



# 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  
**31 December 2012**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 31 DECEMBER 2012

### OPERATIONS

#### Financial summary

Total cash receipts from customers during the quarter ended 31 December 2012 were in excess of \$4.07 million, representing a more than 240% increase on the receipts for the preceding September quarter.

Funds received from the Company's out-licensing program, which included the execution during the quarter of agreements with 454 Life Sciences Corporation (and its affiliates) and One Lambda Inc., together with revenues from GTG's domestic genetic testing business, saw total cash receipts for the first half of the 2013 financial year increase to \$5.26 million.

Domestic testing revenues for the quarter under review continue to exceed budget expectations and, as detailed below, testing throughput of the Company's flagship test BREVAGen™ have demonstrated considerable growth in the December quarter. At the end of the financial half-year, the Company's cash reserves stood at \$5.94 million.

#### BREVAGen™ breast cancer risk test

##### *Samples received to date*

Since launching its BREVAGen™ test in the US market in July 2011, the Company is pleased to advise that the number of samples received in each of the subsequent six quarters has steadily increased, as disclosed in the table below:

Quarter ended	Number of samples received	% increase on previous quarter
December 2012	368	106.7%
September 2012	178	25.4%
June 2012	142	25.7%
March 2012	113	34.5%
December 2011	84	7.7%
September 2011	78	N/A

##### *Expansion of US territories and sale force*

Following the Company's receipt of its Certificate of Compliance issued by the Centers for Medicare and Medicaid Services, GTG submitted applications to 7 of the 8 US States (being Pennsylvania, Rhode Island, Nevada, Tennessee, Maryland, California and Florida) that require additional approvals. The Company has now received "Out of State Licensure" in each of these states, enabling BREVAGen™ to be sold in 49 of the 50 US States.

The Company has also submitted an application along with supporting test documentation to the New York State Department of Health, Clinical Laboratory Evaluation Program ("CLEP") to offer Out of State Clinical Lab services to New York State residents. New York State CLEP has confirmed lodgement of the Company's application with the assignment of a Provider Facility Identifier (PFI # 8705). The BREVAGen™ test validation package is currently in review status by the New York State CLEP and the Company is working with them to schedule an audit of the Company's Melbourne Laboratory by CLEP inspectors later in the 2013 calendar year.

Once New York State approval is granted, the BREVAGen™ test will have been cleared for sale in all 50 US States.



## Quarterly Activities Report for the quarter ended 31 December 2012

### OPERATIONS (cont.)

The Company currently has 10 sales representatives located across mainland United States, with plans to increase the number of representatives in the key territories of Southern California and Chicago, Illinois in the first quarter of 2013. Additional representatives will be added once New York State approval is received.

#### *Other activities*

The Company has recently been granted a Medical Device Establishment License (MDEL) from Health Canada which enables the BREVAGen™ test to be sold into Canada. The Canadian Cancer Society cites that breast cancer is the most common cancer among Canadian women and that one in nine women is expected to develop breast cancer during their lifetime and one in 29 will die of it.

<http://www.cancer.ca/canada-wide/about%20cancer/cancer%20statistics/stats%20at%20a%20glance/breast%20cancer.aspx>

A re-validation study, using a different cohort of Caucasian women >35 years of age, has recently been completed which confirms the power of the BREVAGen™ test in combining clinical risk factors with genetic factors (SNPs) to reclassify women at high or above average risk of breast cancer. Further development work on identifying SNPs associated with breast cancer in other ethnic populations will enable the test to be offered to a wider target audience. Additional cost-effectiveness studies are planned for publication during the first half of the 2013 calendar year.

The Company also continues to work with its ever expanding network of physicians and breast health clinics, such as Noble Hospital in Springfield, Massachusetts, to provide more efficient means of ordering BREVAGen™ tests and receiving results via the provision of electronic Test Requisition Forms (TRFs) and web-based HIPAA compliant result portals.

#### *Changes to the US reimbursement landscape*

Insurance claims for BREVAGen™, to date, have been submitted using the so-called “code stack” of CPT methodology codes. Reimbursement under this regime has been positive, with a low percentage of denials and appeals. However, effective 1 January 2013, the AMA has removed the code stack claim process, requiring companies without a specific CPT code to claim via an “Unlisted Code”. The Company is in the process of implementing a strategy designed to deal with these changes until its application for a specific code for BREVAGen™ is approved. The Company does not foresee a negative impact on revenues as a result of these changes.

In addition, negotiations with Preferred Provider Organisations, for additional contracts to increase the number of covered lives, are in process.

### LICENSING AND IP

#### **Assertion programs**

On 26 May 2011, the Company announced that it had filed a third patent infringement law suit in the US, in the US District Court for the 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.	454 Life Sciences Corporation

The Company is pleased to report that, in prior quarters, Settlement and License Agreements have been executed with Navigenics Inc., Hologic Inc., Eurofins STA Laboratories Inc. and GeneSeek Inc. and, during the current December quarter, with 454 Life Sciences Corporation (and its affiliates). Settlement discussions with certain other parties to the Colorado suit are progressing.



## LICENSING AND IP (cont.)

### Assertion programs (cont.)

In addition to the remaining five parties in the above infringement suit and the further suit announced on 30 August 2012, GTG advised during the quarter that it has initiated legal action in USA against Genesis Genetics Institute LLC, Genetics & IVF Institute Inc., Reprogenetics LLC, Medical Diagnostic Laboratories LLC, Prevention Genetics LLC and Genelex Corporation.

The Company's US attorneys, Sheridan Ross PC, are now preparing additional suits, to be filed when appropriate.

### Other licensing activities

On 18 October 2012, the Company announced that it had executed a covenant not to sue and release agreement with One Lambda Inc. of Canoga Park, California, USA.

On 20 December 2012, the Company reported that its European assertion program had been further refined, such that the associated overhead expenses have been significantly reduced and the potential net revenues increased. Assertion lawyers acting for the Company in several European countries, including Germany and Holland, are now actively preparing legal actions against infringing parties in those countries.

### Status of "179" patent re-examination by USPTO

Also on 20 December 2012, the Company reported that, in the current *ex parte* re-examination of claims 1-18 and 26-32 of the Company's 5,612,179 non-coding DNA patent brought by Merial LLC of Duluth, Georgia, a number of the relevant claims have already been cleared by the US Patent and Trademark Office.

## OTHER COMMERCIAL ASSETS

As part of the Company's strategy to focus on the expansion of its cancer diagnostic franchise, work continues to out-license, co-develop or partner other technologies in which the Group has an interest.

### ImmunAid™

Following its successful capital raising in April 2012, the Company's former subsidiary ImmunAid Limited ("ImmunAid") continues to advance collaborations for the development of its unique "on/off" technology which is based around a novel approach to cancer therapy by the timely reversal of immune system suppression.

Further work is also being undertaken to expand ImmunAid's intellectual property portfolio. GTG retains a 45% equity interest in ImmunAid.

### RareCollect™

Discussions with companies interested in pursuing potential commercial collaborations are continuing, with some progressing with due diligence on the RareCollect™ data and samples.



## Quarterly Activities Report for the quarter ended 31 December 2012

### **CORPORATE MATTERS**

On 18 October 2012, the Company released its 2012 Australian Annual Report to the Market. On the same day, it also released the Notice for its 2012 Annual General Meeting of shareholders which was held at 11.00 am on Tuesday, 27 November 2012 in the "Treetops" Room at Melbourne Museum. Immediately following the AGM, former Directors, Dr. Mel Bridges, Mr. Greg Brown and Mr. Huw Jones left the Board. In addition, at the same time, former Chief Executive Officer, Dr. Paul MacLeman, and former VP Legal and Corporate Development, Dr. David Sparling, resigned from the Company.

As a result of the above changes, Dr. Mal Brandon was appointed as Chairman of the Company's Board on 28 November 2012 and Ms. Alison Mew was appointed permanent Chief Executive Officer on 6 December 2012. Also on that date, Mr. Ben Silluzio was appointed as a Non-Executive Director of Genetic Technologies Limited.

On 19 October 2012, a total of 10,200,000 options that had previously been granted to certain Executives of the Company were exercised. As a result of this exercise, a total of 10,200,000 ordinary shares were issued on that date at an issue price of \$0.045 each, raising \$459,000 in new equity for the Company.

On 24 October 2012, documents were executed by the five parties to the Limited Recourse Loan Agreements referred to in Note 33 of the Company's 2012 Financial Report pursuant to which the Loans were immediately terminated. No funds were ever advanced under the respective Loans.

On 24 October 2012, the Company filed with the US Securities and Exchange Commission its US Annual Report on Form 20-F for the year ended 30 June 2012. This document is available on the Company's website and at [www.sec.gov](http://www.sec.gov)

During the quarter, a total of 2,650,000 options over the Company's ordinary shares were granted and a total of 2,750,000 options were cancelled.

In the week beginning 7 January 2013, Company executives presented at the Cowen 2013 Asia Pacific Life Science Showcase in San Francisco as part of the annual JP Morgan Healthcare Conference. Numerous meetings were also held during that week with US investors and other parties.

### **Signed on behalf of Genetic Technologies Limited**

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ALISON J. MEW  
*Chief Executive Officer*

Dated this 25<sup>th</sup> day of January, 2013

# 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")

**31 DECEMBER 2012**

### Consolidated statement of cash flows

	Current quarter (December 2012) A\$	Year to date (six months) A\$
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	<b>4,072,642</b>	<b>5,263,041</b>
1.2 Payments for (a) staff costs	<b>(2,180,094)</b>	<b>(4,038,419)</b>
(b) advertising and marketing	<b>(217,493)</b>	<b>(420,274)</b>
(c) research and development	<b>(21,400)</b>	<b>(41,197)</b>
(d) leased assets	-	-
(e) other working capital	<b>(2,681,746)</b>	<b>(4,045,988)</b>
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	<b>83,265</b>	<b>170,285</b>
1.5 Interest and other costs of finance paid	<b>(9,824)</b>	<b>(19,756)</b>
1.6 Income taxes paid	-	-
1.7 Grant and other income	-	-
<b>Net operating cash flows</b>	<b>(954,650)</b>	<b>(3,132,308)</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 (December 2012) A\$	Year to date (six months) A\$
1.8 Net operating cash flows (carried forward)	<b>(954,650)</b>	<b>(3,132,308)</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>(14,790)</b>	<b>(23,278)</b>
e) other non-current assets	-	-
1.10 Proceeds from the disposal of:		
a) businesses (item 5)	-	-
b) equity investments	-	<b>46,951</b>
c) intellectual property	-	-
d) physical non-current assets	<b>1,201</b>	<b>1,201</b>
e) joint venture interest	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities (refer note below)	-	-
1.13 Other (provide details if material)	-	-
<b>Net investing cash flows</b>	<b>(13,589)</b>	<b>24,874</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(968,239)</b>	<b>(3,107,434)</b>
<b>Cash flows related to financing activities</b>		
1.15 Net proceeds from the issue of shares	<b>459,000</b>	<b>459,000</b>
1.16 Equity transaction costs	<b>(214,756)</b>	<b>(214,756)</b>
1.17 Net proceeds from borrowings	-	-
1.18 Advances to third parties	<b>(85,677)</b>	<b>(85,677)</b>
1.19 Dividends paid	-	-
1.20 Repayment of finance lease principal	<b>(5,183)</b>	<b>(17,748)</b>
<b>Net financing cash flows</b>	<b>153,384</b>	<b>140,819</b>
<b>Net increase / (decrease) in cash held</b>	<b>(814,855)</b>	<b>(2,966,615)</b>
1.21 Cash at beginning of quarter / year to date	<b>6,743,221</b>	<b>8,900,235</b>
1.22 Exchange rate adjustments	<b>9,064</b>	<b>3,810</b>
1.23 <b>Cash at end of quarter</b>	<b>5,937,430</b>	<b>5,937,430</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>303,646</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 \$81,561 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes \$218,675 in commissions and consulting fees paid to a former Director and substantial shareholder in respect of services rendered to the Company by that individual and parties associated with him, and \$3,410 in consulting fees paid to a former Director.**

**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>	-

+ 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:

	Current quarter (December 2012) \$A	Previous quarter (September 2012) \$A
4.1 Cash on hand and at bank	<b>1,837,430</b>	<b>1,085,547</b>
4.2 Term deposits	<b>4,100,000</b>	<b>5,657,674</b>
4.3 Bank overdraft	-	-
4.4 Commercial Bills of Exchange	-	-
<b>Total cash at end of quarter (item 1.23)</b>	<b>5,937,430</b>	<b>6,743,221</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	<b>Not applicable</b>	<b>Not applicable</b>
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

**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: **25 January 2013**  
*Chief Executive Officer*

Print name: **Alison J. Mew**

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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 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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