

GENETIC TECHNOLOGIES LTD  
Form 20-F  
October 29, 2014  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 20-F**

**REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**  
**For the fiscal year ended June 30, 2014**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

**SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR  
15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report . . . . .

For the transition period from to

Commission file number 0-51504

**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)

**Bronwyn M. Christie**

**Telephone: 011 61 3 8412 7056; Facsimile: 011 61 3 8412 7040**

**Email: Bronwyn.christie@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 30 Ordinary Shares  
and evidenced by American Depositary Receipts**  
Title of each Class

---

Table of Contents

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.

613,918,492 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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

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

---

Table of Contents

**TABLE OF CONTENTS**

<u>Item 1.</u>	<u>Identity of Directors, Senior Management and Advisers</u>	2
<u>Item 1.A</u>	<u>Directors and Senior Management</u>	2
<u>Item 1.B</u>	<u>Advisers</u>	4
<u>Item 1.C</u>	<u>Auditor</u>	4
<u>Item 2.</u>	<u>Offer Statistics And Expected Timetable</u>	4
<u>Item 3.</u>	<u>Key Information</u>	4
<u>Item 3.A</u>	<u>Selected Financial Data</u>	4
<u>Item 3.B</u>	<u>Capitalization and Indebtedness</u>	7
<u>Item 3.C</u>	<u>Reasons for the Offer and Use of Proceeds</u>	7
<u>Item 3.D</u>	<u>Risk Factors</u>	7
<u>Item 4.</u>	<u>Information on the Company</u>	16
<u>Item 4.A</u>	<u>History and Development of the Company</u>	16
<u>Item 4.B</u>	<u>Business Overview</u>	17
<u>Item 4.C</u>	<u>Corporate Structure</u>	43
<u>Item 4.D</u>	<u>Property, Plant and Equipment</u>	44
<u>Item 5.</u>	<u>Operating and Financial Review and Prospects</u>	44
<u>Item 5.A</u>	<u>Operating Results</u>	44
<u>Item 5.B</u>	<u>Liquidity and Capital Resources</u>	50
<u>Item 5.C</u>	<u>Research and Development, Patents and Licenses, etc.</u>	53
<u>Item 5.D</u>	<u>Trend Information</u>	53
<u>Item 5E.</u>	<u>Off-balance sheet arrangements</u>	54
<u>Item 5F.</u>	<u>Information about contractual obligations</u>	54
<u>Item 6.</u>	<u>Directors, Senior Management and Employees</u>	54
<u>Item 6.A</u>	<u>Directors and Senior Management</u>	54
<u>Item 6.B</u>	<u>Compensation</u>	57

Table of Contents

<u>Item 6.C</u>	<u>Board Practices</u>	64
<u>Item 6.D</u>	<u>Employees</u>	66
<u>Item 6.E</u>	<u>Share Ownership</u>	66
<u>Item 7.</u>	<u>Major Shareholders and Related Party Transactions</u>	67
<u>Item 7.A</u>	<u>Major Shareholders</u>	67
<u>Item 7.B</u>	<u>Related Party Transactions</u>	67
<u>Item 7.C</u>	<u>Interests of Experts and Counsel</u>	68
<u>Item 8.</u>	<u>Financial Information</u>	68
<u>Item 8.A</u>	<u>Consolidated Statements and Other Financial Information</u>	68
<u>Item 8.B</u>	<u>Significant Changes to Financial Information</u>	69
<u>Item 9.</u>	<u>The Offer and Listing</u>	72
<u>Item 9.A</u>	<u>Offer and Listing Details</u>	72
<u>Item 9.B</u>	<u>Plan of Distribution</u>	73
<u>Item 9.C</u>	<u>Markets</u>	73
<u>Item 9.D</u>	<u>Selling Shareholders</u>	73
<u>Item 9.E</u>	<u>Dilution</u>	73
<u>Item 9.F</u>	<u>Expenses of the Issue</u>	73
<u>Item 10.</u>	<u>Additional Information</u>	73
<u>Item 10.A</u>	<u>Share Capital</u>	73
<u>Item 10.B</u>	<u>Our Constitution</u>	76
<u>Item 10.C</u>	<u>Material Contracts</u>	77
<u>Item 10.D</u>	<u>Exchange Controls and Other Limitations Affecting Security Holders</u>	77
<u>Item 10.E</u>	<u>Taxation</u>	78
<u>Item 10.F</u>	<u>Dividends and Paying Agents</u>	83
<u>Item 10.G</u>	<u>Statement by Experts</u>	83
<u>Item 10.H</u>	<u>Documents on Display</u>	83
<u>Item 10.I</u>	<u>Subsidiary Information</u>	83
<u>Item 11.</u>	<u>Quantitative And Qualitative Disclosures About Market Risk</u>	83



Table of Contents

<u>Item 12.</u>	<u>Description Of Securities Other Than Equity Securities</u>	84
<u>Item 12.A</u>	<u>Debt Securities</u>	84
<u>Item 12.B</u>	<u>Warrants and Rights</u>	84
<u>Item 12.C</u>	<u>Other Securities</u>	84
<u>Item 12.D</u>	<u>American Depositary Shares</u>	84
<u>Item 13.</u>	<u>Defaults, Dividend Arrearages and Delinquencies</u>	85
<u>Item 14.</u>	<u>Material Modifications to The Rights Of Security Holders and Use Of Proceeds</u>	85
<u>Item 15.</u>	<u>Controls and Procedures</u>	85
<u>Item 15.A</u>	<u>Disclosure controls and procedures</u>	85
<u>Item 15.B</u>	<u>Management s annual report on internal control over financial reporting</u>	85
<u>Item 15.C</u>	<u>Attestation report of the registered public accounting firm</u>	86
<u>Item 15.D</u>	<u>Changes in internal control over financial reporting</u>	86
<u>Item 16.A</u>	<u>Audit Committee Financial Expert</u>	86
<u>Item 16.B</u>	<u>Code Of Ethics</u>	86
<u>Item 16.C</u>	<u>Principal Accountant Fees and Services</u>	87
<u>Item 16.D</u>	<u>Exemptions From The Listing Standards For Audit Committees</u>	88
<u>Item 16.E</u>	<u>Purchases Of Equity Securities By The Issuer And Affiliated Purchasers</u>	88
<u>Item 16.F</u>	<u>Change in Registrant s Certifying Accountant</u>	88
<u>Item 16.G</u>	<u>Corporate Governance</u>	88
<u>Item 16.H</u>	<u>Mine Safety Disclosure</u>	88
<u>Item 17.</u>	<u>Financial Statements</u>	88
<u>Item 18.</u>	<u>Financial Statements</u>	88
<u>Item 19.</u>	<u>Exhibits</u>	88



Table of Contents

**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 F48 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**

## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

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.

---

Table of Contents**PART I****Item 1. Identity of Directors, Senior Management and Advisers****Item 1.A Directors and Senior Management**

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

<b>Name</b>	<b>Position/Function</b>	<b>Business Address</b>
Dr. Malcolm R. Brandon	Non-Executive Chairman	60-66 Hanover Street Fitzroy Victoria 3065 Australia
David N. Carter	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Dr. Mervyn Cass	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Dr. Paul A. Kasian	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Grahame J. Leonard AM	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Prof. Ian F.C. McKenzie	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Dr. Lindsay P. Wakefield	Non-Executive Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia

Table of Contents

The members of Senior Management of the Company as of the date of this Annual Report are as follows:

Name	Position/Function	Business Address
Alison J. Mew	Chief Executive Officer	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Eutillio Buccilli	Chief Financial Officer	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Dr. Richard Allman	Scientific Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Diana Newport	Quality and Business Operations Director	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Luisa Ashdown	Director Global Licensing & IP	60-66 Hanover Street Fitzroy Victoria 3065 Australia
Mark J. Ostrowski	US Senior Vice President  Sales and Marketing  (Phenogen Sciences Inc.)	9115 Harris Corners Parkway Suite 320 Charlotte North Carolina 28269 USA

Table of Contents

**Item 1.B            Advisers**

Our principal bankers, accountants and legal advisers are as follows:

<b>Name of Adviser</b>	<b>Function</b>	<b>Business Address</b>
National Australia Bank Limited	Bankers - Australia	Level 2, 151 Rathdowne Street Carlton Victoria 3053 Australia
Bank of America, N.A.	Bankers - USA	155 Town Centre Drive Mooresville North Carolina 28117 USA
K&L Gates	General Counsel	525 Collins Street Melbourne Victoria 3000 Australia
Sheridan Ross PC	Licensing and Patent Attorneys	1560 Broadway, Suite 1200 Denver Colorado 80202-5141 USA
Greenberg Traurig, LLP	U.S. Securities Counsel	200 Park Avenue New York New York 10166 USA

**Item 1.C            Auditor**

The auditor of the Group's financial statements for the years ended June 30, 2014, 2013 and 2012 was PricewaterhouseCoopers, whose address is 2 Southbank Boulevard, Southbank, Victoria, 3006, Australia. PricewaterhouseCoopers is the Company's current independent registered public accounting firm, an appointment ratified at the Annual General Meeting held on November 25, 2009.

**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, 2014 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, 2014 and 2013 and the statement of comprehensive income/(loss) data for the 2014, 2013 and 2012 fiscal years are derived from our audited consolidated financial statements which are included in this Annual Report. Balance sheet data as of June 30, 2012, 2011 and 2010 and statement of comprehensive income/(loss) data for the 2011 and 2010 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.

Table of Contents

## GENETIC TECHNOLOGIES LIMITED

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)

## FOR 2014, 2013, 2012, 2011 AND 2010

	Year ended June 30, 2014 AUD	Year ended June 30, 2013 AUD	Year ended June 30, 2012 AUD	Year ended June 30, 2011 AUD	Year ended June 30, 2010 AUD
<b>Revenue from operations</b>					
Genetic testing services	4,564,280	3,377,183	3,691,215	4,594,960	4,915,528
Less: cost of sales	(1,837,729)	(1,945,467)	(1,948,625)	(2,034,916)	(2,722,975)
Gross profit from operations	2,726,551	1,431,716	1,742,590	2,560,044	2,192,553
Other revenue	979,879	5,002,354	3,136,406	13,680,741	3,739,747
Gain on deconsolidation of subsidiary	761,361		5,113,175		
Selling and marketing expenses	(6,251,595)	(5,266,818)	(4,384,184)	(3,018,947)	(2,679,979)
General and administrative expenses	(3,173,109)	(4,413,782)	(5,608,038)	(3,696,165)	(3,196,488)
Licensing, patent and legal costs	(1,079,199)	(2,399,824)	(1,267,838)	(4,097,323)	(3,923,102)
Laboratory, research and development costs	(3,298,127)	(3,462,466)	(4,029,369)	(4,380,866)	(6,258,871)
Finance costs	(744,199)	(38,968)	(45,217)	(81,934)	(100,422)
Share of net loss of associates accounted for using the equity method	(362,682)	(437,185)	(132,037)		
Fair value loss on financial liabilities at fair value through profit or loss	(648,374)				
Non-operating income and expenses	955,025	235,490	177,684	(85,771)	425,239
<b>Profit/(loss) from continuing operations before income tax</b>	(10,134,469)	(9,349,483)	(5,296,828)	879,779	(9,801,323)
Net profit from discontinued operation				21,562	446,114
<b>Profit/(loss) before income tax</b>	(10,134,469)	(9,349,483)	(5,296,828)	901,341	(9,355,209)
Income tax expense					
<b>Profit/(loss) for the year</b>	(10,134,469)	(9,349,483)	(5,296,828)	901,341	(9,355,209)
<b>Other comprehensive income/(loss)</b>					
Realized gain on sale of available-for-sale investments transferred from reserve					(170,000)
Exchange gains/(losses) on translation of controlled foreign operations	(149,162)	9,347	(6,818)	(85,079)	(8,623)
Exchange gains/(losses) on translation of non-controlled foreign operations	86	17,073	(296)	(11,585)	3,404
<b>Other comprehensive income/(loss) for the year, net of tax</b>	(149,076)	26,420	(7,114)	(96,664)	(175,219)
<b>Total comprehensive profit/(loss) for the year</b>	(10,283,545)	(9,323,063)	(5,303,942)	804,677	(9,530,428)
<b>Profit/(loss) for the year is attributable to:</b>					
Owners of Genetic Technologies Limited	(10,125,197)	(9,298,367)	(5,287,523)	910,002	(9,343,766)
Non-controlling interests	(9,272)	(51,116)	(9,305)	(8,661)	(11,443)
<b>Total profit/(loss) for the year</b>	(10,134,469)	(9,349,483)	(5,296,828)	901,341	(9,355,209)
<b>Total comprehensive profit/(loss) for the year is attributable to:</b>					
Owners of Genetic Technologies Limited	(10,274,359)	(9,289,020)	(5,294,341)	824,923	(9,522,389)
Non-controlling interests	(9,186)	(34,043)	(9,601)	(20,246)	(8,039)
<b>Total profit/(loss) for the year</b>	(10,283,545)	(9,323,063)	(5,303,942)	804,677	(9,530,428)





Table of Contents**GENETIC TECHNOLOGIES LIMITED****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS) (cont.)****FOR 2014, 2013, 2012, 2011 AND 2010**

	Year ended June 30, 2014 AUD	Year ended June 30, 2013 AUD	Year ended June 30, 2012 AUD	Year ended June 30, 2011 AUD	Year ended June 30, 2010 AUD
<b>Earnings/(loss) per share (cents per share)</b>					
Basic and diluted net profit/(loss) per ordinary share	(1.76)	(1.97)	(1.15)	0.22	(2.46)
Weighted-average shares outstanding	574,557,747	472,084,970	460,402,869	404,605,152	380,965,204

**GENETIC TECHNOLOGIES LIMITED****CONSOLIDATED BALANCE SHEET DATA  
FOR 2014, 2013, 2012, 2011 AND 2010**

	As of June 30, 2014 AUD	As of June 30, 2013 AUD	As of June 30, 2012 AUD	As of June 30, 2011 AUD	As of June 30, 2010 AUD
<b>Assets</b>					
Current assets	4,360,509	2,657,416	9,949,795	6,255,344	4,502,161
Non-current assets	2,368,690	5,662,111	6,491,956	2,667,010	3,777,411
Total assets	6,729,199	8,319,527	16,441,751	8,922,354	8,279,572
<b>Liabilities</b>					
Current liabilities	(2,318,016)	(2,465,016)	(1,930,568)	(2,025,629)	(2,478,943)
Non-current liabilities	(2,583,664)	(96,224)	(108,541)	(82,730)	(82,933)
Total liabilities	(4,901,680)	(2,561,240)	(2,039,109)	(2,108,359)	(2,561,876)
Net assets	1,827,519	5,758,287	14,402,642	6,813,995	5,717,696
<b>Equity</b>					
Contributed equity	90,080,492	83,735,845	83,280,142	72,378,105	72,378,105
Reserves	3,922,140	3,951,771	3,719,419	1,697,914	1,529,142
Accumulated losses	(92,175,113)	(82,049,916)	(72,751,549)	(67,464,026)	(68,374,028)
Non-controlling interests		120,587	154,630	202,002	184,477
Total equity	1,827,519	5,758,287	14,402,642	6,813,995	5,717,696

Table of Contents**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.

<b>Period ended</b>	<b>At period end USD</b>	<b>Average rate USD</b>	<b>High USD</b>	<b>Low USD</b>
<b>Yearly data</b>				
June 2010	0.8480	0.8820	0.9369	0.7751
June 2011	1.0732	0.9905	1.0732	0.8380
June 2012	1.0236	1.0323	1.1026	0.9453
June 2013	0.9165	1.0272	1.0591	0.9165
June 2014	0.9427	0.9186	0.9705	0.8715
<b>Monthly data</b>				
May 2014	0.9298	0.9305	0.9379	0.9215
June 2014	0.9427	0.9365	0.9430	0.9250
July 2014	0.9301	0.9389	0.9488	0.9301
August 2014	0.9344	0.9309	0.9488	0.9263
September 2014	0.8737	0.9042	0.9376	0.8737

**Item 3.B Capitalization and Indebtedness**

Not applicable.

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

Not applicable.

**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 Us**

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

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

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

Since our listing on the Australian Securities Exchange in August 2000, the price of our Ordinary Shares has ranged from a low of \$0.02 to a high of \$1.05 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.

Table of Contents

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:

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

We have never paid a cash dividend on our Ordinary Shares and we do not anticipate paying a cash dividend in the foreseeable future. We intend to retain future cash earnings, if any, for reinvestment in the development and expansion of our business. Whether we pay cash dividends in the future will be at the discretion of our Board of directors and may be dependent on our financial condition, results of operations, capital requirements and any other factors our Board of directors decides is relevant. As a result, an investor may only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock.

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

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

**Because we are not necessarily required to provide you with the same information as an issuer of securities based in the United States, you may not be afforded the same protection or information you would have if you had invested in a public corporation based in the United States.**

We are exempt from certain provisions of the Securities Exchange Act of 1934, as amended, commonly referred to as the Exchange Act, that are applicable to U.S. public companies, including (i) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K; (ii) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; and (iii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time. The exempt provisions would be available to you if you had invested in a U.S. corporation.

Table of Contents

However, in line with the Australian Securities Exchange regulations, we disclose our financial results on a semi-annual basis 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 also be disclosed to the Australian Securities Exchange and 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.

**NASDAQ notice.**

On September 3, 2014, the Company announced that it received a letter dated August 29, 2014, from the Nasdaq Stock Market notifying the Company that for the last 30 consecutive business days prior to August 28, the bid price for the Company's ordinary shares had closed below the minimum \$US1.00 per share requirement for continued inclusion under Nasdaq Marketplace Listing Rules (the Rules). The letter stated that in accordance with the Rules the Company has 180 calendar days, or until February 25, 2015, to regain compliance. Should the Company not regain compliance in the timeframe there may be the possibility of being delisted from the NASDAQ.

The issuance of such notices, by Nasdaq, are a matter of procedure, with the Company currently considering its position and the best course of action available in order to regain compliance.

**In certain circumstances, holders of ADRs 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 ADRs 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 ADRs. As a result, holders of ADRs 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. Up until the year ended June 30, 2011, we have incurred operating losses in every year of our existence. We incurred net losses of \$9,343,766 for year ended June 30, 2010, a net profit of \$910,002 for year ended June 30, 2011, net losses of \$5,287,523 for year ended June 30, 2012, net losses of \$9,298,367 for year ended June 30, 2013 and net losses of \$10,125,197 for year ended June 30, 2014. As of June 30, 2014, we have accumulated losses of \$92,175,113 and the extent of any future losses and whether or not the Company can generate profits remains uncertain.

**The Company's need for equity raising is essential for a going concern.**

During the 2014 financial year, the Company incurred a total comprehensive loss after income tax of \$10,283,545 (2013: \$9,323,063) and net cash outflows from operations of \$10,987,088 (2013: \$7,516,779).

As at June 30, 2014, the Company held cash reserves of \$2,831,085 and had net current assets of \$2,042,493.

Subsequent to balance sheet date, the Company has raised \$4,150,000, before the payment of associated costs, through:

- \$2,150,000 of new finance via the issue of unlisted secured (debt) notes to existing and new Australian institutional and wholesale investors; and
- \$2,000,000 from the sale of its Heritage Australian Genetics business. Whilst subject to conditions precedent the sale is expected to complete within the next month.

Table of Contents

As at the date of this Report, the Company held cash reserves of approximately \$1,395,000.

The cash raised from the above two transactions, combined with its existing cash reserves, will enable the Company to fund its operations in the short to medium term.

However, the continuing viability of the Company and the group's ability to continue as a going concern and meet its debts and commitments as and when they fall due is wholly dependent on the Company being successful in raising additional funds via the issuance of new equity in the near term. Any issuance of new equity will be subject to shareholder approval, which will be sought at the appropriate time.

Due to the significant uncertainty surrounding the timing and quantum of the above event, 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 realise its assets and discharge its liabilities in the normal course of business. However, the Directors believe that the Company will be successful in raising new funds, in the timeframe required, and accordingly, have prepared the financial report on a going concern basis.

If the Company is unable to raise sufficient funding in 2015 (the next fiscal year), it may be unable to continue to operate. There is no assurance that the Company will be successful in obtaining sufficient financing on acceptable terms and conditions to fund continuing operations, if at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue as a going concern.

**Risks Related to our Industry**

**Our sales cycle is typically lengthy.**

The sales cycle for our testing products and license generation is typically lengthy. As a result, we may expend substantial funds and management effort with no assurance of successfully selling our products or services or granting new licenses. Our ability to obtain customers for our genetic testing services depends significantly on the perception that our services can help accelerate efforts in genomics. The sales cycle is typically lengthy. 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. With respect to license generation, it is common for negotiations with licensees to take many months before a license is eventually granted. 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 limited 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 genetic testing services, or which otherwise address the needs of our customers and potential customers. Our competitors in the testing market include private and public sector enterprises located in Australia, the U.S. and elsewhere. Many of the organizations competing with us 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 current and potential competitors have greater name / brand recognition and more extensive collaborative relationships. However, because of our patents, we have virtually no competition in the licensing area.

Our competitive position in the genetic testing area is based upon, amongst other things, our ability to:

- create and maintain scientifically-advanced technology and offer proprietary products and services;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and services;
- obtain required government approvals and other accreditations on a timely basis; and
- successfully market our products and services.

If we are not successful in meeting these goals, our business could be adversely affected. Similarly, our competitors may succeed in developing technologies, products or services that are more effective than any that we are developing or that would render our technology and services obsolete, noncompetitive or uneconomical.

For a full discussion of competition see Item 4.B Competition .

Table of Contents

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

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to genetic technologies. We expect to aggressively patent and protect our proprietary technologies. However, we cannot be certain that any additional patents will be issued to us as a result of our domestic or foreign patent applications or that any of our patents will withstand challenges by others. Patents issued to, or licensed by, us may be infringed or third parties may independently develop the same or similar technologies. Similarly, our patents may not provide us with meaningful protection from competitors, including those who may pursue patents which may prevent, limit or interfere with our products or will 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 and technical resources from our operations and cause distraction to Management.

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

We have relationships with academic consultants and other advisers who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of 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 win those disputes.

**If we are unable to protect our proprietary assets, we may not be able to commercialize products or services.**

Our commercial success partially depends on our ability to obtain patent protection for many aspects of our business, including the products, methods and services we develop. Patents issued to us may not provide us with substantial protection or be commercially beneficial to us. The issuance of a patent is not conclusive as to its validity or its enforceability. In addition, our patent applications or those we have licensed, may not result in issued patents. If our patent applications do not result in issued patents, our competitors may obtain rights to commercialize our discoveries which could harm our competitive position. We also may apply for patent protection on novel genetic variations in known genes and their uses, as well as novel uses for previously identified genetic variations discovered by third parties. In the latter cases, we may need a license from the holder of the patent with respect to such genetic variations in order to make, use or sell any related products. We may not be able to acquire such licenses on terms acceptable to us, if at all.

Certain parties are attempting to rapidly identify and characterize genes and genetic variations through the use of sequencing and other technologies. To the extent that any patents are issued to other parties on such partial or full-length genes or genetic variations or uses for such genes or genetic variations, the risk increases that the sale of products or services developed by us or our collaborators may give rise to claims of patent infringement against us. Others may have filed and, in the future, are likely to file patent applications covering many genetic variations and their uses. Any such patent applications may have priority over our patent applications and could further require us to obtain rights to previously issued patents covering genetic variations. Any license that we may require under any such patent may not be made available to us on commercially acceptable terms, if at all.



Table of Contents

We may be sued for infringing on the intellectual property rights of others. We could also become involved in interference proceedings in the United States Patent and Trademark Office to determine the relative priority of our patents or patent applications and those of the other parties involved in the interference proceeding. Intellectual property proceedings are costly, and could affect our results of operations. These proceedings can also divert the attention of managerial and technical personnel. If we do not prevail in any intellectual property proceeding, in addition to any damages we might have to pay, we could be required to stop the infringing activity, or obtain a license to or design around the intellectual property in question. In interference proceedings, our patent rights could be invalidated and the scope of our patents could be limited. If we are unable to obtain licenses to intellectual property rights that we need to conduct our business, or are unable to design around any third party patent, we may be unable to sell some of our products, which will result in reduced revenue.

We have in the past and may in the future become a party to litigation involving patents and intellectual property rights. We have previously commenced litigation against a number of parties to protect our rights pertaining to our intellectual property. We may in the future receive claims of infringement of intellectual property rights from other parties. If we do not prevail in any future legal proceedings, we may be required to pay significant monetary damages. In addition, we could also be prevented from using certain processes or prevented from selling certain configurations of our products or services that were found to be within the scope of the patent claims. In the event we did not prevail in any future proceeding, we would either have to obtain licenses from the other party, avoid certain product configurations or modify some of our products, services and processes to design around the patents. Licenses could be costly or unavailable on commercially reasonable terms. Designing around patents or focusing efforts on different configurations could be time consuming, and we may have to remove some of our products or services from the market while we were completing redesigns. Accordingly, if we are unable to settle future intellectual property disputes through licensing or similar arrangements, or if any such future disputes are determined adversely to us, our ability to market and sell our products and services could be harmed. This would in turn reduce demands for our services and harm our financial condition and results of operations.

In addition, in order to protect or enforce our patent rights or to protect our ability to operate our business, we may need to initiate other patent litigation against third parties. These lawsuits could be expensive, take significant time to resolve, and could divert Management's attention from other business concerns. These lawsuits could result in the invalidation or limitation in the scope of our patents or forfeiture of the rights associated with our patents. We may not prevail in any such proceedings and a court may find damages or award other remedies in favor of our opposing party in any of these suits. During the course of any future proceedings, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

**We may be subject to professional liability suits and our insurance may not be sufficient to cover damages. If this occurs, our business and financial condition may be adversely affected.**

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of genetic tests. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to professional liability claims and possible adverse publicity. We may be subject to claims resulting from incorrect results of analysis of genetic variations or other screening tests performed using our services. Litigation of such claims could be costly. We could expend significant funds during any litigation proceeding brought against us. Further, if a court were to require us to pay damages to a plaintiff, the amount of such damages could significantly harm our financial condition. Although we have public and product liability insurance coverage under broadform liability and professional indemnity policies, for an aggregate amount of \$60,000,000, 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 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 and blood 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 samples and data from 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. We have never had a reportable serious injury through the date of this Annual Report.

Table of Contents

In addition, our collaborators and service providers may be working with these 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 patient samples that may contain viruses and hazardous 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 \$40,000,000, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. To date, we have not been subject to claims, or ultimately liability, in excess of the amount of our coverage. Our broadform insurance coverage also covers us against losses arising from an interruption of our business activities as a result of the mishandling of such materials. We also maintain workers' compensation insurance, which is mandatory in Australia, covering all of our workers in the event of injury.

**We depend on the collaborative efforts of our academic and corporate partners for research, development and commercialization of some of our products. A breach by our partners of their obligations, or the termination of the relationship, could deprive us of valuable resources and require additional investment of time and money.**

Our strategy for research, development and commercialization of some of our products has historically involved entering into various arrangements with academic and corporate partners and others. As a result, our strategy depends, in part, upon the success of these outside parties in performing their responsibilities. 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 us.

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 occurs, the progress of the Company could be adversely affected and our results of operations and financial condition could suffer.

**Problems associated with international business operations could affect our ability to license our technology and our results of operations.**

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

**Government regulation of genetic research or testing may adversely affect the demand for our services and impair our business and operations.**

From time to time, federal, state and/or local governments adopt regulations relating to the conduct of genetic research and genetic testing. In 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.

Table of Contents

**Gene Patenting Debate in Australia**

In 2008, the Australian Senate commenced an inquiry into the issues surrounding the patenting of genes. The inquiry was due to report its findings in early 2009. On September 30, 2010, the Senate re-referred the matter to the Senate Community Affairs Committee for inquiry and report. Having extended the timeline on several occasions, the Senate inquiry was then interrupted by an Australian Federal election in October 2010.

On November 26, 2010, the report arising from the Senate's inquiry into gene patents was released. It tabled 16 recommendations primarily aimed at making amendments to existing provisions of the Patents Act, while minimizing unforeseen consequences of changes to biotechnology sector, including the potential prohibition on patenting biological materials.

The Senate Report also noted a number of events that may affect further decisions, such as the Private Member's Bill that was introduced into the Federal Parliament. The Private Member's Bill was referred immediately to the Legal and Constitutional Affairs - Legislation Committee for inquiry and report by June 16, 2011. The Report also said the Committee heard conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective, and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology, research and development.

The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill) was introduced in the Lower House of the Australian Parliament on October 18, 2010. On November 26, 2010, the Senate referred the Bill to the Legal and Constitutional Affairs - Legislation Committee. The Committee received 122 submissions and held two public hearings for inquiry where 31 witnesses appeared at the public hearings. On September 22, 2011, the report arising from the Senate's inquiry into the Bill was released. It tabled only one recommendation: The Committee recommends that the Senate should not pass the Bill.

The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2012* was passed into law on March 20, 2012. This legislation does not ban or restrict patents on genetic material other than by raising the bar for the granting of any new patents.

*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 is the exclusive licensee of the BRCA patents in Australia (which includes the 004 patent).

This matter bears a resemblance to the U.S. litigation filed by the American Civil Liberties Union against Myriad's U.S. patent equivalent in which a U.S. 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 U.S. Court of Appeals for the Federal Circuit for reconsideration. On August 16, 2012, the U.S. Court of Appeals for the



## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

Federal Circuit ruled on the Myriad case in the U.S., upholding the patentability of gene patents.

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.

That decision was subsequently appealed by one of the plaintiffs on March 4, 2013. The Australian Federal Court again ruled in favor of Myriad Genetics on September 5th 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.

### **We rely on the services of individuals who possess special skills and experience.**

Much of the future success of the Company depends on the continued service and availability of skilled personnel, including members of its senior executive team, and those in technical, marketing and staff positions. While we actively recruit new employees with such skills and experience to reduce our reliance on these individuals, skilled personnel, with specific experience in the biotechnology industry, are in high demand and competition for their talents is intense.

Table of Contents

**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 results 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 revenues.

Although we are a leader in the field of genetics in Australia, we do not 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.

**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. A risk we face is that individuals or organizations in one or more of the countries in which these patents have issued could take legal action to seek their amendment, revocation or invalidation, something which has happened previously on several occasions in various jurisdictions, though we have prevailed in all such cases.

Furthermore, any time that we initiate legal action against parties that infringe our patents we face a risk that the infringer will defend itself through a counter-claim of patent invalidity or other such claims. Subsequent legal action could potentially overturn, invalidate or limit the scope of our patents.

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

For further information relevant to this subject, refer to the section entitled *Gene Patenting Debate in Australia* earlier in this section 3.D.

**Our genetic testing activities**

There is a view held by some elements of the medical and academic communities that the marketing of some of our cancer predisposition and risk assessment tests is done solely with a commercial objective in mind. In essence, some parties have indicated that, in their view, the risk of inheriting certain types of cancer is too low to warrant the marketing of genetic testing services to the wider cancer community where such promotion may increase anxiety unnecessarily. Guidelines laid down by the Australian National Health Medical Research Council also prevent us from promoting our testing in a manner which may cause any unnecessary alarm .

In recent years, health care payers as well as federal and state governments have focused on containing or reducing health care costs. We cannot predict the effect that any of these initiatives may have on our business. In particular, gene-based therapeutics, if successfully developed and commercialized, are likely to be costly compared to currently available drug therapies. Health care cost containment initiatives focused either on gene-based therapeutics or on genetic testing could result in the growth in the clinical market for genetic testing being curtailed or slowed. In addition, health care cost containment initiatives could also cause pharmaceutical companies to reduce research and development spending. In either case, our business and our operating results could be adversely affected. Further, genetic testing in clinical settings is often billed to third-party payers, including private insurers and governmental organizations. If our current and future clinical products and services are not considered cost-effective by these payers, reimbursement may not be available to users of our services. In this event, potential customers would be much less likely to use our services and our business and operating results could be harmed. Further, the amounts we receive in respect of the tests we perform may fall.

In regards to other medical tests we offer, increased competition from countries such as China and India is likely to make inroads to our marketplaces, offering lower priced tests which may decrease our profitability. Within Australia, the continued performance by public institutions of certain medical diagnostic tests also carries the risk that those institutions may acquire the latest generation of robotic test platforms which are able to perform tests at substantially lower costs. In some cases, these institutions are heavily subsidized by the government and therefore do not have the same commercial and amortization cost bases of a publicly listed company such as Genetic Technologies. As such, they may be able to offer tests at a lower price than we can offer them.

Table of Contents

**Launch of BREVAGenTM**

With the acquisition of our BREVAGenTM breast cancer risk assessment test in 2010 and its subsequent launch in June 2011, a number of potential commercial risks have been identified. The test exists in a new area of genetic testing, being a predictive test, and it will take time for us to establish credibility and educate the potential customer groups we have identified. This may result in a lag in establishing reasonable rates of sales which may be aggravated by any resistance associated with price sensitivity. Despite various studies and review publications, clinician adoption of the test on a regular basis requires substantial resources and effort.

Establishing a new U.S. company, such as we have done with Phenogen Sciences Inc., requires staffing with qualified and experienced salespeople and the identification of territories in which to start selling the test. These salespeople require time to establish customer contact and to convert sales. Invariably, some new employees are not able to adapt to the new sales environment and may need to be replaced after the first stage of selling, potentially hampering growth. Even though the Company's Australian laboratory has now been CLIA certified, U.S. government health care programs could potentially restrict our ability to offer the test in the U.S., thereby restricting our available market.

The U.S. healthcare reimbursement system with which we interact is highly complex, involving a series of independent insurers, together with the insured and other third parties involved to assist with credentialing and the administration of the payment processes. Establishing benchmarks with insurers is a time consuming process which could delay the receipt of initial payments until such time as rules with each provider can be established.

In October 2014 the BREVAGen breast cancer risk assessment test was modified to contain further genetic markers and greater ethnic coverage. The test was relaunched as BREVAGenplus®. The risks associated with the new version of the test remain essentially unchanged.

**Item 4. Information on the Company**

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

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

On October 15, 1999, the Company's corporate status was changed from a No Liability Company to a company limited by shares. On August 29, 2000, following the acquisition of Swiss company GeneType AG, we changed our name to Genetic Technologies Limited, which is our current name. At that time, we phased out our mining activities and became a biotechnology company, following which our stock exchange listing was duly transferred from the mining board of the ASX to the industrial board and our shares were thereafter classified under the industry group Health and Biotechnology, completing our transformation from a mining company into a biotechnology company. Our current activities in biotechnology primarily concentrate on three clearly defined areas of activity which are covered under Item 4.B Business Overview.

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

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

In July 2008, we acquired all of the issued shares of Frozen Puppies Dot Com Pty. Ltd. based in Calga, New South Wales, which was Australia's leading provider of canine reproductive services for a total consideration of \$1,550,097, comprising a combination of shares in the Company (with a value of \$1,041,667) and cash. During the year ended June 30, 2010, a decision was made by the Company to strategically realign its animal business and to focus on the provision of animal genetic tests, rather than the services that were acquired as part of the acquisition of the Frozen Puppies Dot Com business in 2008. Following the disposal of assets related to the reproductive services business during the 2011 financial year, the associated business was discontinued and, as a result, Frozen Puppies Dot Com Pty. Ltd. was subsequently deregistered on June 1, 2011.

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.

Table of Contents

**Item 4.B Business Overview**

We are a biotechnology company focused on expanding our genetic testing business in the Asia-Pacific region and, with the addition of the BREVA Gen™ breast cancer risk assessment test, in the U.S.A. and later in Europe. In addition, we are now pursuing commercial opportunities in other areas of activity:

- (i) out-licensing our non-coding patents globally; and
- (ii) supporting a late-stage research and development project in which we are already involved.

**Industry background**

The Human Genome Project announced (in April 2003) the completion of the first draft of the entire sequence of the human genome. The biotechnology industry has since worked to build upon the vast amount of knowledge generated by that program in order to develop a better understanding of the genetic basis of human health and disease. Increasingly, genetics is being shown to play a key role in the diagnosis and treatment of many diseases in humans, as well as diseases in animals and plants. This increasing understanding of genetics is providing new information for understanding such predisposing or causative factors in many diseases.

Prior to the Human Genome Project, the successful mapping of the Mouse Genome (published in December 2002) permitted, for the first time, a detailed comparison of human genes and mouse genes. One of the key findings that has arisen from this work is the significant role that non-coding DNA plays in controlling gene function in both human genes and mouse genes. For some scientists, but not for our Company, the discovery of the great significance of non-coding DNA to gene function were new, significant and totally unexpected.

A major focus in science is now the identification and analysis of genetic variations and disease-associated genes within the genome. These genetic variations, or polymorphisms, in the DNA sequences vary between individuals. The most common genetic variations are Single Nucleotide Polymorphisms, or SNPs, which are merely a difference in a single nucleotide. The first draft of the human genome identified over 1.4 million SNPs that can be useful as positional signposts for disease-associated DNA sequences in a gene or as markers to map genes along a chromosome. A significant number of these SNPs (perhaps more than 97%) are now known to be non-coding.

**Genomics**

A genome is an organism's complete set of DNA and the study of that DNA is called genomics. Genomes vary in size, with bacteria displaying the smallest known genome at 600,000 DNA base pairs, while human and mouse genomes have over 3 billion. The DNA of the human genome is organized into 24 distinct chromosomes that contain from 50 million to 250 million base pairs on each chromosome. The DNA on each

chromosome contains genes that are specific sequences that encode proteins that actually perform the work within a cell and also make up the cell itself. Surprisingly, only about 2% to 5% of the human genome is organized into coding DNA, with the remainder being considered to be non-coding DNA. The global patent portfolio on which our out-licensing activities is based is centered on proprietary methods for utilizing the valuable information contained within these non-coding regions.

### **Genetic variability**

Almost 99.9% of an individual's genome is identical to that of every other individual's genome. However, even slight variations in sequence can drastically change how a gene functions. Variations can lead to harmless changes, such as blue eyes instead of brown, or to major diseases such as cancer, cystic fibrosis, or cardiovascular disease. Genetic variations can also be responsible for many of the differences in the ways individuals respond to drug therapies. As a result of this knowledge, routine analysis of SNPs and other genetic variations is expected to play an increasingly important role in the discovery and development of new drugs, as well as in a variety of diagnostic therapeutic and other medical and life science applications. Industry sources estimate there are millions of genetic variations in the human genome, creating demand for products and technologies that can quickly and accurately detect and analyze these variations. It is thought that the medicine of the future will be dispensed to a patient based on his or her own specific DNA variations. This type of personalized medicine will require sophisticated genetic tests to determine the genetic composition of an individual, and it is now recognized that such genetic make-up depends not only on the form of the coding DNA, but also the form of the associated non-coding DNA.

### **Genetic tests**

Most genes come in many different forms, called alleles. One or more allele may be associated with a particular disease state. Genetic testing involves the direct examination of an individual's DNA for a DNA marker associated with the allele of interest. The determination of the particular alleles an individual has within his or her DNA is called genotyping.

Table of Contents

The most commonly tested marker of a particular allele is a SNP. As much as 98% of the human genome is considered to be non-coding DNA, the majority of the identified 1.4 million SNPs are also located in non-coding regions of DNA. We believe that a license to our proprietary methods of analyzing non-coding regions of DNA will be absolutely necessary for many of the genetic tests of the future. Similarly, tests for genetic abnormalities or mutations may involve not just individual SNPs, but also groups of SNPs or even larger sequences of DNA, and such abnormal sequences - large or small - may be located either in the coding region alone, or in the non-coding region alone, or in both the coding and non-coding regions of the gene (or genes) under examination. Clearly, the variations within genes that may be responsible for a disease are now known to be much more complicated than was previously understood, and the role of non-coding DNA is now being found to be highly relevant in a growing number of diseases. This similarly applies to genetic disorders in animals and plants. Accordingly, in future, more and more genetic testing will look not only at coding variations, but also at the non-coding variations within a particular gene.

**Building the Genetic Testing Business**

**Background and history of the paternity testing business**

In the early 1990 s, GeneType AG established a small service testing laboratory in Melbourne, Australia, initially to show-case its non-coding inventions, but also to generate revenue to help support and fund its ambitious research programs in those early days. Following the acquisition of several other small DNA testing laboratories in Australia, GeneType AG consolidated its genetic testing business such that the Company is now the largest provider of paternity and related testing services in Australia. Further, our service testing laboratory in Fitzroy (an inner suburb of Melbourne, Victoria) is the leading non-Government genetic testing service provider in Australia. We now have extensive experience in providing DNA-based individuality testing for the resolution of disputed paternity and the determination of familial relationships for immigration purposes.

The most common type of DNA testing is paternity testing - where we determine the father of a given child. In order to perform this test we take a sample from the mother, alleged father and child. The test can also be performed without the mother s sample but this makes the analysis somewhat more complex and the price for the test increases accordingly.

Other types of tests we can offer include:

- Y chromosome testing - determines if two males come from the same paternal line, i.e. have a common father or grandfather.
- Mitochondrial DNA testing - determines if two people come from the same maternal line.
- Sibship testing - determines if people are full siblings, i.e. have the same mother and father.



## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

- Maternity testing - determines the mother of a given child.
- DNA typing - reveals the DNA makeup of an individual.
- Grandparent analysis - determines the grandparents of a given child. This is mainly used when the father of a child is deceased and a will is being contested.
- Antenatal DNA testing - determines the father of an as-yet unborn child.

We issue reports for the Family Court in Australia and provide similar services internationally for the Department of Immigration and Citizenship ( DIAC ). We are one of only two DNA testing laboratories in Australia recognized by DIAC to provide DNA tests for immigration purposes.

Over time, we have gained a reputation as a leading genetic testing laboratory, and progressively, we have received specimens for testing from other countries, most of which are located in the Asia-Pacific region. In addition, we have received requests to perform tests outside of the area of human paternity which has led to the expansion of our testing services, as summarized below.

### **Expansion of testing services beyond paternity testing**

**(1) Medical testing** - the 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 ). This important area of testing has since gained momentum, with the addition of new equipment and new employees joining the Company.

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 has provided the Company with the ability to offer comprehensive testing services to its customer base in the Asia-Pacific region as well as increasing our exposure to other markets.

Table of Contents

In November 2004, the Company announced a strategic alliance with Australian biotechnology company Bionomics Limited for the commercialization of the diagnostic genetic test for the condition Severe Myoclonic Epilepsy in Infancy. This test was the first to expand the Company's human molecular diagnostics focus beyond cancer susceptibility testing. In July 2006, we further cemented our position as Australia's leading independent provider of complex genetic testing services with NATA granting further accreditation of our Melbourne laboratory to provide a wide range of complex genetic tests. Genetic analysis for the predisposition and diagnosis of a wide range of disease states is increasingly being used by clinicians in standard medical practice. We committed to providing the gold standard in testing technology, with superior turn-around times and a substantially more cost efficient service. Attainment of the further accreditation by NATA in the area of complex gene sequencing testing services has enabled various government funded genetics services to utilize the Company's testing service to improve patient care.

Having established an excellent laboratory service with significant excess capacity, the Company announced in July 2008 that a commercial decision had been made to enforce the rights granted to it under an exclusive license from Myriad to perform diagnostic testing of the BRCA1 and BRCA2 genes in Australia and New Zealand. However, following the removal of five Directors from the Board at the Company's Annual General Meeting on November 19, 2008, the new Board undertook a formal review of the Company's decision to enforce its BRCA testing rights and subsequently resolved to immediately revert to its original decision to allow other public laboratories in Australia to freely perform BRCA testing.

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. In November 2009, distribution agreements were executed with Trimgen and Rosetta Genomics of the U.S. to acquire distribution rights for their tests across Oceania. In addition to the current test portfolio, GTG began introducing itself to the global oncology market via regular attendance at international medical conferences and direct to market selling activities. An additional agreement to acquire local distribution rights from Response Genetics of the U.S. was then executed by the Company in January 2010.

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 GTG'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. 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 recognise 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 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 the formal certificate of qualification from CLEP. This approval allows the Company to test BREVAGenTM

## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

samples from residents of New York State (a densely populated state of nearly 20 million people) and completes the out of state licensures allowing the Company to provide testing services to all 50 U.S. states. Genetic Technologies' wholly-owned US subsidiary, Phenogen Sciences Inc., ( Phenogen ) has commenced appointing representatives to cover this state, with a particular emphasis on New York City.

### *Test samples received*

Since launching its BREVA Gen test in the US market in July 2011, the number of test samples received in each of the subsequent ten quarters has increased. The start of CY14 however, brought with it severe winter weather conditions across large tracts of the US and this restricted patient and physician physical access to medical centres and willingness to attend for anything other than urgent medical care. Further to this challenge, the holiday period coincided with the introduction of the Affordable Care Act, which created uncertainty in patients' understanding of their out-of-pocket expense liability that also restricted the uptake of BREVA Gen. As a result, the number of test samples received in the March 2014 quarter, was, for the first time since launch, lower than that of the previous quarter. In the following quarter, the company saw a return of patients to doctors' offices and improved preparedness to take preventative care decisions, resulting in a return to growth in BREVA Gen test samples received during the quarter ended June 30, 2014. Total patient samples received during the quarter were 1,096, representing 37% growth over the March 2014 quarter (800 samples).

Table of Contents

Total samples received for the year of 3,935 was more than double that received in the previous corresponding period, representing an increase of more than 150%, reinforcing the Company's decision to place increased focus on breast centres, radiology groups and high-population, health-conscious territories and this continued focused activity is anticipated to result in further growth over the coming quarters. Further, as a result of both increased test sample numbers and positive reimbursement changes since January 1, 2013, total sales revenue for the year increased by more than 400% over the previous corresponding period.

During the financial year ended June 30, 2012, the Company generated the first sales of its BREVAGentest. 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 BREVAGentests it performs.

In the current year, as a result of historical experience, the Company is able to estimate its revenue deductions and accordingly has recognized deferred revenue of \$446,000. Accordingly, we now recognize revenue on the BREVAGen test at the point of sale when we are able to estimate the transaction price. Historically, we recognized revenue for the BREVAGen test upon cash receipt as we did not have enough history or agreements signed with the insurers to make a reliable estimate of the contract price

*New York State*

On August 30, 2013, the Company announced that it had received its Clinical Laboratory Permit 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 US states. The Company is now able to meet requests received from New York physicians to provide the BREVAGen test to patients as part of their clinical practice and Phenogen Sciences Inc. (Genetic Technologies US subsidiary) has now appointed its first representative to cover this State, with a particular emphasis on New York City.

*Further expansion of the Company's credentialing program*

Credentialing with Preferred Provider Organisations ( PPOs ) allows for expedited claim adjudication as in-network . A PPO is a managed care organisation 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 organisations 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 .

During the year, the Company announced that, through Phenogen Sciences, it had executed a further agreement with InterWest Health to use the InterWest provider network. The execution of this agreement takes to eight the number of such PPO agreements that the Company has now entered into. As at the date of this Report, the cumulative total number of covered lives for which its BREVAGen risk assessment test could be adjudicated as in-network is more than 102 million.

## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

The positive impact of this activity has been demonstrated in reviewing reimbursement payments received in respect of the BREVA Gen test since its launch. 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.

Once in-network, the Company receives improved cash flow via faster payment while still obtaining an acceptable level of reimbursement and reducing the costs incurred through appealing denials. Once BREVA Gen sample volumes reach a significant level and Genetic Technologies has gathered the necessary additional clinical utility data, the Company intends to approach insurers directly to contract.

Credentialing contracts have now 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.

### *Reimbursement*

Up until the end of the 2012 calendar year, insurance claims for BREVA Gen 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.

Table of Contents

As a result of these changes, the Company now uses a Miscellaneous Code when submitting claims for reimbursement from insurers. As part of this transition, the list price for the BREVAGen 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 BREVAGen test under its Patient Protection Program.

Though the Company's reimbursement per test (including write-offs and denials for non-coverage) has increased by more than 30%, the use of a miscellaneous code requires more administration and time by the Insurance Company to adjudicate the claim and thus increasing the time taken to receive reimbursement.

*Cost effectiveness studies to improve reimbursement outcomes*

Further to the publication in the journal of Cancer Prevention Research, Vol 6 (12) dated December 5, 2013: pp 1328-36, demonstrating the cost effectiveness of the BREVAGen test to guide MRI screening, an additional paper has been published demonstrating the cost effectiveness of the BREVAGen test to direct chemoprevention.

On March 7, 2014, GTG announced the publication in the journal Applied Health Economics and Health Policy Vol 12 (2): pp 203-17, of a study entitled Economic Evaluation of Using a Genetic Test to Direct Breast Cancer Chemoprevention in White Women with a Previous Breast Biopsy. This study was a collaborative project between the Company and Archimedes Inc. of San Francisco, a healthcare modelling and analytics organization. The study examined the cost-effectiveness of utilizing BREVAGen to direct tamoxifen chemoprevention.

An in-silico model of breast cancer and health care processes was used to simulate a population of white women aged 40-69, who were at elevated risk for breast cancer due to a history of benign breast biopsy, in a virtual clinical trial. Women were assessed for risk of developing breast cancer using the BREVAGen test to determine eligibility for five years of tamoxifen therapy. The BREVAGen test was most cost-effective when given to patients at an intermediate risk of developing breast cancer (1.2 - 1.66% 5-year risk). The results demonstrated that adding genetic information about breast cancer susceptibility loci to current decision models for breast cancer chemoprevention not only improves clinical outcomes (with an average of 15 breast cancer cases prevented per 1,000 women), but is also cost-effective, with an incremental cost-effectiveness ratio below the benchmark number used by US payers of \$50,000 per quality-adjusted life year (QALY) saved.

Clinical utility studies are currently being designed and will be commenced during the latter part of 2014. The data obtained in these studies will be utilised in the direct contracting discussions with Insurers and self-insured employer groups.

*Further validation studies supporting BREVAGen*

The Company continues to actively progress research programs with leading international academic collaborators to confirm the utility of genomic risk assessment in other ethnic populations and to incorporate the full portfolio of currently known common breast cancer susceptibility variants into the BREVAGen test.

*New Product Development*

Planning is well progressed and the Company is on target to release BREVAGenplus in Q4, CY14. The new version of BREVAGen incorporates an expanded SNP (Single Nucleotide Polymorphism) panel, providing an increase in the predictive power of the test. Importantly, it will also be validated in Hispanic and African American women populations, thereby increasing the applicable market and simplifying the marketing process for BREVAGen in clinics and breast centres.

The launch of this next generation BREVAGen, is anticipated to result in accelerated sample test volume growth.

**(2) Animal testing** - in May 2003, we acquired the assets of Genetic Science Services to expand the range of tests we can offer to include relevant genetic testing in animals - for example, progeny testing in horses, dogs, deer, sexing in birds, and animal disease identification and susceptibility testing for a range of animals, including exotic and zoo animals. This acquisition also allowed the Company to support research projects involving other animals.

In addition to NATA accreditation for complex genetic analysis mentioned above, in 2006 GTG also received NATA accreditation for the provision of canine forensic analysis services. We are the only laboratory in Australia to receive such accreditation. This accreditation ensures that we will continue to be the laboratory of choice for all canine forensic analysis, especially where prosecutions are initiated for dog attacks. In the state of Victoria alone, there are in excess of 7,000 dog incidents reported annually. This accreditation, together with the recent announcement of a genetic test to determine the breed of dogs, places the Company in a strong position to provide genetic analysis services to local councils around Australia. During 2008, the Company launched its Dog Attack Pack, a forensic tool enabling local government officers to collect samples from dog attacks and BITSA, a breed identification test that uses DNA analysis to provide a history of a dog's breed.

Table of Contents

In July 2008, we acquired Frozen Puppies Dot Com Pty. Ltd., an Australian company specializing in canine reproductive services, following which the Company expanded its facilities into territories outside of Australia and developed relationships with breeders and associations in China, Japan, New Zealand and elsewhere. Staff were employed to manage the Company's activities in these territories and purpose-built facilities were established on the outskirts of Beijing, China and in several States of Australia. However, during the year ended June 30, 2010, a decision was made by the Company to strategically realign its animal business and to focus on the provision of animal genetic tests, rather than the services that were acquired as part of the acquisition of the Frozen Puppies Dot Com business in 2008. As a result, most of the centers and related assets were sold off and, following these disposals, Frozen Puppies Dot Com Pty. Ltd. was subsequently deregistered in June 2011.

In September 2009, GTG again won a tender for being the exclusive provider of genetic services to Greyhounds Australasia. At this time, the Company's animal business was re-launched through a new website; [www.animalnetwork.com.au](http://www.animalnetwork.com.au) which provides information on genetic tests, a database of breeder dog results supplied from GTG tests, services and the ability to order tests online.

By late 2009, the new strategy for GTG of focusing on genetic health started to impact the way resources would be used in the animal business. This change in strategic direction meant that many ad-hoc and small / infrequent volume animal tests were eliminated from the animal testing portfolio. A decision to focus solely on canine genetic tests meant an increase in establishing relationships with new channel partners. In the Veterinary market, Gribbles was appointed as the Company's exclusive distribution partner for Australia and New Zealand. In the animal welfare area, our relationship with Lort Smith Animal Hospital continued and additional relationships established with the Animal Welfare Leagues in New South Wales and South Australia and the New Zealand Kennel Club. Outside the main cities, distribution agreements were set up with ART in Rockhampton, Queensland.

**(3) Forensic testing** - recognizing the increasing use of DNA analysis in forensics and the demand this would place on existing government laboratories, in February 2004, the Company successfully gained forensics accreditation from the National Association of Testing Authorities, Australia (NATA). We were the first non-government laboratory in Australia to be awarded this accreditation. Since then, we have developed a highly efficient and technologically advanced forensics laboratory. This capability was substantially advanced by our recent non-coding licensing deal with Applera Corporation under which we secured equipment and supplies essential to conducting forensics analysis. Together with these resources and our experience in DNA analysis, the Company is becoming a major provider of DNA analysis services to the Australian forensics community.

In April 2006, we announced that we had been awarded a contract to supply the New South Wales (N.S.W.) Police Force with DNA analysis services, under which we provided services for an initial trial period of three months. Following this successful trial, we executed a three year contract with the NSW Police Force in January 2008 for DNA analysis services for their volume crime samples, such as burglary and motor vehicle theft. This contract represented a major breakthrough for the Company and was the first time in Australia that any Police Force had awarded a long-term contract to outsource the testing of their crime samples. The initial term of the contract with the NSW Police Force ended in January 2011. The contract has since expired in January 2013.

**(4) Plant testing** - in March 2002, we formed a joint venture with the Victorian State Government's Department of Primary Industry, for the purpose of providing a high throughput genotyping service for plant testing - in order to help plant breeders identify the genes responsible for the detection of commercially relevant traits, such as resistance to disease, accelerated growth and the improvement of crop yields. A new company, AgGenomics Pty. Ltd., was formed, with us as the majority shareholder and the State agency as the minority partner. After a number of years in business, AgGenomics Pty. Ltd. was deregistered on June 20, 2012.



**Australian heritage businesses**

The 2014 financial results for the Company's Australian genetic testing businesses exceeded budget expectations. These well-established heritage businesses, which comprise the provision of a wide range of medical, paternity, forensic and animal genetic tests, continued to maintain dominant positions in a number of their respective markets, despite some considerable price competition from several competitors.

*Sale of heritage Australian Genetics business*

On 22 September 2014, subsequent to balance date the Company announced that it had signed a binding contract of sale for its heritage Australian Genetics business ( Australian Genetics ) to Specialist Diagnostics Services Ltd ( SDS ), the wholly owned pathology subsidiary of Primary Health Care Ltd. The Australian Genetics business provides diagnostic and sequencing services encompassing Australia-only medical, forensic, paternity and animal genomic testing. Under the terms of sale, SDS will acquire the Australian Genetics business for \$2,000,000 in cash. Assuming all conditions are met, settlement of the transaction is expected to occur within the next month.

The divestment of the Australian Genetics business follows the Company's announcement on 15 September 2014, of plans to sell non-core assets and focus business activities on the US MDx market and commercialisation of the Company's lead breast cancer risk test BREVAGen.

Table of Contents

**Our Patent Portfolio**

The acquisition of GeneType AG in August 2000 gave our Company 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. We constantly review our patent portfolio 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. The major families of patents in the portfolio as of the date of this Annual Report include:

- (a) Intron Sequence Analysis;
- (b) Genomic Mapping;
- (c) Perlegen;
- (d) BREVAGen™;
- (e) Laboratory Techniques;
- (f) Ancestral Haplotypes;
- (g) Athletic Performance;
- (h) RareCollect Project.

(a) **The Intron Sequence Analysis patents** allow for the detection of specific motifs within the genetic material in the non-coding regions of DNA which have been shown may be linked to certain alleles or haplotypes within the coding region of the gene. In other words, whereas most geneticists previously looked at the genetic information located within the coding region alone, our inventions have provided a means of also looking at additional useful information which is located within the non-coding part of the gene, and which is now known to also be important in influencing gene function and, in particular, protein production. It is also now known that more than 100 human diseases are associated with genetic changes in the non-coding part of a particular gene and which are linked to the function of the coding part of that gene.

(b) **The Genomic Mapping patents** describe methods for analyzing genetic material collected from various selected populations to identify and locate genes and markers of interest, by identifying highly polymorphic sites throughout the genome and particular haplotypes associated with such sites, all based on a reading of sequence information in the non-coding portions of the genome.

(c) **The Perlegen patents** describe the family of patents that were acquired from Perlegen Sciences, Inc. that provide methods for discovering genetic associations to disease and which build on and augment the Genomic Mapping patents.

(d) **The BREVA Gen™ patents** describe a combination of method and product filings which describes a breast cancer risk assessment test based on both genetic and clinical factors to deliver an improved understanding of an individual's risk of contracting breast cancer.

(e) **The Laboratory Techniques patents** describe a method for identifying band positions in an electrophoretic separation by also including a control, which serves as an internal standard.

(f) **The Ancestral Haplotypes patents** describe a method for determining ancestral haplotypes using haplospecific geometric elements within the major histocompatibility complex multi-gene cluster and methods of genetic analysis involving the amplification of complimentary duplicons. These patents were acquired by the Company from the C.Y. O Connor ERADE Village Foundation in Western Australia.

(g) **The Athletic Performance patents** describe a method that enables aspects of athletic performance to be predicted based on detection of various forms of the alpha actinin 3 (ACTN3) gene. These patents were acquired from the University of Sydney in New South Wales.

(h) **The RareCollect Project patents** comprise a suite of patents, the older ones of which describe a novel and safe method for the isolation and collection of fetal cells from the peripheral blood of a pregnant woman, utilizing various HLA or other markers plus flow cytometry - all without any invasive procedure that might endanger the mother or the child. Together with more recent patents, these form the basis of the intellectual property associated with the RareCollect project.

The many issued, allowed and pending patents claimed by GeneType AG, and which are now owned by our Company, distinguish us from competitors by giving us the legal right to claim ownership of proprietary methods and compositions for analysis of DNA using information contained within non-coding regions and for the isolation of fetal cells. The methods and compositions for analysis of DNA may be used to identify a particular form of a gene or to map the location of a disease-associated gene.

Table of Contents

In total, we have 18 issued patents and 12 patent applications in the United States. Reflecting our international business strategy, we have also sought and been granted foreign patents by many other major industrialized nations, corresponding to each of the major patents already issued in the United States.

Generally, United States patents filed with the United States Patent Office prior to June 8, 1995 have a term of 17 years from the date of issuance, and 20 years from the application filing date or earlier claimed priority date in the case of patents issued from applications filed on or after June 8, 1995. For applications filed after May 29, 2000, the term is 20 years from the date of filing. A minimum term of 17 years is assured, provided the applicant causes no delays during prosecution. Patents in most other countries have a term of 20 years from the date of filing the patent application. Our issued United States patents began to expire in 2009. We intend to continue to file patent applications as we develop new products, technologies and patentable enhancements. Prosecution practices have been implemented to avoid any applicant delays that could compromise the 17-year minimum term. There can be no guarantee that such procedures will prevent the loss of a potential patent term. This is particularly true in the short-term as the patent rules implementing the most recent patent term changes are relatively new and untested.

Complex legal and factual determinations and evolving law make patent protection uncertain. As a result, we cannot be certain that patents will be issued from any of our pending patent applications or from applications licensed to us or that any issued patents will have sufficient breadth to offer meaningful protection. In addition, our issued patents may be successfully challenged, invalidated, circumvented or rendered unenforceable so that our patent rights would not create an effective competitive barrier. Moreover, the laws of some countries may not protect our proprietary rights to the same extent as do the United States patent laws.

In addition to patent protection, we rely on trade secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants are required to sign agreements to assign to us their interests in discoveries, inventions, patents, trademarks and copyrights arising from their work for us. They are also required to maintain the confidentiality of our intellectual property, and refrain from unfair competition with us during their employment and for a certain period of time after their employment with us, which includes solicitation of our employees and customers. We cannot be certain these agreements will not be breached or invalidated. In addition, third parties may independently discover or invent competing technologies or reverse engineer our trade secrets or other technologies.

In the future, we may become involved in lawsuits in which third parties file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technologies licensed to us, or our licensees, or whether those claims will hurt our business. We may be forced to defend against such claims, whether they are with or without merit or whether they are resolved in favor of or against our licensors or us and may face costly litigation and diversion of Management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technologies or enter into licensing agreements. These agreements may oblige us to accept costly terms, which could seriously limit the ability to conduct our operations and affect adversely our financial condition.

In addition, we may become involved in lawsuits in which third parties file claims asserting that one or more of our patents are invalid. We cannot predict whether third parties will assert such claims against us or against the licensees of such patents, or whether those claims will have an adverse impact on our business. We may be forced to defend against such claims, whether they are with or without merit or whether they are resolved in favor of or against our licensees or us and may face costly litigation and diversion of Management's attention.

## Edgar Filing: GENETIC TECHNOLOGIES LTD - Form 20-F

Historically, we have initiated legal proceedings against a number of companies, including Applera Corporation. On December 12, 2005, we announced the final settlement of our patent dispute with Applera, further to a settlement conference held in San Francisco, California. The parties executed a number of binding agreements, including a final Settlement Agreement plus license agreements and a supply agreement and, subsequently, they jointly applied to Northern California District Court requesting that all claims and counterclaims in the legal action be dismissed forthwith. The total value of the consideration receivable by us is approximately \$15 million, payable partly in cash and partly in kind, including agreements supplying the Company with certain Applera equipment, reagents and intellectual property rights.

Table of Contents

Our current patent portfolio is described below. Numbers refers to either provisional, application, publication or patent number.

	Country / region	Numbers	Granted	Pending
<b>INTRON SEQUENCE ANALYSIS</b>				
<b>Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes</b> Earliest priority August 25, 1989	Australia	AU654111	•	
		AU672519	•	
	Austria	AT144797	•	
	Belgium	EP414469	•	
	Canada	CA2023888	•	
	Denmark	DK414469	•	
	Europe	EP414469	•	
	France	EP414469	•	
	Germany	DE69029018	•	
		DD299319	•	
	Great Britain	EP414469	•	
	Greece	GR3022410	•	
	Hong Kong	HK1008053	•	
	Israel	IL95467	•	
	Italy	EP414469	•	
Japan	JP3206812	•		