



# GENETIC TECHNOLOGIES LIMITED

A.B.N. 17 009 212 328

Quarterly Activities Report  
and  
Appendix 4C of the ASX Listing Rules  
for the quarter ended  
**30 June 2010**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 30 JUNE 2010

### OPERATIONS

Cash receipts from customers during the quarter ended 30 June 2010 were \$3.27 million, representing a healthy 89 percent increase over the figure for the previous quarter. This increase was largely due to receipts from non-coding licenses that were granted to several parties during the period under review (refer below).

Revenues from the Company's profiling testing area achieved budget for the year ended 30 June 2010, whilst revenues from the medical testing, animal testing and reproductive services businesses fell below budget. Changes to the Company's reproductive services business have now been introduced which will reduce the Company's future exposure to that business and improve overall profitability.

Encouragingly, whilst total revenues from operations fell below budget, cost reduction and containment initiatives that were implemented during the year ended 30 June 2010 have resulted in a saving of more than \$4.0 million in overall costs, as compared to budget.

### Acquisition of BREVAGen™ Breast Cancer Test and other assets

On 14 April 2010, the Company announced that it had acquired certain assets from US-based Perlegen Sciences, Inc. ("Perlegen") with the main asset being the BREVAGen™ breast cancer risk test. In addition to the BREVAGen™ test, GTG acquired a suite of granted patents valid to 2022 which augment and extend GTG's current non-coding patent portfolio.

BREVAGen™ is a diagnostic test that informs clinicians and patients about individual, non-familial, sporadic risk of breast cancer for women where a breast biopsy outcome is indeterminate. In the US, there are 1.6 million biopsies taken every year for breast cancer and about one million of these are indeterminate, representing a potential market of between US\$400 million to US\$500 million. This product fulfils an unmet need by better classifying women at moderate risk of breast cancer who would potentially benefit from preventive therapy or more intensive monitoring. Preventive therapy has been shown to be 50 percent successful in preventing cancer in at-risk women. The test combines population risk factors based on the Gail Score with validated genetic risk factors to give an integrated, personalised breast cancer risk assessment.

BREVAGen™ is the first test of its kind to give women a cost effective personal assessment of their sporadic risk of breast cancer. The existing treatment guidelines of the American Cancer Society and American Society of Clinical Oncologists stipulate that a physician is to be guided by risk measures to determine the five year and lifetime risk of getting cancer. Existing risk assessments such as the Gail Score are acknowledged to have shortcomings in intermediate risk patients. BREVAGen™ will supply personalised genetic information to make these assessments more robust, enabling better treatment decisions and patient outcomes. To date, there have been over 20 published studies on BREVAGen™ based on studies of over 50,000 women including a peer reviewed publication in 2007 in *Nature*.

The assets acquired by Genetic Technologies not only include the BREVAGen™ breast cancer risk genetic test but also a global patent suite which augments and extends GTG's current non-coding patent portfolio. As the new owner of these patents, GTG is free to incorporate these rights to extend the Company's licensing assertion program. The non-coding portfolio acquired from Perlegen has a patent life extending out to 2022.

As previously announced, GTG intends to launch the BREVAGen™ test first in the US and Australia in the fourth quarter of calendar 2010, followed by a worldwide roll-out. To drive this roll-out, GTG has now appointed Mr. Lewis Stuart as General Manager of its North American molecular diagnostics business. Mr. Stuart brings more than 28 years of US and European health sector sales and marketing experience across multiple therapeutic categories including women's health, infectious disease and endocrinology.



## Quarterly Activities Report for the quarter ended 30 June 2010

### **OPERATIONS (cont.)**

As part of the US roll-out, the Company has now leased premises in Charlotte, North Carolina which will serve as the head office of its newly-incorporated US subsidiary, Phenogen Sciences Inc. Phenogen has been established as the operating entity for the Group's US operations which it is anticipated will, over time, recruit a number of local sales representatives as part of the BREVAGen™ roll-out in the US.

The proposed roll-out of the BREVAGen™ test has already been market researched and mapped and the marketing collateral compiled and prepared for deployment. Further, GTG has already identified initial customers and key opinion leaders and a US reimbursement strategy is in place.

### **LICENSING AND IP**

The Company's intellectual property portfolio, which now includes the patents acquired from Perlegen, continues to strengthen, with 111 patents having now been granted and a further 88 which are pending.

#### **Assertion program**

On 16 February 2010, the Company announced that it had filed a patent infringement suit in respect of its non-coding DNA technologies against nine parties in the US District Court, Western District of Wisconsin. The counter-parties are Beckman Coulter Inc., Monsanto Inc., Interleukin Genetics Inc., Orchid Cellmark Inc., Gen-Probe Inc., Molecular Pathology Laboratory Network Inc., PIC USA Inc., Sunrise Medical Laboratories and Pioneer Hi-Bred International Inc. Since that date, the Company has announced that non-coding licenses have been granted to each of Gen-Probe Inc. and Molecular Pathology Laboratory Network Inc. as part of settlements that have been reached with those parties. Further, settlement discussions with a number of the remaining parties have already commenced.

The case is being prosecuted by the Company's Colorado-based law firm Sheridan Ross PC., a full-service intellectual property law firm which has in the past successfully asserted and defended GTG's intellectual property rights globally and has assembled a team of six partners and associates to support the case. Genetic Technologies has put in place arrangements pursuant to which the Company believes that the patent infringement suit should not have a material adverse impact on its finances.

#### **Other licensing activities**

In addition to licenses granted in settlement of the infringement suit above, the Company announced on 5 May 2010 that a license had been granted to Eragen Biosciences Inc. and, on 29 June 2010, that an extension of the license granted to Quest Diagnostics Inc. had also been granted.

The pursuit of licenses in jurisdictions other than the USA, principally Europe, is continuing.

On 10 May 2010, the Company announced that it had received formal notification from the United States Patent and Trademarks Office (USPTO) that it had upheld, without amendment, all of the claims which formed the basis of the re-examination action (as detailed in the Company's ASX announcement dated 30 June 2009) of the Company's core 5,612,179 non-coding deoxyribonucleic acid (DNA) patent.

In all, the June quarter under review has been the most successful for the Company's licensing team in a number of years and it is anticipated that further licenses will continue to be granted in coming months.



## Quarterly Activities Report for the quarter ended 30 June 2010

### RESEARCH AND DEVELOPMENT

As part of the Company's stronger focus on the cancer diagnostic area, its three research programs are being progressed via co-commercialisation or in some cases partnering.

- The **RareCollect** group has successfully tested the performance of a novel prototype sampling device to recover fetal genetic material from the cervical canal in a pilot scale clinical study. Two further patent applications have been filed relating to the recovery of fetal genetic material from the cervix. Discussions with several large international companies interested in pursuing potential commercial collaborations are continuing.
- An **ImmunAid** proof of concept trial is progressing through the planning phase in conjunction with a US oncology-focused institution while preliminary commercial discussions with institutional and commercial partners continue. A key patent in the ImmunAid patent estate was also granted during the quarter.
- Following on from the *in vitro* studies as part of the Company's **Nematode** project, several of the novel anti-parasitic compounds were sent to commercialisation partners for their review. Activity was demonstrated in these assessments although no lead compound was selected. Further work may be needed to advance a compound into development. The Company is currently in the process of assessing opportunities for partnering this program with a partner who has a stronger veterinary focus.

### CORPORATE MATTERS

On 14 April 2010, the Company announced that it had issued by way of private placement a total of 29,960,351 ordinary shares in the Company. The placement involved the issue of 27,940,530 ordinary shares to an institutional investor group in the USA at a price of \$0.039 each, which raised a total of \$1,089,681 in cash, before the payment of associated expenses. The remaining 2,019,821 ordinary shares, which were issued at a price of \$0.040 each, were issued as partial consideration for the acquisition of assets from Perlegen Sciences, Inc. ("Perlegen"), as detailed above.

All of the shares were issued in accordance with ASX Listing Rule 7.1 and, as such, shareholder approval for the placement was not required. The majority of the net cash proceeds raised from the placement were used by the Company to purchase the BREVAGen™ breast cancer risk test and other assets from Perlegen, as detailed above. Following the issue of the above shares, the total number of ordinary shares on issue had increased to 404,605,152.

On 30 June 2010, the Company announced that, in order to comply with NASDAQ Listing Rule 5450(b)(1)(A), the Company had transferred its listing of its American Depositary Shares, as evidenced by American Depositary Receipts, from the NASDAQ Global Market to the NASDAQ Capital Market, effective from the commencement of trade on 30 June 2010. Listing Rule 5450(b)(1)(A) requires all companies listed on the Global Market to maintain minimum shareholders' equity of USD 10 million. The Company also confirmed that its current NASDAQ ticker symbol, GENE, will remain unchanged.

On 13 July 2010, the Company announced that it had granted a total of 12,000,000 options over ordinary shares in the Company to members of its Senior Executive team. The options, which were issued pursuant to the Company's Employee Share Option Plan that was approved by shareholders on 19 November 2008, have an exercise price that represents a 25% premium to the volume weighted average price of the Company's shares on the ASX for the 20 trading days preceding the date on which the options were granted.

**Signed on behalf of Genetic Technologies Limited**

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DR. PAUL D.R. MacLEMAN  
Chief Executive Officer

Dated this 28<sup>th</sup> day of July, 2010

# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity

**GENETIC TECHNOLOGIES LIMITED**

ABN

**17 009 212 328**

Quarter ended ("current quarter")

**30 JUNE 2010**

### Consolidated statement of cash flows

	Current quarter (June 2010) \$A	Year to date (twelve months) \$A
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	<b>3,268,805</b>	<b>9,675,735</b>
1.2 Payments for		
(a) staff costs	<b>(1,633,360)</b>	<b>(6,621,618)</b>
(b) advertising and marketing	<b>(71,390)</b>	<b>(334,132)</b>
(c) research and development	-	<b>(187,122)</b>
(d) leased assets	-	-
(e) other working capital	<b>(2,019,806)</b>	<b>(7,437,270)</b>
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	<b>36,906</b>	<b>216,017</b>
1.5 Interest and other costs of finance paid	<b>(26,827)</b>	<b>(98,748)</b>
1.6 Income taxes paid	-	-
1.7 Grant and other income	-	<b>572,128</b>
<b>Net operating cash flows</b>	<b>(445,672)</b>	<b>(4,215,010)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

**Consolidated statement of cash flows (cont.)**

	Current quarter (June 2010) \$A	Year to date (twelve months) \$A
1.8 Net operating cash flows (carried forward)	<b>(445,672)</b>	<b>(4,215,010)</b>
<b>Cash flows related to investing activities</b>		
1.9 Payment for the acquisition of:		
a) businesses (item 5)	-	-
b) equity investments	-	-
c) intellectual property	-	-
d) physical non-current assets	<b>(18,985)</b>	<b>(144,796)</b>
e) other non-current assets	<b>(1,265,755)</b>	<b>(1,275,652)</b>
1.10 Proceeds from the disposal of:		
a) businesses (item 5)	-	-
b) equity investments	-	<b>295,195</b>
c) intellectual property	-	-
d) physical non-current assets	-	-
e) joint venture interest	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	<b>(1,284,740)</b>	<b>(1,125,253)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(1,730,412)</b>	<b>(5,340,263)</b>
<b>Cash flows related to financing activities</b>		
1.15 Net proceeds from the issue of shares	<b>1,011,650</b>	<b>1,011,650</b>
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	-
1.18 Repayment of borrowings from third parties	-	-
1.19 Dividends paid	-	-
1.20 Repayment of finance lease principal	<b>(60,754)</b>	<b>(228,129)</b>
<b>Net financing cash flows</b>	<b>950,896</b>	<b>783,521</b>
<b>Net increase / (decrease) in cash held</b>	<b>(779,516)</b>	<b>(4,556,742)</b>
1.21 Cash at beginning of quarter / year to date	<b>4,058,169</b>	<b>7,826,902</b>
1.22 Exchange rate adjustments	<b>27,658</b>	<b>36,151</b>
<b>1.23 Cash at end of quarter</b>	<b>3,306,311</b>	<b>3,306,311</b>

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**  
**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A
1.24	Aggregate amount of payments to the parties included in item 1.2	<b>284,510</b>
1.25	Aggregate amount of loans to the parties included in item 1.11	-
1.26	Explanation necessary for an understanding of the transactions	

**The amount included at Item 1.24 includes \$59,950 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes rental and outgoings of \$140,740 for the Melbourne laboratory premises paid to an entity associated with a former Director and major shareholder, in addition to \$83,820 in consulting fees and commissions paid in respect of services rendered to the Company by that individual.**

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

**During the quarter ended 30 June 2010, the Company issued a total of 2,019,821 ordinary shares as partial consideration for the acquisition of certain assets that collectively form a breast cancer test known as BREVAGen™. The value of the shares issued was \$80,793.**

- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

**None during the quarter under review**

**Financing facilities available**

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

		Amount available \$A	Amount used \$A
3.1	Loan facilities	-	-
3.2	Credit standby arrangements Hire purchase facility	<b>2,500,000</b>	<b>382,640</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

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**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:

- 4.1 Cash on hand and at bank
- 4.2 Term deposits
- 4.3 Bank overdraft
- 4.4 Commercial Bills of Exchange
- Total cash at end of quarter** (item 1.23)

Current quarter (June 2010) \$A	Previous quarter (March 2010) \$A
<b>1,773,152</b>	<b>1,558,169</b>
<b>1,533,159</b>	<b>2,500,000</b>
-	-
-	-
<b>3,306,311</b>	<b>4,058,169</b>

**Acquisitions and disposals of business entities**

- 5.1 Name of entity
- 5.2 Place of incorporation or registration
- 5.3 Consideration for acquisition or disposal (note)
- 5.4 Total net assets
- 5.5 Nature of business

Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
<b>Phenogen Sciences Inc.</b>	<b>Not applicable</b>
<b>Delaware, USA</b>	
<b>Nil</b>	
<b>Nil</b>	
<b>Distribution of BREVAGen™ test in USA</b>	

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here: ..... Date: **28 July 2010**  
*Chief Executive Officer*

Print name: **Dr. Paul D.R. MacLeman**

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+ See chapter 19 for defined terms.

## Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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