase in two trials. The trials are CHIM studies which are a prime way of proof of principle for new infection medicines. Due to the small number of patients being infected and the short treatment time, results of the studies are expected within 12 months. • **NMRC** executed a research agreement with Immuron to develop and clinically evaluate a new therapeutic targeting Campylobacter and ETEC infections. The new hyper-immune therapeutic contains high levels of antibodies which specifically target key protective antigenic targets *Campylobacter jejuni* capsule and ETEC colonization factor antigen I (CFA/I). ***The NMRC has recently received clearance for its IND application from the US FDA to initiate clinical development of the new drug.***

Source: Company, Pitt Street Research

We believe that the collaborative arrangements ensure that Immuron works with well-respected key opinion leaders and laboratories with specific expertise in screening with relevance to a particular indication (Figure 9).

Figure 9: Military infectious diarrhoea etiological agents



Source: Company, Pitt Street Research

Comparable companies

In order to provide an idea of the broad competitive landscape for Immuron (Figure), we have screened companies using the following criteria:

1) Companies based in developed markets with market capitalisation lower than US$500m.
2) Public companies operating in biotechnology industries, focussing on gastrointestinal disorders, and diarrhoea.

RCE

Figure 10: Comparable Companies

Company	Location	Ticker	Market cap (US$m)	Website
Seres Therapeutics, Inc.	US	NasdaqGS:MCRB	279.6	www.serestherapeutics.com
Probi AB	Sweden	OM:PROB	197.3	www.probi.com
Finch Therapeutics Group, Inc.	US	NasdaqGS:FNCH	6.3	www.finchtherapeutics.com
Theriva Biologics, Inc.	US	NYSEAM:TOVX	7.3	therivabio.com
Applied Molecular Transport	US	NasdaqCM:AMTI	5.7	www.appliedmt.com
First Wave BioPharma, Inc.	US	NasdaqCM:FWBI	3.6	www.firstwavebio.com
Recce Pharmaceuticals	Australia	ASX:RCE	57.0	www.recce.com.au
Immuron Ltd.	Australia	ASX:IMC	11.4	www.immuron.com.au

Source: S&P Capital IQ, Pitt Street Research

Seres Therapeutics (Nasdaq: MCRB) develops microbiome therapeutics to treat the modulation of the colonic microbiome. The company's lead product candidate is SER-109, an oral microbiome therapeutic that has completed the Phase III clinical trial for the treatment of recurrent CDI. Its product pipeline also includes SER-155, an investigational oral fermented microbiome therapeutic for the treatment of GI infections, bacteremia, and graft-versus-host-disease in immunocompromised patients. The company was incorporated in 2010 and is headquartered in Massachusetts, US.

Probi AB (OM: PROB), researches, manufactures, and sells probiotics for dietary supplements and food companies. The company conducts research primarily in the fields of GI health, digestive health, immune health, bone health, and iron absorption, as well as children's, women's, and senior health. The company was incorporated in 1991 and is headquartered in Lund, Sweden.

Finch Therapeutics Group, Inc. (Nasdaq: FNCH) develops orally administered biological drugs in the US. The company develops FIN-211, a microbiome candidate designed to address the GI and behavioural symptoms of autism spectrum disorder; and FIN-524, FIN-525, and other microbiome product candidates for inflammatory bowel disease. The company was incorporated in 2014 and is based in Massachusetts, US.

Theriva Biologics, Inc. (NYSEAM: TOVX) develops therapeutics to treat critical diseases. The company's lead product candidates include SYN-004 designed to degrade various commonly used intravenous beta-lactam antibiotics in GI tract; and SYN-020, a recombinant oral formulation for the enzyme intestinal alkaline phosphatase to treat both local GI and systemic diseases. The company is headquartered in Maryland, US.

Applied Molecular Transport Inc. (Nasdaq: AMTI) is engaged in the design and development of a pipeline of oral biologic products to treat autoimmune, inflammatory, metabolic, and other diseases. The company's lead product candidate is AMT-101, a GI-selective oral fusion of rhIL-10 that is in Phase II clinical trials. It also develops AMT-126, a GI-selective oral fusion of interleukin 22, which is in a Phase I clinical trial for diseases related to intestinal epithelium barrier function defects. The company was founded in 2010 and is headquartered in California, US.

First Wave BioPharma, Inc. (Nasdaq: FWBI) is engaged in the research and development of targeted and non-systemic therapies for the treatment of patients with GI diseases. Its product candidates include the biologic adrulipase, a recombinant lipase enzyme designed to enable the digestion of fats and other nutrients; and niclosamide, an oral small molecule with anti-viral and anti-inflammatory properties. The company was incorporated in 2014 and is headquartered in Florida, US.

Recce Pharmaceuticals Ltd (ASX: RCE) is developing synthetic anti-infectives (as distinct from antibiotics) for infectious diseases. The company's lead candidate is RECCE 327 to treat blood infections and sepsis derived from E. coli and S. aureus bacteria, including their superbug forms. It also develops RECCE 529, a synthetic anti-infective for viral infections; and RECCE 435, a synthetic polymer antibiotic formulated for oral use. In addition, the company engages in R327 Intravenous which provides serious/life-threatening bacterial infections, including sepsis which is in the phase 1 trial; urinary tract infections, including urosepsis; rapid infusions sepsis in the phase 2 trial; and R327 Topical offers wound infections, including infected burns; and diabetic foot ulcer infections in Phase 2 trails. Furthermore, the company operates various pre-clinical programs, such as Mycobacterium abscessus which is in phase 1 clinical trial; bacterial sinusitis; and additional TBA. Recce Pharmaceuticals Ltd was incorporated in 2007 and is headquartered in Sydney, Australia.

Our valuation of Immuron

We value Immuron at A$0.25 per share in our base case and A$0.35 in our optimistic case.

We have valued Immuron using a Sum of the Parts approach, evaluating IMC's legacy business, IMM-124E and IMM-529 separately. Our total valuation is A$0.25 per share under our base case projection, while our more optimistic case (or bull case) places the valuation at A$0.35 per share (Figure 11).

Figure 11: Immuron's Sum of the Parts Valuation

Sum of the Parts 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**	**78.58**	**0.34**
Current Price		0.07		0.07
Upside		250%		379%

Estimate: Pitt Street Research

Legacy business

Our key assumptions are as follows:

Forecast horizon – We have considered forecast horizon of 5 years up to FY28. We assume Immuron winds down its legacy business as IMM-124E comes online from FY25 onwards (see below for further details).

Revenues. We model revenues from Travelan in Australia, the USA and Canada as well as Protectyn in Australia. We assume another year of strong growth in FY24 followed by moderating growth thereafter. Our revenues are a function of packages sold and current Travelan prices, which are publicly available at the applicable online outlets where Travelan and Protectyn are sold. We assume an exchange rate of A$1=CA$1.15 & US$0.66.

Costs and margins - We have modelled most of Immuron's expenses for its legacy business to increase in line with inflation.

Discount rate – We use a discount rate of 14.7%, derived from a 4.2% risk free rate of return (using the 10-year Australian government bond), a 7% equity premium (using our standard 5% premium plus a 2% risk premium added on to companies outside the All Ords) and a 1.5x beta.

Corporate tax - We assume a corporate tax rate of 30%, accounting for the multiple markets IMC operates in.

Difference in valuation scenarios – The main difference between our base and bull cases is our revenue growth, we assume FY25 is another year of solid growth and that it moderates thereafter.

With a $29.01m NPV (or 13c per share), IMC's legacy business is 60% of our valuation.

IMM-124E

We assume that it is commercialised in the US and Europe starting in mid CY28 and our model lasts for 10 years thereafter. We utilise forecasts from Lumanity (made available to us by the company) which assume that it can sell 1,360,000 units at $75 per package, leading to $102m in annual sales.

This would represent a ~23% market share of the 6 million Americans per year that travel to highest risk countries and seek advice prior to travel. The 1.36m figure is derived from 80,000 units from clinics, 540,000 from Primary Care Physicians and 735,000 from Travel Med Specialists.

We assume, given the somewhat later stage Immuron is at with this asset and its experience with Travelan, it does not find a partner and commercialises alone – keeping 100% of its revenues. This results in it needing to meet expenses itself. We assume development costs through to FDA approval are US$10m and that selling, general & administrative expenses once commercialised amount to 75% of sales. Our discount rate is 16.2%, derived from a 4% risk-free rate of return, an 8% equity risk premium and a 1.5x beta. Our base case NPV is calculated in USD, risk-discounted 50% and then converted into AUD and is $15.9m or 7c per share.

Our bull case is $23.8m or 10.5c per share and the key difference is our assumption that cash costs are only 70% of sales. IMM-124E is worth 33% of our valuation for the company in our base case and 34% in our bull case.

IMM-529

We have taken a similar approach with IMM-529, evaluating it on a DCF basis assuming a market share capture and we have used the same discount rate (16.2%). However, there are the following differences:

- We do not assume commercialisation until the end of CY29, although we assume modest R&D revenue (~$2.5m a year in the meantime). We assume IND approval and Phase I/II commencement in early CY25, with Phase I/II completion mid-CY26 and Phase III completion in mid-CY28.
- We model the opportunity for *Clostridioides difficile* at ~30,000 patients. The total case numbers in the US are just over 400,000 but the smaller segment is the proportion of patients who experience multiple recurrances[1].
- We assume IMC finds a commercial partner in a deal that will involve up to $50m in royalty payments over 5 years ($5m upfront, $5m at the start of Phase 1, $10m at completion of Phase 1, $10m at the start of Phase 2/3, $20m at completion of Phase 2/3). This is more than enough to account for the estimated A$30m costs for all necessary studies.
- Once approved, IMC gets to keep a 15% royalty on sales, 20% in our bull case.

Our valuation of IMM-529, calculated initially in USD then probability discounted by 50% and converted into AUD, is $3.2m in our base case (or 1.4c per share) and $4.3m in our bull case (or 1.9c) per share. Our base case for IMM-529 is 7% of our total base case valuation while our bull case is 6% of the entire company's NPV.

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 lower-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 programs 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 programs may take longer to execute than expected, negatively affecting investor sentiment toward 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 – Immuron's leadership team

Immuron has an experienced board and management team with diverse experience across biotechnology businesses and in other industries.

Figure 12: Immuron's management and Board Members

Name and Designation	Profile
Paul Brennan **Chairman**	• Mr. Brennan brings a strong clinical background working at various multinational companies. • He was the CEO of PolyNovo Ltd. for 7 years from 2015 to 2021 and took the company from A$30m to a high of A$2bn. • He served as the Marketing Director for Australia and New Zealand, and the Sales Director for New Zealand at Smith & Nephew Healthcare for 6 years.
Dr. Roger Aston **Non-Executive Director**	• Dr. Aston has more than 20 years of experience in the pharmaceutical and biotechnology industries. • He has extensive experience with FDA and EU product registration, clinical trials, global licensing, private placement fundraising, and prospectus preparation.
Daniel Pollock **Non-Executive Director**	• Mr. Pollock is an internationally experienced lawyer with commercial expertise in entries into overseas markets, distribution agreements, and corporate start-ups. • He is the principle of a specialist legal business based in Melbourne, operating internationally. • He has worked with both local and global businesses, and has a strong understanding of rapidly growing, technology-based businesses.
Stephen Anastasiou **Non-Executive Director**	• Mr. Anastasiou has extensive experience in general management, marketing, and strategic planning in the healthcare industry. • Previously associated with KPMG, his breadth of industry experience incorporates diagnostics, ethical, hospital, dental, and OTC products with local and international companies such as Bristol-Myers Squibb. • He is a Director of several unlisted private companies covering a variety of industry sectors, including healthcare and funds management.
Professor Ravi Savarirayan **Non-Executive Director**	• Mr. Savarirayan is a consultant clinical geneticist at the Victorian Clinical Genetics Services since August 1999, as well as Professor and Research Group Leader (Skeletal Biology and Disease) at the Murdoch Children's Research Institute since September 2000. • He is a founding member of the Skeletal Dysplasia Management Consortium since January 2011 and has

	been the Chair of the Specialist Advisory Committee in Clinical Genetics, Royal Australasian College of Physicians since February 2009.
Steven Lydeamore **CEO**	• Mr. Lydeamore, an international pharmaceutical veteran, is the CEO of Immuron since June, 2022. • He has 30 years of international pharmaceutical experience and has worked in Australia, Canada and the US. • He has valuable experience in mergers and acquisitions, finance, business development, sales and marketing, manufacturing, and research and development.
Jerry Kanellos **Chief Operating Officer**	• Dr. Kanellos has over 20 years of experience in the pharmaceutical and biotechnology industries. • He has held leadership roles in business development, project management, IP portfolio management, and research and development. • He has been involved in the establishment and management of several start-up biotechnology companies.
Flavio Palumbo **Chief Commercial Officer**	• Mr. Palumbo has over 20 years of experience in global management and business development. • He has extensive consumer healthcare experience holding leadership roles for GlaxoSmithKline locally (Australia & New Zealand) and globally. • He has also held leadership roles in sales and marketing for Procter & Gamble in the UK, Europe and Australia, and Deloitte in Australia.
Phillip Hains **Company Secretary & Chief Financial Officer**	• Mr. Hains is a Chartered Accountant and has served the needs of a number of public company boards of directors and related committees. • He has over two decades of experience in providing accounting, administration, compliance and general management services. • He also holds an MBA from RMIT and a Public Practice Certificate from the Institute of Chartered Accountants.
Dr. Joanne Casey **Research & Development Manager**	• Dr. Casey has an extensive background in clinical and translational research spanning more than two decades of academic and biotechnology industry environments. • She has been active in the fields of antibody engineering and has gained extensive experience in both research management and project management at the interface of discovery and clinical translation. • She has a PhD (Medicine) from University College London (UCL).

Source: S&P Capital IQ, Pitt Street Research

Appendix II – 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.

Campylobacteriosis – A disease caused by the infection with Campylobacter which is the most common bacterial causes of human gastroenteritis in the world.

CHIM (Controlled Human Infection Model) 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 (a microorganism killed by normal atmospheric concentrations of oxygen) that produces toxins and is the primary cause most often associated with antibiotic-associated diarrhoea.

Enterotoxigenic Escherichia Coli – A strain of the gut bacterium, Escherichia coli, that 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 immune cells make to fight off bacteria, viruses, and other harmful invaders.

Immunoprophylaxis – The prevention of infectious disease through induction or enhancement of specific protective immune responses.

Immunotherapeutic – Treating disease through the use or modification of immune mechanisms.

Irritable Bowel Syndrome – A group of symptoms that affect the digestive system, including repeated pain in the abdomen and changes in the bowel movements, which may be diarrhoea, constipation, or both.

Lipopolysaccharide – A cell wall component characteristic of gram-negative bacteria.

Microbiota/Microbiome – 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.

Pharmacokinetics – The absorption, distribution, metabolism, and excretion of a compound. The word is derived from the Greek words pharmakon (drug) and kinetikos (movement).

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 in a clinical experiment to evaluate the efficacy of another treatment. Placebos do not contain any active ingredients but often still produces a physical effect on the individual.

Appendix III – Immuron's Intellectual Property

WO 2004, 078209, *Composition and method for the treatment and prevention of enteric bacterial infections*, priority date 4 March 2003, invented by Roy Robins-Browne, Grant Rawlin and Gottfried Lichti

- The patent discloses a method to treat enteric diseases or gastrointestinal disorders caused by gram-negative bacteria that involves the administration of a vaccine or hyperimmune material (e.g., colostrum) obtained from a human/non-human host animal immunised using the vaccine. The vaccine comprises an aqueous culture of the gram-negative bacteria and lipopolysaccharide O-antigens, wherein >80% of the antigens are dissociated from the bacterial cell walls. The immunoglobulin-containing hyperimmune material is obtained from the host animal immunised using the specified vaccine and is subjected to purification via filtering, pasteurisation, etc., before being administered to the patient.
- Applications for the patent were filed in Australia, the US, Europe, Canada, Japan, China, Brazil and as WIPO application.
- The patent has been granted in multiple geographies, including Australia, the US, Europe, and Canada.

WO 2022, 011436A1, *Methods of treating coronavirus infection with bovine-hyperimmune colostrum,* priority date 17 July 2021, invented by Jerry Kanellos, Roger Aston and Peter Anastasiou

- The patent pertains to a method to treat and/or prevent coronavirus infection and associated symptoms (e.g., sepsis, bowel pain, nausea, vomiting, and diarrhoea) in a human subject by administering a bovine-hyperimmune colostrum composition. The colostrum composition is prepared by combining hyperimmune colostrum collected from 2 bovine animals treated with vaccines containing enterotoxigenic E. coli lipopolysaccharides and coronavirus antigen, respectively.
- Application for the patent was filed only as a WIPO application.
- The patent is recent and is yet to be granted.

US 2016, 0083457, *Methods and compositions for the treatment and/or prophylaxis of clostridium difficile associated disease,* priority date 19 April 2013, invented by Dena Lyras, Melanie Hutton, Bliss Cunningham, Lucy Li, Glen Carter and Julian Rood

- The patent relates to an antibody composition for the treatment of Clostridium difficile infections and associated symptoms (e.g., diarrhoea, abdominal pain, fever, loss of appetite, weight loss, gastrointestinal damage and cytotoxicity). The composition contains bovine-colostrum-derived polyclonal antibodies with binding affinity towards C. difficile toxin B, vegetative cell antigens and endospore antigens. The composition is claimed to be effective in preventing the recurrence of disease after treatment.
- Applications for the patent were filed in Australia, the US, Europe, Canada, China, and as a WIPO application.
- The patent has been granted in multiple geographies, including Australia, the US, Europe and Canada.

US 2013, 0224216, *Anti-lps enriched immunoglobulin for use in treatment and/or prophylaxis of a pathologic disorder,* priority date 17 August 2011, invented by Yaron Ilan, Gadi Lalazar, Tomer Adar, Meir Mizrahi, Ami Ben-Ya'acov

- The patent discloses colostrum preparations comprising anti-LPS antibodies and immunoglobulins recognising disease-specific antigens to prevent, treat, and/or delay the progression of pathological conditions, such as chronic liver diseases and cirrhosis. The composition helps improve liver function in subjects with the levels of ALT >50 IU/dL, AST >50 IU/dL, AP >70U/L, and CGT >60 U/L, respectively.
- Applications for the patent were filed in Australia, the US, Europe, Canada and as a WIPO application.
- The patent has been granted in multiple geographies, including Australia, the US, and Europe.
- Although the patent was filed by Immuron in 2011, it was assigned to Hadasit Medical Research Services and Development Limited in December 2020.

Appendix IV – Capital structure

Class	In millions	% of fully diluted	Note
Quoted Securities			
Ordinary shares on issue	228	94.0%	
Unquoted			
Options and performance rights	14.6	6.0%	
Fully diluted shares	**242.4**		

Source: Company

Appendix V – Analyst Qualifications

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, and numerous other 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 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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