GENETIC TECHNOLOGIES LTD Form 424B5 December 05, 2016 <u>Table of Contents</u>

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**PROSPECTUS SUPPLEMENT** (to the prospectus dated May 17, 2016)

#### GENETIC TECHNOLOGIES LIMITED

#### 720,000,000 Ordinary Shares represented by 4,800,000 American Depositary Shares

This prospectus supplement relates to the offer and sale of 720,000,000 ordinary shares, represented by 4,800,000 American Depositary Shares, or ADSs. Each ADS represents one hundred and fifty (150) ordinary shares in Genetic Technologies Limited. The ADSs are evidenced by American Depositary Receipts, or ADRs. We refer to the ordinary shares and ADSs collectively as securities in this prospectus supplement.

Our ADSs are listed on the NASDAQ Capital Market under the symbol GENE and our ordinary shares are listed on the Australian Securities Exchange under the symbol GTG. On November 30, 2016, the last sale price of our ADRs on the NASDAQ Capital Market was \$2.19 per ADR and of our ordinary shares on the Australian Securities Exchange was A\$0.018 per share.

The aggregate market value of our outstanding ordinary shares held by non-affiliates as of the date of this prospectus supplement was approximately \$22,896,627, based on 1,715,282,724 ordinary shares outstanding of which 1,693,564,664 were held by non-affiliates, and a per share price of A\$0.018 based on the closing sale price of our ordinary shares on November 30, 2016. We

have sold no securities pursuant to General Instructions I.B.5 of Form F-3 during the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement.

We are selling the securities offered hereby directly to investors. We have retained Maxim Group LLC, or Maxim, to act as placement agent in connection with this offering to use its reasonable best efforts to solicit offers to purchase our ADSs and we have agreed to pay the Placement Agent a fee of 7.0% of the aggregate gross proceeds in this offering. The Placement Agent is not purchasing or selling any securities pursuant to this prospectus supplement or the accompanying prospectus, nor are we requiring any minimum purchase or sale of any specific number of securities. See Plan of Distribution beginning on page S-25 of this prospectus supplement for more information regarding these arrangements.

## Investing in the ADSs involves a high degree of risk. Before buying any securities, you should carefully consider the risk factors described in Risk Factors beginning on page S-5 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement and the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per ADS	Total
Offering Price	\$ 1.25	\$ 6,000,000
Placement agent s fees(1)	\$ 0.0875	\$ 420,000
Proceeds to us (Before Expenses)	\$ 1.1625	\$ 5,580,000

(1)See Plan of Distribution.

## **Maxim Group LLC**

The date of this prospectus supplement is December 5, 2016

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

Unless expressly stated otherwise, all references in this prospectus supplement and the accompanying prospectus to GTG, we, us, our, the Company, or similar references mean Genetic Technologies Limited and its subsidiaries, unless otherwise indicated.

All references to U.S. dollars, \$ or US\$ in this supplement and the accompanying prospectus are to U.S. dollars, and all references to Australian dollars or A\$ are to the currency of Australia.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of our ADSs and supplements information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about us and the securities that we may offer from time to time under our shelf registration statement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control.

You should read this document together with additional information described under the headings Where You Can Find More Information and Incorporation of Certain Information by Reference in this prospectus supplement. We have not authorized any dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any related free writing prospectus. You should not rely upon any information or representation not contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any free writing prospectus that we may authorize to be provided to you. This prospectus supplement, the accompanying prospectus and any related free writing prospectus and any related free writing prospectus supplement, the accompanying prospectus constitute an offer to sell or the solicitation of an offer to bell or the solicitation of an offer to sell or the solicitation in such jurisdiction. You should not assume that the information contained in this prospectus supplement, the accompanying prospectus and any related free writing prospectus and any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus supplement, the accompanying prospectus and any related free writing prospectus and any related free writing prospectus and any related free writing prospectus is delivered or ADS is sold on a later date.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

#### FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated in it by reference contain forward-looking statements that involve risks and uncertainties. Forward-looking statements relate to future events or our future financial performance and include

information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the progress and timing of our clinical trials or product candidate development programs, the effect of existing and future regulations and the effects of competition. These statements are based on our current expectations, beliefs and assumptions, and on information currently available to our management. In some cases, you can identify forward-looking statements by the use of words such as anticipate , expect , intend , plan , seek , may , will , should , could , would , believe , estimate , project , p the negative of such terms or similar expressions. These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors which may cause our actual

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results, levels of activities, performance and other factors to be materially different from those anticipated in such forward-looking statements. Factors that might cause such differences include the risks discussed in Risk Factors.

This list of risk factors is not exclusive and other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements. You should consider these factors and the other cautionary statements made in this prospectus supplement, the accompanying prospectus or the documents we incorporate by reference in this prospectus supplement or the accompanying prospectus as being applicable to all related forward-looking statements wherever they appear in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference. We caution investors not to place significant reliance on the forward-looking statements contained herein. These statements, like all statements in this prospectus supplement, speak only as of the date hereof (unless another date is indicated) and we undertake no obligation to update or revise the statements.

Any statements in this prospectus supplement that relate to the Company s expectations are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act. The Private Securities Litigation Reform Act of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees. Since this information may involve risks and uncertainties and are subject to change at any time, the Company s actual results may differ materially from expected results. Additional risks associated with Genetic Technologies business can be found in its periodic filings with the SEC.

#### PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. The summary may not contain all the information that you should consider before investing in the ADS. You should read the entire prospectus supplement and the accompanying prospectus carefully, including Risk Factors contained in this prospectus supplement and the documents incorporated by reference in the accompanying prospectus, before making an investment decision. This prospectus supplement may add to, update or change information in the accompanying prospectus.

#### **Genetic Technologies Limited**

We are a molecular diagnostics company, based in Melbourne, Australia. Historically, the principal activity of the Company had been the provision of genetic testing services. On September 15, 2014 we announced plans to restructure and realign our group activities, in order to focus our strategy on the U.S. molecular diagnostics market and the commercialisation of our lead breast cancer risk test BREVAGen through our U.S. subsidiary Phenogen Sciences, Inc. In October 2014, we announced the U.S. release of BREVAGen*plus*, an easy-to-use predictive risk test for the millions of women at risk of developing sporadic, or non-hereditary, breast cancer, representing a marked enhancement in accuracy and broader patient applicability, over our first generation BREVAGen product. We also made a pivotal change of sales and marketing emphasis toward large comprehensive breast treatment and imaging centers, which are more complex entities with a longer sales cycle, but higher potential. As part of this realignment, on November 19, 2014 we completed the sale of our Heritage Australian genetics business to Specialist Diagnostic Services Ltd. As part of the Company s strategy to focus on the expansion of its cancer diagnostic franchise, we continue to evaluate opportunities

to sell, out-license or co-develop other assets and technologies in which we have an interest, including our legacy non-coding assertion and licensing program.

Physicians who order clinical tests for their patients represent the primary sources of our testing volume. Fees invoiced to patients and third parties are based on our fee schedule, which may be subject to limitations imposed by third-party payers. The clinical laboratory industry is highly regulated and subject to significant and changing Federal and state laws and regulations. These laws and regulations affect key aspects of our business, including licensure and operations, billing and payment for laboratory services, sales and marketing interactions with ordering physicians, security and confidentiality of health information, and environmental and occupational safety. Oversight by government officials includes regular inspections and audits. We seek to and believe that we do conduct our business in compliance with all applicable laws and regulations.

The United States Clinical Laboratory Improvement Amendments of 1988, or CLIA, extends Federal licensing requirements to all clinical laboratories (regardless of the location, size or type of laboratory), including

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those operated by physicians in their offices, based on the complexity of the tests they perform. CLIA also establishes a stringent proficiency testing program for laboratories and includes substantial sanctions, such as suspension, revocation or limitation of a laboratory s CLIA certificate (which is necessary to conduct business), and significant fines and/or criminal penalties.

CLIA, and its implementing regulations, includes quality standards (establishing Federal quality standards for all clinical laboratories); application and user fee requirements; and enforcement procedures. The quality standard regulations establish varying levels of regulatory scrutiny depending upon the complexity of testing performed. The tests on samples provided through our products are processed at our laboratory in Melbourne, Australia. Our laboratory completed its first CLIA inspection under CLIA guidelines and received its certificate of compliance effective November 17, 2011. A re-certification from CMS i.e. paper survey, was performed in November 2013 and another on-site re-certification followed up in February 2016. Furthermore, our laboratory completed its first CLEP inspection under the NYS DOH CLEP guidelines and received its certificate of compliance effective August 30, 2013. Since the initial survey, the laboratory has been successful in submitting documents via the NYS eCLEP Health Commerce System for each subsequent year to date. The laboratory is expecting an on-site visit in the near future in late 2016 or early 2017.

We believe the Company is in compliance with all applicable federal and state laboratory requirements. Under CLIA, the company remains subject to state and local laboratory regulations. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and some states require additional personnel qualifications, quality control, record maintenance and other requirements.

BREVAGen and BREVAGen*plus* are laboratory developed tests, or LDTs. The federal Food and Drug Administration, or FDA, has regulatory responsibility over, among other areas, instruments, test kits, reagents and other medical devices used by clinical laboratories to perform diagnostic testing. CLIA-certified laboratories, such as ours, frequently develop internal testing procedures to provide diagnostic results to customers. These tests are referred to as laboratory developed tests, or LDTs. LDT s are subject to CMS oversight through its enforcement of CLIA. The FDA has also claimed regulatory authority over all LDTs, but indicates that it has exercised enforcement discretion with regard to most LDTs offered by high complexity CLIA-certified laboratories, and has not subjected these tests to the panoply of FDA rules and regulations governing medical devices. However, the FDA has stated that it has been considering changes in the way it believes that laboratories ought to be allowed to offer these LDTs, and during 2010 publicly announced that it would be exercising regulatory authority over LDTS, using a risk-based approach that will direct more resources to tests with the highest risk of injury. In September 2014, the FDA announced its framework and timetable for implementing this guidance.

#### **Corporate Information**

Our registered office, headquarters and laboratory is located at 60-66 Hanover Street, Fitzroy, Victoria, 3065, Australia and our telephone number is +61 3 8412 7000. The offices of our U.S. subsidiary, Phenogen Sciences Inc., are located at 9115 Harris Corners Parkway, Suite 320, Charlotte, North Carolina, 28269 U.S.A. The telephone number for the Phenogen Sciences office is (877) 992 7382. Our website address is www.gtglabs.com. The information in our website is not incorporated by reference into this prospectus supplement and should not be considered as part of this prospectus supplement.

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## The Offering

Securities offered	720,000,000 ordinary shares represented by 4,800,000 ADSs	
The ADSs	Each ADS represents 150 ordinary shares, no par value. The offered ADSs are evidenced by ADRs.	
Depositary	The Bank of New York Mellon	
Ordinary Shares outstanding before this offering	1,715,282,724 ordinary shares, represented by 11,435,218 ADS.	
Ordinary Shares outstanding after this offering	2,435,282,724 ordinary shares, represented by 16,235,218 ADS.	
Use of proceeds	We intend to use the net proceeds from the sale of Securities for general working capital purposes, including the expansion of our U.S. operations, and the possible acquisition of other complimentary technologies and tests. See Use of Proceeds.	
NASDAQ Capital Market symbol:	GENE	
Risk Factors	This investment involves a high degree of risk. See Risk Factors beginning on page S-5 of this prospectus supplement as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of risks you should consider carefully before making an investment decision.	

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#### **RISK FACTORS**

Before making an investment decision, you should carefully consider the risks described in this prospectus supplement, together with all of the other information incorporated by reference into this prospectus supplement and the accompanying prospectus. The following risks are presented as of the date of this prospectus supplement and we expect that these will be updated from time to time in our periodic reports filed with the Securities and Exchange Commission, or the SEC, which will be incorporated herein by reference. Please refer to these subsequent reports for additional information relating to the risks associated with investing in our ADSs. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose part or all of your investment.

#### **Risks Related to the Offering**

We will have broad discretion in how we use the proceeds, and we may use the proceeds in ways in which you and other shareholders may disagree.

Our management will use its discretion to direct the use of the net proceeds from this offering. We intend to use the net proceeds from this offering for general working capital purposes, including the expansion of our U.S. operations, and the possible acquisition of other complimentary technologies and tests. Our management s judgments may not result in positive returns on your investment and you will not have the opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

#### You will experience immediate and substantial dilution in the net tangible book value per share of the ADSs you purchase.

Since the offering price per share of our ADSs being offered is substantially higher than the net tangible book value per share of our ADSs, you will suffer substantial dilution in the net tangible book value of the ADSs you purchase in this offering. Based on the price of \$1.25 per ADS, if you purchase ADSs in this offering, you will suffer immediate and substantial dilution of approximately \$0.0028 per share (\$0.0421 per ADS) in the net tangible book value of the ADSs. See the section entitled Dilution on page S-24 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase ADSs in this offering.

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

Holders of our ADSs who are U.S. residents face income tax risks. There is a substantial risk that we are, or will become, a passive foreign investment company, commonly referred to as a PFIC. Our treatment as a PFIC could result in a reduction in the after-tax return to the holders of our ADSs and would likely cause a reduction in the value of such ADSs. For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which either (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, cash is considered to be an asset that produces passive income. We believe we were a PFIC for the taxable year ended June 30, 2016 and we expect we will be classified as a PFIC

for the taxable year ended June 30, 2017. If we are classified as a PFIC for U.S. federal income tax purposes, highly complex rules will apply to U.S. holders owning ADSs. Accordingly, you are urged to consult your tax advisors regarding the application of such rules. United States residents should carefully read Item 10.E. Additional Information Taxation United States Federal Income Taxation of our Annual Report on Form 20-F for the fiscal year ended June 30, 2016, for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of our ADSs.

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#### **Risks Related to Our Business and Business Strategy**

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

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

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

Since our listing on the Australian Securities Exchange in August 2000, the price of our Ordinary Shares has ranged from a low of A\$0.010 to a high of A\$0.97 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 following chart illustrates the fluctuation in the price of our shares (in Australian dollars) over the last five years:

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#### (Source: Yahoo Finance: https//au.finance.yahoo.com/)

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

We have never paid a cash dividend on our Ordinary Shares and we do not anticipate paying a cash dividend 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.

#### 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*. The majority of our directors and officers named in this prospectus supplement 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 where the defendant has not been properly served in Australia.

# Because we are not necessarily 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 or 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 financial results on a semi-annual basis (which is performed under International Standard on Review Engagements) and to be fully audited annually (which is performed under International Standards on Auditing) which are required to have a limited review semi-annually and to be fully audited annually. 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 will 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.

## If significant liquidity does not eventuate for our ADSs on NASDAQ, your ability to resell your ADSs could be negatively affected because there would be limited buyers for your interests.

Historically, there was virtually no trading in our ADSs through the pink sheets after the establishment of our Level I ADR Program. However, subsequent to the Level II listing of our ADSs on the NASDAQ Global Market on September 2, 2005, the trading volumes of our ADSs have increased. The Company subsequently

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transferred the listing of its ADSs to the NASDAQ Capital Market effective as from 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.

#### Our Company has a history of incurring losses.

The business now called Genetic Technologies Limited was founded in 1989. With the exception of the year ended June 30, 2011, the Company has incurred operating losses in every year of its existence. As at June 30, 2016, the Company had accumulated losses of \$109,444,248 and the extent of any future losses and whether or not the Company can generate profits in future years remains uncertain. The Company currently does not generate sufficient revenue to cover its operating expenses. We expect our capital outlays and operating expenditures to continue to increase for the foreseeable future as we seek to establish the BREVAGen*plus* test as a leading non-hereditary breast cancer risk assessment test. In order to fund the commercialization of BREVAGen*plus*, further expand our clinical laboratory operations, technologies and research & development activities, we may need to raise additional capital. There is no certainty that the Company will be able to raise additional funds by issuing further shares and/or the raising of debt and, if such funds are available, on what terms the Company would be able to secure them.

#### Going concern.

During the 2016 financial year, the Company incurred a total comprehensive loss after income tax of \$7,151,746 (2015: \$8,396,165) and net cash outflows from operations of \$7,726,838 (2015: \$9,691,528).

As of June 30, 2016, the Company held cash reserves of \$11,179,687 and had net current assets of \$10,798,881.

During the 2017 financial year, the Directors expect increased cash outflows from operations as the Company continues to invest resources in expanding the research & development and sales & marketing activities in support of BREVAGen*plus*® in the U.S. As a result of these expected cash outflows, the Directors intend to raise new equity funding within the next twelve months in order to ensure the Company continues to hold adequate levels of available cash resources to meet creditors and other commitments.

The continuing viability of the Company and its ability to continue as a going concern and meet its debts and commitments as they fall due is dependent on the satisfactory completion of the planned equity raising.

Due to the uncertainty surrounding the timing, quantum or the ability to raise additional funds via the issuance of new equity, there is a material uncertainty that may raise substantial doubt on the Company s ability to continue as a going concern and therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of June 30, 2016, the report of our independent registered public accounting firm in our Annual Report on Form 20-F for the year ended June 30, 2016 includes a going concern explanatory paragraph. However, the Directors believe that the Company will be successful in the above matters and accordingly, have prepared the financial report on a going concern basis. As such no adjustments have been

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made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should the Company not be able to continue as a going concern.

#### **Risks Related to our Industry**

Our sales cycle is typically lengthy.

The sales cycle for our testing products is typically lengthy. As a result, we may expend substantial funds and management effort with no assurance of successfully selling our products or services. Our ability to obtain customers for our molecular risk assessment and predictive genetic testing services depends significantly on the perception that our services can help accelerate efforts in genomics. Our sales effort requires the effective demonstration of the benefits of our services to, and significant training of, many different departments within a potential customer. In addition, we sometimes are required to negotiate agreements containing terms unique to each customer. Our business could also be adversely affected if we expend money without any return.

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

Though we currently have no direct competition in this space, we are currently subject to 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 services, 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:

#### • maintain first to market advantage;

• continue to strengthen and maintain scientific credibility through the process of obtaining scientific validation and undertaken further clinical trials supported by Peer-reviewed publication in medical journals;

- create and maintain scientifically-advanced technology and offer proprietary products and services;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and services;

### • obtain 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 and services obsolete, noncompetitive or uneconomical.

#### 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 as a result of our domestic or foreign patent applications or that any of our issued patents will withstand challenges by others.

In addition, patents issued to, or licensed by us may be infringed or third parties may independently develop the same or similar technologies. Our patents may also 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

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may sue or be sued by third parties regarding our patents and other intellectual property rights, which could further expose our patents to claims of invalidity or unenforceability. These suits are often costly and would divert valuable funds, time and technical resources from our operations and cause a distraction to management.

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

We have relationships with academic consultants 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, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results from operations. To the extent that our scientific consultants develop inventions or processes independently 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 professional liability suits and our insurance may not be sufficient to cover damages. If this occurs, our business and financial condition may be adversely affected.

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 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 services. Litigation of such claims could be costly. We could expend significant funds during any litigation proceeding brought against us. 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 broadform liability and professional indemnity policies, for an aggregate amount of A\$60,000,000, the level or breadth of our coverage may not be adequate to fully cover any potential liability claims. To date we have not been subject to any claims, or ultimately liability, in excess of the amount of our coverage. In addition, we may not be able to obtain additional professional 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 liability litigation upon the reputation and marketability of our technology and products, together with the diversion of the attention of key personnel, could negatively affect our business.

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

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

a reportable event or serious injury.

In addition, our collaborators and service providers may be working with these same types of hazardous materials, including hazardous chemicals, in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials or patient samples that may contain infectious materials. The cost of this liability could exceed our resources. While we maintain broadform liability insurance coverage for these risks, in the amount of up to A\$40,000,000, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. To date, we have not been subject to claims, or ultimately liability, in excess of the amount of our

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coverage. Our broadform insurance coverage also covers us against losses arising from an interruption of our business activities as a result of the mishandling of such materials. We also maintain workers compensation insurance, which is mandatory in Australia, covering all of our workers in the event of injury.

We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialization of some 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 some 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.

Other than our contractual rights under our license agreements, we may be limited in our ability to convince our licensees to fulfill their obligations. If our licensees fail to act promptly and effectively, or if a dispute arises, it could have a material adverse effect on our results of operations and the price of our ordinary shares and ADSs.

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.

We may seek additional collaborative arrangements to develop and commercialize our products in the future. We may not be able to negotiate acceptable arrangements in the future and, if negotiated, we have no certainty that they will be on favorable terms or if they will be successful. In addition, our partners may pursue alternative technologies independently or in collaboration with others as a means of developing treatments for the diseases targeted by their collaborative programs with us. If any of these events occur, the progress of the Company could be adversely affected and our results of operations and financial condition could suffer.

Currently our financial results depend largely on the sales of our breast cancer risk assessment test, BREVAGenplus.

For the near future, we expect to continue to derive a substantial majority of our revenues from sales of one test, our breast cancer risk BREVAGen test. Although in October 2014, we announced the U.S. release of BREVAGen*plus*, a second generation BREVAGen product, we do not expect to recognize significant revenues from this test until significant levels of adoption have been established. If we are unable to increase sales of BREVAGen*plus* or successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve sustained profitability would be impaired.

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

We do not have redundant clinical reference laboratory facilities outside of Melbourne, Australia. Our current lease of laboratory premises expires August 31, 2018. The facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future.

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

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

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical as we continue to develop our technologies and testing processes, continue our international expansion and transition to a company with multiple commercialized products on offer. 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. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and close relationships with medical oncologists, pathologists and other hospital personnel. We may have difficulties sourcing, recruiting or retaining qualified salespeople, which could cause delays or a decline in the rate of adoption of our tests. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development and sales programs. All of our U.S employees are at-will, which means that either we or the employee may terminate their employment at any time.

FDA regulation of LDTs may result in significant changes, and our business could be adversely impacted if we fail to adapt.

Clinical laboratory tests like ours are regulated under the CLIA, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the federal Food and Drug Administration (FDA). The FDA has exercised its discretion and has not subjected most

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Laboratory Developed Tests, or LDTs to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation.

The FDA claims to have regulatory authority over LDTs under the Medical Device Amendments of 1976 and has stated in the past that it would issue guidance to the industry regarding its regulatory approach. In such discussions, the FDA has indicated that it would use a risk-based approach to regulation and would direct more resources to tests with wider distribution and with the highest risk of injury, but that it will be sensitive to the need to not adversely impact patient care or innovation. In October 2014, the FDA announced its framework and timetable for implementing this guidance. We cannot predict the ultimate timing or form of any such guidance or regulation and the potential impact on our existing tests. If adopted, such a regulatory approach by the FDA may lead to an increased regulatory burden, including additional costs and delays in introducing new tests or even continuing with our current tests. While the ultimate impact of the FDA is approach is unknown, it may be extensive and may result in significant changes. Our failure to adapt to these changes could have a material adverse effect on our business.

If the FDA decides to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any future tests, and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

Even if the clinical trials are timely completed, there is no assurance that the results of those trials will be sufficient to support regulatory clearance or approval for the intended indications. Failure of the clinical data to support an intended use of given LDT would likely have an adverse impact on the Company.

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

The clinical laboratory testing industry is subject to extensive federal and state regulation, and many of these statutes and regulations have not been interpreted by the courts. The regulations implementing CLIA set out federal regulatory standards that apply to virtually all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, by requiring that they be certified by the federal government or by a federally approved accreditation agency. CLIA does not preempt state law, which in some cases may be more stringent than federal law and require additional personnel qualifications, quality control, record maintenance and proficiency

testing. The sanction for failure to comply with CLIA and state requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Several states have similar laws and we may be subject to similar penalties. If the certification of one laboratory owned by the Company is suspended or revoked that may preclude the Company from owning or operating any other laboratory in the the U.S. for two years.

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We cannot assure you that applicable statutes and regulations and more specifically, the Food, Drug, and Cosmetic Act, will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and 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 perform to, 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.

Failure to timely or accurately bill for our services could have a material adverse effect on our business.

Billing for clinical testing services is extremely complicated and is subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, Medicare, Medicaid, physicians and hospitals. Changes in laws regulations and contract terms could increase the complexity and cost of our billing process. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures add further cost and complexity to the billing process.

Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense. Failure to timely or correctly bill may lead to us not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing government healthcare programs or private healthcare programs that operate under government contract could lead to various penalties, including: (1) exclusion or suspension from participation in federal health care programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; (3) possible liability under the federal False Claims Act and state analogs, and (4) the loss of various licenses, certificates and authorizations necessary to operate our business, any of which could have a material adverse effect on our results of operations or cash flows.

Failure to comply with complex federal and state laws and regulations related to submission of claims for clinical laboratory services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for clinical laboratory services, including those that relate to coverage of our services under Medicare, Medicaid and other governmental health care programs, the amounts that may be billed for our services and to whom claims for services may be submitted. In addition, we are subject to various laws regulating our interactions with other healthcare providers and with patients, such as the Anti-Kickback Statute, the Anti-Inducement Statute, and the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark law. These laws are complicated.

Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or result in attempts by third-party payers, such as Medicare and Medicaid, to recover payments

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from us that have already been made. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including substantial civil penalties for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare, Medicaid and other federal health care programs. Government authorities or whistleblowers may also assert that violations of laws and regulations related to submission or causing the submission of claims violate the federal False Claims Act, or FCA, or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. Violations of the FCA could result in significant economic liability. The FCA provides that all damages are trebled, and each false claim submitted is subject to a penalty of up to \$21,563 for violations occurring after November 2, 2015 and \$11,000 for violations occurring before November 2, 2015. For example, we could be subject to FCA liability if it were determined that the services we provided were not medically necessary and not reimbursable or if it were determined that we improperly paid physicians who referred patients to our laboratory. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by an entity for services that we performed if we were found to have knowingly participated in the arrangement that resulted in submission of the improper claims.

## Failure to comply with HIPAA, including regarding the use of new standard transactions, may negatively impact our profitability and cash flows.

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

In addition, HIPAA not only seeks to ensure patient privacy, but also requires providers that bill electronically to do so using standard code sets. These HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. As a result of inconsistent application of transaction standards by payers or our inability to obtain certain billing information not usually provided to us by physicians, we could face increased costs and complexity, a temporary disruption in receipts and ongoing reductions in the timeliness of reimbursement. In addition, new requirements for additional standard transactions, such as claims attachments, Version 5010 of the HIPAA Transaction Standards and the ICD-10-CM Code Set, could prove technically difficult, time-consuming or expensive to implement.

## Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

The clinical laboratory testing industry is highly regulated and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal and state laws applicable to billing and claims payment;
- federal and state laboratory anti-mark-up laws;

- federal and state anti-kickback laws;
- federal and state false claims laws;

• federal self-referral and financial inducement prohibition laws, commonly known as the Stark Law, and the state equivalents;

- federal and state laws governing laboratory licensing and testing, including CLIA;
- federal and state laws governing the LDTs;
- HIPAA, along with the revisions to HIPPA as a result of the HITECH Act, and analogous state laws;
- federal, state and foreign regulation of privacy, security, electronic transactions and identity theft;
- federal, state and local laws governing the handling, transportation and disposal of medical and hazardous waste;

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- Occupational Safety and Health Administration rules and regulations;
- changes to laws, regulations and rules as a result of the Health Care Reform Law; and
- changes to other federal, state and local laws, regulations and rules, including tax laws.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of business, there is an ongoing awareness of the importance of compliance with these laws. The growth of our business and sales organization may increase the potential for violating these laws or our internal policies and procedures, despite our ongoing vigilance in maintaining and updating our compliance procedures. The risk of being found in violation of these or other laws and regulations is further increased by the fact that many of them are extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. 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 management s attention. Any determination that we have violated these laws or regulations, or a public announcement that we are being investigated for possible violations of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. In addition, a significant change in any of these laws or regulations may require us to change our business model in order to maintain compliance with these laws or regulations, which could harm our operating results and financial condition.

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

Federal officials responsible for administering and enforcing the healthcare laws and regulations have made a priority of eliminating healthcare fraud. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act of 2010, jointly the Affordable Care Act, includes significant new fraud and abuse measures, including required disclosures of financial arrangements between drug and device manufacturers, on the one hand, and physicians and teaching hospitals, on the other hand. Federal funding available for combating health care fraud and abuse generally has increased. While we seek to conduct our business in compliance with all applicable laws and regulations, many of the laws and regulations applicable to our business, particularly those relating to billing and reimbursement of tests and those relating to relationships with physicians, hospitals and patients, contain language that has not been interpreted by courts. We must rely on our interpretation of these laws and regulations based on the advice of our counsel and regulatory or law enforcement authorities may not agree with our interpretation of these laws and regulations and may seek to enforce legal remedies or penalties against us for violations. From time to time we may need to change our operations, particularly pricing or billing practices, in response to changing interpretations of these laws and regulations or regulatory or judicial determinations with respect to these laws and regulations. These occurrences, regardless of their outcome, could damage our reputation and harm important business relationships that we have with healthcare providers, payers and others. Furthermore, if a regulatory or judicial authority finds that we have not complied with applicable laws and regulations, we could be required to refund amounts that were billed and collected in violation of such laws and regulations. In addition, we may voluntarily refund amounts that were alleged to have been billed and collected in violation of applicable laws and regulations. In either case, we could suffer civil and criminal damages, fines and penalties, exclusion from participation in governmental healthcare programs and the loss of licenses, certificates and authorizations necessary to operate our business, as well as incur liabilities from third-party claims, all of which could harm our operating results and financial condition. Moreover, regardless of the outcome, if we or physicians or other third parties with whom we do business are investigated by a regulatory or law enforcement authority we could incur substantial costs, including legal fees, and our management may be required to divert a substantial amount of time to an investigation.

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To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the United States Department of Health and Human Services Office of Inspector General, or OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the United States Sentencing Commission Guidelines Manual, and for many years the OIG has made available a model compliance program targeted to the clinical laboratory industry. In addition, certain states, such as New York, require that health care providers, such as clinical laboratories, that engage in substantial business under the state Medicaid program have a compliance program that generally adheres to the standards set forth in the Model Compliance Program. Also, under the Affordable Care Act, the U.S. Department of Health and Human Services, or HHS, will require suppliers, such as the Company, to adopt, as a condition of Medicare participation, compliance programs that meet a core set of requirements.

## Failure to maintain the security of patient-related information or compliance with security requirements could damage our reputation with customers, cause us to incur substantial additional costs and become subject to litigation.

Pursuant to HIPAA, and certain similar state laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information. Under the HITECH amendments to HIPAA, HIPAA was expanded to require certain data breach notification, to extend certain HIPAA privacy and security standards directly to business associates, to heighten penalties for noncompliance, and enhance enforcement efforts.

We receive certain personal and financial information about our clients and their patients. In addition, we depend upon the secure transmission of confidential information over public networks. A compromise in our security systems that results in client or patient personal information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely affect our operations, financial condition and liquidity.

## Changes in regulation and policies, including increasing downward pressure on health care reimbursement, may adversely affect reimbursement for diagnostic services and could have a material adverse impact on our business.

Reimbursement levels for health care services are subject to continuous and often unexpected changes, and we face a variety of efforts by government payers to reduce utilization and reimbursement for diagnostic testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, or other policy changes.

The U.S. Congress has considered, at least yearly in conjunction with budgetary legislation, changes to one or both of the Medicare fee schedules under which we receive reimbursement, which include the clinical laboratory fee schedule for our clinical laboratory services. For example, Congress has periodically considered imposing a 20 percent coinsurance on laboratory services. If enacted, this would require us to attempt to collect this amount from patients, although in many cases the costs of collection would exceed the amount actually received.

The CMS pays laboratories on the basis of a of a fee schedule that is reviewed and re-calculated on an annual basis. CMS may change the fee schedule upward or downward on billing codes that we submit for reimbursement on a regular basis. Our revenue and business may be adversely

affected if the reimbursement rates associated with such codes are reduced. Even when reimbursement rates are not reduced, policy changes add to our costs by increasing the complexity and volume of administrative requirements. Medicaid reimbursement, which varies by state, is also subject to administrative and billing requirements and budget pressures. Recently, state budget pressures have caused states to consider several policy changes that may impact our financial condition and results of operations, such as delaying payments, reducing reimbursement, restricting coverage eligibility and service coverage, and imposing taxes on our services.

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# Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

Fees for most laboratory services reimbursed by Medicare are established in the Clinical Laboratory Fee Schedule (CLFS), and fees for other testing reimbursed by Medicare, primarily related to pathology, are covered by the Physician Fee Schedule (PFS). Over the past several years, the Company has experienced governmental pay reductions as a direct result of the Affordable Care Act (ACA), the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the Achieving a Better Life Experience Act of 2014 (ABLE Act). In addition, the Protecting Access to Medicare Act (PAMA), which became law on April 1, 2014, is expected to result in a future net reduction in reimbursement revenue under the CLFS. These laws include provisions designed to control healthcare expenses reimbursed by government programs through a combination of reductions to fee schedules, incentives to providers to participate in alternative payment models such as risk-sharing and new methods to establish and adjust fees.

The Affordable Care Act makes changes that are expected to significantly affect clinical laboratories, among others. Beginning in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. The Consolidated Appropriations Act, 2016 (Dec. 18, 2015) imposed a two-year moratorium on this medical device tax so it would not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on Jan. 1, 2016, and ending on Dec. 31, 2017.

Although the FDA has contended that LDTs are medical devices, none of our products is currently listed with the FDA. We cannot assure you that the tax, once the moratorium sunsets, will not be extended to services such as ours in the future. The Affordable Care Act also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% through 2015 and a productivity adjustment to the CLFS. Moreover, under Protecting Access to Medicare Act, CMS will be required to set and make adjustments to the CLFS using market-based information that reflects the scope of prices paid across the laboratory industry. On October 1, 2015, CMS issued a proposed rule to implement PAMA that would require applicable laboratories, including the Company, to begin reporting their test-specific private payer payment amounts to CMS during the first quarter of 2016. CMS intends to use that private market data to calculate weighted median prices for each test (based on applicable CPT codes) that would represent the new CLFS rates beginning in 2017, subject to certain phase-in limits. For 2017-2019, a test price cannot be reduced by more than 10.0% per year; for 2020-2022, a test price cannot be reduced by more than 15.0% per year. Reporting and pricing will occur every three years, or annually with respect to certain types of tests, to update the CLFS thereafter.

Other significant measures contained in the Affordable Care Act includes, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The Affordable Care Act also includes significant new fraud and abuse measures, including required disclosures by drug and device manufacturers and distributors of financial arrangements with physicians and teaching hospitals. In addition, the Health Care Reform Law establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for services. The IPAB proposals may impact payments for clinical laboratory services beginning in 2016. We are monitoring the impact of the Health Care Reform Law in order to enable us to determine the trends and changes that may be necessitated by the legislation that may potentially impact on our business over time.

In addition to the Affordable Care Act, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012 which in part reduced the potential future cost-based increases to the Medicare Clinical Laboratory Fee Schedule by 2%. Overall the expected total fee cut to the CLFS for 2013 was 2.95% not including a further reduction of 2% from implementation of the automatic expense reductions (sequester) under the Budget Control

Act of 2011 which went into effect for dates of service on or after April 1, 2013. Reductions made by the Congressional sequester are applied to total claims payments made. While these reductions did not result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates, rebasing could occur as a result of future legislation. In 2015, the total fee cut to the CLFS was 0.25%.

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On June 23, 2016, the CMS published a final rule implementing PAMA, which required establishment of a new Medicare reimbursement system for clinical lab tests paid under the CLFS, based on private payer rates, as reported to CMS. Although the new payment system was supposed to go into effect for tests furnished after January 1, 2017, the CMS rulemaking process was delayed, and the new rates will not be effective until January 1, 2018 pursuant to the final rule. Under the new system the Company must collect data on private payer rates and report the data to CMS every three years for most types of tests. The Company does not expect that the new reporting requirements will have a material impact on its business or results of operations. CMS will use the data reported by all applicable labs to calculate a weighted median of private payer rates for each test performed, and that weighted median will be the new Medicare rate. Rate reductions for existing tests under the new system will be phased in over six years. The Company is still assessing the full impact of the final rule, but has been preparing for it for some time.

We cannot be certain that these or future changes will not affect payment rates in the future. We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, cost reduction measures and the expansion in government s role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payers for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

#### Healthcare plans have taken steps to control the utilization and reimbursement of healthcare services, including clinical test services.

We also face efforts by non-governmental third-party payers, including healthcare plans, to reduce utilization and reimbursement for clinical testing services.

The healthcare industry has experienced a trend of consolidation among healthcare insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical testing providers. These healthcare plans, and independent physician associations, may demand that clinical testing providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capped payment arrangements. In addition, some healthcare plans have been willing to limit the PPO or POS laboratory network to only a single national laboratory to obtain improved fee-for-service pricing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost-sharing.

The increased consolidation among healthcare plans also has increased the potential adverse impact of ceasing to be a contracted provider with any such insurer.

We expect continuing efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services. These efforts, including future changes in third-party payer rules, practices and policies, or ceasing to be a contracted provider to a healthcare plan, may have a material adverse effect on our business.

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 services. Accordingly, any regulations of this nature could increase the costs of our operations or restrict our ability to conduct our testing business and might adversely affect our operations and financial condition.

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

We transport specimens from our North Carolina offices in the U.S. to our laboratory located in Melbourne, Australia. Our operations may be adversely impacted by extreme weather conditions or other interruptions 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.

# Failure in our information technology systems could significantly increase testing turn-around time or billing processes and 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, provide test results in a timely manner and/or bill the appropriate party. Breaches with respect to protected health information could result in violations of HIPAA and analogous state laws, and risk the imposition of significant fines and penalties. Failure of our information technology systems could adversely affect our business, profitability and financial condition.

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

In order to assure adequate insurance coverage and favorable insurance reimbursement of our products, we are required to demonstrate the clinical utility of our tests. Clinical utility which is the usefulness of a test for clinical practice (as contrasted with diagnostic accuracy, which is how well the test can determine the presence, absence, or risk of a specific disease) may well be the most significant limitation for the widespread acceptance of molecular diagnostic tools such as BREVAGen*plus*. We are currently undertaking studies intended to demonstrate the clinical utility of our tests in order to assure continued acceptance of the value of our products. These studies will require us to invest considerable financial and management resources without any assurance of favorable results. Successful studies are difficult to plan, execute and validate, because of the time involved and variables that are difficult to control and which can impact outcomes. If we are unable to demonstrate clinical utility, or if our data is deemed insufficient to validate utility, which are required for Medicare coverage, then we may face negative coverage decisions for our products. The resulting negative coverage decisions could have a material adverse effect on our financial conditions and results of operations.

## 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 services, which could materially and adversely affect our financial position.

We do not however undertake any activities in the contentious areas of cloning, stem cell research or other gene-altering areas. As such, many of the ethical issues that may be relevant to other participants in the genetics industry are not necessarily applicable to us.

## Risks Associated with the Out-Licensing of 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 over uses of non-coding DNA have broad scope and have also been the subject of debate and some criticism in the media.

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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 counter-claim of patent invalidity or other such claims. Subsequent legal action could potentially overturn, invalidate or limit the scope of our patents.

Under the relevant Patent Acts in most of the countries in which our non-coding patents have issued, the relevant judicial system has rights to impose compulsory licensing. The relevant governments typically hold march-in rights by which they may unilaterally choose to exploit the technology. To the extent that the Company s non-coding technology is used in the conduct of research, we also face risks, uncertainty and controversy over the licensing of our technology to those conducting the research. Whether or not researchers should be exempted from obligations to take licenses to relevant patents was the subject of another government inquiry conducted by the Australian Council for Intellectual Property who recommended the creation of a research exemption.

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## **RECENT DEVELOPMENTS**

New York License

Notification has been received from NYS DOH CLEP that our validation data and submitted portions of our standard operating material have been routed for review. Whilst under review, we may offer the assay under our current permit. Upon completion of the review, we will be notified that the testing has either been fully approved or that additional information is required in order to achieve final approval. If additional information is requested, we will have 60 business days to provide a response in order to continue making the test available, pending final approval.

We have been advised by NYS DOH CLEP that the letter of notification received may be shared with our New York clients and that we can begin to offer BREVAGenplus in NY State.

As a result of Enhancing the BREVAGenplus test, we need to advise and forward all scientific papers and other information, including sections of our standard operating procedures and marketing material, as it relates to the enhancement, to the NYS DOH CLEP for review and approval. Again, as before, conditional approval will first be granted under our current permit and will be operational until the full assay assessment has been completed and final approval granted or additional information requested in order to achieve final approval.

All relevant documentation, together with covering letter, is on schedule to be filed with NYS DOH CLEP by mid-December 2016.

## **FINRA Inquiry**

On December 1, 2016, we received correspondence from the Financial Industry Regulatory Authority, or FINRA, - Office of Fraud Detection and Market Intelligence.

The basis of the communication was that FINRA is conducting a review of trading in our common stock surrounding our November 29, 2016 news announcement that we had entered into a definitive license agreement with the University of Melbourne for the development and commercialization of a novel colorectal cancer risk assessment test. As requested we spoke with FINRA on December 1, 2016 regarding the events leading up to the news announcement to establish a time line of events.

## **USE OF PROCEEDS**

Assuming the sale of all of the securities being offered under this prospectus supplement, we expect to receive net proceeds of approximately US\$5.0 million from this offering after deducting placement agent fee of 7.0% of the gross proceeds and estimated offering expenses payable by us of approximately US\$500,000. Except as described in any free writing prospectus that we may authorize to be provided to you, we currently intend to use the net proceeds from this offering, if any, primarily for general working capital purposes, including the expansion of our U.S. operations, and the possible acquisition of other complimentary technologies and tests.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we expect to invest the net proceeds in highly liquid investments.

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#### DILUTION

Our net tangible book value as of June 30, 2016 was approximately \$8,379,366 or \$0.0049 per ordinary share. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the total number of ordinary shares outstanding.

After giving effect to the sale by us of 720,000,000 ordinary shares represented by 4,800,000 ADSs offered pursuant to this prospectus supplement at a price of \$1.25 per ADS, and after deducting placement agent fees and other estimated offering expenses, our net tangible book value at June 30, 2016 would have been \$13,459,366, or \$0.0055 per ordinary share (\$0.83 per ADS). This represents an immediate increase in net tangible book value of \$0.0006 per ordinary share to the then existing shareholders and an immediate dilution of \$0.0028 per ordinary share to new investors (\$0.0421 per ADS).

The following table illustrates the net tangible book value dilution per ordinary share to shareholders after the issuance of ordinary shares under this prospectus supplement:

Public offering price per ordinary share	\$	0.0083
Net tangible book value per ordinary share as of June 30, 2016	\$ 0.0049	
Increase per ordinary share attributable to new investors	\$ 0.0006	
Pro Forma net tangible book value per ordinary share after this offering	\$	0.0055
Net tangible book value dilution per ordinary share to new investors	\$	0.0028

This discussion of dilution, and the table quantifying it, assumes no exercise of any outstanding options over our ordinary shares. The table above contains a translation of net tangible book value at June 30, 2016 from Australian dollar amounts into U.S. dollar amounts at specified rates solely for the convenience of the reader. The translation of Australian dollars into U.S. dollars has been made at the exchange rate as quoted by the Federal Reserve Bank of New York on June 30, 2016, which was A\$1 to US\$0.7432.

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### PLAN OF DISTRIBUTION

We are offering the securities through our placement agent, Maxim Group LLC. Subject to the terms and conditions contained in the placement agency agreement, dated December 1, 2016, Maxim Group LLC has agreed to act as the placement agent for the offering on a reasonable best efforts basis. The placement agent is not purchasing or selling any shares by this prospectus supplement or the accompanying prospectus.

We will sell the securities to selected accredited investors under one or more securities purchase agreements entered into between us and each of the investors at the offering price stated on the cover of this prospectus supplement. We currently anticipate that the closing of the sale of the ADSs offered hereby will take place on or about December 6, 2016. Investors will also be informed of the date and manner in which they must transmit the purchase price for the securities. Funds received will be placed into an escrow account, and released to us upon the closing. The offering will terminate on the earlier of the date on which all securities offered are sold or December 6, 2016.

On the scheduled closing date, the following will occur:

• we will receive funds in the amount of the aggregate purchase price for the ADSs we sell;

• we will deliver to each of the investors, through the DWAC system or by book-entry, the ADSs being purchased; and

• Maxim Group LLC will receive a placement agent fee in accordance with the terms of the placement agency agreement.

In accordance with the terms of the placement agency agreement, we will pay the placement agent an aggregate commission equal to 7.0% of the gross proceeds of the sale of the ADSs in the offering. The estimated offering expenses payable by us, in addition to the placement agent fee of \$420,000, are \$500,000 which includes the company legal, accounting and printing costs and various other fees associated with registering and listing the securities.

In addition, the Company has granted Maxim Group LLC a right of first refusal to act as lead managing underwriter and sole book runner or sole placement agent for a period of twelve months from the commencement of sales of the securities in this offering for any and all future public and private equity/equity linked and debt offerings of the Company and its subsidiary outside of Australia and New Zealand.

The Company has also agreed to pay Maxim Group LLC up to \$100,000 for expenses, of which \$25,000 has been paid in advance to cover anticipated accountable expenses. In the event that the placement agency agreement is terminated, we have agreed to pay Maxim Group LLC up to \$25,000 for their actual expenses. Maxim Group LLC will return any portion of the advance not used for actual out-of-pocket expenses.

The placement agent has informed us that it will not engage in over-allotment, stabilizing transactions or syndicate covering transactions in connection with the offering.

The placement agent may, from time to time, engage in transactions with and perform services for us in the ordinary course of its business.

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of representations and warranties contained in the placement agency agreement. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement. Closing of the purchase and sale of the securities is subject to customary closing conditions. The form securities purchase agreement with purchasers and the placement agency agreement will be included as exhibits to a Current Report on Form 6-K that we will file with the SEC in connection with this offering and incorporated by reference into the registration statement of which this prospectus supplement and the accompanying prospectus form a part. See Where You Can Find More Information below.

The transfer agent for our ordinary shares to be issued in this offering is Computershare Trust Company. Our ADSs are listed on the NASDAQ Capital Market under the symbol GENE and our ordinary shares are listed on the Australian Securities Exchange under the symbol GTG.

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#### LEGAL MATTERS

Greenberg Traurig LLP, New York, New York, will be passing upon matters of United States law for us with respect to securities offered by this prospectus supplement. The validity of the ordinary shares represented by ADSs offered in this offering will be passed upon for us by K&L Gates LLP, Melbourne, Australia, our Australian counsel. Maxim is being represented in connection with this offering by Ellenoff Grossman & Schole LLP, New York, NY.

## EXPERTS

The financial statements incorporated in this prospectus supplement by reference to the Annual Report on Form 20-F, as amended, for the year ended June 30, 2016 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company s ability to continue as a going concern as described in Note 2 to the financial statements) of PricewaterhouseCoopers, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement is a part of a registration statement on Form F-3 that we filed on May 17, 2016, with the SEC under the Securities Act of 1933. We refer you to this registration statement, for further information about us and the securities offered hereby.

We file annual and periodic reports and other information with the SEC (Commission File Number 0-51504). These filings contain important information that does not appear in this prospectus supplement or the accompanying prospectus. For further information about us, you may read and copy these filings at the SEC s Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330, and may obtain copies of our filings from the public reference room by calling (202) 551-8090. Our SEC filings are also available on the SEC Internet site at http://www.sec.gov, which contains periodic reports and other information regarding issuers that file electronically. In addition, we make available, without charge, through our website, www.gtglabs.com, electronic copies of various filings with the SEC, including copies of our Annual Report on Form 20-F. The information on our website is not and should not be considered part of this prospectus supplement and is not incorporated into this prospectus supplement by reference.

### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference information into this prospectus supplement, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the SEC. We are incorporating by reference in this prospectus supplement the documents listed below and all amendments or supplements we may file to such documents, as well as any future filings we may make with the SEC on Form 20-F under the Exchange Act, before the time that all of the securities offered by this prospectus supplement have been sold or de-registered.

Our Annual Report on Form 20-F, as amended, for the fiscal year ended June 30, 2016; and

•

• Exhibit 99.2 to our Report on Form 6-K filed or furnished with the SEC on November 23, 2016 and our Report on Form 6-K filed or furnished with the SEC on November 29, 2016.

In addition, we may incorporate by reference into this prospectus supplement our reports on Form 6-K filed after the date of this prospectus supplement (and before the time that all of the securities offered by this prospectus supplement have been sold or de-registered) if we identify in the report that it is being incorporated by reference in this prospectus supplement.

Certain statements in and portions of this prospectus supplement update and replace information in the above listed documents incorporated by reference. Likewise, statements in or portions of a future document incorporated

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by reference in this prospectus supplement may update and replace statements in and portions of this prospectus supplement or the above listed documents.

We will provide you without charge, upon your written or oral request, a copy of any of the documents incorporated by reference in this prospectus supplement, other than exhibits to such documents which are not specifically incorporated by reference into such documents. Please direct your written or telephone requests to Genetic Technologies Limited, 60-66 Hanover Street, Fitzroy, Victoria 3065 Australia, Attention: Company Secretary, telephone +61 3 8412 7000. You may also obtain information about us by visiting our website at http://www.gtglabs.com. The information in our website is not incorporated by reference into this prospectus supplement and should not be considered as part of this prospectus supplement.

We are an Australian company and are a foreign private issuer as defined in Rule 3b-4 under the Exchange Act. As a result, (1) our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act, (2) transactions in our equity securities by our officers and directors are exempt from Section 16 of the Exchange Act, and (3) we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. We make all required filings with the SEC electronically, and these filings are available over the Internet at the SEC s website at http://www.sec.gov.

PROSPECTUS

**Genetic Technologies Limited** 

\$100,000,000

#### **Ordinary Shares Represented by American Depositary Shares**

**Preference Shares** 

Warrants

We may offer the securities described in this prospectus from time to time in amounts, at prices and on terms to be determined at or prior to the time of the offering. We refer to the Ordinary Shares represented by American Depositary Shares, the preference shares and the warrants as the Securities . This prospectus describes the general manner in which our Securities may be offered using this Prospectus. We will provide specific terms and offering prices of these Securities in supplements to this Prospectus. You should read this Prospectus and the accompanying prospectus supplements carefully before you invest in our Securities.

We may offer the Securities through underwriting syndicates managed or co-managed by one or more underwriters or dealers, through agents or directly to investors (including our shareholders), on a continuous or delayed basis. The prospectus supplement for each offering of Securities will describe in detail the plan of distribution for that offering. For general information about the distribution of Securities offered, you should refer to the section entitled Plan of Distribution. The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Our American Depositary Shares (ADSs) are listed on the NASDAQ Capital Market under the symbol GENE and our Ordinary Shares are listed on the Australian Securities Exchange under the symbol GTG. On May 10, 2016, the last sale price of our common stock on the NASDAQ

Capital Market was \$2.18 per share and on the Australian Securities Exchange was A\$0.019per share.

The aggregate market value of our outstanding voting and non-voting common equity held by non-affiliates on May 10, 2016, as calculated in accordance with General Instruction I.B.5. of Form F-3, was approximately \$24,056,209. We have not issued any securities pursuant to Instruction I.B.5. of Form F-3 during the 12 calendar month period that ends on and includes the date hereof.

# Investing in our securities involves a high degree of risk. See Risk Factors beginning on page 4.

## NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is May 17, 2016.

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No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained or incorporated by reference in this prospectus or any accompanying prospectus supplement in connection with the offer made by this prospectus or any accompanying prospectus supplement and, if given or made, such information or representations must not be relied upon as having been authorized by Genetic Technologies Limited. Neither the delivery of this Prospectus or any accompanying prospectus supplement nor any sale made hereunder and thereunder shall under any circumstances create an implication that there has been no change in the affairs of Genetic Technologies Limited since the date hereof. This Prospectus or any accompanying prospectus supplement does not constitute an offer or solicitation by anyone in any state in which such offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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#### ABOUT THIS PROSPECTUS

This Prospectus is part of a registration statement on Form F-3 that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this process, we may, from time to time, sell any combination of the Securities described in this Prospectus in one or more offerings up to a dollar amount of \$100,000,000.

This Prospectus provides you with a general description of the Securities that we may offer. Each time we sell Securities, we will provide a prospectus supplement that will contain specific information about the terms of the offering. The prospectus supplement may also add, update or change information contained in this Prospectus, and may also contain information about any material federal income tax considerations relating to the securities covered by the prospectus supplement. You should read both this Prospectus and any prospectus supplement, together with additional information described below under the heading Where You Can Find More Information, before purchasing any of our Securities. This Prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the Securities, you should refer to the registration statement, including the exhibits. You may read the registration statement and the other reports we file with the SEC at the SEC s offices described under the heading Where You Can Find Additional Information.

To the extent there is a conflict between the information contained in this Prospectus and the prospectus supplement, you should rely on the information in the prospectus supplement, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date - for example, a document incorporated by reference in this Prospectus or any prospectus supplement - the statement in the document having the later date modifies or supersedes the earlier statement.

The information in this Prospectus is accurate as of the date on the front cover. You should not assume that the information contained in this Prospectus is accurate as of any other date.

Unless the context otherwise requires, in this prospectus, GTG, Company, we, us and our refer to Genetic Technologies Limited. References U.S. dollars, USD or \$ are to the lawful currency of the United States and references to AUD or A\$ are to the lawful currency of Australia.

This Prospectus contains translations to certain Australian dollar amounts into U.S. dollars at specified rates solely for the convenience of the reader. Unless otherwise specified, all translations from Australian dollars to U.S. dollars in this prospectus were made at the average interbank rate as of May 10, 2016, which was A\$1.00 to US\$ 0.73456. We make no representation that the Australian dollar or U.S. dollars amounts referred to in this prospectus could have been or could be converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate or at all.

#### FORWARD-LOOKING STATEMENTS

#### **Cautionary Note Regarding Forward-Looking Statements**

This prospectus and the documents incorporated in it by reference contain forward-looking statements that involve risks and uncertainties. Forward-looking statements relate to future events or our future financial performance and include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the progress and timing of our clinical trials or product candidate development programs, the effect of existing and future regulations and the effects of competition. These statements are based on our current expectations, beliefs and assumptions, and on information currently available to our management. In some cases, you can identify forward-looking statements by the use of words such as anticipate , expect , intend , plan , seek , may , will , should , could , would , believe , estimate , project , predict , potential , continue or similar expressions. These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors which may cause our actual results, levels of activities, performance and other factors to be materially different from those anticipated in such forward-looking statements. Factors that might cause such differences include the risks discussed in Risk Factors.

This list of risk factors is not exclusive and other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements. You should consider these factors and the other cautionary statements made in this Prospectus, any prospectus supplement or the documents we incorporate by reference in this Prospectus as being applicable to all related forward-looking statements wherever they appear in this Prospectus, any prospectus supplement or the documents incorporated by reference. We caution investors not to place significant reliance on the forward-looking statements contained herein. These statements, like all statements in this prospectus, speak only as of the date hereof (unless another date is indicated) and we undertake no obligation to update or revise the statements.

Any statements in this Prospectus that relate to the Company s expectations are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act. The Private Securities Litigation Reform Act of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees. Since this information may involve risks and uncertainties and are subject to change at any time, the Company s actual results may differ materially from expected results. Additional risks associated with Genetic Technologies business can be found in its periodic filings with the SEC.

#### ABOUT GENETIC TECHNOLOGIES LIMITED

We were incorporated under the laws of Western Australia on January 5, 1987 as Concord Mining N.L. and operated as a mining company. On August 13, 1991, we changed our name to Consolidated Victorian Gold Mines N.L. On December 2, 1991, we changed our name to Consolidated Victorian Mines N.L. On March 15, 1995, we changed our name to Duketon Goldfields N.L.

On October 15, 1999, the Company s corporate status was changed from a No Liability Company to a company limited by shares. On August 29, 2000, following the acquisition of Swiss company GeneType AG, we changed our name to Genetic Technologies Limited, which is our current name. At that time, we phased out our mining activities and became a biotechnology company, following which our stock exchange listing was duly transferred from the mining board of the ASX to the industrial board and our shares were thereafter classified under the industry

group Health and Biotechnology, completing our transformation from a mining company into a biotechnology company. Our current activities are as a biotechnology Australian-based global genetic testing business specializing in cancer diagnostics, with a focus on women s health.

Our Australian Company Number (ACN) is 009 212 328. Our Australian Business Number (ABN) is 17 009 212 328. We operate pursuant to our constitution, the Australian Corporations Act 2001, the Listing Rules of the Australian Securities Exchange, the Marketplace Rules of NASDAQ and, where applicable, local, state and federal legislation in the countries in which we operate.

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Our registered office, headquarters and laboratory are all located at 60-66 Hanover Street, Fitzroy, Victoria, 3065 Australia. Our telephone number is +61 3 8412 7000. Our website address is www.gtglabs.com. The offices of our U.S. subsidiary, Phenogen Sciences Inc., are located at 9115 Harris Corners Parkway, Suite 320, Charlotte, North Carolina, 28269 U.S.A. The telephone number for the Phenogen Sciences office is +1 877 992 7382. Information on our websites and websites linked to them are not incorporated by reference into, and do not constitute part of, this Prospectus.

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### **RISK FACTORS**

You should be aware that there are various risks to an investment in our Securities, including those described below. You should carefully consider these risk factors, together with all of the other information included and incorporated by reference in this prospectus, before you decide to invest in our Securities.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our ordinary shares could decline, and you may lose all or part of your investment.

### **RISKS RELATED TO OUR BUSINESS**

**Risks Related to Us** 

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

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

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

Since our listing on the Australian Securities Exchange in August 2000, the price of our Ordinary Shares has ranged from a low of \$0.012 to a high of \$0.97 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 following chart illustrates the fluctuation in the price of our shares (in Australian dollars) over the last five years:

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

We have never paid a cash dividend on our Ordinary Shares and we do not anticipate paying a cash dividend 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.

## 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*. The majority of our directors and officers named in this Prospectus 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 where the defendant has not been properly served in Australia.

Because we are not necessarily 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 or 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

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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 financial results on a semi-annual basis (which is performed under International Standard on Review Engagements) and to be fully audited annually (which is performed under International Standards on Auditing) which are required to have a limited review semi-annually and to be fully audited annually. 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 will 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.

# If significant liquidity does not eventuate for our ADSs on NASDAQ, your ability to resell your ADSs could be negatively affected because there would be limited buyers for your interests.

Historically, there was virtually no trading in our ADSs through the pink sheets after the establishment of our Level I ADR Program. However, subsequent to the Level II listing of our ADSs on the NASDAQ Global Market on September 2, 2005, the trading volumes of our ADSs have increased. The Company subsequently transferred the listing of its ADSs to the NASDAQ Capital Market effective as from 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.

#### Our Company has a history of incurring losses.

The business now called Genetic Technologies Limited was founded in 1989. With the exception of the year ended 30 June 2011, the Company has incurred operating losses in every year of its existence. As at June 30, 2015, the Company had accumulated losses of \$100,985,283 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. There is also no certainty that the Company will be able to raise additional funds by issuing further shares and/or the raising of debt and, if such funds are available, on what terms the Company would be able to secure them.

Going concern.

During the 2015 financial year, the Company incurred a total comprehensive loss after income tax of \$8,396,165 (2014: \$10,283,545) and net cash outflows from operations of \$9,691,528 (2014: \$10,987,088).

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As at June 30, 2015, the Company held cash reserves of \$18,341,357 and had net current assets of \$17,830,933.

During the half year ending 31 December 2015, the Company incurred a total comprehensive loss after income tax of \$ 3,019,678 (2014: \$ 4,774,751) and net cash outflows from operations of \$ 4,444,201 (2014: \$ 5,820,310)

As at December 31, 2015, the Company held cash reserves of \$14,519,541 and had net current assets of \$14,729,489.

The cash generated from revenue combined with its existing cash reserves will enable the Company to fund its operations in the next twelve months from the date of this report.

However, we are aware that the long term viability of the Company is directly dependent on the ability to grow revenue, control costs and raise additional funds via the issuance of new equity should the need arise. Any issuance of new equity will be subject to normal risks and therefore could impact the ability of the Company to continue as a going concern. However, the Directors believe that the Company would be successful in raising new funds if the need arises and have prepared the financial report on a going concern basis.

**Risks Related to our Industry** 

## Our sales cycle is typically lengthy.

The sales cycle for our BREVAGen breast cancer risk test is typically lengthy. As a result, we may expend substantial funds and management effort with no assurance of successfully selling the test. Our business could also be adversely affected if we expend money without any return.

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

Though we currently have no direct competition in this space, we are currently subject to 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 BREVAGen breast cancer risk test, or which otherwise address the needs of our customers and potential customers. Our competitors in the testing 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 breast cancer risk testing area is based upon, amongst other things, our ability to:

• maintain first to market advantage;

• continue to strengthen and maintain scientific credibility through the process of obtaining scientific validation and undertaken further clinical trials supported by Peer-reviewed publication in medical journals;

- create and maintain scientifically-advanced technology and offer proprietary products and services
- attract and retain qualified personnel;
- obtain patent or other protection for our products and services;
  - 7

- obtain 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 and services obsolete, noncompetitive or uneconomical.

# We rely heavily upon our patents and proprietary technology and any future claims that our patents are invalid could adversely affect our revenues and our financial condition.

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 as a result 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 have important relationships with external parties over whom we have limited control.

We have relationships with academic consultants 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, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results from operations. To the extent that our scientific consultants develop inventions or processes independently 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 professional liability suits and our insurance may not be sufficient to cover damages. If this occurs, our business and financial condition may be adversely affected.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of genetic tests. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to professional 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 services. Litigation of such claims could be costly. We could expend significant funds during any litigation proceeding brought against us. 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 broadform liability and professional indemnity policies, for an aggregate amount of A\$60,000,000, the level or breadth of our coverage may not be adequate to fully cover any potential liability claims. To date we have not been subject to any claims, or ultimately liability, in excess of the amount of our coverage. In addition, we may not be able to obtain additional professional 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 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.

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

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

In addition, our collaborators and service providers may be working with these same types of hazardous materials, including hazardous chemicals, in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials or patient samples that may contain infectious materials. The cost of this liability could exceed our resources. While we maintain broadform liability insurance coverage for these risks, in the amount of up to A\$40,000,000, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. To date, we have not been subject to claims, or ultimately liability, in excess of the amount of our coverage. Our broadform insurance coverage also covers us against losses arising from an interruption of our business activities as a result of the mishandling of such materials. We also maintain workers compensation insurance, which is mandatory in Australia, covering all of our workers in the event of injury.

We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialization of some 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 some 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.

Other than our contractual rights under our license agreements, we may be limited in our ability to convince our licensees to fulfill their obligations. If our licensees fail to act promptly and effectively, or if a dispute arises, it could have a material adverse effect on our results of operations and the price of our ordinary shares and ADSs.

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

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methods. There may be errors or omissions in this data that would materially adversely affect the development of these methods.

We may seek additional collaborative arrangements to develop and commercialize our products in the future. We may not be able to negotiate acceptable arrangements in the future and, if negotiated, we have no certainty that they will be on favorable terms or if they will be successful. In addition, our partners may pursue alternative technologies independently or in collaboration with others as a means of developing treatments for the diseases targeted by their collaborative programs with us. If any of these events occur, the progress of the Company could be adversely affected and our results of operations and financial condition could suffer.

#### Problems associated with international business operations could affect our results of operations.

We seek to market our growing range of other products and services on a global scale, including in countries that are considered to provide significantly less protection to intellectual property than does the United States and Australia. In addition, a number of other risks are inherent in international transactions and commerce, including political and economic instability, foreign currency exchange fluctuations and changes in tax laws.

#### Currently our financial results depend largely on the sales of our breast cancer risk assessment test, BREVAGenplus.

For the near future, we expect to continue to derive a substantial majority of our revenues from sales of one product, our breast cancer risk test BREVAGen. Although in October 2014, we announced the U.S. release of BREVAGen*plus*, a second generation BREVAGen product, we do not expect to recognize significant revenues from this test until significant levels of adoption have been established. If we are unable to increase sales of our BREVAGen or BREVAGen*plus* or successfully develop and commercialize other tests or enhancements, our ability to achieve sustained revenues would be impaired.

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

We do not have redundant clinical reference laboratory facilities outside of Melbourne, Australia. Our current lease of laboratory premises expires August 31, 2018. The facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future.

If we no longer had our own facility and needed to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which BREVAgen*plus* tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to comply with the required procedures, that this laboratory would be willing to perform the tests on commercially reasonable terms, or that it would be able to meet our quality standards. In order to establish a redundant clinical reference laboratory facility, we would have to spend considerable time and money

securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

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

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be

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critical as we continue to develop our technologies and testing processes, continue our international expansion and transition to a company with multiple commercialized products on offer. 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. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and close relationships with medical oncologists, pathologists and other hospital personnel. We may have difficulties sourcing, recruiting or retaining qualified salespeople, which could cause delays or a decline in the rate of adoption of our tests. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development and sales programs. All of our U.S employees are at-will, which means that either we or the employee may terminate their employment at any time.

#### FDA regulation of LDTs may result in significant changes, and our business could be adversely impacted if we fail to adapt.

Clinical laboratory tests like ours are regulated under the CLIA, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. FDA has exercised its discretion and has not subjected most LDTs to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation.

The FDA claims to have regulatory authority over LDTs under the Medical Device Amendments of 1976 and has stated in the past that it would issue guidance to the industry regarding its regulatory approach. In such discussions, the FDA has indicated that it would use a risk-based approach to regulation and would direct more resources to tests with wider distribution and with the highest risk of injury, but that it will be sensitive to the need to not adversely impact patient care or innovation. In October 2014, the FDA announced its framework and timetable for implementing this guidance. We cannot predict the ultimate timing or form of any such guidance or regulation and the potential impact on our existing tests. If adopted, such a regulatory approach by the FDA may lead to an increased regulatory burden, including additional costs and delays in introducing new tests or even continuing with our current tests. While the ultimate impact of the FDA is approach is unknown, it may be extensive and may result in significant changes. Our failure to adapt to these changes could have a material adverse effect on our business.

If the FDA decides to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any future tests, and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected

deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to

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perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

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

The clinical laboratory testing industry is subject to extensive federal and state regulation, and many of these statutes and regulations have not been interpreted by the courts. The regulations implementing CLIA set out federal regulatory standards that apply to virtually all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, by requiring that they be certified by the federal government or by a federally approved accreditation agency. CLIA does not preempt state law, which in some cases may be more stringent than federal law and require additional personnel qualifications, quality

control, record maintenance and proficiency testing. The sanction for failure to comply with CLIA and state requirements may be suspension, revocation or limitation of a laboratory s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Several states have similar laws and we may be subject to similar penalties.

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 perform to, 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.

Failure to timely or accurately bill for our services could have a material adverse effect on our business.

Billing for clinical testing services is extremely complicated and is subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, Medicare, Medicaid, physicians and hospitals. Changes in laws and regulations could increase the complexity and cost of our billing process. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further cost and complexity to the billing process.

Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and bad debt expense. Failure to timely or correctly bill may lead to us not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows. Failure to comply with applicable laws relating to billing government healthcare programs or private healthcare programs that operate

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under government contract could lead to various penalties, including: (1) exclusion or suspension from participation in Center for Medicare & Medicaid Services (CMS) and other government programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business, any of which could have a material adverse effect on our results of operations or cash flows.

# Failure to comply with complex federal and state laws and regulations related to submission of claims for clinical laboratory services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for clinical laboratory services, including those that relate to coverage of our services under Medicare, Medicaid and other governmental health care programs, the amounts that may be billed for our services and to whom claims for services may be submitted. In addition, we are subject to various laws regulating our interactions with other healthcare providers and with patients, such as the Anti-Kickback Statute, the Anti-Inducement Statute, and the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark law. These laws are complicated.

Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or result in attempts by third-party payers, such as Medicare and Medicaid, to recover payments from us that have already been made. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including substantial civil penalties for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission or causing the submission of claims violate the federal False Claims Act, or FCA, or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. Violations of the FCA could result in significant economic liability. The FCA provides that all damages are trebled, and each false claim submitted is subject to a penalty of up to \$11,000. For example, we could be subject to FCA liability if it were determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician s referrals of unnecessary services to us. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by an entity for services that we performed if we were found to have knowingly participated in the arrangement that resulted in submission of the improper claims.

# Failure to comply with HIPAA, including regarding the use of new standard transactions, may negatively impact our profitability and cash flows.

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

In addition, the HIPAA transaction standards are complex, and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. As a result of inconsistent application of transaction standards by payers or our inability to obtain certain billing information not usually provided to us by physicians, we could face increased costs and complexity, a temporary disruption in receipts and ongoing reductions in the timeliness of reimbursement. In addition, new requirements for additional standard transactions, such as claims attachments, Version 5010 of the HIPAA Transaction Standards and the ICD-10-CM Code Set, could prove technically difficult, time-consuming or expensive to implement.

# Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

The clinical laboratory testing industry is highly regulated and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal and state laws applicable to billing and claims payment;
- federal and state laboratory anti-mark-up laws;
- federal and state anti-kickback laws;
- federal and state false claims laws;

• federal self-referral and financial inducement prohibition laws, commonly known as the Stark Law, and the state equivalents;

- federal and state laws governing laboratory licensing and testing, including CLIA;
- federal and state laws governing the LDTs;
- HIPAA, along with the revisions to HIPPA as a result of the HITECH Act, and analogous state laws;
- federal, state and foreign regulation of privacy, security, electronic transactions and identity theft;
- federal, state and local laws governing the handling, transportation and disposal of medical and hazardous waste;
- Occupational Safety and Health Administration rules and regulations;
- changes to laws, regulations and rules as a result of the Health Care Reform Law; and
- changes to other federal, state and local laws, regulations and rules, including tax laws.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of business, there is an ongoing awareness of the importance of compliance with these laws. The growth of our business and sales organization may increase the potential for violating these laws or our internal policies and procedures, despite our ongoing vigilance in maintaining and updating our compliance procedures. The risk of being found in violation of these or other laws and regulations is further increased by the fact that many of them are extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. 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 management s attention. Any determination that we have violated these laws or regulations, or a public announcement that we are being investigated for possible violations of these laws or regulations, could harm our reputation, operating results and financial condition. If our

operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. In addition, a significant change in any of these laws or regulations may require us to change our business model in order to maintain compliance with these laws or regulations, which could harm our operating results and financial condition.

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

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

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and harm important business relationships that we have with healthcare providers, payers and others. Furthermore, if a regulatory or judicial authority finds that we have not complied with applicable laws and regulations, we could be required to refund amounts that were billed and collected in violation of such laws and regulations. In addition, we may voluntarily refund amounts that were alleged to have been billed and collected in violation of applicable laws and regulations. In either case, we could suffer civil and criminal damages, fines and penalties, exclusion from participation in governmental healthcare programs and the loss of licenses, certificates and authorizations necessary to operate our business, as well as incur liabilities from third-party claims, all of which could harm our operating results and financial condition. Moreover, regardless of the outcome, if we or physicians or other third parties with whom we do business are investigated by a regulatory or law enforcement authority we could incur substantial costs, including legal fees, and our management may be required to divert a substantial amount of time to an investigation.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the United States Health and Human Services Department Office of Inspector General, or OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the United States Sentencing Commission Guidelines Manual, and for many years the OIG has made available a model compliance program targeted to the clinical laboratory industry. In addition, certain states, such as New York, require that health care providers, such as clinical laboratories, that engage in substantial business under the state Medicaid program have a compliance program that generally adheres to the standards set forth in the Model Compliance Program. Also, under the Affordable Care Act, the U.S. Department of Health and Human Services, or HHS, will require suppliers, such as the Company, to adopt, as a condition of Medicare participation, compliance programs that meet a core set of requirements.

Failure to maintain the security of patient-related information or compliance with security requirements could damage our reputation with customers, cause us to incur substantial additional costs and become subject to litigation.

Pursuant to HIPAA, and certain similar state laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information. Under the HITECH amendments to HIPAA, HIPAA was expanded to require certain data breach notification, to extend certain HIPAA privacy and security standards directly to business associates, to heighten penalties for noncompliance, and enhance enforcement efforts.

We receive certain personal and financial information about our clients and their patients. In addition, we depend upon the secure transmission of confidential information over public networks. A compromise in our security systems that results in client or patient personal information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely impact our results of operations, financial condition and liquidity.

Changes in regulation and policies, including increasing downward pressure on health care reimbursement, may adversely affect reimbursement for diagnostic services and could have a material adverse impact on our business.

Reimbursement levels for health care services are subject to continuous and often unexpected changes in policies, and we face a variety of efforts by government payers to reduce utilization and reimbursement for diagnostic testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes.

The U.S. Congress has considered, at least yearly in conjunction with budgetary legislation, changes to one or both of the Medicare fee schedules under which we receive reimbursement, which include the clinical laboratory fee schedule for our clinical laboratory services. For example, Congress has periodically considered imposing a 20 percent coinsurance on laboratory services. If enacted, this would require us to attempt to collect this amount from patients, although in many cases the costs of collection would exceed the amount actually received.

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The CMS pays laboratories on the basis of a fee schedule that is reviewed and re-calculated on an annual basis. CMS may change the fee schedule upward or downward on billing codes that we submit for reimbursement on a regular basis. Our revenue and business may be adversely affected if the reimbursement rates associated with such codes are reduced. Even when reimbursement rates are not reduced, policy changes add to our costs by increasing the complexity and volume of administrative requirements. Medicaid reimbursement, which varies by state, is also subject to administrative and billing requirements and budget pressures. Recently, state budget pressures have caused states to consider several policy changes that may impact our financial condition and results of operations, such as delaying payments, reducing reimbursement, restricting coverage eligibility and service coverage, and imposing taxes on our services.

# Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Affordable Care Act makes changes that are expected to significantly affect clinical laboratories, among others. Beginning in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. Although the FDA has contended that LDTs are medical devices, none of our products is currently listed with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future. The Affordable Care Act also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% through 2015 and a productivity adjustment to the CLFS.

Other significant measures contained in the Affordable Care Act includes, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The Affordable Care Act also includes significant new fraud and abuse measures, including **required** disclosures by drug and device manufacturers and distributors of financial arrangements with physicians and teaching hospitals. In addition, the Health Care Reform Law establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for services. The IPAB proposals may impact payments for clinical laboratory services beginning in 2016. We are monitoring the impact of the Health Care Reform Law in order to enable us to determine the trends and changes that may be necessitated by the legislation that may potentially impact on our business over time.

In addition to the Affordable Care Act, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012 which in part reduced the potential future cost-based increases to the Medicare Clinical Laboratory Fee Schedule by 2%. Overall the expected total fee cut to the CLFS for 2013 was 2.95% not including a further reduction of 2% from implementation of the automatic expense reductions (sequester) under the Budget Control Act of 2011 which went into effect for dates of service on or after April 1, 2013. Reductions made by the Congressional sequester are applied to total claims payments made. While these reductions did not result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates, rebasing could occur as a result of future legislation. In 2015, the total fee cut to the CLFS will be 0.25%.

We cannot be certain that these or future changes will not affect payment rates in the future. We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, cost reduction measures and the expansion in government s role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payers for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Healthcare plans have taken steps to control the utilization and reimbursement of healthcare services, including clinical test services.

We also face efforts by non-governmental third-party payers, including healthcare plans, to reduce utilization and reimbursement for clinical testing services.

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The healthcare industry has experienced a trend of consolidation among healthcare insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical testing providers. These healthcare plans, and independent physician associations, may demand that clinical testing providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capped payment arrangements. In addition, some healthcare plans have been willing to limit the PPO or POS laboratory network to only a single national laboratory to obtain improved fee-for-service pricing. There are also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost-sharing.

The increased consolidation among healthcare plans also has increased the potential adverse impact of ceasing to be a contracted provider with any such insurer.

We expect continuing efforts to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services. These efforts, including future changes in third-party payer rules, practices and policies, or ceasing to be a contracted provider to a healthcare plan, may have a material adverse effect on our business.

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

We transport specimens from our North Carolina offices in the U.S. to our laboratory located in Melbourne, Australia. Our operations may be adversely impacted by extreme weather conditions or other interruptions 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.

# 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. Breaches with respect to protected health information could result in violations of HIPAA and analogous state laws, and risk the imposition of significant fines and penalties. Failure of our information technology systems could adversely affect our reputation, business, profitability and financial condition.

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

In order to assure adequate insurance coverage and favorable insurance reimbursement of our products, we are required to demonstrate the clinical utility of our tests. Clinical utility which is the usefulness of a test for clinical practice (as contrasted with diagnostic accuracy, which is how well the test can determine the presence, absence, or risk of a specific disease) may well be the most significant limitation for the widespread acceptance of molecular diagnostic tools such as BREVAGen*plus*. We are currently undertaking studies intended to demonstrate the clinical utility of our tests in order to assure continued acceptance of the value of our products. These studies will require us to invest considerable financial and management resources without any assurance of favorable results. Successful studies are difficult to plan, execute and validate, because of the time involved and variables that are difficult to control and which can impact outcomes. If we are unable to demonstrate clinical utility, or if our data is deemed insufficient to validate utility, which are required for Medicare coverage, then we may face negative coverage decisions for our products. The resulting negative coverage decisions could have a material adverse effect on our financial conditions and results of operations.

#### Risks associated with Out-licensing of 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 over uses 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 counter-claim of patent invalidity or other such claims. Subsequent legal action could potentially overturn, invalidate or limit the scope of our patents.

Under the relevant Patent Acts in most of the countries in which our non-coding patents have issued, the relevant judicial system has rights to impose compulsory licensing. The relevant governments typically hold march-in rights by which they may unilaterally choose to exploit the technology. To the extent that the Company s non-coding technology is used in the conduct of research, we also face risks, uncertainty and controversy over the licensing of our technology to those conducting the research. Whether or not researchers should be exempted from obligations to take licenses to relevant patents was the subject of another government inquiry conducted by the Australian Council for Intellectual Property who recommended the creation of a research exemption.

## **DESCRIPTION OF OUR SHARE CAPITAL**

#### General

The following description of our share capital is only a summary. We encourage you to read our Constitution which is included as an exhibit to this registration statement of which this Prospectus forms a part. We do not have a limit on our authorized share capital and do not recognize the concept of par value under Australian law. As of June 30, 2015, we had a total of 1,714,191,631 ordinary shares outstanding. Based on a conversion ratio of 150:1, this equated to a total of 11,427,944 American Depositary Shares. As of the date of this Prospectus, these numbers had increased to 1,715,146,337 ordinary shares, representing 11,434,309 American Depositary Shares. No ordinary shares are held by or on behalf of Genetic Technologies Limited. In the following summary, a shareholder is the person registered in our register of members as the holder of the relevant securities.

Our directors and senior management hold a total of 19,581,673 ordinary shares. Certain senior executives also hold 24,236,111 outstanding options to purchase ordinary shares which are exercisable at A\$0.02 at various times up to, and including, November 24, 2020.

We also have employees holding outstanding options to purchase ordinary shares which are exercisable at various dates and for various exercise prices into fully paid ordinary shares. As of December 31, 2015, we had outstanding options to purchase a total of 5,375,000 ordinary shares held by our employees, excluding directors and senior management.

Subject to restrictions on the issue of securities in our Constitution, the *Corporations Act 2001* and the Listing Rules of the Australian Securities Exchange and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with the rights and restrictions and for the consideration that the board of directors determine.

The rights and restrictions attaching to ordinary shares are derived through a combination of our Constitution, the common law applicable to Australia, the Listing Rules of the Australian Securities Exchange, the *Corporations Act 2001* and other applicable law. A general summary of some of the rights and restrictions attaching to ordinary shares are summarized below. Each ordinary shareholder is entitled to receive notice of and to be present, to vote and to speak at general meetings.

#### Changes to Our Share Capital During the Last Five Years

During the last five years, the number of Ordinary Shares on issue has increased as follows:

Number of Ordinary Shares issued / outstanding Movement in share capital / balance \$

As of June 30, 2010		404,605,152	72,378,105
	There were no Ordinary Shares issued in 2011		
As of June 30, 2011		404,605,152	72,378,105
July 27, 2011	Placement of Ordinary Shares as part of capital		
	raising	60,000,000	10,894,537
January 25, 2012	Exercise of 166,667 options @ \$0.045 each	166,667	7,500
As of June 30, 2012		464,771,819	83,280,142
October 19, 2012	Exercise of 10,200,000 options @ \$0.045 each	10,200,000	459,000
January 24, 2013	Exercise of 500,000 options @ \$0.045 each	500,000	22,500
April 10, 2013	Other transaction costs		(25,797)
As of June 30, 2013		475,471,819	83,735,845
August 9, 2013	Issue of shares as part of private placements @		
	\$0.072	14,555,576	1,048,001

Date	Nature of issue	Number of Ordinary Shares issued / outstanding	Movement in share capital / balance \$
August 14, 2013	Issue of shares as part of private placements @	Shares issued / butstanding	Ψ
8	\$0.072	15,999,980	1,151,999
August 30, 2013	Issue of shares as part of private placements @ \$0.072	11,111,111	800,000
October 8, 2013	Issue of shares as part of private placements @ \$0.072	19,277,837	1,388,000
October 9, 2013	Issue of shares as part of private placements @ \$0.072	24,333,333	1,752,000
October 14, 2013	Issue of shares as part of private placements @ \$0.072	5,000,000	360,000
November 18, 2013	Issue of shares as part of private placements @ \$0.072	6,944,445	500,000
December 31, 2013	Issue of shares as part of the conversion of convertible notes	8,714,541	281,722
January 20, 2014	Issue of shares as part of the conversion of convertible notes	16,517,440	569,022
February 12, 2014	Issue of shares as part of the conversion of convertible notes	17,645,870	554,939
February 19, 2014	Issue of shares as part of the conversion of convertible notes	16,379,660	552,975
March 3, 2014	Issue of shares as part of the conversion of convertible notes	15,388,290	548,968
April 10, 2014	Issue of shares as part of the conversion of convertible notes	17,429,100	533,732
May 16, 2014	Shares cancelled as part of the swap deal	(75,937,500)	(3,569,702)
June 3, 2014	Issue of shares in respect of interest rate true up adjustment relating to March and April, under		
1 07 0014	convertible notes	2,117,250	
June 27, 2014	Issue of shares as part of the conversion of convertible notes	22,969,740	531,519
To November, 2013 As of June 30, 2014	Other transaction costs arising on share issue	613,918,492	(658,528) <b>90,080,492</b>
July 9, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	23,227,950	721,403
August 12, 2014	Issue of shares for capitalised interest on convertible notes	5,142,450	
August 20, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	25,817,550	580,783
October 2, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	31,637,640	621,139
October 20, 2014	Issue of shares for capitalised interest on convertible notes	4,787,190	
October 31, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	46,503,360	306,619
November 28, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	27,655,230	234,192

Date	Nature of issue	Number of Ordinary Shares issued / outstanding	Movement in share capital / balance \$
December 5, 2014	Issue of shares as part of the conversion of convertible notes plus capitalised interest	34,100,456	78,546
December 19, 2014	Issue of shares as part of the conversion of convertible	54,100,430	/8,340
December 19, 2014	notes plus capitalised interest	8,059,599	102,685
December 29, 2014	Issue of shares as part of the conversion of convertible	8,039,399	102,085
December 29, 2014	notes plus capitalised interest	8,677,729	102,849
December 30, 2014	Issue of shares as part of private placements @ \$0.0135	19,074,112	257,500
January 9, 2015	Issue of shares as part of the conversion of convertible	17,071,112	257,500
5unuur y 9, 2015	notes plus capitalised interest	8,258,496	113,474
January 22, 2015	Facility fee pursuant to a standby equity placement facility	35,876,392	110,171
January 30, 2015	Issue of shares as part of private placements @ \$0.01407	41,933,191	621,450
January 30, 2015	Exercise of 26,666,667 options @ \$0.015 each	26,666,667	400,000
February 2, 2015	Issue of shares as part of private placements @ \$0.02447	34,066,809	877,561
February 2, 2015	Issue of shares as part of the conversion of convertible		,
	notes	78,181,336	889,000
February 2, 2015	Issue of shares for capitalised interest on convertible notes	2,939,998	33,431
February 9, 2015	Issue of shares as part of private placements @ \$0.020	16,000,000	337,600
February 9, 2015	Exercise of 27,499,999 options @ \$0.015 each	27,499,999	412,500
February 13, 2015	Issue of shares as part of the conversion of convertible		
	notes	1,712,663	51,000
February 13, 2015	Issue of shares for capitalised interest on convertible notes	72,260	2,152
February 13, 2015	Exercise of 37,666,666 options @ \$0.015 each	37,666,666	565,000
February 18, 2015	Issue of shares as part of private placements @ \$0.0695	10,500,000	729,750
February 18, 2015	Exercise of 8,666,667 options @ \$0.015 each	8,666,667	130,000
February 19, 2015	Issue of shares as part of the conversion of convertible		
	notes	5,868,122	275,000
February 19, 2015	Issue of shares for capitalised interest on convertible notes	257,233	12,054
February 19, 2015	Exercise of 13,133,333 options @ \$0.015 each	13,133,333	197,000
February 20, 2015	Issue of shares as part of the conversion of convertible		
	notes	2,713,459	150,000
February 20, 2015	Issue of shares for capitalised interest on convertible notes	119,690	6,616
February 20, 2015	Exercise of 2,000,000 options @ \$0.015 each	2,000,000	30,000

Date	Nature of issue	Number of Ordinary Shares issued / outstanding	Movement in share capital / balance \$
February 20, 2015	Exercise of 7,333,334 options @ \$0.015 each	7,333,334	110,000
March 11,2015	Issue of shares as part of private placements @ \$0.0382	392,670,150	15,000,000
March 11, 2015	Issue of shares as part of private placements @ \$0.0334	107,329,800	3,584,815
To March 2015	Other transaction costs arising on share issue		(2,572,664)
To March 2015	Other transaction costs on placement of shares	4,123,608	(57,736)
As of June 30, 2015		1,714,191,631	115,247,128
July 23, 2015	Issue of shares as part of the conversion of convertible		
	notes	1,006,441	25,000
July 23, 2015	Issue of shares for capitalised interest on convertible		
	notes	84,652	2,103
To July 2015	Other transaction costs arising on share issue		(1,654)
As of December 31, 2015		1,715,282,724	115,272,577

#### Dividends

Holders of ordinary shares are entitled to receive such dividends as may be declared by the board of directors. All dividends are declared and paid according to the amounts paid up on the shares in respect of which the dividend is paid. As of the date of this Prospectus, there have been no dividends paid to holders of ordinary shares.

Any dividend unclaimed after a period of twelve years from the date of declaration of such dividend shall be paid to, and held by, the Public Trustee of Victoria. The payment by the board of directors of any unclaimed dividend, interest or other sum payable on or in respect of an ordinary share or a preference share into a separate account shall not constitute us as a trustee in respect thereof.

#### Constitution

Our constituent document is a Constitution which is similar in nature to the by-laws of a company incorporated under the laws of the U.S. Our Constitution does not provide for or prescribe any specific objects or purposes of the Company. Our Constitution is subject to the terms of the Listing Rules of the Australian Securities Exchange and the *Corporations Act 2001*. Our Constitution may be amended or repealed and replaced by special resolution of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders who vote by person or proxy at a duly convened shareholders meeting. A summary of the key terms of our Constitution are set out in Item 10.B of our Annual Report on Form 20-F that was filed with the SEC on October 24, 2012.

**Shareholders Meetings** 

We must hold an annual general meeting within five months of the end of each fiscal year. Our end of fiscal year is currently June 30 each year. At the annual general meeting, shareholders typically consider the annual financial report, directors report and auditor s report and vote on matters, including the election of directors, the appointment of the auditor (if necessary) and fixing the aggregate limit of non-executive directors remuneration. We may also hold other meetings of shareholders from time to time. The annual general meeting must be held in addition to any other meetings which we may hold.

The board of directors may call and arrange a meeting of shareholders, when and where they decide. The directors must call a meeting of shareholders when requested by shareholders who hold at least 5% of the votes that may be cast at the meeting or at least 100 members who are entitled to vote at the meeting or as otherwise required

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by the *Corporations Act 2001*. Shareholders with at least 5% of the votes that may be cast at a meeting may also call and hold a general meeting, subject to the notification requirements of the *Corporations Act 2001*.

At least 28 calendar days notice must be given of a meeting of shareholders.

Directors, auditors, shareholders, proxies, and attorneys and representatives of shareholders are entitled to attend general meetings. We may refuse admission to the meeting to anyone (other than a director) in accordance with our Constitution and applicable Australian law. For the purpose of determining who is a shareholder at a particular meeting, the directors will determine that shareholders at a specified time (typically this will be 48 hours before the meeting) are taken to be shareholders at the meeting.

The necessary quorum for a meeting of shareholders is three shareholders entitled to vote.

Unless applicable law or our Constitution requires a special resolution, a resolution of shareholders is passed if more than 50% of the votes cast by shareholders entitled to vote are cast in favor of the resolution. A special resolution is passed if the notice of meeting sets out the intention to propose the special resolution and it is passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution.

A special resolution usually involves more important questions affecting the Company as a whole or the rights of some or all of our shareholders. Special resolutions are required in a variety of circumstances under our Constitution and the *Corporations Act 2001*, including without limitation:

- to change our name;
- to amend or repeal and replace our Constitution;
- to approve the terms of issue of preference shares;
- to approve the variation of class rights of any class of shareholders;
- to convert one class of shares into another class of shares;

- to approve certain buy backs of shares;
- to approve a selective capital reduction of our shares;
- to approve GTG financially assisting a person to acquire shares in the Company;
- to remove and replace our auditor;
- to change our company type;
- with the leave of an authorized Australian court, to approve our voluntary winding up;

• to confer on a liquidator of GTG either a general authority or a particular authority in respect of compensation arrangements of the liquidator; and

• to approve an arrangement entered into between a company about to be, or in the course of being, wound up.

## **Shareholder Voting Rights**

At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or

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representative) and entitled to vote has one vote per fully paid ordinary share and that portion of a vote for any partly paid share that the amount paid on the partly paid share bears to the total amounts paid and payable, on a poll. This is subject to any other rights or restrictions which may be attached to any shares. In the case of an equality of votes on a resolution at a meeting (whether on a show of hands or on a poll), the chairman of the meeting has a deciding vote in addition to any vote that the chairman of the meeting has in respect of that resolution.

A poll may be requested by:

- the chairman of the meeting;
- at least five shareholders entitled to vote at the meeting;

• any shareholder or shareholders representing in the aggregate not less than 5% of the total voting rights of all shareholders entitled to vote at the meeting; or

• any shareholder or shareholders holding shares conferring a right to vote at the meeting on which there have been paid up sums representing in the aggregate not less than 5% of the total sum paid up on all the shares conferring that right.

The Listing Rules of the Australian Securities Exchange provide that the votes of certain shareholders must be disregarded in certain circumstances. Generally, a shareholder s vote may be disregarded if the person may benefit from the transaction that is the subject of the resolution (subject to certain exceptions, such as where the benefit is received in their capacity as a shareholder in common with other shareholders). Without limitation, a shareholder s vote may be disregarded in respect of:

• the issue of shares or options, if the shareholder is entitled to acquire securities under the issue or has acquired securities under the issue (subject to a range of exceptions including in respect of a pro-rata offer made to all shareholders) or is entitled to any other sort of benefit as a result of the issue (for example underwriting commissions);

- the amendment of the terms of options, if the shareholder holds the relevant options;
- if the shareholder is a director, to approve an increase in the remuneration payable to the directors;

- if the shareholder is a director, in respect of termination benefits payable to directors;
- the acquisition or disposal of a substantial asset;

• the issue of securities to specified related parties or anyone else the Australian Securities Exchange considers should not be entitled to vote; and

• significant transactions such as changes to the nature and scale of our operations or a change to our main undertaking. The Australian Securities Exchange may also identify a person who in their view should not be entitled to vote.

The *Corporations Act 2001* also prohibits shareholders from voting, or requires their votes to be disregarded, on certain matters where the shareholder may benefit, for example:

- provision of a financial benefit to the shareholder who is a related party;
- approval of a selective buy back of shares from the shareholder; and
- approval of a selective return of capital to the shareholder.
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### **Issue of Shares and Changes in Capital**

Subject to our Constitution, the *Corporations Act 2001*, the Listing Rules of the Australian Securities Exchange and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with preferred, deferred or other special rights and restrictions and for the consideration and other terms that the directors determine. Our power to issue shares includes the power to issue bonus shares (for which no consideration is payable to the Company), preference shares (including redeemable preference shares) and partly paid shares.

Subject to the requirements of our Constitution, the Corporations Act 2001, the Listing Rules of the Australian Securities Exchange and any other applicable law, we may:

• consolidate or divide our share capital into a larger or smaller number by resolution passed by shareholders at a general meeting;

• may reduce our share capital by special resolution passed by at least 75% of the votes cast by shareholders who vote by person or proxy at a duly convened shareholders meeting (and are not otherwise excluded by law) provided that the reduction is fair and reasonable to our shareholders as a whole, and does not materially prejudice our ability to pay creditors;

• undertake an equal access buyback of our ordinary shares by ordinary resolution of shareholders (although if we have bought back less than 10% of our shares over the period of the previous 12 months, shareholder approval may not be required); and

• undertake a selective buyback of certain shareholders shares by special resolution passed by at least 75% of the votes cast by shareholders who vote by person or proxy at a duly convened shareholders meeting (and are not otherwise excluded by law), with no votes being cast in favor of the resolution by any person whose shares are proposed to be bought back or by their associates.

In certain circumstances, including the division of a class of shares into further classes of shares, the issue of additional shares or the issue of a new class of shares, we may require the approval of any class of shareholders whose rights are varied or are taken to be varied by special resolution of shareholders generally and by special resolution of the holder of shares in that class whose rights are varied or taken to be varied.

Dividends may be paid on shares of one class but not another and at different rates for different classes.

### **Liquidation Rights**

After satisfaction of the claims of creditors, preferential payments to holders of outstanding preference shares and subject to any special rights or restrictions attached to shares, on a winding up, any available assets must be used to repay the capital contributed by the shareholders and any surplus must be distributed among the shareholders in proportion to the number of fully paid shares held by them. For this purpose a partly paid share is treated as a fraction of a share equal to the proportion which the amount paid bears to the total issue price of the share before the winding up began.

If we experience financial problems, the directors may appoint an administrator to take over our operations to see if we can come to an arrangement with our creditors. If we cannot agree with our creditors, Genetic Technologies Limited may be wound up.

A receiver, or receiver and manager, may be appointed by order of a court or under an agreement with a secured creditor to take over some or all of the assets of a company. A receiver may be appointed, for example, because an amount owed to a secured creditor is overdue.

We may be wound up by order of a court, or voluntarily if our shareholders pass a special resolution to do so. A liquidator is appointed when a court orders a company to be wound up or the shareholders of a company pass a resolution to wind up the company. A liquidator is appointed to administer the winding up of a company.

#### Calls, Lien and Forfeiture in Respect of Partly Paid Shares

Subject to any special rights or restrictions attached to shares, the board of directors may make calls on the holder of a share for any unpaid portion of the issue price of that share at any time. The directors may make a call payable by installments. If the amount called is not paid by the requisite time, the shareholder must pay GTG interest on the amount unpaid from the date the call becomes payable until and including the date of payment and our costs arising from the non-payment. Joint holders of a share and their respective personal representatives are all jointly and severally liable to pay all calls on the share. The board of directors may recover an amount presently payable as a result of a call by suing the shareholder for the debt, by enforcing the lien on the share or by declaring forfeiture on the share. The forfeiture of a share extinguishes the former shareholder s interest in the share. We have a first ranking lien on each share registered to a shareholder, dividends payable on a shares, proceeds on the sale of a share for an unpaid call or installment that is due but unpaid on the share, any amounts we are required by law to pay in respect of the shares of that shareholder, and in respect of any interest and costs presently payable to GTG by the shareholder. We may sell a share to enforce a lien in certain circumstances. We do not have any partly paid shares outstanding.

#### **Takeovers Act**

There are no limitations, either under the laws of Australia or under the Company s Constitution, to the right of non-residents to hold or vote Genetic Technologies Ordinary Shares other than the Commonwealth Foreign Acquisitions and Takeovers Act 1975 (the Takeovers Act ). The Takeovers Act may affect the right of non-Australian residents, including US residents, to hold Ordinary Shares but does not affect the right to vote, or any other rights associated with, any Ordinary Shares held in compliance with its provisions. Acquisitions of shares in Australian companies by foreign interests are subject to review by the Treasurer of the Commonwealth of Australia under the Takeovers Act. The Takeovers Act applies to any acquisition of outstanding shares of an Australian company that exceeds, or results in a foreign person or persons controlling the voting power of more than a certain percentage of those shares.

The thresholds are 15% where the shares are acquired by a foreign person, or group of associated foreign persons, or 40% in aggregate in the case of foreign persons who are not associated. Any proposed acquisition that would result in an individual foreign person (with associates) holding more than 15% must be notified to the Treasurer in advance of the acquisition. As of October 16, 2012, approximately 34.1% of the outstanding Ordinary Shares in the Company were held by shareholders whose registered addresses were located outside Australia (excluding Ordinary Shares which were held in the form of American Depositary Receipts). In addition to the Takeovers Act, there are statutory limitations in Australia on foreign ownership of certain businesses, such as banks and airlines, not relevant to the Company. However, there are no other statutory or regulatory provisions of Australian law or Australian Securities Exchange requirements that restrict foreign ownership or control of Genetic Technologies.

#### **Change of Control**

Takeovers of listed Australian public companies, such as GTG, are regulated amongst other things by the *Corporations Act 2001* which prohibits the acquisition of a relevant interest in issued voting shares in a listed company if the acquisition will lead to the person s or someone else s voting power in the company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

A relevant interest is defined very broadly to capture most forms of interest in shares. Generally, and without limitation, a person will have a relevant interest in securities if they:

- are the holder of the securities;
- have power to exercise, or control the exercise of, a right to vote attached to the securities; or

• have power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct power or control).

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It does not matter how remote the relevant interest is or how it arises. If two or more people can jointly exercise one of these powers, each of them is taken to have that power.

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

• has entered or enters into an agreement with another person with respect to the securities;

• has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities; or

• has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities,

and the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised, the other person is taken to already have a relevant interest in the securities.

A person will also be regarded as having a relevant interest in voting shares in a company if the non-voting securities in which the person already had a relevant interest become voting shares in the company or there is an increase in the number of votes that may be cast on a poll attached to voting shares that the person already had a relevant interest in. In these circumstances, the acquisition of the relevant interest will occur when the securities become voting shares or the number of votes increases.

There are a number of exceptions to the prohibition on acquiring a relevant interest in issued voting shares in a listed company if the acquisition will lead to the person s or someone else s voting power in the company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%. In general terms, some of the more significant exceptions include:

• when the acquisition results from the acceptance of an offer under a formal takeover bid;

• when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid and the acquisition occurs during the bid period;

• when shareholders of the company approve the takeover by resolution passed at a general meeting;

• an acquisition by a person if, throughout the six months before the acquisition, that person, or any other person, has had voting power in the company of at least 19% and as a result of the acquisition, none of the relevant persons would have voting power in the company more than three percentage points higher than they had six months before the acquisition;

- as a result of a pro-rata issue of shares;
- as a result of dividend reinvestment schemes;
- as a result of underwriting arrangements;
- through operation of law;
- an acquisition which arises through the acquisition of a relevant interest in another listed company;
- an acquisition arising from an auction of forfeited shares; or
- an acquisition arising through a compromise, arrangement, liquidation or buyback.

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Breaches of the takeovers provisions of the *Corporations Act 2001* are criminal offenses. The Australian Securities and Investments Commission and the Australian Takeover Panel have a wide range of powers relating to breaches of takeover provisions including the ability to make orders canceling contracts, freezing transfers of, and rights attached to, securities, and forcing a party to dispose of securities. There are certain defenses to breaches to the takeovers provisions provided in the *Corporations Act 2001*.

### **Disclosure of Interests**

The *Corporations Act 2001* requires that a person must give notice to GTG in the prescribed form within two business days (or in some cases by the next business day) if:

• the person begins to have, or ceases to have, a substantial holding in GTG. A substantial holding will arise if a person and their associates have a relevant interest in 5% or more of the votes in the Company or the person has made a takeover bid for the voting shares in GTG;

- if the person has a substantial holding in GTG and there is a movement of 1% in their holding; or
- if the person makes a takeover bid for GTG.

For the purposes of the notification obligation, a relevant interest in the voting shares is defined very broadly to capture most forms of interests in our shares. Generally, a person will have a relevant interest in securities if such person is the holder of the securities, has power to exercise, or control the exercise of, a right to vote attached to the securities or has power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct control or power). Likewise, associates are defined broadly and include:

- corporate entities owned or controlled by the person;
- corporate entities that control the person;
- corporate entities that are controlled by an entity which controls the person;

• persons with whom the person has or proposes to enter into agreements with which relate to the composition of our board;

• persons with whom the person has or proposes to enter into agreements with which relate to the composition of our board; and

• persons with whom the person is acting or is proposing to act in concert.

The rights attaching to our shares for non-compliance with the disclosure of interest requirements may result in disenfranchisement, loss of entitlement to dividends and other payments and restrictions on transfer. A person who contravenes these obligations is liable to compensate a person for any loss or damage the person suffers because of the contravention.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

### AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, will register and deliver ADSs. Each ADS represents one hundred & fifty ordinary shares (or a right to receive one hundred & fifty ordinary shares) deposited with National Nominees Limited, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary. The depositary s corporate trust office at which the ADSs are administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon s principal executive office is located at One Wall Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American depositary receipt, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by holding ADSs in the Direct Registration System, or (B) indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADS holder. This description assumes you hold your ADSs directly. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADR holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

The Direct Registration System is a system administered by DTC pursuant to which the depositary may register the ownership of uncertificated ADSs, which ownership shall be confirmed by periodic statements issued by the depositary to the ADS holders entitled thereto.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Australian law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary and you, as an ADS holder, and the beneficial owners of ADSs set out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American depositary receipt. Directions on how to obtain copies of those documents are provided under Where You Can Find Additional Information.

#### **Dividends and Other Distributions**

## If we Pay a Dividend or Other Distribution, How Will You Receive Dividends and Other Distributions on the Shares?

In the event that we pay a cash dividend or make another distribution, the depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. You will receive these

distributions in proportion to the number of shares your ADSs represent.

• *Cash.* The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.* 

• *Shares.* The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fractional ,ADS and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares.

• **Rights to Purchase Additional Shares.** If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to you. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. *In that case, you will receive no value for them.* 

If the depositary makes rights available to you, it will exercise the rights and purchase the shares on your behalf. The depositary will then deposit the shares and deliver ADSs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

• **Other Distributions.** The depositary will send to you anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to you unless it receives satisfactory evidence from us that it is legal to make that distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that* you *may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.* 

Deposit, Withdrawal and Cancellation

How Are ADSs Issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons entitled thereto.

How Do ADS Holders Cancel an ADS?

You may turn in your ADSs at the depositary s corporate trust office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to you or a person you designate at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, if feasible.

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**Voting Rights** 

How Do You Vote?

You may instruct the depositary to vote the deposited securities, but only if we ask the depositary to ask for your instructions. *Otherwise, you won t be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.* 

If we ask for your instructions, the depositary will notify you of the upcoming vote and arrange to deliver our voting materials to you. The materials will (1) describe the matters to be voted on and (2) explain how you may instruct the depositary to vote the shares or other deposited securities underlying your ADSs as you direct. For instructions to be valid, the depositary must receive them on or before the date specified. The depositary will try, as far as practical, subject to the laws of Australia and our Constitution, to vote or to have its agents vote the shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you

instruct. Notwithstanding anything to the contrary contained in the deposit agreement, the depositary will not exercise a discretionary proxy in respect of the deposited securities for which it has not timely received instructions.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested*.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we will try to give the depositary notice of any such meeting and details concerning the matters to be voted upon sufficiently in advance of the meeting date.

#### **Fees and Expenses**

Persons Depositing or Withdrawing Shares Must Pay:	For:
• US\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

	US\$0.02 (or less) per ADS A fee equivalent to the fee that would be urities distributed to you had been shares had been deposited for issuance of ADSs	-	Any cash distribution to you Distribution of securities distributed to posited securities which are distributed by to ADS holders
•	US\$1.50 (or less) per ADR	• ADRs	Transfers, combination and split-up of
·	Expenses of the depositary	• (when express • dollars	Cable, telex and facsimile transmissions sly provided in the deposit agreement) Converting foreign currency to U.S.
share underly	Taxes and other governmental charges the the custodian have to pay on any ADS or ng an ADS, for example, stock transfer uty or withholding taxes	•	As necessary
• its agents for s	Any charges incurred by the depositary or servicing the deposited securities	•	As necessary

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

#### **Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any proceeds, or send to you any property, remaining after it has paid the taxes.

Rec If w	classifications, Recapitalizations and Mergers	Then:
•	Change the nominal or par value of our shares	• The securities received by the depositary will become deposited securities. Each ADS will
•	Reclassify, split up or consolidate any of the	automatically represent its equal share of the new
deŗ	posited securities	deposited securities
•	Recapitalize, reorganize, merge, liquidate, sell	• The depositary may, and will if we ask it to,
all	or substantially all of our assets, or take any similar	deliver new ADRs or ask you to surrender your
act	ion	outstanding ADRs in exchange for new ADRs identifying
		the new deposited securities.

#### **Amendment and Termination**

How May the Deposit Agreement Be Amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADS, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.* 

How May the Deposit Agreement Be Terminated?

The depositary will terminate the deposit agreement at our direction by mailing a notice of termination to the ADS holders then outstanding at least 90 days prior to the date fixed in such notice for such termination. The depositary may also terminate the deposit agreement by mailing a notice of termination to us and the ADS holders then outstanding if at any time 90 days shall have expired after the depositary shall have delivered to our company a written notice of its election to resign and a successor depositary shall not have been appointed and accepted its appointment.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect dividends and other distributions on the deposited securities, sell rights and other property, and deliver shares and other deposited securities upon cancellation of ADSs. One year after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest.

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The depositary s only obligations will be to account for the money and other cash. After termination our only obligations will be to indemnify the depositary and to pay fees and expenses of the depositary that we agreed to pay.

#### Limitations on Obligations and Liability

#### Limits on Our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

• are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith

• are not liable if either of us is prevented or delayed by law or circumstances beyond our control from performing our obligations under the deposit agreement;

• are not liable if either of us exercises discretion permitted under the deposit agreement;

• have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other party if it involves expenses or liability unless you furnish satisfactory indemnity;

• may rely upon the advice of or information from legal counsel, accountants, any person presenting shares for deposit and any other holder of ADSs or any other person if we believes in good faith such person is competent to give such advice or information.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

#### **Requirements for Depositary Actions**

Before the depositary will deliver or register a transfer of an ADS, make a distribution on an ADS, or permit withdrawal of shares, the depositary may require:

• payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

• satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

• compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs generally when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

## Your Right to Receive the Shares Underlying Your ADRs

You have the right to cancel your ADSs and withdraw the underlying shares at any time except:

• When temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders meeting; or (iii) we are paying a dividend on our shares.

• When you or other ADS holders seeking to withdraw shares owe money to pay fees, taxes and similar charges.

• When it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

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#### **Pre-Release of ADSs**

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre- release of the ADSs. The depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADSs instead of shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the shares or ADSs to be deposited and assigns all beneficial rights, title and interest in such shares or ADSs to the depositary must be able to close out the pre-release on not more than five business days notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release to 30% of the deposited shares, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so.

#### **DESCRIPTION OF PREFERENCE SHARES**

Our Constitution does not contain any limit on the amount of preference shares that we may issue. Otherwise, with approval of shareholders, our Board of Directors may issue securities with any preferential, deferred or special rights, privileges or conditions or with any restrictions (whether in regard to dividend, voting, return of share capital or otherwise) as the Directors determine. We may issue preference Shares which are, or which at our option or the option of the holder may be, liable to be redeemed or converted into ordinary Shares. The preference shares could be utilized as a method of discouraging, delaying or preventing a change in control of the Company. Although we do not currently intend to issue any preference shares, we cannot assure you that we will not do so in the future.

As of the date of this prospectus, there are no outstanding shares of preference stock of any series.

All preference shares issued by the Company must confer on the holders of those preference Shares: (a) the same rights as holders of ordinary Shares to receive notices, reports and accounts and to attend general meetings of the Company; and (b) the right to vote in each of the following circumstances and in no others: (i) during a period when a dividend (or part of a dividend) for the Share is in arrears: (ii) on a proposal to reduce the Company s Share capital; (iii) on a Resolution to approve the terms of a buy-back agreement: (A) on a proposal that affects rights attached to the Share; (B) on a proposal to wind up the Company; (C) on a proposal to dispose of the whole of the Company s property, business and undertaking; and (iv) during the winding up of the Company.fci The material terms of any series of preferred shares that we offer, together with any material Australian or United States federal income tax considerations relating to such preferred shares, will be described in a prospectus supplement.

#### **DESCRIPTION OF WARRANTS**

We may issue warrants to purchase ordinary shares represented by ADSs in one or more series together with other securities or separately, as described in the applicable prospectus supplement. Below is a description of certain general terms and provisions of the warrants that we may offer. Particular terms of the warrants will be described in the warrant agreements and the prospectus supplement for the warrants.

The applicable prospectus supplement will contain, where applicable, the following terms of and other information relating to the warrants:

- The specific designation and aggregate number of, and the price at which we will issue, the warrants
- The designation, amount and terms of the securities purchasable upon exercise of the warrants;

• If applicable, the exercise price for ordinary shares and the number of ordinary shares to be received upon exercise of the warrants;

• The date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;

• Whether the warrants will be issued in fully registered form or bearer form, in definitive or global form, or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security in that unit;

• Any applicable material U.S. federal or Australian income tax consequences;

• The identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

• The proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;

• If applicable, the date from and after which the warrant and the ordinary shares will be separately transferable;

- If applicable, the minimum or maximum amount of the warrants that may be exercised at any other time;
- Information with respect to book-entry procedures, if any;
- The anti-dilution provisions of the warrants, if any;
- Any redemption or call provisions; and

• Any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

#### ENFORCEABILITY OF CIVIL LIABILITIES

We are a public limited company incorporated under the laws of Australia. A majority of our directors and executive officers are non-residents of the United States, and all or substantially all of the assets of such persons are located outside the United States. As a result, it may not be possible for you to:

• effect service of process within the United States upon any of our directors and executive officers or on us;

• enforce in U.S. courts judgments obtained against any of our directors and executive officers or us in the U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;

• enforce in U.S. courts judgments obtained against any of our directors and executive officers or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or

• to bring an original action in an Australian court to enforce liabilities against any of our directors and executive officers or us based upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments obtained in the U.S. courts against any of our directors and executive officers or us, including actions under the civil liability provisions of the U.S. securities laws.

We have appointed Puglisi & Associates as our agent to receive service of process in any action against us in the state and federal courts sitting in the City of New York, Borough of Manhattan, arising of this offering or any purchase or sale of securities in connection therewith. We have not given consent for this agent to accept service of process in connection with any other claim.

# DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITY

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

#### **USE OF PROCEEDS**

Unless otherwise indicated in an accompanying prospectus supplement, we intend to use the net proceeds from the sale of Securities for general working capital purposes, including the expansion of our U.S. operations, and the possible acquisition of other complimentary technologies and tests.

Proceeds may also be used for other purposes specified in the applicable prospectus supplement.

#### CAPITALIZATION AND INDEBTEDNESS

The following table sets forth our capitalization and indebtedness as of June 30, 2015 and December 31, 2015 in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board. The information in this table should be read in conjunction with and is qualified by reference to the financial statements and notes thereto and other financial information incorporated by reference into this Prospectus.

	June 30, 2015	December 31, 2015
Liabilities		
Current liabilities	1,735,163	1,153,566
Non-current liabilities	25,321	81,104
Equity		
Contributed equity	115,247,128	115,272,576
Reserves	4,697,403	6,035,610
Accumulated losses	(100,985,283)	(105,331,830)
Non-controlling interests		
Total equity and liabilities	20,719,732	17,211,026

#### PRICE HISTORY

#### Markets

The Company s ordinary shares are publicly traded on the Australian Securities Exchange under the symbol GTG and, via Level II American Depositary Receipts, on the NASDAQ Capital Market under the ticker GENE.

**Price Range of Ordinary Shares** 

#### Australian Securities Exchange

The following table sets forth the high and low closing sales prices in Australian dollars of our ordinary shares as reported on the ASX during the periods indicated:

Financial Year	Period Covered	High	Low
		(in \$0.00)	
Yearly data 2011	Year ended June 30, 2011	0.285	0.020
2012	Year ended June 30, 2012	0.350	0.080
2013	Year ended June 30, 2013	0.150	0.060
2014	Year ended June 30, 2014	0.105	0.035
2015	Year ended June 30, 2015	0.087	0.012
Quarterly data 2014	Quarter ended September 30, 2013	0.105	0.075
	Quarter ended December 31, 2013	0.085	0.053
	Quarter ended March 31, 2014	0.074	0.048
	Quarter ended June 30, 2014	0.056	0.035
2015	Quarter ended September 30, 2014	0.044	0.022
	Quarter ended December 31, 2014	0.026	0.013
	Quarter ended March 31, 2015	0.087	0.012
	Quarter ended June 30, 2015	0.045	0.028
2016	Quarter ended September 30, 2015	0.034	0.017
	Quarter ended December 31, 2015	0.034	0.016
	Quarter ended March 31, 2016	0.027	0.018
Monthly data 2016	Month ended January 31, 2016	0.027	0.018
	Month ended February 29, 2016	0.023	0.018
	Month ended March 31, 2016	0.021	0.018
	Month ended April 30, 2016	0.024	0.019

#### NASDAQ Capital Market

The following table sets forth the high and low closing sales prices in United States dollars of our ADSs as reported on the NASDAQ Capital Market during the periods indicated:

Financial Year	Period Covered	High	Low
		(in USD)	
Yearly data 2011	Year ended June 30, 2011	9.80	0.65
2012	Year ended June 30, 2012	11.06	2.29
2013	Year ended June 30, 2013	4.79	2.00
2014	Year ended June 30, 2014	1.24	1.00
2015	Year ended June 30, 2015	11.00	0.31
Quarterly data 2014	Quarter ended September 30, 2013	2.54	2.22
	Quarter ended December 31, 2013	1.85	1.35
	Quarter ended March 31, 2014	1.78	1.39
	Quarter ended June 30, 2014	1.24	1.00
2015	Quarter ended September 30, 2014	1.31	0.50
	Quarter ended December 31, 2014	0.61	0.31
	Quarter ended March 31, 2015	11.00	0.35
	Quarter ended June 30, 2015	6.00	3.00
2016	Quarter ended September 30, 2015	4.10	2.00
	Quarter ended December 31, 2015	4.27	1.76
	Quarter ended March 31, 2016	2.62	1.62
Monthly data 2016	Month ended January 31, 2016	2.62	1.62
	Month ended February 29, 2016	2.46	2.00
	Month ended March 31, 2016	2.43	2.02
	Month ended April 30, 2016	2.76	2.25

#### PLAN OF DISTRIBUTION

We may sell our Securities in any one or more of the following ways, including any combination thereof, from time to time:

- to or through underwriters;
- to or through dealers;

- to our shareholders under a rights entitlement offering;
- through agents; or
- directly to purchasers, including our affiliates.

The prospectus supplement relating to a particular offering of Securities will set forth the terms of such offering, including:

• the type of Securities to be offered;

• the name or names of any underwriters, dealers or agents and the amounts of Securities underwritten or purchased by each of them;

• the purchase price of the offered Securities and the proceeds to us from such sale;

• any underwriting discounts and commissions or agency fees and other items constituting underwriters or agents compensation;

- the initial offering price;
- any discounts or concessions to be allowed or reallowed or paid to dealers;
- any securities exchanges on which such offered Securities may be listed; and
- the names of the selling shareholders and the number of Securities being offered by them.

Any initial offering prices, discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time. In compliance with the guidelines of the National Association of Securities Dealers, Inc., or NASD, the maximum commission or discount to be received by any NASD member or independent broker dealer may not exceed 8% of the aggregate value of the securities offered pursuant to this prospectus.

The distribution of the Securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices.

If Securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the prospectus supplement which will be used by the underwriters to sell the securities. If underwriters are utilized in the sale of the Securities, the Securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of sale.

Our Securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriter or underwriters are utilized in the sale of the Securities, unless otherwise indicated in the prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters are subject to conditions precedent and that the underwriters with respect to a sale of securities will be obligated to purchase all of those securities if they purchase any of those Securities.

We may grant to the underwriters options to purchase additional Securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions. If we grant any over-allotment

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option, the terms of any over-allotment option will be set forth in the prospectus supplement relating to those Securities.

If a dealer is utilized in the sales of Securities in respect of which this prospectus is delivered, we will sell those Securities to the dealer as principal. The dealer may then resell those securities to the public at varying prices to be determined by the dealer at the time of resale. Any reselling dealer may be deemed to be an underwriter, as the term is defined in the Securities Act of 1933, as amended, of the Securities so offered and sold. The name of the dealer and the terms of the transaction will be set forth in the related prospectus supplement.

Offers to purchase Securities may be solicited by agents designated by us from time to time. Any agent involved in the offer or sale of the Securities in respect of which this prospectus is delivered will be named, and any commissions payable by us to the agent will be set forth, in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a reasonable best efforts basis for the period of its appointment. Any agent may be deemed to be an underwriter, as that term is defined in the Securities Act of 1933, as amended, of the Securities so offered and sold.

Offers to purchase Securities may be solicited directly by us and the sale of those Securities may be made by us directly to institutional investors or others, who may be deemed to be underwriters within the meaning of the Securities Act of 1933 as amended, with respect to any resale of those securities. The terms of any sales of this type will be described in the related prospectus supplement.

If so indicated in the prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by institutions to purchase Securities from us pursuant to contracts providing for payments and delivery on a future date. Institutions with which contracts of this type may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but in all cases those institutions must be approved by us. The obligations of any purchaser under any contract of this type will be subject to the condition that the purchase of the Securities shall not at the time of delivery be prohibited under the laws of the jurisdiction to which the purchaser is subject. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of those contracts.

One or more firms, referred to as remarketing firms, may also offer or sell the Securities, if the prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as our agents. These remarketing firms will offer or sell the Securities in accordance with a redemption or repayment pursuant to the terms of the Securities. The prospectus supplement will identify any remarketing firm and the terms of its agreement, if any, with us or any of our subsidiaries and will describe the remarketing firm s compensation. Remarketing firms may be deemed to be underwriters in connection with the Securities they remarket.

Disclosure in the prospectus supplement of our use of delayed delivery contracts will include the commission that underwriters and agents soliciting purchases of the Securities under delayed contracts will be entitled to receive in addition to the date when we will demand payment and delivery of the Securities under the delayed delivery contracts. These delayed delivery contracts will be subject only to the conditions that we describe in the prospectus supplement.

In connection with the offering of Securities, persons participating in the offering, such as any underwriters, may purchase and sell Securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions

created in connection with the offering. Stabilizing transactions consist of bids or purchases for the purpose of preventing or retarding a decline in the market price of the securities, and syndicate short positions involve the sale by underwriters of a greater number of Securities than they are required to purchase from any issuer in the offering. Underwriters also may impose a penalty bid, whereby selling concessions allowed to syndicate members or other broker-dealers in respect of the Securities sold in the offering for their account may be reclaimed by the syndicate if the securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the Securities, which may be higher than the price that might prevail in the open market, and these activities, if commenced, may be discontinued at any time.

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Underwriters, dealers, agents and remarketing firms may be entitled under relevant agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, that may arise from any untrue statement or alleged untrue statement of a material fact or any omission or alleged omission to state a material fact in this Prospectus, any supplement or amendment hereto, or in the registration statement of which this prospectus forms a part, or to contribution with respect to payments which the agents, underwriters or dealers may be required to make.

If securities are sold by means of a rights entitlement offering, the prospectus supplement will set forth the terms and conditions of any such rights entitlement offering, including the manner in which it will be conducted and details on how our shareholders can participate in any such offering. A rights entitlement offering conducted under applicable Australian rules and regulations is a pro rata offering of additional securities to all our eligible shareholders, as at a specified future record date. Under applicable Australian Securities Exchange Listing Rules, shareholder approval is not required for a pro rata rights entitlement offering, nor is the issuance of Securities to an Underwriter of any securities not taken up by the eligible shareholders under such an offering.

#### EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 20-F for the year ended June 30, 2015 have been so incorporated in reliance on the report of PricewaterhouseCoopers, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

#### LEGAL MATTERS

The validity of the securities and certain other legal matters with respect to the laws of Australia will be passed upon for us by K&L Gates (registered in Australia).

#### EXPENSES

The following are the expenses estimated to be incurred by us in connection with the issuance and distribution of the securities registered under this registration statement. All amounts shown are estimates except the SEC registration fee. The estimates do not include expenses related to offerings of particular securities. Each prospectus supplement describing an offering of securities will reflect the estimated expenses related to the offering of securities under that prospectus supplement.

	\$
SEC Registration Fee	10,070
Printing expenses	1,000
Legal fees and expenses of the Company	30,000
Accounting fees and expenses of the Company	25,000
Depositary fees and expenses	10,000

	5,090
Total	79,760

#### **INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference documents we file with the SEC, which means that we can disclose information to you by referring you to those documents. The information incorporated by reference is considered to be part of this Prospectus, and certain later information that we file with the SEC will automatically update and supersede this information. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Prospectus. We incorporate by reference our Annual Report on Form 20-F for the fiscal year ended June 30, 2015 filed on November 13, 2015 and any amendments thereto and our Form 6-K submitted on February 25, 2016.

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All annual reports on Form 20-F that we file with the SEC pursuant to the Exchange Act after the date of this Prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference into this Prospectus and to be part hereof from the date of filing of such documents. We may incorporate by reference any Form 6-K subsequently submitted to the SEC by identifying in such Form that it is being incorporated by reference into this Prospectus.

We shall undertake to provide without charge to each person to whom a copy of this prospectus has been delivered, upon the written or oral request of any such person to us, a copy of any or all of the documents referred to above that have been or may be incorporated into this prospectus by reference, including exhibits to such documents, unless such exhibits are specifically incorporated by reference to such documents. Requests for such copies should be directed to Genetic Technologies Limited, 60-66 Hanover Street, Fitzroy, Victoria 3065 Australia, Attention: Company Secretary, telephone +61 3 8412 7000.

You should rely only on the information incorporated by reference or provided in this Prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement relating to the securities offered by this prospectus with the Securities and Exchange Commission. As permitted by the rules and regulations of the Securities and Exchange Commission, this Prospectus omits certain information contained in the registration statement and the exhibits and schedules filed as a part of the registration statement. For further information about us and the American Depositary Shares to be sold in this offering, you should refer to the registration statement and to the exhibits and schedules filed as part of the registration statement, as well as any documents incorporated by reference therein. Statements contained in this Prospectus regarding the contents of any agreement or other document filed as an exhibit to the registration statement are not necessarily complete, and in each instance reference is made to the copy of the agreement filed as an exhibit to the registration statement or otherwise incorporated by reference therein, each statement being qualified by this reference. This registration statement, including the exhibits and schedules filed as a part of the registration statement, may be inspected at the public reference facilities maintained by the Securities and Exchange Commission at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and at its regional offices located at 233 Broadway, New York, New York 10279 and 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and copies of all or any part thereof may be obtained from such offices upon payment of the prescribed fees. You may call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference rooms and you can request copies of the documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission. In addition, the Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants (including us) that file electronically with the Securities and Exchange Commission which can be accessed at http://www.sec.gov.

We are a foreign private issuer as defined under Rule 405 of the Securities Act. As a result, although we are subject to the informational requirements of the Exchange Act, as a foreign private issuer, we will be exempt from certain informational requirements of the Exchange Act which domestic issuers are subject to, including the proxy rules under Section 14 of the Exchange Act, the insider reporting and short-swing profit provisions under Section 16 of the Exchange Act and the requirement to file current reports on Form 6-K upon the occurrence of certain material events. We intend to fulfill the informational requirements that do apply to us as a foreign private issuer under the Exchange Act. We will also be subject to the informational requirements of the Australian Securities Exchange and the Australian Securities and Investments Commission. You are invited to read and copy reports, statements or other information, other than confidential filings, that we have filed with the Australian Securities Exchange and the Australian Securities Exchange are electronically available from the Australian Securities Exchange s website (http://www.asx.com.au), and you may call the Australian Securities and Investments Commission at +61 3 5177 3988 for information about how to obtain copies of the materials that we file with it.

Except for the specific documents incorporated by reference above, no information available on or through our website, or any other website reference herein, shall be deemed to be incorporated into this prospectus or the registration statement of which it is a part.

GENETIC TECHNOLOGIES LIMITED 720,000,000 Ordinary Shares represented by 4,800,000 American Depositary Shares

PROSPECTUS SUPPLEMENT

Maxim Group LLC