



# 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 September 2011**

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# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 30 SEPTEMBER 2011

### OPERATIONS

Total cash receipts from customers during the quarter ended 30 September 2011 exceeded \$2.3 million. Together with the \$10.9 million in net funds raised from the placement of 60 million shares in late July, the Company's cash reserves had increased to more than \$14.8 million at the end of the quarter.

Gross revenues generated by the Company's testing operations, excluding those forecast for sales of the new BREVAGen™ breast cancer risk test, were slightly ahead of budget for the first quarter of the 2011 financial year.

### Launch of BREVAGen™ breast cancer risk test

In June 2011, the Company launched its new, predictive risk test for the tens of millions of women at intermediate risk of developing breast cancer, BREVAGen™, in the US market.

The Company's US-based subsidiary, Phenogen Sciences Inc., (<http://www.phenogensciences.com>) began its progressive roll-out of BREVAGen™ to obstetricians and gynaecologists in eight territories accessing more than 20 metropolitan areas in the US during the third quarter of 2011, with anticipated territory expansion in the coming months. BREVAGen™ is the first clinically validated breast cancer predictive risk assessment tool that combines a woman's genetic information with clinical data to assist physicians in developing personalized risk management plans.

Over the first 90 days of the launch, the Phenogen sales team made more than 2,800 sales calls, reaching 800 physicians, representing good penetration into its initial tier one targets. During this same timeframe, 600 test kits were placed in targeted accounts, resulting in early adopter BREVAGen™ use within two weeks of launch.

The Company has commenced processing re-imbursements on initial BREVAGen™ test sales. As part of a longer term insured lives contracting and credentialing strategy, the Company has also commenced the credentialing process with the top-10 preferred provider organisations (PPOs) in the US, which represent more than 60 percent of covered lives in the US. In early October, the first PPO contract was finalised with additional contracts anticipated to be completed by the end of the December quarter.

### How BREVAGen™ works

The BREVAGen™ predictive risk test is administered in a physician's office using a simple, non-invasive "cheek-swab". Following analysis in a CLIA-certified laboratory, physicians receive a comprehensive predictive risk assessment report to review with the patient. The patient's risk of breast cancer is calculated by combining their relative risk score from seven genetic markers, called SNP's (single nucleotide polymorphisms), with their Gail score (factors that comprise the patient's clinical make-up including current age, age at menarche, age at live first birth, race/ethnicity, etc.).

The BREVAGen™ test provides five-year and lifetime predictive risk assessments to more accurately evaluate the patient's risk for developing breast cancer, regardless of family history or previous indeterminate test results.

### Clinically validated, proven superior risk assessment

BREVAGen™ has been proven superior in determining breast cancer risk compared to the Gail score alone.<sup>1</sup> In the U.S. Women's Health Initiative (WHI) Clinical Trial, 3,300 women underwent breast cancer assessment utilising the BREVAGen™ test. Of those 3,300 women, 1,664 were diagnosed with breast cancer and 1,636 were in the breast cancer-free control group.

## **OPERATIONS (cont.)**

### **Launch of BREVAGen™ breast cancer risk test (cont.)**

BREVAGen™ is clinically validated to reclassify approximately 64% of women in the intermediate Gail breast cancer risk group (being those with a 1.5% to 2.0% five-year risk), with approximately 28% being reclassified as higher risk candidates for breast cancer.<sup>1</sup> A preventive treatment plan based on this would prevent about 50% of cancers in this group. In addition, more than 36% in this group will be re-stratified down, avoiding unnecessary treatment, side effects and costs. Therefore, approximately two out of three patients in the intermediate Gail risk group will have a more accurate risk assessment to guide their future care.

<sup>1</sup> Mealiffe M., Stokowski R.P., Rhees B.K. et. al. J Nat Cancer Inst. 2010; 102(21): 1618-1627

### **Australian market**

In the medical division, brand awareness continues to increase with interest in our test portfolio through attendance at leading oncology conferences such as "M.O.G.A" and familial breast cancer at "Kconfab".

In forensics, a substantial project was completed on time for the Western Australian Police Force; whilst the current series of work has been completed for the NSW Police Force.

Increased media coverage concerning dangerous / restricted dog breeds and our involvement with key government / animal welfare agencies resulted in higher levels of sales for the Company's BITSA test (breed identification) and the possible use of the test in arbitration to solve claims of breed identification. New direct marketing campaigns timed for the spring puppy selling season have been successful in winning back old customers and increasing the sales for current ones. This effort was concentrated using online media and electronic communication to give customers immediate feedback on receipt of canine disease and trait tests.

## **LICENSING AND IP**

The Company's intellectual property portfolio, which includes the patents acquired from Perlegen Sciences Inc., continues to strengthen, with 117 patents now granted and a further 90 (including divisional and provisional patents) pending.

### **Assertion programs**

On 26 May 2011, the Company announced it had filed a further patent infringement law suit in the US, this time in the US District Court, Western District of Colorado, asserting infringement of its primary non-coding patent against the following parties:

- Agilent Technologies Inc.;
- Bristol-Myers Squibb Company;
- Eurofins STA Laboratories Inc.;
- GlaxoSmithKline PLC;
- Hologic Inc.;
- Merial LLC;
- Navigenics Inc.;
- Neogen Corporation / GeneSeek Inc.;
- Pfizer Inc.; and
- 454 Life Sciences Corporation.

This suit is in addition to a six-party suit filed in January 2011 in the U.S. District Court for the Western District of Texas for infringement of the same technology. The Company is pleased to report that the counterparties to the Texas suit are in active settlement discussions. Subsequent to filing the suit in Colorado, Settlement and License Agreements have been executed with both Navigenics Inc. and Hologic Inc.



## LICENSING AND IP (cont.)

### Assertion programs (cont.)

All infringement suits are prosecuted by the Company's Colorado based law firm Sheridan Ross P.C. and, due to arrangements previously put into place, should not have a material adverse impact on Genetic Technologies' finances.

### Other licensing activities

In addition to the licenses granted as part of the Company's formal assertion program as detailed above, aside from the US law suits, the Company itself is actively pursuing licenses in respect of its non-coding technology in the US and other jurisdictions, principally in Europe. During the September quarter, the Company executed a Settlement and License Agreement with Attomol GmbH of Lipten, Germany under which that company has been granted non-exclusive rights to a number of GTG patents, including non-coding analysis and gene mapping.

## RESEARCH AND DEVELOPMENT

As part of the Company's strategy to place a stronger emphasis on the expansion of its cancer diagnostic franchise, its research programs are being progressed with a view to out-licensing, co-development or partnering the respective technologies.

- The **RareCollect™** project has been presented to a variety of industry players. Discussions with a number of large international companies interested in pursuing potential commercial collaborations are continuing, with several parties now undertaking advanced due diligence on the RareCollect™ data and samples.
- Stakeholders associated with the **ImmunAid™** project are now actively exploring collaboration / partnership discussions with third parties with a view to expediting the development and potential commercialisation of the ImmunAid™ technology. During the quarter under review, the patent portfolio associated with the project continued to expand with a key patent having been secured in Europe.

## CORPORATE MATTERS

On 27 July 2011, GTG announced that it had issued by way of private placement to US and Australian institutional and sophisticated investors a total of 60,000,000 ordinary shares in the Company. The shares were issued in accordance with ASX Listing Rule 7.1 and, as such, shareholder approval was not required. The issue of the shares, which was made at a price of \$0.195 each, raised a total of \$11,700,000, before the payment of associated costs. Following the issue, the number of shares in GTG that were on issue had increased to 464,605,152. Proceeds from the placement will be used to fund potential acquisition growth in the molecular diagnostics field focusing on woman's cancer and management, and to accelerate the roll-out of its breast cancer risk test BREVAGen™ in the US.

On 3 October 2011, the Company announced the appointment of Dr. Mervyn Cass as a Director of the Company.

Also on 3 October 2011, GTG granted a further 1,000,000 options over ordinary shares in the Company to a senior employee. Each option, which was granted at nil cost, entitles the holder to acquire one ordinary share in the Company at a price of \$0.20 at any time up to, and including, 31 July 2016. As at the date of this Report, there were 19,275,000 options outstanding.

On 12 October 2010, the Company released its Notice for the 2011 Annual General Meeting of shareholders which is to be held at **10.00 am on Monday, 21 November 2011** in the "Treetops" Room at Melbourne Museum. On 14 October 2011, the Company released its 2011 Annual Report to the Market. Copies of both documents can be found on the Company's website at [www.gtglabs.com](http://www.gtglabs.com)



Quarterly Activities Report  
for the quarter ended **30 September 2011**

**Signed on behalf of Genetic Technologies Limited**

Dated this 26<sup>th</sup> day of October, 2011

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DR. PAUL D.R. MacLEMAN  
*Chief Executive Officer*

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# 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 SEPTEMBER 2011**

### Consolidated statement of cash flows

	Current quarter (September 2011) \$A	Year to date (three months) \$A
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	<b>2,350,178</b>	<b>2,350,178</b>
1.2 Payments for (a) staff costs	<b>(1,985,196)</b>	<b>(1,985,196)</b>
(b) advertising and marketing	<b>(80,438)</b>	<b>(80,438)</b>
(c) research and development	-	-
(d) leased assets	-	-
(e) other working capital	<b>(1,693,031)</b>	<b>(1,693,031)</b>
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	<b>137,799</b>	<b>137,799</b>
1.5 Interest and other costs of finance paid	<b>(13,755)</b>	<b>(13,755)</b>
1.6 Income taxes paid	-	-
1.7 Grant and other income	-	-
<b>Net operating cash flows</b>	<b>(1,284,443)</b>	<b>(1,284,443)</b>

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

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

	Current quarter (September 2011) \$A	Year to date (three months) \$A
1.8 Net operating cash flows (carried forward)	<b>(1,284,443)</b>	<b>(1,284,443)</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>(34,674)</b>	<b>(34,674)</b>
e) other non-current assets	-	-
1.10 Proceeds from the disposal of:		
a) businesses (item 5)	-	-
b) equity investments	-	-
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>(34,674)</b>	<b>(34,674)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(1,319,117)</b>	<b>(1,319,117)</b>
<b>Cash flows related to financing activities</b>		
1.15 Net proceeds from the issue of shares	<b>10,903,011</b>	<b>10,903,011</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>(12,146)</b>	<b>(12,146)</b>
<b>Net financing cash flows</b>	<b>10,890,865</b>	<b>10,890,865</b>
<b>Net increase / (decrease) in cash held</b>	<b>9,571,748</b>	<b>9,571,748</b>
1.21 Cash at beginning of quarter / year to date	<b>5,104,667</b>	<b>5,104,667</b>
1.22 Exchange rate adjustments	<b>189,687</b>	<b>189,687</b>
1.23 <b>Cash at end of quarter</b>	<b>14,866,102</b>	<b>14,866,102</b>

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**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>79,206</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 \$61,389 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes \$17,817 in commissions and consulting fees paid to a former Director and substantial shareholder 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

**None during the quarter under review**

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>55,732</b>

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

**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 (September 2011) \$A	Previous quarter (June 2011) \$A
<b>1,866,102</b>	<b>1,985,257</b>
<b>13,000,000</b>	<b>3,119,410</b>
-	-
-	-
<b>14,866,102</b>	<b>5,104,667</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>Not applicable</b>	<b>Not applicable</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: **26 October 2011**  
*Chief Executive Officer*

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

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## 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 107: Statement of Cash Flows* apply to this report except for any additional disclosure requested by AASB 107 that are not already itemised in this report.
3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting 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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