

GENETIC TECHNOLOGIES LTD  
Form 20-F  
December 21, 2010  
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**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, 2010**

**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)

**Thomas G. Howitt**

**Telephone: 011 61 3 8412 7050; Facsimile: 011 61 3 8412 7040**

**Email: tom.howitt@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

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

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

404,605,152 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

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

Item 17  Item 18

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

Yes  No

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

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

Yes  No

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**INTRODUCTION**

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

Our consolidated financial statements are set out on pages F1 to F43 of this Annual Report (refer to Item 18 Financial Statements).

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

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

**FORWARD-LOOKING STATEMENTS**

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

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

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

**ENFORCEMENT OF LIABILITIES AND SERVICE OF PROCESS**

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

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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>                                    |
|------------------------|--------------------------|--|
| Sidney C. Hack         | Non-Executive Chairman   | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia |
| Tommaso Bonvino        | Non-Executive Director   | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia |
| Dr. Malcolm R. Brandon | Non-Executive Director   | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia |
| Huw D. Jones           | Non-Executive Director   | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia |

The members of Senior Management 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. Paul D.R. MacLeman | Chief Executive Officer  | 60-66 Hanover Street<br>Fitzroy Victoria 3065 |

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|                       |   |  |
|-----------------------|---|--|
|                       |   | Australia  |
| Thomas G. Howitt      | Chief Financial Officer and<br>Company Secretary  | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia                     |
| Alison J. Mew         | Chief Operating Officer                           | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia                     |
| Dr. David J. Sparling | Vice President<br>Legal and Corporate Development | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia                     |
| Gregory J. McPherson  | Vice President<br>Sales and Marketing             | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia                     |
| Ivan Jasenko          | Quality and Regulatory<br>Manager                 | 60-66 Hanover Street<br>Fitzroy Victoria 3065<br>Australia                     |
| Lewis J. Stuart       | General Manager<br>Phenogen Sciences Inc.         | 9115 Harris Corners Parkway Suite 320<br>Charlotte North Carolina 28269<br>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>  |
|------------------------------|--------------------------------|--|
| PricewaterhouseCoopers       | Auditors                       | 2 Southbank Boulevard<br>Southbank Victoria 3006<br>Australia  |
| Westpac Banking Corporation  | Bankers - Australia            | 530 Collins Street<br>Melbourne Victoria 3000<br>Australia     |
| KeyBank National Association | Bankers - USA                  | 1130 Haxton Drive<br>Fort Collins Colorado 80525<br>USA        |
| Bank of America, N.A.        | Bankers - USA                  | 155 Town Centre Drive<br>Charlotte North Carolina 28117<br>USA |
| Baker & McKenzie             | General Counsel                | 181 William Street<br>Melbourne Victoria 3000<br>Australia     |
| Sheridan Ross PC             | Licensing and Patent Attorneys | 1560 Broadway, Suite 1200<br>Denver Colorado 80202-5141<br>USA |
| Greenberg Traurig, LLP       | U.S. Securities Counsel        | 200 Park Avenue<br>New York New York 10166<br>USA              |

**Item 1.C Auditor**

The auditor of the Group's financial statements for the year ended June 30, 2010 was PricewaterhouseCoopers, whose address is 2 Southbank Boulevard, Southbank, Victoria, 3006, Australia. The auditor of the Group's financial statements for the years ended June 30, 2009, 2008, 2007 and 2006 was Ernst & Young, whose address is 8 Exhibition Street, Melbourne, Victoria, 3000, 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, 2010 is derived from the audited consolidated financial statements of Genetic Technologies Limited, prepared in accordance with International Financial Reporting Standards (IFRS) which became effective for our company as of our fiscal year ended June 30, 2006. Under IFRS 1 *First-time Adoption of International Financial Reporting Standards*, or IFRS 1, a company adopting IFRS for the first time is required to adopt accounting policies that comply with IFRS and related interpretations that are in effect at the reporting date of its first annual financial statements prepared in accordance with IFRS, in our case June 30, 2006.

The balance sheet data as of June 30, 2010 and 2009 and the statement of comprehensive income data for the fiscal years 2010, 2009 and 2008 are derived from our audited consolidated financial statements included in this Annual Report. Balance sheet data as of June 30, 2008, 2007 and 2006 and statement of comprehensive income data for the 2007 and 2006 financial years are derived from our audited consolidated financial statements which are not included in this Annual Report. The data should be read in conjunction with the consolidated financial statements, related notes and other financial information included herein.

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

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## GENETIC TECHNOLOGIES LIMITED

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

FOR 2010, 2009, 2008, 2007 AND 2006

|  | Year ended<br>June 30, 2010<br>AUD | Year ended<br>June 30, 2009<br>AUD | Year ended<br>June 30, 2008<br>AUD | Year ended<br>June 30, 2007<br>AUD | Year ended<br>June 30, 2006<br>AUD |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| <b>Revenue from operations</b>   |                                    |                                    |                                    |                                    |                                    |
| Genetic testing services   | 4,915,528                          | 4,599,286                          | 3,918,692                          | 3,119,131                          | 2,550,221                          |
| Reproductive services  | 890,030                            | 782,803                            |                                    |                                    |                                    |
| Total revenue from operations  | 5,805,558                          | 5,382,089                          | 3,918,692                          | 3,119,131                          | 2,550,221                          |
| Less: cost of sales  | (2,716,657)                        | (2,203,839)                        |                                    |                                    |                                    |
| Gross profit from operations   | 3,088,901                          | 3,178,250                          | 3,918,692                          | 3,119,131                          | 2,550,221                          |
| Other revenue  | 3,951,178                          | 6,012,014                          | 11,689,120                         | 11,595,297                         | 7,407,982                          |
| Other income   | 213,808                            | 787,529                            | 276,606                            | 340,486                            | 708,411                            |
| Employee benefits expenses   | (5,945,605)                        | (6,439,549)                        | (6,568,966)                        | (5,556,644)                        | (5,432,506)                        |
| Amortization and depreciation expenses   | (3,706,330)                        | (3,987,996)                        | (4,755,155)                        | (4,602,992)                        | (4,817,277)                        |
| Impairment losses and other write-downs  | (1,786,533)                        | (318,025)                          | (2,378,000)                        | (1,306,960)                        | (97,500)                           |
| Legal and patent fees  | (1,257,145)                        | (1,386,393)                        | (873,854)                          | (748,605)                          | (1,440,929)                        |
| Administration expenses  | (979,006)                          | (1,304,682)                        | (839,226)                          | (901,380)                          | (910,776)                          |
| Rent and outgoings   | (718,593)                          | (584,980)                          | (533,644)                          | (535,045)                          | (511,050)                          |
| Royalties, license fees and commissions paid                                     | (399,318)                          | (354,684)                          | (889,520)                          | (580,122)                          | (177,283)                          |
| Other laboratory and veterinary expenses   | (357,464)                          | (748,254)                          | (1,599,644)                        | (1,989,098)                        | (2,008,546)                        |
| Marketing and promotion expenses   | (340,630)                          | (272,726)                          | (221,644)                          | (437,087)                          | (502,353)                          |
| Finance costs  | (100,422)                          | (89,499)                           | (66,763)                           | (90,929)                           | (112,082)                          |
| Contract research and trial expenses   | (90,000)                           | (1,209,260)                        | (1,267,748)                        | (1,247,775)                        | (1,345,916)                        |
| Net foreign exchange losses  |                                    |                                    | (254,954)                          | (317,317)                          |                                    |
| Net other expenses   | (928,050)                          | (1,140,066)                        | (1,086,938)                        | (1,086,662)                        | (1,218,519)                        |
| <b>Loss before income tax</b>  | <b>(9,355,209)</b>                 | <b>(7,858,321)</b>                 | <b>(5,451,638)</b>                 | <b>(4,345,702)</b>                 | <b>(7,908,123)</b>                 |
| Income tax expense   |                                    |                                    |                                    |                                    |                                    |
| <b>Loss for the year</b>   | <b>(9,355,209)</b>                 | <b>(7,858,321)</b>                 | <b>(5,451,638)</b>                 | <b>(4,345,702)</b>                 | <b>(7,908,123)</b>                 |
| <b>Other comprehensive income/(loss)</b>   |                                    |                                    |                                    |                                    |                                    |
| Realized gain on sale of available-for-sale investments transferred from reserve | (170,000)                          |                                    |                                    |                                    |                                    |
| Unrealized gain on available-for-sale investments                                |                                    | 170,000                            |                                    |                                    |                                    |
| Exchange gains/(losses) on translation of controlled foreign operations          | (8,623)                            | (13,408)                           | (32,624)                           | (38,535)                           | 26,548                             |
| Exchange gains/(losses) on translation of non-controlled foreign operations      | 3,404                              | 6,133                              | (9,161)                            | (12,999)                           |                                    |
| <b>Other comprehensive income/(loss) for the year, net of tax</b>                | <b>(175,219)</b>                   | <b>162,725</b>                     | <b>(41,785)</b>                    | <b>(51,534)</b>                    | <b>26,548</b>                      |
| <b>Total comprehensive loss for the year</b>                                     | <b>(9,530,428)</b>                 | <b>(7,695,596)</b>                 | <b>(5,493,423)</b>                 | <b>(4,397,236)</b>                 | <b>(7,881,575)</b>                 |
| <b>Loss for the year is attributable to:</b>                                     |                                    |                                    |                                    |                                    |                                    |
| Owners of Genetic Technologies Limited   | (9,343,766)                        | (7,841,073)                        | (5,446,089)                        | (4,328,543)                        | (7,918,773)                        |
| Non-controlling interests  | (11,443)                           | (17,248)                           | (5,549)                            | (17,159)                           | 10,650                             |
| <b>Total loss for the year</b>   | <b>(9,355,209)</b>                 | <b>(7,858,321)</b>                 | <b>(5,451,638)</b>                 | <b>(4,345,702)</b>                 | <b>(7,908,123)</b>                 |



**Total comprehensive loss for the year is attributable to:**

|  |                    |                    |                    |                    |                    |
|--|--------------------|--------------------|--------------------|--------------------|--------------------|
| Owners of Genetic Technologies Limited | (9,522,389)        | (7,684,481)        | (5,478,713)        | (4,367,078)        | (7,892,225)        |
| Non-controlling interests              | (8,039)            | (11,115)           | (14,710)           | (30,158)           | 10,650             |
| <b>Total loss for the year</b>         | <b>(9,530,428)</b> | <b>(7,695,596)</b> | <b>(5,493,423)</b> | <b>(4,397,236)</b> | <b>(7,881,575)</b> |

Table of Contents**GENETIC TECHNOLOGIES LIMITED****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (cont.)****FOR 2010, 2009, 2008, 2007 AND 2006**

|   | Year ended<br>June 30, 2010<br>AUD | Year ended<br>June 30, 2009<br>AUD | Year ended<br>June 30, 2008<br>AUD | Year ended<br>June 30, 2007<br>AUD | Year ended<br>June 30, 2006<br>AUD |
|---|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| <b>Loss per share (cents per share)</b>       |                                    |                                    |                                    |                                    |                                    |
| Basic and diluted net loss per ordinary share | (2.5)                              | (2.1)                              | (2.1)                              | (1.5)                              | (1.2)                              |
| Weighted-average shares outstanding           | 380,965,204                        | 373,906,149                        | 373,906,149                        | 362,389,899                        | 362,389,899                        |

Note: Refer Item 8D in respect of changes to the presentation of these financial statements relating to the disclosure of cost of sales data.

**GENETIC TECHNOLOGIES LIMITED****CONSOLIDATED BALANCE SHEET DATA  
FOR 2010, 2009, 2008, 2007 AND 2006**

|                            | Year ended<br>June 30, 2010<br>AUD | Year ended<br>June 30, 2009<br>AUD | Year ended<br>June 30, 2008<br>AUD | Year ended<br>June 30, 2007<br>AUD | Year ended<br>June 30, 2006<br>AUD |
|----------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| <b>Assets</b>              |                                    |                                    |                                    |                                    |                                    |
| Current assets             | 4,502,161                          | 10,103,166                         | 15,893,852                         | 14,600,846                         | 13,960,666                         |
| Non-current assets         | 3,777,411                          | 7,874,565                          | 8,200,726                          | 14,848,181                         | 19,756,241                         |
| Total assets               | 8,279,572                          | 17,977,731                         | 24,094,578                         | 29,449,027                         | 33,716,907                         |
| <b>Liabilities</b>         |                                    |                                    |                                    |                                    |                                    |
| Current liabilities        | (2,478,943)                        | (3,779,385)                        | (3,047,002)                        | (3,248,763)                        | (2,946,212)                        |
| Non-current liabilities    | (82,933)                           | (86,301)                           | (262,503)                          | (97,455)                           | (528,556)                          |
| Total liabilities          | (2,561,876)                        | (3,865,686)                        | (3,309,505)                        | (3,346,218)                        | (3,474,768)                        |
| Net assets                 | 5,717,696                          | 14,112,045                         | 20,785,073                         | 26,102,809                         | 30,242,139                         |
| <b>Shareholders equity</b> |                                    |                                    |                                    |                                    |                                    |
| Contributed equity         | 72,378,105                         | 71,285,663                         | 70,243,996                         | 70,243,996                         | 70,243,996                         |
| Reserves                   | 1,529,142                          | 1,701,899                          | 1,588,804                          | 1,456,895                          | 1,237,524                          |
| Accumulated losses         | (68,374,028)                       | (59,030,262)                       | (51,189,189)                       | (45,743,100)                       | (41,414,557)                       |
| Minority interests         | 184,477                            | 154,745                            | 141,462                            | 145,018                            | 175,176                            |
| Total shareholders equity  | 5,717,696                          | 14,112,045                         | 20,785,073                         | 26,102,809                         | 30,242,139                         |



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</b> | <b>Average rate</b> | <b>High</b> | <b>Low</b> |
|----------------------|----------------------|---------------------|-------------|------------|
| <b>Yearly data</b>   |                      |                     |             |            |
| June 2006            | 0.7423               | 0.7475              | 0.7781      | 0.7056     |
| June 2007            | 0.8491               | 0.7899              | 0.8491      | 0.7407     |
| June 2008            | 0.9562               | 0.8965              | 0.9644      | 0.7672     |
| June 2009            | 0.8055               | 0.7513              | 0.9797      | 0.6073     |
| June 2010            | 0.8480               | 0.8820              | 0.9369      | 0.7751     |
| <b>Monthly data</b>  |                      |                     |             |            |
| June 2010            | 0.8480               | 0.8539              | 0.8818      | 0.8192     |
| July 2010            | 0.9051               | 0.8786              | 0.9051      | 0.8380     |
| August 2010          | 0.8910               | 0.9004              | 0.9170      | 0.8807     |
| September 2010       | 0.9640               | 0.9398              | 0.9714      | 0.9093     |
| October 2010         | 0.9796               | 0.9811              | 0.9943      | 0.9666     |
| November 2010        | 0.9607               | 0.9889              | 1.0143      | 0.9594     |
| December 2010 (note) | 0.9930               | 0.9850              | 0.9974      | 0.9675     |

Note: Data for the month of December 2010 covers the period up to December 16, 2010.

**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 market;
- 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.

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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 not within our control and general market conditions affecting the biotechnology sector or the stock market generally. The most significant such event of which we have knowledge took place in August 2003 after a television report in Australia on our company was broadcast. During that week, the price of our shares increased from \$0.58 to \$0.87 on a volume of 26,000,000 shares traded, which was exceptionally high for us. The share price subsequently retreated.

In addition, low trading volume may increase the volatility of the price of our ADSs. Trading volume in our Ordinary Shares on other markets has not been historically high, and the trading volume of our ADSs on the NASDAQ Global / Capital Markets has typically also been low. Further, because each of our ADSs represents 30 of our Ordinary Shares, trading volume in our ADSs is lower than that for our Ordinary Shares. 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.

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

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

However, in line with the Australian Securities Exchange regulations, we will disclose our semi-annual results which, in accordance with Australian auditing standards, are required to have a limited review semi-annually and be fully audited annually. The information, which may have an effect on the 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.

**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 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 which is now called Genetic Technologies Limited was founded in 1989. We have incurred operating losses in every year of our existence. We incurred net losses of \$7,918,773 for the year ended June 30, 2006, net losses of \$4,328,543 for year ended June 30, 2007, net losses of \$5,446,089 for year ended June 30, 2008, net losses of \$7,841,073 for year ended June 30, 2009 and net losses of \$9,343,766 for year ended June 30, 2010. As of June 30, 2010, we have accumulated losses of \$68,374,028. As of June 30, 2010, the extent of future losses and the time required to achieve profitability remains uncertain.

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**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 more effective products, the results from our operations and financial condition could be affected.**

We are 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 that 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 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 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 testing and reproductive services area is based upon 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 .

**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 either 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 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.

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**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.

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 possibly 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.

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**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 and data on patient samples. If we, our collaborators or service providers fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict our operations. We have never had a reportable serious injury through the date of this Annual Report.

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 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.

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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 collaborative arrangements in the future and, if negotiated, we have no certainty that they will be on favorable terms or will be successful. In addition, our collaborative 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.**

Apart from accreditation requirements, we are generally not subject to regulation. Federal, state and local governments, however, may adopt regulations relating to the conduct of genetic research and genetic testing. These regulations could limit or restrict genetic research activities as well as genetic testing for research or clinical purposes. In addition, if state and local regulations are adopted, these regulations may be inconsistent with, or in conflict with, regulations adopted by other state or local governments. 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.

In Australia, there is no law that prohibits the performing of a paternity test by using just a sample obtained from a father and child. In May 2003, the Australian Law Reform Commission (ALRC) released its report into Human Genetic Testing in Australia. In relation to paternity testing, it made various recommendations, the most significant of which was that the testing of a child without the knowledge or consent of both parents should be made illegal. In December 2005, the Australian Government formally responded to the ALRC report. Although it accepted most of the report's recommendations, it did not accept its recommendation that it should be illegal to test a child without the knowledge or consent of both parents. Instead, it recommended that the body that formally accredits laboratories, National Association of Testing Authorities (NATA) should review its accreditation requirements for DNA parentage testing to ensure that laboratories meet the highest technical and ethical standards, particularly in relation to consent to testing, protecting the integrity of genetic samples, and providing information about counselling. As of the date of this Annual Report, NATA has made no recommendation in relation to the Government's recommendation.



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

In November 2008, the Federal Government released a discussion paper on non-consensual genetic testing in which it is proposed that such testing be made illegal. The purpose of this paper is to obtain feedback from the public and industry on this issue prior to formulating legislation in this area. In the area of paternity testing, the paper discusses the issue of consent but makes no recommendation as to what the required consent for taking a sample from a child would be. For example, does this require the consent of both parents or just one? If the testing of a sample eventually requires the consent of both parents, then this will have a negative impact on our revenue as father/child testing is a substantial and growing market.

Responses to the discussion paper were submitted by the end of January 2009. It is not known how long the Government will take to consider these submissions nor its timeframe to draft and then pass any proposed legislation. If passed, this legislation will immediately become law in the Australian Capital Territory and the Northern Territory. All other States would then be required to pass mirror legislation but are under no obligation to do so. It is not clear how long it would take the States to pass this legislation.

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**Gene Patenting Debate in Australia – recent developments**

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. Having extended the timeline on several occasions, the Senate inquiry was then interrupted by an Australian Federal election in October 2010. On September 30, 2010, the Senate re-referred the matter to the Senate Community Affairs Committee for inquiry and report.

On November 25, 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 Bill was referred immediately to the Legal and Constitutional Affairs Legislation Committee for inquiry and report by June 16, 2011.

The Report also said that 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 Patent Amendment (Human Genes and Biological Materials) Bill 2010* was introduced in the Lower House of the Australian Parliament on October 18, 2010. The Bill will now be reviewed by the Legal and Constitutional Affairs - Legislation Committee. The Government's response is expected to be received early in calendar 2011. The same Bill, sponsored by Peter Dutton MP and Rob Oakeshott MP, will be introduced in the House of Representatives in February 2011.

*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 striking resemblance to the US litigation filed by the American Civil Liberties Union against Myriad's US patent equivalent in which, during March 2010, a US Federal District Court ruled that isolated DNA sequences are not eligible for patent protection because of the fact that they are derived from natural sources. Myriad has since filed an appeal against the decision.

**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.

**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.

**Licensing**

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 previously happened on several occasions in various jurisdictions, though we have prevailed in all such cases.

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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 Act 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.

During the 2008 calendar year, a Senate Inquiry into matters relating to the granting of patents in Australia over human and microbial genes and non-coding sequences was initiated by the Australian Federal Government. Along with more than 50 other parties representing a wide variety of interested groups, the Company lodged a formal submission to the Inquiry. As of the date of this Report, the final date for the lodging of submissions has passed and the Senate is receiving those which have been lodged ahead of making its recommendations in the 2011 calendar year. Irrespective of the outcome of the Inquiry, the Company anticipates that it will have little, if any, material impact on the Company's business. Refer above for further discussion on the debate surrounding the patenting of genes in Australia.

**Genetic testing**

There is a risk that a moratorium on genetic testing by the Australian Institute of Sport may impact on the commercialization of our sports performance genetic test for the elite competitor market in Australia. However, this moratorium should not impact our ability to distribute this test throughout the rest of the world. There is also a view held by some elements of the medical and academic communities that the marketing of some of our cancer predisposition 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 payors 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 payors, including private insurers and governmental organizations. If our current and future clinical products and services are not considered cost-effective by these payors, 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.

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 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.

#### **Launch of BREVAGenTM**

With the acquisition and proposed launch of our BREVAGenTM breast cancer test, a number of risks have been identified. The test exists in a new area of genetic testing, being a prognostic test, and it may take time for us to establish credibility and educate the various potential customer groups we have identified. This may result in a lag in establishing reasonable rates of sales which may be aggravated by resistance associated with price sensitivity. Despite various studies and review publications, clinician adoption of the test on a regular basis will require substantial resources and effort. Establishing a new U.S. company will require staffing with salespeople and identification of territories in which to start selling the test. These salespeople will require time to establish customer contact and convert sales. The approval of our Australian laboratory as the core testing facility for the BREVAGenTM test is still dependent on us receiving CLIA approval and without it, we are unable to sell the test in the U.S. marketplace. Alternate plans are in place if such approval is not received but this would delay the proposed timing of the launch. Even with CLIA approval being given to our Australian laboratory, U.S. government health care programs could restrict our ability to offer the test in the U.S., thereby restricting our available market.

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**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. 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 type of company was changed from a No Liability Company to a company limited by shares. On August 29, 2000, we changed our name to Genetic Technologies Limited, which is our current name. We were originally incorporated as a mining company and gradually phased out our mining activities and became a biotechnology company with the acquisition of GeneType AG in August 2000. 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 Australian Securities Exchange Listing Rules, the Marketplace Rules of NASDAQ and, where applicable, local legislation.

Since the acquisition of GeneType AG, the directors have disposed of all remaining mining interests so that our activities now focus solely on emerging opportunities in the field of biotechnology. Our current activities in biotechnology primarily concentrate on three clearly defined areas of activity which are covered under Item 4.B Business Overview .

Our registered office, headquarters, laboratory and business activities 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). Information on our website and websites linked to it does not constitute part of this Annual Report.

On August 29, 2000, we acquired 100% of GeneType AG, including all of its valuable patents, and we changed our focus exclusively to the area of biotechnology. We also changed our name to Genetic Technologies Limited to better reflect our new business. In September 2000, our 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 and resources company into a biotechnology company. During 2001, we also acquired 10% of the issued and outstanding shares in Cytomation Inc., based in Fort Collins, Colorado. At that time, Cytomation was a leader in the manufacture and sales of flow cytometers and cell sorters. Also, in December 2001, we acquired an initial shareholding of less than 1% in the issued capital of XY, Inc., a company also based in Fort Collins. In July 2001, we acquired the business of DNA-ID Labs in Perth, Western Australia, as part of our strategy of expanding our paternity testing business in Australia. In March 2002, we formed AgGenomics Pty. Ltd., based in Melbourne, in order to expand our genetic testing services into the field of plant genetics. In May 2003, we acquired the fixed assets of the business Genetic Science Services in Melbourne, in order to further expand into the field of genetic testing. In May 2007, we sold all of our shares in XY, Inc. The total proceeds received from the sale were \$332,709 which resulted in a loss on sale of \$33,307.

In July 2008, we acquired all of the issued shares of Frozen Puppies Dot Com Pty. Ltd. based in Calga, New South Wales, which is 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.

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 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 will be licensed to sell the BREVAGen test, and in future other tests, in the U.S. marketplace.

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In early calendar year 2002, we commenced the process of out-licensing our non-coding patents, announcing several early successes. Since then, we have granted commercial licenses to a total of 47 licensees and 6 research licenses to the following parties, which are listed in reverse chronological order of their effective dates:

**Commercial licensees**

47. Pioneer Hi-Bred International Inc., **USA**
46. Innogenetics NV (medical diagnostic products), **Belgium**
45. Laboratoires Réunis, **Luxembourg**
44. Interleukin Genetics Inc., **USA**
43. Beckman Coulter Inc. / Clinical Data Inc., **USA**
42. Monsanto Company (cattle genetics) **USA**
41. Molecular Pathology Laboratory Network Inc., **USA**
40. EraGen Inc., **USA**
39. Gen-Probe Inc., **USA**
38. TIB MOLBIOL Syntheselabor GmbH, **Germany**
37. Millennium Pharmaceuticals Inc., **USA**
36. GeneDx (Bio Reference Laboratories Inc.), **USA**
35. General Electric Company, **USA**
34. Prometheus Laboratories Inc. **USA**
33. Kimball Genetics Inc., **USA**
32. BioSearch Technologies Inc., **USA**
31. Syngenta Crop Protection AG, **Switzerland**
30. Monsanto Company (swine genetics), **USA**
29. Thermo Fisher Scientific Inc., **USA**
28. Monsanto Company (plant genetics) **USA**
27. Sciona Inc., **USA**
26. Genosense Diagnostics GmbH, **Austria**
25. Innogenetics NV (HLA products), **Belgium**
24. Bovigen LLC, **USA**
23. Optigen LLC, **USA**
22. Applera Corporation, **USA**
- 18 - 21. Four agriculture groups, **New Zealand**
17. Australian Genome Research Facility Limited, **Australia**
16. Bionomics Limited, **Australia**
15. C.Y. O Connor ERADE Village Foundation, **Australia**
14. ViaLactia Biosciences Limited, **New Zealand**
13. MetaMorphix Inc., **USA** (license subsequently terminated)
12. Genzyme Corporation, **USA**
11. Ovita Limited, **New Zealand**
10. Laboratory Corporation of America Holdings, **USA**
9. TM Biosciences Corporation, **Canada**
8. Quest Diagnostics Inc., **USA**
7. ARUP, **USA**
6. Biotage AB, **Sweden**
5. Myriad Genetics Inc., **USA**
4. Perlegen Sciences Inc., **USA**
3. Nanogen Inc., **USA**
2. Sequenom Inc., **USA**
1. Genetic Solutions Pty. Ltd., **Australia**

**Research licensees**

6. Texas A&M University (Merlogen Inc.), **USA**
5. Colorado State University, **USA**
4. University of Technology Sydney, **Australia**
3. King's College, London, **England**
2. University of Sydney, **Australia**
1. University of Utah, **USA**





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It is a priority for the Company to continue to identify additional parties who would benefit from taking a license to the Company's non-coding patents. We are now pursuing negotiations with a number of companies and organizations in USA and Europe that would benefit from taking a license to our non-coding patents or from collaborations with our service testing business.

In order to increase the rate at which these licenses can be secured, the licensing team at the Company's headquarters in Melbourne, Australia has been expanded in recent years by the appointment of additional staff to accelerate the preparation of dossiers on potential licensees. Internationally, independent licensing contractors were previously engaged to represent the Company on the ground in our major markets.

On February 16, 2010, we announced that we had filed a patent infringement suit in respect of our non-coding DNA technologies against nine parties in the US District Court, Western District of Wisconsin. The case is being prosecuted by the Company's Colorado-based law firm Sheridan Ross PC and we have put in place arrangements pursuant to which we believe that the patent infringement suit should not have a material adverse impact on our finances. Since filing the suit, non-coding licenses have been granted by us to Gen-Probe Inc., Molecular Pathology Laboratory Network Inc., Monsanto Company, Beckman Coulter Inc. / Clinical Data Inc., Interleukin Genetics Inc. and Pioneer Hi-Bred International Inc. as part of settlements that have been reached with those parties. Further, settlement discussions with a number of the remaining parties, together with other parties who are not involved with the suit, have also commenced and are progressing.

**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 BREVAGen™ breast cancer test, in the USA 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 certain late-stage research and development projects 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 is now working 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. Our growing understanding of genetics is now providing new information for understanding such predisposing or causative factors in many of these 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, these findings - 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. Our patent portfolio is centered on proprietary methods for utilizing the valuable information contained within these non-coding regions.

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**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.

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 in plants. Accordingly, more and more genetic testing will in future 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 program in those early days. Following the acquisition of several other small DNA testing laboratories in Australia, GeneType AG consolidated the business such that the Company is now the largest provider of paternity and related testing services in Australia.

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In August 2000, we acquired 100% of GeneType AG, including control over all its patents and its service testing business. Later, in July 2001, we acquired the paternity testing business of DNA-ID Labs, another small testing laboratory based in Perth, Western Australia. Overall, we acquired several small businesses, two based in Sydney, New South Wales, one based in Perth and one based in Melbourne, eventually making our service testing laboratory in Melbourne 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, the determination of familial relationships for immigration purposes and for forensic analysis.

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.

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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.
- 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.
- Semen analysis - determines if semen is present on, for example, an article of clothing. If it is, we can DNA type this sample and compare it to a reference sample.

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 started to receive specimens for testing from other countries, most of which are located in the Asia-Pacific region. In addition, we received requests to perform tests outside of human paternity, and this has caused us to consider and now plan a significant expansion of our testing services.

**Expansion of Testing Services Beyond Paternity Testing**

**(1) 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. AgGenomics is located at the Victorian AgriBiosciences Centre at La Trobe University R&D Park in Melbourne, Victoria.

**(2) 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. In June 2003, this facility was granted provisional accreditation by the National Association of Testing Authorities, Australia ( NATA ). This important area of testing continues to build momentum, with the addition of new equipment, new employees joining the Company and new technology becoming available exclusively to us, such that the Australian community now has access to some of the latest technologies available for genetic testing.

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.

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 numerous government funded genetics services to begin utilizing the Company's testing service to improve patient care.

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For the financial year ended June 30, 2010, we generated revenue in the Medical division of \$1.73 million, representing an increase of more than 20% over the previous financial year. 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 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 US to acquire distribution rights for their tests across Oceania. In addition to the current test portfolio, GTG began introducing itself to the Oncology market via regular attendance at 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, GTG took a four month option to investigate the purchase of various assets from Perlegen Sciences, Inc. of Mountain View, California which included the breast cancer non-familial risk assessment test, BREVAGen. Those assets were subsequently purchased in April 2010. Work then began on validating the test in GTG's Melbourne-based 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 USA. Since then, Phenogen Sciences has established an office in Charlotte, North Carolina and employed several key personnel, including a General Manager named Mr. Lewis Stuart.

The BREVAGen test combines a lifestyle risk assessment using the Gail score, with a personalized genetic risk assessment. The two parts give a BREVAGen score for five year and lifetime risk assessment as well as being compared to clinical threshold levels for treatment established by the American Cancer Society and the American Society of Clinical Oncology. We believe there are in the order of one million women a year in the USA who have a breast biopsy result that is not invasive cancer yet they may want to know their future risk of getting breast cancer. BREVAGen is a prognostic tool to help clinicians better determine what sort of proactive treatment or surveillance strategy to employ with such patients.

**(3) 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, for example, the Australian fur seal and various frogs and reptiles.

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.



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During 2008, the Company launched our Dog Attack Pack, a forensic tool enabling local government officers to collect samples from dog attacks and BITSAs, a breed identification test that uses DNA analysis to provide a history of a dog's breed.

In July 2008, we acquired Frozen Puppies Dot Com Pty. Ltd., an Australian company specializing in canine reproductive services. Since then, the Company has made excellent progress expanding its facilities into territories outside of Australia, developing strong relationships with breeders and associations in China, Japan, New Zealand and elsewhere. Staff has been employed to manage the Company's activities in these territories and purpose-built facilities have now been established on the outskirts of Beijing, China and in several States of Australia.

In September 2009, GTG again won a tender for being the exclusive provider of genetic services to Greyhounds Australasia for a period of two years. At this time, the Company's animals 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.

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By late 2009, the new strategy for GTG of focusing on genetic health started to impact the way resources would be used in the animals 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 relationship 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. From April to September 2010, GTG was invited to tender for the provision of canine genetic tests to the China Kennel Union. This is the largest canine club in China with current membership of 176,000 members. GTG subsequently won a three year tender which will be serviced out of the GTG office in Beijing with tests to be conducted in the Company's Melbourne laboratory.

With the increased emphasis and resourcing in the genetic business, a decision was taken during the 2010 financial year to move away from building the Frozen Puppies Dot Com business. As a result, most of the existing centers have now been sold off to various parties who have a reputation for providing reproductive services. GTG is, however, still able to work with those centers to provide its genetic testing services.

**(4) 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 forensics community.

In April 2006, we announced that we had been awarded a contract to supply the New South Wales (NSW) Police Force with DNA analysis services. Under the contract, 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 current contract with the NSW Police Force ends in January 2011. As of the date of this Annual Report, discussions are underway to explore initiating the first one year option and defining the type of work that would be involved. The feedback regarding the contracted work to date has been wholly positive and the turnaround time targets stipulated in the current contract have been well exceeded.

We believe that a significant opportunity exists for the Company to assist other policing authorities to expeditiously process DNA samples and discussions have been held with two other State-based Police forces to investigate how GTG's forensic capability could be utilized in their operations. It is estimated that there is a substantial backlog of DNA samples currently waiting to be processed by these and other police departments throughout Australia. This work would be in addition to the processing of DNA samples collected on an ongoing basis from crime scenes.

**(5) Athletic Performance Testing** - the Company acquired the commercial rights from the University of Sydney for a genetic test, known as the ACTN3 Sports Gene Test, which is capable of determining whether or not this gene is providing athletes with a genetic advantage for sprint-power performance. In September 2005, we announced the official launch of this test in Japan with its Japanese distribution partner, Sportsstyle, to an audience of over 100 sports specialists, including the President of the Japan Federation of Health and Sports. The launch of the ACTN3 SportsGene Test was widely reported in the Japanese press. All commercial ACTN3 SportsGene Tests from Japan are analysed at our laboratory in Melbourne. In conjunction with Sportsstyle, we have held meetings with influential sporting bodies looking to use the ACTN3 SportsGene Test as part of their training and assessment program.

On January 7, 2008, the Company appointed Colorado-based talent identification company EPIC Athletic Performance Inc. ( EPIC ) as a non-exclusive distributor of the ACTN3 SportsGene Test® product in the United States. Samples have been received through calendar 2009, but it is not known at this point whether there is an ongoing market for such a test.

During 2009, distribution agreements / amendments were established in Japan, Western Europe and Greece, with interest having also been received from South America and India. The market for these tests is confined largely to specific professional sporting bodies and as such the volume for such a test is limited to those types of niches.

Distributors are being set in place in various parts of the world to sell the ACTN3 SportsGene Test . More information regarding the market potential of this product will be known by the end of calendar 2010.

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**(6) Reproductive Services** with the acquisition of Frozen Puppies Dot Com Pty. Ltd. in July 2008, the Company acquired a canine fertility clinic in Calga, New South Wales, Australia and established another clinic in Beijing, China. Further clinics were then established with the aim of combining both fertility services and DNA disease and trait tests to customers and breeders in both Australia and overseas. During the 2010 financial year, the Company made the strategic decision to exit this market. For details refer to the Animal Testing section above.

**Our Patent Portfolio**

The acquisition of GeneType AG gave our company ownership rights to a potentially significant portfolio of issued patents. 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) Laboratory Techniques;
- (d) Perlegen;
- (e) BREVAGen ;
- (f) Ancestral Haplotypes;
- (g) Athletic Performance;
- (h) ImmunAid Project;
- (i) Nematode Project; and

(j) 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. The method is useful, for example, in the determination of tissue typing for transplantation in order to test for possible likely acceptance or rejection of bone marrow or tissue grafts. The method is also useful in the detection of genetic changes or mutations in the non-coding region of certain genes associated with a higher incidence of certain genetic diseases, such as cystic fibrosis, susceptibility to breast cancer, multiple sclerosis, Alzheimer's Disease, etc. 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. Similar applications also exist in animals and plants. Several important markers in livestock, for example, have been shown to be located in the non-coding part of the DNA and also linked to particular coding function - for example, marbling or tenderness. It has also been shown that variations in the non-coding DNA of plants can influence their function, including the color of flowers and the timing of germination and growth.

(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 both the coding and the non-coding portions of the genome.

(c) **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.

(d) **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.

(e) **The BREVAGen patents** - describe a combination of method and product filings which describes a breast cancer prognostic test based on both genetic and clinical factors to deliver an improved understanding of an individual's risk of contracting breast cancer.

(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 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.

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**(h) The ImmunAid Project patents** - describe various methods aimed at improving the efficacy of cancer therapy and treatment of HIV-AIDS and form the basis of the ImmunAid project.

**(i) The Nematode Project patents** - describe means to identify and to control a variety of species of parasites. The patent applications describe the use of modern genetic technologies to identify cellular targets for two novel classes of chemicals which can be used to control the major parasitic worms of sheep and cattle. These nematodes are responsible for extensive economic losses to the sheep and cattle industries and are rapidly developing resistance to the existing chemicals. The novel classes of chemical described in these patents offer a safe and highly effective alternative.

**(j) The RareCollect Project patents** - the older patents 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 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 along a chromosome.

In total, we have 13 issued patents and 22 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 largely new and untested.