- 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.
- As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.
- As a result of being a U.S. public company, we are subject to additional regulatory compliance requirements, including Section 404, and if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.
- We will incur significant costs as a result of operating as a company with ADSs that are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.
- The dual listing of our ordinary shares and the ADSs may negatively impact the liquidity and value of the ADSs.
- Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.
- Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.
- A lack of significant liquidity for our ADSs may negatively affect your ability to resell our securities.
- In certain circumstances, holders of ADSs may have limited rights relative to holders of Ordinary Shares.

Risk Related to Taxation

- We may be classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences for U.S. holders.
- If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.
- Changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.
- Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

Risks Related to our Business

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

We, or our licensing partners, may seek regulatory approval for our products or product candidates in multiple 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, 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 labor 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 labor unrest is more common than in Australia or the U.S.;
- 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 Australia 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, 2024, the Company had accumulated losses of A$166,376,076 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. On July 26, 2024 the Company announced that it was restructuring its operating model in order to significantly reduce ongoing operating losses and cash outflows. As part of the restructure the Company will be transitioning to a capital light operating model under which activities such as R&D and new product development, IP creation, laboratory testing, and the introduction of predictive genetic testing products that previously had been carried out in-house, would be variously ceased, outsourced and/or undertaken through partnering. Going forward the focus of the Company would be on growing revenues in its EasyDNA and AffinityDNA business, and commercialization of geneType in the U.S. through strategic partnerships. 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 expanding our revenues, and therefore improving operational profitability, of the recently acquired EasyDNA and AffinityDNA businesses or achieve significant commercial sales of the portfolio to our next generation of geneType risk assessment tests.

We believe that our future success is dependent upon our ability to grow revenues from our existing product offerings and to successfully introduce and sell our newly developed products including our innovative hereditary breast and ovarian cancer test, launched in November 2023, and the geneType Comprehensive Risk Assessment Test launched in March 2024 . 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 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.

We face additional risks as a result of the EasyDNA and AffinityDNA acquisitions. We may be unable to integrate our businesses successfully and realize the anticipated synergies and related benefits of these acquisitions or do so within our anticipated timeframes. Including:

- difficulties in integrating and managing the combined operations of EasyDNA and AffinityDNA, and realizing the anticipated economic, operational, and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical, or financial problems;
- disruptions to the EasyDNA and AffinityDNA businesses and their operations and relationships with service providers and other third parties;
- loss of key employees of EasyDNA and AffinityDNA and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful;
- diversion of management time and focus from operating our business to addressing the EasyDNA and AffinityDNA operations integration challenges;
- diversion of significant resources from the ongoing development of our existing products, services, and operations;
- failure to successfully realize our intended business strategy;
- increase in the operating losses that we expect to incur in future periods;
- regulatory complexities of integrating or managing the combined operations or expanding into other industries or parts of the healthcare industry;
- regulatory developments or enforcement trends focusing on corporate practice of medicine;
- greater than anticipated costs related to the integration of the EasyDNA and AffinityDNA businesses and operations;
- increase in compliance and related costs associated with the addition of a regulated business;

- responsibility for the liabilities of EasyDNA and AffinityDNA, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy practices controls and comply with applicable regulations; and
- potential accounting charges to the extent intangibles recorded in connection with the EasyDNA and AffinityDNA acquisitions, such as goodwill, trademarks, client relationships, or intellectual property, are later determined to be impaired and written down in value.

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

The Company believes that its current GeneType risk assessment tests, along with the pipeline of new tests for additional disease indications 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 at scale. 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 organizations 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;
- 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 of 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.

Security breaches, privacy issues, loss of data and other incidents could compromise sensitive or personal information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including Protected Health Information, (PHI), personally identifiable information, genetic information, credit card information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. In addition, there has recently been a significant increase in ransomware and cyber security attacks related to the ongoing conflict between Russia and Ukraine, which could result in substantial harm to internal systems necessary for running our critical operations and revenue generating services.

The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. For example, we have been subject to phishing incidents in the past, and we may experience additional incidents in the future. Any such breach or interruption could compromise our networks, and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business.

In addition to data security risks, we also face privacy risks. Should we actually violate, or be perceived to have violated, any privacy commitments we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, state data security and data breach notification laws, the European Union’s General Data Protection Regulation, or GDPR, and the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to US$1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to US$50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices, or UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25, 2018. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20M euros or 4% of an organization's annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the third parties who will receive the personal information. The CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. The CCPA does not apply to PHI collected by certain parties subject to HIPAA, or to de-identified data as defined under HIPAA. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches resulting from a business's failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation. On January 1, 2023, the California Privacy Rights Act, or CPRA, is scheduled to go into effect and will substantially amend the CCPA. The CPRA would, among other things, amend the CCPA to give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law.

Virginia, Colorado, and Utah have recently enacted similar privacy acts, and dozens of other states in the United States are currently considering similar consumer data privacy laws, which could impact our operations if enacted. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging United States and international data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We can provide no assurance that we are or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, including civil or criminal penalties, litigation, or damage to our reputation, any of which could have a material adverse effect on 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 fluid (i.e. saliva, blood) as well as tissue samples from customers. 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 customer 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.

Our industry is subject to rapidly changing technology and new and increasing amounts of scientific data related to genes and genetic variants and their role in disease.

Our failure to develop tests to keep pace with these changes could make us obsolete. In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in disease and treatment therapies. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards, all of which could make our tests obsolete. Our future success will also depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our tests could become obsolete and our business adversely affected unless we continually update our offerings to reflect new scientific knowledge about genes and genetic variations and their role in diseases and treatment therapies.

We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialization 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 commercialization 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 commercialization 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 commercialization, or such development or commercialization 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 commercialization 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 partner’s facility becomes inoperable, we may be unable to perform our tests and our business will be harmed.

We have been heavily reliant upon our sole laboratory facilities in Melbourne, Australia, which has been certified under the U.S. CLIA. Our current lease of laboratory premises expires February 28, 2025. To mitigate this risk and to provide expanded testing capacity and flexibility, in June 2024 we formed a partnership with Gene By Gene (GbG), a premier specialty genetic laboratory based in Houston, Texas. GbG’s state-of-the -art, highly accredited facility (CLIA, CAP, AABB and CDPH licensed) has the ability to process more than 25,000 tests per month greatly increasing geneType’s operational capacity. The initial focus of the partnership was to focus on testing and proving the solution in North America. On July 26, 2024 we announced that as part of the restructure of GTG all geneType testing would be moved to GbG, following the success of testing for the North America market. Once we close our Melbourne laboratory facility we will be reliant on GbG to perform our tests, maintain our CLIA and other required certifications or licences. If we were to lose our CLIA certification or other required certifications or licenses, or if the GbG 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 GbG’s 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.

As we no longer will have our own facility we will rely on third parties, that have the required facilities and with established state licensure and CLIA accreditation, to perform our tests. As part of the transition to GbG we have evolved our geneType solution, systems and processes to be able to integrate with third party laboratories providing increased flexibility. However, 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 place of GbG should it be required. In order to re-establish a replacement 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 commercialized 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.

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. Our success also depends on our ability to attract and retain salespeople with extensive experience in oncology and have 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.

As a matter of policy, the FDA generally does not review Direct-to-Consumer LDTs that are created and performed in a single laboratory, if they are offered to patients only when prescribed by a health care provider.

Legislative proposals addressing the FDA’s oversight of LDTs have been introduced in the current and previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. On May 17, 2022, the Senate Health, Education, Labor and Pensions (HELP) Committee released an FDA user fees reauthorization legislative package, which incorporates contents from the Verifying Accurate Leading-edge IVCT Development (VALID) Act that would establish a new category of in vitro clinical tests (IVCTs) comprised of traditional in vitro diagnostics and LDTs, and grant the FDA authority to review and approve them pre-market. Such arrangement increased the likelihood for Congress to pass a legislation that will give the FDA clear authority to regulate LDTs, but the eventual result is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA’s requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA’s requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

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. The regulations implementing CLIA set out federal regulatory standards that apply to virtually all clinical laboratories operating in the U.S. (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 is a U.S. federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the U.S. by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections.

Certain US States also require state laboratory licenses in order to test specimens received from patients residing in those states or requests received from ordering physicians in those states. We currently hold out-of-state laboratory licenses in California, New York, Maryland, Rhode Island, and Pennsylvania.

Further, CLIA does not pre-empt 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, civil and criminal penalties, the imposition of directed plan of correction, and on-site monitoring. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Several states have similar laws, and we may be subject to similar penalties. If the CLIA certification of one laboratory owned by the Company is suspended or revoked that may preclude the Company from owning or operating any other CLIA regulated laboratory for two years. Further, even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We cannot assure you that applicable statutes and regulations 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 authorizations, 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.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are increasing our direct sales and operations personnel outside the United States, in which we have limited experience. We use a limited number of independent distributors to sell our tests internationally, which requires a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti- bribery laws in the jurisdictions in which we operate, including anti-bribery laws in Australia which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

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, 2024, our Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our internal control over financial reporting. We did not identify any material weakness in our internal control over financial reporting during the year. 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 health information privacy laws, including HIPAA or other U.S. federal or state health information privacy and security laws, as applicable, may negatively impact our business.

Pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, covered entities (including health plans, healthcare clearinghouses, and certain healthcare providers), as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Individuals and entities who are subject to HIPAA 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 HITECH, HIPAA 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. Failure to comply with HIPAA or other U.S. federal and state health information privacy and security laws, as applicable, could result in significant penalties

If we or our partners fail to comply with the complex federal, state, local and foreign laws and regulations to the extent 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. The U.S. laws and regulations that may apply to our business 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 standardized 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;
- federal and state fraud and abuse laws, such as false claims and anti-kickback laws, and prohibitions on self-referral;
- Section 216 of the federal Protecting Access to Medicare Act of 2014 ("PAMA"), which requires applicable laboratories to report private payer data in a timely and accurate manner;
- 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 significant administrative civil or criminal penalties, exclusion from participation in state and federal health care programs, imprisonment, disgorgement, and 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 that apply to us, 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 organizations, and other private third-party payers.

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

The healthcare industry is subject to changing political, economic, and regulatory influences that may affect our business. During the past several years, the healthcare industry has been subject to an increase in governmental regulation and subject to potential disruption due to legislative initiatives and government regulation, as well as judicial interpretations thereof. While these regulations may not directly impact us or our offerings in every instance, they will affect the healthcare industry as a whole and may impact patient use of our services. We currently accept payments only from our customers not any third-party payers, such as government healthcare programs or health insurers. Because of this approach, we are not subject to many of the laws and regulations that impact many other participants in the healthcare industry.

If the government asserts broader regulatory control over companies like ours or if we determine that we will change our business model and accept payment from and/or participate in third-party payer programs, the complexity of our operations and our compliance obligations will materially increase. Failure to comply with any applicable federal, state, and local laws and regulations could have a material adverse effect on our business, financial condition, and results of operations.

While we seek to conduct our business in compliance with all applicable healthcare laws and regulations, 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. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state, fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages and fines, disgorgement, additional reporting requirements and oversight, and imprisonment for individuals, as well as contractual damages and reputational harm. We could also be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results. 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 Australian dollar, such as the U.S. dollar, the Euro and the British pound. As a result, we are at risk for exchange rate fluctuations between such foreign currencies and the Australian dollar, which could affect the results of our operations. If the Australian 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. Other than holding foreign currency bank accounts in which revenues from foreign currency denominated sales are held, offering a natural hedge against some foreign currency expenditures, we do not currently utilize other hedging strategies to mitigate foreign currency risk. Even if we were to implement hedging strategies to mitigate foreign currency risk, these strategies might not eliminate our total 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.

Any significant disruption in service on our website or in our computer or logistics systems, whether due to a failure with our information technology systems or that of a third-party vendor, could harm our reputation and may result in a loss of customers.

Customers purchase and access our services through our websites. Our reputation and ability to attract, retain and serve our customers, patients, and members is dependent upon the reliable performance of our website, network infrastructure and content delivery processes. Interruptions in any of these systems, whether due to system failures, computer viruses or physical or electronic break-ins, could affect the security or availability of our website, including our databases, and prevent our customers, patients, and members from accessing and using our services.

Our systems and operations are also vulnerable to damage or interruption from fire, flood, power loss, telecommunications failure, terrorist attacks, acts of war, electronic and physical break-ins, earthquake and similar events. For example, our headquarters are located in Melbourne, Australia where increased bush fire and flood activity has recently been experienced. In the event of any catastrophic failure involving our website, we may be unable to serve our web traffic. In addition, our sole laboratory in Melbourne, Australia is responsible for a significant portion of our operations of our geneType risk assessment tests, these operations would be materially disrupted in the event any of these events were to occur. The occurrence of any of the foregoing risks could result in damage to our systems or could cause them to fail completely, and our insurance may not cover such risks or may be insufficient to compensate us for losses that may occur.

Additionally, our business model is dependent on our ability to deliver kits to customers and have kits processed and returned to us. This requires coordination between our logistics providers and third-party shipping services. Operational disruptions may be caused by factors outside of our control such as hostilities, political unrest, terrorist attacks, natural disasters, pandemics (such as COVID-19) and public health emergencies, affecting the geographies where our operations and customers are located. We may not be effective at preventing or mitigating the effects of such disruptions, particularly in the case of a catastrophic event. In addition, operational disruptions may occur during the holiday season, causing delays or failures in deliveries of our kits. Any such disruption may result in lost revenues, a loss of customers and reputational damage, which would have an adverse effect on our business, results of operations 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 in respect of “non-coding” DNA have broad scope and have also been the subject of debate and some criticism in the media. Individuals or organizations, 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 Australia 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 was the case with 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, will be subject to various risks, including:

- 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 our 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, and corporate practice of medicine limitations. 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, we could be subject to significant penalties. Further, if we were unable to adapt our business model to comply with such laws, 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 utilization of certain tests offered by us and negatively impact our revenues.

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 the Therapeutic Goods Association (TGA), the U.S. by the FDA and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. 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 is required to obtain and maintain 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 or reclassification of the device through the De Novo classification process, 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. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct De Novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents moderate or low risk. De Novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA. Our currently commercialized 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 commercialize 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, government investigation, 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.

Declining general economic or business conditions may have a negative impact on our business.

If the current 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 payers, could be adversely affected, resulting in a negative impact on our business, financial condition, results of operations and cash flows.

RISKS RELATED TO OUR SECURITIES

Our ADSs may be delisted from the NASDAQ Capital Market.

On March 13, 2020, the Company received a determination letter (the “Letter”) from NASDAQ indicating that we did not comply with the stockholders’ equity rule. The Letter indicated 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 stated that since the Company was not compliant 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. The Company subsequently regained compliance with NASDAQ Listing Rule 5550(b)(1) as of August 25, 2020.

On July 21, 2020, we closed a registered direct offering of 1,025,000 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 A$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.

On January 25, 2021, we closed a registered direct offering of 1,250,000 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 A$0.01125 per ordinary share. The gross proceeds for this offering were 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 were subject to shareholder approval, which was granted by shareholders at the Company’s Annual General Meeting (AGM) held 24 November 2021.

On February 8, 2023, we closed a registered direct offering of 3,846,155 ADSs, each representing six hundred (600) of the Company’s ordinary shares, at a purchase price of United States Dollars (US$) US$1.30 per ADS. The gross proceeds for this offering were approximately US$5 million. Against the offering, the Company agreed to issue 250,000 warrants exercisable at US$1.625 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.

On July 17, 2023, the Company received notification from The Nasdaq Stock Market LLC that it is not in compliance with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market, since the closing bid price for the Company’s American Depositary Shares (ADS) on the Nasdaq Capital Market was below US$1.00 for 34 consecutive trading days. Nasdaq Listing Rule 5550(a)(2) requires the ADS to maintain a minimum bid price of US$1.00 per share (the “Minimum Bid Requirement”), and Nasdaq Listing Rule 5810(c)(3)(A) provides that failure to meet such requirement exists if the deficiency continues for a period of 30 consecutive business days. The Notification has no immediate effect on the listing of the Company’s ADS on the Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from the date of Notification, which was July 17, 2023, to regain compliance with the minimum bid requirement, during which time the ADS will continue to trade on the Nasdaq Capital Market. The deficiency was cured in December 2023 following the share consolidation of all classes of the Company’s securities, including ordinary shares at a ratio of one (1) for every parcel of one hundred securities held, such that each hundred ordinary shares of the Company would be combined into one ordinary share of the Company (the “Local Consolidation”). In connection with the Local Consolidation, the Company also simultaneously adjusted its ADS Ratio from the then-existing ratio of one ADS representing 600 ordinary shares to one ADS representing 30 ordinary shares (the “Ratio Change”). Both the Local Consolidation and the Ratio Change became effective at the open of trading on December 14, 2023.

On November 22, 2023, we held our 2023 Annual General Meeting of shareholders (the "2023 Annual Meeting"). At the 2023 Annual Meeting, our shareholders approved a share consolidation of all classes of securities, including ordinary shares at a ratio of one (1) for every parcel of one hundred securities held, such that each hundred ordinary shares of the Company would be combined into one ordinary share of the Company (the "Local Consolidation"). In connection with the Local Consolidation, the Company also simultaneously adjusted its ADS Ratio from the then-existing ratio of one ADS representing 600 ordinary shares to one ADS representing 30 ordinary shares (the "Ratio Change"). Both the Local Consolidation and the Ratio Change became effective at the open of trading on December 14, 2023. Our ordinary shares continue to be traded on the ASX, under the symbol "GTG." The ADSs continue to be traded on The Nasdaq Stock Exchange under the symbol "GENE".

On the effective date of the Ratio Change, ADS holders were required on a mandatory basis to surrender their old ADSs to the depository for cancellation and exchange at a rate of one "new" ADS (CUSIP 37185R406) for every five "old" ADSs (CUSIP 37185R307) surrendered. Holders of ADSs in the Direct Registration System or in brokerage accounts had their ADSs automatically exchanged with no further action. No fraction of an ADS was issued.

On April 18, 2024, we entered into a definitive agreement (the "Purchase Agreement") with institutional investors providing for the issuance of 16,800,000 ordinary shares represented by 560,000 ADSs, and (ii) pre-funded warrants to purchase up to an aggregate 13,200,000 ordinary shares represented by 440,000 ADSs, in a registered direct offering at an offering price of $2.00 per ADS and $1.999 per pre-funded warrant, for aggregate gross proceeds of approximately $2 million. Each pre-funded warrant is exercisable for one ADS at an exercise price of $0.001 per share. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The offering closed on April 22, 2024. In addition, under the Purchase Agreement, the investors received unregistered warrants to purchase up to an aggregate of 30,000,000 ordinary shares represented by 1,000,000 ADSs at an exercise price of $2.00 per ADS (the "Private Placement"). The warrants will be immediately exercisable and will expire five years following the date of issuance. The warrants may be exercised on a cashless basis if there is no effective registration statement registering the ADSs underlying the warrants.

On August 23, 2024, the company received notification from The Nasdaq Stock Market LLC that it is not in compliance with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market, since the closing bid price for the company's American Depositary Shares (ADS) on the Nasdaq Capital Market was below US$1.00 for 30 consecutive trading days. Under Nasdaq Listing Rule 5810(c)(3)(A), the company has a period of 180 calendar days from the date of Notification to regain compliance with the minimum bid requirement, during which time the ADS will continue to trade on the Nasdaq Capital Market. If at any time before February 19, 2025, the bid price of the ADS closes at or above US$1.00 per ADS for a minimum of 10 consecutive business days, the Company will regain compliance with the Minimum Bid Requirement.

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:

- global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and international conflicts, such as the conflict between Russia and Ukraine;
- 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 pricing policies or other practices related to the healthcare 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$0.002 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 recognize 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 authorizations 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.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards and these practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

As a foreign private issuer listed on Nasdaq, we will be subject to their corporate governance listing standards. However, Nasdaq rules permit foreign private issuers to follow the corporate governance practices of its home country. Some corporate governance practices in Australia may differ from Nasdaq corporate governance listing standards. For example, we could include non-independent directors as members of our Remuneration committee, and our independent directors may not necessarily hold regularly scheduled meetings at which only independent members of the board of directors are present. Currently, we follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense. While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made on December 31, 2024. In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if 50% or more of our securities are held by U.S. residents and more than 50% of our senior management or directors are residents or citizens of the United States, we could lose our foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP rather than IFRS, and modify certain of our policies to comply with corporate governance practices required of U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

As a result of being a U.S. public company, we are subject to additional regulatory compliance requirements, including Section 404, and if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Pursuant to Section 404, our management will be required to assess and attest to the effectiveness of our internal control over financial reporting in connection with issuing our consolidated financial statements as of and for the fiscal year ending June 30, 2024. Section 404 also requires an attestation report on the effectiveness of internal control over financial reporting be provided by our independent registered public accounting firm beginning with our annual report following the date on which we are no longer a non-accelerated filer. The cost of complying with Section 404 will significantly increase and management's attention may be diverted from other business concerns, which could adversely affect our results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will further increase expenses. If we fail to comply with the requirements of Section 404 in the required timeframe, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Furthermore, if we are unable to attest to the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, and the market price of our ordinary shares and ADSs could decline. Failure to implement or maintain effective internal control over financial reporting could also restrict our future access to the capital markets and subject each of us, our directors and our officers to both significant monetary and criminal liability. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial position, results and prospects may be adversely affected.

We will incur significant costs as a result of operating as a company with ADSs that are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a company whose ADSs are publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the United States Securities and Exchange Commission, or SEC, and Nasdaq have imposed various requirements on public companies listed in the United States including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company listed in the United States, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

The dual listing of our ordinary shares and the ADSs may negatively impact the liquidity and value of the ADSs.

Our ADSs are listed on Nasdaq and our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may negatively impact the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be negatively impacted by trading in our ordinary shares on the ASX.

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

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

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

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Corporations Act 2001, sets forth various rights and obligations that apply to us as an Australian company and which may not apply to a U.S. corporation. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under our Constitution, which is included as an exhibit to this annual report, prior to investing in our securities.

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.

RISKS RELATED TO TAXATION

We may be classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences for U.S. holders.

In general, a non-U.S. company will be considered a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year in which (1) 75% or more of its gross income consists of passive income (the “income test”) or (2) 50% or more of the average quarterly value of its assets is attributable to assets that produce, or are held for the production of, passive income (the “asset test”). For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation.

Based on the nature and composition of our income, assets, activities and market capitalization, we believe that we were classified as a PFIC for our taxable year ended June 30, 2024. However, our PFIC status is based on an annual determination that is subject to a number of uncertainties and may change from year to year. Our PFIC status will depend on the composition of our income (including with respect to the R&D Tax Credit) and the composition and value of our assets, which may be determined in large part by reference to the market value of the ADSs and our Ordinary Shares, which may be volatile, from time to time. Our status may also depend, in part, on how quickly we utilize the cash we raise in any offering of our securities. There can be no assurance that we will not be considered a PFIC in any past, current or future taxable year, and our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

If we are a PFIC for any taxable year during which a U.S. holder (as defined in the section titled “Item 10.E. Additional Information—Taxation, United States Federal Income Taxation”) holds the ADSs or Ordinary Shares, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. We will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ADSs or Ordinary Shares, regardless of whether we continue to meet the income or asset tests described above, unless the U.S. holder makes a valid and timely qualified electing fund (QEF) or mark-to-market election, or makes a deemed sale election once we cease to be a PFIC; however, we do not currently intend to provide the information necessary for a U.S. holder to make a QEF election. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences to U.S. holders in the event we are classified as a PFIC, see “Item 10.E. Additional Information—Taxation, United States Federal Income Taxation—Passive Foreign Investment Company Rules.”

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder (as defined in the section titled “Item 10.E. Additional Information—Taxation, United States Federal Income Taxation”) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our Ordinary Shares or ADSs, such U.S. holder may be treated, for U.S. federal income tax purposes, as a “United States shareholder” with respect to each “controlled foreign corporation” in our group, if any. Because our group includes a U.S. subsidiary (geneType Inc., previously the named Phenogen Sciences Inc.), certain of our current and future non-U.S. subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low- taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and payment obligations described above. Failure to comply with such obligations may subject a United States shareholder to significant monetary penalties and stall the beginning of the statute of limitations period for relevant U.S. federal income tax returns. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in the Ordinary Shares or ADSs.