Item 3.D Risk Factors

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

Risks Related to our Business and Business Strategy

A material uncertainty exists that may cast significant doubt about our Company's ability to continue as a Going concern.

For the year ending June 30, 2018, the Group incurred a total comprehensive loss of $5,986,838 (2017: $8,534,481) and net cash outflow from operations of $5,621,315 (2017: $6,813,639). As at June 30, 2018 the Group held total cash and cash equivalents of $5,487,035.

During the 2019 financial year, the Directors expect increased cash outflows from operations as the Company continues to invest resources in expanding the research & development, sales & marketing, and blockchain activities in support of the distribution of BREVAGen*plus*® and its pipeline of risk assessment products. 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 Company has subsequent to June 30, 2018 executed an equity placement facility with Kentgrove Capital Pty Ltd whereby it has an opportunity to raise equity funding of up to $20 million in a series of individual placements of up to $1 million (or a higher amount by mutual agreement) over a period of 20 months, expiring April 7, 2020. The Company has in place an open Placement Prospectus, which provides the Company with greater flexibility should the opportunity arise to offer and issue any of the Placement Shares while this Prospectus remains open. Since June 30, 2018, the Company has issued 100,000,000 shares under this facility, resulting in cash inflows from financing of $1,350,000. In addition to this facility the Directors will also consider other sources of equity funding through traditional offerings in either Australia or the United States.

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 planned equity raisings, which are not guaranteed.

Due to the uncertainty surrounding the timing, quantum or the ability to raise additional equity, there is a material uncertainty that may cast significant doubt on the Group's ability to continue as a going concern and therefore, that it may be unable to realise its assets and discharge its liabilities in the normal course of business. However, the Directors believe that the Group 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 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 Group not be able to continue as a going concern.

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.

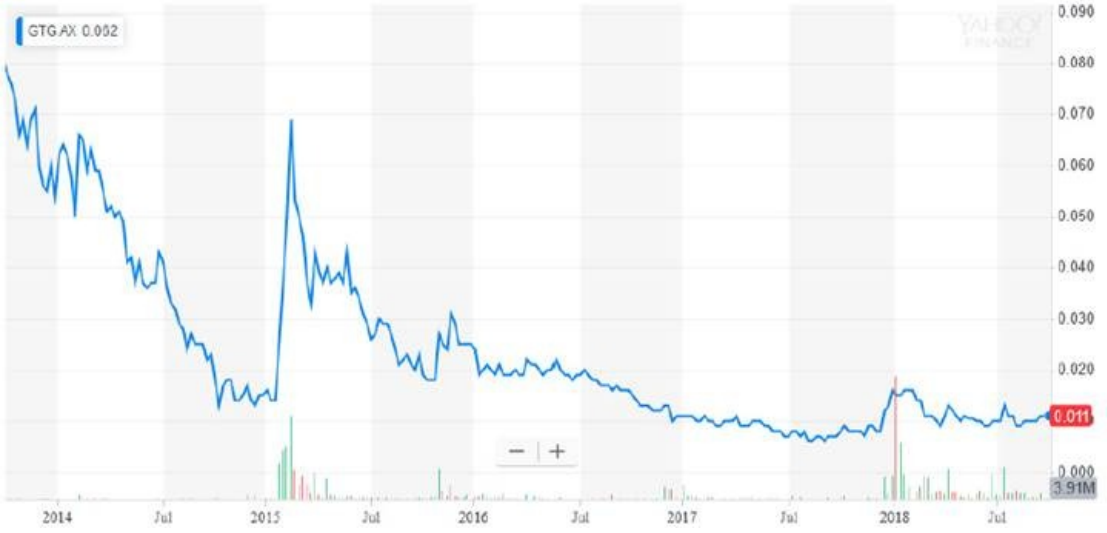
The biotechnology sector can be particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, 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 $0.006 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:



(Refer Item 9.A for more information on key data points on this chart)
(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 declared or paid a cash dividend on our Ordinary Shares and we do not anticipate to do so in the foreseeable future. We intend to retain future cash earnings, if any, for reinvestment in the development and expansion of our business. Whether we pay cash dividends in the future will be at the discretion of our Board of Directors and may be dependent on our financial condition, results of operations, capital requirements and any other factors our Board of Directors decides is relevant. As a result, an investor may only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock, which is uncertain and unpredictable. There is no guarantee that our ordinary shares will appreciate in value or even maintain the price at which an investor purchased the ordinary shares.

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

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

Because we are not 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 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, 2018, the Company had accumulated losses of $123,311,946 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 continue to commercialise existing R&D capabilities, IP and introduce an enhanced BREVAGen*plus* breast cancer risk assessment test and a colon cancer risk assessment test progress development of a suite of genetic screening tests targeting both cancer and non-oncological diseases utilising the latest technology and platforms, and explore and capitalise on blockchain opportunities in the medical and biotech industries.

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. If we fail to generate sufficient revenue and eventually become profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

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 that we were a PFIC for the taxable year ended June 30, 2018 and there is a substantial risk we will be classified as a PFIC for the current taxable year. 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 Tax Consequences" in this Annual Report, for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of our ADSs.

The failure to establish sales, marketing and distribution capacity will materially impact our ability to successfully market and sell our genetic risk assessment tests

We currently have no experience in marketing, sales or distribution of genetic risk assessment tests. We announced in August 2018 that we were transitioning the BREVAGenplus commercial program from a direct salesforce in the US to an ecommerce based sales solution. To successfully establish a web based Consumer Initiated Testing (CIT) platform for the BREVAGenplus and future genetic risk assessment tests, we will have to enter into marketing arrangements with other parties who have established appropriate marketing and sales capabilities in the design and development of a suitable ecommerce platform. We may not be able to enter into marketing arrangements with any marketing party, or if such arrangements are established, our marketing partners may not be able to develop and design an ecommerce sales solution that achieves commercial success for BREVAGenplus or other future genetic risk assessment test. Failure to establish sufficient marketing capabilities through engagement with third party marketing service providers will materially impact our ability to successfully market and sell our tests.

If We Fail To Maintain An Effective System Of Internal Control Over Financial Reporting, We May Not Be Able To Accurately Report Our Financial Results Or Prevent Fraud.

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

As of June 30, 2018 Chief Executive Officer and Chief Financial Officer assessed the effectiveness of our internal control over financial reporting. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework (2013)*. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. In connection with this assessment, we identified the following material weaknesses in internal control over financial reporting as of June 30, 2018.

The Company did not maintain an adequate segregation of duties with respect to internal control over financial reporting, given we have limited accounting personnel to enable and sufficiently evidence an independent review of complex financial reporting matters.

In an effort to remediate the identified material weaknesses and to enhance our overall control environment, we have implemented key steps to ensure continuity in the finance team and ongoing training, which through the introduction of a more controlled month end closing process has provided opportunity for the finance team to take on tasks including the preparation of the month end Finance Board reports and the FY2018 Annual Report which can now be reviewed by the CFO. Refer to Item 15 of this annual report on Form 20-F for further information on our remediation activities. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or that they will prevent potential future material weaknesses.

Risks related to the Company's Blockchain Projects

There is an Uncertain Regulatory Framework for Blockchain Technology. Changes to the framework could negatively affect us.

The regulatory status of blockchain technology is unclear or unsettled in many jurisdictions. It is difficult to predict how or whether governmental authorities will regulate such technologies. It is likewise difficult to predict how or whether any governmental authority may make changes to existing laws, regulations and/or rules that will affect blockchain technology and its applications. Such changes could negatively affect us in various ways, including ceasing the development of our blockchain projects or ceasing operations in a jurisdiction in the event that governmental or other actions make such operations unlawful or commercially undesirable to continue.

Blockchain technology will operate in a new and developing legal and regulatory environment. There is no established body of law or court decisions concerning blockchain and smart contracts. The Company may need to change its business model to comply with these licensing and/or registration requirements (or any other legal or regulatory requirements) in order to avoid violating applicable laws or regulations or because of the cost of such compliance. Uncertainty in how the legal and regulatory environment will develop could negatively impact the Company.

There is a risk that the Company's Blockchain Technology could be Superseded or not function as intended.

There can be no assurance that the technology being proposed to underpin the Company's blockchain applications will not be supplanted by competing protocols that improve upon, or fully replace, the Company's technology. In addition, the Company's use of blockchain may include coding errors or otherwise not function as intended, which may negatively affect its functionality.

Blockchain technology may be subject to risks of hacking and security weakness, which could have an adverse effect on the Company's projects or implementation.

Hackers or other malicious groups or organizations may attempt to interfere with the Company's blockchain in a variety of ways, including but not limited to malware attacks, denial of service attacks, consensus-based attacks, Sybil attacks, smurfing and spoofing. Furthermore, hackers or other individuals may uncover and exploit intentional or unintentional bugs or weaknesses in the network. Any of these risks if they occur could have a materially adverse effect on the Company's projects or the implementation of its blockchain applications.

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.

We are currently subject to increased competition from biotechnology and diagnostic companies, academic and research institutions and government or other publicly-funded agencies that are pursuing products and services which are substantially similar to our molecular risk assessment testing 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 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 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, 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. We do not expect to recognize significant revenues from BREVAGen*plus*, a second generation BREVAGen product, until increased levels of adoption and reimbursement for this test have been established. If we are unable to increase sales of BREVAGen*plus* or successfully develop and commercialize other tests or enhancements, our ability to achieve sustained revenues and profitability would be impacted.

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.

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 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'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.

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 Country for two years.

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

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 rely heavily on communications and information systems to conduct our business. Our operations depend heavily upon the secure transmission of confidential information over public networks. We are transitioning our products' commercial program to an ecommerce based solution, which places our assets, customer data and other personally identifiable data at higher risks. We are making investments to ensure that our employees are aware of cyber security risks facing the Company and how to prevent data breaches. 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. Although we are not aware of the occurrence of any data beaches, we continue to update our cyber security tools and processes in an attempt to keep pace with evolving cyber security risks.

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.

The transition to a direct self-pay program in April 2017 may reduce the reimbursement risks by placing the responsibility for payment purely with the patient, although overall market adoption and revenue generation may be adversely affected.

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 (medical device excise tax “MDET”) 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.Repeal of the MDET was included in the House passed American Health Care Act of 2017 and the Senate’s Better Care Reconciliation Act released on July 13, 2017; however, the Senate has thus far failed to pass its bill to repeal and replace the Affordable Care Act. The moratorium has subsequently on January 22, 2018 been extended for a further period of 2 years. Unless additional action is taken, the MDET will be reinstated on January 1, 2020. The medical device industry has garnered significant support for the permanent repeal of the MDET. It is likely that advocates will continue to push Congress to consider legislation to repeal the MDET before it is reinstated.

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%.

We may also be subject to the U.S. federal Physician Payments Sunshine Act and various state laws on reporting remunerative relationships with healthcare customers. These laws impact the kinds of financial arrangements we may have with hospitals, surgeons or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting, research grants and other arrangements. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services and state attorneys general. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years. If our operations are found to be in violation of these laws, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations.

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 public comment period on the preliminary private payor rate based CLFS payment amounts will close on October 23, 2017 after which CMS will make available final CY 2018 CLFS rates on the CMS website for a January 1, 2018 implementation. 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. Sales volumes and prices of our products depend in large part on the availability of coverage and reimbursement from third-party payors. Third-party payors include governmental programs such as U.S. Medicare and Medicaid, private insurance plans, and workers' compensation plans. These third-party payors may deny coverage or reimbursement for a product or procedure if they determine that the product or procedure was not medically appropriate or necessary. Even though a new product may have been cleared for commercial distribution by relevant regulatory authorities, we may find limited demand for the product until reimbursement approval is assured from multiple governmental and private third-party payors. In the United States, a uniform policy of coverage does not exist across all third-party payors relative to payment of claims for all products. Therefore, coverage and payment can be quite different from payor to payor, and from one region of the country to another. This is also true for foreign countries in that coverage and payment systems vary from country to country.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs through more cost-effective methods of delivering healthcare. All of these types of programs can potentially impact market access for, and pricing structures of our products, which in turn, can impact our future sales. There can be no assurance that third-party reimbursement will be available or adequate, or that current and future legislation, regulation or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell our products on a profitable basis. The unavailability or inadequacy of third-party payor reimbursement could have a material adverse effect on our business, operating results, and financial condition.

Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurances that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

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 development activities. Regulations restricting genetic testing could adversely affect our ability to market and sell our products and services. Accordingly, any regulations of this nature could increase the costs of our operations or restrict our ability to conduct our testing business 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 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.

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

Cyber-attacks or other breaches of information technology security, natural disasters, or acts of terrorism or war may result in hardware failure or disrupt our product testing or research and development activities. There has been a substantial increase in frequency of successful and unsuccessful cyber-attacks on companies in recent years. Such an event may result in our inability, or the inability of our collaborative partners, to operate the facilities to conduct and complete the necessary activities. which even if the event is for a limited period of time, may result in significant expenses and/ or significant damage or delay to our commercial or research activities. While we maintain insurance cover for some of these events, the potential liabilities associated with these events could exceeded the cover we maintain. We are likely to be subject to attempts to breach the security of our networks and information technology infrastructure through cyber-attack, malware, computer viruses or other means of unauthorized access. To date however, we have not been subject to any cyber incidents which individually or in aggregate have resulted in a material impact to our operations or 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 have been 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*. These studies have required 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.

With the change in our pricing and billing model effective April 1, 2017, to a direct patient self-pay model, this requirement has currently become redundant. We recognize, however that scientific papers are an essential marketing tool and that scientific and clinical data are key drivers in commercial adoption. We intend to explore opportunities to engage in further research collaborations to support clinical utility.

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 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.