

GENETIC TECHNOLOGIES LTD

Form F-3/A

May 17, 2016

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Registration No. 333-210965

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Pre-Effective Amendment No.1 to

FORM F-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GENETIC TECHNOLOGIES LIMITED

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

AUSTRALIA; 98-0430700

(Jurisdiction of incorporation or organization and I.R.S. Employer Identification Number)

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(Address and telephone number of Registrant's principal executive offices)

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(Name, address, and telephone number of agent for service)

Copies of all correspondence should be sent to:

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Approximate date of commencement of proposed sale to the public: **From time to time after the effective date of this Registration Statement and as determined in light of market condition**

If only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (2)	Proposed		Amount of registration fee (4)
		maximum aggregate price per unit (2)	Proposed maximum aggregate offering price (2)(3)	
Ordinary shares no par value per share in the form of American Depositary Shares (1)	\$			
Preference Shares				
Warrants				
Total			\$ 100,000,000	\$ 10,070

(1) American Depositary Shares (as evidenced by American Depositary Receipts, each representing 150 ordinary shares) have been registered on a separate registration statement on Form F-6 filed on January 14, 2002 (File No. 333-14270), as amended on September 12, 2012 (File No. 333-183861).

(2) Not specified as to each class of securities to be registered pursuant to General Instruction II.C. of Form F-3.

(3) The registrant is hereby registering an indeterminate number or aggregate principal amount of the securities of the registrant as may from time to time be offered at unspecified prices. The maximum aggregate offering price of all securities covered by this Registration Statement will not exceed \$100,000,000. The Registrant has estimated the proposed maximum aggregate offering price solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933. The securities registered hereunder include securities that may be purchased by underwriters to cover over-allotments, if any.

(4) Calculated pursuant to Rule 457(o) under the Securities Act of 1933

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

You should read this Prospectus and the accompanying prospectus supplements carefully before you invest in our Securities.

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SUBJECT TO COMPLETION, DATED May 17, 2016

The information in this prospectus is not complete and may be changed. We cannot sell these securities until the registration statement that we have filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell, nor does it solicit offers to buy, these securities in any state where the offer or sale is not permitted.

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.

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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 , 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.

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

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we file with the SEC at the SEC's website or 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 to "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. dollar amounts referred to in this prospectus could have been or could be converted into U.S. dollars or

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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, 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.

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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.

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, of civil liabilities predicated solely upon federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

Because we are not 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

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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).

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.

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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;

- 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

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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.

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

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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.

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, BREVAGen^{plus}.

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.

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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 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.

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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's 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.

