Item 3.B Capitalisation and Indebtedness

Not applicable.

Item 3.C Reasons for the Offer and Use of Proceeds

Not applicable.

Item 3.D Risk Factors

Before you purchase our ADSs, you should be aware that there are risks, including those described below. You should consider carefully these risk factors together with all of the other information contained elsewhere in this Annual Report before you decide to purchase our ADSs.

Risks Related to our Business

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

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

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

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

Our Company has a history of incurring losses.

We have incurred operating losses in every year since the year ended June 30, 2011. As at June 30, 2021, the Company had accumulated losses of A$143,075,218 and the extent of any future losses and whether or not the Company can generate profits in future years remains uncertain. The Company currently does not generate sufficient revenue to cover its operating expenses. We expect our capital outlays and operating expenditures to remain constant for the foreseeable future as we continue to focus on R&D and new product development, IP creation and the introduction of predictive genetic testing products. If we fail to generate sufficient revenue and eventually become profitable, or if we are unable to fund our continuing losses by raising additional financing when required, our shareholders could lose all or part of their investments.

We may not be successful in transitioning from our existing product portfolio to our next generation of risk assessment tests, and our newly developed approach to marketing and distribution of such products may not generate revenues.

Although we developed and marketed our BREVAGen™ and BREVAGen*plus* products in the recent past, and had internally developed product distribution teams in both Australia and the U.S., we believe that our future success is dependent upon our ability to successfully introduce and sell our newly developed products, "GeneType for Breast Cancer", "GeneType for Colorectal Cancer" and or COVID severity risk test. Although we believe that we now have world class products that are poised to be an important part of making predictive genetic testing a mainstream healthcare activity, we may not be successful in transitioning from our existing products to these products, and there can be no assurance that the demand for these new products will develop. Furthermore, we plan to introduce our new products to healthcare providers through a global network of distribution partners instead of through our own sales force. Although we believe that we are building worthwhile sales and distribution relationships with experienced United States distribution firms, there can be no assurance that we will be able to enter into distribution arrangements on terms satisfactory to us, and that our marketing strategy will be successful and result in significant revenues.

Our products may never achieve significant market acceptance.

We may expend substantial funds and management effort on the development and marketing of our predictive genetic testing products with no assurance that we will be successful in selling our products or services. Our ability to enter into distribution arrangements to successfully sell our molecular risk assessment and predictive genetic testing products and services will depend significantly on the perception that our products and services can reduce patient risk and improve medical outcomes, and that our products and services are superior to existing tests. Our business could also be adversely affected if we expend money without any return.

Failure to demonstrate the clinical utility of our products could have a material adverse effect on our financial condition and results of operations.

The Company believes that its GeneType for Breast Cancer, GeneType for Colorectal Cancer and COVID severity risk tests, along with the pipeline of new tests under development have the capacity to transform health outcomes for entire populations. However, it is critical for the Company to demonstrate the clinical utility of its new products. Clinical utility is the usefulness of a test for clinical practice. If the Company is unable to demonstrate clinical utility, or if the data is deemed insufficient to validate utility, there may be insufficient demand for the Company's products.

If our competitors develop superior products, our operations and financial condition could be affected.

We are currently subject to increased competition from biotechnology and diagnostic companies, academic and research institutions and government or other publicly-funded agencies that are pursuing products and services which are substantially similar to our molecular risk assessment testing products, or which otherwise address the needs of our customers and potential customers.

Our competitors in the predictive genetic testing and assessment market include private and public sector enterprises located in Australia, the U.S. and elsewhere. Many of the organisations competing with us are much larger and have more ready access to needed resources. In particular, they would have greater experience in the areas of finance, research and development, manufacturing, marketing, sales, distribution, technical and regulatory matters than we do. In addition, many of the larger current and potential competitors have already established name / brand recognition and more extensive collaborative relationships.

Our competitive position in the molecular risk assessment and predictive testing area is based upon, amongst other things, our ability to:

- continue to strengthen and maintain scientific credibility through the process of obtaining scientific validation through clinical trials supported by peer-reviewed publication in medical journals;
- create and maintain scientifically advanced technology and offer proprietary products and services;
- continue to strengthen and improve the messaging regarding the importance and value that our cancer risk assessment tests provide to patients and physicians;
- diversify our product offerings in disease types other than breast cancer, colorectal cancer and COVID severity risk test;
- obtain and maintain patent or other protection for our products and services;
- obtain and maintain required government approvals and other accreditations on a timely basis; and
- successfully market our products and services.

If we are not successful in meeting these goals, our business could be adversely affected. Similarly, our competitors may succeed in developing technologies, products or services that are more effective than any that we are developing or that would render our technology, products and services obsolete, noncompetitive or uneconomical.

We have important relationships with external parties over whom we have limited control.

We have relationships with academic consultants, research collaborators at other institutions and other advisers who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results from operations. To the extent that our scientific consultants, collaborators or advisors develop inventions or processes that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, and we may not be successful with any dispute outcomes.

We may be subject to liability and our insurance may not be sufficient to cover damages.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of molecular risk assessment and predictive tests. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to professional and product liability claims and possible adverse publicity. We may be subject to claims resulting from incorrect results of analysis of genetic variations or other screening tests performed using our products. Litigation of such claims could be costly. Further, if a court were to require us to pay damages to a plaintiff, the amount of such damages could be significant and severely damage our financial condition. Although we have public and product liability insurance coverage under broad form liability and professional indemnity policies, the level or breadth of our coverage may not be adequate to fully cover any potential liability claims. In addition, we may not be able to obtain additional liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of professional and/or product liability litigation upon the reputation and marketability of our technology and products, together with the diversion of the attention of key personnel, could negatively affect our business.

We use potentially hazardous materials, chemicals and patient samples in our business and any disputes relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development, production and service activities involve the controlled use of hazardous laboratory materials and chemicals, including small quantities of acid and alcohol, and patient tissue samples. We do not knowingly deal with infectious samples. We, our collaborators and service providers are subject to stringent Australian federal, state and local laws and regulations governing occupational health and safety standards, including those governing the use, storage, handling and disposal of these materials and certain waste products. However, we could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If we, our collaborators or service providers fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict our operations.

In addition, our collaborators and service providers may be working with these same types of hazardous materials, including hazardous chemicals, in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials or patient samples that may contain infectious materials. The cost of this liability could exceed our resources. While we maintain broad form liability insurance coverage for these risks, the level or breadth of our coverage may not be adequate to fully cover potential liability claims.

We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialisation of our products. A breach by our partners of their obligations, or the termination of the relationship, could deprive us of valuable resources and require additional investment of time and money.

Our strategy for research, development and commercialisation of our products has historically involved entering into various arrangements with academic, corporate partners and others. As a result, the success of our strategy depends, in part, upon the strength of those relationships and these outside parties undertaking their responsibilities and performing their tasks to the best of their ability and responding in a timely manner. Our collaborators may also be our competitors. We cannot necessarily control the amount and timing of resources that our collaborators devote to performing their contractual obligations and we have no certainty that these parties will perform their obligations as expected or that any revenue will be derived from these arrangements.

If our collaborators breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities in a timely manner, the development or commercialisation of the product candidate or research program under such collaborative arrangement may be delayed. If that is the case, we may be required to undertake unforeseen additional responsibilities or to devote unforeseen additional funds or other resources to such development or commercialisation, or such development or commercialisation could be terminated. The termination or cancellation of collaborative arrangements could adversely affect our financial condition, intellectual property position and general operations. In addition, disagreements between collaborators and us could lead to delays in the collaborative research, development, or commercialisation of certain products or could require or result in formal legal process or arbitration for resolution. These consequences could be time-consuming and expensive and could have material adverse effects on the Company.

We rely upon scientific, technical and clinical data supplied by academic and corporate collaborators, licensors, licensees, independent contractors and others in the evaluation and development of potential therapeutic methods. There may be errors or omissions in this data that would materially adversely affect the development of these methods.

If our sole laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.

We rely on our sole laboratory facilities in Melbourne, Australia, which has been certified under the U.S. Clinical Laboratory Improvements Amendments ("CLIA"). Our current lease of laboratory premises expires February 28, 2022. The facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. If we were to lose our CLIA certification or other required certifications or licenses, or if the facility is harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, it will be difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future.

If we no longer had our own facility and needed to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation. We cannot assure you that we would be able to find another CLIA certified facility willing to comply with the required procedures, that this laboratory would be willing to perform the tests on commercially reasonable terms, or that it would be able to meet our quality standards. In order to establish a redundant clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical as we continue to develop our technologies and testing processes, continue our international expansion and transition to a company with multiple commercialised products. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

During the year, we experienced significant changes in our executive officers, including the appointment of Simon Morriss as our Chief Executive Officer on February 1, 2021 with Jerzy Muchnicki who had been acting CEO since September 21, 2019, stepping into the role of Chief Medical Officer and Executive Director. Mike Tonroe has been appointed Chief Financial Officer in June 15, 2021 taking over from Philip Hains who had been in role since July 15, 2019, While we believe our current executive officers have the skills and experience to enable us to execute our business plan, these changes may nevertheless result in a transition phase that could adversely affect our operations in the short-term.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including licensed laboratory technicians, chemists, biostatisticians and engineers. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses. In addition, if there were to be a shortage of clinical laboratory scientists in coming years, this would make it more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and close relationships with medical oncologists, pathologists and other hospital personnel. We may have difficulties sourcing, recruiting or retaining qualified salespeople, which could cause delays or a decline in the rate of adoption of our tests. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development and sales programs.

Changes in the way that the FDA regulates our tests could result in the delay or additional expense in offering our tests and tests that we may develop in the future.

Historically, the U.S. Food and Drug Administration ("FDA") has exercised enforcement discretion with respect to most laboratory-developed tests ("LDTs") and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA publicly announced its intention to regulate certain LDTs and issued two draft guidance documents that set forth a proposed phased-in risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. However, these guidance documents were withdrawn at the end of the Obama administration and replaced by an informal discussion paper reflecting some of the feedback that FDA had received on LDT regulation. The FDA acknowledged that the discussion paper in January 2017 does not represent the formal position of the FDA and is not enforceable. Nevertheless, the FDA wanted to share its synthesis of the feedback that it had received in the hope that it might advance public discussion on future LDT oversight. Notwithstanding the discussion paper, the FDA continues to exercise enforcement discretion and may decide to regulate certain LDTs on a case-by-case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Our business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or changing interpretations of, CLIA or state laboratory licensing laws to which we are subject.

The clinical laboratory testing industry is subject to extensive federal and state regulation, and many of these statutes and regulations have not been interpreted by the courts. The regulations implementing CLIA set out federal regulatory standards that apply to virtually all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, by requiring that they be certified by the federal government or by a federally approved accreditation agency. CLIA does not preempt state law, which in some cases may be more stringent than federal law and require additional personnel qualifications, quality control, record maintenance and proficiency testing. The sanction for failure to comply with CLIA and state requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Several states have similar laws and we may be subject to similar penalties. If the certification of one laboratory owned by the Company is suspended or revoked that may preclude the Company from owning or operating any other laboratory in the Country for two years.

We cannot assure you that applicable statutes and regulations and more specifically, the Food, Drug, and Cosmetic Act, will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorisations, which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly.

Failure to establish and comply with appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services and in the design, manufacture and marketing of our products could adversely affect the results of our operations and adversely impact our reputation.

The provision of clinical testing services, and the design, manufacture and marketing of diagnostic products involve certain inherent risks. The services that we provide and the products that we design, manufacture and market are intended to provide information for healthcare providers in providing patient care. Therefore, users of our services and products may have a greater sensitivity to errors than the users of services or products that are intended for other purposes. Similarly, negligence in performing our services can lead to injury or other adverse events. We may be sued under common law, physician liability or other liability law for acts or omissions by our laboratory personnel. We are subject to the attendant risk of substantial damages awards and risk to our reputation.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to design and implement an effective system of internal control may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs and our Ordinary Shares.

As of June 30, 2021, our Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our internal control over financial reporting. In connection with this assessment, we are satisfied that remediation of the material weakness in relation to segregation of duties identified as of June 30, 2020 had occurred. Refer to Item 15.B for the description of the material weakness and Item 15.D for the efforts undertaken to remediate the material weakness identified as of June 30, 2020.

To remediate the previously identified material weakness and to enhance our overall control environment, we continued to implement policies and procedures to ensure segregation of duties are appropriate as of June 30, 2021, and continuous training for the finance team is in place. However, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent potential future material weaknesses.

Failure to comply with HIPAA, including regarding the use of new "standard transactions," may negatively impact our business.

Pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information, as well as standards for electronic transactions, including specified transaction and code set rules. Under the 2009 HITECH amendments to HIPAA, the law was expanded, including requirements to provide notification of certain identified data breaches, direct patient access to laboratory records, the extension of certain HIPAA privacy and security standards directly to business associates, and heightened penalties for noncompliance, and enforcement efforts.

If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.

Our operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among other things:

- CLIA, which requires that laboratories obtain certification from the federal government, and state licensure laws;
- FDA laws and regulations;
- HIPAA, which imposes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardised electronic transactions; amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general and impose requirements for breach notification;
- state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators;
- the federal anti-kickback law, or the Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the federal Physician Payments Sunshine Act, which requires medical device manufactures to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members;
- Section 216 of the federal Protecting Access to Medicare Act of 2014 (“PAMA”), which requires applicable laboratories to report private payor data in a timely and accurate manner beginning in 2017 and every three years thereafter (and in some cases annually);
- state laws that impose reporting and other compliance-related requirements; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratory’s ability to provide or receive payment for our services. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private, party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organisations, and other private third-party payors.

A failure to comply with any of federal or state laws applicable to our business, particularly laws related to the elimination of healthcare fraud, may adversely impact our business.

Federal officials responsible for administering and enforcing the healthcare laws and regulations have made a priority of eliminating healthcare fraud. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act of 2010, jointly the “Affordable Care Act,” includes significant fraud and abuse measures, including required disclosures of financial arrangements between drug and device manufacturers, on the one hand, and physicians and teaching hospitals, on the other hand. Federal funding available for combating health care fraud and abuse generally has increased. While we seek to conduct our business in compliance with all applicable laws and regulations, many of the laws and regulations applicable to our business, particularly those relating to billing and reimbursement of tests and those relating to relationships with physicians, hospitals and patients contain language that has not been interpreted by courts. We must rely on our interpretation of these laws and regulations based on the advice of our counsel and regulatory or law enforcement authorities may not agree with our interpretation of these laws and regulations and may seek to enforce legal remedies or penalties against us for violations. From time to time we may need to change our operations, particularly pricing or billing practices, in response to changing interpretations of these laws and regulations or regulatory or judicial determinations with respect to these laws and regulations. These occurrences, regardless of their outcome, could damage our reputation and harm important business relationships that we have with healthcare providers, payers and others.

We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.

We receive a portion of our revenues and pay a portion of our expenses in currencies other than the United States dollar, such as the Australian dollar, the Euro and the British pound. As a result, we are at risk for exchange rate fluctuations between such foreign currencies and the United States dollar, which could affect the results of our operations. If the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses. We may not be able to offset adverse foreign currency impact with increased revenues. We do not currently utilise hedging strategies to mitigate foreign currency risk and even if we were to implement hedging strategies to mitigate foreign currency risk, these strategies might not eliminate our exposure to foreign exchange rate fluctuations and would involve costs and risks of their own, such as ongoing management time and expertise, external costs to implement the strategies and potential accounting implications.

Government regulation of genetic research or testing may adversely affect the demand for our services and impair our business and operations.

In addition to the regulatory framework governing healthcare, genetic research and testing has been the focus of public attention and regulatory scrutiny. From time to time, federal, state and/or local governments adopt regulations relating to the conduct of genetic research and genetic testing. In the future, these regulations could limit or restrict genetic research activities as well as genetic testing for research or clinical purposes. In addition, if such regulations are adopted, these regulations may be inconsistent with, or in conflict with, regulations adopted by other government bodies. Regulations relating to genetic research activities could adversely affect our ability to conduct our research and development activities. Regulations restricting genetic testing could adversely affect our ability to market and sell our products and services. Accordingly, any regulations of this nature could increase the costs of our operations or restrict our ability to conduct our testing business.

Failure in our information technology systems could significantly increase testing turn-around times or impact on the billing processes or otherwise disrupt our operations.

Our laboratory operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Sustained system failures or interruption of our systems in our laboratory operations could disrupt our ability to process laboratory requisitions, perform testing, and provide test results in a timely manner and/or billing process. Failure of our information technology systems could adversely affect our business and financial condition.

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

Cyber-attacks or other breaches of information technology security, natural disasters, or acts of terrorism or war may result in hardware failure or disrupt our product testing or research and development activities. There has been a substantial increase in frequency of successful and unsuccessful cyber-attacks on companies in recent years. Such an event may result in our inability, or the inability of our collaborative partners, to operate the facilities to conduct and complete the necessary activities, which even if the event is for a limited period of time, may result in significant expenses and/ or significant damage or delay to our commercial or research activities. While we maintain insurance cover for some of these events, the potential liabilities associated with these events could exceeded the cover we maintain.

Ethical and other concerns surrounding the use of genetic information may reduce the demand for our services.

Public opinion regarding ethical issues related to the confidentiality and appropriate use of genetic testing may influence government authorities to call for limits on, or regulation of the use of, genetic testing. In addition, such authorities could prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Furthermore, adverse publicity or public opinion relating to genetic research and testing, even in the absence of any governmental regulation, could reduce the potential markets for our products and services.

Risks associated with our intellectual property.

The patenting of genes and issues surrounding access to genetic knowledge are the subjects of extensive and ongoing public debate in many countries. By way of example, the Australian Law Reform Commission has previously conducted two inquiries into the social uses of genetic information. The patents we hold overuses of “non-coding” DNA have broad scope and have also been the subject of debate and some criticism in the media. Individuals or organisations, in any one of the countries in which these patents have issued, could take legal action to seek their amendment, revocation or invalidation, something which has happened previously, on several occasions in various jurisdictions, though we have prevailed in all such cases. Furthermore, any time that we initiate legal action against parties that infringe our patents we face a risk that the infringer will defend itself through a counterclaim of patent invalidity or other such claims. Subsequent legal action could potentially overturn, invalidate or limit the scope of our patents.

We rely heavily upon patents and proprietary technology that may fail to protect our business.

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to genetic technologies. We expect to aggressively patent and protect our proprietary technologies. However, we cannot be certain that any additional patents will be issued to us because of our domestic or foreign patent applications or that any of our patents will withstand challenges by others. Patents issued to, or licensed by us may be infringed or third parties may independently develop the same or similar technologies. Similarly, our patents may not provide us with meaningful protection from competitors, including those who may pursue patents which may prevent, limit or interfere with our products or which may require licensing and the payment of significant fees or royalties by us to such third parties in order to enable us to conduct our business. We may sue or be sued by third parties regarding our patents and other intellectual property rights. These suits are often costly and would divert valuable funds, time and technical resources from our operations and cause a distraction to management.

We also rely upon unpatented proprietary technologies and databases. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies and databases, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

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

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending such rights in such other jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights for our business in such jurisdictions, the value of those rights may be diminished and we may face additional competition from others in those jurisdictions. In addition, many countries limit the enforceability of patents against governments agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patent.

Our operations may be adversely affected by the effects of extreme weather conditions or other interruptions in the timely transportation of specimens.

We may be required to transport specimens from the U.S. or other distant locations to our laboratory located in Melbourne, Australia. Our operations may be adversely impacted by extreme weather conditions or other interruptions such as the COVID pandemic in the timely transportation of such specimens or otherwise to provide our services, from time to time. The occurrence of any such event and/or a disruption to our operations as a result may harm our reputation and adversely impact our results of operations.

Our CIT Platform will expose us to various risks.

Our Consumer Initiated Testing platform (CIT), allows consumers to directly request any of our tests online with a practitioner involved in the process via telemedicine, will be subject to various risks, including but not limited to:

- The risk of failure to protect personal medical information;
- The risk of breach of cyber security for the platform; and
- The risk that the platform will fail to perform as expected.

Our ability to conduct telehealth services in a particular U.S. state or non-U.S. jurisdiction is dependent upon the applicable laws governing remote healthcare, the practice of medicine and healthcare delivery in general in such location which are subject to changing political, regulatory and other influences. Some state medical boards have established new rules or interpreted existing rules in a manner that limits or restricts the practice of telemedicine. The extent to which a U.S. state or non-U.S. jurisdiction considers particular actions or relationships to constitute practicing medicine is subject to change and to evolving interpretations by (in the case of U.S. states) medical boards and state attorneys general, among others, and (in the case of non-U.S. jurisdictions) the relevant regulatory and legal authorities, each with broad discretion. Accordingly, we must monitor our compliance with law in every jurisdiction in which we operate, on an ongoing basis, and we cannot provide assurance that our activities and arrangements, if challenged, will be found to be in compliance with the law. If a successful legal challenge or an adverse change in the relevant laws were to occur, and we were unable to adapt our business model accordingly, our operations in the affected jurisdictions would be disrupted, which could have a material adverse effect on our business, financial condition and results of operations.

Discontinuation or recalls of existing testing products or our customers using new technologies to perform their own tests could adversely affect our business.

Discontinuation or recalls of existing testing products or our customers using new technologies to perform their own tests could adversely affect the Company’s business. Manufacturers may discontinue or recall reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenue. In addition, advances in technology may lead to the development of more cost-effective technologies such as point-of-care testing equipment that can be operated by physicians or other healthcare providers in their offices or by patients themselves without requiring the services of freestanding clinical laboratories. Development of such technology and its use by our customers could reduce the demand for our laboratory testing services and the utilisation of certain tests offered by us and negatively impact our revenues.

Even if we are able to successfully transition our current lab facilities into a COVID-19 testing facility, there can be no assurances that we will generate revenue from COVID-19 testing.

The Company has not had any material conversations or entered into any agreements with a third party regarding the performance of COVID-19 testing and there is no guarantee that we will ever enter into any such agreements. As a result, despite our potential ability to conduct COVID-19 testing, there can be no assurances that we will be able to commercialise such ability to generate any revenue.

We may not be able to produce a PRS test that successfully allows for the assessment of risk in fully vaccinated populations

In response to the global COVID-19 pandemic, we have completed the development of our COVID-19 risk test, which we believe may allow for the assessment of risk of an individual contracting a serious disease as a result of the contracting the COVID-19 virus (see “Recent Developments”). We may be unable to produce a test that successfully allows for the assessment of risk in a in fully vaccinated populations. If the outbreak is effectively contained or the risk of infection is diminished or eliminated before we can successfully develop and manufacture a PRS test, we may be unable to successfully generate revenue from the development of the PRS test. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our PRS test, if developed, may not be deemed useful or effective enough by the market.

Because the PRS test may not be able to obtain necessary regulatory clearance, we may not generate any revenue.

All of our existing products are subject to regulation in Australia by CLIA, the U.S. by the FDA and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organisations. The process of obtaining required approvals or clearances for a potential new product varies according to the nature of and uses for a specific product. These processes can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for the product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country. The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may be required to abandon the PRS after devoting substantial time and resources to its development.

If our PRS test receives necessary CLIA and FDA approvals, it will be subject to continuing governmental regulations and additional foreign regulations.

If the FDA determines that enforcement discretion is not appropriate or that LDTs are generally subject to FDA regulation and that premarket review, including clearance or approval, is required for our PRS tests or any of our future tests, diagnostic test kits that we may develop, or other products that would be classified as medical devices, the process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k)-clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA’s satisfaction the safety and efficacy of the device for its intended use. Our currently commercialised products have not received FDA clearance or approval, as they are marketed under the FDA’s enforcement discretion for LDTs. Even if regulatory clearance or approval of a product is required and granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialise the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions.

We are also subject to other federal, state, and foreign regulation concerning the manufacture and sale of our products. Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible, any of which could adversely affect our business, operating results and prospects.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

We may be subject to liability for our current products or for our planned COVID-19 testing and our insurance may not be sufficient to cover damages.

Our current business and potential COVID-19 testing exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of molecular risk assessment and predictive tests. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to professional and product liability claims and possible adverse publicity. We may be subject to claims resulting from incorrect results of analysis of genetic variation or other screening tests performed using our products or from any future COVID-19 testing. Litigation of such claims could be costly. Further, if a court were to require us to pay damages to a plaintiff, the amount of such damages could be significant and severely damage our financial condition. Although we have public and product liability insurance coverage under broad form liability and professional indemnity policies, the level or breadth of our coverage may not be adequate to fully cover any potential liability claims. In addition, we may not be able to obtain additional liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of professional and/or product liability litigation upon the reputation and marketability of our technology and products, together with the diversion of the attention of key personnel, could negatively affect our business.

Declining general economic or business conditions, including as a result of the recent COVID-19 outbreak, may have a negative impact on our business.

Continuing concerns over economic and business prospects in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, coupled with the prospect of decreased business and consumer confidence and increased unemployment resulting from the recent COVID-19 outbreak, may precipitate an economic slowdown and recession. If the economic climate deteriorates, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition, results of operations and cash flows.

The COVID-19 pandemic is having a negative impact on global markets and business activity, which has had an effect on the operations of the Company, including but not limited to, that sales of our products have been impacted not only by the inability for consumers to visit their practitioners but also the difficulty our sales team is having in arranging face to face meetings with practitioners. Our sales team has found it very difficult to reach practitioners to build on the sales momentum created prior to the pandemic,. Additionally, in response to the COVID-19 pandemic, the Company has done the following:

- Moved forward with its Consumer Initiated Testing platform (CIT), as previously announced on April 1, which allows for consumers to directly request any of the Company’s tests online with a practitioner involved in the process via telemedicine. The platform is live, which we believe it will ensure that sales will be able to recommence in the event a lockdown is maintained and it opens up another significant sales channel.

- We have also launched the Polygenic Risk Score (or PRS) test for COVID-19, which will allow for the assessment of risk of an individual contracting a serious disease as a result of the contracting the COVID-19 virus. The proposed test will be designed using the same strategies used to build our existing GeneType for breast and colorectal cancer tests. Our objective will be to produce a test that can predict “disease severity” using either genetic information alone (PRS) or a combination of genetic and clinical information. Biobank data will be interrogated to discover any informative genetic and phenotypic associations.

These new COVID-19 related activities will provide some revenue opportunities for us in the short term and will assist in the development of additional tests the Company is currently working on. We have not made significant progress to date that would lead to orders or requests to increase capacity and there is no guarantee we will ever receive orders or requests.

Item 3. Key Information (cont.)

Item 3.D Risk Factors (cont.)

Risks Related to our Securities

Our ADSs may be delisted from the NASDAQ Capital Market.

In 2019, we were subject to NASDAQ delisting proceedings as a result of our failure to maintain the bid price of the ADS above the minimum $1.00 per share requirement and because our reported stockholders' equity was less than the minimum specified amount of $2,500,000 as of December 31, 2018. We regained compliance with NASDAQ's Listing Rules with respect to our bid price as a result of the adjustment to the ratio of the ADSs that took effect on August 15, 2019, and we regained compliance with the minimum stockholders' equity requirement by raising gross proceeds of approximately $3,043,000 in a rights offering completed on October 29, 2019. On November 6, 2019, we received a letter from NASDAQ notifying us that we had regained compliance with the equity rule (the "Compliance Letter").

On March 13, 2020, we received a determination letter (the "Letter") from NASDAQ indicating that we did not comply with the stockholders' equity rule. The Letter indicates that Listing Rule 5815(d)(4)(B) does not permit an issuer that is deficient in stockholders' equity to present a plan of compliance to the NASDAQ Staff if such issuer has failed to comply with that provision within one year of a Hearing Panel (the "Panel") determination of compliance. The Letter states that since we are out of compliance with the equity rule within one year of the Compliance Letter, the Staff cannot allow us to submit a plan of compliance. We requested an appeal hearing with the Panel to review the delisting determination. Upon NASDAQ's receipt of the hearing request by the Company, NASDAQ stayed the suspension of our securities and the filing of the Form 25-NSE pending the Panel's decision. An oral hearing took place on April 30, 2020 and in a letter dated May 12, 2020, the Panel granted the Company the full 180 day extension until September 9, 2020, to publicly disclose full compliance with the minimum shareholder equity requirement under NASDAQ rules. Subsequent to this, the Company has regained compliance with NASDAQ Listing Rule 5550(b)(1) as of August 25, 2020 (refer to sequence of events below).

On April 2, 2020, we closed a registered direct offering of 1,028,574 ADSs, at a purchase price of $1.75 per ADS (the "First April Offering"). H.C. Wainwright & Co., LLC acted as the placement agent for this offering. We intend to use the net proceeds from this offering to support the introduction and distribution of our new products in the United States, for general product research and development, including the development of polygenic risk tests with TGen in the United States, for implementation of our consumer initiated testing platform, and for working capital. The Company issued 40,114,200 warrants to H.C. Wainwright & Co on April 3, 2020, exercisable at US$0.00365 each, expiring in 5 years from issue date. The warrants are exercisable for fully paid ordinary shares.

On April 17, 2020, we announced that we have developed a detailed implementation plan to enable a temporary transition of our genetic testing laboratory to a high-throughput COVID-19 testing laboratory, should it be required by government agencies to assist with demand (we have not received any such requests to date and there is no guarantee that we will ever receive such requests). Initial work to identify laboratory workflows, instrument modification, laboratory compliance for biologics and contaminated materials handling has commenced. Secure supply chain of test reagents has been confirmed. We believe we are prepared to commence testing within 21 days of receiving a request to assist with demand, if any.

On April 22, 2020, we closed a registered direct offering of 722,502 ADSs at a purchase price of $2.00 per ADS (the "Second April Offering," and together with the First April Offering, the "April Offerings"). H.C. Wainwright & Co., LLC acted as the placement agent for this offering. We intend to use the net proceeds of this offering to support the introduction and distribution of our new products in the United States, for general product research and development, including the development of polygenic risk tests with TGen in the United States, for implementation of our consumer initiated testing platform and preparation for potential COVID-19 testing as well as for working capital. The Company issued 28,177,578 warrants to H.C. Wainwright & Co on April 22, 2020, exercisable at US$0.00417 each, expiring in 5 years from issue date. The warrants are exercisable for fully paid ordinary shares.

On May 26, 2020, we completed a capital raise by offering of (i) 3,500,000 American Depositary Shares ("ADSs"), for a purchase price of United States Dollars (US$) US$2.00 per ADS (each representing six hundred (600) of the Company's ordinary shares) and (ii) 500,000 pre-funded warrants to purchase one ADS (the "Pre-Funded Warrants") for a purchase price of US$1.9999 per Pre-Funded Warrant. H.C. Wainwright & Co., LLC acted as the placement agent for this offering. In connection with such offering, the Company agreed to issue 156,000,000 warrants exercisable at US$0.004166 each, expiring in 5 years from issue date, to H.C. Wainwright & Co.

On July 21, 2020, we closed a registered direct offering of 1,025,000 American Depository Shares (ADSs), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of United States Dollars (US$) US$5.00 per ADS - or in Australian dollars $0.012 per ordinary share. The gross proceeds for this offering were approximately US$5.1 million. Against the offering, the Company agreed to issue 39,975,000 warrants exercisable at US$0.0104 each, expiring in 5 years from issue date, to H.C. Wainwright & Co which would form part of cost of raising capital.

As of August 25, 2020, the Company has regained compliance with the equity requirement of NASDAQ Listing Rule 5550(b)(1), as required by the Hearings Panel decision dated May 12, 2020.

On January 25, 2021, we closed a registered direct offering of 1,250,000 American Depository Shares (ADSs), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of United States Dollars (US$) US$5.25 per ADS - or in Australian dollars $0.01125 per ordinary share. The gross proceeds for this offering was approximately US$6.56 million. Against the offering, the Company agreed to issue 48,750,000 warrants exercisable at US$0.010938 each, expiring in 5 years from issue date, to H.C. Wainwright & Co which would form part of cost of raising capital. The said warrants are subject to shareholder approval.

However, there can be no assurance that we will be successful in these in maintaining net assets compliance and our securities will remain listed on the NASDAQ Capital Market. The delisting of our ADSs by NASDAQ would have material negative impacts on the liquidity of our securities and our ability to raise future capital.

Our stock price is volatile and can fluctuate significantly based on events not in our control and general industry conditions. As a result, the value of your investment may decline significantly.

The biotechnology sector can be particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- product development events;
- the outcome of litigation;
- decisions relating to intellectual property rights;
- the entrance of competitive products or technologies into our markets;
- new medical discoveries;
- the establishment of strategic partnerships and alliances;
- changes in reimbursement policies or other practices related to the pharmaceutical industry; or
- other industry and market changes or trends.

Since our listing on the Australian Securities Exchange in August 2000, the price of our Ordinary Shares has ranged from a low of A$0.006 to a high of A$0.88 per share. Further fluctuations are likely to occur due to events which are not within our control and general market conditions affecting the biotechnology sector or the stock market generally.

In addition, low trading volume may increase the volatility of the price of our ADSs. A thin trading market could cause the price of our ADSs to fluctuate significantly more than the stock market as a whole. For example, trades involving a relatively small number of our ADSs may have a greater impact on the trading price for our ADSs than would be the case if the trading volume were higher.

The fact that we do not expect to pay cash dividends may lead to decreased prices for our stock.

We have never declared or paid a cash dividend on our Ordinary Shares and we do not anticipate doing so in the foreseeable future. We intend to retain future cash earnings, if any, for reinvestment in the development and expansion of our business. Whether we pay cash dividends in the future will be at the discretion of our Board of Directors and may be dependent on our financial condition, results of operations, capital requirements and any other factors our Board of Directors decides is relevant. As a result, an investor may only recognise an economic gain on an investment in our stock from an appreciation in the price of our stock, which is uncertain and unpredictable. There is no guarantee that our Ordinary Shares will appreciate in value or even maintain the price at which an investor purchased the Ordinary Shares.

You may have difficulty in effecting service of legal process and enforcing judgments against us and our management.

We are a public company limited by shares, registered and operating under the Australian *Corporations Act 2001*. All of our directors and officers named in this Annual Report reside outside the U.S. Substantially all, or a substantial portion of, the assets of those persons are also located outside the U.S. As a result, it may not be possible to affect service on such persons in the U.S. or to enforce, in foreign courts, judgments against such persons obtained in U.S. courts and predicated on the civil liability provisions of the federal securities laws of the U.S. Furthermore, substantially all of our directly owned assets are located outside the U.S., and, as such, any judgment obtained in the U.S. against us may not be collectible within the U.S. There is doubt as to the enforceability in the Commonwealth of Australia, in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated solely upon federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

Because we are not required to provide you with the same information as an issuer of securities based in the United States, you may not be afforded the same protection or information you would have if you had invested in a public corporation based in the United States.

We are exempt from certain provisions of the Securities Exchange Act of 1934, as amended, commonly referred to as the Exchange Act, that are applicable to U.S. public companies, including (i) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q and current reports on Form 8-K; (ii) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorisations in respect of a security registered under the Exchange Act; and (iii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time. The exempt provisions would be available to you if you had invested in a U.S. corporation.

However, in line with the Australian Securities Exchange regulations, we disclose our reviewed financial results on a semi-annual basis (under International Standard on Review Engagements) and our audited financial results on an annual basis (under International Standards on Auditing). The information, which may have an effect on our stock price on the Australian Securities Exchange, will be disclosed to the Australian Securities Exchange and also the Securities Exchange Commission. Other relevant information pertaining to our Company will also be disclosed in line with the Australian Securities Exchange regulations and information dissemination requirements for listed companies. We provide our semi-annual results and other material information that we make public in Australia in the U.S. under the cover of an SEC Form 6-K. Nevertheless, you may not be afforded the same protection or information, which would be made available to you, were you investing in a United States public corporation because the requirements of a Form 10-Q and Form 8-K are not applicable to us.

A lack of significant liquidity for our ADSs may negatively affect your ability to resell our securities.

Our ADSs have traded on the NASDAQ Capital Market since June 30, 2010. An active trading market for the ADSs, however, may not be maintained in the future. If an active trading market is not maintained, the liquidity and trading prices of the ADSs could be negatively affected.

In certain circumstances, holders of ADSs may have limited rights relative to holders of Ordinary Shares.

The rights of holders of ADSs with respect to the voting of Ordinary Shares and the right to receive certain distributions may be limited in certain respects by the deposit agreement entered into by us and The Bank of New York Mellon. For example, although ADS holders are entitled under the deposit agreement, subject to any applicable provisions of Australian law and of our Constitution, to instruct the depositary as to the exercise of the voting rights pertaining to the Ordinary Shares represented by the American Depositary Shares, and the depositary has agreed that it will try, as far as practical, to vote the Ordinary Shares so represented in accordance with such instructions, ADS holders may not receive notices sent by the depositary in time to ensure that the depositary will vote the Ordinary Shares. This means that, from a practical point of view, the holders of ADSs may not be able to exercise their right to vote. In addition, under the deposit agreement, the depositary has the right to restrict distributions to holders of the ADSs in the event that it is unlawful or impractical to make such distributions. We have no obligation to take any action to permit distributions to holders of our American Depositary Receipts, or ADSs. As a result, holders of ADSs may not receive distributions made by us.

There is a substantial risk that we are a passive foreign investment company, or PFIC, which subjects U.S. investors to adverse tax rules.

Holders of our ADSs who are U.S. residents face income tax risks. There is a substantial risk that we are a passive foreign investment company, commonly referred to as a PFIC. Our treatment as a PFIC could result in a reduction in the after-tax return to the holders of our ADSs. For U.S. federal income tax purposes, we are classified as a PFIC for any taxable year in which either (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. As a result of our substantial cash position in relation to our other assets, we believe that we have been a PFIC in our most recent taxable years and will continue to be a PFIC in the current tax year. Highly complex rules apply to U.S. holders owning ADSs. Accordingly, you are urged to consult your tax advisors regarding the application of such rules. United States residents should carefully read “Item 10.E. Additional Information—Taxation, United States Federal Income Tax Consequences” in this Annual Report, for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of our ADSs.