Form 20-F filed with the SEC

Melbourne, Australia, October 29, 2021: Immuron Limited (ASX: IMC; NASDAQ: IMRN) ("Immuron" or the "Company"), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutic products for the prevention and treatment of gut-mediated pathogens, advises that it has filed Form 20-F with the US Securities and Exchange Commission (the "SEC").

A copy of the Form 20-F follows after this page.

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

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2021

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to _____

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number 000-38104

IMMURON LIMITED
(Exact name of Registrant as specified in its charter
and translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Level 3, 62 Lygon Street, Carlton South, Victoria, 3053, Australia
(Address of principal executive offices)

Dr. Jerry Kanellos, Chief Executive Officer
Level 3, 62 Lygon Street, Carlton South, Victoria, 3053, Australia
+61 (0)3 9824 5254 **(phone);** +61 (0)3 9822 7735 **(fax)**
(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing 40 Ordinary Shares	**IMRN**	**The NASDAQ Stock Market LLC**
Warrants (expiring June 2022)	**IMRNW**	**The NASDAQ Stock Market LLC**

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

Ordinary Shares, as of June 30, 2021 227,246,596

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§2232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Emerging growth company ☒	Non-accelerated filer ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

INTRODUCTION

We are a commercial and clinical-stage biopharmaceutical company with a proprietary technology platform focused on the development and commercialization of a novel class of specifically targeted polyclonal antibodies that we believe can address significant unmet medical needs. Our polyclonal antibodies offer delivery within the gastrointestinal ("GI") tract and essentially do not cross into the bloodstream, potentially leading to much improved safety and tolerability, without sacrificing efficacy. We believe that our lead drug candidates, currently in clinical development, have the potential to transform the existing treatment paradigms for moderate to severe campylobacteriosis, Enterotoxigenic *Escherichia coli* (ETEC) infections, travelers' diarrhea and for *Clostridiodes difficile (C.difficle)* infections. We currently market our flagship commercial products Travelan® and Protectyn® in Australia, where both products are listed medicines on the Australian Register for Therapeutic Goods. Travelan® (AUST L 106709) is an over-the-counter product indicated to reduce the risk of travelers' diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial and is sold in pharmacies throughout Australia. Protectyn® is currently sold online and in health practitioner clinics and is marketed as an immune supplement to help maintain a healthy digestive function and liver. We also market Travelan® (NPN 80046016) in Canada where it is licensed as a natural health product indicated to reduce the risk of travelers' diarrhea, and presently market Travelan® in the U.S. as a dietary supplement for digestive tract protection.

We also have several early-stage assets under development. Our technology platform can be used to block viruses or bacteria and neutralize the toxins they produce at mucosal surfaces such as the Gastrointestinal tract. We have completed the manufacture of three new *Shigella*-specific therapeutic products using proprietary vaccines developed by the Walter Reed Army Institute of Research (WRAIR). This collaboration aims to develop an oral therapeutic for shigellosis, a severe form of dysentery that affects about 165 million people a year, mostly children, and causes up to a million deaths. Symptoms of shigellosis, also known as bacillary dysentery, include severe and bloody diarrhea, fever, and stomach cramps. We also are pursuing a research program focused on the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19. Our Hyper-immune Bovine Colostrum used to manufacture our commercial products Travelan® and Protectyn® has demonstrated antiviral activity against SARS-CoV-2 in laboratory studies. Our research is focused on identifying the inhibitory substance/s unique to the colostrum samples.

Our American Depositary Shares (each, an "ADS" and, collectively the "ADSs") and warrants (each, a "Warrant" and collectively, the "Warrants") are listed on The NASDAQ Capital Market under the symbols "IMRN" and "IMRNW", respectively. Each ADS represents 40 of our ordinary shares, no par value. Each Warrant has a per ADS exercise price of US$10.00 and expires five years from the date of issuance. Our ordinary shares are also listed on the Australian Securities Exchange under the symbol "IMC."

Our consolidated financial statements appearing in this annual report are prepared in Australian dollars and in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements appearing in this annual report comply with the IFRS.

In this annual report, all references to "U.S. dollars" or "US$" are to the currency of the United States, and all references to "Australian dollars", "A$" or "$" are to the currency of Australia. Unless otherwise indicated or the context implies otherwise, items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in Australian dollar ("A$" or "$"), which is Immuron Limited's functional and presentation currency. Unless otherwise indicated or the context implies otherwise all references to "we," "us," or "our" refers to Immuron Limited, an Australian corporation.

Statements made in this annual report concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this annual report or to any registration statement or annual report that we previously filed, you may read the document itself for a complete description of its terms.

Except for the historical information contained in this annual report, the statements contained in this annual report are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1995, as amended, with respect to our business, financial condition and results of operations. Such forward-looking statements reflect our current view with respect to future events and financial results. We urge you to consider that statements which use the terms "anticipate," "believe," "expect," "plan," "intend," "estimate," or the negative of these terms or other comparable terminology. are intended to identify forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements expressed or implied by such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly release any update or revision to any forward-looking statements to reflect new information, future events or circumstances, or otherwise after the date hereof. We have attempted to identify significant uncertainties and other factors affecting forward-looking statements in the Risk Factors section that appears in Item 3.D. "*Key Information-Risk Factors.*"

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Consolidated Financial Data

The tables below set forth selected consolidated financial data as of and for the five years ended June 30, 2021, which is derived from our audited consolidated financial statements. The audited consolidated financial statements as of June 30, 2021 and 2020 appear in this annual report. The consolidated income statement data for the years ended June 30, 2021, 2020 and 2019 and the consolidated balance sheet data as of June 30, 2021 and 2020 are derived from our audited consolidated financial statements included in "ITEM 18: Financial Statements". The consolidated financial data as of June 30, 2019, 2018 and 2017 and for the years ended June 30, 2018 and 2017 have been derived from our audited consolidated financial statements, which are not included in this annual report. The selected consolidated financial data set forth below should be read in conjunction with and is qualified entirely by reference to Item 5. "Operating and Financial Review and Prospects" and our consolidated financial statements and notes thereto included elsewhere in this annual report.

Statement of Comprehensive Income:

	For the year ended June 30,				
	2021 A$	**2020 A$**	**2019 A$**	**2018 A$**	**2017 A$**
Consolidated Statement of Profit or Loss and Other Comprehensive Income Data:					
Revenue from contracts with customers	**145,776**	2,518,566	2,387,426	1,842,909	1,396,197
Cost of Goods Sold	**(51,071)**	(688,836)	(667,371)	(418,693)	(337,546)
Gross Profit	**94,705**	1,829,730	1,720,055	1,424,216	1,058,651
Other Income	**617,110**	473,674	532,050	1,849,163	1,605,987
Other gains/(losses) – net	**(1,342,293)**	11,335	38,413	95,167	(375,479)
Expenses:					
General and administrative expenses	**(3,978,679)**	(3,703,990)	(3,694,306)	(3,410,254)	(2,682,766)
Share-based payment expenses	**(2,116,013)**	533,912	(1,343,500)	(59,975)	(522,665)
Research and development expenses	**(1,367,054)**	(1,178,685)	(1,044,528)	(2,257,224)	(4,630,674)
Selling and marketing expenses	**(287,684)**	(871,551)	(864,644)	(686,714)	(1,271,526)
Operating loss	**(8,379,908)**	(2,905,575)	(4,656,460)	(3,045,621)	(6,818,472)
Finance income	**9,204**	—	39	1,238	8,386
Finance expenses	**(13,761)**	(21,631)	—	(24,199)	(89,654)
Finance costs - net	**(4,557)**	(21,631)	39	(22,961)	(81,268)
Loss before income tax	**(8,384,465)**	(2,927,206)	(4,656,421)	(3,068,582)	(6,899,740)
Income Tax Expense	—	—	—	—	—
Loss for the period	**(8,384,465)**	(2,927,206)	(4,656,421)	(3,068,582)	(6,899,740)
Other comprehensive income					
Items that may be reclassified to profit or loss:					
Exchange differences on translation of foreign operations	(14,953)	102,938	61,846	(79,599)	40,017
Total Comprehensive Loss for the Period	**(8,399,418)**	(2,824,268)	(4,594,575)	(3,148,181)	(6,859,723)
Loss per share, basic and diluted (in cents per share)	**(3.79)**	(1.66)	(3.22)	(2.30)	(6.48)
Weighted-average number of shares outstanding, basic and diluted	**221,062,229**	176,393,354	144,740,535	133,660,556	105,866,110

	As of June 30,				
	2021 A$	2020 A$	2019 A$	2018 A$	2017 A$
Consolidated Statement of Financial Position Data:					
Cash and cash equivalents	**25,047,281**	3,250,468	5,119,887	4,727,430	3,994,924
Total current assets	**25,752,778**	4,409,041	6,682,444	7,050,437	8,267,654
Total assets	**27,053,106**	6,202,163	8,561,647	9,242,688	8,286,491
Total current liabilities	**1,121,853**	516,411	1,195,531	803,338	1,711,565
Total liabilities	**1,158,049**	558,250	1,210,511	803,338	1,711,565
Total equity	**25,895,057**	5,643,913	7,351,136	8,439,350	6,574,926

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Investing in our ADSs involves a high degree of risk and uncertainty. You should carefully consider the risks and uncertainties described below before investing in our ADSs. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be harmed. In that case, the price of our ADSs could decline, and you could lose all or part of your investment.

Summary of Risk Factors

The following summarizes some, but not all, of the risks provided below. Please carefully consider all of the information discussed in this Item 3.D. "Risk Factors" in this annual report for a more thorough description of these and other risks:

Summary of Risks Related to Our Financial Condition

As a company predominantly focused on the research and development activities of our existing patent portfolio we have incurred operating losses; we expect to continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

Summary of Risks Related to Our Business

Clinical trials are expensive and time consuming, and their outcome is uncertain.

We may not be successful in obtaining or maintaining other rights necessary for the development of our pipeline through acquisitions and in-licenses.

We grant licenses to our collaborators to use our hyper-immune colostrum technology exclusively for the development of product candidates for certain conditions.

We may not be able to complete the development of IMM-124E, IMM-529 or develop other pharmaceutical products.

Our research and development efforts will be seriously jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will negatively impact our business and operations.

We face competition from entities that have developed or may develop product candidates for our target disease indications, including companies developing novel treatments and technology platforms based on modalities and technology similar to ours. If these companies develop technologies or product candidates more rapidly than we do or their technologies, including delivery technologies, are more effective, our ability to develop and successfully commercialize product candidates may be compromised.

Our product candidates and the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval.

We currently depend upon a sole manufacturer of our lead compound and on a sole manufacturer to produce finished drug products and could incur significant costs and delays if we are unable to promptly find a replacement for either of them.

Our future prospects may also be dependent on our or our collaborators' ability to successfully develop a pipeline of additional product candidates, and we and our collaborators may not be successful in efforts to use our platform technologies to identify or discover additional product candidates.

We may not be able to obtain orphan drug exclusivity for some of our product candidates.

Summary of Risks Related to Government Regulation

If we do not obtain the necessary governmental approvals, we will be unable to commercialize our pharmaceutical products.

Our product candidates are based on our hyper-immune colostrum technology. Currently, no prescription product candidates utilizing our technology have been approved for commercial sale and our approach to the development of our technology may not result in safe, effective or marketable products.

We are early in our product development efforts and have only two product candidates in early-stage clinical trials. All of our other current product candidates are still in preclinical development. We have no late-stage clinical trials (post-proof of concept) and may not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

Summary of Risks Related to Our Intellectual Property

Our success depends upon our ability to protect our intellectual property and our proprietary technology, to operate without infringing the proprietary rights of third parties and to obtain marketing exclusivity for our products and technologies.

We may face difficulties in certain jurisdictions in protecting our intellectual property rights, which may diminish the value of our intellectual property rights in those jurisdictions.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

Summary of Risks Related to Our Securities

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADS.

As a foreign private issuer, we are permitted, and we expect to follow certain home country corporate governance practices in lieu of certain NASDAQ requirements applicable to domestic issuers. This may afford less protection to holders of our ADSs.

As a foreign private issuer, we are permitted to file less information with the SEC than a company incorporated in the U.S. Accordingly, there may be less publicly available information concerning us than there is for companies incorporated in the U.S.

We are an emerging growth company as defined in the JOBS Act and the reduced disclosure requirements applicable to emerging growth companies may make the ADS less attractive to investors and, as a result, adversely affect the price of the ADS and result in a less active trading market for the ADS.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, the price of our ordinary shares and ADSs could decline significantly and raising capital could be more difficult.

ADS holders may be subject to additional risks related to holding ADS rather than ordinary shares.

Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.

You will have limited ability to bring an action against us or against our directors and officers, or to enforce a judgment against us or them, because we are incorporated in Australia and certain of our directors and officers reside outside the U.S.

Australian companies may not be able to initiate shareholder derivative actions, thereby depriving shareholders of the ability to protect their interests.

Anti-takeover provisions in our Constitution and our right to issue preference shares could make a third-party acquisition of us difficult.

Risks Related to Our Financial Condition

COVID-19

Judgement has been exercised in considering the impacts that the Coronavirus (COVID-19) pandemic has had, or may have, on the group based on known information. This consideration extends to the nature of the products and services offered, customers, supply chain, staffing and geographic regions in which the group operates. Sales of Travelan have significantly dropped from March 2020 and as at reporting date it is unknown the prolonged effect that COVID-19 will continue to have on sales.

As a company predominantly focused on the research and development activities of our existing patent portfolio we have incurred operating losses; we expect to continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred losses in every period since we began operations in 1994 and we have reported net losses of A$8,384,465, A$2,927,206, A$4,656,421, A$3,068,582 and A$6,899,740 during the fiscal years ended June 30, 2021, 2020, 2019, 2018 and 2017, respectively. As of June 30, 2021, our accumulated deficit was A$65,932,888. We are budgeting to continue to incur additional operating losses for the next several years as we expand our research and development activities for the treatment of infectious diseases, commence new trials for our product candidate IMM-529 for C. *difficile*, and potential other assets/indications. We may never be able to achieve or maintain profitability.

Our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including:

- the continued progress of our research and development programs;
- the timing, scope, results and costs of pre-clinical studies and clinical trials;
- the cost, timing and outcome of regulatory submissions and approvals;
- determinations as to the commercial potential of our product candidates;
- spending on our marketed assets;
- our ability to successfully expand our contract manufacturing services;
- our ability to establish and maintain collaborative arrangements; and
- the status and timing of competitive developments.

As of June 30, 2021, we had A$25,047,281 in cash and cash equivalents. Developing prescription products is expensive and we will need to secure additional financing in order to continue to meet our longer-term business objectives, including advancement of our research and development programs. We may also require additional funds to pursue regulatory clearances, defend our intellectual property rights, establish commercial scale manufacturing facilities, develop marketing and sales capabilities and fund operating expenses. We intend to seek such additional funding through public or private financings and/or through licensing of our assets or strategic alliances or other arrangements with corporate partners. The global economic climate could adversely impact our ability to obtain such funding, license our assets or enter into alliances or other arrangements with corporate partners. Any shortfall in funding could result in our having to curtail or cease our operations, including our research and development activities, which would be expected to adversely affect our business, financial condition and results of operations.

We have never generated any revenue from prescription product sales and this area of our business may never be profitable.

Our ability to generate significant revenue from prescription products and achieve profitability depends on our ability to, alone or with strategic collaboration partners, successfully complete the development of and obtain the regulatory approvals for our prescription product candidates, to manufacture sufficient supply of our product candidates, to establish a sales and marketing organization or suitable third-party alternative for the marketing of any approved products and to successfully commercialize any approved products on commercially reasonable terms. All of these activities will require us to raise sufficient funds to finance business activities. Currently, we do not expect any milestone payments from our collaborative partners to be significant in the foreseeable future. However, we are actively pursuing potential partner collaboration. In addition, we do not anticipate generating revenue from commercializing product candidates for the foreseeable future, if ever.

Our ability to generate future revenues from commercializing our intellectual property ("IP") assets depends heavily on our success in:

- establishing proof of concept in preclinical studies and clinical trials for our product candidates;
- successfully completing clinical trials of our product candidates;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- maintaining, protecting and expanding our intellectual property portfolio, and avoiding infringing on intellectual property of third parties;
- establishing and maintaining successful licenses, collaborations and alliances with third parties;
- developing a sustainable, scalable, reproducible and transferable manufacturing process for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide products and services adequate, in amount and quality, to support clinical development and commercialization of our product candidates, if approved;
- launching and commercializing any product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining market acceptance of any product candidates that receive regulatory approval as viable treatment options;
- obtaining favorable coverage and reimbursement rates for our products from third-party payors;
- addressing any competing technological and market developments;
- identifying and validating new product candidates; and
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter.

The process of developing product candidates for the prevention and treatment of gut mediated pathogens contains several inherent risks and uncertainties, including clinical and regulatory risks.

Even if one or more of our product candidates is approved for commercial sale, we may incur significant costs associated with commercializing any approved product candidate. As one example, our expenses could increase beyond expectations if we are required by the Food and Drug Administration, or FDA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations, which could have an adverse effect on our business, financial condition, results of operations and prospects.

We are a commercial and development stage company and our success is uncertain.

We are a commercial and clinical-stage biopharmaceutical company and our pharmaceutical products are designed to treat a range of infectious diseases. Other than our Travelan and Protectyn products, we have not sufficiently advanced the development of any of our products, including our current lead product candidate, IMM-124E, to market or generate revenues from their commercial application. Our current or any future product candidates, if successfully developed, may not generate sufficient or sustainable revenues to enable us to be profitable.

We receive Australian government research and development income tax concession refunds. If our research and development expenditures are not deemed eligible for the refund, we may encounter difficulties in the funding of future research and development projects, which could harm our operating results.

We have historically received, and expect to continue to receive, refunds from the Australian Federal Government's Research and Development Tax Incentive program, under which the government provides a cash refund for the 43.5% of eligible research and development expenditures by small to medium size Australian entities during the year ended June 30, 2021, which are defined as Australian entities with less than A$20 million in revenue, having a tax loss.

The Research and Development Tax Incentive refunds are made by the Australian federal government for eligible research and development purposes based on the filing of an annual application and subsequent income tax returns for the fiscal year. We recognized Research and Development Tax Concession Incentive refunds in the fiscal years ended June 30, 2020, June 30, 2019, June 30, 2018 and June 30, 2017 of A$308,225, A$531,005, A$1,849,123 and A$1,575,315, respectively, and we have recognized A$306,154 for the fiscal year ended June 30, 2021, that includes an estimate of the receipt for the claim yet to be filed.

These refunds are available to fund our ongoing activities including our research and development activities in Australia, as well as activities in the U.S. to the extent such overseas-based expenses relate to our activities in Australia, do not exceed half the expenses for the relevant activities and are approved by the Australian government. To the extent our research and development expenditures are deemed to be "ineligible," then our refunds would decrease. In addition, the Australian government may in the future modify the requirements of or reduce the amounts or percentage claimable in turn reducing the refunds available under the Research and Development Tax Incentive program, or discontinue the incentive program entirely. Any such change in the Research and Development Tax Incentive program would have a negative effect on our future cash flows and our potential associated future expenditures.

Risks Related to Our Business

A variety of general risk factors associated with commercializing our products and product candidates internationally could materially adversely affect our business.

We, or our licensing partners, may seek regulatory approval for our products or product candidates in multi- jurisdictions, accordingly, we expect that we will be subject to additional risks for our products and product candidates related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labour laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labour unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as in the EU or the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our or our licensing partners' international operations may materially adversely affect our ability to attain or maintain profitable operations.

We are faced with uncertainties related to our research.

Our research programs are based on scientific hypotheses and experimental approaches that may not lead to desired results. In addition, the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic and collaborator scientific constraints. Success in one stage of testing is not necessarily an indication that the particular program will succeed in later stages of testing and development. It is not possible to predict whether any of the drugs designed for these programs will prove to be safe, effective, and suitable for human use. Each drug will require additional research and development, scale-up, formulation and extensive clinical testing in humans. Unsatisfactory results obtained from a particular study relating to a program may cause us to abandon our commitment to that program or to the lead compound or product candidate being tested. The discovery of toxicities, lack of sufficient efficacy, unacceptable pharmacology, inability to increase scale of manufacture, market attractiveness, regulatory hurdles, competition, as well as other factors, may make our targets, lead therapies or product candidates unattractive for further development or unsuitable for human use, and we may abandon our commitment to that program, target, lead therapy or product candidate. Any delay in obtaining or failure to obtain required approvals could materially and adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact the price of the ADS. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

Clinical trials are expensive and time consuming, and their outcome is uncertain.

In order to obtain approvals to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our potential partners will have to conduct extensive preclinical testing and "adequate and well- controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Even if we obtain positive results from preclinical or initial clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our technology. The failure of clinical trials to demonstrate safety and efficacy for a particular desired indication could harm development of that product candidate for other indications as well as other product candidates.

We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not meet our deadlines or otherwise conduct the studies as required, we may be delayed in progressing, or ultimately may not be able to progress, product candidates to clinical trials, our clinical development programs could be delayed or unsuccessful, and we may not be able to commercialize or obtain regulatory approval for our product candidates when expected, or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on third parties to conduct the clinical trials for IMM-124E and IMM-529, and preclinical studies for our other product candidates, and therefore the timing of the initiation and completion of these trials and studies is reliant on third parties and may occur at times substantially different from our estimates or expectations.

If we cannot contract with acceptable third parties on commercially reasonable terms, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed or discontinued.

We may experience delays in one or any of our clinical trial programs that could have an adverse effect on our business and operations, and future commercialization opportunities of our clinical pipeline.

To the extent we do our best to plan and mitigate against known risk aspects of our clinical trial programs, we do not know with any certainty whether the planned clinical trials will begin on time, whether we will complete any of our clinical trials on schedule, or at all, or within the forecasted budget. Our ability to commence and complete clinical trials may be delayed by many factors, including, but not limited to:

- government or regulatory delays, including delays in obtaining approvals from applicable hospital ethics committees and internal review boards;
- slower than expected patient enrollment;
- our inability to manufacture sufficient quantities of our new proprietary compound or our other product candidates or matching controls;
- unforeseen safety issues; or
- lack of efficacy or unacceptable toxicity during the clinical trials or non-clinical studies.

Patient enrollment is a function of, among other things, the nature of the clinical trial protocol, the existence of competing protocols, the size and longevity of the target patient population, and the availability of patients who comply with the eligibility criteria for the clinical trial. Delays in planned patient enrollment may result in increased costs, delays or termination of the clinical trials. Moreover, we rely on third parties such as clinical research organizations to assist us in clinical trial management functions including clinical trial database management, statistical analyses, site management and monitoring. Any failure by these third parties to perform under their agreements with us may cause the trials to be delayed or result in a failure to complete the trials.

If we experience delays in testing, in gaining the receipt of necessary approvals, or if we need to perform more, larger or more complex clinical trials than planned, our product development costs may increase. Significant delays could adversely affect the commercial prospects of our product candidates and our business, financial condition and results of operations.

We may not be successful in obtaining or maintaining other rights necessary for the development of our pipeline through acquisitions and in-licenses.

Our product candidates may require specific formulations to work effectively, and efficiently, and rights to such formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify on terms that we find acceptable, or at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

We rely on research institutions to conduct our clinical trials and we may not be able to secure and maintain research institutions to conduct our future trials.

Our reliance upon research institutions, including public and private hospitals and clinics, provides us with less control over the timing and cost of clinical trials, clinical study management personnel and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to secure, maintain, or quickly replace the research institution with another qualified institution on acceptable terms.

We grant licenses to our collaborators to use our hyper-immune colostrum technology exclusively for the development of product candidates for certain conditions.

We may out-license to our collaborators the right to use our hyper-immune colostrum technology for the development of product candidates for certain conditions, so long as our collaborators comply with certain requirements. That means that once our technology is licensed to a collaborator for a specified condition, we are generally prohibited from developing product candidates for that condition and from licensing to any third party for that condition. The limitations imposed by these exclusive licenses could prevent us from expanding our business and increasing our development of product candidates with new collaborators, both of which could adversely affect our business and results of operations.

We may not be able to complete the development of IMM-124E, IMM-529 or develop other pharmaceutical products.

We may not be able to progress with the development of our current, or any future, pharmaceutical product candidates to a stage that will attract a suitable collaborative partner for the development of any current or future pharmaceutical product candidates. The projects initially specified in connection with any such collaboration and any associated funding may change or be discontinued as a result of changing interests of either the collaborator or us, and any such change may change the budget for the projects under the collaboration. Additionally, our research may not lead to the discovery of additional product candidates, and any of our current and future product candidates may not be successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards and receive regulatory approval, be capable of being produced in commercial quantities at reasonable costs, or be successfully or profitably marketed, either by us or a collaborative partner. The products we develop may not be able to penetrate the potential market for a particular therapy, or indication, or gain market acceptance among health care providers, patients and third-party payers. We cannot predict if or when the development of IMM-124E, IMM-529 or any future pharmaceutical product will be completed or commercialized, whether funded by us, as part of a collaboration or through a grant.

We may need to prioritize the development of our most promising candidates at the expense of the development of other products.

We may need to prioritize the allocation of development resources and/or funds towards what we believe to be our most promising product or products. The nature of the drug development process is such that there is a constant availability of new information and data that could positively or adversely affect any of our products in development. We cannot predict how such new information and data may impact in the future the prioritization of the development of our current or future product candidates or that any of our products, regardless of its development stage or the investment of time and funds in its development, will continue to be funded or developed.

Our research and development efforts will be seriously jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

Our future success depends to a large extent on the continued services of our senior management and key scientific personnel, including Dr. Jerry Kanellos who is currently our Chief Executive Officer.

Competition among biotechnology and pharmaceutical companies for qualified employees is intense, including competition from larger companies with greater resources, and we may not be able to continue to attract and retain qualified management, technical and scientific personnel critical to our success. Our success is highly dependent on our ability to develop and maintain important relationships with leading academic institutions and scientists who conduct research at our request or assist us in formulating our research and development strategies. These academic and scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these collaborators may have arrangements with other companies to assist such companies in developing technologies that may prove competitive to ours.

If we are unable to successfully keep pace with technological change or with the advances of our competitors, our technology and products may become obsolete or non-competitive.

The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our competitors are numerous and include major pharmaceutical companies, biotechnology firms, universities and other research institutions. These competitors may develop technologies and products that are more effective than any that we are developing, or which would render our technology and products obsolete or non-competitive. Many of these competitors have greater financial and technical resources and manufacturing and marketing capabilities than we do. In addition, many of our competitors have much more experience than we do in pre-clinical testing and human clinical trials of new or improved drugs, as well as in obtaining regulatory approvals.

We know that competitors are developing or manufacturing various technologies or products for the treatment of diseases that we have targeted for product development. Some of these competitive products use therapeutic approaches that compete directly with our product candidates. Our ability to further develop our products may be adversely affected if any of our competitors were to succeed in obtaining regulatory approval for their competitive products sooner than us.

Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will negatively impact our business and operations.

Our current or future products may not achieve market acceptance even if they are approved by regulatory authorities. The degree of market acceptance of such products will depend on a number of factors, including:

- the receipt and timing of regulatory approvals for the uses that we are studying;
- the establishment and demonstration to the medical community of the safety, clinical efficacy or cost-effectiveness of our product candidates and their potential advantages over existing therapeutics and technologies; and
- the pricing and reimbursement policies of governments and third-party payors.

Physicians, patients, third-party payors or others in the medical community may not be receptive to our product candidates, and we may not generate any future revenue from the sale or licensing of our product candidates.

Even if we obtain approval for a product candidate, we may not generate or sustain revenue from sales of the product if the product cannot be sold at a competitive cost or if it fails to achieve market acceptance by physicians, patients, third-party payors or others in the medical community. These market participants may be hesitant to adopt a novel treatment based on hyper-immune colostrum technology, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the safety and efficacy of our product candidates;
- our ability to offer our products for sale at competitive prices;
- the relative convenience and ease of administration of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- the terms of any approvals and the countries in which approvals are obtained;
- limitations or warnings contained in any labeling approved by the FDA or comparable foreign regulatory authorities;
- conditions upon the approval imposed by FDA or comparable foreign regulatory authorities, including, but not limited to, a Risk Evaluation and Mitigation Strategy (“REMS”);
- the willingness of patients to try new treatments and of physicians to prescribe these treatments;
- the availability of government and other third-party payor coverage and adequate reimbursement; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Additional risks apply in relation to any disease indications we pursue which are classified as rare diseases and allow for orphan drug designation by regulatory agencies in major commercial markets, such as the U.S. or European Union. If pricing is not approved or accepted in the market at an appropriate level for any approved product for which we pursue and receive an orphan drug designation, such product may not generate enough revenue to offset costs of development, manufacturing, marketing and commercialization despite any benefits received from the orphan drug designation, such as market exclusivity, for a period of time. Orphan exclusivity could temporarily delay or block approval of one of our products if a competitor obtains orphan drug designation for its product first. However, even if we obtain orphan exclusivity for one of our products upon approval, our exclusivity may not block the subsequent approval of a competitive product that is shown to be clinically superior to our product.

Market size is also a variable in disease indications not classified as rare. Our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

We face competition from entities that have developed or may develop product candidates for our target disease indications, including companies developing novel treatments and technology platforms based on modalities and technology similar to ours. If these companies develop technologies or product candidates more rapidly than we do or their technologies, including delivery technologies, are more effective, our ability to develop and successfully commercialize product candidates may be compromised.

The development and commercialization of pharmaceutical products is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or could develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community, patients and third-party payors, and any new treatments that enter the market.

We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing, and may in the future try to develop, product candidates. We are aware of multiple companies that are working in the field of infectious diseases, travelers' diarrhea and C. *difficile* therapeutics, including Cosmo Technologies, PanTheryx, Proctor and Gamble, and Scandinavian BioPharma which are all developing therapeutics for travelers' diarrhea and, Acetelion, Assembly Biotechnology, Creston Pharma, Da Volterra, Seres, Synthetic Biotechnology and Rebiotix Inc. for C. *difficile*.

We have limited large scale manufacturing experience with our product candidates. Delays in manufacturing sufficient quantities of such materials to the required standards for pre-clinical and clinical trials may negatively impact our business and operations.

While we have extensive experience in producing therapeutic colostrum, we may not be able to manufacture sufficient quantities of our product candidates in a cost-effective or timely manner. Manufacturing includes the production, formulation and stability testing of an active pharmaceutical ingredient and its formulation into pharmaceutical products, such as capsules or tablets. Any delays in production would delay our pre-clinical and human clinical trials, which could adversely affect our business, financial condition and operations.

We may be required to enter into contracting arrangements with third parties to manufacture our product candidates for large-scale, pre-clinical and/or clinical trials. We may not be able to make the transition from laboratory-scale to development-scale or from development-scale to commercial production. We may need to develop additional manufacturing resources, enter into collaborative arrangements with other parties who have established manufacturing capabilities, or have third parties manufacture our products on a contract basis. We may not have access on acceptable terms to the necessary and substantial financing that would be required to scale-up production and develop effective commercial manufacturing processes and technologies. We may not be able to enter into collaborative or contracting arrangements on acceptable terms with parties that will meet our requirements for quality, quantity and timeliness.

If we are not able to obtain an acceptable purity for any product candidate or an acceptable product specification, pre-clinical and clinical trials would be delayed, which could adversely affect the priority of the development of our product candidates, our business, financial condition and results of operations. This may adversely impact the cost of goods or feasibility of market scale.

Our product candidates and the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval.

Treatment with our product candidates may produce undesirable side effects or adverse reactions or events. If any such adverse events occur, our clinical trials could be suspended or discontinued, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial. If we elect or are required to delay, suspend or discontinue any clinical trial of any of our product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

We currently depend upon a sole manufacturer of our lead compound and on a sole manufacturer to produce finished drug products and could incur significant costs and delays if we are unable to promptly find a replacement for either of them.

At this time, we are relying on a single manufacturer to develop Good Manufacturing Practice ("GMP"), processes for our lead compound. Our lead compound, IMM-124E, is manufactured by Synlait Milk Limited based in New Zealand. This manufacturer enables efficient large-scale manufacture of colostrum to provide drug substance for our current and prospective clinical trials. We also rely on contract manufacturers such as Mayne Pharma International and Australian Blister Sealing to produce all of our marketed products and PCI Clinical Services to package our investigational drug products. We are actively seeking additional and back-up manufacturers but may be unsuccessful in our efforts or may incur material additional costs and substantial delays.

The failure to establish sales, marketing and distribution capability would materially impair our ability to successfully market and sell our pharmaceutical products.

We currently have limited experience in the marketing, sales or distribution of pharmaceutical products. If we develop any commercially marketable pharmaceutical products and decide to perform our own sales and marketing activities, we will require additional resources and, will need to hire sales and marketing personnel which will require additional capital. Qualified personnel may not be available in adequate numbers or at a reasonable cost. Furthermore, our sales staff may not achieve success in their marketing efforts. Alternatively, we may be required to enter into marketing arrangements with other parties who have established appropriate marketing, sales and distribution capabilities. We may not be able to enter into marketing arrangements with any marketing partner, or if such arrangements are established, our marketing partners may not be able to commercialize our products successfully. Other companies offering similar or substitute products may have well-established and well-funded marketing and sales operations in place that will allow them to market their products more effectively. Failure to establish sufficient marketing capabilities would materially impair our ability to successfully market and sell our pharmaceutical products.

If healthcare insurers and other organizations do not pay for our products, or impose limits on reimbursement, our future business may suffer.

The drugs we hope to develop may be rejected by the marketplace due to many factors, including cost. The continuing efforts of governments, insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability and those of our potential customers, suppliers and collaborative partners, as well as the availability of capital. In Australia and certain foreign markets, the pricing or profitability of prescription pharmaceuticals is already subject to government control. We expect initiatives for similar government control at both the state and federal level to continue in the U.S. and elsewhere. The adoption of any such legislative or regulatory proposals could adversely affect our business and prospects.

Our ability to commercially exploit our products successfully will depend in part on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Third-party payors, such as government and private health insurers, are increasingly challenging the price of medical products and services. Uncertainty exists as to the reimbursement status of newly approved health care products and in foreign markets, including the U.S. If third-party coverage is not available to patients for any of the products we develop, alone or with collaborators, the market acceptance of these products may be reduced, which may adversely affect our future revenues and profitability. In addition, cost containment legislation and reductions in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.

We may be exposed to product liability claims, which could harm our business.

The testing, marketing, and sale of human health care products also entail the inherent risk of product liability. We may incur substantial liabilities or be required to limit development or commercialization of our products if we cannot successfully defend ourselves against product liability claims. We have historically obtained no fault compensation insurance for our clinical trials and will continue to obtain similar coverage for all future clinical trials. Such coverage may not be available in the future on acceptable terms, or at all. This may result in our inability to pursue further clinical trials or to obtain adequate protection in the event of a successful claim. We may not be able to obtain product liability insurance in the event of the commercialization of a product or such insurance may not be available on commercially reasonable terms. Even if we have adequate insurance coverage, product liability claims, or recalls could result in negative publicity or force us to devote significant time, attention and financial resources to those matters.

Breaches of network or information technology security, natural disasters or terrorist attacks could have an adverse effect on our business.

Cyber-attacks or other breaches of network or information technology ("IT") security, natural disasters, terrorist acts or acts of war may cause equipment failures or disrupt our research and development operations. In particular, both unsuccessful and successful cyber-attacks on companies have increased in frequency, scope and potential harm in recent years. Such an event may result in our inability, or the inability of our partners, to operate the research and development facilities, which even if the event is for a limited period of time, may result in significant expenses and/or significant damage to our experiments and trials. In addition, a failure to protect employee confidential data against breaches of network or IT security could result in damage to our reputation. Any of these occurrences could adversely affect our results of operations and financial condition.

We expect to expand our drug development, regulatory and business development capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of drug development, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a materially adverse effect on our business.

Positive results from preclinical studies of our product candidates are not necessarily predictive of future results of planned clinical trials of our product candidates.

Positive results in preclinical proof-of-concept and animal studies of our product candidates may not result in positive results in clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early stage clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory authority approval. If we fail to produce positive results in our clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

Our future prospects may also be dependent on our or our collaborators' ability to successfully develop a pipeline of additional product candidates, and we and our collaborators may not be successful in efforts to use our platform technologies to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our platform technology. We only have three product candidates currently in clinical development and several in early stage research and preclinical development.

Our other product candidates derived from our platform technology may not successfully complete IND-enabling studies, and our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our and our collaborators' research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may not demonstrate the necessary preclinical outcomes to progress to clinical studies, or our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

If any of these events occur, we may be forced to discontinue our development efforts for a program or programs. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We may not be able to obtain orphan drug exclusivity for some of our product candidates.

Of our current product candidates, the only one designed for treatment of an indication that would likely qualify for rare disease status is IMM-529 for the treatment of recurrent C. *difficile*. Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs or biological products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. The FDA may also designate a product as an orphan drug if it is intended to treat a disease or condition of more than 200,000 individuals in the U.S. and there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product candidate. Under the European Union orphan drug legislation, a rare disease or condition means a disease or condition which affects not more than five in ten thousand persons in the European Union at the time of the orphan drug designation application.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for that time period. During the marketing exclusivity period, in the European Union, the European Medicines Agency, or the EMA, is precluded from approving a similar drug with an identical therapeutic indication. The applicable period is seven years in the U.S. and ten years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition, and the same drug could be approved for a different condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug, made by a competitor, for the same condition if the FDA concludes that the competitive product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, the EMA can approve a competitive product if the orphan drug no longer meets the criteria for orphan designation (including sufficient profitability), if the competitive product is safer, more effective or otherwise clinically superior, or if the orphan drug cannot be supplied in sufficient quantities.

We have not entered into agreements with any third-party manufacturers to support commercialization of our pharmaceutical product candidates. Additionally, no manufacturers have experience producing our product candidates at commercial levels, and any manufacturer that we work with may not achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.

We have not yet secured manufacturing capabilities for commercial quantities of our product candidates or established facilities in the desired locations to support commercialization of our product candidates. We intend to rely on third-party manufacturers for commercialization, and currently we have only entered into agreements with such manufacturers to support our clinical trials for IMM-124E. We may be unable to negotiate agreements with third-party manufacturers to support our commercialization activities on commercially reasonable terms.

We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Currently, we do not have the capacity to manufacture our product candidates on a commercial scale. In addition, our product candidates are novel, and no manufacturer currently has experience producing our product candidates on a large scale. If we are unable to engage manufacturing partners to produce our product candidates on a larger scale on reasonable terms, our commercialization efforts will be harmed.

Even if we timely develop a manufacturing process and successfully transfer it to the third-party manufacturers of our product candidates, if such third-party manufacturers are unable to produce the necessary quantities of our product candidates, or do so in compliance with Current Good Manufacturing Practice ("cGMP") or with pertinent foreign regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our product candidates, if approved, may be impaired.

Risks Related to Government Regulation

If we do not obtain the necessary governmental approvals, we will be unable to commercialize our pharmaceutical products.

Our ongoing research and development activities are, and the production and marketing of our pharmaceutical product candidates derived from such activities will be, subject to regulation by numerous international regulatory authorities. Prior to marketing, any therapeutic product developed must undergo rigorous pre-clinical testing and clinical trials and, to the extent that any of our pharmaceutical products under development are marketed abroad, by the relevant international regulatory authorities. For example, in Australia, principally the Therapeutics Goods Administration ("TGA"), the FDA in the U.S.; the Medicines and Healthcare products Regulatory Agency, ("MHRA") in the United Kingdom; the Medical Products Agency ("MPA") in Sweden; and the EMA in Europe. These regulatory processes can take many years and require the expenditure of substantial resources. Governmental authorities may not grant regulatory approval due to matters arising from pre-clinical animal toxicology, safety pharmacology, drug formulation and purity, clinical side effects or patient risk profiles, or medical contraindications. Failure or delay in obtaining regulatory approvals would adversely affect the development and commercialization of our pharmaceutical product candidates. We may not be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our pharmaceutical product candidates.

We will not be able to commercialize any current or future product candidates if we fail to adequately demonstrate their safety, efficacy and superiority over existing therapies.

Before obtaining regulatory approvals for the commercial sale of any of our pharmaceutical products, we must demonstrate through pre-clinical testing and clinical studies that our product candidates are safe and effective for use in humans for each target indication. Results from early clinical trials may not be predictive of results obtained in large-scale, later-stage clinical testing. Even though a potential drug product shows promising results in clinical trials, regulatory authorities may not grant the necessary approvals without sufficient safety and efficacy data.

We may not be able to undertake further clinical trials of our current and future product candidates as therapies for infectious diseases, C. *difficile* or other indications or to demonstrate the safety and efficacy or superiority of any of these product candidates over existing therapies or other therapies under development, or enter into any collaborative arrangement to commercialize our current or future product candidates on terms acceptable to us, or at all. Clinical trial results that show insufficient safety and efficacy could adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for a product candidate, our products may remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved biologics license application ("BLA") is obligated to monitor and report to the FDA adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable foreign, federal and state laws.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to permit government reimbursement of our product by government-sponsored third-party payors;
- refuse to approve a pending BLA or supplements to a BLA submitted by us for other indications or new product candidates;
- seize our product; or
- refuse to allow us to enter into or continue supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenues.

Healthcare reform measures and other statutory or regulatory changes could adversely affect our business.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our business. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA"), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program.

If we fail to comply with our reporting and payment obligations under the Medicaid program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations.

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress has considered various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development costlier. Additional legislation or regulation, if any, relating to the implementation of cost containment measures or other aspects of drug development may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

Our product candidates are based on our hyper-immune colostrum technology. Currently, no prescription product candidates utilizing our technology have been approved for commercial sale and our approach to the development of our technology may not result in safe, effective or marketable products.

We have concentrated our product research and development efforts on our hyper-immune colostrum technology, and our future success depends on successful clinical development of this technology. We plan to develop a pipeline of product candidates using our technology and deliver therapeutics for a number of infectious and life-threatening conditions, including moderate to severe campylobacteriosis, C. *difficile* Infections ("CDI"), Shigellosis (bacillary dysentery) and Traveler's Diarrhea.

The scientific research that forms the basis of our efforts to develop product candidates is based on the pre-clinical and clinical data in conditions such as CDI, Shigellosis (bacillary dysentery) and Traveler's Diarrhea, and the identification, optimization and delivery of hyper-immune colostrum-based product candidates is relatively new. The scientific evidence to support the feasibility of successfully developing therapeutic treatments based on our technology is preliminary and limited. There can be no assurance that any development and technical problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may be unable to reach an agreement on favorable terms, or at all, with providers of vectors needed to optimize delivery of our product candidates to target disease cells and we may also experience unanticipated problems or delays in expanding our manufacturing capacity or transferring our manufacturing process to commercial partners, any of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

Only a few product candidates based on our technology have been tested in either animals or humans. We may discover that the applications of our pharmaceutical drug candidates do not possess properties required for a therapeutic benefit. In addition, application of hyper-immune- based products in humans may result in safety problems. We currently have only limited long-term data, and no conclusive evidence, to suggest that we can effectively produce efficacious therapeutic treatments using our hyper-immune colostrum technology.

We are early in our product development efforts and have only two product candidates in early-stage clinical trials. All of our other current product candidates are still in preclinical development. We have no late-stage clinical trials (post-proof of concept) and may not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of biologics is subject to extensive regulation by the FDA and other regulatory authorities, and these regulations differ from country to country. We do not have any prescription products on the market and are early in our development efforts. We have two product candidates in clinical trials and all of our other product candidates are in preclinical development. All of our current and future product candidates are subject to the risks of failure typical for development of biologics. The development and approval process is expensive and can take many years to complete, and its outcome is inherently uncertain. In addition, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

We have not submitted an application, or received marketing approval, for any of our product candidates and will not submit any applications for marketing approval for several years. We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals for prescription product candidates. To receive approval, we must, among other things, demonstrate with evidence from clinical trials that the product candidate is both safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development.

The FDA and foreign regulatory authorities also have substantial discretion in the pharmaceutical and biological product approval process. The numbers, types and sizes of preclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or the decision not to approve an application. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the patients recruited for a particular clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the results of clinical trials may not confirm the positive results from earlier preclinical studies or clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of FDA or comparable foreign regulatory authorities to support the submission of a biologics license application, or BLA, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may only agree to approve a product candidate under conditions that are so restrictive that the product is not commercially viable;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulations in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining or failure to obtain required approvals could materially and adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact the price of the ADSs. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

We are not permitted to market our product candidates in the U.S. or in other countries until we receive approval of a BLA from the FDA or marketing approval from applicable regulatory authorities outside the U.S. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the U.S., which will significantly impair our ability to generate any revenues. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations on the indicated uses for which we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales.

Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability.

If our ability to use cumulative carry forward net operating losses is or becomes subject to certain limitations, our results of operations and financial condition may be adversely affected.

We are an Australian company subject to taxation in Australia and other jurisdictions. As of June 30, 2021, our cumulative operating losses have a total potential tax benefit of A$11,486,431 at local tax rates (excluding other temporary differences). These losses may be available for use once we are in a tax profitable position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdictions. Tax losses are able to be carried forward at their nominal amount indefinitely in Australia and for losses generated prior to January 1, 2018 for up to 20 years in the U.S. as long as certain conditions are met. In order to use these tax losses, it is necessary to satisfy certain tests and, as a result, we cannot assure you that the tax losses will be available to offset profits if and when we earn them. Utilization of our net operating loss and research and development credit carryforwards in the U.S. may be subject to substantial annual limitation due to ownership change limitations that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as amended. Our carry forward net operating losses in the U.S. first start to expire in 2035.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act.

Our business operations may be subject to anti-corruption laws and regulations, including restrictions imposed by the U.S. Foreign Corrupt Practices Act the FCPA. The FCPA and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. We cannot provide assurance that our internal controls and procedures will always protect us from criminal acts committed by our employees or third parties with whom we work. If we are found to be liable for violations of the FCPA or similar anti-corruption laws in international jurisdictions, either due to our own acts or out of inadvertence, or due to the acts or inadvertence of others, we could suffer from criminal or civil penalties which could have a material and adverse effect on our results of operations, financial condition and cash flows.

Risks Related to Our Intellectual Property

Our success depends upon our ability to protect our intellectual property and our proprietary technology, to operate without infringing the proprietary rights of third parties and to obtain marketing exclusivity for our products and technologies.

Any future success will depend in large part on whether we can:

- obtain and maintain patents to protect our own products and technologies;
- obtain orphan designation for our products and technologies;
- obtain licenses to the patented technologies of third parties;
- operate without infringing on the proprietary rights of third parties; and
- protect our trade secrets, know-how and other confidential information.

Patent matters in biotechnology are highly uncertain and involve complex legal and factual questions. Accordingly, the availability and breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. Any of the pending or future patent applications filed by us or on our behalf may not be approved, we may not develop additional proprietary products or processes that are patentable, or we may not be able to license any other patentable products or processes.

Our products may be eligible for orphan designation for particular therapeutic indications that are of relatively low prevalence and for which there is no effective treatment. Orphan drug designation affords market exclusivity post marketing authorization for a product for a specified therapeutic utility. The period of orphan protection is dependent on jurisdiction, for example, seven years in the U.S. and ten years in Europe. The opportunity to gain orphan drug designation depends on a variety of requirements specific to each marketing jurisdiction and can include; a showing of improved benefit relative to marketed products, that the mechanism of action of the product would provide plausible benefit and the nature of the unmet medical need within a therapeutic indication. It is uncertain if our products will be able to obtain orphan drug designation for the appropriate indications and in the jurisdictions sought.

Our commercial success will also depend, in part, on our ability to avoid infringement of patents issued to others. If a court determines that we were infringing any third-party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. Licenses required under patents held by third parties may not be made available on terms acceptable to us, or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, export, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents, and any of these circumstances could adversely affect our business, financial condition and results of operations.

We may have to resort to litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third-party proprietary rights. We may have to defend the validity of our patents in order to protect or enforce our rights against a third party. Third parties may, in the future, assert against us infringement claims or claims that we have infringed a patent, copyright, trademark or other proprietary right belonging to them. Any infringement claim, even if not meritorious, could result in the expenditure of significant financial and managerial resources and could negatively affect our profitability. While defending our patents, the scope of the claim may be reduced in breadth and inventorship of the claimed subject matter, and proprietary interests in the claimed subject matter may be altered or reduced. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Any such litigation or proceedings, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such litigation or proceedings could prevent us from developing, manufacturing or commercializing our products and could adversely affect our business, financial condition and results of operations.

The patents for our product candidates have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the U.S. and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review or by procedural delays before the relevant patent office. However, such an extension may not be granted, or if granted, the applicable time period or the scope of patent protection afforded during any extension period may not be sufficient. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

We may face difficulties in certain jurisdictions in protecting our intellectual property rights, which may diminish the value of our intellectual property rights in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the U.S. and the European Union, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition and results of operations may be adversely affected.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to ours but that are not covered by the claims of the patents that we own;
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights;
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;

- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges;
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business; and/or
- Compulsory licensing provisions of certain governments to patented technologies that are deemed necessary for the government to access.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents involves both technological complexity and legal complexity and is costly, time-consuming and inherently uncertain. In addition, the America Invents Act was recently enacted in the U.S., resulting in significant changes to the U.S. patent system. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent with regard to the type of amendments that are allowed during prosecution. These changes could limit our ability to obtain new patents in the future that may be important for our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third-party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

Risks Related to Our Securities

The market price and trading volume of our ADS may be volatile and may be affected by economic conditions beyond our control.

The market price of our ADS may be highly volatile and subject to wide fluctuations. In addition, the trading volume of the ADS may fluctuate and cause significant price variations to occur. If the market price of the ADS declines significantly, you may be unable to resell your ADS at or above the purchase price, if at all. We cannot assure you that the market price of the ADS will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the ADS or result in fluctuations in their price and trading volume include:

- actual or expected fluctuations in our operating results;
- changes in market valuations of similar companies;
- changes in our key personnel;
- changes in financial estimates or recommendations by securities analysts;
- trading prices of our ordinary shares on the Australian Securities Exchange ("ASX");
- changes in trading volume of ADS on The NASDAQ Capital Market, or NASDAQ, and of our ordinary shares on the ASX;
- sales of the ADS or ordinary shares by us, our executive officers or our shareholders in the future; and
- conditions in the financial markets or changes in general economic conditions.

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADS.

Our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADS. However, the dual listing of our ordinary shares and ADS may dilute the liquidity of these securities in one or both markets and may impair the development of an active trading market for the ADS in the U.S. The trading price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

As a foreign private issuer, we are permitted, and we expect to follow certain home country corporate governance practices in lieu of certain NASDAQ requirements applicable to domestic issuers. This may afford less protection to holders of our ADSs.

As a foreign private issuer whose shares are listed on NASDAQ, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the NASDAQ Stock Market Rules. Among other things, as a foreign private issuer we have elected to follow home country practice with regard to, the composition of the board of directors and the audit committee, the financial expert, director nomination procedure, compensation of officers and quorum at shareholders' meetings. In addition, we may follow our home country law, instead of the NASDAQ Stock Market Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Accordingly, our shareholders may not be afforded the same protection as provided under NASDAQ's corporate governance rules. See Item 16G - Corporate Governance.

As a foreign private issuer, we are permitted to file less information with the SEC than a company incorporated in the U.S. Accordingly, there may be less publicly available information concerning us than there is for companies incorporated in the U.S.

As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a U.S. company whose securities are registered under the Exchange Act, nor are we required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, there may be less information publicly available concerning us than there is for a company that files as a domestic issuer.

We are an emerging growth company as defined in the JOBS Act and the reduced disclosure requirements applicable to emerging growth companies may make the ADS less attractive to investors and, as a result, adversely affect the price of the ADS and result in a less active trading market for the ADS.

We are an emerging growth company as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. For example, we have elected to rely on an exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act relating to internal control over financial reporting, and we will not provide such an attestation from our auditors for so long as we qualify as an emerging growth company.

We may avail ourselves of these disclosure exemptions until we are no longer an emerging growth company. We cannot predict whether investors will find the ADS less attractive because of our reliance on some or all of these exemptions. If investors find the ADS less attractive, it may cause the trading price of the ADS to decline and there may be a less active trading market for the ADS.

We will cease to be an emerging growth company upon the earliest of:

- the end of the fiscal year in which the fifth anniversary of completion of our initial public offering ("IPO") occurs;
- the end of the first fiscal year in which the market value of our ordinary shares held by non-affiliates exceeds US$700 million as of the end of the second quarter of such fiscal year;
- the end of the first fiscal year in which we have total annual gross revenues of at least US$1.07 billion; and
- the date on which we have issued more than US$1 billion in non-convertible debt securities in any rolling three-year period.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, the price of our ordinary shares and ADSs could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. As of June 30, 2021, our management determined that we had no material weaknesses in our internal control over financial reporting. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our ordinary shares and ADSs could drop significantly.

ADS holders may be subject to additional risks related to holding ADS rather than ordinary shares.

ADS holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks:

- As an ADS holder, we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the ADR depositary as permitted by the amended and revised deposit agreement among the Company, The Bank of New York Mellon, as depositary, and owners and holders of our ADSs (the "Deposit Agreement");

- distributions on the ordinary shares represented by your ADS will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution; and

- We and the ADR depositary may amend or terminate the Deposit Agreement without the ADS holders' consent in a manner that could prejudice ADS holders.

You must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis.

As a holder of ADS (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADS, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADS only in accordance with the Deposit Agreement relating to the ADS. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the Deposit Agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date. If we so instruct, the ADR depositary will mail to holders of ADS the notice of the meeting and a statement as to the manner in which voting instructions may be given by holders as soon as practicable after receiving notice from us of any such meeting. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADS for which the ADR depositary fails to receive timely voting instructions will not be voted.

If we are classified as a "passive foreign investment company," then our U.S. shareholders could suffer adverse tax consequences as a result.

Generally, if, for any taxable year, at least 75% of our gross income is passive income (including our pro rata share of the gross income of our 25% or more owned corporate subsidiaries) or at least 50% of the average quarterly value of our total gross assets (including our pro rata share of the gross assets of our 25% or more owned corporate subsidiaries) is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, a U.S. holder of our ordinary shares or ADSs may suffer adverse tax consequences, including having gains recognized on the sale of our ordinary shares or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares or ADSs by individuals who are U.S. holders, and having interest charges added to their tax on distributions from us and on gains from the sale of our ordinary shares or ADS. See "Taxation—United States Federal Income Tax Considerations—*Passive Foreign Investment Company*."

Our status as a PFIC may also depend, in part, on how quickly we utilize any cash proceeds from any offering. Since PFIC status depends on the composition of our income and the composition and value of our assets, which may be determined in large part by reference to the market value of our ordinary shares or ADS, which may be volatile, there can be no assurance that we will not be a PFIC for any taxable year. While we expect that we were not a PFIC for our taxable year ended June 30, 2021, no assurance of our PFIC status can be provided for such taxable year or future taxable years. Prospective U.S. investors should discuss the issue of our possible status as a PFIC with their tax advisors.

Currency fluctuations may adversely affect the price of our ordinary shares and ADS.

Our ordinary shares are quoted in Australian dollars on the ASX and the ADS are quoted in U.S. dollars on NASDAQ. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of the ADS. In the past year the Australian dollar has generally weakened against the U.S. dollar. However, this trend may not continue and may be reversed. If the Australian dollar weakens against the U.S. dollar, the U.S. dollar price of the ADS could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged.

We have never declared or paid dividends on our ordinary shares and we do not anticipate paying dividends in the foreseeable future.

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment will only occur if our ADS price appreciates.

You may not receive distributions on our ordinary shares represented by the ADS or any value for such distribution if it is illegal or impractical to make them available to holders of ADS.

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depositary for the ADS has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADS represent. However, in accordance with the limitations set forth in the Deposit Agreement, it may be unlawful or impractical to make a distribution available to holders of ADS. We have no obligation to take any other action to permit the distribution of the ADS, ordinary shares, rights or anything else to holders of the ADS. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADS.

Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADS.

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the Australian Corporations Act 2001, or the Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' or ADS holders' opportunity to sell their ordinary shares or ADSs and may further restrict the ability of our shareholders and ADS holders to obtain a premium from such transactions. See Item 10. – Additional Information "Change of Control".

Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.

As an Australian company, we are subject to different corporate requirements than a corporation organized under the laws of the states of the U.S. Our Constitution, as well as the Australian Corporations Act, set forth various rights and obligations that are unique to us as an Australian company. These requirements may operate differently than those of many U.S. companies. See Item 10 - Additional Information.

You will have limited ability to bring an action against us or against our directors and officers, or to enforce a judgment against us or them, because we are incorporated in Australia and certain of our directors and officers reside outside the U.S.

We are incorporated in Australia, certain of our directors and officers reside outside the U.S. and substantially all of the assets owned by such persons are located outside of the U.S.. As a result, it may be impracticable or at least more expensive for you to bring an action against us or against these individuals in Australia in the event that you believe that your rights have been infringed under the applicable securities laws or otherwise.

You may be subject to limitations on transfer of the ADSs.

The ADSs are only transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deem it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the Deposit Agreement, or for any other reason.

Australian companies may not be able to initiate shareholder derivative actions, thereby depriving shareholders of the ability to protect their interests.

Australian companies may not have standing to initiate a shareholder derivative action in a federal court of the U.S. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect to any such action, may result in the rights of shareholders of an Australian company being more limited than those of shareholders of a company organized in the U.S. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. Australian courts are also unlikely to recognize or enforce against us judgments of courts in the U.S. based on certain liability provisions of U.S. securities law and to impose liabilities against us, in original actions brought in Australia, based on certain liability provisions of U.S. securities laws that are penal in nature. Although the courts of Australia may recognize and enforce the non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits upon being satisfied about all the relevant circumstances upon which such judgment was obtained, there is no statutory recognition in Australia of judgments obtained in the U.S..

Anti-takeover provisions in our Constitution and our right to issue preference shares could make a third-party acquisition of us difficult.

Some provisions of our Constitution may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable, including provisions that only require one-third of our board of directors to be elected annually and authorize our board of directors to issue an unlimited number of shares of capital stock and preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares by amending the Constitution.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

We were incorporated under the laws of the Commonwealth of Australia in 1994 and have been listed on the ASX since April 30, 1999. Our ADSs and Warrants have traded on The NASDAQ Capital Market since June 13, 2017. Our principal executive office is located at Level 3, 62 Lygon Street, Carlton South, Victoria, Australia 3053 and our telephone number is +61 (0)3 9824 5254. Our agent for service in the U.S. is Puglisi & Associates, 850 Library Avenue, Suite 204, Newark, DE 19711.

B. BUSINESS OVERVIEW

We are a commercial and clinical-stage biopharmaceutical company with a proprietary technology platform focused on the development and commercialization of a novel class of specifically targeted polyclonal antibodies that we believe can address significant unmet medical needs. Our oral polyclonal antibodies offer delivery within the gastrointestinal ("GI") tract and essentially do not cross into the bloodstream, potentially leading to much improved safety and tolerability, without sacrificing efficacy. We currently market our flagship commercial products Travelan® and Protectyn® in Australia, where both products are listed medicines on the Australian Register for Therapeutic Goods. Travelan® (AUST L 106709) is an over-the-counter orally administered passive immunotherapeutic product and is indicated to reduce the risk of travelers' diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial and is sold in pharmacies throughout Australia. Protectyn® (AUST L 231001) is currently sold online and in health practitioner clinics and is marketed as an immune supplement to help maintain a healthy digestive function and liver. We also market Travelan® (NPN 80046016) in Canada where it is licensed as a natural health product indicated to reduce the risk of travelers' diarrhea, and presently market Travelan® in the U.S. as a dietary supplement for digestive tract protection.

We currently have three lead drug candidates in clinical development, which we believe have the potential to transform the existing treatment paradigms for moderate to severe campylobacteriosis, *Clostridiodies difficle (C.difficle) Infections,* Enterotoxigenic *Escherichia coli* (ETEC) infections and travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce.

We also have several early-stage assets under development. Our technology platform can be used to block viruses or bacteria and neutralize the toxins they produce at mucosal surfaces such as the Gastrointestinal tract. We have completed the manufacture of three new *Shigella*-specific therapeutic products using proprietary vaccines developed by the Walter Reed Army Institute of Research (WRAIR). This collaboration aims to develop an oral therapeutic for shigellosis, a severe form of dysentery that affects about 165 million people a year, mostly children, and causes up to a million deaths. Symptoms of shigellosis, also known as bacillary dysentery, include severe and bloody diarrhea, fever, and stomach cramps. We are also pursuing a research program focused on the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19. Our Hyper-immune Bovine Colostrum used to manufacture our commercial products Travelan® and Protectyn® has demonstrated antiviral activity against SARS-CoV-2 in laboratory studies. Our research is focused on identifying the inhibitory substance/s unique to the colostrum samples.

Travelan sales for fiscal year 2021, 2020 and 2019 were gross A$166 thousand (net: A$146 thousand), A$2.7 million (net: A$2.5 million) and A$2.5 million (net: A$2.3 million), respectively.

OUR STRATEGY

Our goal is to become one of the leading biopharmaceutical companies developing and commercializing therapeutics to address increased unmet medical needs in the anti-infective area. The critical components of our strategy include:

- Advancing our lead oral polyclonal antibody drug candidates presently in clinical development for the treatment of moderate to severe campylobacteriosis, travelers' diarrhea and to treat recurrent *C. difficile* infections (CDI);
- Leveraging our technology platform and our collaborations to expand our differentiated polyclonal-based product pipeline across multiple indications including various novel anti-infective programs with the U.S. Department of Defense (DoD);
- Continuing to invest in and growing Travelan and Protectyn sales worldwide, including in the U.S., Australia, Canada, and in new markets;
- Continuing to invest in mechanism of action studies that expand our understanding of our novel mechanism of action across our targeted diseases and conditions, and potentially identify new opportunities for investment; and
- Protect and leverage our intellectual property portfolio and patents. We believe that our intellectual property protection strategy, grounded in securing composition of matter patents on the biologics we develop, as well as broader patents to protect our technology platform, has best positioned us to gain broad and strong protection for our assets.

OUR PLATFORM

Our platform technology is based on oral polyclonal immunoglobulins. Prior to calving, cows are immunized with proprietary vaccines to ensure maximum immunogenicity and after calving, the first milk, called bovine colostrum is harvested and processed to produce a hyper-immune bovine colostrum powder. This proprietary process of vaccinating cows with specific vaccines generated against antigens for therapeutic targets ensures that the colostrum contains a high concentration of polyclonal antibodies and high concentrations of immunoglobulin G1 against the specified antigens. The technology can be applied to a variety of diseases.

The underlying nature of our platform technology enables the development of medicines across a large range of infectious diseases. The platform can be used to block viruses or bacteria at mucosal surfaces (such as the GI tract) and neutralize the toxins they produce. Additionally, the dairy origins of our antibodies enable us to commercialize our platform through most regulatory pathways, including prescription (Rx), medical foods, over-the-counter medicines, and dietary supplements.

The active pharmaceutical ingredient (API) for a particular application is prepared using the first milking colostrum of dairy cows that have been immunized with patented vaccines for the specific therapeutic use to produce very high levels of antibodies against selected surface antigens. Pregnant dairy cows at commercial dairy farms are immunized through a proprietary process. Such inoculation of dairy cows with specific vaccines activates a generalized immune response in the host animal to produce antibodies which recognize and bind to bacterial cell-surface epitopes that the vaccines were designed against. These polyclonal antibodies in the harvested bovine colostrum are present in high concentration within the raw material which is further processed to produce the final drug product which contains at least 35% immunoglobulins (Ig), composed mainly of IgG (mostly IgG1).

Risk management covering the source of colostrum must focus on assurance of absence of Bovine Spongiform Encephalopathy (“BSE”), commonly known as Mad Cow Disease attributable to the liquid raw product. BSE is a transmissible and fatal neurodegenerative disease that affects cattle. BSE has never been detected in cattle in Australia or New Zealand. The World Organization for Animal Health recognizes both countries as having a negligible BSE risk status. Australia and New Zealand are two of only 16 countries in the world to-date assessed by the European Union as meeting all criteria for the lowest geographical BSE risk level.

OUR PIPELINE

We presently have three drug candidates in clinical development that have the potential to transform the existing treatment paradigms for moderate to severe campylobacteriosis, recurrent *C. difficile* infections, Enterotoxigenic *Escherichia coli* (ETEC) infections and travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. As we have already reported to our shareholders, the sales of Travelan remain severely impaired due to COVID-19 restrictions and the associated reduction in long-haul travel impact every Travelan® market. The COVID-19 pandemic resulted in international travel restrictions and brought to an abrupt halt the travel plans of millions throughout the world. Many countries went into total lockdown with people unable to leave their homes except for very limited purposes. The sales of Travelan are likely to remain suppressed until the impact of COVID-19 on travel restrictions and lockdowns by government bodies are reduced. The company is pleased to report albeit a small uplift of sales in the United States as domestic and international travel resumes on the back of over 380 million total vaccine doses administered in the country to date. The pandemic has also caused significant disruptions to global clinical development with many planned studies being delayed, paused or closed.

Immuron's IMM-124E used to manufacture Travelan® and Protectyn® demonstrates antiviral activity against the COVID-19 virus in laboratory studies

The company announced to the market in July 2020 that the hype-Immune bovine colostrum used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan® and Protectyn® demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19. The in-vitro assessment of the neutralization of SARS-CoV-2 was performed on four production lots of product used to manufacture Travelan® and Protectyn® using the SARS-CoV-2 hCoV-19/Australia/VIC01/2020 virus obtained from Melbourne's Peter Doherty Institute for Infection and Immunity.

In May 2021, the company reported that Monash University Research Scientists at the Biomedicine Discovery Institute had completed the developed of two new immunologically based assays utilizing two recombinant reagents, the SARS-CoV-2 Spike protein and a receptor binding domain protein obtained from Melbourne's Peter Doherty Institute for Infection and Immunity. The studies completed by Monash suggested that the SARS-CoV-2 inhibitory activity in the hyper-Immune colostrum used to manufacture Travelan® and Protectyn® does not target the spike protein or the receptor binding domain that the virus uses to dock to the cells it infects. The research team has also completed the purification of the major immune components (IgA and IgG) from the hype-Immune bovine colostrum.

CSIRO Biomedical Manufacturing has also completed additional characterization work performed on the hype-Immune bovine colostrum which demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The work focused on peptide sequencing by liquid chromatography tandem-mass spectrometry (LC-MS/MS) and identified several Ig-like proteins as major components that appear to be enriched in bovine colostrum samples compared to Control Milk Powder. The LC-MSMS analysis is very sensitive and detected a total of 375 proteins across all samples tested. Work continues with the data analysis to identify other key proteins unique to the colostrum samples that are not present in the milk powder controls. Once completed the neutralizing activity of the various immune components will be tested against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2).

We know that SARS-CoV-2 causes an influenza-like disease that is primarily thought to infect the lungs with transmission through the respiratory route ranging from mild respiratory symptoms to severe lung injury, multiorgan failure, and death. Understandably, respiratory symptoms have dominated the clinical focus, however gastrointestinal symptoms such as diarrhea, vomiting, and abdominal pain are also observed in a subset of patients often presenting with no respiratory symptoms. In the United States the Centers for Disease Control and Prevention updated the symptoms of coronavirus to include diarrhea. Clinical research suggests that the Gastrointestinal tract may present another viral target organ. The virus RNA has been detected in anal swabs of some patients even after nasopharyngeal testing has turned negative, and cells in the inner-gut lining express high amounts of the angiotensin-converting enzyme 2 (ACE2) receptor that SARS-CoV-2 uses to gain entry to cells implying the potential for gastrointestinal infection and a fecal–oral transmission route. However, fecal–oral transmission has not been demonstrated to be a significant factor in the pandemic and the current research is still inconclusive. The company has filed a provisional patent application in respect of the findings.

In July 2020 we announced the findings of 360 biolabs, a Melbourne-based Contract Research Organization using the SARS-CoV-2 hCoV-19/Australia/VIC01/2020 virus obtained from Melbourne's Peter Doherty Institute for Infection and Immunity. The in-vitro assessment of the neutralization of SARS-CoV-2 was performed on four production lots of product used to manufacture Travelan® and Protectyn®. The In-vitro susceptibility of the virus to IMM-124E was determined using a quantitative assay which measures virus replication in the presence of increasing concentrations of the product compared to replication in the absence of the product. The effective concentration of IMM-124E was reported as the concentration of the product at which virus replication is inhibited by 50 percent (EC_{50}) or 90 percent (EC_{90}).

All four production lots produced mean EC_{50} values of 40.5 to 91.9 ug/mL and inhibited viral replication at concentrations which there was no observed cell toxicity. The concentration of IMM-124E at which virus replication was inhibited by 90 percent (EC_{90}) produced mean EC_{90} values ranging from 48.7 to 155.4 ug/mL for all four lots tested again at concentrations at which there was no observed cell toxicity. A commercially available high protein milk powder product was used as a placebo in the studies and produced EC_{50} values greater than the observed cellular cytotoxicity concentration of >4800 ug/mL. The control milk powder inhibited viral replication at doses> 25,000 ug/mL and more importantly did not inhibit viral replication at doses at which it was cytotoxic to cells. Another major finding made during the study was that cell viability in the presence of IMM-124E was greatly enhanced when compared to placebo. IMM-124E improved cell viability by 180 to 260% relative to controls. These results indicate that IMM-124E at concentrations which inhibited SARS-CoV-2 replication also improved cell viability.

US Department of Defense New Drug Candidate to treat moderate to severe campylobacteriosis and Enterotoxigenic Escherichia coli (ETEC) infections.

The COVID-19 pandemic has disrupted clinical trials globally and following over a 12-month hiatus the NMRC has reported that most of the inpatient clinical trial sites in the USA are slowly coming off COVID-19 based restrictions and the Company looks forward to the recommencement of the planned NMRC clinical development programs. In July 2020, Immuron announced that the NMRC received written guidance from the U.S. Food and Drug administration (FDA) in relation to the clinical development pathway of a new investigational drug which the company is developing to treat moderate to severe campylobacteriosis and Enterotoxigenic Escherichia coli (ETEC) infections. The Type B meeting with the FDA discussed the Chemistry, Manufacturing and Controls including the proposed release testing specifications of the product as well as the planned clinical studies evaluating the safety and efficacy of the product. The NMRC has addressed the FDA questions posed in the briefing documentation and is in the process of finalizing the IND application.

The company initiated the second vaccination campaign in March 2021 and utilized the bispecific vaccine developed by the NMRC which is made up of the capsule of *C. jejuni* chemically conjugated to the CFA/I pilin of ETEC. The second vaccination campaign was successfully completed in May 2021 and each animal in the second herd received three doses of the vaccine. The hyper-immune colostrum was harvested in July 2021 and samples were shipped to the NMRC for immunological evaluation. The NMRC confirmed that the conjugated vaccine produced a robust immunological response and reported that the new Hyper-immune therapeutic contains high levels of antibodies which specifically target *Campylobacter jejuni* capsule and Enterotoxigenic *Escherichia coli* (ETEC) colonization factor antigen 1 (CFA/1). These are key antigenic targets predicted to be protective against diarrhea induced by both pathogens.

The manufacturing campaign for the drug substance was completed in August 2021 and the company plans to complete the manufacture of active drug product in October 2021. Once completed the investigational medical products will be transferred to the Johns Hopkins Bloomberg School of Public Health (JHBSPH) in the USA the clinical trial site which will be conducting the two planned Controlled Human Infection Model clinical studies. Work on the Investigational New Drug (IND) application and the clinical protocols for evaluating the safety and efficacy of the product in moderate to severe campylobacteriosis and Enterotoxigenic Escherichia coli (ETEC) infections continues. The NMRC now plans to file the IND application with the U.S. Food and Drug administration (FDA) in Q1 2022. The ability of the new hyperimmune product to protect volunteers from moderate to severe campylobacteriosis and ETEC disease will be assessed during two inpatient clinical trials the first of which is scheduled to commence in the first half of 2022.

For all the disruption caused by the COVID-19 pandemic, our partnerships with components of the US Department of Defense remain strong, close, and strategically vital. We will continue the clinical development of a new oral therapeutic to treat moderate to severe campylobacteriosis and Enterotoxigenic *Escherichia coli* (ETEC) infections in conjunction with the US Naval Medical Research Centre.

IMM-124E Travelers' Diarrhea Efficacy Field Trial

Several meetings have been held this year with our US Department of Defense (US DoD) associates to review the proposed company sponsored phase III clinical trial protocol, address key questions identified by the FDA clinical reviewers and to identify potential endemic countries and clinical sites of interest to the US DoD. During these meetings the company was invited to present its strategic plan for the Biologics License Application (BLA), to the Military Infectious Diseases Research Program (MIDRP). MIDRP manages research and development programs for the US DoD and its mission is to protect the U.S. military against naturally occurring infectious diseases via the development of U.S. Food and Drug Administration (FDA) approved vaccines, drugs, and diagnostic assays. The meeting also focused on funding opportunities available to support the BLA and the associated approval process, as well as to provide some additional insights on the processes the company would need to navigate to advance Travelan with FDA licensure and DoD acquisition.

The proposed development program is based on the past commercial and clinical trial experience with Travelan®. Two company sponsored clinical studies have demonstrated that Travelan® conferred 84% to over 90% protective efficacy against moderate to severe diarrhea upon challenge with ETEC in comparison to a placebo. These clinical studies were performed using two different doses of Travelan® (200 mg and 400 mg), administered 3 times a day. Ongoing discussions with Army and Navy leadership have highlighted that such a regimen is cumbersome for military personnel deployed in austere environments and military field studies have shown that compliance is low with products dosed more than once per day. The rationale behind the company's proposal is to leverage the current BLA program to obtain US Government funding to test the efficacy of one large daily dose regimen of Travelan® in a controlled human infection model (CHIM) clinical study using the ETEC strain H10407. This dose regime is potentially more amenable for use in military populations. Results of the proposed clinical study will inform dosing in the planned pivotal Phase 3 studies for BLA licensure.

The company's presentation was held on the 25 May 2021 and was well attended by the US Government sponsors. The Government reviewers were very much engaged and interested in the technology and the proposal. Advanced Technology International (ATI), the MTEC Consortium Management Firm formally notified the Company on the 25 June 2021 that our proposal was considered eligible for award and requested Immuron to submit a full proposal for consideration which was prepared and submitted to the MTEC Contracts team on the 13 July 2021. The company received formal notification confirming that the US Government sponsors had completed the evaluation of our proposal and intends to select it for award subject to funding availability.

Uniformed Services University Phase II P4TD Field Trial targeting travelers' diarrhea

The company received a purchase order and in May 2021 supplied Travelan® drug substance (IMM-124E) to support the Uniformed Services University (USU) planned clinical trial program to evaluate the efficacy of Travelan® and two other non-antibiotic OTC products in Travelers' Diarrhea. USU's Infectious Diseases Clinical Research Program (IDCRP), the UK Ministry of Defense and the New York City Travel Clinic are jointly planning to conduct a randomized clinical trial to evaluate the efficacy of three nutraceutical products for TD and inform strategies for Defense Force Health Protection. The P4TD study is a randomized, double-blind, placebo controlled multicenter clinical trial designed to evaluate the effectiveness of 3 commercially available nutraceuticals: A prebiotic (Bimuno®), a probiotic (Florastor®) and IMM-124E (Travelan®) passive immunoprophylaxis verses a placebo, for prophylaxis during deployment or travel to a high-TD risk region

IMM-124E is manufactured from colostrum harvested from dairy cows that have been immunized against the 13 most common pathogenic strains of enterotoxigenic *E.coli* (ETEC). IMM-124E is designed to block and reduce bacterial growth without negatively impacting essential microbiota, and is a first-in-class, oral polyclonal antibody therapeutic which targets gram negative ETEC and other cross-reactive pathogenic bacteria in the gut, leading to the blockage of their pathologic activities.

Earlier Clinical Studies on IMM-124E

IMM-124E was evaluated as a potential drug to treat non-alcoholic steatohepatitis (NASH) under FDA IND #014933. The primary endpoint was the mean change from baseline in the hepatic fat fraction (HFF, %), as measured by MRI at week 24 for two doses of IMM-124E compared with placebo. Both doses of IMM-124E did not lead to significant reduction in fat at the end of 24 weeks of therapy. Topline results from this earlier IMM-124E phase II NASH clinical study were reported in March 2018. The 24-week treatment study which was conducted in Australia, Israel, and the U.S. involved 133 biopsy-proven NASH patients. The study results demonstrated that IMM-124E, a first-in-class, oral antibody therapy targeting the endotoxin lipopolysaccharide (LPS) and other bacterial components in the gastrointestinal tract, resulted in a statistically significant reduction of serum LPS in patients with biopsy proven NASH. IMM-1214E was developed to target ETEC pathogens, preventing LPS from translocating into the portal circulation. The study results demonstrated a statistically significant reduction of serum LPS levels in the drug treatment arms when compared to placebo, providing proof-of-concept for a novel mechanism of action. Serum ALT was also significantly reduced when compared to placebo as well as AST and cytokeratin-18 (CK-18) demonstrating metabolic endotoxemia can be decreased with IMM-124E which can lower serum LPS levels and reduce LPS -associated liver inflammation. The data showed a small statistically significant reduction in serum lipopolysaccharide (LPS), and reductions in two biomarkers associated with liver function, but the drug did not display signs of clinical benefit in reducing fat content of the liver in patients with NASH. Consequently, we decided not to continue clinical development of IMM-124E specifically to treat NASH. Data from this trial, however, showed that IMM-124E was not systemically absorbed, and the trial provided further support for IMM-124E's safety profile, and for its potential use in other therapeutics areas.

Two additional clinical studies, sponsored and funded by the National Institute of Health, have been performed with IMM-124E: 1) a Phase II clinical study in patients with severe alcoholic hepatitis (SAH) conducted under FDA IND #015675, and 2) a Phase II clinical study in pediatric patients with non-alcoholic fatty liver disease (NAFLD) conducted under FDA IND #017066.

Top-line results from the SAH trial with Dr. Arun Sanyal of Virginia Commonwealth University as the lead Principal Investigator were released on August 8, 2019. The primary objective of this study was to evaluate the safety and efficacy of IMM-124E at two oral dosage levels as compared with a placebo in patients with severe alcoholic hepatitis and with all patients being treated with steroids. A total of 57 patients with SAH with a model for end stage liver disease (MELD) score ranging from 21-28 were enrolled into the clinical study and were treated with either IMM-124E or placebo for 28 days (placebo N=20, IMM-124E 2400 mg/day N=18, IMM-124E 4800 mg/day N= 19). No suspected unexpected serious adverse reactions were reported and no differences in serious adverse events (SAE) were observed across the three arms of the study and no SAE was considered related to the study drug by investigators. Both doses of IMM-124E in the study (2400mg and 4800mg) were well tolerated. There were 9 deaths reported over a six-month period for the entire cohort and there were no significant differences across study groups. The data showed that IMM-124E is safe to use in patients with SAH but does not reduce circulating lipopolysaccharide levels, mortality or have an impact on MELD score in the study population, and we will not continue clinical development of IMM-124E specifically to treat SAH.

The COVID-19 pandemic has also impacted the IMM-124E pediatric clinical study in Nonalcoholic Fatty Liver Disease. The study's Principle Investigator Dr Miriam Vos from the Emory University School of Medicine closed the study earlier this year with only 22 subjects out of a target 40 completed the study protocol. The study findings were reported as negative as there was no substantial changes in ALT (Primary study end point) in the active arm of the study when compared to placebo.

IMM-529 to Treat Recurrent C. difficile Infections (CDI)

The company has completed the assessment of the acceptability of the orphan drug designation (ODD) application for IMM-529. Based on the literature related to *Clostridiodes difficile*, treatment of recurring infection, and the information available on the center for disease control (CDC) and prevention site, our regulatory consultants have concluded that it would be challenging to secure an ODD designation for IMM-529 based on the available data.

The company has established a Medical Advisory Committee to review the clinical development plans and establish a clinical protocol for IMM-529 in recurrent *Clostridiodes difficle* Infections (CDI). Members include Professor Teena Chopra, Professor of Medicine Wayne State University School of Medicine, Detroit Michigan. Professor Chopra is an Infectious Disease Epidemiologist with a specific interest in CDI. Professor Paul Feuerstadt assistant Clinical Professor of Medicine, Yale University School of Medicine and Professor Sahil Khanna, Professor of Medicine at the Mayo Clinic. The committee members have an in depth understanding on CDI and currently treat a large number of patients with recurring CDI. The Medical Advisory Committee has completed their review of the clinical trial protocol following several meetings held this year and we are currently in the process of finalizing the clinical protocol, identifying suitable clinical trial sites and updating the Project plan which will be presented to the Board of Directors for approval.

Background on *C. difficile*

C. difficile is a gram-positive, toxin-producing, spore-forming bacterium that generally causes severe and persistent diarrhea in infected individuals, but can also lead to more severe outcomes, including in the most serious cases, death. *C. difficile* infection (CDI) is most often associated with the prior use of antibiotics. The U.S. Centers for Disease Control has identified CDI as one of the top three most urgent antibiotic-resistant bacterial threats in the U.S. and is now the most common cause of hospital acquired infection in the U.S. CDI is responsible for approximately 29,000 deaths in the U.S. annually. The prevalence of CDI is estimated at more than 450,000 infections annually, with nearly 100,000 cases of first recurrences. Research suggests that the risk of recurrence is approximately 25% after the primary occurrence of CDI, 40% after a first recurrence and greater than 60% for those experiencing two or more recurrences. CDI leads to an increased length of hospitalization and as of 2015, an estimated US$1.1 billion in health care costs annually in the U.S. The rise of community-acquired CDI is now a growing problem and led to the recognition that CDI is not simply limited to just hospitals. This increase in CDI incidence, which is now a growing problem worldwide due to the widespread and increased use of antibiotics, is the driver behind a growing market for *C. difficile* therapeutics. The CDI market across the seven major markets of the US, France, Germany, Italy, Spain, the UK and Japan, is set to grow from $630 million in 2016 to almost $1.7 billion by 2026, representing a compound annual growth rate of 10.2%.

C. difficile can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon. In the most serious cases, *C. difficile* infections can lead to fulminant colitis, megacolon and even death from colon perforation and peritonitis. *C difficile* is acquired from contact with humans or objects harboring these bacteria. It can be commonly acquired during hospitalization. Up to 30% of those who have spent a prolonged period in the hospital leave carrying these bacteria in the bowel flora, especially if antibiotics have been administered. This is because CDI is most often associated with the prior use of broad-spectrum antibiotics, which decrease the natural resistance of the body to *C. difficile*. Chronic CDI is estimated to occur in perhaps 15-30% of those infected. In some cases, reinfections can occur with the same or with a different strain. Risk factors for relapse include the number of previous episodes, the need to use antibiotics recurrently, and older age groups.

Human infection occurs through ingestion of the highly infectious spores, which survive acid and bile on their passage into the bowel. Normally, this infectious process may be eradicated or substantially reduced by the normal bowel flora since the microbes that collectively make up the flora provide colonization resistance against pathogenic species through competition for essential nutrients and attachment sites to the gut wall. However, if the bowel flora is suppressed because of concomitant use of antibiotics, or if the bowel flora has a deficiency, *C. difficile* can colonize the flora and remain with the patient. In some individuals, it seems that antibiotics are not required for colonization to take place, which may be related to inadequate defense of the naturally occurring flora within the bowel.

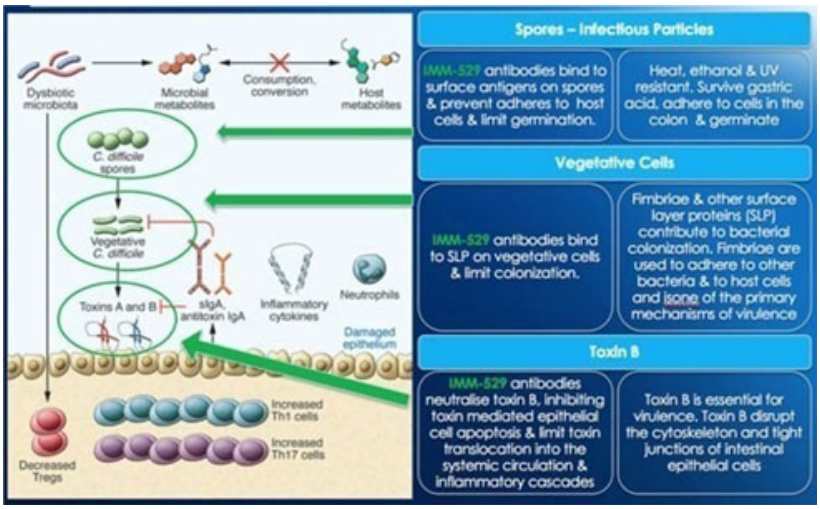
When *C. difficile* takes hold, the toxins produced by the bacterium, especially Toxin B, act by inactivation of Rho GTPases leading to cell death, and stimulation of an inflammatory cascade that exacerbates tissue damage, diarrhea, and pseudomembranous colitis. When faced with a CDI infection, the standard of care is typically either a course of vancomycin or metronidazole, both of which are broad spectrum antibiotics. While these agents are very effective at treating the primary infections, they also severely impact the rest of the gut flora, creating an ideal environment for the *C. difficile* spores to once again take hold. This creates a vicious cycle, as more courses of antibiotic treatments worsen recurrence. Vancomycin and metronidazole treatments are plagued by increasing rate of CDI recurrences, underscoring the need for new treatments. There is also growing concern of resistance to vancomycin treatment.

C. difficile is a very hardy organism, most likely because it sheds spores that are unable to be eradicated by any known antibiotics. Since *C. difficile* spores are able to survive for long periods of time outside of the body, and because healthcare settings are often sites of significant antibiotic use, CDI transmission rates in hospitals, long-term acute care facilities and nursing homes have been increasing. CDI is also a cause of morbidity and mortality among hospitalized cancer patients and bone marrow transplant patients, as their immune systems are suppressed by cytotoxic drugs and sometimes by antibiotics that are administered to prevent opportunistic infections.

IMM-529 – Novel Triple Action offers a Revolutionary Treatment for Recurrent CDI

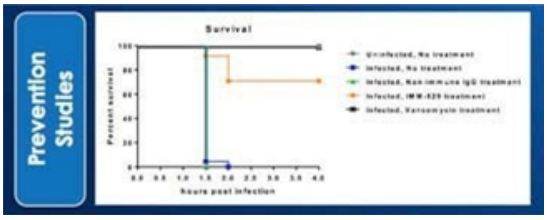
Our second lead compound, IMM-529, targets the *C. difficile* bacterium and contains polyclonal antibodies cross-reactive to Toxin B, spores and vegetative cells of the bacterium. IMM-529 is an oral biologic which does not destroy the microbiome like antibiotic treatments, allowing the microbiome to return to a healthy state, while treating the virulent CDI. The antibodies in IMM-529 have been demonstrated to be cross-reactive with a variety of human and animal *C. difficile* isolates and to their associated Toxin B, vegetative cells and spore components. The antibodies in IMM-529 have also been shown to neutralize Toxin B from a historical *C. difficile* strain (630), and from a hypervirulent strain which caused recent worldwide outbreaks.

IMM-529 was developed and tested extensively in pre-clinical models in collaboration with Dr. Dena Lyras and her team at Monash University, Australia. Dr. Lyras is one of the world's foremost experts in *C. difficile*. IMM-529 targets the virulent Toxin B, the spores and the vegetative cells. It is a three-pronged approach that is unique and which has yielded promising results in pre-clinical studies, including (1) prevention of primary disease, (2) treatment of primary disease and (3) suppression of disease recurrence. To our knowledge, IMM-529 is, to date, the only investigational drug that has shown therapeutic potential in all three phases of the disease.

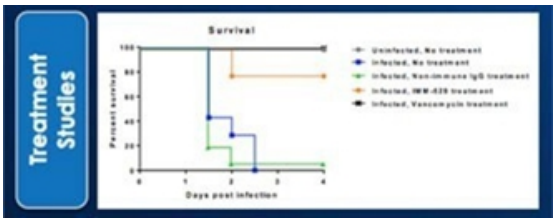


Preclinical studies with IMM-529 yielded promising results in a number of pre-clinical animal models (shown below). All results were highly statistically significant:

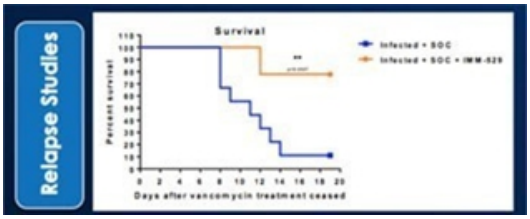
- Prevention of *C. difficile* infection: approximately 70% (17/24) survival vs. 0% survival in the control groups:
  - Control group #1 (0/14) treated with water; and
  - Control group #2 (0/15) treated with non-hyperimmune colostrum.



- Treatment: approximately 80% survival (11/14) vs. <7% survival in the control groups:
  - Control group #1 (0/14): Treated with water alone following vancomycin treatment; and
  - Control group #2 (1/15): Treated with non-hyperimmune colostrum following vancomycin treatment.



- Relapse: approximately 90% survival in IMM-529 + vancomycin group (n=7/9); vs. 11% survival in the control group which received vancomycin alone (n=1/9).



The results of these studies were published in Scientific Reports (Hutton et al. Bovine antibodies targeting primary and recurrent *Clostridium difficile* disease are potent antibiotic alternatives), SCI Rep. 2017 Jun 16:7(1):3665.

Phase I/IIa clinical trial of IMM-529 in *C. difficile* patients

A first-in-man Phase I/II clinical trial was initiated at two clinical sites in Israel at the end of 2017 in CDI patients. This trial was intended to evaluate the safety, tolerability and effectiveness of IMM-529 together with standard of care (SOC) antibiotic treatment in patients with CDI.

On March 19, 2019, we provided an update regarding the status of the IMM-529 clinical trial in patients with CDI, along with a refocusing of our efforts to develop IMM-529. The Phase I/II clinical trial of IMM-529 in patients with *C. difficile* initiated at the end of 2017 at two clinics in Israel provided us with disappointing numbers of enrolled patients. Only 9 out of 60 patients have been randomized into the study and the company has decided to close these sites. We decided to further develop IMM-529 to treat CDI patients through a formal filing of an IND with FDA, and to develop a new clinical plan for the drug candidate with input from FDA. The focus for IMM-529 will be to explore how the drug can be developed to determine its impact on reducing recurrent CDI disease, a major unmet medical need in treatment of patients suffering with *C. difficile* infections. We are planning to file a Type B meeting request with FDA to develop IMM-529 to treat patients with CDI.

IMM-529 – Competitive Advantage

We believe that IMM-529 has novel competitive advantages:

- ***Triple Mechanism of Action –*** IMM-529 not only targets Toxin B, but also contains antibodies to spores and vegetative cells. This is unique among all clinical drug candidates currently in development.
- ***Effective Against Virulent Strains –*** As discussed above, IMM-529 has been shown to be effective against a number of virulent strains of CDI, providing a strong proof-of-concept model that IMM-529 can be a frontline agent.
- ***Effective in All Phases of the Disease*** – IMM-529 has been shown to be an effective agent in animal models designed to mimic all phases of the disease including prevention of infection, treatment of primary disease and recurrence. This is novel compared to all of our competitors and indicates a much larger potential use for IMM-529 than current development programs which primarily target recurrence.
- ***Oral Therapy –*** IMM-529 is an oral therapy lessening costs/burden issues covering patients, hospitals and the healthcare system overall.
- ***Not an Antibiotic –*** IMM-529 is not an antibiotic, and only targets components of *C. difficile* - its Toxin B, spores and vegetative cells. Consequently, IMM-529 is not expected to negatively impact the bacterial flora, allowing the flora to return to normal, while fighting the primary infection / recurrence.

Other Development Programs

We also have a research collaboration with the U.S. Department of Defense (DoD) involving programs with the Walter Reed Army Institute of Research, for the development of three Shigella-specific therapeutic products.

Collaborations with U.S. Army and U.S. Navy. We believe that our collaborations with the DoD are a powerful validation of the potential of our platform to develop novel anti-infectives. These collaborations also open the door to explore and develop potentially low risk / low cost therapeutics with some of the most advanced research facilities in the world. The DoD earlier commissioned several studies to characterize the polyclonal antibodies contained in Travelan. The aim was to conduct trials to determine the product's effectiveness in neutralizing pathogenic GI bacterial infections as a preventative treatment for U.S. military personnel and civilians stationed or traveling in locations where such infections can be debilitating.

Armed Forces Research Institute of Medical Sciences. In June 2016, we signed an agreement with the Walter Reed Army Institute of Research ("WRAIR") to develop a therapeutic for a form of dysentery that kills up to one million people a year. WRAIR is the largest and most diverse biomedical research organization in the DoD.

The project's aim is to develop an oral therapeutic for shigellosis, a severe form of dysentery that affects about 165 million people a year, mostly children, and causes up to a million deaths. Symptoms of shigellosis, also known as bacillary dysentery, include severe and bloody diarrhea, fever, and stomach cramps. We plan to develop the product for both civilian and military use in areas where endemic diseases such as shigellosis can compromise the health and readiness of the local community, travelers, contractors and defense personnel.

In January 2018, we reported that the DoD-commissioned study showed Travelan was immunologically reactive to a number of dangerous and potentially fatal infectious bacteria. The Department of Enteric Diseases unit of the Armed Forces Research Institute of Medical Sciences ("AFRIMS") performed the study. It took place at a WRAIR laboratory in Bangkok, Thailand. The study, one of three involving Travelan, looked at 60 clinical isolates of each of Campylobacter, ETEC, and Shigella obtained from infected U.S. defense personnel in southeast Asia between 1993 and 2016. The study indicated that, compared to the control, Travelan antibodies were reactive to all 180 clinical isolates.

In September 2018, we reported the findings of a study conducted by AFRIMS. The study evaluated the therapeutic potential of Travelan in a non-human primate ("NHP") preclinical Shigella challenge model that closely mimics the disease seen in humans. The study was performed in collaboration with the Department of Enteric Diseases and the Department of Veterinary Medicine, AFRIMS, and the Department of Enteric Infections, Bacterial Diseases Branch, WRAIR. The placebo-controlled study was carried out in 12 NHPs segregated into 2 groups: a Travelan treatment cohort of 8 and a placebo cohort of 4, which were treated with either Travelan or placebo respectively twice daily for a total of 12 doses over a 6-day period. The animals received treatment for 3 days prior to oral challenge with approximately 3×10^9 viable *Shigella flexneri* strain 2a organisms. All (4 of 4 - 100%) placebo-treated animals displayed acute dysentery symptoms within 24 to 36 hours of the *Shigella flexneri* 2a challenge. Seven of the eight individuals in the Travelan treatment cohort (87.5%) remained symptom-free to 4 days post the *Shigella flexneri* 2a challenge. Only one of the Travelan-treated cohort displayed dysentery symptoms during the same time frame as the placebo arm. Once the treatment period was concluded a second individual in the Travelan treatment group developed symptoms. Six of the eight Travelan treated cohort animals remained symptom-free to the conclusion of the study which was 11 days post the *Shigella flexneri* 2a challenge.

In June 2019, we updated the market on the latest developments arising from our cooperative research and development efforts with the DoD. AFRIMS completed the histopathological analysis, which provides a comprehensive view of the clinical disease and its effect on tissues of gut, revealed that all animals in the placebo-treated group displayed severe inflammation in different parts of the gastrointestinal tract. These animals also had very high levels of inflammatory cytokines (IL-1b, IL-6 and IL-8) in fecal samples collected throughout the study. The inflammation seen in the gastrointestinal tract and the increase in inflammatory cytokines in the feces were closely associated with the observed clinical outcomes of dysentery. Only 3 of the 8 Travelan-treated animals had signs of inflammation in the gastrointestinal tract, and only 2 of those had high levels of inflammatory cytokines in fecal samples. All other animals in the Travelan-treated group were clinically healthy and did not excrete any inflammatory cytokines. Overall the results suggest that Travelan® is functionally cross-reactive and may have prophylactic activity against Shigellosis.

In June 2019, we also reported the completion of the manufacture of three new *Shigella*-specific therapeutic products using proprietary vaccines developed by WRAIR. The immune reactivity of the three hyper-immune Shigella specific products were evaluated by the WRAIR using Enzyme-Linked ImmunoSorbent Assay and Western Blot analysis. The antibodies in the products were shown to react with the specific antigens present in the vaccines. The antibodies within the three products were also reactive to 4 different clinical isolates of Shigella (*S. flexneri* 2a, *S. flexneri* 3a, *S. flexneri* 6, and *S. sonnei*). The three Immuron *Shigella*-specific therapeutic products will now go on to evaluation in WRAIR's preclinical models of shigellosis.

In September 2019, we announced the results of the study, sponsored by the DoD and funded through the Defense Health Agency, which was performed at the overseas laboratory of the WRAIR located in Bangkok, Thailand. The goal was to investigate the breadth of Travelan®'s immunological reactivity against pathogenic *Vibrio cholera* bacterial isolates. Clinical isolates were collected from infected personnel located in Bangladesh, Cambodia, and Thailand, enabling researchers to gauge Travelan®'s potential against bacterial strains typically seen in the field. When compared to a placebo control, researchers found that the polyclonal antibodies comprising Immuron's Travelan® product were reactive to all 71 clinical isolates from these infected individuals. The ability of Travelan® to bind these bacteria highlights the broad-spectrum recognition by Travelan® of surface antigens on potentially debilitating and even life-threatening bacteria.

U.S. Naval Medical Research Center ("NMRC").

In October 2019, we announced that the U.S. Department of Defense had approved USD$3.7 million in funding in connection with a new research agreement with the Naval Medical Research Center (NMRC), Silver Spring, MD, USA to develop and clinically evaluate a new oral therapeutic targeting Campylobacter and ETEC. The focus of this new agreement will be to develop a combined Campylobacter and enterotoxigenic *E. coli* (ETEC)-specific anti-microbial preventative for clinical evaluation. Under this agreement, Immuron and NMRC will be collaborating on the manufacture and evaluation of the new product designed to protect against travelers' diarrhea caused by Campylobacter and ETEC pathogens. The protective efficacy of the product will be tested utilizing two controlled human infection-model clinical trials, with one trial focusing on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis, and the second trial focusing on ETEC infections.

Campylobacter's main reservoir is poultry; however, humans can contract the disease from contaminated food. At least a dozen species of *Campylobacter* have been implicated in human disease, with *C. jejuni* and *C. coli* being the most common. *C. jejuni* is now recognized as one of the main causes of bacterial foodborne disease in many developed countries as well as developing countries where poultry is common.

ETEC is one of the leading bacterial causes of diarrhea in the developing world, as well as the most common cause of travelers' diarrhea. Conservative estimates suggest that each year, about 157,000 deaths occur, mostly in children, from ETEC, but no vaccines exist, highlighting the need for new treatment modalities.

Accordingly, we believe that the breadth and depth of our technology, and the support we are receiving from the NIH, the DoD and other leading institutions and Key Opinion Leaders, demonstrates the importance of our technology platform, and makes us truly a unique and attractive player in the therapeutic areas we are targeting.

OUR ADVISORY BOARD

Our company's programs are supported by an advisory board consisting of:

- Professor Teena Chopra, Professor of Medicine Wayne State University School of Medicine, Detroit Michigan. Professor Chopra is an Infectious Disease Epidemiologist with a specific interest in CDI.

- Professor Paul Feuerstadt is an attending Gastroenterologist at the Gastroenterology Center of Connecticut/PACT-Gastroenterology Center Hamden, CT and is also an Assistant Clinical Professor of Medicine at and the Yale University School of Medicine, New Haven, CT and the Frank H. Netter School of Medicine of Quinnipiac University, Hamden, CT.

- Professor Sahil Khanna, Professor of Medicine at the Mayo Clinic. Professor Khanna clinical practice focusses on the care and treatment of patients with CDI and he was instrumental in the establishment and implementation of the Fecal Microbiota Transplantation program at Mayo Clinic, Rochester, MN.

- Dr. Glenn Tillotson is a healthcare scientist with sound global infectious disease (ID) background and experience in anti-infective drug development and global medical educational and medical affairs. He has developed a significant network of sites/experts in the ID field and has authored many publications in the various aspects of ID.

- Dr. Dena Lyras (PhD) – Monash University. Dr. Lyras, an associate professor at Monash University, is one of the world's leading experts in C. *difficile*. Dr. Lyras has spent her research career developing world-leading knowledge of C. *difficile*. She was the lead author of a seminal study published in Nature in 2009, which shed new light on the essential role specific toxins play in causing disease, a discovery that disproved prevailing opinion.

- Dr. Arun Sanyal (MD**) –** University of Virginia. Professor of Medicine and Former Chairman of the Division of Gastroenterology, Hepatology and Nutrition, VCU Medical Center. Dr. Sanyal is an internationally renowned expert in liver diseases. He is a former President of the American Association for the Study of Liver Diseases and is the current Chair of the Liver Study Section at the NIH.

- Dr. Stephen Harrison (MD) – Professor of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland; Physician, San Antonio Military Medical Center, Fort Sam Houston, San Antonio, Texas. Chief of Residents, Internal Medicine, Brooke U.S. Army Medical Center. Dr. Harrison is an internationally renowned expert in NASH and his group has published seminal work on many aspects in the field. Dr. Harrison is the Principal Investigator of Galectin's GR-MD-02's Phase 2 trial and hold's key roles in other leading clinical NASH studies.

- Dr. Miriam Vos (MD) – Emory University. Dr. Vos is an associate professor of pediatrics at the Emory University School of Medicine, and an attending Hepatologist at Children's Healthcare of Atlanta. She specializes in the treatment of GI disease in children as well as fatty liver disease and obesity. Dr. Vos is also the author of The No-Diet Obesity Solution for Kids.

- Dr. Manal Abdelmalek (MD) – Duke University Medical Center. Dr. Abdelmalek is Associate Professor of Medicine at Duke Medical University Medical Center, Division of Gastroenterology & Hepatology, Section of Hepatobiliary Diseases & Liver Transplantation. Dr. Abdelmalek is a leading investigator in the field of NASH.

- Dr. Gerhard Rogler (MD, PhD) – Zurich University. Dr. Rogler was the principal investigator of our Colitis preclinical program. He ceased to be a member of our advisory board when the scientific results were published on January 25, 2019. Dr. Rogler is the Chairman of the Scientific Advisory Board of the University of Zurich and Professor of Gastroenterology and Hepatology and Consultant Gastroenterologist at the Division of Gastroenterology & Hepatology, Department of Medicine, Zürich University Hospital, Switzerland.

OUR MARKETED ASSETS

Travelan – Our Flagship Commercial Asset. Travelan is our over-the-counter gastrointestinal and digestive health supplement. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709), and is indicated to reduce the risk of Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the FDA.

The COVID-19 pandemic caused massive international travel restrictions in mid to late March 2020, affecting every Travelan® market, which had a flow-on effect to Q4 FY20 Travelan® sales due to the product's positioning as a Travelers' Diarrhea therapeutic. Gross worldwide sales of Travelan® increased by 5% in the 2020 fiscal year to A$2.7M. This decline in global sales followed on from a strong period of ~60% growth in the first 3 quarters of 2020. In the 2021 fiscal year, gross worldwide sales of Travelan® significantly decreased to A$165,686. We re-focused our marketing to promote Travelan® and its sister product, Protectyn®, for their gut and digestive health benefits. When travel stops and lockdown requirements see people isolated at home, dietary habits change, with an increasing prevalence of home food preparation and deliveries of take-away meals. With these adjustments comes the increased risk of variable personal and commercial food hygiene standards.

OVERVIEW OF TECHNOLOGY

We are a commercial and clinical-stage Australian biopharmaceutical company with a proprietary technology platform focused on developing a novel class of biological polyclonal antibodies that can address significant unmet medical needs. Our primary focus is on developing first-in-class oral polyclonal antibodies drugs to treat a range of infectious diseases. Compared to other therapeutics, our oral polyclonal antibodies offer targeted delivery within the gastrointestinal tract and do not cross into the bloodstream, potentially leading to much improved safety and tolerability.

The underlying nature of our platform technology enables the development of medicines across a large range of infectious diseases. The platform can be used to directly block viruses or bacteria and neutralize the toxins they produce at mucosal surfaces (such as the GI tract). Additionally, the dairy origins of our antibodies enable us to commercialize our platform through most regulatory pathways, including prescription, medical foods, over-the-counter medicines, and dietary supplements.

Manufacturing Process

Our active pharmaceutical ingredients are manufactured under cGMP conditions and many of the components are the same as those of normal cow's milk. However, the main differentiation between milk and our active ingredient constituents is the presence of antibodies in bovine colostrum of the order of 35-45% by weight of dry colostrum powder. The main classes of immunoglobulins found in the active ingredient are IgG with smaller amounts of IgM and IgA. Immunoglobulins account for up to 70–80% of the total protein content in colostrum, whereas in milk they account for only 1–2% of total protein. The major class of immunoglobulin G found in bovine colostrum is IgG1 making up between 65% and 90% of total immunoglobulins, in contrast to milk which comprises predominantly IgA.

Vaccination

The active drug substance is prepared using the first milking colostrum of dairy cows that have been immunized with patented vaccines to produce very high levels of specific antibodies against selected surface antigens. Pregnant dairy cows at commercial dairy farms are immunized through a proprietary process.

Colostrum

The colostrum is harvested from immunized Holstein Friesian and Jersey cows registered for milk production for human consumption and at the time of harvesting are free from antibiotics. They are not given steroids at any stage of the process. Colostrum is harvested at the first milking which will be within twelve hours of calving, leaving plenty for the calf to feed on.

Once harvested, preparation of the active ingredient complies with processes that are regulated by Dairy Safe standards in addition to the TGA, which is a Federal requirement and known globally for its stringent criteria. The raw colostrum material is first pasteurized then cooled and centrifuged using a milk separator to remove somatic cells, cell debris, some bacteria and fat. It is then subjected to membrane ultra-filtration, removing much of the water, salts and lactose. The colostrum wet concentrate is then spray dried to produce a powder, which is milled to 200 microns. The processes are typical for the dairy industry and for production of dairy foods. After spray drying, the active ingredient is ready for further processing into the oral dosage form.

Tableting

The product excipients are all standard, FDA acceptable oral compounds that are granulated, milled and finally compressed into caplets and blister packaged (pharmaceutical grade packaging materials).

Batch Consistency

The IgG component of our active ingredient ranges between 36% and 45%. The parameters are stable within batches and across batches. Our product is stable according to ICH guidelines and the IgG component of our active ingredient is stable over time and is manufactured under cGMP conditions with all associated QA and QC processes ensuring the stability of these parameters.

Trademarks

We have rights to trademarks and trade names (both registered and unregistered) used in this Annual Report on Form 20-F (this "Annual Report") which are important to our business.

These trademarks are as follows:

- Immuron (registration in U.S.);
- Travelan (registration in U.S., Australia, Canada and China); and
- Protectyn (registration in Australia and Canada);

Solely for convenience, trademarks and trade names referred to in this Annual Report appear without the "®" or "™" symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name or service mark of any other company appearing in this Annual Report is the property of its respective holder.

PATENTS

We have a policy to identify, capture and protect all relevant intellectual property associated within our core business strategies. We own a number of patent families that have been filed to protect both the vaccine that is used to generate our colostrum enriched with antibodies of choice, as well as methods of treating certain conditions with the resulting hyper-immune colostrum.

Our patent rights are supplemented by a comprehensive body of confidential and proprietary expertise that has been developed over many years and relates to the methods of production of the hyper-immune colostrum. These trade secrets include information relating to the production system and an effective immunization process that is approved by an independent animal ethics committee.

During the year ended June 30, 2021, we continued to expand our patent portfolio in various global jurisdictions.

A summary of our principal patent families is set out in the table below:

Number	Country	Status	Expiry
Composition and Method for the Treatment and Prevention of Enteric Bacterial Infections			
2004216920	Australia	Granted	March 4, 2024
2,517,911	Canada	Granted	March 4, 2024
EP 16020270.1	Europe	Accepted	March 4, 2024
230664 B	India	Granted	March 4, 2024
542088	New Zealand	Granted	March 4, 2024
9,402,902	USA	Granted	March 4, 2024
8,637,025	USA	Granted	February 25, 2028
Methods and Compositions for the Treatment and/or Prophylaxis of Clostridium Difficile Associated Disease			
2014253685	Australia	Granted	April 17, 2034
2,909,636	Canada	Pending	April 17, 2034
2986316	Europe	Pending	April 17, 2034
14/785,527	USA	Granted	April 17, 2034
20210506081.2	China	Pending	April 17, 2034
713233	New Zealand	Granted	April 17, 2034
Methods and Compositions			
PCT/AU2021/050772	International	Pending	July 17, 2041

REGULATORY CONSIDERATIONS

Our clinical assets are considered as biologics by the FDA, conferring 12 years of market exclusivity from date of approval in the U.S. for approved drugs derived from our technology program. New products in Europe have 10 years of market exclusivity.

Our ongoing research and development activities, and the production and marketing of our pharmaceutical product candidates derived from those activities will be subject to regulation by human research ethics committees and institutional research boards, as well as numerous governmental authorities in Australia, principally the TGA, the FDA in the U.S., the MHRA in the United Kingdom and the EMA in Europe. Prior to marketing, any therapeutic product developed must undergo rigorous pre-clinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the TGA and, to the extent that any of our pharmaceutical products under development are marketed abroad, by foreign regulatory agencies, including the FDA, EMA and MHRA.

Clinical trials can take many years to complete and require the expenditure of substantial resources. The length of time varies substantially according to the type, complexity, novelty and intended use of the product candidate. We cannot make any assurances that once clinical trials are completed by us or our collaborative partners, we will be able to submit as scheduled a marketing approval request to the applicable governmental regulatory authority, or that such request and application will be reviewed and cleared by such governmental authority in a timely manner, or at all. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible and commercially appropriate, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our pharmaceutical products candidates. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our pharmaceutical product candidates and could adversely impact our business, financial condition and results of operations.

During the course of clinical trials and non-clinical studies, including toxicology studies, product candidates may exhibit unforeseen and unacceptable drug-related toxicities or side effects. If any unacceptable toxicities or side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products. In addition, unacceptable toxicities could ultimately prevent the clearance of our product candidates by human research ethics committees, institutional research boards, the TGA, EMA, FDA or other regulatory authority for any or all targeted indications. Even after being cleared by a regulatory authority, any of our products may later be shown to be unsafe or not to have its purported effect, thereby preventing widespread use or requiring withdrawal from the market. We cannot make any assurances that IMM-124E, IMM-529 or any other development or product candidate will be safe or effective when administered to patients.

C. ORGANIZATIONAL STRUCTURE

We have three wholly-owned subsidiaries, Immuron Inc., Anadis EPS Pty Ltd (formed for the sole purpose to act as trustee for the Immuron Limited Executive Officer Share Plan Trust) and Immuron Canada Ltd. All costs associated with the operations of these companies are borne by Immuron Limited. Anadis ESP Pty Ltd does not form a part of the consolidated accounts as they are not material.

D. PROPERTY, PLANT AND EQUIPMENT

Our corporate headquarters are located at Level 3, 62 Lygon Street, Carlton South, Victoria, 3053, Australia. Our principal office is located at Suite 10, 25-37 Chapman Street, Blackburn North, Victoria 3130 and consists of approximately 1,500 square feet of office and warehouse space under a lease agreement which is expiring in December 2021, with an ongoing further three-year option for extension. We have no dedicated research and development facility as our research and development activities are provided by third party suppliers who are responsible for their own premises. We believe that our existing facilities are adequate for our current needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis includes certain forward-looking statements with respect to the business, financial condition and results of operations of our company. The words "estimate", "project", "intend", "expect" and similar expressions are intended to identify forward-looking statements within the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated by such forward-looking statements, including those risk factors contained in Item 3.D. of this Annual Report. You should read the following discussion and analysis in conjunction with our consolidated financial statements and the notes thereto included in this Annual Report.

A. Operating Results

Background

We were incorporated under the laws of Australia in 1994 and have been listed on the ASX since April 30, 1999. Our ADSs and Warrants have traded on The NASDAQ Capital Market since June 13, 2017.

Our consolidated financial statements appearing in this annual report comply with IFRS as issued by IASB. In this annual report, all references to "U.S. dollars" or "US$" are to the currency of the U.S., and all references to "Australian dollars", "A$" or "$" are to the currency of Australia. Unless otherwise indicated or the context implies otherwise, items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in Australian dollar ("A$" or "$"), which is Immuron Limited's functional and presentation currency. All of our revenues are generated in Australian dollars, United States dollars and Canadian dollars, and the majority of our expenses are incurred in Australian dollars.

Critical Accounting Policies

The following is a summary of the material accounting policies adopted by us in the preparation of the financial report. The accounting policies have been consistently applied, unless otherwise stated.

Basis of Consolidation

The consolidated financial statements incorporate the financial statements of our company and the entities controlled by us (our subsidiaries) referred to as "the group" or "the Group" in the financial statements. Control is achieved where the consolidated entity is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity.

A list of controlled entities is contained in note 10 to the financial statements. All controlled entities have a June 30 financial year-end. All intra-group transactions, balances, income and expenses are eliminated in full on consolidation. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with those policies applied by the parent entity. Subsidiaries are accounted for at cost in the parent entity.

Revenue Recognition

(i) Sale of hyperimmune products

Revenue arises mainly from the sale hyperimmune products. To determine whether to recognize revenue, the group follows the process of identifying the contract with a customer, identifying the performance obligations, determining the transaction price, allocating the transaction price to the performance obligations and recognising revenue when performance obligations are satisfied.

Revenue from the sale of hyperimmune products is recognized when or as the group transfers control of the assets to the customer.

There is no variable consideration or significant cost to obtain the contract. There is no warranties and no refunds. Returns are provided where this is outlined in a customer agreement.

(ii) Financing components

The group does not expect to have any contracts where the period between the transfer of the promised goods or services to the customer and payment by the customer exceeds one year. As a consequence, the group does not adjust any of the transaction prices for the time value of money.

Fair value of R&D tax incentive

The group's research and development (R&D) activities are eligible under an Australian government tax incentive for eligible expenditure. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. Amounts are recognized when it has been established that the conditions of the tax incentive have been met and that the expected amount can be reliably measured. For the year ended June 30, 2021, the group has included an item in other income of A$306,154 (2020: A$308,225) to recognize income over the period necessary to match the grant on a systematic basis with the costs that they are intended to compensate. Furthermore, the group subsequently received additional $50,055 in current financial year as part of the R&D claim for financial year ended 30 June 2020.

Intangible Assets – Research & Development

Expenditure on research activities, undertaken with the prospect of obtaining new scientific or technical knowledge and understanding, is recognized in the statement of profit or loss and other comprehensive income as an expense when it is incurred.

Expenditure on development activities, being the application of research findings or other knowledge to a plan or design for the production of new or substantially improved products or services before the start of commercial production or use, is capitalized if it is probable that the product or service is technically and commercially feasible, will generate probable economic benefits and adequate resources are available to complete development and cost can be measured reliably. Other development expenditure is recognized in the statement of profit or loss and other comprehensive income as an expense as incurred.

Interest Bearing Loans and Borrowings

Generally, loans and borrowings are initially recognized at cost, being the fair value of the consideration received net of issue costs associated with the borrowing. After initial recognition, interest bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Amortized cost is calculated by taking into account any issue costs and any discount or premium on settlement.

Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realizable value. Cost comprises direct material, freight and import duty. Management classifies a portion of inventory as a current asset based on an assessment of expected use in the next 12 months. The remainder is classified as a non-current asset.

Costs are assigned to individual items of finished goods inventory on basis of weighted average costs. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

Share-based payments

Share-based compensation benefits may be provided through the issue of fully paid ordinary shares under the Immuron Employee Share and Option Plan ("ESOP"). Options are also granted to employees and consultants in accordance with the terms of their respective employment and consultancy agreements. Any options granted are made in accordance with the terms of our ESOP.

The fair value of options granted under employment and consultancy agreements are recognized as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognized over the period during which the employees become unconditionally entitled to the options.

The fair value at grant date is determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the vesting and performance criteria, the impact of dilution, the non-tradable nature of the option, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option.

The fair value of the options granted excludes the impact of any non-market vesting conditions (for example, profitability and sales growth targets). Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. At each reporting date, the entity revises its estimate of the number of options that are expected to become exercisable. The employee benefit expense recognized each period takes into account the most recent estimate. The impact of the revision to original estimates, if any, is recognized in the statement of profit or loss and other comprehensive in come with a corresponding adjustment to equity.

Upon the exercise of options, the balance of the share-based payments reserve relating to those options is transferred to contributed equity.

Critical Accounting Estimates and Judgments

Management evaluates estimates and judgments incorporated into the financial statements based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both internally and externally.

R&D tax incentive

The Group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme.

For the year ended June 30, 2021 the Group has recorded other income of $306,154 (2020: $308,225) to recognize this amount which relates to this financial year. Furthermore, the Group subsequently received additional $50,055 in current financial year as part of the R&D claim for financial year ended June 30, 2020.

Impairment of inventories

The provision for impairment of inventories assessment requires a degree of estimation and judgement. The level of the provision is assessed by taking into account the recent sales experience, the ageing of inventory, and in particular, the shelf life of inventories that affects obsolescence. Expected shelf-life is reassessed on a regular basis with reference to stability tests which are conducted by an expert engaged by the Company.

Inventory split

During the current financial period, management performed an assessment on its raw materials and its utilization within 12 months from reporting date. Management determined that no raw materials relating to Colostrum will be consumed within 12 months from reporting date; the remaining balance of $1,266,587 (2020: $1,722,349) will be consumed after 12 months from reporting dates.

During the year ended June 30, 2020, management has performed an assessment on its raw materials and their utilization within 12 months from reporting date and have determined none of raw materials relating to Colostrum is expected to be consumed within 12 months (2019: $225,765) and the remaining balance of $1,722,349 (2019: $1,862,063) is expected to be consumed after 12 months from reporting date.

Provision for employee benefits

Provision for employee benefits represents amounts accrued for annual leave and long service leave. The current portion for this provision includes the total amount accrued for annual leave entitlements and the amounts accrued for long service leave entitlements that have vested due to employees having completed the required period of service. Refer to note 1(r) for policies on provisions.

Share-based payments

The value attributed to share options and remunerations shares issued is an estimate calculated using an appropriate mathematical formula based on an option pricing model. The choice of models and the resultant option value require assumptions to be made in relation to the likelihood and timing of the conversion of the options to shares and the value of volatility of the price of the underlying shares.

Fair value measurement hierarchy

The preparation of the financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgments, estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgments, estimates, and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgments and estimates will seldom equal the related actual results. The judgments, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed within the relevant sections where applicable.

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

Results of Operations

The following discussion relates to our consolidated results of operations, financial condition and capital resources. You should read this discussion in conjunction with our consolidated financial statements and the notes thereto contained elsewhere in this Annual Report.

Comparison of the fiscal years ended June 30, 2021 and 2020

Revenue and Other income

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2021 A$	2020 A$	A$
Revenue:			
Revenue from contracts with customers	**145,776**	2,518,566	(2,372,790)
Other Income:			
Australian Federal R&D tax concession refund	**356,209**	308,225	47,984
COVID-19 government assistance	**161,600**	154,904	6,696
R&D grants	**74,821**	—	74,821
Other income	**24,480**	10,545	13,935
Total Other Income	**617,110**	473,674	**143,436**

Revenues received from the sale of goods decreased by A$2,372,790, or 94%, from fiscal 2020 to fiscal 2021, primarily due to the sales decline in the Australian, U.S. and North American markets for Travelan products due to the prolonged Covid-19 pandemic. We anticipate that revenues from sales of our Travelan product will not be able to increase in the near future.

For the fiscal 2021, the group has included an item in other income of $306,154 (2020: $308,225) to recognize income over the year necessary to match the R&D tax incentive on a systematic basis with the costs that they are intended to compensate. Furthermore, the group subsequently received additional $50,055 in fiscal 2021 as part of the R&D claim for fiscal 2020. As a result, our R&D tax concession income recognized for fiscal 2021 has slightly decreased as compared to for fiscal 2020. The overall decrease is attributed to a decrease in R&D tax concession expenditure relating to eligible research and development.

The group's other grant income consists of grants received by the group with relation to COVID-19. Grants are recognized as other income when the group is reasonably assured that it will comply with the conditions attaching to it and the grant will be received. For the year ended 30 June 2021, the group has recognized $161,600 (2020: $154,904) in the COVID-19 government assistance packages and a $74,821 (2020: Nil) R&D grant from the Henry M Jackson Foundation.

Other (residual) income, which is income from inventory disposal and freight income, increased by A$13,935 in fiscal 2021, primarily due to the disposal of inventory of A$23,249.

Cost of Goods Sold and Gross Profit

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2021 A$	2020 A$	A$
Revenue from contracts with customers	**145,776**	2,518,566	(2,372,790)
Cost of Goods Sold	**(51,071)**	(688,836)	637,765
Gross Profit	**94,705**	1,829,730	(1,735,025)

Our key manufacturing partners provide us with a quality product at a known price which from a strategic point of view provides us with certainty around the manufacturing margins. The Company's cost of goods sold margin increased to 35% in fiscal 2021 from 27% in fiscal 2020.

Expenses

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2021 A$	2020 A$	A$
Expenses:			
General and administrative expenses	**3,978,679**	3,703,990	274,689
Share-based payment expenses	**2,116,013**	(533,912)	2,649,925
Research and development expenses	**1,367,054**	1,178,685	188,369
Selling and marketing expenses	**287,684**	871,551	(583,867)
Total expenses	**7,749,430**	5,220,314	**2,529,116**

General and administrative expenses. General and administrative expenses increased by A$274,689 from fiscal 2020 to fiscal 2021. The increase is mainly attributed to additional consulting services provided to the Company.

Share-based payment expenses. Share-based payment expenses increased by A$2,649,925 from fiscal 2020 to fiscal 2021. The increase is mainly attributed to the share-based payments made to employees, consultants and directors of the Company amounting to A$2,116,013 in fiscal 2021 compared to A$73,088 in fiscal 2020. In addition, options granted to Dr Gary Jacob on 11 February 2019 and valued at $975,000 in the 30 June 2019 financials were subject to shareholder approval. In line with IFRS 2, these were re-measured at grant date 6 November 2019 after being approved by shareholders with a value of $368,000, being a revaluation of $607,000 in the 30 June 2020 financials.

Research and development expenses. Research and development expenses increased by A$188,369 from fiscal 2020 to fiscal 2021. The slight increase in the research and development expenditure reflects the Company's continued strategic focus and development.

Selling and marketing expenses. Selling and marketing expenses decreased by A$583,867 from fiscal 2020 to fiscal 2021 as the sales decline due to the prolonged Covid-19 pandemic.

Loss for the period. As a result of the foregoing, our loss for the period after income tax benefit increased by A$5,457,259, or 186%, from A$2,927,206 in fiscal 2020 to A$8,384,465 in fiscal 2021.

Given our, and our subsidiaries', history of recent losses, we have not recognized a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether we, or our subsidiaries, will generate sufficient future taxable income against which we can utilize these unused tax losses and any uncalculated potential deferred tax assets, together with any other temporary differences. Should the need arise, we can, and will, revisit this position.

Comparison of the fiscal years ended June 30, 2020 and 2019

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2020 A$	2019 A$	A$
Revenue:			
Revenue from contracts with customers	2,518,566	2,387,426	131,140
Other Income:			
Australian Federal R&D tax concession refund	308,225	531,005	(222,780)
Other grants	154,904	—	154,904
Other income	10,545	1,045	9,500
Total Other Income	473,674	532,050	(58,376)

Revenues received from the sale of goods increased by A$131,140, or 5%, from fiscal 2019 to fiscal 2020. The COVID-19 pandemic caused massive international travel restrictions in mid to late March 2020, affecting every Travelan® market which had a flow-on effect to Q4 FY20 Travelan® sales due to the product's positioning as a Travelers' Diarrhea therapeutic. This decline in global sales followed on from a strong period of ~60% growth in the first 3 quarters of 2020. In April we re-focussed our marketing to promote Travelan® and its sister product, Protectyn®, for their gut and digestive health benefits.

Our R&D tax concession income recognized during fiscal 2020 decreased by A$222,780 compared to fiscal 2019. The overall decrease is attributed to a decrease in R&D tax concession expenditure relating to eligible research and development.

The group's other grant income consists of grants received by the group with relation to COVID-19. Grants are recognized as other income when the group is reasonably assured that it will comply with the conditions attaching to it and the grant will be received. For the year ended 30 June 2020, the group has recognized A$154,904 in assistance packages.

Other (residual) income, which is interest income, increased by A$9,500 in fiscal 2020, primarily due to an increase in cash and cash equivalents.

Cost of Goods Sold and Gross Profit

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2020 A$	2019 A$	A$
Revenue from contracts with customers	2,518,566	2,387,426	131,140
Cost of Goods Sold	(688,836)	(667,371)	(21,465)
Gross Profit	**1,829,730**	**1,720,055**	**109,675**

Our key manufacturing partners provide us with a quality product at a known price, which, from a strategic point of view, provides us with certainty around the manufacturing margins. The Company's cost of goods sold margin was broadly maintained year on year with a slight decrease to 27% in fiscal 2020 from 28% in fiscal 2019. As we expand our sales efforts in North America, we have been able to maintain economies of scale thereby broadly maintaining our cost of goods sold margins.

Expenses

	For the fiscal year ended June 30,		Increase/ (Decrease)
	2020 A$	2019 A$	A$
Expenses:			
General and administrative expenses	3,170,078	5,037,806	(1,867,728)
Research and development expenses	1,178,685	1,044,528	134,157
Selling and marketing expenses	871,551	864,644	6,907
Total expenses	**5,220,314**	**6,946,978**	**(1,726,664)**

General and administrative expenses. General and administrative expenses decreased by A$1,867,728 from fiscal 2019 to fiscal 2020. The decrease is mainly attributed to the share-based payments made to employees, consultants and directors of the Company amounting to A$1,343,500 in fiscal 2019 compared to A$(533,912) in fiscal 2020 and the resignation of Dr Gary S. Jacob and Mr Richard Jay Berman during fiscal 2020. In December 2019, a revaluation of share-based payments made to Dr Gary S. Jacob results in a decrease of A$607,000 in the share-based payment expense recognized in fiscal 2020.

The value and revaluation of the options granted to Dr Gary S. Jacob and Mr Richard Jay Berman did not result in an actual allocation of shares. The exercise price of the options is A$0.50 per share.

Research and development expenses. Research and development expenses increased by A$134,157 from fiscal 2019 to fiscal 2020. The increase in the research and development expenditure reflects the Company's new strategic focus and development pipeline during fiscal 2020.

Selling and marketing expenses. Selling and marketing expenses increased by A$6,907 from fiscal 2019 to fiscal 2020 as we increased our promotional efforts for Travelan, our existing flagship consumer product.

Loss for the period. As a result of the foregoing, our loss for the period after income tax benefit decreased by A$1,729,215, or 37%, from A$4,656,421 in fiscal 2019 to A$2,927,206 in fiscal 2020.

Given our and our subsidiaries' history of recent losses, we have not recognized a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether we, or our subsidiaries, will generate sufficient future taxable income against which we can utilize these unused tax losses and any uncalculated potential deferred tax assets, together with any other temporary differences. Should the need arise, we can, and will, revisit this position.

Inflation and Seasonality

Management believes inflation has not had a material impact on our company's operations or financial condition and that our operations are not currently subject to seasonal influences.

Conditions in Australia

We are incorporated under the laws of, and our principal offices and research and development facilities are located in, the Commonwealth of Australia. Therefore, we are directly affected by political and economic conditions in Australia. See Item 3.D. "Key Information – Risk Factors" for a description of factors that could materially affect our operations.

B. LIQUIDITY AND CAPITAL RESOURCES

We have incurred cumulative losses and negative cash flows from operations since our inception in 1994 and as of June 30, 2021 we had accumulated losses of A$65,932,888.

In July 2019, the Company completed an underwritten public offering of 339,130 ADSs at a public offering price of US$4.00 per ADS for gross proceeds US$1,356,520 (prior to deducting underwriting discounts, commissions and other estimated offering expenses). In May 2019, the Company completed an underwritten public offering of 500,000 ADSs at a public offering price of US$4.00 per ADS for gross proceeds US$2,000,000 (prior to deducting underwriting discounts, commissions and other estimated offering expenses). In June 2017, we sold 610,000 ADSs and Warrants to purchase 701,500 ADSs (not including the 35,075 Representative's Warrants) in an initial public offering in the U.S. The aggregate net offering proceeds to us, after deducting underwriting discounts and commissions, was US$5,673,000. Additionally, in mid-March 2018, we completed a A$5,161,585 private placement with a large US institutional investment fund. The funds will support current and future clinical programs, support continued Travelan marketing, and our working capital. We anticipate that we will continue to incur losses for the foreseeable future. We expect that as we continue research efforts and the development of our product candidates, hire additional staff, including clinical, scientific, operational, financial and management personnel we will need additional capital to fund our operations which we may raise through a combination of equity offerings, debt financings, other third-party funding and other collaborations, strategic alliances and licensing arrangements.

The commitment to these projects will require additional external funding, at least until we are able to generate sufficient cash flow from sale of one or more of our products to support our continued operations. If adequate funding is not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Management is continuing its efforts to obtain additional funds so that we can meet our obligations and sustain operations.

The sale of additional equity or convertible debt could result in additional dilution to our shareholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are unable to secure adequate additional funding we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm our business.

We do not currently have any credit facilities in place.

As of June 30, 2021, we had cash of A$25,047,281 as compared to cash of A$3,250,468 as of June 30, 2020. The company is in a position to meet future commitments in the current business cycle and pay its debts as and when they fall due. Furthermore, the company is able to progress its research and development programs for at least the next 12 months. The annual report has been prepared on a going concern basis. Accordingly, the annual report does not include adjustments relating to the recoverability and classification of recorded asset amounts, or the amounts and classification of liabilities that might be necessary should the group not continue as a going concern. The company is a going concern and is of the opinion that no asset is likely to be realized for an amount lower than the amount at which it is recorded in our Consolidated Statement of Financial Position as of June 30, 2021.

We expect that our current cash, cash equivalents will be sufficient to fund our capital requirements for at least 12 months from the issuance date of the financial statements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies for our product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- revenue received from commercial sales of any of our product candidates that may receive regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we need to in-license or acquire other products and technologies.

In connection with our initial public offering in June 2017, we sold Warrants to purchase 701,500 ADSs at an initial exercise price of US$10.00 per ADS. The Warrants will expire five years from the date of issuance. Any proceeds from the exercise of the Warrants will be added to our working capital.

Upon the closing of our initial public offering, we issued Warrants to purchase 30,500 ADSs to the representatives (the "Representative's Warrants"). The Representative's Warrants are exercisable at a per ADS exercise price equal to US$12.50. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering. Any proceeds from the exercise of the Representative's Warrants will be added to our working capital.

In connection with our public offering in May and July 2019, we issued Warrants to purchase 20,000 and 13,565 ADSs to the representatives (the "Representative's Warrants"), respectively. The Representative's Warrants are exercisable at a per ADS exercise price equal to US$5.00. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering. Any proceeds from the exercise of the Representative's Warrants will be added to our working capital.

Cash flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	For the year ended June 30,		
	2021	**2020**	**2019**
	A$	**A$**	**A$**
Net cash used in operating activities	(4,078,747)	(3,147,328)	(1,798,579)
Net cash (used in)/from investing activities	2,574	(864)	(2,008)
Net cash from financing activities	26,480,182	1,156,952	2,069,183

Operating activities. During the twelve months ended June 30, 2020 and 2021, net cash used in operating activities increased by A$931,419 from A$3,147,328 to A$4,078,747, respectively. Net cash used in operating activities increased by A$1,348,749 from A$1,798,579 in fiscal year 2019 to A$3,147,328 in fiscal year 2020. The use of net cash in all periods resulted from our ordinary business operations. Net cash used in operating activities increased by approximately 30% in fiscal year 2021 due to more prompt payments to suppliers during the year which resulted in increase in operational cash payments.

Investing activities. Net cash used in investing activities during the twelve months ended June 30, 2021, 2020 and 2019 were relatively minimal and solely related to interest received and pertained to purchases of office and computer equipment.

Financing activities. During the twelve months ended June 30, 2021, net cash provided by financing activities was A$26,480,182, which comprised of proceeds from issue of securities through a public offering of ADSs (less costs associated with the issue).

During the twelve months ended June 30, 2020, net cash provided by financing activities was A$1,156,952, which comprised of proceeds from issue of securities through a public offering of ADSs (less costs associated with the issue).

During the twelve months ended June 30, 2019, net cash provided by financing activities was A$2,069,183, which comprised of proceeds from issue of securities through a public offering of ADSs (less costs associated with the issue).

Contractual Obligations

The group had no contractual obligations other than those disclosed in Note 14. Leases. The group had no contingent liabilities at 30 June 2021 (2020: nil).

Off balance sheet arrangements

We are not a party to any material off-balance sheet arrangements. In addition, we have no unconsolidated special purpose financing or partnership entities that are likely to create material contingent obligations.

Quantitative and qualitative disclosures about market risks

We are exposed to market risk related to changes in interest rates and exchange rates. As of June 30, 2021, we had cash and cash equivalents of A$25,047,281, primarily held in bank accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected primarily by changes in the general level of Australian interest rates. We are exposed to interest rate risks relating to our cash and borrowings. Interest rate risk is the risk that a financial instrument's value will fluctuate as a result of changes in market interest rates.

We are exposed to fluctuations in foreign currencies that arise from foreign currencies held in bank accounts and the translation of results from our operations outside Australia. Our foreign exchange exposure is primarily to the U.S. dollar and Canadian dollar. Foreign currency risks arising from commitments in foreign currencies are managed by holding cash in that currency. Foreign currency translation risk is not hedged.

C. Research and Development, Patents and Licenses

In recent years, we have continued our practice of building valuable research collaborations with institutes based in Australia, the United States, Europe and other countries to enable us to investigate a variety of therapeutic indications including Campylobacter, ETEC, Shigella and Clostridiodies Infections. These collaborative arrangements ensure that we work with well-respected key opinion leaders and laboratories with specific expertise in screening and animal modelling of relevance to the particular indication, without incurring ongoing administrative and personnel costs. We maintain in-house patent counsel and research and development project expertise to coordinate these research collaborations.

When a lead compound is identified as suitable for clinical development, we establish a project team to coordinate all non-clinical and clinical development and manufacturing activities. Typically, we would project manage all the project activities, tasks and milestones and engage clinical research organizations and contract manufacturing organizations to assist. We manage our manufacturing campaigns through contract manufacturing organizations for quality assurance and cGMP compliance. All clinical, non-clinical, clinical development and manufacturing of our compounds is performed in compliance with the appropriate governing authorities, regulators and standards (for example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Research and development expenses amounted to A$1,044,528, A$1,178,685 and A$1,367,054 during the years ended June 30, 2019, 2020 and 2021, respectively. Costs associated with patent applications and defense of patent applications are classified as research and development expenses and amounted to approximately A$142,000, A$79,000 and A$61,000, during the years ended June 30, 2019, 2020 and 2021, respectively.

Our research and development expenses consist primarily of expenses for contracted research and development activities conducted by third parties on our behalf, including personnel, testing facilities and other payments in accordance with our research and clinical agreements. Research and development expenses also include costs associated with the acquisition and development of patents. Due to the numerous variables and the uncertain nature of the development of a clinical compound, including obtaining regulatory approvals, we are not able to reasonably estimate the nature, timing and costs of the future expenditures necessary to complete our research and development projects, the anticipated completion dates of each project and when material net cash flows from our research and development programs will commence.

D. Trend Information

We are a commercial and clinical development stage company, and while we believe that our technology will offer novel therapeutic strategies into an expanding market, we cannot predict with any degree of accuracy the outcome of our research or commercialization efforts. Accordingly, any trends within the markets in which we operate are expected to have more direct impact on our business in the event that we are successful in commercializing our new product candidates, including our current lead product candidates.

Over the past few years, there has been increasing pressure to reduce drug prices in the developed markets as a consequence of political initiatives and regulations aiming to curb continuous increases in healthcare spending. Any revenue we earn in the future may be negatively affected by such political initiatives and regulations. The increased burden of healthcare costs in the aging population have led to an increased focus on reducing costs and, therefore, have further increased the pressure to lower drug prices. We expect this trend to continue in the years ahead. However, we believe spending in the healthcare industry, as compared to many other industries, is less linked to economic trends. We expect sales growth to continue at higher levels in emerging markets and also for niche, orphan indications. We also expect that demographic developments, increased treatment penetration, especially in newly established drug markets, and better diagnostic tools to enable the tailoring of drugs to specific needs, will result in continuing growth in overall global drug sales.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

As of September 27, 2021, our directors and executive officers are as follows:

Name	Age	Position
Dr. Roger Aston	65	Non-Executive Chairman
Mr. Daniel Pollock	60	Non-Executive Director
Mr. Stephen Anastasiou	64	Non-Executive Director
Prof. Ravi Savarirayan	54	Non-Executive Director
Dr. Jerry Kanellos, Ph.D.	59	Chief Executive Officer
Mr. Phillip Hains	62	Chief Financial Officer and Secretary

There are no family relationships among our directors and senior executives.

Dr. Roger Aston has been a member of our board of directors and the board's Independent Non-Executive Chairman since March 2012. He also has special responsibilities as a member of the audit and risk committee and chair of the remuneration committee. Dr. Aston holds a BSc (Hons) and PhD. He has more than 20 years' experience in the pharmaceutical and biotechnology industries. Dr Aston was previously the chief executive officer and a director of Mayne Pharma Group Limited (ASX: MYX). Prior to his position at Mayne Pharma, some of his previous positions have included chief executive officer of Peptech Limited (ASX: PTD), director of Cambridge Antibody Technology Limited (LSE: CAT and NASDAQ: CATG) and chairman of Bio Focus Plc (formerly: Cambridge Drug Discovery Limited). Dr Aston was also founder and chief executive officer of Biokine Technology Ltd (UK) prior to its acquisition by the Peptech Group. Dr Aston was also a director of pSivida Ltd. During the past 20 years of his career, Dr Aston has been closely involved in the development of many successful pharmaceutical and biotechnology companies. He has extensive experience including negotiating global license agreements, overseeing product registration activities with the FDA, the establishment and implementation of guidelines and operating procedures for manufacturing and clinical trials, overseeing manufacturing of human and veterinary products, private and public fund-raising activities and the introduction of corporate governance procedures. Dr. Aston's other current directorships are with Oncosil Limited (ASX: OSL) since March 2013, Pharmaust Limited (ASX: PAA) since August 2013, and Resapp Health Limited (ASX: RAP) since July 2015. He held the position of director and chairman of Regeneus Limited (ASX:RGS) until April 2019.

Daniel Pollock has been a member of our board of directors and our Independent Non-Executive Director since October 2012. He also has special responsibilities as chair of the audit and risk committee and a member of the remuneration committee. Mr. Pollock holds a Bachelor of Laws and Diploma in Professional Legal Practice and is a lawyer admitted in both Scotland and Australia and holding practicing certificates in both jurisdictions. He is a sole practitioner in his own legal firm based in Melbourne which operates internationally and specializes in commercial law. Further, he is executive director and co-owner of Great Accommodation Pty Ltd, a property management business operating in Victoria. Mr. Pollock has had historical involvement as a seed investor and board member of a number of small unlisted companies. The most recent of these was an e-pharmacy company where he was heavily involved in its commercial growth and ultimate sale to a large listed health services company.

Stephen Anastasiou has been a member of our board of directors and our Independent Non-Executive Director since May 2013. Mr. Anastasiou holds a Bachelor of Science (Hons), Graduate Diploma in Marketing and Master of Business Administration. He has over 20 years of experience in general management, marketing and strategic planning within the healthcare industry. His breadth of experience incorporates medical diagnostics, pharmaceuticals, hospital, dental and over-the-counter products, with companies including the international pharmaceutical company Bristol-Myers Squibb (NYSE: BMY). While working with KPMG Peat Marwick as a management consultant, Mr. Anastasiou previously led project teams in a diverse range of market development and strategic planning projects in both the public and private sector. He is also a director and shareholder of a number of unlisted private companies, covering a variety of industry sectors that include healthcare and funds management. Mr. Anastasiou's companies have participated in several corporate transactions involving business units and brands of multinational and Australian companies.

Professor Ravi Savarirayan has been a member of our board of directors and our Independent Non-Executive Director since April 2017. Prof. Savarirayan holds a Doctor of Medicine from the University of Melbourne, a Bachelor of Medicine and Bachelor of Surgery from the University of Adelaide, is a Fellow of the Royal Australasian College of Physicians (FRACP) and is a member of the American Academy of Physician Assistants (ARC-PA, Hons). He has been a consultant clinical geneticist at the Victorian Clinical Genetics Services since August 1999, as well as professor and research group leader of skeletal biology and disease at the Murdoch Children's Research Institute since September 2000. Prof. Savarirayan has served as a founding member of the Skeletal Dysplasia Management Consortium since January 2011 and has acted as the chair of the specialist advisory committee in clinical genetics at the Royal Australasian College of Physicians since February 2009. He was president of the International Skeletal Dysplasia Society from July 2009 to June 2011 and has been an invited member of several international working committees on constitutional diseases of bone. Prof. Savarirayan's primary research focus is on inherited disorders of the skeleton causing short stature, arthritis and osteoporosis. He has published over 150 peer-reviewed articles, collaborating with peers from over 30 countries. He has been on the editorial board of Human Mutation since January 2009, European Journal of Human Genetics since July 2007, American Journal of Medical Genetics since December 2011 and the Journal of Medical Genetics since June 2005.

Dr. Jerry Kanellos, Ph.D. has been our Chief Executive Officer since March 2020 and our Chief Operating Officer since July 2015, and also served as our CEO from August 2017 until November 2018 and our Chief Scientific Officer from July 2015 to November 2018. In addition, since April 2018, Dr. Kanellos has served as a director of Immuron Canada Limited. Dr. Kanellos has over 25 years of experience in the pharmaceutical and biotechnology industry, and has held leadership roles in executive management, business development, project management, intellectual property portfolio management research and development. From 2008 until 2012, Dr. Kanellos was the Chief Operating Officer of TransBio Limited where he was responsible for the strategic identification, development and maintenance of commercial partnerships globally, along with development, management and maintenance responsibility for the intellectual property portfolio, research and development and technology transfer. Prior to this, Dr. Kanellos worked for five years as a consultant to the biotechnology industry and provided development and commercialization strategies for various bodies including academic institutes, private and publicly listed companies and government departments both national and international. He has also been involved in the establishment and management of several startup biotechnology companies. During his ten year tenure in research and development at CSL Limited, a global specialty biotherapeutics company that develops and delivers innovative biotherapies, Dr. Kanellos gained considerable experience in the international drug development process, formulation development through to pharmaceutical scale up and cGMP manufacture successfully leading the Chemistry Manufacturing and Controls programs for the approval, manufacture and launch of several products. Dr. Kanellos holds a PhD degree in Medicine from the University of Melbourne.

Company secretary

Mr. Phillip Hains was appointed as the secretary of the Company in April 2013. Mr. Hains is a Chartered Accountant operating a specialist public practice, 'The CFO Solution'. The CFO Solution focuses on providing back office support, financial reporting and compliance systems for listed public companies. A specialist in the public company environment, Mr. Hains has served the needs of a number of company boards and their related committees. He has over 30 years of experience in providing businesses with accounting, administration, compliance and general management services. He holds a Master of Business Administration from RMIT University and a Public Practice Certificate from the Chartered Accountants Australia and New Zealand.

B. COMPENSATION

Our remuneration policy is designed to ensure that directors and senior management are appropriately remunerated having regard to their relevant experience, their performance, the performance of our company, industry norms and standards and the general pay environment as appropriate. Our remuneration policy has been established to enable us to attract, motivate and retain suitably qualified directors and senior management who will create value for shareholders.

Our remuneration policy is not directly based on our earnings. Our earnings have remained negative since inception due to the nature of our company. Shareholder wealth reflects this speculative and volatile market sector. No dividends have ever been declared by us. We continue to focus on the research and development of our intellectual property portfolio with the objective of achieving key development and commercial milestones in order to add further shareholder value.

Non-Executive Director Remuneration

Similarly, our remuneration policy is designed to ensure that non-executive directors are appropriately remunerated with respect to their relevant experience, individual performance, the performance of our company, industry norms/standards and the general pay environment as appropriate.

Our Constitution and the ASX Listing Rules specify that the aggregate remuneration of non-executive directors shall be determined from time to time by a meeting of shareholders. An amount (not exceeding the amount approved at the shareholders' meeting) is determined by the Board and then divided between the non-executive directors. The latest determination was at the shareholders' meeting held on November 19, 2018 when shareholders approved the aggregate maximum cash sum to be paid or provided as remuneration to the directors as a whole (other than the managing director and executive directors) for their services as A$500,000 per annum. This compensation is cash based and includes stock-based compensation. As per the ASX announcement on 27 April 2020, the Board of Directors have resolved, for the foreseeable future, to relinquish cash payments of fees from 1 April 2020 and in lieu of the same receive common stock in the company.

In the year ended June 30, 2021, our Non-Executive directors received an aggregate of A$2,532,170, including superannuation and additional consulting fees, and our executive directors received A$1,673,681. The manner in which the aggregate remuneration is apportioned among non-executive directors is reviewed periodically. The Board is responsible for reviewing its own performance. Both Board and Board committee performance is monitored on an informal basis throughout the year with a formal review conducted during the financial year. No retirement benefits are payable other than statutory superannuation, if applicable.

Executive Director and Executive Officer Remuneration

Our remuneration policy is also designed to ensure that executive directors are appropriately remunerated with respect to their relevant experience, individual performance, the performance of our company, industry norms/standards and the general pay environment as appropriate.

Our non-executive directors are responsible for evaluating the performance of the Chief Executive Officer ("CEO") who in turn evaluates the performance of the other senior executives. The evaluation process is intended to assess our business performance, whether long-term strategic objectives are being achieved, and the achievement of individual performance objectives.

The performance of our CEO and senior executives are monitored on an informal basis throughout the year and a formal evaluation is performed annually.

Fixed Remuneration. Executives' fixed remuneration comprises salary and superannuation and is reviewed annually by the CEO, and in turn, the Remuneration Committee. This review takes into account the executives' experience, performance in achieving agreed objectives and market factors as appropriate.

Variable Remuneration - Short Term Incentive Scheme. Executives may be entitled to receive a combination of short term incentives ("STI") and long term incentives ("LTI") as part of their total remuneration if they achieve certain performance indicators as set by the Board. These STI /LTI may be paid either by cash, or a combination of cash and the issue of equity in our company, at the determination of the Board and Remuneration Committee.

The Remuneration Committee approves the issuance of bonuses following the recommendations of the CEO in the annual review of the performance of the executives, and our company as a whole, against agreed key performance indicators ("KPIs").

Variable Remuneration - Long Term Incentive Scheme. Executives may also be provided with longer-term incentives through our Employee Share and Option Plan ("ESOP") that was approved by shareholders at our annual general meeting held on November 13, 2014. The goal of the ESOP is to allow the executives to participate in, and benefit from, the growth of our company as a result of their efforts and to assist in motivating and retaining those key employees over the long term. Continued service is the condition attached to the vesting of the options. The Board at its discretion determines the total number of options granted to each executive.

Remuneration paid in Fiscal 2021

The following table sets forth all compensation we paid for the year ended June 30, 2021 with respect to each of our executive officers and directors during the 2021 fiscal year:

2021	Short-term benefits			Post-employment benefits	Long-term benefits		Share-based payments		
	Cash salary and fees A$	Cash bonus A$	Annual leave A$	Super-annuation A$	Long service leave A$	Other* A$	Shares[1] A$	Options[2] A$	Total A$
Non-executive directors									
Dr Roger Aston[3]	35,000	-	-	3,325	-	178,500	37,837	394,020	648,682
Mr Daniel Pollock[4]	30,000	-	-	2,850	-	178,500	33,075	394,020	638,445
Mr Stephen Anastasiou[5]	25,000	-	-	-	-	178,500	25,000	394,020	622,520
Prof. Ravi Savarirayan[6]	25,002	-	-	-	-	178,500	25,000	394,020	622,522
Executive directors									
Mr Peter Anastasiou[7]	25,000	-	-	-	-	857,138	25,000	394,020	1,301,158
Other KMP									
Dr Jerry Kanellos	310,000	50,000	32,609	21,694	8,220	-	-	-	372,523
Total KMP compensation	**450,002**	**50,000**	**32,609**	**27,869**	**8,220**	**1,571,138**	**145,912**	**1,970,100**	**4,205,850**

Notes

1. Due to the ongoing crisis of COVID-19, the groups directors decided to forgo cash payments of their director fees from 1 April 2020 to 31 December 2020 and instead receive shares of that value. At 30 June 2020, no shares have been issued to directors however the expense of the shares owed to them is $73,088. As at 30 June 2021, the expenses of have been reclassified from reserves to share capital and 2,737,500 shares with a total value of $219,000 have been issued to directors given the shareholders' approval at the AGM held on 29 October 2020.

2. Given the shareholders' approval at the AGM held on 29 October 2020, a total of 9,000,000 ESOP Options were issued to directors on 13 November 2020 and valued at $1,970,100 in total using the Black-Scholes option pricing model.

*Notes to Other**

3. Dr Roger Aston received $178,500 of consulting services in relation to research and development portfolio and clinical review.

4. Mr Daniel Pollock received $178,500 of consulting services in relation to contracts and legal activities.

5. Mr Stephen Anastasiou received $178,500 of consulting services in relation to strategic marketing consultancy and monitoring, strategic market analysis, planning and trend monitoring.

6. Prof. Ravi Savarirayan received $178,500 of consulting services in relation to scientific strategy and evaluation of current and future medical/scientific projects, patent lodging, and day to day operational management inputs/activities.

7. Mr Peter Anastasiou resigned on 24 September 2021. During FY 2021, he received $857,138 of consulting fees for the development of the IMM-124E cover antibody research and patents, fees and bonuses for initiation, management of capital raise.

Employment Agreements with Executive Officers

We have contracts with all of our senior management and employees, and letters of appointment for each of our directors.

Jerry Kanellos

On July 23, 2015, we entered into an Executive Service Agreement with Dr. Jerry Kanellos (the "Kanellos Agreement"), pursuant to which Dr. Kanellos is serving as our Chief Operating & Scientific Officer. Pursuant to the Kanellos Agreement, we will pay Dr. Kanellos A$160,000 per annum. Following Dr. Kanellos' appointment as Interim-Chief Executive Officer on August 3, 2017, we increased his base salary to A$210,000 per annum plus 9.5% Australia superannuation guarantee equating to a total remuneration package of A$229,950 per annum. On November 19, 2018, Dr. Jerry Kanellos resigned as Interim CEO and moved to the role of Chief Operating Officer on the same date with no change in remuneration. On March 25, 2020, Dr. Jerry Kanellos was appointed as CEO. Following Dr. Kanellos' appointment as CEO, we increased his base salary to A$260,000 per annum plus 9.5% Australia superannuation guarantee equating to a total remuneration package of A$284,700 per annum.

Our Board will consider a short and long term share and/or share option incentive package for Dr. Kanellos after twelve months of continuous employment, subject to any applicable shareholder approval. We or Dr. Kanellos may terminate the Kanellos Agreement without cause on thirty days' written notice. Subject to applicable laws and rules, we may elect to pay Dr. Kanellos thirty days' base salary instead of providing notice. We may also terminate the Kanellos Agreement for Cause (as defined in the Kanellos Agreement).

Employee Share Option Plan

Under the term of the ESOP the Board may offer options to key management staff and consultants and in special circumstances may provide financial assistance to an entitled option holder to assist in the exercise of the ESOP options. The aggregate number of shares that may be issued upon the exercise of the ESOP options, together with all other share purchase plans for eligible persons, may not at any time exceed 5% of the total number of our outstanding ordinary shares.

The assessed fair value of options granted to personnel at their grant date is allocated equally over the period from grant date to vesting date, and the amount for the current financial year is included in the remuneration table as set out above. Fair values at grant date are determined using the Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option. The expected price volatility is based on the historic volatility (based on the remaining life of the options), adjusted for any expected changes to future volatility due to publicly available information.

As of June 30, 2021 the number of options over ordinary shares in our company held by each director and other key management personnel of our company, including their personally related parties, are set out below.

As of June 30, 2021 our executive officers and directors as a group, then consisting of seven persons, held options under our ESOP to purchase an aggregate of 10,422,680 ordinary shares. Of such options, options to purchase 8,100,000 ordinary shares at an exercise price of A$0.12 expire on April 14, 2024, options to purchase 1,322,680 ordinary shares at an exercise price of US$10 per 40 options expire on June 13, 2022, and options to purchase 1,000,000 ordinary shares at an exercise price of A$0.50 expire on July 1, 2021.

C. Board Practices

As of June 30, 2021, our board of directors consisted of seven members. Directors are elected at each annual general meeting of our shareholders and serve until their successors are elected or appointed unless their office is earlier vacated. We believe that each of our directors has relevant industry experience. The membership of our board of directors is directed by the following requirements:

- our Constitution specifies that there must be a minimum of three directors and a maximum of ten directors, and our board of directors may determine the number of directors within those limits;
- as set forth in our Board Charter, the membership of the board of directors should consist of a majority of independent directors who satisfy the criteria recommended by the ASX Corporate Governance Principles and Recommendations of the Australian Securities and Investments Commission ("ASIC");
- the Chairman of our Board should be an independent director who satisfies the criteria for independence recommended by the ASX Corporate Governance Principles and Recommendations; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience, and time commitment to properly fulfill its responsibilities or have ready access to such skills where they are not available.

Our board of directors has delegated responsibility for the conduct of our businesses to the Chief Executive Officer, but remains responsible for overseeing the performance of management. Our board of directors has established delegated limits of authority, which define the matters that are delegated to management and those that require board of directors' approval. Under the Corporations Act, at least two of our directors must be resident Australians. None of our directors have any service contracts with us that provide for benefits upon termination of employment.

We have not entered into any service contracts with our directors providing for benefits upon termination of employment.

Committees

To assist our board of directors with the effective discharge of its duties, it has established a Remuneration and Nomination Committee and an Audit and Risk Committee, which committees operate under a specific charter approved by our board of directors.

Remuneration and Nomination Committee

The members of our Remuneration and Nomination Committee are Roger Aston and Daniel Pollock, each of whom our board of directors has determined meets the criteria for independence under NASDAQ Listing Rule 5605(a)(2). Dr. Aston acts as chairman of the committee. The committee's role involves:

- identifying, evaluating and recommending qualified nominees to serve on our board of directors;
- evaluating, adopting and administering our compensation plans and similar programs advisable for us, as well as modifying or terminating existing plans and programs;
- establishing policies with respect to equity compensation arrangements; and
- overseeing, reviewing and reporting on various remuneration matters to our board of directors.

Audit and Risk Committee

The members of our Audit and Risk Committee are Daniel Pollock and Roger Aston, each of whom our board of directors has determined meets the criteria for independence of audit committee members set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable rules of the NASDAQ Capital Market. Each member of our audit committee meets the financial literacy requirements of the listing standards of the NASDAQ Capital Market. Daniel Pollock acts as the chairman of the audit committee. The principal duties and responsibilities of our audit committee include, among other things:

- overseeing and reporting on various auditing and accounting matters to our board of directors, including the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices;
- overseeing and reporting on various risk management matters to our board of directors;
- considering and approving or disapproving all related-party transactions;
- reviewing our annual and semi-annual financial statements and reports and discussing the statements and reports with our independent registered public accounting firm and management;
- reviewing and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- evaluating the performance of our independent registered public accounting firm and deciding whether to retain their services; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

D. EMPLOYEES

As of June 30, 2021, we had four full-time employees. Of these full-time employees, two are employed in manufacturing and quality control positions, one is employed in U.S. sales, one is our COO and CEO.

Our employees are located in Australia and the U.S.

E. SHARE OWNERSHIP

Beneficial Ownership of Executive Officers and Directors

The following table sets forth certain information as of September 27, 2021 regarding the beneficial ownership of our ordinary shares by each of our directors and executive officers and by all of our directors and executive officers as a group.

Unless otherwise indicated, to our knowledge each shareholder possesses sole voting and investment power over the ordinary shares listed subject to community property laws, where applicable. None of our shareholders have different voting rights from other shareholders.

Name	Number of Ordinary Shares Beneficially Owned [1]	Percentage of Ownership [2]
Dr. Roger Aston[3]	3,320,376	1.45%
Mr. Daniel Pollock[4]	2,568,030	1.12%
Mr. Stephen Anastasiou[5]	7,990,668	3.47%
Prof. Ravi Savarirayan[6]	1,777,840	*
Dr. Jerry Kanellos (PhD)[7]	-	*
Mr. Phillip Hains	816,804	*
Officers and directors as a group (6 persons)[8]	16,473,718	7.01%

* Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them. Except as set forth herein, the address for each of the persons listed in the table above is Immuron Limited, Level 3, 62 Lygon Street, Carlton South, Victoria, Australia 3053.

(2) The percentages shown are based on 227,246,596 ordinary shares outstanding as of September 27, 2021, but do not include (i) 16,568,318 ordinary shares issuable upon the exercise of currently exercisable options that are traded on the ASX and (ii) 27,541,160 ordinary shares issuable upon exercise of outstanding warrants. Certain warrants have an exercise price of US$10.00 per ADS while other warrants have an exercise price of US$5.00, US$12.50 and US$23.4375 per ADS.

(3) Includes warrants to purchase 1,800,000 ordinary shares.

(4) Includes warrants to purchase 1,800,000 ordinary shares.

(5) Includes warrants to purchase 3,108,280 ordinary shares.

(6) Includes warrants to purchase 900,000 ordinary shares.

(7) Since the fiscal 2021 year-end, options to purchase 1,000,000 ordinary shares expired on July 1, 2021.

(8) Includes options to purchase 7,608,280 ordinary shares.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth as of September 27, 2021 certain information regarding the beneficial ownership by all shareholders known to us to own beneficially 5% or more of our ordinary shares:

	Ordinary Shares Beneficially Owned [1]	
Shareholder	**Number**	**Percent [2]**
BNYMC Group	97,848,520	43.06%
Grandlodge Capital Pty Ltd[3]	12,261,419	5.40%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.

(2) The percentages shown are based on 227,246,596 ordinary shares outstanding as of September 27, 2021, but do not include (i) 16,568,318 ordinary shares issuable upon the exercise of currently exercisable options that are traded on the ASX and (ii) 27,541,160 ordinary shares issuable upon exercise of outstanding warrants. Certain warrants have an exercise price of US$10.00 per ADS while other warrants have an exercise price of US$5.00, US$12.50 and US$23.4375 per ADS.

(3) Includes warrants to purchase 14,400 ordinary shares. Mr. Peter Anastasiou (resigned on 24 September 2021) is the majority owner of Grandlodge.

Significant Changes in the Ownership of Major Shareholders

Previous substantial shareholders Citicorp Nominees Pty Limited and Authentics Australia Pty Ltd ceased to be major shareholders following the issuance of securities pursuant to our public offering in July 2020 as their existing shareholdings were diluted below 5% ownership.

Major Shareholders Voting Rights

All of our shareholders, including the shareholders listed below, have the same voting rights attached to their ordinary shares.

Record Holders

As of September 27, 2021, there were 2,895 Immuron shareholders holding 227,246,596 fully paid ordinary shares. These numbers are not representative of the number of beneficial holders of our shares nor are they representative of where such beneficial holders reside, since many of these ordinary shares were held of record by brokers or other nominees. The majority of trading by our U.S. investors is done by means of ADS that are held of record by HSBC Nominees Ltd., which held 98,045,283 (43.14%) of our ordinary shares as of such date.

B. Related Party Transactions

Grandlodge Capital Pty Ltd is an entity part-owned and operated by our non-executive director Mr. Stephen Anastasiou. Mr. Peter Anastasiou (a director resigned on 24 September 2021) and Mr. David Plush is also owners of Grandlodge, and its associated entities.

Commenced on June 1, 2013, Grandlodge provides warehousing, distribution and invoicing services for our products for A$70,000 per year. During the 2020 financial year, the fees of A$70,000 equivalent were repaid by issuance of 437,500 ordinary shares based on a price of A$0.16 per share representing the share price of our ordinary shares at the commencement date of an oral agreement between us and Grandlodge. During the 2019 financial year, the fees of A$70,000 equivalent were repaid by issuance of 437,500 ordinary shares based on a price of A$0.16 per share representing the share price of our ordinary shares at the commencement date of an oral agreement between us and Grandlodge. During the 2018 financial year, the fees of A$140,000 equivalent were repaid by issuance of 875,000 ordinary shares based on a set price of A$0.16 per share representing the share price of our ordinary shares at the commencement date of an oral agreement between us and Grandlodge. The 875,000 shares issued to Grandlodge were in relation to the 2017 and 2018 financial years.

Fair value of equity instruments: Shares issued to Grandlodge Pty Ltd for services. Commencing 1 June 2013, Immuron Limited contracted Grandlodge on normal commercial terms and conditions to provide warehousing, distribution, and invoicing services for Immuron's products for A$70,000 per annum. The terms of the agreement was to have fees payable in new fully paid ordinary shares in Immuron Limited as a set price of A$0.16 per share. The fair value of the equity instrument has been identified as not having been previously assessed and accounted for in accordance with IFRS 2 Share Based Payments. Management has undertaken an assessment of the impact of this and concluded this to be an immaterial error. This has been corrected in the prior year by restating the prior period financial statements presented and the related notes included herein to present the fair value of equity instruments issued. The immaterial error to record the fair value of the equity instruments issued for the years 30 June 2014 to 30 June 2017 resulted in an increase of A$297,204 in share capital and a corresponding increase in accumulated losses. The impact of the 2014-2017 revision has been also reflected in the 30 June 2018 and 30 June 2019 years presented. General and administrative expenses have been revised to increase by A$57,653 and A$23,678 for the fair value of the equity instruments issued in 2018 and 2019 respectively, with a corresponding increase in share capital for the same amount.

A new agreement to provide warehousing, distribution, and invoicing services for Immuron's products commenced on July 1, 2020. Grandlodge was contracted on commercial terms to provide warehousing, distribution and invoicing services for Immuron's products for $70,000 per annum. The terms of the agreement were to have fees payable in cash.

Grandlodge is reimbursed in cash for all reasonable costs and expenses incurred in accordance with their scope of works under the oral agreement, unless both Grandlodge and we agree to an alternative method of payment. The oral agreement may be terminated by either party upon providing the other party with 30 days written notice of the termination of the agreement.

Effective January 2016, we executed a Lease Agreement with Wattle Laboratories Pty Ltd, ("Wattle"), an entity part-owned and operated by our non-executive director, Mr. Stephen Anastasiou, whereby we lease part of their Blackburn office facilities for our operations at a rental rate of A$38,940 per year, payable in monthly installments. The rental agreement is subject to annual rental increases, and effective January 2017, the annual rent was increased to A$39,525. The lease is for a three-year term with an additional three-year option period. The lease may be terminated by either party upon six months' written notice. During the fiscal years ended June 30, 2018, 2019 and 2020, we paid Wattle A$30,019, A$53,958 and A$41,369 (excluding Goods and Services Tax), respectively. The lease was renewed, commencing January 1, 2019 for three years.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See our consolidated financial statements, including the notes thereto, included in Item 18.

Legal Proceedings

We are not involved in any legal proceedings nor are we subject to any threatened litigation that is material to our business or financial condition.

Dividend Distribution Policy

We have never paid cash dividends to our shareholders. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Any future dividend policy will be determined by the Board of Directors and will be based upon various factors, including our results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as the Board of Directors may deem relevant.

B. Significant Changes

There have been no significant changes in the operation or financial condition of our company since June 30, 2021.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Australian Securities Exchange

Our ordinary shares have traded on the ASX since April 30, 1999 under the symbol IMC.

NASDAQ Capital Market

Our ADSs and Warrants have been listed on The NASDAQ Capital Market under the symbol “IMRN” and “IMRNW”, respectively, since June 13, 2017.

B. Plan of Distribution

Not applicable.

C. Markets

The principal listing of our ordinary shares is on the ASX, and since June 9, 2017, our ADSs and warrants have traded on The NASDAQ Capital Market.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Our Constitution

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of our company. Our Constitution is subject to the terms of the ASX Listing Rules and the Corporations Act. It may be amended or repealed and replaced by special resolution of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete or to constitute a definitive statement of the rights and liabilities of our shareholders. Our Constitution is filed as an exhibit to this Annual Report.

Interested Directors

A director may not vote in respect of any contract or arrangement in which the director has, directly or indirectly, any material interest according to our Constitution. Such director must not be counted in a quorum, must not vote on the matter and must not be present at the meeting while the matter is being considered. However, that director may execute or otherwise act in respect of that contract or arrangement notwithstanding any material personal interest.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests or conflicts of interests and prohibits directors from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of related party benefits to our directors.

Borrowing Powers Exercisable by Directors

Pursuant to our Constitution, the management and control of our business affairs are vested in our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or any uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, in each case, in the manner and on terms it deems fit.

Retirement of Directors

Pursuant to our Constitution and the ASX Listing Rules, there must be an election of directors at each annual general meeting. The directors, other than the managing director, who are to stand for election at each annual general meeting are: (i) any director required to retire after a period of three years in office, (ii) any director appointed by the other directors in the year preceding the annual general meeting, (iii) any new directors, or (iv) if no person is standing for election for the aforementioned reasons then the director longest in office since last being elected. A director, other than the director who is the Chief Executive Officer, must retire from office at the conclusion of the third annual general meeting after which the director was elected. Retired directors are eligible for a re-election to the board of directors unless disqualified from acting as a director under the Corporations Act or our Constitution.

Rights and Restrictions on Classes of Shares

The rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that our directors may issue shares with preferred, deferred or other special rights, whether in relation to dividends, voting, return of share capital or otherwise as our board of directors may determine. Subject to any approval which is required from our shareholders under the Corporations Act and the ASX Listing Rules (see "—Exemptions from Certain NASDAQ Corporate Governance Rules" and "—Change of Control"), any rights and restrictions attached to a class of shares, we may issue further shares on such terms and conditions as our board of directors resolve. Currently, our outstanding share capital consists of only one class of ordinary shares.

Dividend Rights

Our board of directors may from time to time determine to pay dividends to shareholders. All dividends unclaimed for one year after having been declared may be invested or otherwise made use of by our board of directors for our benefit until claimed or otherwise disposed of in accordance with our Constitution.

Voting Rights

Under our Constitution, and subject to any voting exclusions imposed under the ASX Listing Rules (which typically exclude parties from voting on resolutions in which they have an interest), the rights and restrictions attaching to a class of shares, each shareholder has one vote on a show of hands at a meeting of the shareholders unless a poll is demanded under the Constitution or the Corporations Act. On a poll vote, each shareholder shall have one vote for each fully paid share and a fractional vote for each share held by that shareholder that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid to such date on that share. Shareholders may vote in person or by proxy, attorney or representative. Under Australian law, shareholders of a public company are not permitted to approve corporate matters by written consent. Our Constitution does not provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depositary to vote the number of deposited ordinary shares their ADSs represent.

Right to Share in Our Profits

Pursuant to our Constitution, our shareholders are entitled to participate in our profits only by payment of dividends. Our board of directors may from time to time determine to pay dividends to the shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

Rights to Share in the Surplus in the Event of Liquidation

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our liquidation, subject to the rights attaching to a class of shares.

Redemption Provision for Ordinary Shares

There are no redemption provisions in our Constitution in relation to ordinary shares. Under our Constitution, any preference shares may be issued on the terms that they are, or may at our option be, liable to be redeemed.

Variation or Cancellation of Share Rights

Subject to the terms of issue of shares of that class, the rights attached to shares in a class of shares may only be varied or cancelled by a special resolution of our company together with either:

- a special resolution passed at a separate general meeting of members holding shares in the class; or
- the written consent of members with at least 75% of the shares in the class.

Directors May Make Calls

Our Constitution provides that subject to the terms on which the shares have been issued directors may make calls on a shareholder for amounts unpaid on shares held by that shareholder, other than monies payable at fixed times under the conditions of allotment. Shares represented by the ADSs are fully paid and are not subject to calls by directors.

General Meetings of Shareholders

General meetings of shareholders may be called by our board of directors. Except as permitted under the Corporations Act, shareholders may not convene a meeting. The Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting or at least 100 shareholders who are entitled to vote at the general meeting. Notice of the proposed meeting of our shareholders is required at least 28 clear days prior to such meeting under the Corporations Act.

Foreign Ownership Regulation

There are no limitations on the rights to own securities imposed by our Constitution. However, acquisitions and proposed acquisitions of securities in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Foreign Acquisitions and Takeovers Act 1975, or the FATA, which generally applies to acquisitions or proposed acquisitions:

- by a foreign person (as defined in the FATA) or associated foreign persons that would result in such persons having an interest in 20% or more of the issued shares of, or control of 20% or more of the voting power in, an Australian company; and
- by non-associated foreign persons that would result in such foreign person having an interest in 40% or more of the issued shares of, or control of 40% or more of the voting power in, an Australian company, where the Australian company is valued above the monetary threshold prescribed by FATA.

However, no such review or approval under the FATA is required if the foreign acquirer is a U.S. entity and the value of the target is less than A$1.094 million.

The Australian Federal Treasurer may prevent a proposed acquisition in the above categories or impose conditions on such acquisition if the Treasurer is satisfied that the acquisition would be contrary to the national interest. If a foreign person acquires shares or an interest in shares in an Australian company in contravention of the FATA, the Australian Federal Treasurer may order the divestiture of such person's shares or interest in shares in that Australian company.

Ownership Threshold

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a shareholder to notify us and the ASX once it, together with its associates, acquires a 5% interest in our ordinary shares, at which point the shareholder will be considered to be a "substantial" shareholder. Further, once a shareholder owns a 5% interest in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its holding of our ordinary shares, and must also notify us and the ASX on its ceasing to be a "substantial" shareholder.

Issues of Shares and Change in Capital

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with preferred, deferred or other special rights and restrictions and for the consideration and other terms that the directors determine.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may consolidate or divide our share capital into a larger or smaller number by resolution, reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole and does not materially prejudice our ability to pay creditors) or buy back our ordinary shares whether under an equal access buy-back or on a selective basis.

Change of Control

Takeovers of listed Australian public companies, such as ours are regulated by the Corporations Act, which prohibits the acquisition of a "relevant interest" in issued voting shares in a listed company if the acquisition will lead to that person's or someone else's voting power in our company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities, including any indirect or direct power or control.

If, at a particular time, a person has a relevant interest in issued securities and the person:

- has entered or enters into an agreement with another person with respect to the securities;
- has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities (whether the right is enforceable presently or in the future and whether or not on the fulfillment of a condition);
- has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; or
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised; the other person is presumed to already have a relevant interest in the securities.

There are a number of exceptions to the above prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid, the acquisition occurs during the bid period, the bid is for all the voting shares in a bid class and the bid is unconditional or only conditioned on prescribed matters set out in the Corporations Act;
- when shareholders of our company approve the takeover by resolution passed at general meeting;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other person has had voting power in our company of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in our company more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a rights issue;
- when the acquisition results from the issue of securities under dividend reinvestment schemes;
- when the acquisition results from the issue of securities under underwriting arrangements;
- when the acquisition results from the issue of securities through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another listed company which is listed on a prescribed financial market or a financial market approved by ASIC;
- an acquisition arising from an auction of forfeited shares conducted on-market; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. ASIC and the Australian Takeover Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders canceling contracts, freezing transfers of, and rights attached to, securities, and forcing a party to dispose of securities. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

Access to and Inspection of Documents

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our registers on the payment of a prescribed fee. Shareholders are not required to pay a fee for inspection of our registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

C. Material Contracts

We entered into a Development and Supply Agreement with Synlait Milk Ltd. on June 21, 2016. Pursuant to the agreement, Synlait Milk, a large dairy farm company located in New Zealand, agreed to vaccinate their cow herds with IMM- 124E vaccine and to collect the hyperimmune colostrum from the first milking of the cows at calving. This colostrum, which contains the vaccine antibodies, is then spray or freeze dried and tested for the vaccine properties. If levels of the vaccine are sufficient and meet our product specifications, the dried hyperimmune colostrum is then shipped to our warehouse in Melbourne, Australia.

On February 16, 2016, we entered into a Convertible Security and Share Purchase Agreement with SBI Investments which provided us with a line of funding from which we could draw down funding to continue our ongoing operations. The convertible note comprised of three tranches, of which we drew down the first two tranches, totaling A$1.2 million in the aggregate. The note was repayable in 18 equal monthly installments payable on the 15th day of each month either by the issuance of equity at a discount to the market rate at the time of issue, or by a cash payment plus a 2.5% premium. The final payment with respect to this convertible note was repaid on September 10, 2017.

D. Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital, or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Cash Transaction Reports Agency, which monitors such transactions, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

The Foreign Acquisitions and Takeovers Act 1975

Under Australian law, in certain circumstances foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without notification to or approval from the Australian Treasurer. These limitations are set forth in the Australian Foreign Acquisitions and Takeovers Act, or the Takeovers Act.

Under the Takeovers Act, as currently in effect, any foreign person, together with associates, is prohibited from acquiring 15% or more of the shares in any company having total assets exceeding A$252 million or more. In addition, a foreign person may not acquire shares in a company having total assets of A$252 million or more if, as a result of that acquisition, the total holdings of all foreign persons and their associates will exceed 40% in aggregate without the approval of the Australian Treasurer. However, for "U.S. Investors" and investors from certain other countries, a threshold of A$1.094 million applies (except in certain circumstances) to each of the previous acquisitions. A "U.S. Investor" is defined by the Takeovers Act as a U.S. national or a U.S. enterprise.

If the necessary approvals are not obtained, the Treasurer may make an order requiring the acquirer to dispose of the shares it has acquired within a specified period of time. Under the current Australian foreign investment policy, however, it is unlikely that the Treasurer would make such an order where the level of foreign ownership exceeds 40% in the ordinary course of trading, unless the Treasurer finds that the acquisition is contrary to the national interest. The same rule applies if the total holdings of all foreign persons and their associates already exceeds 40% and a foreign person (or its associate) acquires any further shares, including in the course of trading in the secondary market of the ADSs. At present, we do not have total assets of A$252 million.

If the level of foreign ownership exceeds 40% at any time, we would be considered a foreign person under the Takeovers Act. In such event, we would be required to obtain the approval of the Treasurer for our company, together with our associates, to acquire (i) more than 15% of an Australian company or business with assets totaling over A$252 million; or (ii) any direct or indirect ownership interest in Australian residential real estate.

The percentage of foreign ownership in our company would also be included in determining the foreign ownership of any Australian company or business in which it may choose to invest. Since we have no current plans for any such acquisitions and do not own any property, any such approvals required to be obtained by us as a foreign person under the Takeovers Act will not affect our current or future ownership or lease of property in Australia.

Our Constitution does not contain any additional limitations on a non-resident's right to hold or vote our securities.

Australian law requires the transfer of shares in our company to be made in writing. No stamp duty will be payable in Australia on the transfer of ADSs.

E. TAXATION

The following is a discussion of Australian and U.S. tax considerations material to our shareholders. To the extent that the discussion is based on tax legislation which has not been subject to judicial or administrative interpretation, the views expressed in the discussion might not be accepted by the tax authorities in question or by court. The discussion is not intended, and should not be construed, as legal or professional tax advice and does not exhaust all possible tax considerations.

Holders of our ADSs should consult their own tax advisors as to the United States, Australian or other tax consequences of the purchase, ownership and disposition of ADSs, including, in particular, the effect of any foreign, state or local taxes.

AUSTRALIAN TAX CONSIDERATIONS

In this section, we discuss the material Australian tax considerations that apply to non-Australian tax residents with respect to the acquisition, ownership and disposal of the absolute beneficial ownership of ADSs, which are evidenced by ADRs. This discussion is based upon existing Australian tax law as of the date of this annual report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian income tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty.

Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the purchase, ownership and disposition of the ADSs or shares.

Nature of ADSs for Australian Taxation Purposes

Holders of our ADSs are treated as the owners of the underlying ordinary shares for Australian income tax and capital gains tax purposes.

Therefore, dividends paid on the underlying ordinary shares will be treated for Australian tax purposes as if they were paid directly to the owners of ADSs, and the disposal of ADSs will be treated for Australian tax purposes as the disposal of the underlying ordinary shares. In the following analysis we discuss the application of the Australian income tax and capital gains tax rules to non-Australian resident holders of ADSs.

Taxation of Dividends

Australia operates a dividend imputation system, under which dividends may be declared to be 'franked' to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends that are not franked or are partly franked and are paid to non-Australian resident shareholders are subject to dividend withholding tax, but only to the extent the dividends are not franked.

Unfranked dividends paid to a non-resident shareholder are subject to withholding tax at 30%, unless the shareholder is a resident of a country with which Australia has a double taxation agreement. In accordance with the provisions of the Double Taxation Convention between Australia and the U.S., the maximum rate of Australian tax on unfranked dividends to which a resident of the U.S. is beneficially entitled is 15%, where the U.S. resident holds less than 10% of the voting rights in our company, or 5% where the U.S. resident holds 10% or more of the voting rights in our company. The Double Taxation Convention between Australia and the U.S. does not apply to limit the tax rate on dividends where the ADSs are effectively connected to a permanent establishment or a fixed base carried on by the owner of the ADSs in Australia through which the shareholder carries on business or provides independent personal services, respectively.

Tax on Sales or other Dispositions of Shares - Capital Gains Tax

Australian capital gains derived by non-Australian residents in respect of the disposal of capital assets that are not taxable Australian property will be disregarded. Non-Australian resident shareholders will not be subject to Australian capital gains tax on the capital gain made on a disposal of our shares, unless they, together with associates, hold 10% or more of our issued capital, tested either at the time of disposal or over any continuous 12 month period in the 24 months prior to disposal, and the value of our shares at the time of disposal are wholly or principally attributable to Australian real property assets.

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rate. Previously, certain shareholders, such as individuals were entitled to a discount of 50% for capital gains on shares held for greater than 12 months. However, as part of the 2012-2013 Federal Budget measures, the Australian Government announced changes to the application of the CGT discount for foreign resident individuals on taxable Australian assets, including shares. These changes became effective on 29 June 2013.

The effect of the change is to:

- Retain access to the full CGT discount for discount capital gains of foreign resident individuals in respect of the increase in the value of a CGT asset that occurred before 9 May 2013; and

- Remove the CGT discount for discount capital gains for foreign resident individuals that arise after 8 May 2013.

Foreign residents will still have access to a discount on discount capital gains accrued prior to 8 May 2013 provided they choose to obtain a market valuation for their assets as at that date.

Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

Tax on Sales or other Dispositions of Shares - Shareholders Holding Shares on Revenue Account

Some non-Australian resident shareholders may hold shares on revenue rather than on capital account, for example, share traders. These shareholders may have the gains made on the sale or other disposal of the shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian resident shareholders assessable under these ordinary income provisions in respect of gains made on shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5% for non-Australian resident individuals. Some relief from the Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the U.S. and Australia, for example, because the shareholder does not have a permanent establishment in Australia.

To the extent an amount would be included in a non-Australian resident shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

Dual Residency

If a shareholder were a resident of both Australia and the U.S. under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the U.S. and Australia, the Australian tax applicable would be limited by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

Stamp Duty

A transfer of shares of a company listed on the ASX is not subject to Australian stamp duty except in some circumstances where one person, or associated persons, acquires 90% or more of the shares.

Australian Death Duty

Australia does not have estate or death duties. No capital gains tax liability is realized upon the inheritance of a deceased person's shares.

The disposal of inherited shares by beneficiaries, may, however, give rise to a capital gains tax liability.

Goods and Services Tax

The issue or transfer of shares will not incur Australian goods and services.

UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain material U.S. federal income tax consequences that generally apply to U.S. Holders (as defined below) who hold ADSs as capital assets. This summary is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations promulgated thereunder, judicial and administrative interpretations thereof, and the bilateral taxation convention between Australia and the U.S. (the "Tax Treaty"), all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively.

This summary does not discuss all the tax consequences that may be relevant to an investment in ADSs by a U.S. Holder in light of such holder's particular circumstances or to U.S. Holders subject to special rules, including broker-dealers, banks or other financial institutions, traders in securities who elect to use a mark-to-market method of accounting for securities holdings, insurance companies, investors liable for alternative minimum tax, tax-exempt organizations, regulated investment companies or real estate investment trusts, non-resident aliens of the U.S. or taxpayers whose functional currency is not the U.S. dollar, partnerships or other pass-through entities for U.S. federal income tax purposes or persons holding ADSs through any such entities, persons who acquired their ADSs through the exercise or cancellation of any employee stock options or otherwise as compensation for their services, investors that actually or constructively own 10% or more of our shares by vote or value, and investors holding ADSs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction.

If a partnership or an entity treated as a partnership for U.S. federal income tax purposes owns ADSs, the U.S. federal income tax treatment of a partner in such a partnership will generally depend upon the status of the partner and the activities of the partnership. A partnership that owns ADSs and each partner in such partnership should consult its own tax advisors about the U.S. federal income tax consequences of holding and disposing of ADSs.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of U.S. federal estate and gift tax, state, local or foreign taxation. You are urged to consult your tax advisors regarding the particular U.S. federal income tax consequences to you relating to the purchase, ownership and disposition of ADSs, the consequences to you under any foreign taxing jurisdiction, as well as the U.S. federal, state and local tax considerations of an investment in ADSs.

For purposes of this summary, the term "U.S. Holder" means an (i) individual who is a citizen or, for U.S. federal income tax purposes, a resident of the U.S., (ii) a corporation or other entity taxable as a corporation created or organized in or under the laws of the U.S. or any political subdivision thereof, (iii) an estate whose income is subject to U.S. federal income tax regardless of its source, or (iv) a trust if (a) a court within the U.S. is able to exercise primary supervision over administration of the trust, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (b) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

Taxation of Dividends on ADSs

For U.S. federal income tax purposes, U.S. Holders of ADSs will be treated as owning the underlying ordinary shares represented by the ADSs held by them. Subject to the passive foreign investment company, or PFIC rules discussed below, the gross amount of any distributions received with respect to the underlying ordinary shares represented by the ADSs, including the amount of any taxes withheld therefrom, will constitute dividends for U.S. federal income tax purposes, to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. You will be required to include this amount of dividends in gross income as ordinary income. Distributions in excess of our earnings and profits will be treated as a non-taxable return of capital to the extent of your tax basis in the ADSs, and any amount in excess of your tax basis will be treated as gain from the sale of ADSs. See "*Disposition of ADSs*" below for the discussion on the taxation of capital gains. Dividends will not qualify for the dividends-received deduction generally available to corporations under Section 243 of the Code.

Dividends that we pay in Australian dollars, including the amount of any Australian taxes withheld therefrom, will be included in your income in a U.S. dollar amount calculated by reference to the exchange rate in effect on the day such dividends are received. A U.S. Holder who receives payment in Australian dollars and converts Australian dollars into U.S. dollars at an exchange rate other than the rate in effect on such day will likely have a foreign currency exchange gain or loss, which would be treated as U.S.-source ordinary income or loss.

Subject to complex limitations, any Australian withholding tax imposed on our dividends will be a foreign income tax eligible for credit against a U.S. Holder's U.S. federal income tax liability (or, alternatively, for deduction against income in determining such tax liability). The limitations set forth in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the U.S. federal income taxes otherwise payable with respect to each such class of income. Dividends generally will be treated as foreign-source passive category income or general category income for U.S. foreign tax credit purposes, depending upon the holder's circumstances. The rules relating to the determination of the foreign tax credit are complex. You should consult with your own tax advisors to determine whether and to what extent you would be entitled to this credit.

Subject to certain limitations, "qualified dividend income" received by a non-corporate U.S. Holder will be subject to tax at a reduced maximum tax rate of 20 percent. Distributions taxable as dividends generally qualify for the 20 percent rate provided that either: (i) the issuer is entitled to benefits under the Tax Treaty or (ii) the ADSs are readily tradable on an established securities market in the U.S. and certain other requirements are met. We believe that we are entitled to benefits under the Tax Treaty and that the ADSs currently are readily tradable on an established securities market in the U.S. However, no assurance can be given that the ADSs will remain readily tradable. Furthermore, the reduced rate does not apply to dividends received from PFICs. The amount of foreign tax credit is limited in the case of foreign qualified dividend income. U.S. Holders of ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

Disposition of ADSs

If you sell or otherwise dispose of ADSs, you will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amounts realized on the sale or other disposition and your adjusted tax basis in the ADSs. Subject to the PFIC rules discussed below, such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if you have held the ADSs for more than one year at the time of the sale or other disposition. In general, any gain that you recognize on the sale or other disposition of ADSs will be U.S.-source for purposes of the foreign tax credit limitation; losses will generally be allocated against U.S.-source income. Deduction of capital losses is subject to certain limitations under the Code. U.S. Holders are urged to consult their tax advisors regarding the tax consequences that may occur when a foreign withholding tax is imposed on a disposition of our ADSs, including the availability of the foreign tax credit under such U.S. Holder's particular circumstances.

Passive Foreign Investment Company

The Code provides special, generally adverse, rules regarding certain distributions received by U.S. Holders with respect to, and sales, exchanges and other dispositions, including pledges, of, shares of stock of a PFIC. A foreign corporation will be a PFIC for any taxable year if at least 75% of its gross income for the taxable year is passive income or at least 50% of its gross assets during the taxable year, based on a quarterly average and generally by value, produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions and gains from the disposition of assets that produce or are held for the production of passive income. In determining whether a foreign corporation is a PFIC, a pro-rata portion of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Based on our business results for the last fiscal year and the composition of our assets, we believe that we were not a PFIC for U.S. federal income tax purposes for the taxable year ended June 30, 2021. However, the determination of PFIC status is a factual determination that must be made annually at the close of each taxable year and therefore, there can be no certainty as to our PFIC status for a taxable year until the close of that taxable year. Our PFIC status could change depending upon, among other things, a decrease in the trading price of our ordinary shares or ADSs and how quickly we make use of the cash proceeds from any offering, as well as changes in the composition and relative values of our assets and the composition of our income. Moreover, the rules governing whether certain assets are active or passive are complex and in some cases their application can be uncertain. If we were a PFIC in any year during a U.S. Holder's holding period for the ordinary shares or ADSs, we generally would continue to be treated as a PFIC for each subsequent year during which the U.S. Holder owned the ordinary shares or ADSs.

If we are a PFIC for any taxable year during which a U.S. Holder holds ordinary shares or ADSs, any "excess distribution" that the holder receives and any gain recognized from a sale or other disposition (including a pledge) of such ordinary shares or ADSs will be subject to special tax rules, unless the U.S. Holder makes a mark-to-market election (provided the ADSs are "marketable") or qualified electing fund election, as discussed below. Any distribution in a taxable year that is greater than 125% of the average annual distribution received by a U.S. Holder during the shorter of the three preceding taxable years or such holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we were a PFIC in the U.S. Holder's holding period, will be treated as ordinary income arising in the current taxable year; and
- the amount allocated to each other year will be subject to income tax at the highest rate in effect for that year and applicable to the U.S. Holder and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

If we are a PFIC, the tax liability for amounts allocated to years prior to the year of disposition or excess distribution cannot be offset by any net operating loss, and gains (but not losses) recognized on the transfer of the ordinary shares or ADSs cannot be treated as capital gains, even if the ordinary shares or ADSs are held as capital assets. In addition, non-corporate U.S. Holders will not be eligible for reduced rates of taxation on any dividends that we pay if we are a PFIC for either the taxable year in which the dividend is paid or the preceding year. Furthermore, unless otherwise provided by the U.S. Treasury Department, each U.S. Holder of a PFIC is required to file an annual report containing such information as the U.S. Treasury Department may require.

If we are a PFIC for any taxable year during which any of our non-U.S. subsidiaries is also a PFIC, a U.S. Holder of ordinary shares or ADSs during such year would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules to such subsidiary. You should consult your tax advisors regarding the tax consequences if the PFIC rules apply to any of our subsidiaries.

In certain circumstances, in lieu of being subject to the adverse tax rules discussed above, you may make an election to include gain on the stock of a PFIC as ordinary income under a mark-to-market method, provided that such stock is regularly traded on a qualified exchange, or "marketable". Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on NASDAQ, which constitutes a qualified exchange. As stated above, the ADSs will be listed on NASDAQ. However, there can be no assurance that the ADSs will be "regularly traded" for purposes of the mark-to-market election. It should also be noted that it is intended that only the ADSs and not the ordinary shares will be listed on NASDAQ. While we would expect the Australian Stock Exchange, on which the ordinary shares are listed, to be considered a qualified exchange, no assurance can be given as to whether the Australian Stock Exchange is a qualified exchange, or that the ordinary shares would be traded in sufficient frequency to be considered regularly traded for these purposes. Additionally, because a mark-to-market election cannot be made for equity interests in any lower-tier PFIC that we may own, a U.S. Holder that makes a mark-to-market election with respect to its ADSs may continue to be subject to the PFIC rules with respect to any indirect investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. If you make an effective mark-to-market election, you will include as ordinary income in each year that we are a PFIC, the excess of the fair market value of your ordinary shares or ADSs at the end of your taxable year over your adjusted tax basis in such ordinary shares or ADSs. You will be entitled to deduct as an ordinary loss in each such year the excess of your adjusted tax basis in the ordinary shares or ADSs over their fair market value at the end of the year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. If you make an effective mark-to-market election, any gain you recognize upon the sale or other disposition of your ordinary shares or ADSs in a year that we are a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. Any gain or loss you recognize upon the sale or other disposition of your ordinary shares or ADSs in a year when we are not a PFIC will be a capital gain or loss. See *Disposition of ADSs above* for the treatment of capital gains and losses.

Your adjusted tax basis in the ordinary shares or ADSs will be increased by the amount of any income inclusion and decreased by the amount of any losses under the mark-to-market rules. If you make a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ordinary shares or ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. You are urged to consult your tax advisors about the availability of the mark-to-market election, and whether making the election would be advisable in your particular circumstances. In the case of a valid mark-to-market election, any distributions we make would generally be subject to the rules discussed above under "*Taxation of Dividends*," except the reduced rates of taxation on any dividends received from us would not apply if we are a PFIC.

Alternatively, you can sometimes avoid the PFIC rules described above by electing to treat us as a "qualified electing fund" under Section 1295 of the Code. However, this option will not be available to you because we do not intend to comply with the requirements necessary to permit you to make this election.

U.S. Holders are urged to contact their own tax advisors regarding the determination of whether we are a PFIC and the tax consequences of such status.

Additional Tax on Investment Income

U.S. Holders that are individuals, estates, or trusts and whose income exceeds certain thresholds will be subject to a 3.8% Medicare contribution tax on net investment income, which will include dividends on and capital gains from the sale or other taxable disposition of ADSs, subject to certain limitations and exceptions.

Backup Withholding and Information Reporting

Payments in respect of ADSs may be subject to information reporting to the IRS and to U.S. backup withholding tax at a rate equal to the fourth lowest income tax rate applicable to individuals (which, under current law, is 24%). Backup withholding will not apply, however, if you (i) are a corporation or come within certain exempt categories and demonstrate the fact when so required or (ii) furnish a correct taxpayer identification number and make any other required certification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder's U.S. tax liability. A U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS, which is generally an annual income tax return.

U.S. Holders who are individuals generally will be required to report our name, address, and such information relating to an interest in the ADSs as is necessary to identify the class or issue of which the ADSs are a part. These requirements are subject to exceptions, including an exception for ADSs held in accounts maintained by certain financial institutions and an exception applicable if the aggregate value of all "specified foreign financial assets" (as defined in the Code) does not exceed $50,000.

U.S. Holders should consult their tax advisors regarding the application of these information reporting rules.

F. Dividends And Paying Agents

Not applicable.

G. Statement By Experts

Not applicable.

H. Documents on display

We are subject to the reporting requirements of the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 thereunder. As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act, transactions in our equity securities by our officers and directors are exempt from reporting and the "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we file with the Securities and Exchange Commission an annual report on Form 20-F containing financial statements that have been examined and reported on, with an opinion expressed by, an independent registered public accounting firm, and we submit reports to the Securities and Exchange Commission on Form 6-K containing (among other things) press releases and unaudited financial information for the first six months of each fiscal year. We post our annual report on Form 20-F on our website (www.immuron.com.au/corporate-directory-and-governance) promptly following the filing of our annual report with the Securities and Exchange Commission. The information on our website is not incorporated by reference into this Annual Report.

This Annual Report and the exhibits thereto and any other document we file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Exchange Act file number for our Securities and Exchange Commission filings is 001-38104.

The Securities and Exchange Commission maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the Securities and Exchange Commission using its EDGAR (Electronic Data Gathering, Analysis, and Retrieval) system.

The documents concerning our company referred to in this Annual Report may also be inspected at our offices located at Level 3, 62 Lygon Street, Carlton Victoria, Australia, 3053.

I. SUBSIDIARY INFORMATION

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our excess cash in interest-bearing accounts and term deposits with banks in Australia. Our management believes that the financial institutions that hold our investments are financially sound and accordingly, minimal credit risk exists with respect to these investments. Certain of our cash equivalents are subject to interest rate risk. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. Our major market risk is changes in foreign exchange rates as we had approximately A$25,047,281 on deposit on June 30, 2021.

We conduct our activities almost exclusively in Australia. We are required to make certain payments in U.S. dollars and other currencies, however such payments are not significant to our operations and we believe an adverse movement in end-of-period exchange rates would not have a material impact on our operating results. In the twelve months ended June 30, 2021, the Australian dollar depreciated against the U.S. dollar.

We do not currently utilize derivative financial instruments or other financial instruments subject to market risk.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Description of the Warrants

The following summary of certain terms of the Warrants is not complete and is subject to, and qualified in its entirety by the provisions of the ADS Warrant Agent Agreement and Form of Global Warrant to Purchase ADSs, which are incorporated by reference as exhibits to this annual report.

Global Certificates, Book-entry Interests. The Warrants are represented by one or more global certificates in registered form. The global certificate are deposited with the Warrant Agent as custodian for DTC and registered in the name of Cede & Co., as nominee of DTC. Ownership of interests in the global warrant certificate will be limited to persons that have accounts with DTC or persons that have accounts with DTC participants. Book-entry interests in the Warrants will be shown on, and transfers of such interests will be effected only through records maintained by DTC and its participants. So long as the Warrants are held in global form, DTC will be considered the sole holder of the Warrants. Beneficial owners must rely on the procedures of the participants through which they own book-entry interests to exercise their Warrants or transfer their Warrants.

Exercisability. The Warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of ADSs purchased upon such exercise. We will pay the ADS issuance fee of US$0.05 per ADS and any other applicable charges and taxes in connection with any such exercise.

Maximum Percentage. A holder of a Warrant will not have the right to exercise such Warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates and certain other persons), would beneficially own in excess of 4.99% (the "Maximum Percentage") of the ordinary shares outstanding immediately after giving effect to such exercise. Subject to certain exceptions, "beneficial ownership" for purposes of determining the Maximum Percentage is calculated in accordance with Section 13(d) of the Exchange Act and the regulations of the SEC thereunder. Upon request by a Warrant holder, we will provide current information regarding the number of our outstanding ordinary shares.

Exercise Price. The initial exercise price per ADS purchasable upon exercise of the Warrants is US$10.00.

Restrictive Legend Events. We will notify the Warrant Agent and each holder if we are unable to deliver ADSs via DTC transfer or otherwise (without restrictive legend), because (a) the SEC has issued a stop order with respect to the registration statement relating to the ADSs, (b) the SEC otherwise has suspended or withdrawn the effectiveness of such registration statement, either temporarily or permanently, (c) we have suspended or withdrawn the effectiveness of the registration statement, either temporarily or permanently, or (d) otherwise (each a "Restrictive Legend Event"). If a Restrictive Legend Event occurs after a Warrant holder has exercised a Warrant in accordance with its terms but prior to the delivery of the ADSs, or if we do not cause the depositary to timely deliver ADSs to a Warrant holder upon exercise of the Warrants, we will be obligated to pay a cash buy-in amount to the holder of the Warrants who did not receive ADSs upon such holder's exercise of Warrants.

Anti-Dilution Provisions. The exercise price per Warrant and the numbers of Warrants will be subject to adjustment from time to time in accordance with the ASX Listing Rules upon the occurrence of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications, rights issues, or similar events affecting our ADSs or ordinary shares, or upon the occurrence of a change in ADS ratio.

Warrant Agent and Exchange Listing. The Warrants are issued in registered form under an ADS Warrant Agent Agreement between The Bank of New York Mellon, as warrant agent and us and listed on the NASDAQ Capital Market under the symbol "IMRNW".

Rights as a Shareholder. Except as otherwise provided in the ADS Warrant Agent Agreement or by virtue of such holder's ownership of ADSs or ordinary shares, holders of Warrants do not have rights or privileges of a holder of ADSs or ordinary shares, including any voting rights, until the holder exercises the Warrant.

C. Other Securities

Not applicable.

D. American Depository Shares

Fees and Charges Payable by ADS Holders

The table below summarizes the fees and charges that a holder of our ADSs may have to pay, directly or indirectly, to our depositary, The Bank of New York Mellon, pursuant to the Amended and Revised Deposit Agreement, between Immuron Limited and The Bank of New York Mellon, as depositary, and Owners and Holders of the American Depositary Shares, which was filed as Exhibit 4.1 to Amendment No.4 of our Registration Statement on Form F-1/A filed with the SEC on May 18, 2017, and the types of services and the amount of the fees or charges paid for such services. The disclosure under this heading "Fees and Charges Payable by ADS Holders" is subject to and qualified in its entirety by reference to the full text of the Deposit Agreement. The holder of an ADS may have to pay fees and charges in connection with ownership of the ADS:

Persons depositing or withdrawing shares or ADS holders must pay:	***For*:**
US$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the Deposit Agreement terminates
US$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders
US$0.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the Deposit Agreement) converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the Deposit Agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

Fees and Payments Made by Us to the Depositary

For the year ended June 30, 2021, we paid The Bank of New York Mellon a total of US$5,180 for services pursuant to the 2020 Annual General Meeting (AGM).

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Our management, after evaluating the effectiveness of our disclosure controls and procedures as of the evaluation date, concluded that as of the evaluation date, our disclosure controls and procedures were effective.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2021, utilizing the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

B. Management's Report on Internal Control over Financial Reporting

Management's Completed Actions.

Due to the many completed actions taken by the Company, management has concluded that the material weakness identified as of June 30, 2020 has been eliminated as of June 30, 2021. We, along with our Audit Committee, will continue to monitor and evaluate the effectiveness of these remedial actions and make further changes as deemed appropriate. Management, with the oversight of our Audit Committee, has devoted considerable effort to remediate as of June 30, 2021 the material weakness identified as of June 30, 2020, which is evidenced through the completed actions during fiscal 2021 detailed below.

Completed Actions

- Evaluate the staffing level and qualifications of finance department personnel, make changes and continue to invest in training where deemed appropriate;
- Preparation of accounting position papers for complex accounting issues to ensure compliance with all applicable accounting standards;
- Undertake a review of contracts in place to ensure compliance with the applicable accounting standards and to ensure complex accounting issues have been identified; and
- Utilize external resources, to ensure compliance with the applicable accounting standards and to ensure complex accounting issues have been identified.

Management's Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act).

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS, as issued by IASB. Management regularly monitors its internal control over financial reporting, and actions are taken to correct deficiencies as they are identified.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our company's Registered Public Accounting firm due to a transition period established by the rules of the SEC for "emerging growth companies" and our non-accelerated filing status.

D. Changes in Internal Control over Financial Reporting

See "Completed Actions" above for changes in internal controls over financial reporting.

As of October 29, 2021, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the period covered by this annual report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

We currently do not have a financial expert sitting as a member of the audit committee. We believe that the cost related to retaining a financial expert on the audit committee at this time is prohibitive as we are a small company that needs to apply our limited cash resources to the development of our product portfolio, which we believe is in the best interest of our shareholders. Our audit committee members include a highly experienced commercial lawyer, and a former biotechnology and pharmaceutical company CEO who continues to serve as a director of many other biotechnology and pharmaceutical companies. The committee currently believes that these skills sets, together with the support of Company Secretary and CFO who also sit as advisors to this committee and hold Accounting, Chartered Accountant, and MBA degrees, provide sufficient expertise for this committee to be able to serve and function effectively for the purpose for which it is intended.

ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics that applies to all senior financial officers of our company, including our chief executive officer, chief financial officer, chief accounting officer or controller, or persons performing similar functions. The code of ethics is publicly available under "Investor Centre" on our website at *www.Immuron.com*. Written copies are available upon request. If we make any substantive amendment to the code of ethics or grant any waivers, including any implicit waiver, from a provision of the codes of ethics, we will disclose the nature of such amendment or waiver on our website.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Public Accountants

The following table sets forth, for each of the years indicated, the fees billed by Grant Thornton Audit Pty Ltd.

	Year Ended June 30,	
	2021	**2020**
	A$	**A$**
Audit and review of financial statements [(1)]	**179,742**	160,918
	179,742	160,918

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted policies and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm. Pre-approval of an audit or non-audit service may be given as a general pre-approval, as part of the audit committee's approval of the scope of the engagement of our independent registered public accounting firm, or on an individual basis. Any proposed services exceeding general pre-approved levels also requires specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the Securities and Exchange Commission, and also requires the audit committee to consider whether proposed services are compatible with the independence of the registered public accounting firm. All of the fees described above were pre- approved by our Audit Committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Issuer Purchase of Equity Securities

Neither we, nor any affiliated purchaser of our company, has purchased any of our securities during the year ended June 30, 2021.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT.

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

The NASDAQ rules allow for a foreign private issuer, such as our company, to follow our home country practices in lieu of certain of the NASDAQ's corporate governance standards. We rely on exemptions from certain corporate governance standards that are contrary to the laws, rules, regulations or generally accepted business practices in Australia. These exemptions being sought are described below:

- We rely on an exemption from the independence requirements for a majority of our board of directors as prescribed by NASDAQ Listing Rules. The ASX Listing Rules do not require us to have a majority of independent directors although ASX Corporate Governance Principles and Recommendations do recommend a majority of independent directors. During fiscal 2021, we did not, have a majority of directors who were "independent" as defined in the ASX Corporate Governance Principles and Recommendations, which definition differs from NASDAQ's definition.

- We rely on an exemption from the requirement that our independent directors meet regularly in executive sessions under NASDAQ Listing Rules. The ASX Listing Rules and the Corporations Act do not require the independent directors of an Australian company to have such executive sessions.

- We rely on an exemption from the quorum requirements applicable to meetings of shareholders under NASDAQ Listing Rules. In compliance with Australian law, our Constitution provides that three shareholders present, in person or by proxy, attorney or a representative, shall constitute a quorum for a general meeting. NASDAQ Listing Rules require that an issuer provide for a quorum as specified in its by-laws for any meeting of the holders of ordinary shares, which quorum may not be less than 33% (1/3) of the outstanding shares of an issuer's voting ordinary shares.

- We rely on an exemption from the requirement prescribed by NASDAQ Listing Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and the ASX Listing Rules differ from NASDAQ requirements, with the ASX Listing Rules providing generally for prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12-month period (but, in determining the 15% limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties (as defined in the ASX Listing Rules) and (iii) issuances of securities to directors or their associates under an employee incentive plan.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Our company has elected to furnish financial statements and related information specified in Item 18.

ITEM 18. FINANCIAL STATEMENTS

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date/ Period End Date
1.1	Constitution of Registrant.	F-1	3.1	12/21/2016
2.1	Form of Amended and Revised Deposit Agreement between Immuron Limited and The Bank of New York Mellon, as depositary, and Owners and Holders of the American Depositary Shares	F-1/A	4.1	5/8/2017
2(d)	Description of Securities	20-F	2(d)	10/28/2020
4.1	Development and Supply Agreement by and between Immuron Limited and Synlait Milk Ltd. dated June 28, 2013	F-1/A	10.1	2/9/2017
4.2	Variation of Development and Supply Agreement by and between Immuron Limited and Synlait Milk Ltd. dated June 21, 2016 (1)	F-1/A	10.2	2/9/2017
4.3	Marketing and Master Distribution Agreement by and between Immuron Limited and UniFirst-First Aid Corporation d/b/a MEDIQUE Products dated as of June 28, 2016 (1)	F-1/A	10.3	2/9/2017
4.4	Convertible Security and Share Purchase Agreement by and between Immuron Limited and SBI Investments dated February 16, 2016	F-1/A	10.8	4/10/2017
4.5	Executive Service Agreement by and between Immuron Limited and Dr. Jerry Kanellos dated July 23, 2015	F-1/A	10.10	2/9/2017
4.6	Commercial Lease Agreement with Wattle Laboratories Pty Ltd.	20-F	4.4	6/30/2019
4.7	Executive Employment Agreement by and between Immuron Limited and Dr. Gary S. Jacob dated February 11, 2019	20-F	4.7	6/30/2019
4.8	Form of Underwriting Agreement by and between Immuron Limited and ThinkEquity, a Division of Fordham Financial Management, Inc. dated May 23, 2019	6-K	1.1	5/24/2019
4.9	Form of Underwriting Agreement by and between Immuron Limited and ThinkEquity, a Division of Fordham Financial Management, Inc. dated July 16, 2019	6-K	1.1	7/19/2019
4.10	Form of Securities Purchase Agreement dated as of July 21, 2020 between Immuron Limited and the investors listed therein	6-K	10.1	7/23/2020
4.11	Engagement Letter by and between Immuron Limited and H.C. Wainwright & Co., LLC dated July 20, 2020	6-K	10.2	7/23/2020
4.12	Amendment to Engagement Letter by and between Immuron Limited and H.C. Wainwright & Co., LLC dated July 22, 2020	6-K	10.3	7/23/2020
4.13	Form of Compensation Warrant to be issued by Immuron Limited on July 23, 2020	6-K	10.4	7/23/2020
8.1	List of Subsidiaries of the Registrant.	20-F	8.1	10/28/2019
12.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act, as amended.			
12.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act, as amended.			
13.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
13.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
23.1*	Consent of Grant Thornton Audit Pty Ltd			
101. INS*	Inline XBRL Instance Document			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document			
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document			
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document			
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).			

* Filed herewith.

(1) Confidential treatment has been sought for certain portions of this document

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Immuron Limited

Opinion on the financial statements

We have audited the accompanying consolidated statements of financial position of Immuron Limited and subsidiaries (the "Company") as of June 30, 2021 and 2020, the related consolidated statements of profit or loss and other comprehensive income, changes in equity, and cash flows for each of the three years in the period ended June 30 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2021, in conformity with International Financial Reporting Standards, as issued by International Accounting Standards Board.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON AUDIT PTY LTD

We have served as the Company's auditor since 2018.

Melbourne, Australia
October 29, 2021

Consolidated Statement of Profit or Loss and Other Comprehensive Income
For the year ended 30 June

	Notes	2021 A$	2020 A$	2019 A$
Revenue from contracts with customers	2	**145,776**	2,518,566	2,387,426
Cost of Goods Sold		**(51,071)**	(688,836)	(667,371)
Gross Profit		**94,705**	**1,829,730**	**1,720,055**
Other Income	2	**617,110**	473,674	532,050
Other gains/(losses) – net	2	**(1,342,293)**	11,335	38,413
Expenses				
General and administrative expenses	3	**(3,978,679)**	(3,703,990)	(3,694,306)
Share-based payment expenses	19	**(2,116,013)**	533,912	(1,343,500)
Research and development expenses		**(1,367,054)**	(1,178,685)	(1,044,528)
Selling and marketing expenses	3	**(287,684)**	(871,551)	(864,644)
Operating loss		**(8,379,908)**	**(2,905,575)**	**(4,656,460)**
Finance income		**9,204**	—	39
Finance expenses		**(13,761)**	(21,631)	—
Finance costs - net		**(4,557)**	**(21,631)**	**39**
Loss Before Income Tax		**(8,384,465)**	**(2,927,206)**	**(4,656,421)**
Income Tax Expense	4	—	—	—
Loss for the Period		**(8,384,465)**	**(2,927,206)**	**(4,656,421)**
Other comprehensive income				
Items that may be reclassified to profit or loss:				
Exchange differences on translation of foreign operations		(14,953)	102,938	61,846
Total Comprehensive Loss for the Period		**(8,399,418)**	**(2,824,268)**	**(4,594,575)**
Basic/Diluted Loss per Share (in cents per share)	6	**(3.79)**	(1.66)	(3.22)

The accompanying notes form part of these financial statements.

Consolidated Statement of Financial Position
As of 30 June

	Notes	2021 A$	2020 A$
ASSETS			
Current Assets			
Cash and cash equivalents	7	**25,047,281**	3,250,468
Trade and other receivables	8	**334,707**	327,689
Inventories	9	**292,532**	797,690
Other current assets		**78,258**	33,194
Total Current Assets		**25,752,778**	4,409,041
Non-Current Assets			
Plant and equipment		**33,741**	70,773
Inventories	9	**1,266,587**	1,722,349
Total Non-Current Assets		**1,300,328**	1,793,122
TOTAL ASSETS		**27,053,106**	6,202,163
LIABILITIES			
Current Liabilities			
Trade and other payables	11	**758,494**	384,397
Provision for sales returns	12	**213,024**	—
Employee benefit obligations		**129,837**	89,838
Other current liabilities		**20,498**	42,176
Total Current Liabilities		**1,121,853**	516,411
Non-Current Liabilities			
Employee benefit obligations		**36,196**	22,910
Other non-current liabilities		—	18,929
Total Non-Current Liabilities		**36,196**	41,839
TOTAL LIABILITIES		**1,158,049**	558,250
NET ASSETS		**25,895,057**	5,643,913
EQUITY			
Issued capital	15	**88,361,303**	62,426,991
Reserves	16	**3,466,642**	1,133,345
Accumulated losses		**(65,932,888)**	(57,916,423)
TOTAL EQUITY		**25,895,057**	5,643,913

The accompanying notes form part of these financial statements.

Consolidated Statement of Changes in Equity
For the year ended 30 June

	Issued Capital A$	Reserves A$	Accumulated Losses A$	Total A$
Balance as at 30 June 2018	**58,237,314**	**3,096,308**	**(52,894,272)**	**8,439,350**
Loss after income tax expense for the year	—	—	(4,656,421)	(4,656,421)
Other comprehensive income for the period	—	61,846	—	61,846
Total comprehensive loss for the period	**—**	**61,846**	**(4,656,421)**	**(4,594,575)**
Transactions with owners in their capacity as owners				
Shares issued, net of costs	2,052,461	—	—	2,052,461
Options/warrants issued/expensed	—	1,453,900	—	1,453,900
Options/warrants exercised	100	(100)	—	—
Options/warrants lapsed/expired	—	(311,635)	311,635	—
Balance as at 30 June 2019	**60,289,875**	**4,300,319**	**(57,239,058)**	**7,351,136**
Change in accounting policy	—	—	(1,479)	(1,479)
Revised total equity at 1 July 2019	**60,289,875**	**4,300,319**	**(57,239,058)**	**7,351,136**
Loss after income tax expense for the year	—	—	(2,927,206)	(2,927,206)
Other comprehensive income for the period	—	102,938	—	102,938
Total comprehensive loss for the period	**—**	**102,938**	**(2,927,206)**	**(2,824,268)**
Transactions with owners in their capacity as owners				
Shares issued, net of costs	1,652,436	—	—	**1,652,436**
Options/warrants issued/expensed	484,680	(484,680)	—	—
Options/warrants lapsed/expired	—	(2,251,320)	2,251,320	—
Re-valuation of options issued in prior period	—	(607,000)	—	(607,000)
Share-based payment expenses	—	73,088	—	73,088
Balance as at 30 June 2020	**62,426,991**	**1,133,345**	**(57,916,423)**	**5,643,913**
Loss after income tax expense for the year	—	—	(8,384,465)	(8,384,465)
Other comprehensive income for the period	—	(14,953)	—	(14,953)
Total comprehensive loss for the period	**—**	**(14,953)**	**(8,384,465)**	**(8,399,418)**
Transactions with owners in their capacity as owners				
Shares issued, net of costs	24,386,005	—	—	24,386,005
Options/warrants issued/expensed	—	3,003,060	—	3,003,060
Options/warrants exercised	1,329,307	(213,722)	—	1,115,585
Options/warrants forfeited	—	(368,000)	368,000	—
Shares issued to directors	145,912	—	—	**145,912**
Transfer to share capital	73,088	(73,088)	—	—
Balance as at 30 June 2021	**88,361,303**	**3,466,642**	**(65,932,888)**	**25,895,057**

The accompanying notes form part of these financial statements.

Consolidated Statement of Cash Flows
For the year ended 30 June

	Note	2021 A$	2020 A$	2019 A$
Cash flows Related to Operating Activities				
Receipts from customers		**192,185**	2,914,614	2,619,477
Payments to suppliers and employees		**(4,865,633)**	(6,748,674)	(5,608,262)
Other - R&D tax concession refund		**358,280**	531,828	1,190,206
Government grants and other grants received		**236,421**	154,904	-
Net Cash Flows Used In Operating Activities	18	**(4,078,747)**	(3,147,328)	(1,798,579)
Cash Flows Related to Investing Activities				
Payment for purchases of plant and equipment		**(6,630)**	(864)	(2,047)
Interest received		**9,204**	-	39
Net Cash Flows (Used In)/From Investing Activities		**2,574**	(864)	(2,008)
Cash Flows Related to Financing Activities				
Proceeds from issues of securities		**29,281,421**	1,957,164	2,894,238
Capital raising costs		**(2,746,871)**	(374,728)	(825,055)
Proceeds from borrowings		**212,794**	—	—
Repayment of borrowings		**(212,794)**	(366,655)	—
Principal elements of lease payments		**(40,607)**	(41,390)	—
Interest and other costs of finance paid		**(13,761)**	(17,439)	—
Net Cash Flows From Financing Activities		**26,480,182**	1,156,952	2,069,183
Net increase in cash and cash equivalents		**22,404,009**	(1,991,240)	268,596
Cash and cash equivalents at the beginning of the year		**3,250,468**	5,119,887	4,727,430
Effects of exchange rate changes on cash and cash equivalents		**(607,196)**	121,821	123,861
Cash and Cash Equivalents at the End of the Year	7	**25,047,281**	**3,250,468**	**5,119,887**

The accompanying notes form part of these financial statements.

Notes to the Consolidated Financial Statements

Note 1. Summary of Significant Accounting Policies

Corporate Information

The consolidated financial report of Immuron Limited ("the Company") for the year ended June 30, 2021, 2020 and 2019 was authorized for issue in accordance with a resolution of the Directors on October 29, 2021.

Immuron Limited is a listed public company limited by shares incorporated and domiciled in Australia whose shares are publicly traded on the Australian Securities Exchange (ASX) and The NASDAQ Capital Market ("NASDAQ").

The Group's principal activity is oral immunotherapy research and development and product sales focused on bovine-colostrum enriched with antibodies of choice for the treatment and prevention of a range of infectious diseases. Product sales comprise Travelan which is indicated to reduce the risk of contracting travelers' diarrhea and Protectyn an OTC immune supplement for GI tract and liver health.

(a) Basis of preparation

These general purpose financial statements have been prepared in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board and the *Corporations Act 2001*. Immuron Limited is a for-profit entity for the purpose of preparing the financial statements.

(i) Compliance with IFRS

The consolidated financial statements of the Immuron Limited group also comply with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

(ii) Historical cost convention

The financial statements have been prepared on a historical cost basis.

(iii) Significant estimates and judgements

Going concern

The group is in a position to meet future commitments in the current business cycle and pay its debts as and when they fall due. Furthermore, the group is able to progress its research and development programs for at least the next 12 months. The annual report has been prepared on a going concern basis. Accordingly, the annual report does not include adjustments relating to the recoverability and classification of recorded asset amounts, or the amounts and classification of liabilities that might be necessary should the group not continue as a going concern.

COVID-19

Judgement has been exercised in considering the impacts that the Coronavirus (COVID-19) pandemic has had, or may have, on the group based on known information. This consideration extends to the nature of the products and services offered, customers, supply chain, staffing and geographic regions in which the group operates. Sales of Travelan have significantly dropped from March 2020 and as at reporting date it is unknown the prolonged effect that COVID-19 will continue to have on sales.

This note provides a list of the significant accounting policies adopted in the preparation of these consolidated financial statements to the extent they have not already been disclosed in the other notes above. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the group consisting of Immuron Limited and its subsidiaries.

(iv) New standards and interpretations not yet adopted

There are no standards that are not yet effective and that would be expected to have a material impact on the Company in the current or future reporting years and on foreseeable future transactions.

(v) Revision of immaterial error

During the year ended June 2020 the following immaterial error corrections were identified.

Representative warrants

Immuron Limited raised capital in June 2017 and May 2019, representative warrants were included as part of these public offerings. These were not identified and accounted for at the time of these capital raisings.

Management has undertaken an assessment of the impact of this and concluded this to be an immaterial error. This has been corrected in the prior year by restating prior period financial statements presented and the related notes included herein to include the representative warrants.

Reserves as of 30 June 2017 has been revised to increase by A$489,586 for the June 2017 representative warrants (1,220,000 options) with a corresponding decrease in share capital of the same amount. The impact of the 2017 revision has been also reflected in the 30 June 2018 and 30 June 2019 years presented.

Reserves as of 30 June 2019 has been revised to increase by A$110,400 for the May 2019 representative warrants (800,000 options) with a corresponding decrease in share capital of the same amount.

Summary of significant accounting policies

The following is a summary of the material accounting policies adopted by the Company in the preparation of the financial report. The accounting policies have been consistently applied, unless otherwise stated.

(b) Principles of consolidation

(i) Subsidiaries

Subsidiaries are all entities (including structured entities) over which the group has control. The group controls an entity when the group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the group.

Intercompany transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the group.

(c) Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. This has been identified as the executive management team consisting of the CEO and COO.

(d) Foreign currency translation

(i) Functional and presentation currency

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in Australian dollar ("A$" or "$"), which is Immuron Limited's functional and presentation currency.

(ii) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statement of profit or loss and other comprehensive income, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statement of profit or loss and other comprehensive income on a net basis within other gains/(losses).

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at fair value through profit or loss are recognized in profit or loss as part of the fair value gain or loss and translation differences on non-monetary assets such as equities classified as at fair value through other comprehensive income are recognized in other comprehensive income.

(iii) Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each consolidated balance sheet presented are translated at the closing rate at the date of that consolidated balance sheet;
- income and expenses for each consolidated statement of profit or loss and consolidated statement of profit or loss and other comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

(e) Revenue recognition

(i) Sale of hyperimmune products

Revenue arises mainly from the sale hyperimmune products. To determine whether to recognize revenue, the group follows the process of identifying the contract with a customer, identifying the performance obligations, determining the transaction price, allocating the transaction price to the performance obligations and recognising revenue when performance obligations are satisfied.

Revenue from the sale of hyperimmune products is recognized when or as the group transfers control of the assets to the customer.

There is no variable consideration or significant cost to obtain the contract. There are no warranties and no refunds. Returns are provided where this is outlined in a customer agreement.

(ii) Financing components

The group does not expect to have any contracts where the period between the transfer of the promised goods or services to the customer and payment by the customer exceeds one year. As a consequence, the group does not adjust any of the transaction prices for the time value of money.

(f) Government grants

Grants from the government are recognized at their fair value where there is a reasonable assurance that the grant will be received and the group will comply with all attached conditions.

Fair value of other grants

The group's other grant income consists of grants received by the group with relation to COVID-19. Grants are recognized as other income when the group is reasonable assured that it will comply with the conditions attaching to it and the grant will be received. For the year ended 30 June 2020, the group has recognized A$154,904 in assistance packages.

(g) Income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the company and its subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

(h) AASB Interpretation 23 Uncertainty over Income Tax Treatments

Interpretation 23 requires the assessment of whether the effect of uncertainty over income tax treatments should be included in the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates. The Interpretation outlines the requirements to determine whether an entity considers uncertain tax treatments separately, the assumptions an entity makes about the examination of tax treatments by taxation authorities, how an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates and how an entity considers changes in facts and circumstances.

The group has adopted Interpretation 23 from 1 July 2019, based on an assessment of whether it is 'probable' that a taxation authority will accept an uncertain tax treatment. This assessment takes into account that for certain jurisdictions in which the group operates, a local tax authority may seek to open a group's books as far back as inception of the group. Where it is probable, the group has determined tax balances consistently with the tax treatment used or planned to be used in its income tax filings. Where the group has determined that it is not probable that the taxation authority will accept an uncertain tax treatment, the most likely amount or the expected value has been used in determining taxable balances (depending on which method is expected to better predict the resolution of the uncertainty). There has been no impact from the adoption of Interpretation 23 in this reporting period.

(i) Leases

The accounting policies for the group's leases are explained in note 14(iii).

(j) Impairment of assets

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

(k) Cash and cash equivalents

For the purpose of presentation in the consolidated statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the consolidated balance sheet.

(l) Trade receivables

Trade receivables are recognized initially at fair value and subsequently measured at amortised cost using the effective interest method, less loss allowance. See note 21(b) for a description of the group's impairment policies.

(i) Classification as trade receivables

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. Trade receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. The group holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method. Details about the group's impairment policies and the calculation of the loss allowance are provided below.

(ii) Accrued receivables

These amounts primarily comprise receivables from the Australian Taxation Office in relation to the R&D tax incentive.

(iii) Fair value of trade and other receivables

Due to the short-term nature of the current receivables, their carrying amount is considered to be the same as their fair value.

(iv) Impairment and risk exposure

Information about the impairment of trade receivables and the group's exposure to credit risk and foreign currency risk can be found in note 21.

(m) Inventories

Raw materials and stores, work in progress and finished goods

Raw materials and stores, work in progress and finished goods are stated at the lower of cost and net realisable value. Cost comprises direct materials, direct labour and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs are assigned to individual items of inventory on the basis of weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

(n) Investments and other financial assets

(i) Classification

The group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income or through profit or loss); and
- those to be measured at amortised cost.

The classification depends on the group's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss and other comprehensive income. For investments in equity instruments that are not held for trading, this will depend on whether the group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI).

(ii) Recognition and derecognition

Regular way purchases and sales of financial assets are recognized on trade-date, the date on which the group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the group has transferred substantially all the risks and rewards of ownership.

(iii) Measurement

At initial recognition, the group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

(iv) Impairment

The group assesses on a forward looking basis the expected credit losses associated with its debt instruments carried at amortised cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables, the group applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables, see note 21(b) for further details.

(v) Income recognition Interest income

Interest income is recognized using the effective interest method. When a receivable is impaired, the group reduces the carrying amount to its recoverable amount, being the estimated future cash flow discounted at the original effective interest rate of the instrument, and continues unwinding the discount as interest income. Interest income on impaired loans is recognized using the original effective interest rate.

(o) Property, plant and equipment

Property, plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over their estimated useful lives or, in the case of leasehold improvements and certain leased plant and equipment, the shorter lease term as follows:

- Plant and equipment 2 - 5 years
- Furniture, fittings and equipment 3 - 15 years
- Right-of-use assets 3 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in profit or loss.

(p) Intangible assets

Research and development

Expenditure on research activities, undertaken with the prospect of obtaining new scientific or technical knowledge and understanding, is recognized in the consolidated statement of profit or loss and other comprehensive income as an expense when it is incurred.

Expenditure on development activities, being the application of research findings or other knowledge to a plan or design for the production of new or substantially improved products or services before the start of commercial production or use, is capitalised if it is probable that the product or service is technically and commercially feasible, will generate probable economic benefits, adequate resources are available to complete development and cost can be measured reliably. Other development expenditure is recognized in the consolidated statement of profit or loss and other comprehensive income as an expense as incurred.

(q) Trade and other payables

These amounts represent liabilities for goods and services provided to the group prior to the end of financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortised cost using the effective interest method.

(r) Employee benefits

(i) Short-term obligations

Liabilities for wages and salaries, including non-monetary benefits, annual leave and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheet.

(ii) Other long-term employee benefit obligations

In some countries, the group also has liabilities for long service leave and annual leave that are not expected to be settled wholly within 12 months after the end of the period in which the employees render the related service. These obligations are therefore measured as the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting period using the projected unit credit method.

Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the end of the reporting period of high-quality corporate bonds with terms and currencies that match, as closely as possible, the estimated future cash outflows. Remeasurements as a result of experience adjustments and changes in actuarial assumptions are recognized in profit or loss.

The obligations are presented as current liabilities in the balance sheet if the entity does not have an unconditional right to defer settlement for at least twelve months after the reporting period, regardless of when the actual settlement is expected to occur.

(iii) Share-based payments

Share-based compensation benefits are provided to employees via the 'executive share and option plan' (ESOP). Information relating to these schemes is set out in note 19.

Employee options

The fair value of options granted under the ESOP is recognized as a share-based payment expense with a corresponding increase in equity. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including any market performance conditions (e.g. the company's share price);
- excluding the impact of any service and non-market performance vesting conditions (e.g. profitability, sales growth targets and remaining an employee of the company over a specified time period); and
- including the impact of any non-vesting conditions (e.g. the requirement for employees to save or holdings shares for a specific period of time).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the entity revises its estimates of the number of options that are expected to vest based on the non-market vesting and service conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

(s) Contributed equity

Ordinary shares are classified as equity.
Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

(t) Loss per share

(i) Basic loss per share

Basic loss per share is calculated by dividing:

- the loss attributable to owners of the company, excluding any costs of servicing equity other than ordinary shares
- by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

(ii) Diluted loss per share

Diluted loss per share adjusts the figures used in the determination of basic loss per share to take into account:

- the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and
- the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

(u) Rounding of amounts

The company is of a kind referred to in ASIC Legislative Instrument 2016/191, relating to the 'rounding off' of amounts in the financial statements. Amounts in the financial statements have been rounded off in accordance with the instrument to the nearest dollar.

(v) Goods and services tax (GST)

Revenues, expenses and assets are recognized net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognized as part of the cost of acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the consolidated balance sheet.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flows.

Critical Accounting Estimates and Judgments

Management evaluates estimates and judgments incorporated into the financial statements based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both internally and externally.

Share-based payments

The value attributed to share options and remunerations shares issued is an estimate calculated using an appropriate mathematical formula based on an option pricing model. The choice of models and the resultant option value require assumptions to be made in relation to the likelihood and timing of the conversion of the options to shares and the value of volatility of the price of the underlying shares.

Fair value of options granted

The assessed fair value of options at grant date was determined using the Black-Scholes option pricing model that takes into account the exercise price, term of the option, security price at grant date and expected price volatility of the underlying security, the expected dividend yield, the risk-free interest rate for the term of the security and certain probability assumptions.

Impairment of inventories

The provision for impairment of inventories assessment requires a degree of estimation and judgement. The level of the provision is assessed by taking into account the recent sales experience, the ageing of inventory, and in particular, the shelf life of inventories that affects obsolescence. Expected shelf-life is reassessed on a regular basis with reference to stability tests which are conducted by an expert engaged by the Company. A comprehensive stability study was completed in September 2019 and the reported findings support a shelf life of at least 130 months for the colostrum drug substance.

There was a $328,833 (2020: Nil) finished goods impairment and a $430,932 (2020: Nil) raw materials impairment of inventories recognised during year ended 30 June 2021 for inventory obsolescence in the consolidated statement of profit or loss and other comprehensive income.

Inventory split

During the year ended 30 June 2021, management performed an assessment of its raw materials and utilisation within 12 months from reporting date. Management determined no raw materials relating to Colostrum will be consumed within 12 months from reporting date (2020: Nil); the remaining balance of A$1,266,587 (2020: A$1,722,349) was estimated to be consumed beyond 12 months.

Provision for employee benefits

Provision for employee benefits represents amounts accrued for annual leave and long service leave. The current portion for this provision includes the total amount accrued for annual leave entitlements and the amounts accrued for long service leave entitlements that have vested due to employees having completed the required period of service. Refer to note 1(q) for policies on provisions.

R&D tax incentive

The Group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme.

For the year ended June 30, 2021 the Group has recorded other income of A$306,154 (2020: A$308,225) to recognise income over the year necessary to match the R&D tax incentive on a systematic basis with the costs that they are intended to compensate. Furthermore, the group subsequently received additional A$50,055 in current financial year as part of the R&D claim for financial year ended 30 June 2020.

Fair value measurement hierarchy

The preparation of the financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgments, estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgments, estimates, and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgments and estimates will seldom equal the related actual results. The judgments, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed within the relevant sections where applicable.

The fair value of the convertible notes classified as Level 3 were determined by the use of valuation model. These include discounted cash flow analysis and the use of observable inputs that required significant adjustments based on unobservable inputs.

Note 2. Revenue and other income

	30 June 2021 A$	30 June 2020 A$	30 June 2019 A$
Revenue			
Revenue from Operating Activities			
Revenue from contracts with customers	**145,776**	2,518,566	2,387,426
Total Revenue from Operating Activities	**145,776**	**2,518,566**	**2,387,426**
Other Income			
Australian Federal R&D Tax Concession Refund	**356,209**	308,225	531,005
COVID-19 government assistance	**161,600**	154,904	-
R&D grants	**74,821**	-	-
Other income	**24,480**	10,545	1,045
Total Other Income	**617,110**	**473,674**	**532,050**
Other Gains/(Losses) – Net			
Net foreign exchange gains/(losses)	**(582,528)**	11,335	51,807
Net impairment losses	**(759,765)**	-	(13,394)
Total Other Gains/(Losses) – Net	**(1,342,293)**	**11,335**	**38,413**

Notes

(i) Sale of hyperimmune products

Revenue arises mainly from the sale of products in the hyperimmune category. To determine whether to recognise revenue, the group follows the process of identifying the contract with a customer, identifying the performance obligations, determining the transaction price, allocating the transaction price to the performance obligations and recognising revenue when performance obligations are satisfied.

Revenue from the sale of hyperimmune products is recognised when or as the group transfers control of the assets to the customer.

There is no variable consideration or significant cost to obtain the contract. There is no warranties and no refunds. Returns are provided where this is outlined in a customer agreement.

(ii) Fair value of R&D tax incentive

The group's research and development (R&D) activities are eligible under an Australian government tax incentive for eligible expenditure. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. Amounts are recognised when it has been established that the conditions of the tax incentive have been met and that the expected amount can be reliably measured. For the year ended 30 June 2021, the group has included an item in other income of $306,154 (2020: $308,225) to recognise income over the year necessary to match the R&D tax incentive on a systematic basis with the costs that they are intended to compensate. Furthermore, the group subsequently received additional $50,055 in current financial year as part of the R&D claim for financial year ended 30 June 2020.

(iii) Fair value of COVID-19 government assistance and R&D grants

The group's other grant income is recognised when compliance with the conditions attached to the grant have been determined and the group has ascertained the grant will be received.

For the year ended 30 June 2021, the group has recognised $161,600 (2020: $154,904) in the COVID-19 government assistance packages and a $74,821 (2020: Nil) R&D grant from the Henry M Jackson Foundation.

Note 3. Expenses

	30 June 2021 A$	30 June 2020 A$	30 June 2019 A$
General and administrative expenses			
Accounting and audit	**547,055**	389,798	496,983
Bad debts	**5,472**	26,983	50,429
Consulting	**126,215**	181,474	243,508
Depreciation	**43,662**	44,056	5,287
Employee benefits	**1,775,809**	1,531,037	1,599,023
Expected credit losses	**(30,055)**	(3,991)	34,046
Insurance	**341,202**	469,844	307,757
Investor relations	**38,568**	197,839	128,415
Legal	**205,722**	184,382	171,145
Listing and share registry	**292,113**	212,236	186,013
Occupancy	**-**	51,973	105,606
Superannuation	**41,964**	48,877	55,176
Travel and entertainment	**1,398**	91,347	159,911
Other	**589,554**	278,135	151,007
	3,978,679	3,703,990	3,694,306
Research and development expenses			
Consulting	**1,006,086**	262,720	430,996
Project research and development	**360,968**	915,965	613,532
	1,367,054	1,178,685	1,044,528
Selling and marketing expenses			
Selling	**25,858**	340,046	277,478
Marketing	**90,652**	295,261	377,427
Distribution costs	**171,174**	236,244	209,739
	287,684	871,551	864,644

Note 4. Income Tax Benefit

	30 June 2021 A$	30 June 2020 A$
Unused tax losses for which no deferred tax asset has been recognised	**44,178,579**	40,018,956
Potential tax benefit @ 26% (2020: 27.5%)	**11,486,431**	11,005,213

Numerical reconciliation of income tax expense to prima facie tax payable

	30 June 2021 A$	30 June 2020 A$
Loss from continuing operations before income tax expense	**(8,384,465)**	(2,927,206)
Tax at the Australian tax rate of 26% (2020: 27.5%)	**(2,179,961)**	(804,982)
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:		
R&D tax incentive	**(92,614)**	(84,762)
Accounting expenditure subject to R&D tax incentive	**212,907**	194,855
Share-based payments	**550,163**	(146,826)
Net impact of other amounts not deductible (taxable)	**428,003**	(18,678)
Subtotal	**(1,081,502)**	(860,393)
Tax losses and other timing differences for which no deferred tax asset is recognised	**1,081,502**	860,393
Income tax expense	**-**	-

Note 5. Key Management Personnel Compensation

This note details the nature and amount of remuneration for each Director of Immuron Limited, and for the Key Management Personnel.

The Directors of Immuron Limited during the year ended June 30, 2021 were:

The following persons held office as Directors of Immuron Limited during the financial year:

Dr Roger Aston, Independent Non-Executive Chairman
Mr Peter Anastasiou, Executive Vice Chairman (resigned on 24 September 2021)
Mr Daniel Pollock, Independent Non-Executive Director
Mr Stephen Anastasiou, Independent Non-Executive Director
Prof. Ravi Savarirayan, Independent Non-Executive Director

The following persons held office as Key Management Personnel of Immuron Limited during the financial year ended June 30, 2021:

Dr Jerry Kanellos, Chief Operating Officer and Chief Executive Officer.

The aggregate compensation made to Directors and Other Key Management Personnel of the Company is set out below:

	30 June 2021 A$	30 June 2020 A$	30 June 2019 A$
Key Management Personnel Compensation			
Short-term employee benefits	**450,002**	**867,054**	952,406
Other short-term benefits, including consulting services by KMP and their related entities	**1,603,747**	-	-
Post-employment benefits	**27,869**	**29,213**	32,300
Long-term benefits	**8,220**	**3,610**	3,652
Share-based payment expenses to KMP and their related entities	**2,116,012**	**73,088**	1,296,400
Total Key Management Personnel Compensation	**4,205,850**	**972,965**	**2,284,758**

Note 6. Loss per Share

	30 June 2021 A$	30 June 2020 A$	30 June 2019 A$
Basic/Diluted loss per share (in cents)	**3.79**	1.66	3.22
a) Net loss used in the calculation of basic and diluted loss per share	**8,384,465**	2,927,206	4,656,421
b) Weighted average number of ordinary shares outstanding during the period used in the calculation of basic and diluted loss per share	**221,062,229**	176,393,354	144,740,535

The Company is currently in a loss making position and thus the impact of potential issuance of shares is concluded as anti-dilutive which includes the Company's options and warrants and convertible notes payable. Treasury shares are excluded from the calculation of weighted average number of ordinary shares.

Note 7. Cash

	30 June 2021 A$	30 June 2020 A$
Cash at Bank and in hand:		
Cash at bank and in hand	**25,047,281**	3,250,468
Total Cash	**25,047,281**	**3,250,468**

Note 8. Trade and Other Receivables

	30 June 2021 A$	30 June 2020 A$
Current		
Trade receivables*	**28,553**	49,519
Loss allowance	**-**	(30,055)
Accrued income**	**306,154**	308,225
Total Trade and Other Receivables	**334,707**	327,689

* All trade receivables are non-interest bearing.

** Primarily comprises of receivables from the Australian Tax Office in relation to R&D tax concession for the year.

Note 9. Inventories

	30 June 2021			30 June 2020		
	Current A$	**Non-current A$**	**Total A$**	Current A$	Non-current A$	Total A$
Raw materials and stores (Colostrum)	**-**	**1,266,587**	**1,266,587**	-	1,722,349	1,722,349
Work in progress	-	-	-	117,576	-	117,576
Finished goods (Travelan and Protectyn)	**292,532**	**-**	**292,532**	680,114	-	680,114
	292,532	**1,266,587**	**1,559,119**	797,690	1,722,349	2,520,039

Note 10. Controlled Entities

The Company's subsidiaries at 30 June 2021 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Company, and the proportion of ownership interests held equals the voting rights held by the Company. The country of incorporation or registration is also their principal place of business.

	Country of Incorporation	Percentage of Ownership 30 June 2021	Percentage of Ownership 30 June 2020
Parent Entity:			
Immuron Limited	Australia	—	—
Subsidiaries of Immuron Limited:			
Immuron Inc.	USA	100%	100%
Anadis EPS Pty Ltd	Australia	100%	100%
IMC Canada Ltd.	Canada	100%	100%

Note 11. Trade and Other Payables

	30 June 2021 A$	30 June 2020 A$
Current		
Trade payables	**106,893**	157,644
Accrued expenses	**625,980**	210,734
Other payables	**25,621**	16,019
Total	**758,494**	384,397

Note 12. Provision for Sales Returns

Sales return provision due to the ongoing COVID-19 pandemic	2021 A$
Carrying amount at the start of the year	**-**
Sales return provision recognised	**213,024**
Amounts transferred from non-current	**-**
Carrying amount at the end of the year	**213,024**

The sales return provision has been assessed by management based on external reports on stock held by distributors. The timing and amount of the obligation are uncertain but are expected to be settled in the next year.

Note 13. Contingent liabilities and Commitments

The group had no contingent liabilities or commitments at June 30, 2021 (2020: Nil).

Note 14. Leases

(i) Amounts recognized in the balance sheet

The balance sheet shows the following amounts relating to leases:

	30 June 2021 A$	30 June 2020 A$
Right-of-use assets[1]		
Properties	**19,471**	58,095
	19,471	58,095
Lease liabilities[2]		
Current	**20,498**	42,176
Non-current	**-**	18,929
	20,498	61,105

1. Included in the line item 'property, plant and equipment' in the consolidated balance sheet.

2. Included in the line items 'other current liabilities' and 'other non-current liabilities' in the consolidated balance sheet.

(ii) Amounts recognized in the statement of profit or loss

The statement of profit or loss shows the following amounts relating to leases:

	2021 A$	2020 A$
Depreciation charge of right-of-use assets		
Properties	**38,624**	38,729
	38,624	38,729
Interest expense (included in finance cost)	**1,152**	4,192
Expense relating to short-term leases (included in other expenses)	**-**	-
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	**-**	-
Expense relating to variable lease payments not included in lease liabilities (included in other expenses)	**-**	-
Cash paid for principal payments	**40,607**	41,390

The total finance cash outflow for leases in 2021 was A$1,152.

The total finance cash outflow for leases in 2020 was A$4,192.

(iii) The group's leasing activities and how these are accounted for

In January 2019, the group entered into a three-year commercial lease in Blackburn North. The lease is for the use of warehousing and office facilities. This lease includes an extension option for a further 3 years by written request to the landlord before 31 December 2021. There is no variability and no covenants included in the lease.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payment that are based on an index or a rate
- amounts expected to be payable by the lessee under residual value guarantees
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the interest rate implicit in the lease, if that rate can be determined, or the group's incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date, less any lease incentives received
- any initial direct costs, and
- restoration costs.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT-equipment and small items of office furniture.

Note 15. Share capital

	2021 Shares	2020 Shares	2019 Shares	2021 A$	2020 A$	2019 A$
Ordinary shares						
Fully paid	**227,246,596**	178,279,566	163,215,706	**88,361,303**	62,426,991	60,289,875
	227,246,596	178,279,566	163,215,706	**88,361,303**	62,426,991	60,289,875

(i) Movements in ordinary shares:

Details	Number of shares	Total A$
Balance at 30 June 2018	**142,778,206**	**58,237,314**
Issue at $0.16 in lieu of payment for services (2018-11-22)[1]	437,500	93,678
Issue at US$0.10 pursuant to ADS public offering (2019-05-30)[2]	20,000,000	2,894,238
Reclassify exercised options from reserves to share capital	—	100
Transaction costs arising on representative warrants issued[3]	—	(110,400)
Less: Transaction costs arising on share issues	—	(825,055)
Balance at 30 June 2019	**163,215,706**	**60,289,875**
Issue at US$0.10 pursuant to ADS public offering (2019-07-19)	13,565,200	1,926,186
Issue at A$0.16 in lieu of payment for services (2019-11-12)[1]	437,500	100,978
Exercise of NASDAQ Warrants (2020-06-23)	86,240	72
Exercise of representative warrants (2020-06-15, 2020-06-22)	974,920	540,062
Transaction costs arising on representative warrants issued	—	(55,454)
Less: Transaction costs arising on share issues	—	(374,728)
Balance at 30 June 2020	**178,279,566**	**62,426,991**
Exercise of representative warrants (2020-07-02)	5,720	-
Issue at US$0.47 pursuant to ADS public offering (2020-07-24)	42,666,720	28,165,836
Issue at $0.50 on exercise of ESOP unlisted options (2020-07-24)	100,000	50,000
Issue at US$0.25 on exercise of NASDAQ Warrants (2020-07-27)	3,008,000	1,051,626
Issue at US$0.25 on exercise of NASDAQ Warrants (2020-07-29)	40,000	13,959
Transfer from reserves on exercise of ESOP unlisted options (2020-07-24)	-	15,700
Transfer from reserves on exercise of NASDAQ Warrants (2020-07-27, 2020-07-29)	-	1,012
Issue at A$0.08 in lieu of cash for services rendered (2020-11-13)	2,737,500	219,000
Transfer from reserves on cashless exercise of ESOP unlisted options (2021-02-09)	409,090	197,010
Less: Transaction costs arising on share issues	-	(3,779,831)
Balance at 30 June 2021	**227,246,596**	**88,361,303**

Notes

1. Mr Peter (resigned 24 September 2021) and Mr Stephen Anastasiou are directors and majority shareholders of Grandlodge Capital Pty Ltd (Grandlodge). As per an agreement which commenced on 1 June 2013 and expired on 30 June 2020, Immuron Limited contracted Grandlodge on normal commercial terms and conditions to provide warehousing, distribution and invoicing services for Immuron Limited's products for A$70,000 per annum. These fees would be payable in new fully paid ordinary shares in Immuron Limited at a set price of A$0.16 per share, representing Immuron Limited's shares price at the commencement of the agreement. The above amount is the fair value of the equity instrument.

2. On 30 May 2019, 500,000 American Depository Shares (ADS) were issued at US$4.00 each. Each ADS is equivalent to 40 ordinary shares, i.e. 20,000,000 at US$0.10 each (A$0.1447).

(ii) Ordinary shares

Ordinary shares entitle the holder to participate in dividends, and to share in the proceeds of winding up the company in proportion to the number of and amounts paid on the shares held.

On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

Ordinary shares have no par value and the Company does not have a limited amount of authorized capital.

(iii) Options

Information relating to options, including details of options issued, exercised and lapsed during the financial year and options outstanding at the end of the reporting period, is set out in notes 15 and 18.

Note 16. Other reserves

The following table shows a breakdown of the consolidated statement of financial position line item 'other reserves' and the movements in these reserves during the year. A description of the nature and purpose of each reserve is provided below the table.

	Notes	Share-based payments A$	Foreign currency translation A$	Total other reserves A$
At 1 July 2018		**3,139,625**	**(43,317)**	**3,096,308**
Currency translation differences		-	61,846	61,846
Other comprehensive income		**-**	**61,846**	**61,846**
Transactions with owners in their capacity as owners				
Options and warrants issued/expensed		1,453,900	-	1,453,900
Options and warrants exercised		(100)	-	(100)
Options and warrants lapsed/expired		(311,635)	-	(311,635)
At 30 June 2019		**4,281,790**	**18,529**	**4,300,319**

	Notes	Share-based payments A$	Foreign currency translation A$	Total other reserves A$
At 1 July 2019		**4,281,790**	**18,529**	**4,300,319**
Currency translation differences		-	102,938	102,938
Other comprehensive income		-	102,938	102,938
Transactions with owners in their capacity as owners				
Share-based payment expenses	16(iv)	73,088	-	73,088
Options and warrants issued/expensed		(484,680)	-	(484,680)
Options and warrants lapsed/expired		(2,251,320)	-	(2,251,320)
Re-valuation of options issued in prior period	16(iii)	(607,000)	-	(607,000)
At 30 June 2020		**1,011,878**	**121,467**	**1,133,345**

	Notes	Share-based payments A$	Foreign currency translation A$	Total other reserves A$
At 1 July 2020		**1,011,878**	**121,467**	**1,133,345**
Currency translation differences		-	(14,953)	(14,953)
Other comprehensive income		-	(14,953)	(14,953)
Transactions with owners in their capacity as owners				
Transfer to share capital	16(iv)	(73,088)	-	(73,088)
Options and warrants issued/expensed	16(ii)	3,003,060	-	3,003,060
Options and warrants exercised	16(ii)	(213,722)	-	(213,722)
Options and warrants forfeited		(368,000)	-	(368,000)
At 30 June 2021		**3,360,128**	**106,514**	**3,466,642**

(i) Nature and purpose of other reserves

Share-based payments

The share-based payment reserve records items recognized as expenses on valuation of share options and warrants issued to key management personnel, other employees and eligible contractors.

Foreign currency translation

Exchange differences arising on translation of foreign controlled entities are recognized in other comprehensive income as described in note 1(d) and accumulated in a separate reserve within equity. The cumulative amount is reclassified to profit or loss when the net investment is disposed of.

(ii) Movements in options and warrants:

Details	Notes	Number of options	Total A$
Balance at 30 June 2018		**72,569,180**	**3,139,625**
Issue of ESOP unlisted options at $0.50 (2018-07-13)		1,300,000	204,100
Issue of ESOP unlisted options at $0.50 (2018-11-26)		2,000,000	164,400
Lapse of ESOP unlisted options at $0.50 (2018-10-01)		(1,050,000)	(98,385)
Issue of ESOP unlisted options at $0.50 (2019-02-11)		5,000,000	975,000
Lapse of unlisted options at $0.57 (2019-02-24)		(1,000,000)	(185,601)
Lapse of unlisted options at $1.892 (2019-02-28)		(15,380)	(1,173)
Lapse of unlisted options at $0.30 (2019-05-28)		(140,056)	(13,390)
Reclassify exercised options from reserves to share capital		-	(100)
Reclassify lapsed options from reserves to accumulated losses		-	(13,086)
Issue of representative warrants (2019-05-23)[1]		800,000	110,400
Balance at 30 June 2019		**79,463,744**	**4,281,790**
Re-valuation of options issued in prior period (2019-11-06)	16(iii)	-	(607,000)
Issue of representative warrants (2019-07-16)		542,600	55,454
Lapse of unexercised options at $0.50 (2019-11-27)		(7,625,532)	(2,086,920)
Lapse of unexercised options at $0.55 (2019-11-30)		(25,289,894)	-
Lapse of unexercised options at $0.50 (2020-06-30)		(2,000,000)	(164,400)
Exercise of NASDAQ Warrants at US$10 per 40 options (2020-06-23)		(218,800)	(72)
Exercise of representative warrants (2020-06-15, 2020-06-22)		(2,065,000)	(540,062)
Balance at 30 June 2020		**42,807,118**	**938,790**
Exercise of representative warrants (2020-07-2)		(9,640)	-
Exercise of ESOP unlisted options at $0.50 (2020-07-24)		(100,000)	(15,700)
Exercise of NASDAQ Warrants at US$10 per 40 options (2020-07-27, 2020-07-29)		(3,048,000)	(1,012)
Lapse of unexercised options (2020-09-25)		(5,000,000)	(368,000)
Issue of representative warrants at US$23.44 per 40 options (2020-07-24)		2,560,000	1,032,960
Issue of ESOP unlisted options at $0.12 (2020-10-29)		9,000,000	1,970,100
Cashless exercise of ESOP unlisted options at $0.12 (2021-02-09)		(900,000)	(197,010)
Reclassify share-based payments expenses from reserves to share capital	16(iv)	-	(73,088)
Balance at 30 June 2021		**45,309,478**	**3,360,128**

On 13 July 2018, the Company issued Dr. Jerry Kanellos, Chief Operating Officer of Immuron Limited, 1,000,000 unlisted options exercisable at $0.50 on or before 1 July 2021.

On 26 November 2018, the Company issued Mr. Richard J. Berman, a Non-Executive Director of Immuron Limited, 2,000,000 unlisted options exercisable at $0.50 on or before June 30, 2021. During the 2019 annual general meeting, the shareholders approved the issuance of the options to Richard Berman.

On 11 February 2019, the Company issued Dr. Gary S. Jacob 5,000,000 unlisted options exercisable at $0.50. These options were subsequently forfeited on September 25, 2020, being 6 months after his resignation.

Given the shareholders' approval at the AGM held on 29 October 2020, a total of 9,000,000 ESOP Options were issued to directors on 13 November 2020.

(iii) Revaluation of options issued in prior period

Options granted to Dr Gary Jacob on 11 February 2019 and valued at $975,000 in the 30 June 2019 financials were subject to shareholder approval. In line with IFRS 2, these were re-measured at grant date 6 November 2019 after being approved by shareholders with a value of $368,000, being a revaluation of $607,000 in the 30 June 2020 financials.

(iv) Share-based payment expenses

Due to the ongoing crisis of COVID-19, the groups directors decided to forgo cash payments of their director fees from 1 April 2020 to 31 December 2020 and instead receive shares of that value. In prior year, no shares were issued to directors, however the expense of the shares owed to them was A$73,088. As at 30 June 2021, shares have been issued to directors given the shareholders' approval at the AGM held on 29 October 2020.

Note 17. Segment Reporting

Description of segments and principal activities

The group has identified its operating segments based on the internal reports that are reviewed and used by the executive management team in assessing performance and determining the allocation of resources.

Management considers the business from both a product and a geographic perspective and has identified two reportable segments:

Research and development (R&D): income and expenses directly attributable to the group's R&D projects performed in Australia, Israel and United States.

Hyperimmune products: income and expenses directly attributable to Travelan and Protectyn activities which occur in Australia, the United States, Canada and the rest of the world.

Financial breakdown

The segment information for the reportable segments for the year ended June 30, 2021 is as follows:

2021	Research and development A$	Hyperimmune products A$	Other A$	Total A$
Hyperimmune products revenue	-	145,776	-	145,776
Cost of sales of goods	-	(51,071)	-	(51,071)
Gross profit	**-**	**94,705**	**-**	**94,705**
Other income	431,030	24,480	161,600	617,110
Other gains/(losses) – net	-	(759,765)	(582,528)	(1,342,293)
General and administrative expenses	-	-	(3,978,679)	(3,978,679)
Share-based payment expenses	-	-	(2,116,013)	(2,116,013)
Research and development expenses	(1,367,054)	-	-	(1,367,054)
Selling and marketing expenses	-	(287,684)	-	(287,684)
Operating profit/(loss)	**(936,024)**	**(928,264)**	**(6,515,620)**	**(8,379,908)**
Finance income	-	-	9,204	9,204
Finance costs	-	-	(13,761)	(13,761)
Income tax expense	-	-	-	-
Profit/(loss) for the year	**(936,024)**	**(928,264)**	**(6,520,177)**	**(8,384,465)**
Assets				
Segment assets	306,154	1,587,672	25,159,280	27,053,106
Total assets	**306,154**	**1,587,672**	**25,159,280**	**27,053,106**
Liabilities				
Segment liabilities	243,565	284,657	629,827	1,158,049
Total liabilities	**243,565**	**284,657**	**629,827**	**1,158,049**

The segment information for the reportable segments for the year ended June 30, 2020 is as follows:

2020	Research and development A$	Hyperimmune products A$	Other A$	Total A$
Hyperimmune products revenue	-	2,518,566	-	2,518,566
Cost of sales of goods	-	(688,836)	-	(688,836)
Gross profit	**-**	**1,829,730**	**-**	**1,829,730**
Other income	308,225	10,545	154,904	473,674
Other gains/(losses) – net	-	-	11,335	11,335
General and administrative expenses	-	-	(3,170,078)	(3,170,078)
Research and development expenses	(1,178,685)	-	-	(1,178,685)
Selling and marketing expenses	-	(871,551)	-	(871,551)
Operating profit/(loss)	**(870,460)**	**968,724**	**(3,003,839)**	**(2,905,575)**
Finance income	-	-	-	-
Finance costs	-	-	(21,631)	(21,631)
Income tax expense	-	-	-	-
Profit/(loss) for the year	**(870,460)**	**968,724**	**(3,025,470)**	**(2,927,206)**
Assets				
Segment assets	308,225	2,539,503	3,354,435	6,202,163
Total assets	**308,225**	**2,539,503**	**3,354,435**	**6,202,163**
Liabilities				
Segment liabilities	101,092	30,377	426,781	558,250
Total liabilities	**101,092**	**30,377**	**426,781**	**558,250**

The segment information for the reportable segments for the year ended June 30, 2019 is as follows:

2019	Research and development A$	Hyperimmune products A$	Other A$	Total A$
Hyperimmune products revenue	-	2,387,426	-	2,387,426
Cost of sales of goods	-	(667,371)	-	(667,371)
Gross profit	**-**	**1,720,055**	**-**	**1,720,055**
Other income	531,005	1,045	-	532,050
Other gains/(losses) – net	-	(13,394)	51,807	38,413
General and administrative expenses	-	-	(5,037,806)	(5,037,806)
Research and development expenses	(1,044,528)	-	-	(1,044,528)
Selling and marketing expenses	-	(864,644)	-	(864,644)
Operating profit/(loss)	**(513,523)**	**843,062**	**(4,985,999)**	**(4,656,460)**
Finance income	-	-	39	39
Profit/(loss) for the year	**(513,523)**	**843,062**	**(4,985,960)**	**(4,656,421)**
Assets				
Segment assets	531,828	2,705,330	5,324,489	8,561,647
Total assets	**531,828**	**2,705,330**	**5,324,489**	**8,561,647**
Liabilities				
Segment liabilities	221,520	191,836	797,155	1,210,511
Total liabilities	**221,520**	**191,836**	**797,155**	**1,210,511**

Information on geographical regions:

The group derives revenue from the transfer of hyperimmune products at a point in time in the following major product lines and geographical regions:

	Travelan			Protectyn		
	Australia	United States	Other	Australia	Other	Total
2021	**A$**	**A$**	**A$**	**A$**	**A$**	**A$**
Hyperimmune products revenue[1]	**(10,308)**	**4,264**	**101,639**	**50,181**	**-**	**145,776**
Revenue from external customers	**(10,308)**	**4,264**	**101,639**	**50,181**	**-**	**145,776**

1. Returns are provided where outlined in a customer's agreement.

	Travelan			Protectyn		
	Australia	United States	Other	Australia	Other	Total
2020	**A$**	**A$**	**A$**	**A$**	**A$**	**A$**
Hyperimmune products revenue	**1,240,393**	**926,325**	**301,915**	**49,933**	**-**	**2,518,566**
Revenue from external customers	**1,240,393**	**926,325**	**301,915**	**49,933**	**-**	**2,518,566**

	Travelan			Protectyn		
	Australia	United States	Other	Australia	Other	Total
2019	**A$**	**A$**	**A$**	**A$**	**A$**	**A$**
Segment revenue	1,162,628	1,016,468	149,283	58,683	364	2,387,426
Revenue from external customers	1,162,628	1,016,468	149,283	58,683	364	2,387,426

Information on major customers:

During the years ended June 30, 2021, 2020 and 2019, the Company had the following major customers in the hyperimmune product segment with revenues amounting to 10 percent or more of total group revenues:

	2021	2020	2019
	A$	**A$**	**A$**
Customer A	**41,040**	**-**	-
Customer B	**27,563**	-	-
Customer C	**25,319**	**-**	-
Customer D	**23,214**	**462,490**	611,920
Customer E	**22,886**	**-**	-
Customer F	**-**	**442,916**	228,661
Customer G	**-**	**438,065**	659,637
Customer H	**-**	**327,559**	266,111
Customer I	**-**	**227,952**	249,522
	140,022	**1,898,982**	**2,015,851**

Note 18. Cash Flow Information

(a) Reconciliation of cash flow from operations with loss after income tax

	30 June 2021 A$	30 June 2020 A$	30 June 2019 A$
Net Loss for the Year	**(8,384,465)**	(2,927,206)	(4,656,421)
Adjustments for			
Depreciation expense	**43,662**	44,056	5,287
Distribution costs	**-**	70,000	70,000
Expected credit losses	**(30,055)**	(3,991)	34,046
Finance costs	**13,761**	21,631	—
Finance income	**(9,204)**	-	(39)
Leave provision expense	**53,610**	19,717	4,580
Share-based payments (income)/expenses	**2,116,013**	(533,912)	1,343,500
Unrealized net foreign currency gains	**592,243**	(18,883)	(62,015)
Change in operating assets and liabilities:			
Add decrease in trade and other receivables	**23,037**	641,236	680,337
Add (increase) / decrease in inventories	**960,920**	(113,635)	263,365
Add (increase) / decrease in other operating assets	**(45,065)**	16,096	92,510
Add (decrease) / increase in trade and other payables	**586,796**	(362,437)	426,271
	(4,078,747)	(3,147,328)	(1,798,579)

(b) Non-cash financing and investing activities

See note 19 for details regarding issues of options to employees and for details surrounding the issue of shares to suppliers.

Note 19. Share-based Payments

a) Executive share and option plan

The establishment of the 'executive share and option plan' (ESOP) was approved by shareholders at the 2017 annual general meeting. The plan is designed to provide long-term incentives for executives (including directors) to deliver long-term shareholder returns. Participation in the plan is at the board's discretion and no individual has a contractual right to participate in the plan or to receive any guaranteed benefits.

Options issued to Dr Gary Jacob expire within 6 months upon his resignation without good reason or termination. All other options issued expire upon departure from the company if they are determined to be a 'bad leaver'.

Set out below are summaries of all listed and unlisted options, including those issued under ESOP:

	2021		2020		2019	
	Average exercise price per share option (A$)	**Number of options**	**Average exercise price per share option (A$)**	**Number of options**	**Average exercise price per share option (A$)**	**Number of options**
As at 1 July	**0.40**	**42,807,118**	0.46	79,463,744	0.45	72,569,180
Granted during the year	**0.28**	**11,560,000**	0.18	542,600	0.47	9,100,000
Exercised during the year	**0.23**	**(4,057,640)**	0.18	(424,840)	-	-
Forfeited/lapsed during the year	**0.50**	**(5,000,000)**	0.52	(36,774,386)	0.53	(2,205,436)
As at 30 June	**0.31**	**45,309,478**	0.40	42,807,118	0.46	79,463,744
Vested and exercisable at 30 June	**0.31**	**45,309,478**	0.40	42,807,118	0.46	79,463,744

Share options outstanding at the end of the year have the following expiry date and exercise prices:

Grant date	**Expiry date**	**Exercise price (A$ unless stated otherwise)**	**Share options 30 June 2021**	Share options 30 June 2020
2012-06-29	2021-11-30	1.944	14,493	14,493
2012-06-29	2022-01-17	1.876	29,668	29,668
2017-06-13 (warrants)	2022-06-13	USD 0.25	24,493,200	27,541,200
2018-03-15	2023-03-15	0.468	7,897,647	7,897,647
2017-06-09 (warrants)	2022-06-08	USD 0.3125	198,240	198,240
2018-03-15	2023-03-15	0.585	526,510	526,510
2019-05-23 (warrants)	2024-05-23	USD 0.125	173,600	181,600
2019-07-16 (warrants)	2024-07-16	USD 0.125	116,120	117,760
2018-07-13	2021-07-01	0.500	1,200,000	1,300,000
2019-11-06	2024-02-10	0.500	-	5,000,000
2020-10-29	2024-04-14	0.12	8,100,000	-
2020-07-24 (warrants)	2025-07-21	USD 0.5859	2,560,000	-
Total			45,309,478	42,807,118
Weighted average remaining contractual life of options outstanding at end of period			1.58	2.28

(i) Fair value of options granted

The assessed fair value of options at grant date was determined using the Black-Scholes option pricing model that takes into account the exercise price, term of the option, security price at grant date and expected price volatility of the underlying security, the expected dividend yield, the risk-free interest rate for the term of the security and certain probability assumptions.

The model inputs for options granted under ESOP during the year ended June 30, 2021 included:

Grant date	Expiry date	Exercise price (A$)	No. of options	Share price at grant date (A$)	Expected volatility	Dividend yield	Risk- free interest rate	Fair value at grant date per option (A$)
2020-07-24	2025-07-21	0.83	2,560,000	0.50	127.93%	0.00%	0.43%	0.4035
2020-10-29	2024-04-14	0.12	9,000,000	0.25	142.70%	0.00%	0.13%	0.2189
			11,560,000					

The model inputs for options granted under ESOP during the year ended June 30, 2020 included:

Grant date	Expiry date	Exercise price (A$)	No. of options	Share price at grant date (A$)	Expected volatility	Dividend yield	Risk- free interest rate	Fair value at grant date per option (A$)
2019-11-06	2024-02-10	0.50	5,000,000	0.15	98	0.00%	0.88%	0.0736
			5,000,000					

The model inputs for options granted under ESOP during the year ended June 30, 2019 included:

Grant date	Expiry date	Exercise price (A$)	No. of options	Share price at grant date (A$)	Expected volatility	Dividend yield	Risk- free interest rate	Fair value at grant date per option (A$)
2018-07-13	2021-07-01	0.50	1,300,000	0.32	92.00%	0.00%	2.09%	0.1570
2018-11-26	2020-06-30	0.50	2,000,000	0.34	92.00%	0.00%	2.02%	0.0822
2019-02-11	2024-02-11	0.50	5,000,000	0.29	100.00%	0.00%	1.69%	0.1950
			8,300,000					

The expected life of the options is based on historical data and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

b) Expenses arising from share-based payment transactions

Total expenses arising from share-based payment transactions recognized during the period were as follows:

	2021 A$	2020[1] A$	2019 A$
Options issued under ESOP	**1,970,100**	(607,000)	1,343,500
Share-based payments to directors[2]	**145,913**	73,088	-
	2,116,013	(533,912)	1,343,500

1. Options granted to a former managing director on 11 February 2019 and valued at $975,000 in the 30 June 2019 financials were subject to shareholder approval. In line with IFRS 2, these were re-measured at grant date 6 November 2019 after being approved by shareholders with a value of $368,000, being a revaluation of $607,000 in the 30 June 2020 financials.

2. Due to the ongoing crisis of COVID-19, the groups directors decided to forgo cash payments of their director fees and instead receive shares of that value. As at 30 June 2021, shares have been issued to directors for the director fees of $145,913 incurred during the financial year ended 30 June 2021 and $73,088 incurred during the financial year ended 30 June 2020, given the shareholders' approval at the AGM held on 29 October 2020.

Note 20. Related Party Transactions

(a) Subsidiaries

Interests in subsidiaries are set out in note 10.

(b) Transactions with other related parties

The following transactions occurred with related parties:

	2021 A$	2020 A$	2019 A$
Amounts settled in cash or shares for goods and services			
Purchases of various goods and services from entities controlled by key management personnel (i)	110,607	142,347	147,636

(i) Purchases from entities controlled by key management personnel

The group acquired the following goods and services from entities that are controlled by members of the group's key management personnel:

- rental of an office suite (Wattle Laboratories Pty Ltd); and

Effective January 2016, we executed a Lease Agreement with Wattle Laboratories Pty Ltd, ("Wattle"), an entity part-owned and operated by our non-executive directors, Mr. Peter Anastasiou (a director resigned on 24 September 2021) and Mr. Stephen Anastasiou, whereby we lease part of their Blackburn office facilities for our operations at a rental rate of A$38,940 per year, payable in monthly installments. The rental agreement is subject to annual rental increases, and effective January 2017, the annual rent was increased to A$39,525. The lease is for a three-year term with an additional three-year option period. The lease may be terminated by either party upon six months' written notice. During the fiscal years ended June 30, 2019, 2020 and 2021, we paid Wattle A$53,958, A$41,369 and A$40,607 (excluding Goods and Services Tax), respectively. The lease was renewed, commencing January 1, 2019 for three years.

- warehousing, distribution and invoicing services (Grandlodge Capital Pty Ltd).

Grandlodge Capital Pty Ltd is an entity part-owned and operated by our non-executive director Mr. Stephen Anastasiou. Mr. Peter Anastasiou (a director resigned on 24 September 2021) and Mr. David Plush are also owners of Grandlodge, and its associated entities.

Commenced on June 1, 2013, Grandlodge provides warehousing, distribution and invoicing services for our products for A$70,000 per year. The terms of the agreement were to have fees payable in new fully paid ordinary shares in Immuron Limited as a set price of A$0.16 per share. The fair value of the equity instrument has been assessed and accounted for in accordance with IFRS 2 Share Based Payments in the 2020 financial statements. During the 2020 financial year, the fees of A$100,978 equivalent were repaid by issuance of 437,500 ordinary shares based on their fair value. During the 2019 financial year, the fees of A$93,678 equivalent were repaid by issuance of 437,500 ordinary shares based on based on their fair value.

Grandlodge is reimbursed in cash for all reasonable costs and expenses incurred in accordance with their scope of works under the oral agreement, unless both Grandlodge and we agree to an alternative method of payment. The oral agreement may be terminated by either party upon providing the other party with 30 days written notice of the termination of the agreement.

A new agreement commenced on July 1, 2020. Grandlodge was contracted on commercial terms to provide warehousing, distribution and invoicing services for Immuron's products for $70,000 per annum. The terms of the agreement were to have fees payable in cash.

Aggregate amounts of each of the above types of other transactions with key management personnel of Immuron Limited:

	2020 A$	2020 A$	2019 A$
Amounts settled in cash or shares during the period			
Rental of an office suite from Wattle Laboratories Pty Ltd	**40,607**	**41,369**	53,958
Services rendered by Grandlodge Capital Pty Ltd	**70,000**	**100,978**	93,678
	110,607	**142,347**	147,636

(c) Outstanding balances arising from sales/purchases of goods and services

The following balances are outstanding at the end of the reporting period in relation to transactions with related parties:

	2021 A$	2020 A$	2019 A$
Current payables (purchases of goods and services)			
Entities controlled by key management personnel	**70,000**	**-**	-

Note 21. Financial Risk Management Objectives and Policies

This note explains the Group's exposure to financial risks and how these risks could affect the Group's future financial performance.

The Group's risk management is predominantly controlled by the Board. The Board monitors the Group's financial risk management policies and exposures and approves substantial financial transactions. It also reviews the effectiveness of internal controls relating to market risk, credit risk and liquidity risk.

Risk Management Policy

The Board is responsible for overseeing the establishment and implementation of the risk management system, and reviews and assesses the effectiveness of the Company's implementation of that system on a regular basis.

The Board and Senior Management identify the general areas of risk and their impact on the activities of the Company, with Management performing a regular review of:

- the major risks that occur within the business; the degree of risk involved;
- the current approach to managing the risk; and
- if appropriate, determine:
  - any inadequacies of the current approach; and
  - possible new approaches that more efficiently and effectively address the risk.

Management report risks identified to the Board through the monthly Operations Report.

The Company seeks to ensure that its exposure to undue risk which is likely to impact its financial performance, continued growth and survival is minimised in a cost effective manner.

(a) Market risk

Foreign exchange risk

The Group undertakes certain transactions denominated in foreign currency and is exposed to foreign currency risk through foreign exchange rate fluctuations.

Foreign exchange rate risk arises from financial assets and financial liabilities denominated in a currency that is not the group's functional currency. Exposure to foreign currency risk may result in the fair value of future cash flows of a financial instrument fluctuating due to the movement in foreign exchange rates of currencies in which the group holds financial instruments which are other than the Australian dollar (AUD) functional currency of the group including United States dollar (USD), Canadian dollar (CAD) and Israeli Shekel (ILS). This risk is measured using sensitivity analysis and cash flow forecasting. The cost of hedging at this time outweighs any benefits that may be obtained.

Exposure

The Group's exposure to foreign currency risk at the end of the reporting period, expressed in Australian dollars, was as follows:

	2021		2020		
	USD $	**CAD $**	USD $	CAD $	ILS $
Cash and cash equivalents	**2,742,688**	**108,688**	2,954,589	107,605	-
Trade receivables	**23,801**	**-**	45,591	-	-
Trade payables	**18,556**	**43,466**	29,946	1,923	41,771
Total exposure	**2,785,045**	**152,154**	3,030,126	109,528	41,771

Sensitivity

As shown in the table above, the Group is primarily exposed to changes in USD/AUD exchange rates. The sensitivity of profit or loss to changes in the exchange rates arises mainly from USD denominated financial instruments. The impact on other components of equity arises from the translation of foreign subsidiary financial statements into AUD.

The Group has conducted a sensitivity analysis of its exposure to foreign currency risk. The Group is currently materially exposed to the United States dollar (USD). The sensitivity analysis is conducted on a currency-by-currency basis using the sensitivity analysis variable, which is based on the average annual movement in exchange rates over the past five years at year-end spot rates. The variable for each currency the group is materially exposed to is listed below:

- USD: 4.9% (2020: 3.3%)

	Impact on loss for the period		Impact on other components of equity	
	2021	2020	**2021**	2020
	A$	A$	**A$**	A$
USD/AUD exchange rate – change by 4.9% (2020: 3.3%)	**136,467**	99,994	**5,219**	4,035

* Holding all other variables constant

Loss is more sensitive to movements in the AUD/USD exchange rates in 2021 than 2020 because of the increased amount of USD denominated cash and cash equivalents and the increased variability of the AUD/USD exchange rate. Equity is more sensitive to movements in the AUD/USD exchange rates in 2021 than 2020 because of the increased size of the foreign currency translation reserve for the subsidiary with USD functional currency. The group's exposure to other foreign exchange movements is not material.

(b) Credit risk

Exposure to credit risk relating to financial assets arises from the potential non-performance by counterparties of contract obligations that could lead to a financial loss to the group.

(i) Risk management

Credit risk is managed through the maintenance of procedures (such as the utilisation of systems for the approval, granting and renewal of credit limits, regular monitoring of exposures against such limits and monitoring the financial stability of significant customers and counterparties), ensuring to the extent possible that customers and counterparties to transactions are of sound credit worthiness. Such monitoring is used in assessing receivables for impairment. Credit terms are normally 30 days from the invoice date.

Risk is also minimised through investing surplus funds in financial institutions that maintain a high credit rating.

(ii) Security

For some trade receivables the group may obtain security in the form of guarantees, deeds of undertaking or letters of credit which can be called upon if the counterparty is in default under the terms of the agreement.

(iii) Impairment of financial assets

The group has one type of financial asset subject to the expected credit loss model:

- trade receivables for sales of inventory

While cash and cash equivalents are also subject to the impairment requirements of IFRS 9, the identified impairment loss was immaterial.

Trade receivables

The group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables assets have been grouped based on shared credit risk characteristics and the days past due.

The expected loss rates are based on the payment profiles of sales over a period of 60 months before June 30, 2021 and the corresponding historical credit losses experienced within this period. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

On that basis, the loss allowance as at June 30, 2021 was determined as follows for trade receivables:

	Days past due						
30 June 2021	**Current A$**	**1-30 A$**	**31-60 A$**	**61-90 A$**	**91-120 A$**	**121+ A$**	**Total A$**
Expected credit loss rate	0.00%	0.00%	13.07%	21.88%	34.09%	53.58%	
Gross carrying amount	23,801	4,752	-	-	-	-	28,553
Loss allowance	**-**	**-**	**-**	**-**	**-**	**-**	**-**

On that basis, the loss allowance as at June 30, 2020 was determined as follows for trade receivables:

	Days past due						
30 June 2020	**Current A$**	**1-30 A$**	**31-60 A$**	**61-90 A$**	**91-120 A$**	**121+ A$**	**Total A$**
Expected credit loss rate	0.60%	8.06%	0.00%	23.35%	38.30%	100.00%	
Gross carrying amount	2,820	1,055	-	14,476	7,447	23,721	49,519
Loss allowance	**17**	**85**	**-**	**3,380**	**2,852**	**23,721**	**30,055**

Trade receivables are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the group, and a failure to make contractual payments for a period of greater than 121 days past due.

Impairment losses on trade receivables are presented as net impairment losses within operating profit. Subsequent recoveries of amounts previously written off are credited against the same line item.

Previous accounting policy for impairment of trade receivables

In the prior year, the impairment of trade receivables was assessed based on the incurred loss model. Individual receivables which were known to be uncollectible were written off by reducing the carrying amount directly. The other receivables were assessed collectively to determine whether there was objective evidence that an impairment had been incurred but not yet been identified. For these receivables the estimated impairment losses were recognized in a separate provision for impairment. The Group considered that there was evidence of impairment if any of the following indicators were present:

- significant financial difficulties of the debtor;
- probability that the debtor will enter bankruptcy or financial reorganization; and
- default or late payments (more than 121 days overdue).

Receivables for which an impairment provision was recognized were written off against the provision when there was no expectation of recovering additional cash.

(c) Liquidity risk

Liquidity risk arises from the possibility that the group might encounter difficulty in settling its debts or otherwise meeting its obligations related to financial liabilities. The group manages this risk through the following mechanisms:

- preparing forward looking cash flow analyses in relation to its operating, investing and financing activities;
- obtaining funding from a variety of sources;
- maintaining a reputable credit profile;
- managing credit risk related to financial assets;
- investing cash and cash equivalents and deposits at call with major financial institutions; and
- comparing the maturity profile of financial liabilities with the realisation profile of financial assets.

Maturities of financial liabilities

The tables below analyze the group's financial liabilities into relevant maturity groupings based on their contractual maturities. The amounts disclosed in the table are the contractual discounted cash flows.

Contractual maturities of financial liabilities At 30 June 2021	Less than 6 months A$	6 - 12 months A$	Between 1 and 2 years A$	Between 2 and 5 years A$	Over 5 years A$	Total contractual cash flows A$	Carrying amount (assets)/ liabilities A$
Trade and other payables	**132,514**	**-**	**-**	**-**	**-**	**132,514**	**132,514**
Lease liabilities	**20,498**	**-**	**-**	**-**	**-**	**20,498**	**20,498**
Total	**153,012**	**-**	**-**	**-**	**-**	**153,012**	**153,012**
At 30 June 2020							
Trade and other payables	173,663	-	-	-	-	173,663	173,663
Lease liabilities	20,890	21,286	21,286	-	-	63,462	63,462
Total	**194,553**	**21,286**	**21,286**	**-**	**-**	**237,125**	**237,125**

Note 22. Events occurring after the Reporting Date

In May 2021, Immuron identified a transformational COVID-19 asset, for which it entered a binding contract to acquire. The company's securities were placed in suspension by the Australian Securities Exchange (ASX) until the company met the requirements set out by the Exchange. Unfortunately, after filing an ASX In-Principal Advice Application and subsequent lengthy discussions and exchanges with the ASX, Immuron was unable to satisfy the ASX that the combined group, following the proposed acquisition, would meet the requirements of the Listing Rules. Ultimately the ASX has an absolute discretion whether to approve such a major acquisition. Immuron is now unable to satisfy the pre-conditions for this proposed acquisition due to the expiration of the existing contractual timetable and will not proceed with the proposed acquisition in its present form.

On 23 September 2021, as a result of the company not proceeding with the major transaction the ASX has lifted the suspension and the company's securities have now re-commenced trading on the ASX and NASDAQ official list.

On 24 September 2021, Mr Peter Anastasiou resigned as a director of the company.

No other matter or circumstance has occurred subsequent to period end that has significantly affected, or may significantly affect, the operations of the group, the results of those operations or the state of affairs of the group or economic entity in subsequent financial years.

Note 23. Company Details

The registered office of the Company is:

Level 3, 62 Lygon Street, Carlton, Victoria, Australia 3053.

The principal place of business of the Company is:

Unit 10, 25-37 Chapman Street, Blackburn, Victoria, Australia 3130.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this report on its behalf.

Immuron Limited

By: /s/ Jerry Kanellos
Jerry Kanellos
Chief Executive Officer

Dated: October 29, 2021

Exhibit 12.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended

I, Jerry Kanellos, certify that:

1. I have reviewed this annual report on Form 20-F of Immuron Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a- 15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2021

By: /s/ Jerry Kanellos
Jerry Kanellos
Chief Executive Officer

* The originally executed copy of this Certification will be maintained at the Registrant's offices and will be made available for inspection upon request.

Exhibit 12.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended

I, Philip Hains, certify that:

1. I have reviewed this annual report on Form 20-F of Immuron Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a- 15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2021

By: /s/ Phillip Hains
Phillip Hains
Chief Financial Officer

* The originally executed copy of this Certification will be maintained at the Registrant's offices and will be made available for inspection upon request.

Exhibit 13.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Immuron Limited (the "Company") on Form 20-F for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerry Kanellos, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

October 29, 2021

By: /s/ Jerry Kanellos
Jerry Kanellos
Chief Executive Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

Exhibit 13.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Immuron Limited (the "Company") on Form 20-F for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Philip Hains, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

October 29, 2021

By: /s/ Phillip Hains
Phillip Hains
Chief Financial Officer

* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated October 29, 2021 with respect to the consolidated financial statements of Immuron Limited (and subsidiaries) included in the Annual Report on Form 20-F for the year ended June 30, 2021.

We consent to the incorporation by reference of the said report in the Registration Statement of Immuron Limited on Form F-3 (File No. 333-230762) and Post Effective Amendment on Form F-3 to F-1 (File No. 333-215204).

/s/ GRANT THORNTON AUDIT PTY LTD

Melbourne, Australia
October 29, 2021