	As of June 30,				
	2022 A$	2021 A$	2020 A$	2019 A$	2018 A$
Consolidated Statement of Financial Position Data:					
Cash and cash equivalents	22,110,278	25,047,281	3,250,468	5,119,887	4,727,430
Total current assets	23,672,152	25,752,778	4,409,041	6,682,444	7,050,437
Total assets	24,855,824	27,053,106	6,202,163	8,561,647	9,242,688
Total current liabilities	1,502,976	1,121,853	516,411	1,195,531	803,338
Total liabilities	1,678,423	1,158,049	558,250	1,210,511	803,338
Total equity	23,177,401	25,895,057	5,643,913	7,351,136	8,439,350

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 undertaking research and development activities of our existing patent portfolio we have incurred operating losses; we may 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.

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, however during the fiscal year 2022 sales have started to recover.

As a company undertaking research and development activities of our existing patent portfolio we have incurred operating losses; we may 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$2,854,254, A$8,384,465, A$2,927,206, A$4,656,421 and A$3,068,582 during the fiscal years ended June 30, 2022, 2021, 2020, 2019 and 2018, respectively. As of June 30, 2022, our accumulated deficit was A$68,425,281. We may 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 increase in sales of our marketed products, Travelan® and Protectyn®;
- 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, 2022, we had A$22,110,278 in cash and cash equivalents. Developing prescription products is expensive and we may 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 may 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 new 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:

- increasing sales of commercial products through investment in sales and marketing initiatives, expansion in sales channels and geographies, product development and broader applications;
- 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 tax incentive 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, 2022, 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 Incentive refunds in the fiscal years ended June 30, 2021, June 30, 2020, June 30, 2019 and June 30, 2018 of A$356,209, A$308,225, A$531,005 and A$1,849,123, respectively, and we have recognized A$257,500 for the fiscal year ended June 30, 2022, 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 Mr Steven Lydeamore who is currently our Chief Executive Officer and Dr. Jerry Kanellos who is currently our Chief Operating 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, PaxVax Bermuda Limited, Proctor and Gamble, Salix Pharmaceuticals Inc and Scandinavian BioPharma which are all developing therapeutics for travelers' diarrhea and, Acetelion, Assembly Biotechnology, Creston Pharma, Da Volterra, Finch Therapeutics, MaaT Pharma, Merck, Rebiotix Inc., Seres, Synthetic Biotechnology and Vedanta Biosciences 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 moderate to severe campylobacteriosis, 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, 2022, our cumulative operating losses have a total potential tax benefit of A$12,014,532 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.

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, 2022, 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, 2022, 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.