

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

The following risks relate specifically to our business and should be considered carefully. Our business, financial condition and results of operations could be harmed by any of the following risks. As a result, the trading price of our ordinary shares and our American Depositary Shares, or ADSs, could decline and the holders could lose part or all of their investment.

Risks Related to Our Business

We have a history of operating losses and may not achieve or maintain profitability in the future.

We have experienced significant recurring operating losses and negative cash flows from operating activities since inception. For example, for the years ended June 30, 2020 and 2019, we had net losses of \$13.5 million and \$18.3 million, respectively.

We are a development stage biotech company developing pharmaceutical product candidates and the success of our product candidates is therefore uncertain. We focus on the development of immunotherapeutic products for the treatment of cancer and autoimmune diseases. We, and our partners, have four product candidates under development : IMP321 (also known as “eftilagimod alpha” or “efti”), IMP761, IMP701 and IMP731, all of which are related to lymphocyte activation gene 3, or LAG-3, a gene linked to the regulation of T cells in immune responses.

We expect to continue to incur losses from operations for the foreseeable future and expect the costs of drug development to increase in the future as more patients are recruited to the clinical trials. In particular, we expect to continue to incur significant losses in carrying out clinical trials of IMP321 and ongoing research and preclinical development in terms of immunotherapy product candidates, such as IMP761. Because of the numerous risks and uncertainties associated with the development, manufacturing, sales and marketing of therapeutic products such as IMP321 and IMP761, we may experience larger than expected future losses and may never become profitable.

Moreover, there is a substantial risk that we, or our development partners, may not be able to complete the development of our current product candidates or develop other pharmaceutical products. It is possible that none of them will be successfully commercialized, which would prevent us from ever achieving profitability.

We have no medicinal products approved for commercial sale and no source of consistent material revenue.

Currently, we have no products approved for commercial sale and to date have not generated material revenue from product sales. We are largely dependent on the future success of our product candidates.

The LAG-3 related product candidates were acquired by us through the acquisition of the French privately owned and venture capital backed company Immutep SA, a biopharmaceutical company in the rapidly growing field of Immuno-Oncology in December 2014. This acquisition significantly expanded our clinical development product portfolio to other categories of immunotherapies. It also provided the business with partnerships with two of the world’s largest pharmaceutical companies.

We have four LAG-3 product candidates. The most advanced of the four is IMP321(INN: eftilagimod alpha). IMP321 is a recombinant protein typically used in conjunction with other therapies (e.g. chemotherapy or other immunotherapy) to amplify a patient’s immune response. The development and manufacturing of IMP321 is being conducted in conjunction with EOC Pharma in China. We entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the United States and Canada), through a subsidiary, to evaluate the combination of our immune activator, IMP321 with MSD’s anti-PD-1 therapy pembrolizumab in phase II clinical trials. We also entered into a clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany, and Pfizer for a Phase I clinical trial that will evaluate the clinical benefits of combining our immune stimulator, IMP321, with avelumab, a PD-L1 blocking antibody.

Our second LAG-3 product candidate is IMP701, an antagonist antibody that acts to stimulate T cell proliferation in cancer patients. IMP701 was licensed to CoStim Pharmaceuticals, which was subsequently acquired by Novartis. Novartis is solely responsible for development and manufacturing of IMP701. Our third LAG-3 product candidate is IMP731, a depleting antibody that could remove T cells involved in autoimmunity. IMP731 has been licensed to GlaxoSmithKline, or GSK, which is solely responsible for its development and manufacturing. Our fourth LAG-3 product candidate is IMP761, an early stage product candidate which is being developed as our first agonist antibody of LAG-3. In addition to these products Immuteq has a dedicated R&D laboratory close to Paris with ongoing research capabilities. Immuteq also currently generates modest income from sales of LAG-3 research reagents.

Our ability to generate product revenue depends on a number of factors, including but not limited to our ability to:

- successfully complete clinical development of, and receive regulatory approval for, our product candidates;
- set an acceptable price for our products, if approved, and obtain adequate coverage and reimbursement from third-party payors;
- obtain commercial quantities of our products, if approved, at acceptable cost levels; and
- successfully market and sell our products, if approved.

There can be no assurance that our or our partners' ability to develop any product candidate, will be successful or our ability to obtain the necessary regulatory approvals with respect to any of the foregoing will be successful. As a result, the prolonged inability to generate revenue may adversely impact our business operations.

The increase in expenses may adversely impact our business if our sources of funding and revenue are insufficient.

We anticipate that as the costs related to the clinical trials for IMP321 will increase, we will require additional funds to achieve our long-term goals of commercialization and further development of IMP321 and other product candidates. In addition, we will require funds to pursue regulatory applications, defend intellectual property rights, increase contracted manufacturing capacity, potentially develop marketing and sales capability and fund operating expenses. We intend to seek such additional funding through public or private financings and/or through licensing of our assets or other arrangements with corporate partners. However, such financing, licensing opportunities or other arrangements may not be available from any sources on acceptable terms, or at all. Any shortfall in funding could result in us having to curtail or cease our operations including research and development activities, thereby harming our business, financial condition and results of operations.

In addition, because of the numerous risks and uncertainties associated with product candidate development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could significantly increase beyond current expectations if the applicable regulatory authorities require further studies in addition to those currently anticipated. In any case, even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of such products and there can be no guarantee that we will ever generate significant revenues.

We will require additional financing and may be unable to raise sufficient capital, which could have a material impact on our research and development programs or commercialization of our products or product candidates.

We have historically devoted most of our financial resources to research and development, including pre-clinical and clinical development activities. To date, we have financed a significant amount of our operations through public and private financings. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. The amount of such future net losses, as well as the possibility of future profitability, will also depend on our success in developing and commercializing products that generate significant revenue. Our failure to become and remain profitable would depress the value of our ordinary shares or ADSs and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We anticipate that our expenses will increase substantially for the foreseeable future if, and as, we:

- continue our research and preclinical and clinical development of our product candidates;
- expand the scope of our current proposed clinical studies for our product candidates;
- initiate additional preclinical, clinical or other studies for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;

- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a publicly quoted company and our product development and planned future commercialization efforts;
- add an internal sales force; and
- experience any delays or encounter issues with any of the above.

Until our product candidates become commercially available, we will need to obtain additional funding in connection with the further development of our product candidates. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. As such, additional financing may not be available to us when needed, on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or obtain funds by entering agreements on unattractive terms. Our resource allocation decisions and the elimination of development programs may result in the failure to capitalize on profitable market opportunities. Furthermore, any additional equity fundraising in the capital markets may be dilutive for stockholders and any debt-based funding may bind us to restrictive covenants and curb our operating activities and ability to pay potential future dividends even when profitable. We cannot guarantee that future financing will be available in sufficient amounts or on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our common stock and ADSs to fall.

If we are unable to secure sufficient capital to fund our operations, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. For example, additional strategic collaborations could require us to share commercial rights to our product candidates with third parties in ways that we do not intend currently or on terms that may not be favorable to us. Moreover, we may also have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

We may find it difficult to enroll patients in our current and any future clinical trials, and patients could discontinue their participation in our current and any future clinical trials, which could delay or prevent our current and any future clinical trials of our product candidates and make those trials more expensive to undertake.

Identifying and qualifying patients to participate in current and any future clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in any future clinical trials because of negative publicity from adverse events in the biotechnology industry. Patients may be unavailable for other reasons, including competitive clinical trials for similar patient populations, and the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed. If we have difficulty enrolling a sufficient number of patients to conduct any future clinical trials as planned, we may need to delay, limit or discontinue those clinical trials. Clinical trial delays could result in increased costs, slower product development, setbacks in testing the safety and effectiveness of our technology or discontinuation of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete any future clinical trials in a timely manner. Patient enrollment is affected by factors including:

- finding and diagnosing patients;
- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions of the potential advantages of the product being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

If we are unable to successfully develop related diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.

We may have to develop related diagnostics for some of our therapeutic product candidates. Such related diagnostics are subject to regulation by the FDA and typically to comparable foreign regulatory authorities as medical devices and typically require separate regulatory approval or clearance prior to commercialization. Marketing approval or clearance of the diagnostic will require sufficient data to support its safety and efficacy. In addition, at least in some cases, the FDA and comparable foreign regulatory authorities may require the development and regulatory approval or clearance of a related diagnostic as a condition to approving our therapeutic product candidates. While we have some, limited experience in developing diagnostics, we plan to rely in large part on third parties to perform these functions. We may seek to enter into arrangements with one or more third parties to create a related diagnostic for use with our current or future product candidates.

If we or any third parties that we engage to assist us, are unable to successfully develop or obtain marketing approval or clearance for related diagnostics for our therapeutic product candidates, or experience delays in doing so:

- the development of relevant product candidates may be delayed or impaired altogether if we are unable to appropriately select patients for enrollment in our clinical trials;
- our relevant therapeutic product candidate may not receive marketing approval if its effective use depends on a related diagnostic in the regulatory authority's judgment; and
- we may not realize the full commercial potential of any therapeutic product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our therapeutic product candidates.

If any of these events were to occur, our business would be harmed.

We are exposed to significant risks related to our ongoing research and development efforts and might not be in a position to successfully develop any product candidate. Any failure to implement our business strategy could negatively impact our business, financial condition and results of operations.

The development and commercialization of IMP321, IMP701, IMP761 and IMP731, or any other product candidate we may develop, is subject to many risks, including:

- additional clinical or pre-clinical trials may be required beyond what we currently expect;
- regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- regulatory authorities may disagree with our proposed design of future clinical trials;
- regulatory authorities may delay approval of our product candidates, thus preventing milestone payments from our collaboration partners;
- regulatory authorities may not accept data generated at our clinical study sites;
- we may be unable to obtain and maintain regulatory approval of our product candidate in any jurisdiction;
- the prevalence and severity of any side effects of any product candidate could delay or prevent commercialization, limit the indications for any approved product candidate, require the establishment of a risk evaluation and mitigation strategy, or REMS, or cause an approved product candidate to be taken off the market;
- regulatory authorities may identify deficiencies in our manufacturing processes or facilities or those of our third-party manufacturers;
- regulatory authorities may change their approval policies or adopt new regulations;
- the third-party manufacturers we expect to depend on to supply or manufacture our product candidates may not produce adequate supply;

- we, or our third-party manufacturers, may not be able to source or produce current Good Manufacturing Practice (cGMP) materials for the production of our product candidates;
- we may not be able to manufacture our product candidates at a cost or in quantities necessary to make commercially successful products;
- we may not be able to obtain adequate supply of our product candidates for our clinical trials;
- we may experience delays in the commencement of, enrolment of patients in and timing of our clinical trials;
- we may not be able to demonstrate that our product candidates are safe and effective as a treatment for its indications to the satisfaction of regulatory authorities, and we may not be able to achieve and maintain compliance with all regulatory requirements applicable to our product candidates;
- we may not be able to maintain a continued acceptable safety profile of our products following approval;
- we may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept our product candidates;
- we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations, and the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations will affect our profitability;
- we may experience competition from existing products or new products that may emerge;
- we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our product candidates; and
- we may not be able to obtain and maintain coverage and adequate reimbursement from third-party payors.

If any of these risks materializes, we could experience significant delays or an inability to successfully develop and commercialize IMP321 and IMP761, or any other product candidate we or our partners may develop, which would have a material adverse effect on our business, financial condition and results of operations.

Positive results from preclinical studies of our product candidates are not necessarily predictive of the results of our 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 can be 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.

We may not make acquisitions in the future, or if we do, we may not be successful in integrating the acquired company, either of which could have a materially adverse effect on our business.

We completed our acquisition of Immuteq S.A.S., in December 2014 for consideration of up to US\$25 million in cash and stock. Although we have completed the integration of Immuteq's business into our own, we may never achieve, the full benefit of the clinical development expectations, product portfolio enhancements or revenue generations we expected at the time of the acquisition. In addition, even if we achieve the expected benefits, we may be unable to achieve them within the anticipated time frame. Also, there may be unexpected problems in the business unrelated to the Immuteq acquisition that have a negative effect on our business. If we fail to implement our business strategy, we may be unable to achieve expected results and our business, financial condition and results of operations may be materially and adversely affected.

Immuteq S.A.S. is the only significant acquisition in our recent history. Identifying strategic acquisitions is part of our business plan. There is, however, no assurance that we will be successful in identifying, negotiating, or consummating any future acquisitions. If we fail to make any future acquisitions, our growth rate could be materially and adversely affected. Any additional acquisitions we undertake could involve the dilutive issuance of equity securities, incurring indebtedness and/or incurring large one-time expenses. In addition, acquisitions involve numerous risks, including difficulties in assimilating the acquired company's operations, the diversion

of our management's attention from other business concerns, risks of entering into markets in which we have had no or only limited direct experience, and the potential loss of customers, key employees and drivers of the acquired company, all of which could have a materially adverse effect on our business and operating results. If we make acquisitions in the future, we cannot guarantee that we will be able to successfully integrate the acquired companies or assets into our business, which would have a materially adverse effect on our business, financial condition, and results of operations.

Ongoing and future clinical trials of product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals for commercial sale.

Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety and to understand the product candidate's side effects at various doses and schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. Further, Phase III clinical trials may not show sufficient safety or efficacy to obtain regulatory approval for marketing. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could require that the clinical trial be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors. If we suffer any significant delays, quality issues, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue the development of our products or product candidates or generate revenue and our business may be severely harmed.

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

The clinical development, manufacturing, sales and marketing of our products are subject to extensive regulation by regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere. Despite the substantial time and expense invested in preparation and submission of a Biologic License Application or equivalents in other jurisdictions, regulatory approval is never guaranteed. The number, size and design of preclinical studies and clinical trials that will be required will vary depending on the product, the disease or condition for which the product is intended to be used and the regulations and guidance documents applicable to any particular product. The FDA or other regulators can delay, limit or deny approval of a product for many reasons, including, but not limited to, the fact that regulators may not approve our or a third-party manufacturer's processes or facilities or that new laws may be enacted or regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product.

IMP321 and our other product candidates are undergoing clinical trials; however, successful results in the trials and in the subsequent application for marketing approval are not guaranteed. Without additional clinical trials any other product candidate in the current portfolio cannot obtain a regulatory approval. If we are unable to obtain regulatory approvals, we will not be able to generate revenue from this product candidate or any other candidate. Even if we receive regulatory approval for IMP321 or any product candidate, our profitability will depend on our ability to generate revenues from their sale or the licensing of our technology.

Even if our product candidates receive regulatory approval, it may still face development and regulatory difficulties that may delay or impair future sales of product candidates.

Even if we or our licensing partners receive regulatory approval to sell IMP321 or any other product candidate, the relevant regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labelling, packaging, adverse event reporting, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies. In addition, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. In addition, new statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our products.

We have limited manufacturing experience with our product candidates.

We have no manufacturing capabilities and are dependent on third parties for cost effective manufacture and manufacturing process development of the company's product candidates. Problems with third party manufacturers or the manufacturing process, or the scaling up of manufacturing activities as such may delay clinical trials and commercialization of our product candidates. To minimize the chance of these kinds of disruption, we enter into advance purchase agreements for reagents wherever possible.

Biological product candidates like IMP731, IMP701, IMP761 or IMP321 usually have more complicated manufacturing procedures than chemically produced therapies. The change of manufacturing partners, manufacturing process changes or changes of other nature could impact the product quality and affect the comparability of different product batches. A lack of comparability could significantly impact the development timelines and could even lead to a situation where regulatory bodies require additional or new pre-clinical or clinical development.

To the extent we rely significantly on contractors, we will be exposed to risks related to the business and operational conditions of our contractors.

We are a small company, with few internal staff and limited facilities. We are and will be required to rely on a variety of contractors to manufacture and transport our products, to perform clinical testing and to prepare regulatory dossiers. Adverse events that affect one or more of our contractors could adversely affect us, such as:

- a contractor is unable to retain key staff that have been working on our product candidates;
- a contractor is unable to sustain operations due to financial or other business issues;
- a contractor loses their permits or licenses that may be required to manufacture our products or product candidates; or
- errors, negligence or misconduct that occur within a contractor may adversely affect our business.

We depend on, and will continue to depend on, collaboration and strategic alliances with third partners. To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

An important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into partnerships and strategic alliances with other pharmaceutical companies or other industry participants. For example, we currently have collaborative arrangements with EOC Pharma for the development of IMP321 for China, Hong Kong, Macau and Taiwan. Any revenues from sales of any of our partnered product candidates will depend on the success of the collaboration partner.

Any partnerships or alliance we have or may have in the future may be terminated for reasons beyond our control or we may not be able to negotiate future alliances on acceptable terms, if at all. These arrangements may result in us receiving less revenue than if it sold its products directly, may place the development, sales and marketing of its products outside of its control, may require it to relinquish important rights or may otherwise be on unfavorable terms. Collaborative arrangements or strategic alliances will also subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partner/collaborators may devote to the product candidates;
- strategic partner/collaborators may experience financial difficulties;
- the failure to successfully collaborate with third parties may delay, prevent or otherwise impair the development or commercialization of our product candidates or revenue expectations;
- products being developed by partners/collaborators may never reach commercial stage resulting in reduced or even no milestone or royalty payments;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete their obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing product candidates.

Because we rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party supply and manufacturing partners to manufacture and supply the materials for our research and development and preclinical and clinical study supplies. We do not own manufacturing facilities or supply sources for such materials.

There can be no assurance that our supply of research and development, preclinical and clinical development biologics and other materials will not be limited, interrupted or restricted in certain geographic regions, be of satisfactory quality or continue to be available at acceptable prices. Replacement of a third-party manufacturer could require significant effort, cost and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which would be costly and delay any future clinical trials.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party. These factors increase our reliance on our manufacturers and may require us to obtain a license from a manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines of the FDA and comparable foreign regulatory authorities. The delays and costs associated with the verification of a new manufacturer could increase our costs and delay the development of our product candidates.

We expect to continue to rely on third-party manufacturers for preclinical and clinical grade product candidates and if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements could adversely affect our business in a number of ways, including:

- an inability to conduct necessary preclinical studies to progress our product candidates to clinical trials;
- an inability to initiate or continue any future clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of a collaborator;
- subjecting our product candidates to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

We and our collaborators may disagree over our right to receive payments under our collaboration agreements, potentially resulting in costly litigation and loss of reputation.

Our ability to receive payments under our collaboration agreements depends on our ability to clearly delineate our rights under those agreements. We have out-licensed portions of our intellectual property to our collaborators with the intent that our collaborators will develop product candidates. However, a collaborator may use our intellectual property without our permission, dispute our ownership of intellectual property rights, or argue that our intellectual property does not cover, or add value to, any product candidates they develop. If a dispute arises, it may result in costly patent office procedures and litigation, and our collaborator may refuse to pay us while the dispute is ongoing. Furthermore, regardless of any resort to legal action, a dispute with a collaborator over intellectual property rights may damage our relationship with that collaborator and may also harm our reputation in the industry. Even if we are entitled to payments from our collaborators, we may not actually receive these payments, or we may experience difficulties in collecting the payments to which we believe we are entitled. After our collaborators launch commercial products containing our licensed traits, we will need to rely on the good faith of our collaborators to report to us the sales they earn from these products and to accurately calculate the payments we are entitled to, a process that will involve complicated and difficult calculations. Although we seek to address these concerns in our collaboration agreements by reserving our right to audit financial records, such provisions may not be effective.

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

Changes in our senior management may be disruptive to our business and may adversely affect our operations. For example, when we have changes in senior management positions, we may elect to adopt different business strategies or plans. Any new strategies or plans, if adopted, may not be successful and if any new strategies or plans do not produce the desired results, our business may suffer.

Moreover, competition among biotechnology and pharmaceutical companies for qualified employees is intense and as such we may not be able to attract and retain personnel critical to our success. Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our product development and commercialization activities.

In addition, biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our product candidates may be or become uncompetitive. To remain competitive, we must employ and retain suitably qualified staff that are continuously educated to keep pace with changing technology, but may not be in a position to do so.

Future potential sales of our products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

There is a risk that IMP321 or any other product candidate may not gain market acceptance among physicians, patients and the medical community, even if they are approved by the regulatory authorities. The degree of market acceptance of any of our approved products will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive products;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our products;
- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

Physicians, patients, payers or the medical community may be unwilling to accept, use or recommend our product candidates which would adversely affect our potential revenues and future profitability.

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.

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 payers, and any new treatments that enter the market.

There may be a significant number of products that 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.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources and experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position.

Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or non-competitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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

Our product candidates may be rejected by the market due to many factors, including cost. The continuing efforts of governments, insurance companies and other payers of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability. In Australia and certain foreign markets, the pricing of pharmaceutical products is already subject to government control. We expect initiatives for similar government control to continue in the United States and elsewhere. The adoption of any such legislative or regulatory proposals could harm our business and prospects.

Successful commercialization of our product candidates 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 insurers and other organizations. Our product candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Third-party payers are increasingly challenging the price of medical products and treatment. If third party coverage is not available for our products the market acceptance of these products will be reduced. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues lower than anticipated. If the price for our product candidates decreases or if governmental and other third-party payers do not provide adequate coverage and reimbursement levels our potential revenue and prospects for profitability will suffer.

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

The testing, marketing and sale of therapeutic products entails an inherent risk of product liability. We rely on a number of third party researchers and contractors to produce, collect, and analyze data regarding the safety and efficacy of our product candidates. We also have quality control and quality assurance in place to mitigate these risks, as well as professional liability and clinical trial insurance to cover financial damages in the event that human testing is done incorrectly or the data is analyzed incorrectly.

Notwithstanding our control procedures, we may face product liability exposure related to the testing of our product candidates in human clinical trials. If any of our products are approved for sale, we may face exposure to claims by an even greater number of persons than were involved in the clinical trials once marketing, distribution and sales of our products begin. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize products and product candidates.

With respect to product liability claims, we could face additional liability beyond insurance limits if testing mistakes were to endanger any human subjects. In addition, if a claim is made against us in conjunction with these research testing activities, the market price of our ordinary shares or ADSs may be negatively affected.

We and our development partners, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and our development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our third-party manufacturers and suppliers may also produce hazardous waste products. National, state and local laws and regulations in the United States, Australia and other countries govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development and commercialization efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and any future clinical trials, regulatory approvals or product commercialization progress could be suspended.

Our status as emerging growth company may reduce the amount of information available to investors

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Accordingly, this allows us to postpone the date by which we must comply with some of the laws and regulations that are otherwise applicable to public companies and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our ordinary shares or ADSs.

We would cease to be an “emerging growth company” upon the earliest of: (i) the last day of our fiscal year following the fifth anniversary of the date of the first sale of our initial U.S. public offering, which closed on July 5, 2017; (ii) the last day of the first fiscal year in which we have total annual gross revenues of at least US\$1.1 billion; (iii) the date on which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares (including ordinary shares represented by ADSs) that is held by non-affiliates exceeds US\$700 million as of the end of the second quarter of our last completed fiscal year; and (iv) the date on which we have issued more than US\$1 billion in non-convertible debt during a three-year period.

For so long as we remain an “emerging growth company,” we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not “emerging growth companies,” including, but not limited to, the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting. As a result, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting for so long as we qualify as an “emerging growth company,” which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our non-clinical studies and clinical trials.

Public health crises such as pandemics or similar outbreaks might adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, COVID-19 has spread to most countries in the world.

As a result of the COVID-19 outbreak, or similar pandemics, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances at contract research organizations and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or not wanting to attend hospital visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by national, state or local governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration, the European Medicines Agency, the Australian Therapeutic Goods Administration or other foreign regulatory agencies, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in our supply chain or distribution vendors’ ability to ship product candidates; and
- limitations on employee resources that would otherwise be focused on the conduct of our non-clinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our American Depositary Shares, or ADSs, and for the securities of other biotech companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our ADSs or such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in countries, business closures or business disruptions and the effectiveness of actions taken in countries to contain and treat the disease.

Additionally, COVID-19 may hinder the ability of our license partners to continue the development of our licensed product candidates. This may result in the delay or the inability of the partners to execute on their development plans which, in turn, may cause delays in or the inability to achieve the clinical, regulatory and sales milestones which trigger payments to us under the terms of our license agreements. This may have a material adverse effect on our financial results and operations as the related milestone payments may not be received at the expected time, if at all.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technology.

Our success is to a certain degree also dependent on our ability to obtain and maintain patent protection or where applicable, to receive/maintain orphan drug designation/status and resulting marketing exclusivity for our product candidates.

We may be materially adversely affected by our failure or inability to protect our intellectual property rights. Without the granting of these rights, the ability to pursue damages for infringement would be limited. Similarly, any know-how that is proprietary or particular to our technologies may be subject to risk of disclosure by employees or consultants despite having confidentiality agreements in place.

Any future success will depend in part on whether we can obtain and maintain patents to protect our own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of third parties. Biotechnology patent matters can involve complex legal and scientific questions, and it is impossible to predict the outcome of biotechnology and pharmaceutical patent claims. Any of our future patent applications may not be approved, or we may not develop additional products or processes that are patentable. Some countries in which we may sell our product candidate or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the United Kingdom, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Even if we are able to obtain patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

Moreover, any of our pending applications may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, the Australian Patent and Trademark Office and/or any patents issuing thereon may become involved in opposition, derivation, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to the inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S., the EU, Australia and elsewhere. Such challenges may result in loss of ownership or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the EU, Australia and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights.

Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful.

Intellectual property rights of third parties could adversely affect our ability to commercialize our products, such that we could be required to litigate with or obtain licenses from third parties in order to develop or market our products. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success may somewhat depend upon our future ability and the ability of our potential collaborators to develop, manufacture, market and sell our product candidates without infringing valid intellectual property rights of third parties.

If a third-party intellectual property right exists it may require the pursuit of litigation or administrative proceedings to nullify or invalidate the third-party intellectual property right concerned, or entry into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders, including our competitors, may bring infringement claims against us. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims or otherwise resolve such claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our product candidate.

If we fail to settle or otherwise resolve any such dispute, in addition to being forced to pay damages, we or our potential collaborators may be prohibited from commercializing any product candidates we may develop that are held to be infringing, for the duration of the patent term. We might, if possible, also be forced to redesign our formulations so that we no longer infringe such third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our technology and product candidates, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our product candidates.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us. In other cases, we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various corresponding governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We may become involved in lawsuits to protect and defend our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property and we may inadvertently infringe the patent or intellectual property of others. To counter infringement or unauthorized use, we may be required to file claims, and any related litigation and/or prosecution of such claims can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid in whole or in part, unenforceable, or construe the patent's claims narrowly allowing the other party to commercialize competing products on the grounds that our patents do not cover such products.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. 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. The effects of patent litigation or other proceedings could therefore have a material adverse effect on our ability to compete in the marketplace.

If we do not obtain patent term extension for our products, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any products we may develop, we may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the drug testing phase and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Other jurisdictions including Australia, Europe and Japan have similar extension of term provisions, whilst other countries do not have any such provisions.

Confidentiality and invention assignment agreements with our employees, advisors and consultants 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, advisors and consultants to enter into confidentiality and invention assignment agreements with us. However, current or former employees, advisors and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality and invention assignment 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 and invention assignment 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.

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 our intellectual property rights.
- 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 any pending patent applications that we have filed, or will file, 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 by our competitors.
- 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.
- Ownership of our patents or patent applications may be challenged by third parties.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

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 candidate.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and exploiting patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and exploiting biopharmaceutical patents is costly, time-consuming and inherently uncertain. 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. Such examples include:

- *Impression Products, Inc. v. Lexmark International, Inc.* (2017), where the Court applied an international exhaustion of rights standard and held that the sale of a patented item in a foreign country exhausted patent rights in the item being sold regardless of any post-sale restrictions the patentee attempted to impose.
- *TC Heartland LLC v. Kraft Foods Group Brands LLC* (2017), the Court applied a narrow interpretation to the term “resides” and held that patent infringement cases must be heard in the district within which the defendant is incorporated. This decision limits the ability of the patentee to “forum shop” when bringing an action for infringement.
- *Nautilus, Inc. v. Biosig Instruments, Inc.* (2014), where the Court imposed a stricter requirement for clarity of claim language than previously applied by the Federal Circuit, thereby making it easier to invalidate patents for insufficiently apprising the public of the scope of the invention.
- *Limelight Networks, Inc. v. Akamai Technologies, Inc.* (2014), where the Court articulated a standard for inducement of infringement that makes it more difficult to establish liability for inducing infringement of a multi-step method claim that is performed by multiple parties.
- *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013), where the Court held that isolated naturally-occurring DNA is patent ineligible subject matter.
- *KSR v. Teleflex* (2007), where the Court decided unanimously that the Federal Circuit Court had been wrong in taking a narrow view of when an invention is “obvious” and thus cannot be patented.

- eBay Inc. v. MercExchange, LLC (2006), where the Court heightened the standard for an injunction after a finding of patent infringement.
- Merck KGaA v. Integra Lifesciences (2004), where the Court adopted an expansive interpretation of the activities associated with regulatory approval exempt from patent infringement.

In addition, the America Invents Act, or AIA, has been enacted in the United States, resulting in significant changes to the U.S. patent system. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the combination of the U.S. Supreme Court decisions and AIA has created uncertainty with respect to the value of patents, once obtained. A few highlights of changes to U.S. patent law under the AIA are:

- Under the AIA, a patent is awarded to the “first-inventor-to-file” rather than the first to invent.
- There is a new definition of prior art which removes geographic and language boundaries found in the pre-AIA law. At the same time, certain categories of “secret” prior art have been eliminated.
- The AIA introduced new procedures for challenging the validity of issued patents: post-grant review and inter partes review.
- Patent owners under the AIA may now request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent.
- The AIA allows third parties to submit any patent, published application, or publication relevant to examination of a pending patent application with a concise explanation for inclusion during prosecution of the patent application.

The “first-inventor-to-file” system and the new definitions of prior art apply to U.S. patent applications with claims having an effective filing date on or after March 16, 2013. Until at least 2034, patent practice will involve both pre-AIA and AIA laws. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to exploit 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 in the type of amendments that are allowed during prosecution. Changes in patent law or patent jurisprudence could limit our ability to obtain new patents in the future that may be important for our business.

We may face difficulties with protecting our intellectual property in certain jurisdictions, 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 EU, 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.

Some countries in Europe and China 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 are, 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 or commercial advantage may be impaired and our business and results of operations may be adversely affected.

Risks Relating to Our Securities

Our stock price is volatile and could decline significantly.

The market price of our ordinary shares and ADSs historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due to factors specific to us, to changes in analysts’ recommendations and earnings estimates, to arbitrage between our Australian-listed ordinary shares and our NASDAQ-listed ADSs, to changes in exchange rates, or to factors affecting the biopharmaceutical industry or the securities markets in general. Market fluctuations, as well as general political and economic conditions, such as a recession, interest rate or currency fluctuations, could adversely affect the market price of our securities.

For example, during the last two fiscal years, the market price for our ordinary shares on the Australian Securities Exchange and ADSs on NASDAQ has ranged from a low of A\$0.10 and US\$0.53, respectively, to a high of A\$0.56 and US\$4.21, respectively. We may experience a material decline in the market price of our shares, regardless of our operating performance. Therefore, a holder of our ordinary shares or ADSs may not be able to sell those ordinary shares or ADSs at or above the price paid by such holder for such shares or ADSs. Price declines in our ordinary shares or ADSs could result from a variety of factors, including many outside our control. These factors include:

- the results of pre-clinical testing and clinical trials by us and our competitors;
- unforeseen safety issues or adverse side effects resulting from the clinical trials or the commercial use of our product candidate;
- regulatory actions in respect of any of our products or the products of any of our competitors;
- announcements of the introduction of new products by us or our competitors;
- market conditions, including market conditions in the pharmaceutical and biotechnology sectors;
- increases in our costs or decreases in our revenues due to unfavorable movements in foreign currency exchange rates;
- developments or litigation concerning patents, licenses and other intellectual property rights;
- litigation or public concern about the safety of our potential products;
- changes in recommendations or earnings estimates by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- additions or departures of key personnel;
- changes in third-party reimbursement policies; and
- developments concerning current or future strategic alliances or acquisitions.

In addition, volatility and low market price of our ordinary shares and/or ADSs may adversely impact investors' interest in our securities. A decline in investors' interest may prompt further volatility and decrease in market price.

Our ordinary shares may be considered a "penny stock" under SEC regulations which could adversely affect market trading in our ADSs.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. During the fiscal year ended June 30, 2020, our ordinary shares traded on the NASDAQ from low of US\$0.53 to a high of US\$3.10 per share. During the fiscal year ended June 30, 2019, our ordinary shares traded on the NASDAQ from a low of US\$1.71 to a high of US\$4.21 per share. Penny stock rules impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors." The term "accredited investor" refers generally to institutions with assets in excess of US\$5,000,000 or individuals with a net worth in excess of US\$1,000,000 or annual income exceeding US\$200,000 or US\$300,000 jointly with their spouse in each of the prior two years.

The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC, which provides (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation of such duties or other requirements of the securities laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and the significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form, including language, type size and format, as the SEC shall require by rule or regulation.

The broker-dealer also must provide, prior to effecting any transaction in a penny stock, the customer with (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) a monthly account statement showing the market value of each penny stock held in the customer's account.

In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement as to transactions involving penny stocks, and a signed and dated copy of a written suitability statement.

These disclosure requirements may significantly burden trading in, and delay the execution of transactions in, our ADSs. Thus, if our ADSs are considered penny stock, these disclosure requirements may adversely impact market trading in our ADSs.

If we are or become a passive foreign investment company (PFIC), then that would subject our U.S. investors to adverse tax rules.

Holders of our ADSs who are U.S. residents face income tax risks if we are a passive foreign investment company, or PFIC, which could result in a reduction in the after-tax return to a "U.S. Holder" of our ADSs and reduce the value of our ADSs. For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, cash is considered to be an asset that produces passive income.

If we are classified as a PFIC in any year that a U.S. Holder owns ADSs, the U.S. Holder will generally continue to be treated as holding ADSs of a PFIC in all subsequent years, notwithstanding that we are not classified as a PFIC in a subsequent year. Dividends received by the U.S. Holder and gains realized from the sale of our ADSs would be taxed as ordinary income and subject to an interest charge. We urge U.S. investors to consult their own tax advisors about the application of the PFIC rules and certain elections that may help to minimize adverse U.S. federal income tax consequences in their particular circumstances.

We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that holders of shares and ADSs may not receive any return on their investment from dividends.

To date, we have not declared or paid any cash dividends on our ordinary shares and currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. Dividends may only be paid out of our profits. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors. Our holders of shares and ADSs may not receive any return on their investment from dividends. The success of your investment will likely depend entirely upon any future appreciation of the market price of our ordinary shares and ADSs, which is uncertain and unpredictable. There is no guarantee that our ordinary shares and ADSs will appreciate in value or even maintain the price at which you purchased your ordinary shares and ADSs.

Currency fluctuations may adversely affect the price of the ADSs relative to the price of our ordinary shares.

The price of our ordinary shares is quoted in Australian dollars and the price of our ADSs is quoted in U.S. dollars. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of our ADSs and the U.S. dollar equivalent of the price of our ordinary shares. In the last two years, the value of the Australian dollar remained relatively stable against the U.S. dollar. There can be no assurance, however, that this trend will continue. If the Australian dollar weakens against the U.S. dollar, the U.S. dollar price of the ADSs could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged.

The requirements of being a public company may strain our resources and divert management's attention and if we are unable to maintain effective internal control over financial reporting in the future, the accuracy and timeliness of our financial reporting may be adversely affected.

As a publicly-traded company, we are subject to the reporting requirements of the U.S. Securities Exchange Act of 1934, as amended (the Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file certain reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, beginning with fiscal year ended on June 30, 2013, we have performed system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We have in prior fiscal years identified material weaknesses that have been remediated. If we identify material weaknesses in future periods or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be restated, we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the market price of our stock could decline.

The listing of our securities on stock exchanges in different countries may adversely impact their liquidity.

Our ordinary shares are listed and traded on the ASX, NASDAQ and on Over The Counter markets within Germany. Price levels for our ordinary shares could fluctuate significantly on either market, independent of our share price on the other market. Investors could seek to sell or buy our shares to take advantage of any price differences between the three markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in our share prices on either exchange and the volumes of shares available for trading on either exchange. In addition, holders of shares in either jurisdiction will not be immediately able to transfer such shares for trading on the other markets without effecting necessary procedures with our transfer agent. This could result in time delays and additional cost for our shareholders. Further, if we are unable to continue to meet the regulatory requirements for listing on the ASX and NASDAQ, we may lose our listing on any of these exchanges, which could impair the liquidity of our shares.

Risks Related to an Investment in Our ADSs

Our ADS holders are not shareholders and do not have shareholder rights.

The Bank of New York Mellon, as depositary, registers and delivers our American Depositary Shares, or ADSs. Our ADS holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADSs. Holders of our ADSs will have ADS holder rights. A deposit agreement among us, the depositary and our ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. For a description of ADS holder rights, see “Item 12. Description of Securities Other than Equity Securities–D. American Depositary Shares.”

Our shareholders have shareholder rights. Australian law and our constitution govern shareholder rights. For a description of our shareholders’ rights, see “Item 10. Additional Information–B. Memorandum and Articles of Association.” Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares.

Our ADS holders do not have the same voting rights as our shareholders. ADS holders may exercise voting rights with respect to the underlying ordinary shares only in accordance with the provisions of the deposit agreement. Under the deposit agreement, ADS holders vote by giving voting instructions to the depositary. Upon receipt of instructions, the depositary will try to vote in accordance with those instructions. Otherwise, ADS holders will not be able to vote unless they withdraw the ordinary shares underlying their ADSs.

If we ask for our ADS holders’ instructions, the depositary will notify our ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as practical, subject to Australian law and the provisions of the depositary agreement, to vote the shares as our ADS holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADS holders. We cannot assure our ADS holders that they will learn of ordinary shareholders’ meetings and receive the voting materials in time to instruct the depositary or withdraw the underlying ordinary shares. This means that there is a risk that our ADS holders may not be able to exercise voting rights and there may be nothing they can do if their shares are not voted as they requested.

Our ADS holders do not have the same rights to receive dividends or other distributions as our shareholders.

Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary stock and we do not anticipate paying any cash dividends in the foreseeable future). Dividends may be paid on shares of one class but not another and at different rates for different classes. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to our ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Our ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADS holders amounts distributed by us as a dividend or distribution.

There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADSs.

The deposit agreement with the depositary generally requires the depositary to convert foreign currency it receives in respect of deposited securities into U.S. dollars and distribute the U.S. dollars to ADS holders, provided the depositary can do so on a reasonable basis. If it does not convert foreign currency, the depositary may distribute the foreign currency only to those ADS holders to whom it is possible to do so. If a distribution is payable by us in Australian dollars, the depositary will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, our ADS holders may lose some of the value of the distribution. The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. This means that our ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available.

If we fail to comply with the Nasdaq listing requirements, Nasdaq could delist the ADSs, which could limit liquidity of the ADSs and adversely affect our business and access to future capital.

The ADSs are listed on the Nasdaq Global Market under the symbol "IMMP." In the past we have failed, and in the future we may again fail, to comply with the Nasdaq Global Market regulations and listing requirements as to minimum stockholders' equity, minimum market value, minimum total assets and revenue, minimum bid price, minimum public float and/or other requirements, and as a result Nasdaq may initiate procedures to delist the ADSs from the Nasdaq Global Market, which may adversely affect our business.

If we fail to meet Nasdaq's continued listing rules, the ADSs may be delisted from the Nasdaq Global Market. Delisting from the Nasdaq Global Market could have an adverse effect on our business, including our ability to access future capital, and on the trading of the ADSs. If a delisting of the ADSs were to occur, the ADSs may trade in the over-the-counter market such as on the OTC Bulletin Board or on the "pink sheets". The over-the-counter market is generally considered to be a less efficient market, and this could diminish investors' interest in the ADSs as well as significantly impact the price and liquidity of the ADSs. Any such delisting may also adversely affect the trading of the ADSs by ADS holders, or impede them from liquidating their holdings. Delisting may also adversely impact the success of future issues of securities or the possibility to receive additional financing, particularly in the United States.

Risks Relating to Our Location in Australia

Currency fluctuations may expose us to increased costs and revenue decreases.

Our business is affected by fluctuations in foreign exchange rates. Our expenses are denominated in Australian dollars, U.S. dollars and European euro. Last two years, the Australian dollar had depreciated against the U.S. dollar and European Euro, whereas in fiscal 2017, the Australian dollar had appreciated against the U.S. dollar and European Euro. We conduct clinical trials in many different countries and we have manufacturing of our product candidate undertaken outside of Australia, which exposes us to potential cost increases resulting from fluctuations in exchange rates. In fiscal 2020, we made net foreign exchange gain of A\$346,000 as a result of currency fluctuations. In fiscal 2019, we made net foreign exchange gain of A\$494,000 as a result of currency fluctuations. In fiscal 2018, there was a foreign exchange gain of A\$323,000 as a result of currency fluctuations. Currency fluctuations could, therefore, cause our costs to increase and revenues to decline.

Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.

We are incorporated in Australia and are subject to the takeovers laws of Australia. Amongst other things, we are subject to the Corporations Act 2001 (Commonwealth of Australia). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares (including through the acquisition of ADSs) if the acquisition of that interest will lead to a person's or someone else's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Exceptions to the general prohibition include circumstances where the person makes a formal takeover bid for us, if the person obtains shareholder approval for the acquisition or if the person acquires less than 3% of the voting power of us in any rolling six month period. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.