



# **GENETIC TECHNOLOGIES LIMITED**

(Exact name of Registrant as specified in its charter)

**N/A**

(Translation of Registrant's name into English)

**AUSTRALIA**

(Jurisdiction of incorporation or organization)

**60-66 Hanover Street, Fitzroy, Victoria, 3065, Australia**

**Telephone: 011 61 3 8412 7000; Facsimile: 011 61 3 8412 7040**

(Address of principal executive offices)

**Kevin Fischer**

**Telephone: 011 61 3 8412 7000; Facsimile: 011 61 3 8412 7040**

**Email: kevin.fischer@gtglabs.com**

**60-66 Hanover Street, Fitzroy, Victoria, 3065, Australia**

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act. **None**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

**American Depositary Shares each representing 150 Ordinary Shares**

**and evidenced by American Depositary Receipts**

Title of each Class

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Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. **None**

Number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

2,435,282,724 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Note: Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, and emerging growth company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Emerging growth company

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If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  Yes  No

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The term new or revised financial accounting standard refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued  
by the International Accounting Standards Board

Other

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes  No

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**INTRODUCTION**

In this Annual Report, the Company, Genetic Technologies, we, us and our refer to Genetic Technologies Limited and its consolidated subsidiaries.

Our consolidated financial statements are set out on pages F1 to F39 of this Annual Report (refer to Item 18 Financial Statements).

References to the ADSs are to our ADSs described in Item 12.D American Depositary Shares and references to the Ordinary Shares are to our Ordinary Shares described in Item 10.A Share Capital.

Our fiscal year ends on June 30 and references in this Annual Report to any specific fiscal year are to the twelve month period ended on June 30 of such year.

**FORWARD-LOOKING STATEMENTS**

This Annual Report contains forward-looking statements that involve risks and uncertainties. We use words such as anticipates, believes, plans, expects, future, intends and similar expressions to identify such forward-looking statements. This Annual Report also contains forward-looking statements attributed to certain third parties relating to their estimates regarding the growth of Genetic Technologies and related service markets and spending. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us described below under the caption Risk Factors and elsewhere in this Annual Report.

Although we believe that the expectations reflected in such forward-looking statements are reasonable at this time, we can give no assurance that such expectations will prove to be correct. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations are contained in cautionary statements in this Annual Report including, without limitation, in conjunction with the forward-looking statements included in this Annual Report and specifically under Item 3.D Risk Factors.

All subsequent written and oral forward-looking statements attributable to us are expressly qualified in their entirety by reference to these cautionary statements.

**ENFORCEMENT OF LIABILITIES AND SERVICE OF PROCESS**

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We are incorporated under the laws of Western Australia in the Commonwealth of Australia. The majority of our directors and executive officers, and any experts named in this Annual Report, reside outside the U.S. Substantially all of our assets, our directors' and executive officers' assets and such experts' assets are located outside the U.S. As a result, it may not be possible for investors to affect service of process within the U.S. upon us or our directors, executive officers or such experts, or to enforce against them or us in U.S. courts, judgments obtained in U.S. courts based upon the civil liability provisions of the federal securities laws of the U.S. In addition, we have been advised by our Australian solicitors that there is doubt that the courts of Australia will enforce against us, our directors, executive officers and experts named herein, judgments obtained in the U.S. based upon the civil liability provisions of the federal securities laws of the U.S. or will enter judgments in original actions brought in Australian courts based upon the federal securities laws of the U.S.

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**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

Not applicable

**Item 2. Offer Statistics and Expected Timetable**

Not applicable.

**Item 3. Key Information**

**Item 3.A Selected Financial Data**

The following selected financial data for the five years ended June 30, 2018 is derived from the audited consolidated financial statements of Genetic Technologies Limited, prepared in accordance with International Financial Reporting Standards ( IFRS ) as issued by the International Accounting Standards Board, which became effective for our Company as of our fiscal year ended June 30, 2006.

The balance sheet data as of June 30, 2018 and 2017 and the statement of comprehensive income/(loss) data for the 2018, 2017 and 2016 fiscal years are derived from our audited consolidated financial statements which are included in this Annual Report. Balance sheet data as of June 30, 2016, 2015 and 2014 and statement of comprehensive income/ (loss) data for the 2015 and 2014 financial years are derived from our audited consolidated financial statements which are not included in this Annual Report. The data should be read in conjunction with the consolidated financial statements, related notes and other financial information included herein.

All amounts are stated in Australian dollars as of June 30, as noted.

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## GENETIC TECHNOLOGIES LIMITED

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/ (LOSS)

FOR 2018, 2017, 2016, 2015 AND 2014

	Year ended June 30, 2018 AUD	Year ended June 30, 2017 AUD	Year ended June 30, 2016 AUD	Year ended June 30, 2015 AUD	Year ended June 30, 2014 AUD
<b>Revenue from operations</b>					
Genetic testing services	189,254	518,506	824,586	2,011,918	4,564,280
Less: cost of sales	(300,088)	(492,417)	(743,060)	(891,243)	(1,837,729)
Gross profit from operations	(110,834)	26,089	81,526	1,120,675	2,726,551
Other revenue			300,548	1,027,151	863,832
Gain on deconsolidation of subsidiary					761,361
Selling and marketing expenses	(1,066,404)	(2,721,474)	(3,186,497)	(4,504,299)	(6,251,595)
General and administrative expenses	(3,015,818)	(3,109,530)	(3,429,357)	(4,222,988)	(3,173,109)
Licensing, patent and legal costs			(103,581)	(435,418)	(1,079,199)
Laboratory, research and development costs	(2,210,498)	(2,366,334)	(2,584,752)	(2,851,665)	(3,298,127)
Finance costs	(28,843)	(31,995)	(28,889)	(264,694)	(744,199)
Foreign exchange gains reclassified on liquidation of subsidiary	527,049				
Gain on disposal of business				1,396,798	
Impairment of intangible asset expense		(544,694)			
Fair value loss on ImmunAid option fee				(795,533)	
Share of net loss of associates accounted for using the equity method					(362,682)
Fair value gain/ (loss) on financial liabilities at fair value through profit or loss				349,246	(648,374)
Non-operating income and expenses	441,476	344,112	492,037	370,557	1,071,072
<b>Profit/(loss) from continuing operations before income tax</b>	(5,463,872)	(8,403,826)	(8,458,965)	(8,810,170)	(10,134,469)
Net profit from discontinued operation					
<b>Profit/(loss) before income tax</b>	(5,463,872)	(8,403,826)	(8,458,965)	(8,810,170)	(10,134,469)
Income tax expense					
<b>Profit/(loss) for the year</b>	(5,463,872)	(8,403,826)	(8,458,965)	(8,810,170)	(10,134,469)
<b>Other comprehensive income/(loss)</b>					
Exchange gains/(losses) on translation of controlled foreign operations	(522,966)	(130,655)	1,307,219	414,005	(149,162)
Exchange gains/(losses) on translation of non-controlled foreign operations					86
<b>Other comprehensive income/(loss) for the year, net of tax</b>	(522,966)	(130,655)	1,307,219	414,005	(149,076)
<b>Total comprehensive profit/(loss) for the year</b>	(5,986,481)	(8,534,481)	(7,151,746)	(8,396,165)	(10,283,545)
<b>Profit/(loss) for the year is attributable to:</b>					
Owners of Genetic Technologies Limited	(5,463,872)	(8,403,826)	(8,458,965)	(8,810,170)	(10,125,197)
Non-controlling interests					(9,272)
<b>Total profit/(loss) for the year</b>	(5,463,872)	(8,403,826)	(8,458,965)	(8,810,170)	(10,134,469)
<b>Total comprehensive profit/(loss) for the year is attributable to:</b>					
Owners of Genetic Technologies Limited	(5,986,838)	(8,534,481)	(7,151,746)	(8,396,165)	(10,274,359)
Non-controlling interests					(9,186)

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<b>Total comprehensive profit/(loss) for the year</b>	(5,986,838)	(8,534,481)	(7,151,746)	(8,396,165)	(10,283,545)
<b>Earnings/(loss) per share (cents per share)</b>					
Basic and diluted net profit/(loss) per ordinary share	(0.22)	(0.40)	(0.49)	(0.82)	(1.76)
Weighted-average shares outstanding	2,435,282,724	2,121,638,888	1,715,214,158	1,072,803,358	574,557,747

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## GENETIC TECHNOLOGIES LIMITED

CONSOLIDATED BALANCE SHEET DATA  
FOR 2018, 2017, 2016, 2015 AND 2014

	As of June 30, 2018 AUD	As of June 30, 2017 AUD	As of June 30, 2016 AUD	As of June 30, 2015 AUD	As of June 30, 2014 AUD
<b>Assets</b>					
Current assets	5,990,697	11,631,649	12,131,070	19,566,096	4,360,509
Non-current assets	175,284	476,648	1,158,616	1,153,636	2,368,690
Total assets	6,165,981	12,108,297	13,289,686	20,719,732	6,729,199
<b>Liabilities</b>					
Current liabilities	(1,450,713)	(1,465,293)	(1,332,189)	(1,735,163)	(2,318,016)
Non-current liabilities	(3,390)	(63,960)	(74,308)	(25,321)	(2,583,664)
Total liabilities	(1,454,103)	(1,529,253)	(1,406,497)	(1,760,484)	(4,901,680)
Net assets	4,711,878	10,579,044	11,883,189	18,959,248	1,827,519
<b>Equity</b>					
Contributed equity	122,372,662	122,382,625	115,272,576	115,247,128	90,080,492
Reserves	5,651,162	6,044,493	6,054,861	4,697,403	3,922,140
Accumulated losses	(123,311,946)	(117,848,074)	(109,444,248)	(100,985,283)	(92,175,113)
Non-controlling interests					
Total equity	4,711,878	10,579,044	11,883,189	18,959,248	1,827,519

## Exchange rates

The following table sets forth, for the periods and dates indicated, certain information concerning the noon buying rate in New York City for Australian dollars expressed in U.S. dollars per \$1.00 as certified for customs purposes by the Federal Reserve Bank of New York.

Period ended	At period end USD	Average rate USD	High USD	Low USD
<b>Yearly data</b>				
June 2014	0.9427	0.9186	0.9705	0.8715
June 2015	0.7704	0.8365	0.9488	0.7566
June 2016	0.7432	0.7289	0.7817	0.6855
June 2017	0.7676	0.7562	0.7680	0.7387
June 2018	0.7399	0.7753	0.8105	0.7355
<b>Monthly data</b>				
April 2018	0.7543	0.7684	0.7784	0.7543
May 2018	0.7570	0.7525	0.7595	0.7445
June 2018	0.7399	0.7498	0.7677	0.7355
July 2018	0.7438	0.7403	0.7466	0.7322
August 2018	0.7192	0.7325	0.7428	0.7192
September 2018	0.7238	0.7206	0.7278	0.7107
October 19, 2018	0.7132			

**Item 3.B Capitalization and Indebtedness**

Not applicable.

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

Not applicable.

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**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 BREVAGenplus® 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.**



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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.

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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.

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**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.

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**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.

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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.

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**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;

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- 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.

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**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<sup>plus</sup> 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.

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**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.

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**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.

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**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.

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**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 breaches, 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.

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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 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

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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

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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

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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 exceed 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 BREVA*Genplus*. 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.

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

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to genetic technologies. We expect to aggressively patent and protect our proprietary technologies. However, we cannot be certain that any additional patents will be issued to us as a result of our domestic or foreign patent applications or that any of our 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 may face difficulties in certain jurisdictions in protecting our intellectual property rights, which may diminish the value of our intellectual property rights in those jurisdictions.**

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights for our business in such jurisdictions, the value of those rights may be diminished and we may face additional competition from others in those jurisdictions.

In addition, many countries limit the enforceability of patents against governments agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patent.

**Item 4. Information on the Company**

**Item 4.A History and Development of the Company**

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

On October 15, 1999, the Company's corporate status was changed from a No Liability Company to a company limited by shares. On August 29, 2000, following the acquisition of Swiss company GeneType AG, we changed our name to Genetic Technologies Limited, which is our current name. At that time, the mining activities were phased out to focus on becoming 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 in biotechnology primarily concentrate on one clearly defined area of activity which is covered under Item 4.B Business

Overview .

In October 2009, a new strategic direction was established to focus efforts in creating a portfolio of tests that would be aimed at assisting medical clinicians with cancer management. This would comprise tests that were created by the Company and in-licensed from third parties which would then be marketed by Genetic Technologies in the Asia-Pacific region.

On April 14, 2010, we announced that we had acquired certain assets from Perlegen Sciences, Inc. in California, with the main asset being the BREVAGen breast cancer risk assessment test ( BREVAGen ). In addition to the BREVAGen test, we also acquired a suite of patents valid to 2022 which augment and extend our current non-coding patent portfolio. On June 28, 2010, we incorporated a wholly-owned subsidiary named Phenogen Sciences Inc. in the State of Delaware which commenced selling the BREVAGen test in the U.S. marketplace in June 2011. In October 2014, the Company released its next generation breast cancer risk assessment test BREVAGen*plus*® .

During 2014, the Directors considered an offer by Specialist Diagnostic Services Ltd (SDS), the wholly owned pathology subsidiary of Primary Health Care Ltd., to purchase the assets of the Australian Genetic testing business, which included Paternity, Forensics, Animal and Medical testing for the ANZ region. In September 2014, the Company signed a binding Sale and Purchase Agreement with SDS.

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On November 19, 2014, the Company completed the sale of its Heritage Australian Genetics business to SDS.

As part of the Company's strategy to focus on the expansion of its cancer diagnostic franchise, we continue to evaluate opportunities to sell, out-license or co-develop other assets and technologies in which we have an interest.

In line with this strategy, in November 2016, the Company executed an exclusive worldwide license agreement with The University of Melbourne, for the development and commercialization of a novel colorectal cancer (CRC) risk assessment test, providing the Company with an opportunity to enhance its pipeline of risk assessment products. Additionally, in June 2017, the Company executed an investigator initiated Research Agreement with The Ohio State University, reflecting the growing awareness of the Company's expertise in SNP-based risk assessment.

During the current financial year, the Company executed a further Collaborative research & services agreement with The University of Melbourne, with the research designed to broaden the applicability of BREVAGenplus®, enabling its use by women with extended family history of breast cancer as well as increase the range of factors analyzed in assessing breast cancer. In addition., the Company has commenced development of a pipeline of other cancer and disease target tests for its predictive technologies, initially focusing on:

- Prostate cancer
- Melanoma
- Type 2 Diabetes
- Cardiovascular disease

On February 15, 2018, following changes to composition of the majority of the Board on January 31, 2018, the Company announced that it had entered into a non-binding terms sheet with Blockchain Global Limited (BCG) with the objective of providing a framework for entering into a strategic alliance with BCG to explore potential medical and biotech blockchain applications to provide efficiencies and new opportunities leveraging off the Company's existing genomics business and BCG's extensive blockchain application experience. This collaboration has subsequently (August 2, 2018) been formalized through a framework agreement.

***Corporate Information***

Our registered office, headquarters and laboratory is located at 60-66 Hanover Street, Fitzroy, Victoria, 3065, Australia and our telephone number is +61 3 8412 7000. The offices of our U.S. subsidiary, Phenogen Sciences Inc., are located at 1300 Baxter Street, Suite 157, Charlotte, North Carolina, 28269 U.S.A. The telephone number for the Phenogen Sciences office is (877) 992 7382. Our website address is [www.gtglabs.com](http://www.gtglabs.com). The information in our website is not incorporated by reference into this



Annual Report and should not be considered as part of this Annual Report.

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.

## **Item 4.B Business Overview**

### **Description of our Business**

Founded in 1989, Genetic Technologies Listed on the ASX (GTG) in 2000 and NASDAQ (GENE) in 2005, Genetic Technologies is today a molecular diagnostics company that offers predictive testing and assessment tools to help physicians proactively manage women's health. The Company's lead product, BREVAGen*plus*, is a clinically validated risk assessment test for non-hereditary breast cancer and is first in its class. BREVAGen*plus* improves upon the predictive power of the first generation BREVAGen test and is designed to facilitate better informed decisions about breast cancer screening and preventive treatment plans. BREVAGen*plus* expands the application of BREVAGen from Caucasian women to include African-Americans and Hispanics, and is directed towards women aged 35 years or above, who have not had breast cancer and have one or more risk factors for developing breast cancer.

The Company has successfully launched the first generation BREVAGen test across the U.S. via its U.S. subsidiary Phenogen Sciences Inc. and the addition of BREVAGen*plus*, launched in October 2014, significantly expands the applicable market. The Company markets BREVAGen*plus* to healthcare professionals in comprehensive breast health care and imaging centers, as well as to obstetricians/gynecologists (OBGYNs) and breast cancer risk assessment specialists (such as breast surgeons).

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**The Genetic Testing Business**

Following the acquisition of Genetype AG in 1999 and the subsequent renaming to Genetic Technologies Limited, the Company focused on establishing a genetic testing business, which over the following decade saw it become the largest provider of paternity and related testing services in Australia. The Company's service testing laboratory in Melbourne became the leading non-Government genetic testing service provider in Australia. The genetic testing services of the Company expanded to include at certain times:

- *Medical testing*
- *Animal Testing*
- *Forensic Testing*
- *Plant Testing*

The acquisition of GeneType AG also provided the Company with ownership rights to a potentially significant portfolio of issued patents. During the intervening years, this portfolio has since been expanded by both organic growth and the acquisition of intellectual property assets from third parties. The patent portfolio is constantly reviewed to ensure that we maintain potentially important patents but at the same time keep costs to a minimum by no longer pursuing less commercially attractive and relevant intellectual property.

A strategic alliance with Myriad Genetics Inc. delivered to the Company exclusive rights in Australia and New Zealand to perform DNA testing for susceptibility to a range of cancers. In April 2003, we established our cancer susceptibility testing facility within our Australian laboratory. In June 2003, this facility was granted provisional accreditation by the National Association of Testing Authorities, Australia (NATA).

In November 2003, the Company joined the world-wide genetic testing network GENDIA as the sole reference laboratory for the network in Australia and New Zealand. GENDIA consists of more than 50 laboratories from around the world, each contributing expertise in their respective disciplines to create a network capable of providing more than 2,000 different genetic tests. This provided the Company with the ability to offer comprehensive testing services to its customer base in the Asia-Pacific region as well as increasing its exposure to other markets.

In December 2009, Genetic Technologies negotiated an exclusive option to investigate the purchase of various assets from Perlegen Sciences, Inc. of Mountain View, California which included a breast cancer non-familial risk assessment test, BREVAGen. Those assets were subsequently purchased by the Company in April 2010. Work then began on validating the test in the Company's Australian laboratory as well as initiating the process for obtaining CLIA certification which would enable the Company to undertake the testing of samples received from the U.S. market. By July 2010, a new U.S. subsidiary named Phenogen Sciences Inc. had been incorporated by the Company in Delaware to market and distribute the BREVAGen test across mainland U.S.A.

On September 15, 2014 we announced plans to restructure and realign our group activities, in order to focus our strategy on the U.S. molecular diagnostics market and the commercialisation of our lead breast cancer risk test BREVAGen through our U.S. subsidiary Phenogen Sciences, Inc. In October 2014, we announced the U.S. release of BREVAGen<sup>plus</sup>, an easy-to-use predictive risk test for the millions of women

at risk of developing sporadic, or non-hereditary, breast cancer, representing a marked enhancement in accuracy and broader patient applicability, over our first generation BREVAGen product. We also made a pivotal change of sales and marketing emphasis toward large comprehensive breast treatment and imaging centres, which are more complex entities with a longer sales cycle, but higher potential.

As part of this realignment, on November 19, 2014 we completed the sale of our Heritage Australian genetics business to Specialist Diagnostic Services Ltd. As part of the Company's strategy to focus on the expansion of its cancer diagnostic franchise, we continue to evaluate opportunities to sell, out-license or co-develop other assets and technologies in which we have an interest, including our legacy non-coding assertion and licensing program.

**BREVAGenplus is a State-of-the-Art Breast Cancer Risk Assessment Test designed to enable a more personalized breast cancer risk assessment in a greater number of women**

The identification, in 2007, of a number of single nucleotide polymorphisms (SNPs), each with an associated small relative risk of breast cancer, led to the development of the first commercially available genetic risk test for sporadic breast cancer, BREVAGen™. The Company launched the product, in the U.S. in June 2011. In October 2014, Genetic Technologies released its next generation breast cancer risk assessment test, BREVAGenplus. This new version of the test incorporates a 10-fold expanded panel of genetic markers (SNPs), known to be associated with the development of sporadic breast cancer, providing an increase in predictive power relative to its first-generation predecessor test. In addition, the new test is clinically validated in a broader population of women including, African American and Hispanic women. This increases the applicable market beyond the Caucasian only indication of the first generation test, and simplifies the marketing process in medical clinics and breast health centres in the U.S.

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The expanded panel of SNPs incorporated into BREVAGen*plus* were identified from multiple large-scale genome-wide association studies and subsequently tested in case-control studies utilising specific Caucasian, African American and Hispanic patient samples.

BREVAGen*plus* is a first-in-class, clinically validated, predictive risk test for sporadic breast cancer which examines a woman's clinical risk factors, combined with seventy seven scientifically validated genetic biomarkers (SNPs), to allow for more personalised breast cancer risk assessment and risk management.

Physicians worldwide look largely to family history of breast cancer as an indication of risk in patients for developing this disease. However, 85% of women who develop breast cancer have little or no family history of developing the disease and BREVAGen*plus* is designed to help elucidate risk in this group of women.

Targeted towards women over the age of 35 who have little or no family history of breast cancer but harbor one or more known clinical risk factors such as early menstruation, late childbirth, late menopause, a history of atypical or benign breast biopsies, BREVAGen*plus* provides a more accurate tool for assessing a woman's personal risk of developing breast cancer.

In addition, women designated as having dense breasts upon mammographic evaluation are recognized as being at elevated risk of developing breast cancer, which makes these patients potential candidates for the BREVAGen*plus* test. Several U.S. States have enacted legislation, which mandates that breast density be documented on mammogram reports, and encourages physicians to discuss risk profiles and risk reduction strategies with these patients. Recent scientific evidence indicates that BREVAGen*plus* may help to properly identify the high risk women in this category. It is expected that more U.S. jurisdictions will adopt similar legislation in the coming years, increasing awareness of the correlation between dense breast and breast cancer risk amongst healthcare providers, patients and health insurance payers.

In April 2011, the Company announced that it had gained certification of its Australian laboratory under the U.S. Clinical Laboratories Improvements Amendments, as regulated by the Centers for Medicare and Medicaid in Baltimore, Maryland. This certification, which enables the Company to accept and test samples from U.S. residents, was the culmination of preparations required for the U.S. launch of the Company's BREVAGen test which occurred in June 2011. Phenogen Sciences has since established an office in Charlotte, North Carolina.

In August 2012, the Company announced that it had received European CE Mark approval for BREVAGen, which will allow BREVAGen to be sold in the EU and other countries that recognize the CE Mark.

During the first half of the 2013 financial year, the Company announced that it had received licensure to sell BREVAGen into the states of California, Maryland, Pennsylvania, Rhode Island and Florida, bringing the total number of U.S. states in which the BREVAGen test can be sold to 49 of the 50 U.S. states. In July 2013, the Company was inspected by a representative of the New York State Department of Health, Clinical Laboratory Evaluation Program (CLEP). The Company's laboratory received an inspection result with no deficiencies reported and, on August 30, 2013, the Company announced that it had received its Clinical Laboratory Permit (CLEP) from the New York State Department of Health. This permit, which allows the Company to offer the BREVAGen test to residents of New York State, completed the final out-of-state licensure allowing the Company to provide testing services to all 50 U.S. states.

From its headquarters in Melbourne, Victoria, the Company's laboratory holds a number of accreditations including:

- The Clinical Laboratory Improvement Amendments (CLIA) license required for all laboratories offering testing the U.S.;
- The Clinical Laboratory Evaluation Program (CLEP) license, an additional certification required to offer tests in New York State;
- A Medical Device Establishment License (MDEL) required for Canada;
- The BREVA*Genplus*® test is CE marked for sale in Europe;

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

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The United States Clinical Laboratory Improvement Amendments of 1988, or CLIA, extends Federal licensing requirements to all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, based on the complexity of the tests they perform. CLIA also establishes a stringent proficiency testing program for laboratories and includes substantial sanctions, such as suspension, revocation or limitation of a laboratory's CLIA certificate (which is necessary to conduct business), and significant fines and/or criminal penalties.

CLIA, and its implementing regulations, includes quality standards (establishing Federal quality standards for all clinical laboratories); application and user fee requirements; and enforcement procedures. The quality standard regulations establish varying levels of regulatory scrutiny depending upon the complexity of testing performed. The tests on samples provided through our products are processed at our laboratory in Melbourne, Australia. Our laboratory completed its first CLIA inspection under CLIA guidelines and received its certificate of compliance effective November 17, 2011. A re-certification from CMS i.e. paper survey, was performed in November 2013 and another on-site re-certification followed up in February 2016. A paper survey was conducted in November 2017 and the company's next scheduled re-certification survey is due in November 2019. Furthermore, our laboratory completed its first CLEP inspection under the NYS DOH CLEP guidelines and received its certificate of compliance effective August 30, 2013. Since the initial survey, the laboratory has been successful in submitting documents via the NYS eCLEP Health Commerce System for each subsequent year to date. Although no firm date has been provided, the laboratory is expecting an on-site visit in the near future.

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

The CLIA regulations apply to laboratory developed test (LDT) medical device. The FDA defines a LDT as an in vitro diagnostic test that is manufactured by and used within a single laboratory (i.e. a laboratory with a single CLIA certificate). As with other in vitro diagnostic tests, LDTs are considered devices, as defined by the Federal Food, Drug and Cosmetic Act (FD&CA), and are therefore subject to regulatory oversight by FDA. When a laboratory develops a test system such as an LDT in-house without receiving FDA clearance or approval, the CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment, see 42 CFR 493.1253(b)(2) (establishment of performance specifications). This analytical validation is limited, however, to the specific conditions, staff, equipment and patient population of the particular laboratory, so the findings of these laboratory-specific analytical validation are limited in how they can be commercialized outside of the laboratory that did the analysis. Furthermore, the laboratory's analytical validation of LDTs is reviewed during its routine CLIA biennial survey after the laboratory has already started testing.

BREVAgen and BREVAgen<sup>plus</sup> are laboratory developed tests, or LDTs. The federal Food and Drug Administration, or FDA, has regulatory responsibility over, among other areas, instruments, test kits, reagents and other medical devices used by clinical laboratories to perform diagnostic testing. CLIA-certified laboratories, such as ours, frequently develop internal testing procedures to provide diagnostic results to customers. These tests are referred to as laboratory developed tests, or LDTs. LDTs are subject to CMS oversight through its enforcement of CLIA. The FDA has also claimed regulatory authority over all LDTs, but indicates that it has exercised enforcement discretion with regard to most LDTs offered by high complexity CLIA-certified laboratories, and has not subjected these tests to the panoply of FDA rules and regulations governing medical devices. However, the FDA has stated that it has been considering changes in the way it believes that laboratories ought to be allowed to offer these LDTs, and during 2010 publicly announced that it would be exercising regulatory authority over LDTs, using a risk-based approach that will direct more resources to tests with the highest risk of injury. In September 2014, the FDA announced its framework and timetable for implementing this guidance. In 2017, FDA announced its position that FDA and CMS should share oversight of LDTs and also reiterated that already marketed LDTs would be grandfathered. In its prospective approach, FDA proposed a four year phase in period for pre-market review of LDTs and this approach can affect new or modified current products.

*Test samples received since launch*

Since launching its BREVAGen test in the U.S. market in July 2011, followed by the U.S. release of, in October 2014, the number of test samples received up to balance date June 30, 2018, was 11,042 tests.

During the financial year ended June 30, 2012, the Company generated the first sales of its BREVAGen test. Whilst not material to the overall result, in accordance with revenue recognition principles, due to the relatively limited numbers of tests sold in that first year of launch, the income generated from these sales was recorded on a cash basis Effective January 1, 2013, significant changes in the US reimbursement system have impacted (positively) on the amounts the Company has since received for the BREVAGen tests it performs. As of June 2014, the Company had enough historical data to use to enable it to determine a reliable estimate of the

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amount of revenue expected to be received. Accordingly the Group up to June 30, 2017 recognized the revenue on the BREVAGen test on an accruals basis. With the transition to a patient self-pay program from April 1, 2017, revenues are recognized on an individual billed basis from July 1, 2017.

In an ongoing effort to establish the most optimal methodology to effectively market the product and improve overall market adoption, during September 2017, the Company transitioned the BREVAGen<sup>plus</sup> commercial program from a direct salesforce in the U.S. to an ecommerce based solution that will allow the consumer to initiate the testing via a consumer initiated testing (CIT) platform via the Company's U.S. subsidiary, Phenogen Sciences Inc. website. This transition is ongoing as the Company seeks to effectively address all of the regulatory requirements of a CIT solution.

*Further expansion of the Company's credentialing program*

Credentialing with Preferred Provider Organization ( PPOs ) Networks allows for expedited claim adjudication as in-network . A PPO is a managed care organization of medical doctors, hospitals and other health care providers which has covenanted with insurers or third-party administrators to provide health care, at reduced rates, to the clients of the respective insurer or administrator. Credentialing is a process whereby provider organizations such as physicians, care facilities and ancillary providers (including testing service providers such as Phenogen Sciences) contract directly with the PPO. Contracts with PPOs are fundamental to having claims for the BREVAGen test adjudicated as in-network .

Credentialing contracts have been executed between the Company and InterWest Health, FedMed Inc., MultiPlan Network, Three Rivers Provider Network, Prime Health Services, National Preferred Provider Network / PlanCare America / Ohio Preferred Provider Network LLC (NPPN / OPPN), Galaxy Health Network and Fortified Provider Network.

Historically, the positive impact of this activity was reflected in the fact that the average reimbursement received in respect of claims that were adjudicated as in-network was significantly higher than the amounts received in respect of claims that were adjudicated as out-of-network , with the time taken to collect the funds also being materially shorter.

Ongoing challenges experienced with the traditional reimbursement system resulted in the Company transitioning to a patient self-pay program on April 1, 2017 (see Reimbursement below). This change currently eliminates the need for credentialing and the role of the PPOs for new test samples received subsequent to this date.

*Reimbursement*

Up until the end of the 2012 calendar year, insurance claims for BREVAGen were submitted using the so-called code stack of CPT methodology codes. Reimbursement under this regime was positive, with a low percentage of denials and appeals. However, effective January 1, 2013, the AMA removed the code stack claim process, requiring tests without a specific CPT code to be claimed via an Unlisted or Miscellaneous Code .



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As a result of the above changes the Company up to April 1, 2017 used a miscellaneous code when submitting claims for reimbursement from insurers. As part of this transition, the list price for the BREVA Gen test was increased to enable the Company to receive payment for aspects of the test that were not previously available under the code stack. Importantly, notwithstanding this, the Company did not seek to increase the maximum out-of-pocket amount that a given patient is required to pay for a BREVA Gen<sup>plus</sup> test under its Patient Protection Program.

These ongoing reimbursement challenges through the use of a miscellaneous CPT code, as well as overall pressure on the U.S. health care market to lower cost and maximize efficiency were major factors in the Company's decision to transition from a traditional reimbursement system through insurance providers to a direct patient self-pay program from April 1, 2017. Converting to a direct pay relationship with patients is aimed at providing economic and process certainty to the transaction for the healthcare provider and the patient. The change is expected to eliminate ongoing reimbursement issues being experienced, such as low levels of reimbursement, prolonged payment time, patient confusion around eligibility and financial responsibility and poor coverage

### *Clinical utility studies and peer-review publications to drive reimbursement outcome*

With effect from April 1, 2017, the Company transitioned from a traditional reimbursement system through insurance providers, to a direct patient self-pay program. This shift has implications for the series of clinical utility studies, the first two of three which had commenced in the fourth quarter of 2016, that were designed as a means to achieve reimbursement coverage through the private insurers. With the change in the pricing model, that requirement has become redundant.

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We recognize, however that scientific papers are an essential marketing tool and that scientific and clinical data are key drivers in to help strengthen our commercial position. We intend to explore opportunities to engage in further research collaborations to support clinical utility.

Physicians and the major breast health centers seek multiple points of confirmation that the medical device works as intended and leads to a meaningful improvement in women's health. Therefore, the more papers that are published on BREVAGen<sup>plus</sup>, profiling its performance characteristics including clinical validity and utility, the more likely physicians will be to use the test

The Company had previously conducted multiple scientific studies to develop and validate the first generation BREVAGen test as well as created two health economic models to demonstrate potential cost savings and health benefits associated with the BREVAGen test. Importantly, due to the nature of the technology and the specific improvements incorporated in BREVAGen<sup>plus</sup>, the research undertaken and published based on the original version of the test remains applicable to the new and improved BREVAGen<sup>plus</sup> test.

Following is a list of peer-reviewed publications on the BREVAGen test, to date:

- 1) **Cost-effectiveness of a Genetic Test for Breast Cancer Risk** . *Cancer Prevention Research*. 2013 Dec; 6(12):1328-36.
- 2) **Economic Evaluation of Using a Genetic Test to Direct Breast Cancer Chemoprevention in White Women with a Previous Breast Biopsy** . *Applied Health Economics and Health Policy*. 2014 Apr; 12(2):203-17.
- 3) **Using SNP genotypes to improve the discrimination of a simple breast cancer risk prediction model** . *Breast Cancer Res Treat*. 2013 Jun; 139(3):887-96.
- 4) **Assessment of clinical validity of a breast cancer risk model combining genetic and clinical information** . *J Natl Cancer Inst*. 2010 Nov 3; 102(21):1618-27.
- 5) **SNP s and Breast cancer risk prediction for African-American and Hispanic women.** *Breast Cancer Research & Treatment*. 2015 Dec; 4(3): 583-89.
- 6) **Breast cancer risk prediction based on clinical models and 77 independent risk-associated SNPs in women aged under 50 years: Australian Breast Cancer Family Registry** *Cancer, Epidemiology, Biomarkers and Prevention*. 2016 Feb; 25(2): 359-65.

7) **Prediction of breast cancer risk based on profiling with common genetic variants** . J Natl Cancer Inst. 2015; 107(5):doi:10.1093/jnci/djv036. doi: 10.1093/jnci/djv036.

And supporting presentations:

- 1) Jacoby E, DiCicco, Allman R. (2013). Impact of genomics on the assessment and management of breast cancer risk in a women s healthcare clinic. Proceedings of the National Consortium of Breast Centers March 2013.
- 2) Fohlse HJ, Dinh TA, Allman R. (2013). Genetic testing for breast cancer risk estimation A cost-effectiveness analysis. Presented at The California Pacific Medical Centre Breast Cancer Risk Assessment Workshop June 2013.
- 3) Fohlse HJ, Dinh TA, Allman R. (2013). Genetic testing for breast cancer risk estimation A cost-effectiveness analysis. Presented at the San Antonio Breast Cancer Symposium December 2013.
- 4) Allman R, Dite GS, Hopper JL. (2015). Should women with a projected 5-year risk of developing breast cancer of 1.4% or higher be offered pharmacologic risk reduction? World Congress on Controversies in Breast Cancer: 22-24 October 2015.
- 5) Dite GS, Allman R, Hopper JL (2014). Value of adding Single-Nucleotide Polymorphism panel markers to phenotypic algorithms of Breast Cancer risk. Presented at the San Antonio Breast Cancer Symposium December 2014.

Although there is strong scientific data behind *BREVA Genplus*, there is always a need for further clinical data to show clinical efficacy and utility of the product. As such, in June 2017, we have engaged in a research collaboration with The Ohio State University which is conducting a clinical trial surrounding the efficacy of polygenic risk in patient management of at-risk women. Our medical affairs team continues to engage with other influential medical centers across the U.S. in order to facilitate further research collaborations that will continue to support the utility of polygenic risk in clinical practice.

#### ***Research & Development Projects***

During the year ended June 30, 2018, Genetic Technologies supported the following research programs, details of which have been provided below;



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- *BREVA*Gen*plus*
- Colorectal Cancer Risk Assessment Test
- Research collaboration with The Ohio State University
- Expanded range of other cancer and disease target predictive risk assessment tests

In previous years, other projects, which have since been terminated or otherwise commercialized, have also been supported by the Company. The Company is constantly seeking new opportunities. Historically some projects have arisen from new inventions made by the Company while some have been made by others who have approached the Company seeking collaboration and support for their activities.

By its very nature, research is unpredictable and involves a considerable element of risk. Such risks may relate to scientific concepts, the implementation of the science, the protection of any inventions made and the success or otherwise in persuading others to respect the intellectual property acquired or created by the Company. Specifically, patents filed may not issue or may later be challenged by others. Even if patents issue, the methods described may, with time, be superseded by alternative methods which may prove to be commercially more attractive. Even if patents issue and the methods developed are successfully reduced to practice and can be shown to be commercially relevant, there is still no assurance that other parties will respect the patents or will take licenses to use the intellectual property. In such circumstances, it is possible that legal action will be necessary to enforce the Company's rights. Such action, in turn, raises a new series of risks including potentially significant legal costs and uncertain outcomes.

To the extent that delays are encountered in concluding the research projects, additional costs may be incurred. Further, the projected revenues from the projects may also be deferred, potentially impacting on the Company's liquidity. In such cases, the Company may seek to partner with outside parties, who will contribute to the costs of research in return for an interest in the project, or the Company may seek to raise additional working capital from the Market. In a worst case scenario, the projects may well be closed down with no valuable intellectual property having been created for the Company.

***BREVA*Gen*plus*® Project**

In June 2011, the Company launched the first iteration of the breast cancer risk assessment test; *BREVA*Gen. In October 2014, Genetic Technologies released its next-generation breast cancer risk assessment test, *BREVA*Gen*plus*. This new version of the test incorporates a 10-fold expanded panel of genetic markers (SNPs), known to be associated with the development of sporadic breast cancer, providing an increase in predictive power relative to its first-generation predecessor test. In addition, the new test has been studied in a broader population of women including, African American and Hispanic women. This increases the applicable market beyond the Caucasian only application of the first generation test, and simplifies the marketing process in medical clinics and breast health centres in the U.S. The expanded panel of SNPs incorporated into *BREVA*Gen*plus* were identified from multiple large-scale genome-wide association studies and subsequently tested in case-control studies utilising specific Caucasian, African American and Hispanic patient samples.

Further modifications to BREVA*Genplus* were implemented in December 2016. Changes included a simplification of the clinical risk questionnaire, utilized in BREVA*Genplus*, from the seven questions of the Gail Model to just two questions: Age and Any First Degree Relatives. Additionally, test results are now reported as a 5-year Absolute Risk of Developing Breast Cancer. This approach is modelled on that of Mavaddat et al (2015) 107(5): djv036 and provides multiple product benefits. It simplifies the data-input requirement by the physician, aligns the product more firmly with U.S. clinical guidelines, in particular, the United States Preventative Services Task Force (USPSTF) recommendation statement on chemoprevention of breast cancer, and automatically strengthens the validation data by tying the test to a multinational study of approximately 80,000 women.

#### **Colorectal Cancer (CRC) risk assessment test Project**

On November 29, 2016, Genetic Technologies announced the signing of an exclusive worldwide license agreement with The University of Melbourne for the development and commercialization of a novel colorectal cancer (CRC) risk assessment test.

The core technology behind this test was developed by a research team at the University's Centre for Epidemiology and Biostatistics, with results from preliminary modelling studies first published online in *Future Oncology* on February 1, 2016, in a Paper entitled "Quantifying the utility of single nucleotide polymorphisms to guide colorectal cancer screening," 2016 Feb; 12(4), 503-13. This simulated case-control study of 1 million patients indicated that a panel of 45 known susceptibility SNPs can stratify the population into clinically useful CRC risk categories. In practice, the technology could be used to identify people at high risk for CRC who should be subjected to intensive screening, ultimately reducing the risk of occurrence and death from the disease. Those identified as low risk of CRC can be spared expensive and invasive screening, thereby preventing adverse events and unjustified expenses.

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A scientific validation study supporting this work has been completed, and a report of the research program progress has been delivered to the Company. Whilst the terms of the Agreement are confidential, these events represent an important first milestone in the development of a new test as the Company seeks to diversify its product pipeline and become a key player in the SNP-based cancer risk assessment landscape.

The fundamental technology is similar to the BREVAGen<sup>plus</sup> test and is expected to fit synergistically into the Company's existing infrastructure and processes.

The Company is on track to begin the commercialisation process for the new colon cancer screening test in October 2018. A scientific validation study was completed during the current year, the results of which confirm previously evaluated modelling data. Test design and identification of relevant reporting requirements are in progress.

**Research Collaboration with The Ohio State University**

On June 15, 2017 the Company executed a Clinical Study Agreement with The Ohio State University, Technology Commercialization Office and Division of Human Genetics. This is an investigator-initiated study in which Genetic Technologies was approached to be the collaborating partner, reflecting the growing awareness of the Company's expertise in SNP-based risk assessment.

The terms and conditions of the Agreement are confidential; however Genetic Technologies will supply novel SNP-based genotyping for a clinical research study, through its CLIA laboratory facility, on a fee for service basis. The Company will be responsible for the development and validation of the new assay, although the fundamental technology is similar to the BREVAGen<sup>plus</sup> test and will fit synergistically into the Company's existing laboratory infrastructure and processes. Importantly, if the first phase of the study is successful, several other major genetics centers in the U.S. have expressed an interest in joining the study.

This collaborative study provides two tangible benefits for the Company:

- (i) engagement and collaboration with high profile cancer genetics researchers in the U.S. who are at the forefront of risk assessment research; and
- (ii) the resulting data can be used to inform the design of future pipeline products

Whilst sample collection by the University has been slower than expected during the current year, the Company remains committed to delivering a high standard of service as envisaged under the terms of the agreement.

## **New Product Development**

Whilst very much at an early stage of activity, during the current year, the Company commenced development of a suite of genetic screening tests targeting both cancer and non-oncological diseases, including:

- Prostate Cancer
- Melanoma
- Type 2 Diabetes
- Cardiovascular Disease

The new risk assessment tests represent a significant market opportunity. To assist with this programme GTG is investigating alternative technology and platforms for performing the Company's genetic testing.

## **Blockchain Projects**

Through a strategic alliance with Blockchain Global Limited (BCG) and establishment of a new functional team, the Company is actively engaging with stakeholders and pursuing opportunities that potentially allow it to not only build on the genomic assets and expertise that it has developed to date but also take advantage of the new and developing opportunities that blockchain digital platforms may create in the medical and biotech industries. Blockchain technology presents a unique opportunity for the Company to contribute to the advancement of cancer research and to improve the health of individuals around the world. The security and privacy inherent in the blockchain provides a means by which individuals can share their genomic information while retaining control of their personal medical records.



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Through the wholly owned subsidiary, GeneVentures, the Company is actively seeking to assist with efforts required for the successful introduction of products or services into the biotech market through;

- Expertise in commercialising and operationalising new medical technology
- Knowledge and experience applying blockchain technology to the biotech sector
- Introduction of cutting-edge technology solutions into the US and APAC
- Marketing in support of product launches
- Pathways to development resources for blockchain solutions

As part of our blockchain initiative, to date we have commenced work with several organisations, including Swisstec Helath Analytics Limited to develop a blockchain-enabled platform to address the retail market in Southeast Asia, and Project Shivom (Omix Ventures) whose platform will act as a distribution channel for existing and planned genetic risk screening tests in India.

**Historical Research Projects**

Following a significant corporate restructure undertaken during the 2015 fiscal year, a strategic decision was made to focus the Company on the US diagnostics market and all historical research projects were ceased.

***Competition***

The medical diagnostics and biotechnology industries is subject to intense competition. As more information regarding cancer genomics and personalized medicine becomes available to the public, we anticipate that more products aimed at identifying cancer risk will be developed and that these products may compete with ours. However, the use of Single Nucleotide Polymorphisms (SNPs), for disease risk prediction is still a relatively new field of medicine.

Until recently, there have been no active direct competitors marketing an assay similar to that of BREVAGEN*plus* in the sporadic breast cancer risk assessment space. Effective August 31, 2017, Myriad Genetic Laboratories Inc. announced that it will market a new breast cancer risk-prediction tool, which according to our early understanding is a direct competitor for BREVAGEN*plus*. Similarly, effective March 14, 2018, Ambry Genetics Corporation launched a precision risk tool that provides lifetime breast cancer risk information and from information we have available is a direct competitor to BREVAGEN*plus*. Other organizations such as 23andMe and Color Genomics in the U.S. have also over the past few years developed SNP based risk tests that whilst not currently direct competitors to BREVAGEN*plus*, are attracting significant consumer interest.

In recent years, a number of other organizations, including deCODE (Iceland), 23andMe, Intergenetics, and Navigenics (subsequently acquired by Life Technologies – now ThermoFisher) have attempted to commercialize SNP-based genetic tests, to both physicians and consumers, to assess sporadic breast cancer risk in relevant patient populations. But either due to a lack of adequate and compelling scientific validation, and/or sufficient commercial impetus and capability, these efforts have led to lackluster market adoption, resulting in either the dissolution of these businesses or a marked change in their strategy and ultimate competitive posture to genuinely challenge the efforts of the Company to commercialize and grow its BREVAGEN*plus* franchise. New entrants that we are aware of that are in early stages of product development include Counsyl Inc. and Invitae Corporation in the U.S.

Nonetheless, there are a number of academic centers and affiliated research and development bodies, in the U.S and in Europe, that are reportedly exploring the validity and clinical viability of SNP-based commercial tests in the clinical setting, but it is unclear to what extent these entities currently represent a direct or indirect potential competitive liability to the Company. A number of established, mature laboratory services companies, such as Ambry Genetics, and Laboratory Corporation of America, among others, have the demonstrable product development, marketing skill and resources to enter into this market for sporadic breast cancer risk assessment. Many of these larger potential competitors have already established name and brand recognition and more extensive collaborative relationships, but again, it is unclear to what extent these potential competitive threats could manifest in the near-to-long term.

The Company continues to invest in proprietary, differentiating features of its BREVAGEN*plus* test offering to diminish any prospective efforts of a potential competitor, be they an established commercial laboratory provider, a research/academic test development or laboratory services entity. Therefore, any imminent bona fide risk that any one of these entities represents to the continued success and growth of the Company's BREVAGEN*plus* commercialization efforts and market-leading position in this area is not clear.

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The Company's competitive position in the genetic 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
- continue to strengthen and improve the messaging and the importance and value of the breast cancer information that BREVAGen<sup>plus</sup> provides to Physicians
- 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.

**Environmental Regulations**

The Company's operations are subject to environmental regulations under Australian State legislation. In particular, the Company is subject to the requirements of the *Environment Protection Act 1993*. A license has been obtained under this Act to produce listed waste.



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Fitzroy, Victoria

Genetic Technologies Limited rents the offices and laboratory premises which are located at 60-66 Hanover Street, Fitzroy, Victoria, Australia (an inner suburb of Melbourne) from Crude Pty. Ltd. The three year lease is due to expire on August 31, 2018. The anticipated total rental charge in respect of the year ending June 30, 2018 is approximately \$35,676. On July 3, 2018 the lease agreement for the Fitzroy premises in Melbourne was extended for 3 years from September 1, 2018 to August 31, 2021.

Charlotte, North Carolina

Phenogen Sciences Inc., a wholly-owned subsidiary of Genetic Technologies Limited, rents office premises which are located at 9115 Harris Corners Parkway, Suite 320, Charlotte, North Carolina, USA from New Boston Harris Corners LLC. This lease expired on October 31, 2017. It was then followed by a month to month lease. The anticipated total rental charge in respect of the year ending June 30, 2018, based on the month to month lease, is approximately USD 4,404. Phenogen Sciences Inc. entered into a 2 year lease agreement effective July 23, 2018 for premises situated at Suite 157, 1300 Baxter Street, Charlotte, North Carolina.

**Item 5. Operating and Financial Review and Prospects**

You should read the following discussion and analysis in conjunction with Item 3.A Selected Financial Data and our financial statements, the notes to the financial statements and other financial information appearing elsewhere in this Annual Report. In addition to historical information, the following discussion and other parts of this Annual Report contain forward-looking statements that reflect our plans, estimates, intentions, expectations and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. See the Risk Factors section of Item 3 and other forward-looking statements in this Annual Report for a discussion of some, but not all, factors that could cause or contribute to such differences.

**Item 5.A Operating Results**

**Overview**

Founded in 1989, Genetic Technologies is an established Australian-based molecular diagnostics company that offers predictive genetic testing and risk assessment tools, with a current focus on women's health. During the year ended June 30, 2015 the Company divested its interest in other genetic testing services, which up until then together with licensing of non-coding technology had provided the main source of income to fund operations, to concentrate on the principal activity of the provision of molecular risk assessment for cancer.

In August 2017 the Company initiated a comprehensive strategic review, whereby it appointed Roth Capital Partners LLC, a U.S. based investment firm, to explore a wide range of strategic alternatives including a business combination or strategic merger, reverse merger, sale of

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the Company or its assets, in-licensing assets, an acquisition, or other transaction designed to maximize near and long term value for the Company's shareholders. Following a significant change to the composition of the Board of Directors on January 31, 2018, which saw three new Directors elected, the Company elected not to pursue any of the potential strategic opportunities that were identified during the comprehensive review undertaken by Roth Capital Partners during the latter half of 2017, instead electing to focus on commercialising existing R&D capabilities, IP and BREVAGen*plus* to achieve better patient outcomes and exploring blockchain opportunities.

The operating result for the year ended June 30, 2018 is directly reflective of these activities.

Since inception up to June 30, 2018, we have incurred \$123,311,946 in accumulated losses. Our losses have resulted principally from costs incurred in research and development, general and administrative and sales and marketing costs associated with our operations. Refer to the Consolidated Statements of Operations in Item 18.

During the 2018 financial year, Genetic Technologies Limited and its subsidiaries generated consolidated gross revenues from continuing operations, excluding other income, of approximately \$0.2 million, a decrease from \$0.5 million in 2017 and \$ 0.8 million in 2016. As the Company continues to explore the optimal methodology to effectively market its product offering, the comparisons reflect;

- a. the impact of the substantial restructuring changes that took place during 2015,
- b. the slow growth rates being experienced in the market adoption of the BREVAGen*plus* breast cancer risk assessment test in the U.S.,
- c. the impact of the change to a patient self-pay billing model in 2017, and
- d. whilst undertaking a comprehensive review of strategic alternatives for the Company, the transition from a direct salesforce in the U.S. to an ecommerce CIT platform in September 2017

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**Fiscal year**

As an Australian company, our fiscal, or financial, year ends on June 30 each year. We produce audited consolidated accounts at the end of June each year and provide reviewed half-yearly accounts for the periods ending on December 31 each year, both of which are prepared in accordance with International Financial Reporting Standards ( IFRS ) as issued by the International Accounting Standards Board.

**Recent Accounting Pronouncements**

In respect of the year ended June 30, 2018, the Group has assessed all new accounting standards mandatory for adoption during the current year, noting no new standards which would have a material effect on the disclosure in these financial statements. There has been no effect on the profit and loss or the financial position of the Group. Certain new accounting standards and interpretations have been published that are not mandatory for June 30, 2018 reporting periods. The Group's and the parent entity's assessment of the impact of these new standards and interpretations is set out in Note 2(b) of the attached financial statements.

**Critical Accounting Policies**

The accounting policies which are applicable to the Group and the parent entity are set out in Notes 2(c) to 2(u) of the attached financial statements.

**Comparison of the year ended June 30, 2018 to the year ended June 30, 2017**

**Revenues from operations**

During 2018, the Group continued to focus on achieving market acceptance and physician adoption of the BREVAGen*plus*® breast cancer risk assessment test in the U.S. through its wholly owned U.S. subsidiary, Phenogen Sciences Inc.

During the 2018 financial year, Genetic Technologies Limited and its subsidiaries generated consolidated gross revenues from continuing operations, excluding other revenue, of \$189,254 compared to \$518,506 in the preceding year. The overall decline of \$329,252 is as a result of a \$197,734 reduction in previously accrued BREVAGen™ and BREVAGen*plus* revenues, driven by ongoing reduced test samples and collection rates, with the balance of \$131,518 of the differential directly attributable to a decrease in the overall combined sales of the BREVAGen™ and BREVAGen*plus*® tests. Samples received for BREVAGen™ and BREVAGen*plus*® tests during 2018 were 405 compared to 895 in the previous financial year.

Overheads decreased by \$1,603,539 compared with 2017. The combined areas of selling/ marketing, administration, licensing and operations (excluding net foreign currency losses) totaled \$6,449,923 for the year compared with \$8,053,462 for 2017. The overall decrease is reflective of the ongoing commitment to effectively manage overhead spending, and a transition from a direct salesforce to an ecommerce based solution in the U.S.

The loss for the 2017 year of \$8,403,826 (2018: \$5,463,872) includes a \$544,694 (2018: Nil) expense for the impairment of intangible assets.

#### **Cost of sales**

Our cost of sales from continuing operations decreased by 39% from \$492,417 to \$300,088. BREVAGenplus® direct materials utilized decreased by 45% from \$172,070 to \$ 93,869 as a result of the reduced number of samples received. Depreciation expense attributable to the laboratory testing equipment increased by \$ 5,286 whilst direct labour costs decreased by \$64,077 as a result of a continued streamlining of the laboratory team to match the reduced samples received. There was a decrease in inventories written off of \$44,765 in 2018, which included BREVAGenplus® materials that had expired during the year of \$ 24,506.

#### **Selling and marketing expenses**

Selling and marketing expenses decreased by \$1,655,070 (61%) to \$1,066,404 during the 2018 financial year. Personnel related costs decreased by \$822,151 (54%) as a direct result of the transition from a direct sales force in the U.S. to an ecommerce web enabled sales platform to sell BREVAGenplus. Fees paid billing and collection services decreased by \$208,974 to \$49,086 as the Company terminated its agreement with a service provider in 2017 and introduced a patient self-pay pricing model for its tests. Marketing and promotion costs decreased by \$242,058 (93%) as certain sponsorship agreements and other marketing activities were not pursued in light of the strategic review initiated by the Company in August 2017.



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**General and administrative expenses**

General and administrative expenses (excluding net foreign currency losses) increased by \$210,519 (7%) to \$3,144,178 during the financial year.

Personnel related costs increased by \$270,993 (18%) as a result of the payout to the previous CEO on his departure in February 2018, as well as 3 additional headcount engaged in February 2018 to oversee the blockchain opportunities being pursued by the Company. This was offset by a decrease in audit, accounting and tax fees of \$129,736 in line with streamlined commercial operations.

**Laboratory, research and development costs**

Laboratory, research and development costs decreased by \$155,836 (7%) to \$2,210,498 during the 2018 financial year. As a result of lower test samples received, there was a reduction in 1 part time position, and 1 full time positions resigned during the year, which when combined with reductions in headcount in the previous year, resulted in a decrease in employee related costs of \$216,041 (26%) to \$611,888. Patent & legal costs increased by \$95,320 (22%) to \$534,235 as the Company continued to strengthen its patent portfolio around the BREVA Genplus technology and Colorectal Cancer research project. Laboratory materials related to in-house research and development work performed on the BREVA Genplus, CRC & OSU projects increased by \$182,767 to \$220,809. This was offset by a decrease of \$100,000 (100%) in fees payable to the University Of Melbourne as part of the Colorectal Cancer research project.

**Finance costs**

Finance costs decreased by \$3,152 (10%) to \$ 28,843 during the 2018 year. Finance costs incurred in 2018 and 2017 were primarily bank charges.

**Non-Operating income and expenses**

Other income and expenses included the following movements:

- Research and development tax credit of \$299,351 in the current financial year increased by \$46,192. The research tax credit is recognized on an accrual basis when realizable. There was an increase in laboratory supplies used in research activities of \$ 182,767 as the Company refocused on the BREVA Genplus and CRC projects in the second half of the year, whilst license fees payable to the University of Melbourne for the CRC project decreased by \$100,000.

- Export Marketing And Development Grant of \$126,907 for eligible expenditure related to 2016 & 2017 was received during the year. The grant was not previously recognized by the Company as there was no reasonable assurance of receipt.
- A net foreign currency gain of \$128,360 (2017; loss of \$175,871) was recorded for the year. The profit is primarily driven by the translation of US dollar cash reserves to Australian dollars at June 30, 2018.
- An impairment expense of \$544,694 was recognized in the prior year ending June 30, 2017 (2018: \$ Nil) relating to the BREVA Gen intangible assets was recognized. The assets have were impaired in line with IAS 36, Impairment of assets and the Company's accounting policy, as disclosed in note 2 of the 2018 Annual Report

**Comparison of the year ended June 30, 2017 to the year ended June 30, 2016**

**Revenues from operations**

The Group's primary focus during 2017 was aimed at achieving market acceptance and physician adoption of the BREVA Gen *plus*® breast cancer risk assessment test in the U.S. through its wholly owned U.S. subsidiary, Phenogen Sciences Inc. This strategy resulted in the implementation of several modifications to the BREVA Gen *plus*® test as well as the transition from a traditional reimbursement system through insurance providers to a direct patient self-pay program in an effort to simplify the BREVA Gen *plus*® billing and collection policy. An enhanced medical affairs presence together with a refined marketing message, with a focus on health care provider education have been key elements in the drive to achieve this market acceptance and adoption.

During the 2017 financial year, Genetic Technologies Limited and its subsidiaries generated consolidated gross revenues from continuing operations, excluding other revenue, of \$518,506 compared to \$824,586 in the preceding year. The overall decline of \$306,080 is as a result of a \$191,661 reduction in previously accrued BREVA Gen<sup>TM</sup> and BREVA Gen *plus* revenues, driven by ongoing

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reduced test samples and collection rates, with the balance of \$114,419 of the differential directly attributable to a decrease in the overall combined sales of the BREVAGen™ and BREVAGenplus® tests. Samples received for BREVAGen™ and BREVAGenplus® tests during 2017 were 895 compared to 1,184 in the previous financial year.

Overheads decreased by \$852,040 compared with 2016. The combined areas of selling/ marketing, administration, licensing and operations (excluding net foreign currency losses) totaled \$8,053,462 for the year compared with \$8,905,502 for 2016. The overall decrease is reflective of the ongoing commitment to effectively manage overhead spending.

The loss for the year of \$8,403,826 includes a \$544,694 expense for the impairment of intangible assets. No significant items were reported during the previous financial year.

**Cost of sales**

Our cost of sales from continuing operations decreased by 34% from \$743,060 to \$492,417. There was a slight increase in BREVAGenplus® direct materials utilized of \$12,814 as a result of the operating inefficiencies of performing testing on a reduced number of samples received. Depreciation expense attributable to the laboratory testing equipment increased by \$ 10,890 whilst direct labor costs decreased by \$46,347 as a result of a streamlined laboratory team. There was a decrease in inventories written off of \$228,000 in 2017, which included BREVAGenplus® materials that had expired during the year of \$ 53,856.

**Other revenue**

Other revenue which in prior years included total revenues generated from our licensing and royalty and annuity activities decreased by \$300,548 (100%) to \$ Nil. This decrease is attributable to the expiry of a license agreement with Applera Corporation December 2015 as well as being reflective of the Company's restructuring activities initiated in 2015, whereby focus on the previous licensing and assertion program was minimized.

Although there was an overall change in focus during 2015 to grow sales revenues of BREVAGenplus® in the U.S, the Company will continue to use Sheridan Ross to assist with its licensing and intellectual property activities.

**Selling and marketing expenses**

Selling and marketing expenses decreased by \$465,023 (15%) to \$2,721,474 during the 2017 financial year. Personnel related costs decreased by \$201,799 (12%) as a direct result of ongoing natural attrition within the U.S. sales and marketing team. Fees paid for public relations services decreased by \$207,361 to \$Nil as the Company terminated its agreement with a service provider in 2016.

**General and administrative expenses**

General and administrative expenses (excluding net foreign currency losses) decreased by \$68,124 (2%) to \$2,933,659 during the financial year.

In line with streamlined commercial operations subsequent to the 2015 restructuring, fees for tax advice and compliance, accounting and other services decreased by \$55,259 (34%) to \$107,997. In the absence of any specific U.S. filing such as an f-3 shelf filing undertaken in the U.S. during 2016, Legal and other U.S. regulatory costs incurred under a streamlined operating structure decreased by 32% (\$58,006) to \$125,992

**Licensing, patent and legal costs**

No Licensing, patent and legal costs were incurred during 2017. The last of the personnel associated with the Licensing assertion program left the Company in July 2015 and consulting fees paid in relation to the program ceased in November 2014. Prior year costs have been combined with Laboratory, research and development costs for disclosure purposes in the Statement of Comprehensive Income/ (loss) for 2017.

**Laboratory, research and development costs**

Laboratory, research and development costs decreased by \$321,999 (12%) to \$2,366,334 during the 2017 financial year. As a result of lower test samples received, there was a reduction in 2 part time and 1 full time positions during the year, which resulted in a decrease in employee related costs of \$72,384 (8%) to \$827,929. Patent & legal costs decreased by \$59,724 (12%) to \$438,915, primarily (\$49,212 or 82% of the decrease) attributable to the restructuring activities of 2015, and the decision to no longer actively pursue the



Company's cash & cash equivalents. The Company's cash and cash equivalents were \$5,487,035 as of June 30, 2018.

During the year ended June 30, 2018, we incurred comprehensive losses of \$5,986,838. During the year ended June 30, 2017, we incurred comprehensive losses of \$8,534,481. During the year ended June 30, 2016, we incurred comprehensive losses of \$7,151,746.

During the year ended June 30, 2018, the Company's net cash flows used in continuing operations were \$5,621,315. During the year ended June 30, 2017, the Company's net cash flows used in continuing operations were \$6,813,639. During the year ended June 30, 2016, the Company's net cash flows used in continuing operations were \$7,726,838.

The Directors expect increased cash outflows from operations during the 2019 financial year as the Company continues to invest resources in expanding the research & development, particularly the enhancement of the BREVA*Genplus* test, development of the colorectal cancer risk assessment test and a suite of genetic screening tests targeting both cancer and non-oncological diseases, exploring distribution activities of BREVA*Genplus* in the U.S. and Asia as well as embracing blockchain opportunities in the medical and biotech space. As a result of these expected cash outflows, the Directors have 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 over a period of 20 months, expiring April 2020. In addition to this facility, the Directors will also consider other sources of equity funding through traditional offerings in either Australia or the U.S.

**Going Concern.** The longer-term 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 Company's ability to continue as a going concern and therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business. However, the Directors believe that the Company will be successful in the above matters and accordingly, have prepared the attached financial report on a going concern basis.

**Operating Activities.** Our net cash from / (used in) operating activities was \$ (5,621,315), \$(6,813,639) and \$(7,726,838) for the years ended June 30, 2018, 2017 and 2016, respectively. Cash from / (used in) operating activities for each period consisted

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primarily of losses incurred in operations reduced by impairment of intangible assets expenses, depreciation and amortization expenses, share based payments expenses, foreign exchange movements and unrealized profits and losses relating to investments. In approximate order of magnitude, cash outflows typically consist of staff-related costs, marketing expenses, service testing expenses, general and administrative expenses, legal/patent fees and research and development costs.

**Investing Activities.** Our net cash (used in) investing activities was \$(2,385), \$(182,149) and \$(296,331) for the years ended June 30, 2018, 2017 and 2016, respectively. During the year ended June 30, 2017, \$52,650 was received from the sale of unutilized laboratory equipment that was superfluous to the requirements of the Company's current operations following the 2015 divestment of the Heritage business. Apart from the purchase of plant and equipment of \$2,385 in 2018, \$234,799 in 2017 and \$303,462 in 2016, we had no other significant capital expenditures for the years ended June 30, 2018, 2017 and 2016.

**Financing Activities.** Our net cash from / (used in) financing activities was \$(9,963), \$7,110,049 and \$(1,654) for the years ended June 30, 2018, 2017 and 2016, respectively. During the year ended June 30, 2017, the Company generated cash flows of \$8,049,369 from the issue of 720,000,000 ordinary shares and \$295,110 from a facility fee rebate on previously issued shares less costs associated with the transactions of \$(1,234,430). No new financing activities were undertaken for the years ended June 30, 2018 and 2016,

**Future cash requirements**

The Directors have undertaken an assessment of the Company's ability to pay its debts as and when they fall due. As part of this assessment, the Directors have had regard to the Company's cash flow forecasts for the twelve month period from the date at which the Financial Report was authorized and lodged and the cash balance on hand as of that date. The Directors recognize that there is uncertainty in the consolidated entity's cash flow forecasts, and that 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 successful completion of planned equity raisings.

We do not have any lines of credit and nominal credit card facilities with National Australia Bank Limited ( NAB ) and Bank of America, N.A. which, as of June 30, 2018, had total available credit of \$171,739

**Operating leases**

We are obligated under two operating leases that were in place at June 30, 2018. These leases relate to the premises occupied by the Company in Fitzroy, Victoria, Australia and by its U.S. subsidiary, Phenogen Sciences Inc., in Charlotte, North Carolina, U.S.A.

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The future minimum lease payments in respect of the two operating leases that were in place and had remaining non-cancellable lease terms as of June 30, 2018 were \$41,625.

### Item 5.C **Research and Development, Patents and Licenses, etc.**

Our principal business is biotechnology, with a historical emphasis on genomics and genetics, the licensing of our non-coding patents, reduction to practice of our fetal cell patents and expansion of the related service testing business. Research and development expenditure as below is reflective of the changes implemented during 2015 following the sale of the Australian Heritage business in November 2014, and a focus the BREVA*Genplus*® breast cancer risk test. In November 2016, we commenced work on the colorectal cancer (CRC) risk assessment test project, and in June 2017 we commenced work on the Ohio State University research collaboration.

The following table details historic R&D expenditure by project.

	2018	2017	2016
	\$	\$	\$
RareCollect (1)	12,555	10,782	59,453
BREVA <i>Genplus</i>	266,723	216,121	282,460
Colorectal Cancer Risk Assessment Test	114,315	114,651	
Ohio State University	48,377		



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Other general R&D	18,544	77,044	53,625
Total R&D expense	460,514	418,598	395,538
Other expenditure	5,634,088	8,847,846	9,680,597
Total expenditure	6,094,602	9,266,444	10,076,136
R&D as a % of total expenditure	8%	5%	4%

(1) The RareCollect project ceased during 2014. The costs incurred since then relate to legal fees associated with the patent portfolio.

## Item 5.D Trend Information

### The direction of genetic research and breast cancer

During the 1990s, the two major susceptibility genes for breast cancer, *BRCA1* and *BRCA2*, were identified. Mutations in these genes account for approximately 30% of the familial risk for breast cancer. Following these discoveries, a large number of candidate gene studies were conducted over the following decade, aimed at identifying moderate and low-penetrance alleles believed to be responsible for the remaining familial risk.

In 2007, one of the very first large scale genome-wide association studies (GWAS) reported five significant loci associated with breast cancer risk. It was these loci which formed the basis of the Company's first generation BREVAGen breast cancer risk assessment test. Further GWAS continue to provide additional loci associated with breast cancer risk and these are incorporated into the Company's second generation BREVAGen*plus* test. The Company continues to monitor developments in the field.

Following the success of the initial GWAS for breast cancer and improvements in the technology required to conduct the studies, many international research groups are now investigating genetic associations with different types of cancer and other multifactorial diseases. These studies are likely to lead to new genetic tests for disease susceptibility, both in cancer and other diseases.

Our ability to produce such tests will depend on our ability to secure licensing agreements to the underlying technology or to take part in the basic research studies.

We believe that the demand for genetic risk assessment testing is in its infancy and will continue to grow in the coming years.

## Item 5E. Off-balance sheet arrangements

We are not a party to any material off-balance sheet arrangements. In addition, we have no unconsolidated special purpose financing or partnership entities that are likely to create any material contingent obligations.

**Item 5F. Information about contractual obligations**

The table below shows the contractual obligations and commercial commitments as of June 30, 2018:

	0-1 year	>1-<3 years	>3-<5 years	>5 years
Operating lease commitments	\$ 41,625	\$	\$	\$

The above financial obligations are in respect of leases over office and laboratory premises.

On July 3, 2018 the lease agreement for the Fitzroy premises in Melbourne was extended for 3 years from September 1, 2018 to August 31, 2021. In addition, Phenogen Sciences Inc. has vacated the Harris Corners Parkway office in Charlotte and entered into a 2 year lease agreement effective July 23, 2018 for premises at 1300 Baxter Street, Suite 157, Charlotte, North Carolina.

**Item 6. Directors, Senior Management and Employees**

**Item 6.A Directors and Senior Management**

The Directors of the Company as of the date of this Annual Report are:

**Dr Paul A. Kasian, PhD, MBA, GAICD** (*Chairman & Chief Executive Officer*)

Dr Kasian was appointed to the Board on December 12, 2013 and became Chairman of the Company on January 31, 2018 and interim, part time CEO on February 6, 2018. He brings to the Board a combination of expertise in strategic business leadership and biotech investment giving him a deep understanding on key value drivers for companies in generating shareholder value. He is an experienced

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executive director with demonstrated domestic and international success in funds management, encompassing senior leadership, investment and risk roles.

Dr Kasian has held senior leadership positions in a number of investment groups, and has significant funds management experience in Australia leading investment in the healthcare and life sciences sector. He holds a PhD in Microbiology and a Master of Business Administration, both from the University of Melbourne, and is a Graduate Member of the Australian Institute of Company Directors. Dr Kasian is also a non-executive director and the Chairman of IODM Limited (ASX: IOD), and former Non-Executive Director of ELK OrthoBiologics and Blockchain Global Limited.

**Dr Lindsay Wakefield, MBBS (*Non-Executive*)**

Dr Wakefield was appointed to the Board on September 24, 2014. He started Safetech in 1985 and over the next 25 years Safetech became a force in the Australian material handling and lifting equipment market, designing and manufacturing a wide range of industrial products. In 1993, he left Medicine to become the fulltime CEO of the Company. In 2006 Safetech was awarded the Telstra Australian National Business of the Year. In 2013 Safetech merged and ultimately acquired Tieman Materials Handling. Dr. Wakefield continues as the CEO of the Company. It is Australia's largest manufacturer and supplier of dock equipment, freight hoists and custom lifting solutions. Safetech employs approximately 100 people. Dr. Wakefield has been a Biotech investor for more than 20 years.

**Dr Jerzy (George) Muchnicki (*Executive*)**

Dr Muchnicki was appointed to the Board on January 31, 2018 and has also been appointed to the role of part time Business Development Director. George graduated from Monash University having held positions in private practice for some 25 years to head of student health at Melbourne University. For the past 14 years he has been mostly involved in commercialisation and funding R&D in the biotechnology sector from gene silencing to regenerative medicine.

Dr Muchnicki brings with him strong commercial and medical skills, including broad interests in software development, blockchain and sustainable building materials. He is a co-founder and Non-Executive Director of Speed Panel Holdings a world leader in fire rated and acoustic wall solutions. He is also the co-founder of Candlebets, a software development company that is creating blockchain enabled platforms for the gaming industry.

**Mr Peter Rubinstein (*Non-Executive*)**

Mr Peter Rubinstein was appointed to the Board on January 31, 2018. He has over 20 years' experience in early stage technology commercialisation through to public listings on the ASX. He is a lawyer, having worked at one of the large national firms prior to moving in house at Montech, the commercial arm of Monash University.

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Mr Rubinstein has had significant exposure to the creation, launch and management of a diverse range of technology companies including in biotech, digital payments and renewable energy. Peter is also Chairman of DigitalX Limited (DCC) and an advisor to Blockchain Global Limited.

### **Mr Xue (Sam) Lee** *(Non-Executive)*

Mr Sam Lee was appointed to the Board on January 31, 2018. He is the founder and CEO of Blockchain Global Limited, which offers one of Australia's largest cryptocurrency exchanges, blockchain consulting and blockchain incubation services, assisting with over \$200m in blockchain related investments with offices in Melbourne, New York, Kobe, Shanghai and Dalian.

Mr Lee is a frequent speaker at Blockchain Summits, DLT Conferences and has been a panellist at the World Economic Forum. Mr Lee is also a Director of ASX listed DigitalX Limited (DCC), a leading blockchain advisory company.

### **Directors who held office during the year**

Names of directors who vacated their roles during the year are as follows;

### **Dr Malcolm R. Brandon**, BScAgr, PhD *(Non-Executive) Resigned January 30, 2018*

Dr Brandon was appointed to the Board on October 5, 2009 and as its Chairman on November 28, 2012.

### **Mr Eutillio Buccilli** *(Executive) Stepped Down as CEO and Director on February 6, 2018*

Mr Buccilli was appointed to the Board in June 2015. He joined the Company in June 2014 as Chief Financial Officer. In November 2014, he was appointed to the position of Chief Operating Officer and Chief Financial Officer and was subsequently appointed Chief Executive Officer in February 2015.

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**Mr Grahame Leonard AM, BA (Hons), LLB, CA, CPA, FAICD (Dip), AFAIM (Non-Executive) Resigned January 30, 2018**

Mr Leonard was appointed to the Board on November 29, 2013 and also served as Chairman of the Company's Audit Committee.

**Senior Management**

We have a professional team of qualified and experienced personnel, including a number of research and development scientists and technicians. The Group currently has 15 full-time-equivalent employees in addition to the 2 part time executive Directors and three Non-executive Directors listed above. Of the total number of personnel, three have Doctorate qualifications. In addition to the interim part time Chief Executive Officer and Business Development Director, Dr Kasian and Dr Muchnicki respectively whose details are noted above, the members of the Company's Senior Leadership Team as of the date of this Report, and a brief summary of their relevant experience, are as follows:

**Kevin Fischer, FCPA, FGIA, FCIS, B. Com. (Chief Financial Officer)**

Mr. Fischer was appointed Company Secretary on January 13, 2016 following his appointment as Chief Financial Officer on November 2, 2015. He has over ten years' experience in senior finance roles with successful diagnostic companies, such as QIAGEN and Cellectis. Mr. Fischer is a Fellow CPA and Chartered Secretary who has significant experience in the financial management and reporting for international operations.

**Dr. Richard Allman, PhD (Scientific Director)**

Dr. Allman joined the Company in 2004 and was appointed as Scientific Director in December 2012. He has over 20 years of scientific and research experience in both the academic arena in the UK and the commercial sector in Australia. He has wide experience in research leadership, innovation management, and intellectual property strategy, covering oncology, diagnostics, and product development. Prior to entering the biotech sector, Dr. Allman's academic career encompassed oncology research, drug development, and assay design.

**Item 6.B Compensation**

Details of the nature and amount of each major element of the compensation of each director of the Company and each of the named officers of the Company and its subsidiaries, for services in all capacities during the financial year ended June 30, 2018 and 2017 are listed below. All figures are stated in Australian dollars (AUD).

Name and title of Non-Executive Directors	Year	Short-term		Post-employment Superannuation*	Other long- term benefits	Share-based Options	Totals
		Salary/fees \$	Other \$				
Dr Lindsay Wakefield	2018	57,186		5,433			62,619
	2017	56,065		5,326			61,391
Mr Xue Lee (2)	2018	23,827		2,264			26,091
	2017						
Grahame Leonard AM (4)	2018	33,358		3,169			36,527
	2017	56,065		5,326			61,391

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(1) Mr Rubinstein was appointed as a Non-executive Director on January 31, 2018.

(2) Mr Lee was appointed as a Non-executive Director on January 31, 2018.

(3) Dr Brandon resigned as the Non-executive Chairman on January 30, 2018.

(4) Mr Leonard resigned as a Director on January 30, 2018.

Table of Contents**Key Management Personnel**

Name and title of Executives Directors	Year	Short-term		Post-employment Superannuation*	Other long-term benefits**	Share-based Options ***	Termination benefits	Totals
		Salary/fees \$	Other \$					
Dr Paul Kasian (1) Chairman & Interim CEO	2018	89,099		8,464	44			97,607
	2017	56,065		5,326				61,391
Eutillio Buccilli (3) Ex - Executive Director & Chief Executive Officer	2018	186,621		25,000	802	45,639	164,760	422,822
	2017	313,650	33,000	32,566	19,297	45,639		444,152
<b>Executives</b>								
Diana Newport (4) Quality & Ops. Director	2018	73,469		6,980	(10,137)	18,257		88,569
	2017	105,493		10,022	10,962	10,533		137,010
Kevin Fischer (6) Chief Financial Officer	2018	171,666	51,500	17,505	3,187	28,450		272,308
	2017	168,300	12,600	17,575	9,421	22,330		230,226
Dr Susan Gross (8) US-Senior Medical Director	2018	41,545			1,867	(3,150)		40,262
	2017	165,262	7,481		1,978	3,150		177,871
Total remuneration of Key Management Personnel	2018	1,114,544	101,088	96,315	2,371	130,385	164,760	1,609,463
	2017	1,457,444	76,013	101,320	61,594	121,269		1,817,640

Notes pertaining to changes during the year:

(1) Dr Kasian was appointed as the Chairman on January 31, 2018 and interim CEO on February 6, 2018, having previously served as a Non-Executive Director since his appointment in December 2013. Included in the 2018 total remuneration is an amount of \$18,689 attributable to his executive role as interim CEO (2017: Nil). The 2017 fees are all Non-Executive Director fees.

(2) Dr Muchnicki was appointed as Business Development Director on January 31, 2018. Included in the 2018 total remuneration is an amount of \$16,774 attributable to his executive role as Business Development Director

(3) Mr Buccilli stepped down from his position of Executive Director and Chief Executive officer on February 6, 2018. Included in the termination benefits paid to Mr Buccilli are ; 3 months notice pay; pro-rata bonus entitlement calculated up to that date being 3 months from

February 6, 2018.

(4) Ms Newport held the role of Quality & Operations Director until her resignation on May 1, 2018.

(5) Other includes a bonus paid or payable to Dr Allman in the amount of \$49,588 under a retention bonus scheme awarded to KMP.

(6) Other includes a bonus paid or payable to Mr Fischer in the amount of \$51,500 under a retention bonus scheme awarded to KMP.



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(7) Mr Saunders held the role of Vice President Sales & Marketing for Phenogen Sciences Inc. (USA) until his termination on November 30, 2017

(8) Dr Gross held the role of Senior Medical Director for Phenogen Sciences Inc. (USA) until her termination on September 15, 2017.

Referencing the previous two tables:

\* Post-employment benefits as per Corporations Regulation 2M.3.03 (1) Item 7

\*\* Other long-term benefits as per Corporations Regulation 2M.3.03 (1) Item 8

\*\*\* Equity settled share-based payments as per Corporations Regulation 2M.3.03 (1) Item 11

The details of those Executives nominated as Key Management Personnel under section 300A of the *Corporations Act 2001* have been disclosed in this Report. No other employees of the Company meet the definition of Key Management Personnel as defined in *IAS 24 / (AASB 124) Related Party Disclosures*, or senior manager as defined in the *Corporations Act*

Executive officers are those officers who were involved during the year in the strategic direction, general management or control of the business at a company or operating division level. The remuneration paid to Executives is set with reference to prevailing market levels and comprises a fixed salary, various short term incentives (which are linked to agreed key performance indicators), and an option component. Options are granted to Executives in line with their respective levels of experience and responsibility.

**Options exercised, granted, and forfeited as part of remuneration during the year ended June 30, 2018**

Details of the options held by the Executives nominated as Key Management Personnel during the year ended June 30, 2018 are set out below. As at June 30, 2018, there were 3 executives and 1 employee who held options that had been granted under the Company's respective option plans.

During the 2018 financial year no options granted as equity compensation benefits to Executives were exercised, and no new options were granted as equity compensation benefits to Executives. The following options previously granted as equity compensation benefits to Executives were forfeited during the year;

Name of Executive	Options Forfeited	Exercise price	Fair value per option	Final vesting date
Diana Newport	4,000,000	\$ 0.01	\$ 0.0050	Feb 16, 2022
Diana Newport	2,500,000	\$ 0.02	\$ 0.0026	Mar 31, 2021
Chris Saunders	5,000,000	\$ 0.01	\$ 0.0050	Feb 16, 2022
Chris Saunders	5,000,000	\$ 0.02	\$ 0.0024	Nov 24, 2020
Dr. Susan Gross	2,500,000	\$ 0.01	\$ 0.0050	Feb 16, 2022
Totals	19,000,000			

**Options exercised, granted and forfeited as part of remuneration during the year ended June 30, 2017**

During the 2017 financial year 21,500,000 options were granted as equity compensation benefits to Executives. No options were exercised or forfeited.

**Fair values of options**

Fair values at grant date are independently determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option.

Table of Contents**Option holdings of Key Management Personnel June 30, 2018**

Name of option holder	Opening balance	Granted	Number of options Exercised	Lapsed	Closing balance	Vesting as at year end Exercisable	Not exercisable	Financial year in which options vest	Fair Value yet to vest \$
<b>Executive</b>									
Paul Kasian									
Jerzy Muchnicki*	6,666,667				6,666,667	6,666,667		2015	
Eutillio Buccilli	14,236,111				14,236,111	14,236,111		2018	
Diana Newport	6,500,000			(6,500,000)					
Richard Allman	10,000,000				10,000,000	6,666,667	3,333,333	2019	16,667
Kevin Fischer	10,000,000				10,000,000	6,666,667	3,333,333	2019	16,667
Chris Saunders	10,000,000			(10,000,000)					
Susan Gross	2,500,000			(2,500,000)					
Totals	59,902,778			(19,000,000)	40,902,778	34,236,112	6,666,666		33,334

\* Options held by Dr Muchnicki when appointed as a Director on January 31, 2018

**Option holdings of Key Management Personnel June 30, 2017**

Name of option holder	Opening balance	Granted	Number of options Exercised	Lapsed	Closing balance	Vesting as at year end Exercisable	Not exercisable	Financial year in which options vest	Fair Value yet to vest \$
<b>Executive</b>									
Eutillio Buccilli	14,236,111				14,236,111	7,118,055	7,118,056	2018	90,777
Diana Newport	2,500,000	4,000,000			6,500,000	1,250,000	5,250,000	2019	30,719
Richard Allman	5,000,000	5,000,000			10,000,000	2,500,000	7,500,000	2019	46,438
Kevin Fischer	5,000,000	5,000,000			10,000,000	2,500,000	7,500,000	2019	56,883
Chris Saunders	5,000,000	5,000,000			10,000,000	2,500,000	7,500,000	2019	56,883
Susan Gross		2,500,000			2,500,000		2,500,000	2019	20,000
Totals	31,736,111	21,500,000			53,236,111	15,868,055	37,368,056		301,700

\* Options vest and are exercisable at any time after the date on which they meet the vesting conditions as described above

**Options**

We introduced a Staff Share Plan on November 30, 2001. On November 19, 2008, the shareholders of the Company approved the introduction of a new Employee Option Plan. Collectively, these Plans establish the eligibility of our employees and those of any subsidiaries, and of consultants and independent contractors to a participating company who are declared by the Board to be eligible, to participate. Broadly speaking, the respective Plans permits us, at the discretion of the Board, to issue traditional options (with an exercise price). The Plans conform to the IFSA Executive Share and Option Scheme Guidelines and, where participation is to be made available to staff who reside outside

Australia, there may have to be modifications to the terms of grant to meet or better comply with local laws or practice.

As of June 30, 2018, there were 3 executives and 1 employee who held options that had been granted under the Company's respective option plans. Options issued under the Plan carry no rights to dividends and no voting rights.

Options issued under the Plans during the following financial years are as follows:

Year ended June 30, 2016:

During the year ended June 30, 2016, a total of 33,736,111 options over the Company's ordinary shares were issued to certain employees of the Group as follows:

*Key Management Personnel (KMP)- see above for more details;* During the year there were two issues of options to KMP the first being 24,236,111 options that were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.02 each up to, and including, November 24, 2020. The second issue was of 7,500,000 options that were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.02 each up to, and including, March 31, 2021. All options granted to KMP during 2016 are exercisable at any time after

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the date on which the Option meets its vesting conditions, namely the 3 month volume weighted average price (VWAP) of shares as traded on the ASX as follows (subject to any adjustments in the vesting conditions as contained in the option terms) - further details as described in the preceding section.

**Other employees of Phenogen Sciences Inc.:** During the year there were two issues of options to other employees of the Group the first being 1,500,000 options that were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.058 each up to, and including, September 14, 2020. The second issue was of 500,000 options that were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.039 each up to, and including, January 31, 2021. All options granted to these employees during 2016 are exercisable in three equal tranches after 12 months, 24 months and 36 months from the date of grant, respectively.

During the 2016 financial year, no options were exercised and 4,125,000 options that had previously been issued to employees were forfeited. Option holders do not have any right, by virtue of their options, to participate in any share issue of the Company or any related body corporate.

Year ended June 30, 2017:

During the year ended June 30, 2017, a total of 22,750,000 options over the Company's ordinary shares were issued to certain employees of the Group as follows:

**Key Management Personnel (KMP) - see above for more details;** 21,500,000 options were issued to KMP in February 2017. The options were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.01 each up to, and including February 16, 2022. The options vest based on non-market performance conditions (requirement to remain employed by the Company) in three tranches commencing on the date of the 2017 Annual General Meeting (AGM) of the Company and then at each of the 12 and 24 month anniversaries thereafter. The fair value of each option granted is estimated by an external valuer using a Black-Scholes option-pricing model further details as described in the preceding section

**Other employees of Phenogen Sciences Inc.:** During the year 1,250,000 options were issued to a number of employees of the Company's US Subsidiary, Phenogen Sciences Inc. The options were issued at no charge, and entitle the holder to acquire one ordinary share in the Company at an exercise price of \$0.01 each up to, and including February 16, 2022. The options vest based on non-market performance conditions (requirement to remain employed by the Company) in three equal tranches commencing on the date of the 2017 Annual General Meeting (AGM) of the Company and then at each of the 12 and 24 month anniversaries thereafter. The fair value of each option granted is estimated by an external valuer using a Black-Scholes option-pricing model.

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During the 2017 financial year, no options were exercised and 1,500,000 options that had previously been issued to employees were forfeited. Option holders do not have any right, by virtue of their options, to participate in any share issue of the Company or any related body corporate.

### Year ended June 30, 2018:

During the 2018 financial year, no options over ordinary shares pursuant to the Employee Option Plan were granted or exercised and 20,000,000 options that had previously been issued to employees were forfeited. Option holders do not have any right, by virtue of their options, to participate in any share issue of the Company or any related body corporate.

As of the date of this Annual Report, there was a total of 34,736,111 unlisted employee options outstanding.

Options granted under the Employee Option Plan carry no rights to dividends and no voting rights and generally have an expiry date of nearly five years from the date of grant.

During the years ended June 30, 2018, 2017 and 2016, the Company recorded a share-based payments expense in respect of the options granted of \$129,635, \$ 120,287 and \$50,239.

This share based payment expense is included within selling and marketing costs, general and administrative costs, licensing, patent and legal costs, and laboratory research and development costs in the statement of comprehensive income/ (loss). The following is additional information relating to the options granted under the respective Plans as of June 30, 2018:

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Range of exercise prices	Number of options	Options outstanding		Remaining weighted average contractual life (years)	Options exercisable	
		Weighted average exercise price	Weighted average exercise price		Number of options	Weighted average exercise price
\$0.01 - \$0.10	34,736,111	\$	0.017	2.83	27,736,111	\$ 0.019
\$0.11 - \$0.20		\$				\$
	34,736,111	\$	0.017	2.83	27,736,111	\$ 0.019

The following is additional information relating to the options granted under the respective Plans as of June 30, 2017:

Range of exercise prices	Number of options	Options outstanding		Remaining weighted average contractual life (years)	Options exercisable	
		Weighted average exercise price	Weighted average exercise price		Number of options	Weighted average exercise price
\$0.01 - \$0.10	54,736,111	\$	0.016	3.96	15,868,056	\$ 0.020
\$0.11 - \$0.20		\$				\$
	54,736,111	\$	0.016	3.96	15,868,056	\$ 0.020

The following is additional information relating to the options granted under the respective Plans as of June 30, 2016:

Range of exercise prices	Number of options	Options outstanding		Remaining weighted average contractual life (years)	Options exercisable	
		Weighted average exercise price	Weighted average exercise price		Number of options	Weighted average exercise price
\$0.01 - \$0.10	33,486,111	\$	0.022	4.47	83,333	\$ 0.040
\$0.11 - \$0.20		\$				\$
	33,486,111	\$	0.022	4.47	83,333	\$ 0.040

The fair value for the options issued to employees was estimated at the date of grant using either a Monte Carlo simulation analysis or Black-Scholes option pricing valuation model;

**Key Management Personnel (KMP)** with the following range of assumptions for June 30:

	2018	2017	2016
Risk Free Interest Rate		2.19%	1.93% to 2.22%
Expected Dividend Yield			
Historic and Expected Volatility		60%	80%
Option Exercise Prices		\$0.010	\$0.020
Weighted Average Exercise Price		\$0.010	\$0.020
Expected Lives		4.50 years	4.50 years
Valuation Model		Black-Scholes	Monte Carlo

**Other employees of Phenogen Sciences Inc.:** with the following range of assumptions for June 30:

	<b>2018</b>	<b>2017</b>	<b>2016</b>
Risk Free Interest Rate		2.19%	1.93% to 2.22%
Expected Dividend Yield			
Historic and Expected Volatility		60%	80%
Option Exercise Prices		\$0.010	\$0.039 to \$0.058
Weighted Average Exercise Price		\$0.010	\$0.053
Expected Lives		4.50 years	4.40 years
Valuation Model		Black-Scholes	Black-Scholes



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**Indemnification and Insurance with respect to Directors**

We are obligated pursuant to an indemnity agreement, to indemnify the current Directors and executive officers and former Directors against all liabilities to third parties that may arise from their position as Directors or officers of the Company and our controlled entities, except where to do so would be prohibited by law. In addition, we currently carry insurance in respect of Directors and officers liabilities for current and former Directors, Company Secretary and executive officers or employees.

**Item 6.C Board Practices**

**The Board of Directors**

Under our Constitution, our Board of Directors is required to comprise at least three Directors. As of the date of this Annual Report, our Board comprised five Directors.

The role of the Board includes:

- (a) Reviewing and making recommendations in remuneration packages and policies applicable to directors, senior executives and consultants.
- (b) Nomination of external auditors and reviewing the adequacy of external audit arrangements.
- (c) Establishing the overall internal control framework over financial reporting, quality and integrity of personnel and investment appraisal. In establishing an appropriate framework, the board recognized that no cost effective internal control systems will preclude all errors and irregularities.
- (d) Establishing and maintaining appropriate ethical standards in dealings with business associates, suppliers, advisers and regulators, competitors, the community and other employees.
- (e) Identifying areas of significant business risk and implementing corrective action as soon as practicable after a risk is identified.

## (f) Nominating of audit and remuneration committee members.

The Board meets to discuss business regularly throughout the year, with additional meetings being held when circumstances warrant. Included in the table below are details of the meetings of the Board and the sub-committees of the Board that were held during the 2018 financial year.

	Directors meetings		Audit Committee meetings		Remuneration Committee meetings	
	Attended	Eligible	Attended	Eligible	Attended	Eligible
Dr Malcolm Brandon	9	9				
Mr. Eutillio Buccilli	9	9			2	2
Mr. Grahame Leonard A.M.	8	9	2	3		
Dr Paul Kasian	15	15	3	3	3	3
Dr Lindsay Wakefield	15	15	5	5	3	3
Dr. Jerzy Muchnicki	6	6	2	2		
Mr. Peter Rubinstein	6	6	2	2	1	1
Mr Xue Lee	3	6				



Majority of Independent Directors: We follow home country practice rather than NASDAQ's requirement in Marketplace Rule 4350(c) (1) that the majority of the Board of each issuer be comprised of independent directors as defined in Marketplace Rule 4200. As of the date of this Annual Report, our Board of Directors does not comprise of a majority of independent directors. The Company intends to review its composition in the future as operations expand; however, the Company believes that the current Board structure is best suited to enable the Company to deliver shareholder value.

Compensation of Officers: We follow home country practice rather than NASDAQ's requirement in Marketplace Rule 4350(c)(3) that chief executive compensation be determined or recommended to the Board by the majority of independent directors or a compensation committee of independent directors. Similarly, compensation of other officers is not determined or recommended to the Board by a majority of the independent directors or a compensation committee comprised solely of independent directors. These decisions are made by our remuneration committee which at June 30, 2018 is not comprised of a majority of independent directors. The members are however considered by the Board to currently be the best fit for the committee taking into account the current Board composition. As the operations of the Company develop, the Board will reassess the composition of the Remuneration Committee.

Nomination: We follow home country practice rather than NASDAQ's requirement in Marketplace Rule 4350(c)(4) that director nominees be selected or recommended by a majority of the independent directors or by a nominations committee comprised of independent directors. These decisions are made by our full Board which is comprised of a majority of independent directors. The ASX does not have a requirement that each listed issuer have a nominations committee or otherwise follow the procedures embodied in NASDAQ's Marketplace Rule. Furthermore, no law, rule or regulation of the ASIC has such a requirement nor does the applicable

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corporate law legislation. Accordingly, selections or recommendations of director nominees by a committee that is not comprised of a majority of directors that are not independent is not prohibited by the laws of Australia.

Quorum: We follow home country practice rather than NASDAQ's requirement in Marketplace Rule 4350(f) that each issuer provide for a quorum of at least 33 1/3 percent of the outstanding shares of the issuer's ordinary stock (voting stock). Pursuant to our Constitution we are currently required to have a quorum for a general meeting of three persons. The practice followed by us is not prohibited by Australian law.

Shareholder Approval for Capital Issuance: We have elected to follow certain home country practices in lieu of NASDAQ Marketplace Rule 5635. For example, the Company is entitled to an annual 15% of capital placement capacity under ASX Listing Rule 7.1 without shareholder approval. If this amount of annual entitlement is aggregated with an additional placement of ordinary shares, including through the grant of options over ordinary shares, that exceeds 20% of the outstanding share capital, only the excess over the 15% annual allowance requires shareholder approval under Australian law. Such home country practice is not prohibited by the laws of Australia.

**Item 6.D Employees**

As of the date of this Annual Report, the Group comprising the Company and its subsidiaries, employed 16 full-time equivalent employees. The number of full-time equivalent employees as of the end of each respective financial year ended June 30 are as follows:

2018	15
2017	20
2016	25

**Item 6.E Share Ownership**

The relevant interest of the directors in the share capital of the Company as notified by them to the Australian Securities Exchange in accordance with section 205G(1) of the *Corporations Act 2001* as of the date of this Annual Report is as follows:

Director	Ordinary shares	Percentage of Capital held
Dr. Paul Kasian	256,410	0.010%
Dr. Lindsay Wakefield	7,754,763	0.305%
Dr. Jerzy Muchnicki	20,903,244	0.822%
Mr. Peter Rubinstein	47,282,700	1.859%

Notes: Dr Wakefield also has a direct interest in 570,500 shares, and Mr Lee has a direct interest in 59,594,850 ordinary shares (represented by 397,299 American Depositary Receipts). Apart from the above, no Director holds any interest in the shares and options of the Company as at the date of this Report.

**Item 7. Major Shareholders and Related Party Transactions**

**Item 7.A Major Shareholders**

As at the date of this Annual Report, there are no shareholders who are the beneficial owner of 5% or more of our voting securities;

The number of Ordinary Shares on issue in Genetic Technologies as of the date of this Annual Report was 2,544,115,824. The number of holders of Ordinary Shares in Genetic Technologies as of the date of this Annual Report was approximately 4,472.

The Company is not aware of any direct or indirect ownership or control of it by another corporation(s), by any foreign government or by any other natural or legal person(s) severally or jointly. Principal shareholders do not enjoy any special or different voting rights from those to which other holders of Ordinary Shares are entitled. The Company does not know of any arrangements, the operation of which may at a subsequent date result in a change in control of the Company.

**Item 7.B Related Party Transactions**

During the year ended June 30, 2018, the only transactions between entities within the Group and other related parties occurred, are as listed below. Except where noted, all amounts were charged on similar to market terms and at commercial rates.

*Debt convertible notes*

During the year ended June 30, 2015 the Company finalized the raising of \$2,150,000 via the issue of unlisted secured (debt) notes to existing and new Australian institutional and wholesale investors. The debt notes carried a 10.0% coupon rate, and as approved at the

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Annual General Meeting, held on 25 November 2014, became convertible notes which could convert into ordinary shares (at a 10.0% discount to the 5 day VWAP). These convertible notes also carry free attached options to purchase further shares in the Company.

\$125,000 of these convertible notes were issued to a holder associated with Dr Lindsay Wakefield, a Company director at the time of issue, on the same terms and conditions as other note holders, all of which were converted during the year ended June 30, 2015. The 8,333,333 share options attached to these convertible notes remain unexercised at June 30, 2018. Dr Muchnicki and Mr Rubinstein, both of whom were elected as Directors of the Company on January 31, 2018, also participated in the debt convertible notes raising, and at June 30, 2018 indirectly held 6,666,667 and 5,000,000 options respectively.

*Blockchain Global Limited*

As announced by the Company on February 15, 2018, a non-binding terms sheet with Blockchain Global Limited (**BCG**) was entered to provide a framework for continuing discussions between the two companies, with the proposed transaction being subject to shareholder approval (by non-associated Shareholders); and as announced by the Company on August 2, 2018, a framework agreement with BCG was entered formalizing the non-binding terms sheet and providing a framework for a strategic alliance between the Company and BCG, with this Framework Agreement only becoming binding on the Company obtaining the approval of non-associated Shareholders. This framework includes a proposed issuance of 486,000,000 shares to BCG in 3 tranches subject to the achievement of certain milestones.

A number of Directors of the Company presently or previously have had involvement with BCG. Mr Sam Lee has a direct and indirect share interest in BCG of 21% and is a director of BCG. Mr Peter Rubinstein has a direct and indirect share interest in BCG of 8% and is a consultant to BCG. Dr George Muchnicki has a direct and indirect share interest in BCG of 3.4%. Dr Paul Kasian was previously a director of BCG until July 2018. No transactions between the Company and BCG took place during the year ended June 30, 2018.

There were no transactions with parties related to Key Management Personnel during the year other than that disclosed above.

**Item 7.C Interests of Experts and Counsel**

Not applicable.

**Item 8. Financial Information**

**Item 8.A Consolidated Statements and Other Financial Information**

The information included in Item 18 of this Annual Report is referred to and referenced into this Item 8.A.

### **Litigation and other legal proceedings**

#### *Australian Federal Court Patent Proceeding*

In June 2010, a group of Australian plaintiffs initiated litigation in the Australian Federal Court challenging the validity of certain claims of an Australian patent owned by Myriad Genetics Inc. (Australian patent 686004 - 004 ). Genetic Technologies was named as a respondent to this matter by virtue of the fact that Genetic Technologies was the exclusive licensee of the BRCA patents in Australia (which includes the 004 patent).

This matter bears a striking resemblance to the US litigation filed by the American Civil Liberties Union against Myriad's US patent equivalent in which a US Federal District Court ruled that isolated DNA sequences are not eligible for patent protection because of the fact that they are products of nature . On July 29, 2011, Myriad successfully appealed this decision with the Federal Circuit Court of Appeals reversing the decision of the United States District Court for the Southern District of New York. On March 26, 2012 the U.S. Supreme Court remanded the case back to the US Court of Appeals for the Federal Circuit for reconsideration. On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit ruled on the Myriad in the U.S., upholding the patentability of gene patents. On June 13, 2013, the U.S. Supreme Court allowed an appeal, and found that claims for isolated genomic DNA were invalid.

On September 30, 2011, Genetic Technologies filed documents with the Australian Federal Court to the effect that the Company submits to the orders of the Court and takes no further part in the proceedings. On February 15, 2013, the Australian Federal Court ruled in favor of Myriad Genetics in this matter.

Myriad Genetics argued that by virtue of the process of extracting the gene from the body, it had satisfied the requirements of an invention according to section 18(1) (a) of the Patents Act which states that an invention must be a manner of manufacture . Based on previous case law, the Court held that a manner of manufacture requires an artificial state of affairs of some discernible effect that is of economic significance.



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That decision was subsequently appealed by one of the plaintiffs on March 4, 2013. The Full Federal Court again ruled in favour of Myriad Genetics on September 5, 2014. The decision by the court leaves intact its earlier ruling that isolated gene sequences, even if they contain the same information as DNA sequences in the body, become a manufactured object as a result of the isolation process, conferring on them an artificial state, and making them patentable.

On September 16, 2014, the plaintiff sought special leave to appeal from the Full Federal Court's decision to the High Court of Australia, which was granted on February 13, 2015. The plaintiff filed a formal appeal to the High Court shortly thereafter, on February 27, 2015. Genetic Technologies did not contest the special leave application or the appeal to the High Court.

On October 7, 2015 the High Court found claims 1 to 3 (directed to isolated gene sequences) of the '004 patent invalid. The High Court held that whether or not an invention is an artificial state of affairs is not the only factor relevant to whether a patent defines a manner of manufacture. The High Court took into account a number of other policy considerations, including:

- a. whether patentability of the invention is consistent with the overarching purposes of the Patents Act (i.e., stimulating, rather than chilling, innovation);
- b. whether patentability of the invention would enhance or detract from the coherence of the law relating to inherent patentability;
- c. whether patentability of the invention is consistent with Australia's international obligations and the patent laws of other countries; and
- d. whether patentability of the class of invention as claimed would involve law-making of a kind that should be done by the legislature;

before concluding that claims 1 to 3 of the '004 patent did not define a manner of manufacture.

The challenge by the plaintiffs did not affect the validity of the remaining claims (4-30) of the '004 Patent. While the '004 patent reached the end of its 20 year term and therefore expired on August 11, 2015, similar claims in other, subsisting patents (including those directed to probes and methods for diagnostic testing relating to specific genes) remain enforceable, affording a monopoly over many uses of gene sequences.

**Dividends**

Until our businesses are profitable beyond our expected research and development needs, our Directors are unlikely to be able to recommend that any dividend be paid to our shareholders. Our Directors will not resolve a formal dividend policy until we generate profits. Our current intention is to reinvest our income in the continued development and expansion of our businesses.

**Item 8.B Significant Changes to Financial Information**

Our consolidated financial statements are set out on pages F1 to F39 of this Annual Report (refer to Item 18).

**Significant other changes**

- A reduced physical headcount in the US as the Company transitioned the BREVAGenplus® commercial programme from a direct salesforce to an ecommerce based solution. Under the new program, it is planned that the consumer will be able to initiate the testing by accessing the Consumer Initiated Testing (CIT) platform via the Company's U.S. subsidiary, Phenogen Sciences, Inc. website.
- On February 2, 2018, the Company entered into a non-binding terms sheet with Blockchain Global Limited (BCG), which outlined a proposed strategic alliance between the parties with respect to the provision of a suite of blockchain opportunities to the Company to leverage off its existing genetics testing platform, existing CLIA approved laboratory and long history in genomics, along with BCG's extensive blockchain experience, with the proposed issue of 486,000,000 shares to BCG in 3 tranches subject to the achievement of certain milestones. Although subject to final shareholder approval, the strategic alliance has subsequently been formalized through a Framework Agreement, executed between the parties on August 2, 2018.

*Changes to the Board of Directors*

The following changes to the Board of Directors took place during the year ended June 30, 2018;

- Dr Malcolm R Brandon resigned January 30, 2018
- Mr Grahame Leonard resigned January 30, 2018
- Mr Peter Rubinstein appointed January 31, 2018
- Dr George Muchnicki appointed January 31, 2018
- Mr Sam Lee appointed January 31, 2018

- Mr Eutillio Buccilli resigned February 6, 2018

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**Significant events after balance date**

The following significant events have occurred after balance date;

- The Company has renewed the lease agreement for its Fitzroy premises in Melbourne for a further period of 3 years from September 1, 2018 to August 31, 2021. The Company has also entered into a 2 year lease for new premises in Charlotte, North Carolina, commencing July 23, 2018 to July 31, 2020.
- A Framework Agreement with Blockchain Global Limited ( **BCG** ) was entered into on August 2, 2018. The Agreement formalizes the non-binding terms sheet that was entered into between the parties on February 2, 2018, which outlined a proposed strategic alliance with respect to the provision of a suite of blockchain opportunities to the Company, with the proposed issue of 486,000,000 shares to BCG in 3 tranches subject to the achievement of certain milestones.
- On August 8, 2018, the Company executed an Equity Placement Facility with Kentgrove Capital Pty Ltd. Under the Facility, Kentgrove Capital may provide the Company with up to A\$20 million of equity capital in a series of individual placements of up to \$1 million (or a higher amount by mutual agreement) over the next 20 months. Following the execution of the Facility and under a Prospectus as lodged with ASIC, the Company has issued:
  - 12,500,000 Options, exercisable at \$0.0153 each, expiring 3 years after issue (Establishment Options), to Kentgrove Capital Pty Ltd in its capacity as trustee of the Kentgrove Capital Growth Fund (Kentgrove) (Option Offer).
  - 8,833,100 Shares (Establishment Shares) to Kentgrove in lieu of payment of an Establishment Fee (Establishment Share Offer).
  - 100,000,000 Shares (Collateral Shares) to Kentgrove as security for the Company's obligations under the equity placement facility with Kentgrove.

The issue of the establishment and collateral shares to Kentgrove has resulted in an increase of the issued share capital of the Company to 2,544,115,824.

Under the lodged Prospectus, the Company will also have the ability to offer and issue up to 441,655,004 Placement Shares either to Kentgrove under the Kentgrove Facility, or to other investors as determined by the Board, to raise up to \$5,000,000. Prospectus currently has a closing date of November 9, 2018. 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.

- Following the recommendation of the Remuneration Committee, and subsequent Board approval in July 2018, the Board has agreed to award the Directors of the Company Share Options pursuant to the Company's Employee Share Option Plan. Subject to Shareholder approval, the quantum of the award, ranging in value from \$75k to \$150k will be aligned to the individual Directors responsibilities and activities. In addition, the Board has agreed to grant to Dr Kasian, in his role as interim CEO, 50 million Options subject to certain market related vesting conditions. The issue of such Options will be subject to all necessary Shareholder approvals being obtained.
- The Company has executed an Agreement with Swisstec Health Analytics on July 30, 2018 which sets out the principal commercial terms on which the Company intends to appoint Swisstec as a non-exclusive distributor for hospitals in Asia. In accordance with the terms of this agreement, the Company has acquired a 5% equity stake in Swisstec, and has provided Swisstec with \$250k to facilitate their expansion into hospitals in the Asian region.
- The Company has signed a Heads of Agreement with Beijing Zishan Health Consultancy Limited. The Agreement provides a framework according to which the two parties will explore opportunities to achieve market entry, through a Joint Venture, for GTG's genomic tests into the health sector in the People's Republic of China.

**Item 9. The Offer and Listing**

**Item 9.A Offer and Listing Details**

The Company's Ordinary Shares were listed on the Australian Securities Exchange (the ASX) in July 1987. Set out below is the highest and lowest market quotations for the Ordinary Shares reported on the Daily Official List of the ASX since July 1, 2011.

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Financial Year	Period Covered	High	Low	
(in \$0.00)				
<b>Yearly data</b> 2014	Year ended June 30, 2014	0.105	0.035	
	2015 Year ended June 30, 2015	0.087	0.012	
	2016 Year ended June 30, 2016	0.039	0.016	
	2017 Year ended June 30, 2017	0.021	0.007	
	2018 Year ended June 30, 2018	0.018	0.006	
<b>Quarterly data</b> 2017	Quarter ended September 30, 2016	0.020	0.014	
	Quarter ended December 31, 2016	0.021	0.010	
	Quarter ended March 31, 2017	0.012	0.009	
	Quarter ended June 30, 2017	0.011	0.007	
	2018	Quarter ended September 30, 2017	0.008	0.006
		Quarter ended December 31, 2017	0.016	0.007
		Quarter ended March 31, 2018	0.021	0.008
		Quarter ended June 30, 2018	0.015	0.008
<b>Monthly data</b> 2018	Month ended May 31, 2018	0.012	0.009	
	Month ended June 30, 2018	0.012	0.008	
	Month ended July 31, 2018	0.015	0.010	
	Month ended August 31, 2018	0.012	0.009	
	Month ended September 30, 2018	0.012	0.010	
	Period ended October 24, 2018	0.017	0.010	

As of the date of this Annual Report, we had 2,644,115,824 Ordinary Shares on issue, without par value. See Item 10B Our Constitution for a detailed description of the rights attaching to our shares and Item 12D American Depositary Receipts for a description of the rights attaching to the American Depositary Shares.

The Company's securities are also listed on NASDAQ Capital Market (under the ticker GENE) in the form of American Depositary Shares. During January 2015, the Company undertook a reverse stock split (consolidation) which had the effect of resetting the ratio of 1 ADS representing 30 Ordinary shares to 1 ADS representing 150 Ordinary shares. Since listing on the NASDAQ Global Market on September 2, 2005, the ADSs have traded in a range from a low of USD 0.31 to a high of USD 13.85. The most recent sale of the Company's ADSs, as recorded on October 24, 2018, occurred at a price of USD 1.24.

Following the listing of the Company's ADRs in September 2005, our Ordinary Shares are registered under Section 12 of the Securities Exchange Act of 1934 and we file an Annual Report with the Securities and Exchange Commission on Form 20-F. As a foreign private issuer, we are not be subject to the proxy rules under Section 14 of the Securities Exchange Act of 1934, and our officers, Directors and principal stockholders are not subject to the insider short-swing profit disclosure and recovery provisions of Section 16 of that Act.

Starting in January 14, 2002, the ADSs traded in the USA over-the-counter market under the symbol GNTLY and dealers' prices for the ADSs were been quoted in the pink sheets published by the National Quotations Bureau, Inc. Commencing on September 2, 2005, our ADSs were listed on the NASDAQ Global Market and, subsequently, the NASDAQ Capital Market, under the ticker GENE.

The Company has registered one class of American Depositary Shares (ADSs) on Form F-6 pursuant to the U.S. Securities Act of 1933, as amended. One ADS represents 150 Ordinary Shares without par value. As of June 30, 2018 there was a total of 10,706,141 ADSs outstanding,

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representing approximately 65.94% of the Company's total issued capital as of that date.

The table below sets forth the high and low sales prices in United States dollars for the ADSs during the periods indicated:

<b>Financial Year</b>	<b>Period Covered</b>	<b>High</b>	<b>Low</b>
		<b>(in USD)</b>	
<b>Yearly data</b> 2014	Year ended June 30, 2014	1.24	1.00
2015	Year ended June 30, 2015	11.00	0.31
2016	Year ended June 30, 2016	4.27	1.62
2017	Year ended June 30, 2017	2.27	0.75
2018	Year ended June 30, 2018	2.05	0.70

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<b>Quarterly data 2017</b>	Quarter ended September 30, 2016	2.27	1.70
	Quarter ended December 31, 2016	2.89	1.04
	Quarter ended March 31, 2017	1.38	1.05
	Quarter ended June 30, 2017	1.27	0.75
2018	Quarter ended September 30, 2017	0.94	0.70
	Quarter ended December 31, 2017	1.79	0.75
	Quarter ended March 31, 2018	2.05	1.02
	Quarter ended June 30, 2018	1.47	0.93
<b>Monthly data 2018</b>	Month ended May 31, 2018	1.38	1.03
	Month ended June 30, 2018	1.21	0.93
	Month ended July 31, 2018	2.04	0.93
	Month ended August 31, 2018	1.22	1.06
	Month ended September 30, 2018	1.18	1.03
	Period ended October 24, 2018	1.48	1.03

**Item 9.B Plan of Distribution**

Not applicable.

**Item 9.C Markets**

Effective September 2, 2005, our ADSs were listed on the NASDAQ Global Market under the ticker GENE . Effective July 1, 2010, the ADSs were transferred to the NASDAQ Capital Market. The ticker remained unchanged. Our Ordinary Shares are listed and trade on the Australian Securities Exchange under the code GTG .

**Item 9.D Selling Shareholders**

Not applicable.

**Item 9.E Dilution**

Not applicable.



**Item 9.F Expenses of the Issue**

Not applicable.

**Item 10. Additional Information**

**Item 10.A Share Capital**

As of June 30, 2018, we had a total of 2,435,282,724 Ordinary Shares on issue. None of these shares were subject to any form of escrow as of that date and, as such, all of the shares were listed on the Australian Securities Exchange and were freely tradable.

Based on our review of shareholder records (based solely on the addresses), as of June 30, 2018 there were 35 U.S. resident shareholders of our Ordinary Shares holding 2,018,616 shares representing 0.080% of the total issued and outstanding Ordinary Shares. Our Ordinary Shares do not have a par value. These figures do not include any Ordinary Shares which may be held by U.S. residents in the form of American Depositary Receipts (ADRs).

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

<b>Date</b>	<b>Nature of issue</b>	<b>Number of Ordinary Shares issued / outstanding</b>	<b>Movement in share capital / balance \$</b>
<b>As of June 30, 2013</b>		<b>475,471,819</b>	<b>83,735,845</b>
August 9, 2013	Issue of shares as part of private placements @ \$0.072	14,555,576	1,048,001
August 14, 2013	Issue of shares as part of private placements @ \$0.072	15,999,980	1,151,999
August 30, 2013	Issue of shares as part of private placements @ \$0.072	11,111,111	800,000
October 8, 2013	Issue of shares as part of private placements @ \$0.072	19,277,837	1,388,000
October 9, 2013	Issue of shares as part of private placements @ \$0.072	24,333,333	1,752,000
October 14, 2013	Issue of shares as part of private placements @ \$0.072	5,000,000	360,000
November 18, 2013	Issue of shares as part of private placements @ \$0.072	6,944,445	500,000
December 31, 2013	Issue of shares as part of the conversion of convertible notes	8,714,541	281,722
January 20, 2014	Issue of shares as part of the conversion of convertible notes	16,517,440	569,022
February 12, 2014	Issue of shares as part of the conversion of convertible notes	17,645,870	554,939
February 19, 2014	Issue of shares as part of the conversion of convertible notes	16,379,660	552,975
March 3, 2014	Issue of shares as part of the conversion of convertible notes	15,388,290	548,968
April 10, 2014	Issue of shares as part of the conversion of convertible notes	17,429,100	533,732
May 16, 2014	Shares cancelled as part of the swap deal	(75,937,500)	(3,569,702)
June 3, 2014	Issue of shares in respect of interest rate true up adjustment relating to March and April, under convertible notes	2,117,250	
June 27, 2014	Issue of shares as part of the conversion of convertible notes	22,969,740	531,519
To November, 2013	Other transaction costs arising on share issue		(658,528)
<b>As of June 30, 2014</b>		<b>613,918,492</b>	<b>90,080,492</b>

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<b>Date</b>	<b>Nature of issue</b>	<b>Number of Ordinary Shares issued / outstanding</b>	<b>Movement in share capital / balance \$</b>
July 9, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	23,227,950	721,403
August 12, 2014	Issue of shares for capitalized interest on convertible notes	5,142,450	
August 20, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	25,817,550	580,783
October 2, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	31,637,640	621,139
October 20, 2014	Issue of shares for capitalized interest on convertible notes	4,787,190	
October 31, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	46,503,360	306,619
November 28, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	27,655,230	234,192
December 5, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	34,100,456	78,546
December 19, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	8,059,599	102,685
December 29, 2014	Issue of shares as part of the conversion of convertible notes plus capitalized interest	8,677,729	102,849
December 30, 2014	Issue of shares as part of private placements @ \$0.0135	19,074,112	257,500
January 9, 2015	Issue of shares as part of the conversion of convertible notes plus capitalized interest	8,258,496	113,474
January 22, 2015	Facility fee pursuant to a standby equity placement facility	35,876,392	
January 30, 2015	Issue of shares as part of private placements @ \$0.01407	41,933,191	621,450
January 30, 2015	Exercise of 26,666,667 options @ \$0.015 each	26,666,667	400,000
February 2, 2015	Issue of shares as part of private placements @ \$0.02447	34,066,809	877,561
February 2, 2015	Issue of shares as part of the conversion of convertible notes	78,181,336	889,000
February 2, 2015	Issue of shares for capitalized interest on convertible notes	2,939,998	33,431
February 9, 2015	Issue of shares as part of private placements @ \$0.020	16,000,000	337,600
February 9, 2015	Exercise of 27,499,999 options @ \$0.015 each	27,499,999	412,500
February 13, 2015	Issue of shares as part of the conversion of convertible notes	1,712,663	51,000
February 13, 2015	Issue of shares for capitalized interest on convertible notes	72,260	2,152
February 13, 2015	Exercise of 37,666,666 options @ \$0.015 each	37,666,666	565,000
February 18, 2015	Issue of shares as part of private placements @ \$0.0695	10,500,000	729,750
February 18, 2015	Exercise of 8,666,667 options @ \$0.015 each	8,666,667	130,000
February 19, 2015	Issue of shares as part of the conversion of convertible notes	5,868,122	275,000
February 19, 2015	Issue of shares for capitalized interest on convertible notes	257,233	12,054
February 19, 2015	Exercise of 13,133,333 options @ \$0.015 each	13,133,333	197,000
February 20, 2015	Issue of shares as part of the conversion of convertible notes	2,713,459	150,000
February 20, 2015	Issue of shares for capitalized interest on convertible notes	119,690	6,616
February 20, 2015	Exercise of 2,000,000 options @ \$0.015 each	2,000,000	30,000
February 20, 2015	Exercise of 7,333,334 options @ \$0.015 each	7,333,334	110,000
March 11, 2015	Issue of shares as part of private placements @ \$0.0382	392,670,150	15,000,000
March 11, 2015	Issue of shares as part of private placements @ \$0.0334	107,329,800	3,584,815
To March 2015	Other transaction costs arising on share issue		(2,572,664)
To March 2015	Other transaction costs on placement of shares	4,123,608	(57,736)
<b>As of June 30, 2015</b>		<b>1,714,191,631</b>	<b>115,247,128</b>
July 23, 2015	Issue of shares as part of the conversion of convertible notes	1,006,441	25,000
July 23, 2015	Issue of shares for capitalized interest on convertible notes	84,652	2,102
July 27, 2015	Other transaction costs arising on share issue		(1,654)
<b>As of June 30, 2016</b>		<b>1,715,282,724</b>	<b>115,272,576</b>



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<b>Date</b>	<b>Nature of issue</b>	<b>Number of Ordinary Shares issued / outstanding</b>	<b>Movement in share capital / balance \$</b>
December 6, 2016	Issue of shares as part of private placements	720,000,000	8,049,369
To January 2017	Other transaction costs arising on share issue		(1,228,129)
March 16, 2017	Kentgrove Facility Fee Rebate		295,110
March 16, 2017	Other transaction costs on Kentgrove Facility Fee Rebate		(6,301)
<b>As of June 30, 2017</b>		<b>2,435,282,724</b>	<b>122,382,625</b>
December 7, 2017	Other transaction costs on prior private placements		(9,963)
<b>As of June 30, 2018</b>		<b>2,435,282,724</b>	<b>122,372,662</b>

As at June 30, 2014, Notes with a face value of USD 3,250,000 had been converted by Ironridge in return for which Ironridge received 117,161,871 ordinary shares (including ordinary shares issued in lieu of interest payment and an interest true-up adjustment). The balance of the notes were fully converted during 2015 in return for which Ironridge received 164,771,370 ordinary shares (including ordinary shares issued in lieu of interest payment).

During September 2014 the Company finalized the raising of \$2,150,000 via the issue of unlisted secured (debt) notes to existing and new Australian institutional and wholesale investors. The debt notes carried a 10.0% coupon rate, and as approved at the Annual General Meeting, held on November 25, 2014, became convertible notes which could convert into ordinary shares (at a 10.0% discount to the 5 day VWAP). These convertible notes also carry free attached options to purchase further shares in the Company.

\$2,125,000 of the convertible notes, together with the capitalized interest, had been converted into 150,961,041 ordinary shares in the Company at June 30, 2015.

On July 23, 2015 the balance of \$25,000 convertible notes plus capitalized interest was converted into 1,091,093 ordinary shares in the Company.

On December 2, 2014, the Company granted a total of 143,333,333 fully vested options over ordinary shares in the Company to the holders of convertible notes. The options, which were granted at no cost, entitle the holders to acquire one ordinary share at a price of \$0.015 at any time up to, and including December 2, 2018. At June 30, 2015, 122,966,666 options had been exercised for an increase in capital of \$ 1,844,500. As at the date of this report, 20,366,667 of these options remain unexercised.

During December 2014, the Company raised \$ 257,500 from existing shareholders through the issue of 19,074,112 new shares as part of a Share Purchase Plan.

In March 2015 an additional \$ 18,354,815 capital was raised at a weighted average issue price of \$ 0.0372 per share from professional and sophisticated investors in the United States through an offer of 499,999,950 fully paid ordinary shares, represented by 3,333,333 with each ADS representing 150 ordinary shares).

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During January 2015 year the Company entered into a standby equity placement facility with Kentgrove, an investment fund managed by Kentgrove Capital Pty Ltd.

Key terms of the Standby Equity Placement Facility:

- Standby equity placement facility of up to A\$24,000,000 with a maturity date January 21, 2017.
- Multiple placements permitted.
- For each placement, shares are issued at a 5% discount to a volume weighted average price (VWAP) over the period of the placement.
- A facility fee of 2.33% of the facility amount is payable, to be satisfied by the issue of shares. The facility fee, less 20%, will be rebated at termination or at maturity, pro rata for any amount of the facility that is unutilized.
- The commencement fee rebate may be paid by cash or shares.

As at June 30, 2016, the Company has issued 142,500,000 shares to Kentgrove under the standby facility for \$ 2,566,361.

As of June 30, 2016 and 2015, the following outstanding unlisted options, together with their respective ASX codes and expiry dates, were convertible into Ordinary Shares. The exercise prices are quoted in Australian dollars.

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In December 2016 an additional \$ 8,049,369 capital was raised at a weighted average issue price of \$ 0.0113 per share from professional and sophisticated investors in the United States through an offer of 720,000,000 fully paid ordinary shares, represented by 4,800,000 ADS s (with each ADS representing 150 ordinary shares).

In March 2017, the company received \$295,110 as a rebate of a facility fee originally provided to Kentgrove Capital on commencement of a standby equity placement facility agreement entered into in January 2015 that was paid on expiry of the facility agreement on January 21, 2017 in accordance with the agreement, representing a reduction in total equity transaction costs associated with the commencement of the facility.

As of June 30, 2018 and 2017, the following outstanding unlisted options, together with their respective ASX codes and expiry dates, were convertible into Ordinary Shares. The exercise prices are quoted in Australian dollars.

Option description	2018	Weighted ave. exercise price	2017	Weighted ave. exercise price
<b>Unlisted employee options</b>				
GTGAD (expiring September 14, 2020)			250,000	\$ 0.058
GTGAD (expiring November 24, 2020)	19,236,111	\$ 0.020	24,236,111	\$ 0.020
GTGAD (expiring March 31, 2021)	5,000,000	\$ 0.020	7,500,000	\$ 0.020
GTGAD (expiring February 16, 2022)	10,500,000	\$ 0.010	22,750,000	\$ 0.010
	34,736,111	\$ 0.017	54,736,111	\$ 0.016
<b>Unlisted options attached to convertible notes</b>				
GTGAC (expiring December 2, 2018)	20,366,667	\$ 0.015	20,366,667	\$ 0.015
Balance at the end of the financial year	55,102,778	\$ 0.016	75,102,778	\$ 0.016
Exercisable at the end of the financial year	48,102,722	\$ 0.017	36,234,722	\$ 0.017

**Item 10.B Our Constitution**

At the Annual General Meeting of the Company held on November 23, 2005, the shareholders resolved to replace the existing Constitution with a revised version. A copy of the Constitution has been posted on the Company s website: [www.gtglabs.com](http://www.gtglabs.com). The principal changes which have been implemented in the new Constitution may be summarized as follows:

- **General changes** – general changes are proposed to make the Constitution consistent with best practice, update legal matters under the existing Constitution consistent with legislative and regulatory developments and to address certain content and language aspects.
- **ASX Listing Rules** – it provides that the Listing Rules prevail in the event of any inconsistency.
- **Shares** – it allows the Directors to issue shares subject to the *Corporations Act 2001* and the Listing Rules.

- Proportionate takeover power the existing Constitution has a clause in it requiring shareholder approval to be obtained before any proportionate takeover is made. However, that clause is ineffective because it needs to have been renewed at least every three years in accordance with the requirements of the Corporations Act. The new Constitution does not include this clause on the basis that it offers no real benefit.
- Unmarketable parcels the new Constitution permits the Company to sell holdings of less than a marketable parcel in accordance with the procedural and timing requirements of the Listing Rules. This only applies if a shareholder has an opportunity to opt out of any proposed sale arrangement and does not do so.
- Notice of shareholders meetings the new Constitution enables notice of shareholders meetings to be given by electronic means.



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- Changes to general meetings the new Constitution enables the Directors to change the venue for, and postpone or cancel a general meeting if such meeting is unnecessary, in the interests of shareholders, if the venue would be unreasonable or impractical, or for reasons of efficiency. This does not apply in the event of a meeting requisitioned by shareholders.
- Quorum for shareholders meetings a quorum of three shareholders represents a quorum for shareholders meetings, whether by way of being personally present, attorney, proxy or corporate representative.
- Casting vote the Chairman of a shareholders meeting does not have a casting vote.
- Number of Directors it contemplates that the number of Directors need to be not less than three nor more than the number determined by the Directors which, until otherwise determined, is ten.
- Share qualification a Director need not hold any shares in the Company in order to be a Director.
- Alternate directors there are no provisions entitling the Directors to appoint alternate directors, on the basis that this is an outdated and undesirable approach.<sup>4</sup>
- Directors tenure of office a Director must retire from office or seek re-election by no later than the third Annual General Meeting following his or her appointment or re-election or three years, whichever is longer (other than the Managing Director).
- Vacation of office the office of a Director is automatically vacated if the Director is an Executive Director under an employment agreement and that agreement terminates, unless the Board otherwise determines.
- Powers of Directors the Directors have a general power to manage the Company's business.
- Meetings of Directors the Directors may meet in person or by electronic means.

- Quorum for Directors meetings the quorum for Directors meetings is three, unless otherwise determined.
- Casting vote the Chairman has a casting vote at Directors meetings.
- Indemnity the new Constitution contains an updated indemnity clause in favor of the current and former Directors, Secretaries indemnifying them from liability consistent with the Corporations Act provisions and to the maximum extent permitted by law.
- Insurance the Company must maintain and pay insurance premiums with respect to its current and former Directors, Secretaries and other officers to the extent permitted by law.
- Access current and former Directors may access the financial and other records of the Company for the purposes of legal proceedings involving the person.

#### **Item 10.C Material Contracts**

On August 8, 2018, the Company executed an Equity Placement Facility with Kentgrove Capital Pty Ltd. Under the Facility, Kentgrove Capital may provide the Company with up to A\$20 million of equity capital in a series of individual placements of up to \$1 million (or a higher amount by mutual agreement) over the next 20 months (refer to Note 29 of the Financial Report for details)

There were no other material contracts entered into during the year preceding the date of this Annual Report which were outside the ordinary course of business

#### **Item 10.D Exchange Controls and Other Limitations Affecting Security Holders**

Under existing Australian legislation, the Reserve Bank of Australia does not inhibit the import and export of funds, and, generally, no permission is required to be given to Genetic Technologies for the movement of funds in and out of Australia. However, payments to or from (or relating to) Iraq, its agencies or nationals, the government or a public authority of Libya, or certain Libyan undertakings, the authorities in the Federal Republic of Yugoslavia (Serbia and Montenegro) or their agencies, the Taliban (also referred to as the Islamic Emirate of Afghanistan), or the National Union for the Total Independence of Angola (also known as UNITA), its senior officials or the adult members of their immediate families, may not be made without the specific approval of the Reserve Bank of Australia.

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Accordingly, at the present time, remittances of any dividends, interest or other payment by Genetic Technologies to non-resident holders of Genetic Technologies securities in the U.S. are not, subject to the above, restricted by exchange controls or other limitations.

**Takeovers Act**

There are no limitations, either under the laws of Australia or under the Company's Constitution, to the right of non-residents to hold or vote Genetic Technologies Ordinary Shares other than the Commonwealth Foreign Acquisitions and Takeovers Act 1975 (the Takeovers Act). The Takeovers Act may affect the right of non-Australian residents, including U.S. residents, to hold Ordinary Shares but does not affect the right to vote, or any other rights associated with, any Ordinary Shares held in compliance with its provisions. Acquisitions of shares in Australian companies by foreign interests are subject to review and approval by the Treasurer of the Commonwealth of Australia under the Takeovers Act. The Takeovers Act applies to any acquisition of outstanding shares of an Australian company that exceeds, or results in a foreign person or persons controlling the voting power of more than a certain percentage of those shares. The thresholds are 15% where the shares are acquired by a foreign person, or group of associated foreign persons, or 40% in aggregate in the case of foreign persons who are not associated. Any proposed acquisition that would result in an individual foreign person (with associates) holding more than 15% must be notified to the Treasurer in advance of the acquisition. There are statutory limitations in Australia on foreign ownership of certain businesses, such as banks and airlines, not relevant to the Company. However, there are no other statutory or regulatory provisions of Australian law or Australian Securities Exchange requirements that restrict foreign ownership or control of Genetic Technologies.

**Corporations Act 2001**

As applied to Genetic Technologies Limited, the *Corporations Act 2001* (the *Corporations Act 2001*) prohibits any legal person (including a corporation) from acquiring a relevant interest in Ordinary Shares if after the acquisition that person or any other person's voting power in Genetic Technologies Limited increases from 20% or below to more than 20%, or from a starting point that is above 20% and below 90%.

This prohibition is subject to a number of specific exceptions set out in section 611 of the *Corporations Act 2001* which must be strictly complied with to be applicable.

In general terms, a person is considered to have a relevant interest in a share in Genetic Technologies if that person is the holder of that share, has the power to exercise, or control the exercise of, a right to vote attached to that share, or has the power to dispose of, or to control the exercise of a power to dispose of that share.

It does not matter how remote the relevant interest is or how it arises. The concepts of power and control are given wide and extended meanings in this context in order to deem certain persons to hold a relevant interest. For example, each person who has voting power above 20% in a company or a managed investment scheme which in turn holds shares in Genetic Technologies is deemed to have a relevant interest in those Genetic Technologies shares. Certain situations (set out in section 609 of the *Corporations Act 2001*) which would otherwise constitute the holding of a relevant interest are excluded from the definition.

A person's voting power in Genetic Technologies Limited is that percentage of the total votes attached to Ordinary Shares in which that person and its associates (as defined in the *Corporations Act 2001*) holds a relevant interest.

#### **Item 10.E Taxation**

This summary of material tax consequences is based on the tax laws of the United States (including the Internal Revenue Code of 1986, as amended, its legislative history, existing and proposed regulations thereunder, published rulings and court decisions) and on the Australian tax law and practice as in effect on the date hereof. In addition, this summary is based on the income tax convention between the United States and Australia (the Treaty). The foregoing laws and legal authorities as well as the Treaty are subject to change (or changes in interpretation), possibly with retroactive effect. Finally, this summary is based in part upon the representations of our ADR Depository and the assumption that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms.

The discussion does not address any aspects of U.S. taxation other than federal income taxation or any aspects of Australian taxation other than federal income taxation, stamp duty and goods and services tax. This discussion does not necessarily address all aspects of U.S. or Australian federal tax considerations that may be important to particular investors in light of their individual investment circumstances or investors subject to special tax regimes, like broker-dealers, insurance companies, banks or other financial institutions, tax-exempt organizations, regulated investment companies, real estate investment trusts or financial asset securitization investment trusts, persons who actually or constructively own 10% or more of our ADRs or Ordinary Shares, persons who hold ADRs or Ordinary Shares as part of a straddle, hedge, conversion or constructive sale transaction or other integrated transaction, persons who

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have elected mark-to-market accounting, U.S. holders whose functional currency is not the U.S. dollar, U.S. expatriates, investors liable for the alternative minimum tax, partnerships and other pass-through entities, or persons who acquired their ADRs or Ordinary Shares through the exercise of options or similar derivative securities or otherwise as compensation. Prospective investors are urged to consult their tax advisers regarding the U.S. and Australian federal, state and local tax consequences and any other tax consequences of owning and disposing of ADRs and shares.

**Australian Tax Consequences**

In this section, we discuss Australian tax considerations that apply to non-Australian tax residents who are residents of the United States with respect to the ownership and disposal by the absolute beneficial owners of ADRs. This summary does not discuss any foreign or state tax considerations, other than stamp duty.

**Nature of ADRs for Australian Taxation Purposes**

ADRs held by a U.S. holder will be treated for Australian taxation purposes as being held under a bare trust for that holder. Consequently, the underlying Ordinary Shares will be regarded as owned by the ADR holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying Ordinary Shares will also be treated as dividends paid to the ADR holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis, we discuss the tax consequences to non-Australian resident holders of Ordinary Shares which, for Australian taxation purposes, will be the same as to U.S. holders of ADRs.

**Taxation of Dividends**

Australia operates a dividend imputation system under which dividends may be declared to be franked to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends payable by our company to non-Australian resident stockholders will be subject to dividend withholding tax, to the extent the dividends are unfranked. Dividend withholding tax will be imposed at 30%, unless a stockholder is a resident of a country with which Australia has a double taxation agreement. Under the provisions of the Treaty, the Australian tax withheld on unfranked dividends paid by us to which a resident of the United States is beneficially entitled is generally limited to 15% if the U.S. resident holds less than 10% of the voting rights of our company, unless the shares are effectively connected to a permanent establishment or fixed base in Australia through which the stockholder carries on business or provides independent personal services, respectively. Where a U.S. corporate resident holds 10% or more of the voting rights of our company, the withholding tax rate is reduced to 5%.

**Tax on Sales or other Dispositions of Shares - Capital Gains Tax**

Non-Australian resident stockholders who hold their shares in us on capital account will not be subject to Australian capital gains tax on any gain made on a sale or other disposal of our shares, unless they hold 10% or more of our issued capital and the Company holds real property situated in Australia, the market value of which is 50% or more of the market value of the Company. The Australian Taxation Office maintains the view that the Treaty does not limit Australian capital gains tax. Australian capital gains tax applies to net capital gains charged at a taxpayer's marginal tax rate but, for certain stockholders, a discount of the capital gain may apply if the shares have been held for 12 months or more. For

individuals, this discount is 50%. For superannuation funds, the discount is 33%. There is no discount for a company that derives a net capital gain. Net capital gains are calculated after deducting capital losses, which may only be offset against such gains.

#### **Tax on Sales or other Dispositions of Shares - Stockholders Holding Shares on Revenue Account**

Some non-Australian resident stockholders may hold shares on revenue rather than on capital account, for example, share traders. These stockholders may have the gains made on the sale or other disposal of the shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia. Non-Australian resident stockholders assessable under these ordinary income provisions in respect of gains made on shares held on revenue account would be assessed for those gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Some relief from the Australian income tax may be available to non-Australian resident stockholders under the Treaty, for example, because the stockholder derives business profits not through a permanent establishment in Australia. To the extent an amount would be included in a non-Australian resident stockholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the stockholder would not be subject to double tax on any part of the income gain or capital gain.

#### **Dual Residency**

If a stockholder were a resident of both Australia and the United States under the respective domestic taxation laws of those countries, that stockholder may be subject to tax as an Australian resident. If, however, the stockholder is determined to be a U.S. resident for the purposes of the Treaty, the Australian tax would be subject to limitation by the Treaty. Stockholders should obtain specialist taxation advice in these circumstances.

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**Stamp Duty**

Any transfer of shares through trading on the Australian Securities Exchange, whether by Australian residents or foreign residents, is not subject to stamp duty within Australia.

**Australian Death Duty**

Australia does not have estate or death duties. Further, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. However, the subsequent disposal of the shares by beneficiaries may give rise to a capital gains tax liability.

**Goods and Services Tax**

The issue or transfer of shares will not incur Australian goods and services tax and does not require a stockholder to register for Australian goods and services tax purposes.

**United States Federal Income Taxation**

As used below, a U.S. holder is a beneficial owner of an ADR that is, for U.S. federal income tax purposes, (i) a citizen or resident alien individual of the United States, (ii) a corporation (or an entity treated as a corporation) created or organized under the law of the United States, any State thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax without regard to its source or (iv) a trust if (1) a court within the United States is able to exercise primary supervision over the administration of the trust, and one or more United States persons have the authority to control all substantial decisions of the trust, or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person. For purposes of this discussion, a non-U.S. holder is a beneficial owner of an ADR that is (i) a nonresident alien individual, (ii) a corporation (or an entity treated as a corporation) created or organized in or under the law of a country other than the United States or a political subdivision thereof or (iii) an estate or trust that is not a U.S. Holder. If a partnership (including for this purpose any entity treated as a partnership for U.S. federal tax purposes) is a beneficial owner of an ADR, the U.S. federal tax treatment of a partner in the partnership generally will depend on the status of the partner and the activities of the partnership. A holder of an ADR that is a partnership and partners in that partnership should consult their own tax advisers regarding the U.S. federal income tax consequences of holding and disposing of ADRs. We have not sought a ruling from the Internal Revenue Service ( IRS ) or an opinion of counsel as to any U.S. federal income tax consequence described herein. The IRS may disagree with the description herein, and its determination may be upheld by a court.

GIVEN THE COMPLEXITY OF THE TAX LAWS AND BECAUSE THE TAX CONSEQUENCES TO ANY PARTICULAR INVESTOR MAY BE AFFECTED BY MATTERS NOT DISCUSSED HEREIN, PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE SPECIFIC TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF ADRs, INCLUDING THE APPLICABILITY AND EFFECT OF STATE, LOCAL AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL TAX LAWS.

### **Nature of ADRs for U.S. Federal Income Tax Purposes**

In general, for U.S. federal income tax purposes, a holder of an ADR will be treated as the owner of the underlying shares. Accordingly, except as specifically noted below, the tax consequences discussed below with respect to ADRs will be the same as for shares in the Company, and exchanges of shares for ADRs, and ADRs for shares, generally will not be subject to U.S. federal income tax.

### **Taxation of Dividends**

**U.S. Holders.** In general, subject to the passive foreign investment company rules discussed below, a distribution on an ADR will constitute a dividend for U.S. federal income tax purposes to the extent that it is made from our current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, it is generally treated as a non-taxable reduction of basis to the extent of the U.S. holder's tax basis in the ADR on which it is paid, and to the extent it exceeds that basis it will be treated as capital gain. For purposes of this discussion, the term "dividend" means a distribution that constitutes a dividend for U.S. federal income tax purposes. The Company has not maintained and does not plan to maintain calculations of earnings and profits under U.S. federal income tax principles. Accordingly, it is unlikely that U.S. Holders will be able to establish that a distribution by the Company is in excess of its current and accumulated earnings and profits (as computed under U.S. federal income tax principles). Therefore, a U.S. Holder should expect that a distribution by the Company will generally be treated as taxable in its entirety as a dividend to U.S. Holders for U.S. federal income tax purposes even though the distribution may be treated in whole or in part as a non-taxable distribution for Australian tax purposes.

The gross amount of any dividend on an ADR (which will include the amount of any Australian taxes withheld) generally will be subject to U.S. federal income tax as foreign source dividend income, and will not be eligible for the corporate dividends received



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deduction. The amount of a dividend paid in Australian dollars will be its value in U.S. dollars based on the prevailing spot market exchange rate in effect on the day the U.S. holder receives the dividend or, in the case of a dividend received in respect of an ADR, on the date the Depository receives it, whether or not the dividend is converted into U.S. dollars. A U.S. holder will have a tax basis in any distributed Australian dollars equal to its U.S. dollar amount on the date of receipt, and any gain or loss realized on a subsequent conversion or other disposition of Australian dollars generally will be treated as U.S. source ordinary income or loss. If dividends paid in Australian dollars are converted into U.S. dollars on the date they are received by a U.S. holder, the U.S. holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

Subject to certain exceptions for short-term and hedged positions, a dividend that a non-corporate holder receives on an ADR will be subject to a maximum federal income tax rate of 20% if the dividend is a qualified dividend. A dividend on an ADR will be a qualified dividend if (i) either (a) the ADRs are readily tradable on an established market in the United States or (b) we are eligible for the benefits of a comprehensive income tax treaty with the United States that the Secretary of the Treasury determines is satisfactory for purposes of these rules and that includes an exchange of information program, and (ii) we were not, in the year prior to the year the dividend was paid, and are not, in the year the dividend is paid, a passive foreign investment company ( PFIC ). The ADRs are listed on the NASDAQ Capital Market, which should qualify them as readily tradable on an established securities market in the United States. In any event, the Treaty satisfies the requirements of clause (i) (b), and we are a resident of Australia entitled to the benefits of the Treaty. However, based on our audited financial statements and relevant market and shareholder data, we believe we were a PFIC for U.S. federal income tax purposes for our taxable years ended June 30, 2017 and June 30, 2018, and expect to be classified as a PFIC in the current taxable year. Given that the determination of PFIC status involves the application of complex tax rules, and that it is based on the nature of our income and assets from time to time, no assurances can be provided that we will or will not be considered a PFIC for any past or future taxable years. In addition, as described in the section below entitled Passive Foreign Investment Company Rules, if we were a PFIC in a year while a U.S. holder held an ADR, and if the U.S. holder has not made a qualified electing fund election effective for the first year the U.S. holder held the ADR, the ordinary share underlying the ADR remains an interest in a PFIC for all future years or until such an election is made. The IRS takes the position that such rule will apply for purposes of determining whether an ADR is an interest in a PFIC in the year a dividend is paid or in the prior year, even if we do not satisfy the tests to be a PFIC in either of those years. Even if dividends on the ADRs would otherwise be eligible for qualified dividend treatment, in order to qualify for the reduced qualified dividend tax rates, a non-corporate holder must hold the ordinary share on which a dividend is paid for more than 60 days during the 120-day period beginning 60 days before the ex-dividend date, disregarding for this purpose any period during which the non-corporate holder has an option to sell, is under a contractual obligation to sell or has made (and not closed) a short sale of substantially identical stock or securities, is the grantor of an option to buy substantially identical stock or securities or, pursuant to Treasury regulations, has diminished such holder's risk of loss by holding one or more other positions with respect to substantially similar or related property. In addition, to qualify for the reduced qualified dividend tax rates, the non-corporate holder must not be obligated to make related payments with respect to positions in substantially similar or related property. Payments in lieu of dividends from short sales or other similar transactions will not qualify for the reduced qualified dividend tax rates.

A non-corporate holder that receives an extraordinary dividend eligible for the reduced qualified dividend rates must treat any loss on the sale of the stock as a long-term capital loss to the extent of the dividend. For purposes of determining the amount of a non-corporate holder's deductible investment interest expense, a dividend is treated as investment income only if the non-corporate holder elects to treat the dividend as not eligible for the reduced qualified dividend tax rates. Special limitations on foreign tax credits with respect to dividends subject to the reduced qualified dividend tax rates apply to reflect the reduced rates of tax.

The U.S. Treasury has announced its intention to promulgate rules pursuant to which non-corporate holders of stock of non-U.S. corporations, and intermediaries through whom the stock is held, will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. Because those procedures have not yet been issued, it is not clear whether we will be able to comply with them.

Non-corporate holders of ordinary shares are urged to consult their own tax advisers regarding the availability of the reduced qualified dividend tax rates with respect to dividends received on the ADRs in the light of their own particular circumstances.

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Any Australian withholding tax imposed on dividends received with respect to the ADRs will be treated as a foreign income tax eligible for credit against a U.S. holder's U.S. federal income tax liability, subject to generally applicable limitations under U.S. federal income tax law. For purposes of computing those limitations separately under current law for specific categories of income, a dividend generally will constitute foreign source passive category income or, in the case of certain holders, general category income. A U.S. holder will be denied a foreign tax credit with respect to Australian income tax withheld from dividends received with respect to the ADRs to the extent the U.S. holder has not held the ADRs for at least 16 days of the 30-day period beginning on the date which is 15 days before the ex-dividend date or to the extent the U.S. holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a U.S. holder has substantially diminished its risk of loss on the ADRs are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex, and U.S. holders are urged to consult with their own tax advisers to determine whether and to what extent they

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will be entitled to foreign tax credits as well as with respect to the determination of the foreign tax credit limitation. Alternatively, any Australian withholding tax may be taken as a deduction against taxable income, provided the U.S. holder takes a deduction and not a credit for all foreign income taxes paid or accrued in the same taxable year. In general, special rules will apply to the calculation of foreign tax credits in respect of dividend income that is subject to preferential rates of U.S. federal income tax.

**Non-U.S. holders.** A dividend paid to a non-U.S. holder of an ADR will not be subject to U.S. federal income tax unless the dividend is effectively connected with the conduct of trade or business by the non-U.S. holder within the United States (and is attributable to a permanent establishment or fixed base the non-U.S. holder maintains in the United States if an applicable income tax treaty so requires as a condition for the non-U.S. holder to be subject to U.S. taxation on a net income basis on income from the ADR). A non-U.S. holder generally will be subject to tax on an effectively connected dividend in the same manner as a U.S. holder. A corporate non-U.S. holder under certain circumstances may also be subject to an additional branch profits tax, the rate of which may be reduced pursuant to an applicable income tax treaty.

**Taxation of Capital Gains**

**U.S. Holders.** Subject to the passive foreign investment company rules discussed below, on a sale or other taxable disposition of an ADR, a U.S. holder will recognize capital gain or loss in an amount equal to the difference between the U.S. holder's adjusted basis in the ADR and the amount realized on the sale or other disposition, each determined in U.S. dollars. Such capital gain or loss will be long-term capital gain or loss if at the time of the sale or other taxable disposition the ADR has been held for more than one year. In general, any adjusted net capital gain of an individual is subject to a maximum federal income tax rate of 20%. Capital gains recognized by corporate U.S. holders generally are subject to U.S. federal income tax at the same rate as ordinary income. The deductibility of capital losses is subject to limitations.

Any gain a U.S. holder recognizes generally will be U.S. source income for U.S. foreign tax credit purposes, and, subject to certain exceptions, any loss will generally be a U.S. source loss. If an Australian tax is paid on a sale or other disposition of an ADR, the amount realized will include the gross amount of the proceeds of that sale or disposition before deduction of the Australian tax. The generally applicable limitations under U.S. federal income tax law on crediting foreign income taxes may preclude a U.S. holder from obtaining a foreign tax credit for any Australian tax paid on a sale or other disposition of an ADR. The rules relating to the determination of the foreign tax credit are complex, and U.S. holders are urged to consult with their own tax advisers regarding the application of such rules. Alternatively, any Australian tax paid on the sale or other disposition of an ADR may be taken as a deduction against taxable income, provided the U.S. holder takes a deduction and not a credit for all foreign income taxes paid or accrued in the same taxable year.

**Non-U.S. Holders.** A non-U.S. holder will not be subject to U.S. federal income tax on gain recognized on a sale or other disposition of an ADR unless (i) the gain is effectively connected with the conduct of trade or business by the non-U.S. holder within the United States (and is attributable to a permanent establishment or fixed base the non-U.S. holder maintains in the United States if an applicable income tax treaty so requires as a condition for the non-U.S. holder to be subject to U.S. taxation on a net income basis on income from the ADR), or (ii) in the case of a non-U.S. holder who is an individual, the holder is present in the United States for 183 or more days in the taxable year of the sale or other disposition and certain other conditions apply. Any effectively connected gain of a corporate non-U.S. holder may also be subject under certain circumstances to an additional branch profits tax, the rate of which may be reduced pursuant to an applicable income tax treaty.

**Passive Foreign Investment Company Rules**

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A special set of U.S. federal income tax rules applies to a foreign corporation that is a PFIC for U.S. federal income tax purposes. As noted above, based on our audited financial statements and relevant market and shareholder data, we believe that we were a PFIC for U.S. federal income tax purposes for our taxable years ended June 30, 2017 and June 30, 2018, and expect to be classified as a PFIC in our current taxable year. In addition, given that the determination of PFIC status involves the application of complex tax rules, and that it is based on the nature of our income and assets from time to time, no assurances can be provided that we will or will not be considered a PFIC for any past or future taxable years.

In general, a foreign corporation is a PFIC if at least 75% of its gross income for the taxable year is passive income or if at least 50% of its assets for the taxable year produce passive income or are held for the production of passive income. In general, passive income for this purpose means, with certain designated exceptions, dividends, interest, rents, royalties (other than certain rents and royalties derived in the active conduct of trade or business), annuities, net gains from dispositions of certain assets, net foreign currency gains, income equivalent to interest, income from notional principal contracts and payments in lieu of dividends. Passive assets are those assets that are held for production of passive income or do not produce income at all. Thus cash will be a passive asset. Interest, including interest on working capital, is treated as passive income for purposes of the income test. The determination of whether a foreign corporation is a PFIC is a factual determination made annually and is therefore subject to change. Subject to exceptions pursuant to

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certain elections that generally require the payment of tax, once stock in a foreign corporation is stock in a PFIC in the hands of a particular shareholder that is a United States person, it remains stock in a PFIC in the hands of that shareholder.

If we are treated as a PFIC, contrary to the tax consequences described in U.S. Federal Income Tax Considerations Taxation of Dividends and U.S. Federal Income Tax Considerations Taxation of Capital Gains above, a U.S. holder that does not make an election described in the succeeding two paragraphs would be subject to special rules with respect to (i) any gain realized on a sale or other disposition of an ADR (for purposes of these rules, a disposition of an ADR includes many transactions on which gain or loss is not realized under general U.S. federal income tax rules) and (ii) any excess distribution by the Company to the U.S. holder (generally, any distribution during a taxable year in which distributions to the U.S. holder on the ADR exceed 125% of the average annual taxable distributions (whether actual or constructive and whether or not out of earnings and profits) the U.S. holder received on the ADR during the preceding three taxable years or, if shorter, the U.S. holder's holding period for the ADR). Under those rules, (i) the gain or excess distribution would be allocated ratably over the U.S. holder's holding period for the ADR, (ii) the amount allocated to the taxable year in which the gain or excess distribution is realized would be taxable as ordinary income in its entirety and not as capital gain, would be ineligible for the reduced qualified dividend rates, and could not be offset by any deductions or losses, and (iii) the amount allocated to each prior year, with certain exceptions, would be subject to tax at the highest tax rate in effect for that year, and the interest charge generally applicable to underpayments of tax would be imposed in respect of the tax attributable to each of those years. A U.S. holder who owns an ADR during any year we are a PFIC will generally have to file IRS Form 8621. A failure to file this return will suspend the statute of limitations with respect to any tax return, event, or period to which such report relates (potentially including with respect to items that do not relate to a U.S. Holder's investment in the ADRs).

The special PFIC rules described above will not apply to a U.S. holder if the U.S. holder makes a timely election, which remains in effect, to treat the Company as a qualified electing fund ( QEF ) in the first taxable year in which the U.S. holder owns an ADR and the Company is a PFIC and if the Company complies with certain reporting requirements. Instead, a shareholder of a QEF generally is currently taxable on a pro rata share of the Company's ordinary earnings and net capital gain as ordinary income and long-term capital gain, respectively. Neither that ordinary income nor any actual dividend from the Company would qualify for the 20% maximum tax rate on dividends described above if the Company is a PFIC in the taxable year the ordinary income is realized or the dividend is paid or in the preceding taxable year. We have not yet determined whether we would make the computations necessary to supply U.S. holders with the information needed to report income and gain pursuant to a QEF election. It is, therefore, possible that U.S. holders would not be able to make or retain a QEF election in any year we are a PFIC. Although a QEF election generally cannot be revoked, if a U.S. holder made a timely QEF election for the first taxable year it owned an ADR and the Company is a PFIC (or is treated as having done so pursuant to any of certain elections), the QEF election will not apply during any later taxable year in which the Company does not satisfy the tests to be a PFIC. If a QEF election is not made in that first taxable year, an election in a later year generally will require the payment of tax and interest.

In lieu of a QEF election, a U.S. holder of stock in a PFIC that is considered marketable stock could elect to mark the stock to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the stock and the U.S. holder's adjusted basis in the stock. Losses would be allowed only to the extent of net mark-to-market gain previously included in income by the U.S. holder under the election for prior taxable years. A U.S. holder's adjusted basis in the ADRs will be adjusted to reflect the amounts included or deducted with respect to the mark-to-market election. If the mark-to-market election were made, the rules set forth in the second preceding paragraph would not apply for periods covered by the election. A mark-to-market election will not apply during any later taxable year in which the Company does not satisfy the tests to be a PFIC. In general, the ADRs will be marketable stock if the ADRs are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter on a national securities exchange that is registered with the SEC or on a designated national market system or on any exchange or market that the Treasury Department determines to have rules sufficient to ensure that the market price accurately represents the fair market value of the stock. Under current law, the mark-to-market election may be available to U.S. holders of ADRs because the ADRs are listed on the Nasdaq Capital Market, which constitutes a qualified exchange, although there can be no assurance that the ADRs will be regularly traded for purposes of the mark-to-market election or that the ADRs will continue to be listed on the Nasdaq Capital Market.

Given the complexities of the PFIC rules and their potentially adverse tax consequences, U.S. holders of ADRs are urged to consult their tax advisers about the PFIC rules, including the availability of, and consequences to them of making a QEF election or a mark-to-market election

with respect to the ordinary shares in the event that the Company is classified as a PFIC for any taxable year.

**Medicare Surtax on Net Investment Income**

Non-corporate US Holders whose income exceeds certain thresholds generally will be subject to 3.8% surtax on their Net Investment Income (which generally includes, among other things, dividends on, and capital gain from the sale or other taxable disposition of, the ADRs). Absent an election to the contrary, if a QEF election is available and made, QEF inclusions will not be included in net investment income at the time a US Holder includes such amounts in income, but rather will be included at the time

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distributions are received or gains are recognized. Non-corporate US Holders should consult their own tax advisors regarding the possible effect of such tax on their ownership and disposition of the Common Shares, in particular the applicability of this surtax with respect to a non-corporate US Holder that makes a QEF or mark-to-market election in respect of their Common Shares.

**Information Reporting and Backup Withholding**

Dividends paid on, and proceeds from the sale or other disposition of, an ADR to a U.S. holder generally may be subject to information reporting requirements and may be subject to backup withholding unless the U.S. holder provides an accurate taxpayer identification number or otherwise establishes an exemption. The amount of any backup withholding collected from a payment to a U.S. holder will be allowed as a credit against the U.S. holder's U.S. federal income tax liability and may entitle the U.S. holder to a refund, provided certain required information is furnished to the Internal Revenue Service. A non-U.S. holder generally will be exempt from these information reporting requirements and backup withholding tax but may be required to comply with certain certification and identification procedures in order to establish its eligibility for exemption.

Under U.S. federal income tax law and U.S. Treasury Regulations, certain categories of U.S. holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. For example, all U.S. holders of PFIC stock are generally required to make annual return filings reporting their PFIC ownership and certain other information that the IRS may require. U.S. holders are urged to consult with their own tax advisors concerning such reporting requirements.

**Reporting Obligations of Individual Owners of Foreign Financial Assets**

Section 6038D of the Code generally requires U.S. individuals (and possibly certain entities that have U.S. individual owners) to file IRS Form 8938 if they hold certain specified foreign financial assets, the aggregate value of which exceeds \$50,000. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-US. person, any financial instrument or contract held for investment that has an issuer or counterparty other than a U.S. person and any interest in a foreign entity.

THE DISCUSSION ABOVE IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO AN INVESTMENT IN ADRs. HOLDERS AND POTENTIAL HOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISERS CONCERNING THE TAX CONSEQUENCES RELEVANT TO THEM IN THEIR PARTICULAR SITUATION.

**Item 10.F Dividends and Paying Agents**

No dividends have been paid by the Company or recommended by the directors since the end of the previous financial year.

**Item 10.G Statement by Experts**

Not applicable.

**Item 10.H Documents on Display**

The documents concerning the Company which are referred to in this Annual Report may be inspected at the offices of the Company at 60-66 Hanover Street, Fitzroy, Victoria 3065 Australia. Following our listing on NASDAQ Global Market in September 2005, we are now subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, and, in accordance therewith, we are required to file reports, including annual reports on Form 20-F, and other information with the U.S. Securities and Exchange Commission in electronic form. As a foreign private issuer, we are required to make filings with the Commission by electronic means. Any filings we make electronically will be available to the public over the Internet at the Commission's website at <http://www.sec.gov>. We also maintain a website at [www.gtglabs.com](http://www.gtglabs.com). Information on our website and websites linked to it do not constitute a part of this Annual Report.

**Item 10.I Subsidiary Information**

The following is a list of the Company's subsidiaries as of the date of this Annual Report:

<b>Name of subsidiary</b>	<b>Place of incorporation</b>	<b>Interest held</b>
GeneType Corporation	California, U.S.A.	100%
GeneType Pty. Ltd.	Victoria, Australia	100%
Genetic Technologies Corporation Pty. Ltd.	New South Wales, Australia	100%
Geneventures Pty. Ltd.*	New South Wales, Australia	100%
Phenogen Sciences Inc.	Delaware, U.S.A.	100%



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\* Previously RareCollect Pty Ltd name changed on April 6, 2018

**Item 11. Quantitative and Qualitative Disclosures about Market Risk**

Our market risk relates primarily to exposure to changes in foreign currency exchange rates and interest rates. Refer Note 28 of the attached financial statements for further analysis surrounding market risk.

**Interest Rate Risk.** As of June 30, 2018 we had \$5,487,035 in cash & cash equivalents of which \$2,394,754 was subject to interest rate risk. Interest income earned on the cash balances is affected by changes in the levels of market interest rates. We invest excess cash in interest-bearing, investment-grade securities and time deposits in high-quality institutions. We do not utilize derivative financial instruments, derivative commodity instruments, positions or transactions in any material matter.

Accordingly, we believe that, while the investment-grade securities and time-deposits we hold are subject to changes in financial standing of the issuer of such securities, the principal is not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments. Since we hold cash and cash equivalents in Banks which are located outside Australia, we are subject to certain cross-border risks, though due to the size of the holdings these risks are not generally significant.

**Foreign Currency Exchange Rate Risk.** We operate in Australia with active operations in the U.S.A., and are accordingly subject to certain foreign currency exposure. This includes foreign-currency denominated receivables, payables, debt, and other balance sheet positions as well as future cash flows resulting from anticipated transactions including intra-group transactions. Historically, currency translation gains and losses have been reflected as adjustments to stockholders' equity, while transaction gains and losses have been reflected as components of income and loss. Transaction gains and losses could be material depending upon changes in the exchange rates between the Australian dollar and the U.S. dollar. A significant amount of our current revenue is denominated in U.S. dollars which provides us with a limited natural hedge against exchange rate movements.

**Item 12. Description of Securities Other Than Equity Securities**

**Item 12.A Debt Securities**

Not applicable.

**Item 12.B Warrants and Rights**

Not applicable.

**Item 12.C Other Securities**

Not applicable

**Item 12.D American Depositary Shares**

Not applicable.