

For personal use only



# **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 March 2014**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 31 MARCH 2014

### OPERATIONS

#### Financial summary

Total cash receipts from customers during the quarter ended 31 March 2014 were \$1.4 million taking the equivalent figure to more than \$3.7 million for the nine-month period ended on that date.

Domestic testing revenues for the quarter under review continue to exceed budget expectations and the revenue received for the Company's flagship test BREVAGen™ in the March quarter grew more than 39% over the preceding December quarter. As reported in the Company's 2013 Annual Report, the revenues generated from the sale of the BREVAGen test are still recorded on a cash, not an accruals, basis. The Company anticipates that this treatment will change at the end of the 2014 financial year, with an appropriate upward adjustment to revenues being made at that time.

#### BREVAGen™ breast cancer risk test

##### *Test samples received to date*

For the first time since the launch of BREVAGen in July 2011, the number of test samples received in the most recent quarter, was lower than that of the previous quarter. The numbers of BREVAGen samples received in the first quarter of CY2014 fell to 800 from the prior fourth quarter 2013 of 1125. The company believes that the reasons for this softening in demand was a result of a combination of the beginning of the new insurance year, an extremely severe winter during which physician consultations dropped markedly across the board; together with the implementation of the Affordable Care Act in the US, which affected the "discretionary" health spend by patients. Nevertheless, the numbers still represented a 99% increase over the same quarter in 2013 and the Company believes that the upward trend will resume in the next quarter and beyond. This trend will be augmented by not only additional geographic territories in large population density locations, but a significant number of large breast care facilities which are adopting BREVAGen as part of the care service they provide their patients. The launch of the next generation BREVAGen later this calendar year, is anticipated to result in a further increase in test volumes.

##### *New Product Development*

Planning is well underway and the Company is on track to introduce the next generation of BREVAGen for launch in the fourth quarter of this calendar year. This new version of BREVAGen will incorporate an expanded SNP panel, which will increase the predictive power of the test and ensure the product utilises the latest advances in scientific knowledge of the genetic basis of breast cancer. Furthermore, the new test will be applicable to additional ethnicities (African American and Hispanics) which will expand the application of the test to a broader target population and provide a test that clinics and breast centres will be able to apply to a large proportion of their patients. The Company believes that increased sample test volumes will be received by the laboratory as a result of this new product introduction.

##### *Reimbursement*

As mentioned in previous Activities Reports, until the end of 2012, insurance claims for BREVAGen were submitted using the so-called "code stack" of CPT methodology codes. Reimbursement under this regime was positive, with a low percentage of denials and appeals. However, effective 1 January 2013, the AMA removed the code stack claim process, requiring tests without a specific CPT code to be claimed via an "Unlisted or Miscellaneous Code".

As a result of the change from "Stacked Codes" to a "Miscellaneous Code" for insurance claims, the Company's reimbursement per test (including write-offs and denials for non-coverage) has increased by more than 30%. However, the use of a Miscellaneous code requires more administration and time by the Insurance company to adjudicate the claim and thus increases the time taken to receive the reimbursement.



## Quarterly Activities Report for the quarter ended 31 March 2014

### OPERATIONS (cont.)

#### *Cost effectiveness studies to improve reimbursement outcomes*

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

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

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

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

### LICENSING AND IP

#### **Non-coding Assertion Program**

On 24 December 2013, the Company reported that several significant cases pending in the District of Delaware - including cases against Bristol Myers Squibb, Pfizer and Merial - had each been allocated to the same Judge. While they remain separate cases, this consolidation will offer certain efficiencies to the legal processes now under way, and could possibly also speed up the process for GTG.

On 12 February 2014, the Company announced it has received a further ExParte Re-Examination Certificate from the United States Patent and Trademark Office (“USPTO”) – dated 10 February 2014 (the “Certificate”). This Certificate follows a third request by Merial L.L.C. of Duluth, Georgia, who had asked the USPTO to undertake further re-examination of various claims of the Company’s U.S. Patent No. 5,612,179 (the ‘179 patent), previously reported by GTG on 30 September 2013. The USPTO Certificate again confirmed the validity of the patent claims, and no amendments were made to the ‘179 patent.

On 12 March 2014, the Company announced that the United States District Court for the Northern District of California had issued an Order denying a motion brought by Agilent Technologies, Inc. (“Agilent”), to dismiss the patent infringement law suit initiated against it by GTG. This action had been filed by GTG in 2011, in the District Court of Colorado, but was then moved at the request of Agilent to the District Court in the Northern District of California. Thereafter, both sides filed motions to support their opposing legal perspectives. Most recently, Agilent moved to have GTG’s complaint dismissed, arguing the relevant GTG patent covers natural phenomena - or laws of nature - that are not entitled to patent protection, and that the Court should therefore dismiss the action. On 9 March 2014, the Court issued an Order denying Agilent’s motion to dismiss.



## Quarterly Activities Report for the quarter ended 31 March 2014

### LICENSING AND IP (cont.)

GTG has also pursued actions in Delaware against several entities - Natera, Inc, HistoGenetics, LLC and Laboratory Corporation of America Holdings. In mid-April, the Court agreed that the Natera action could be transferred to Northern District of California.

GTG has also been pursuing an action against Medical Diagnostic Laboratories LLC in the District of New Jersey, and Glaxo-SmithKline LLC in the Middle District of North Carolina.

In addition to the above, GTG's U.S.-based patent attorneys, Sheridan Ross, are now reviewing the files of several other entities who were recently found to be infringing the GTG patents. Such efforts are actively supported by Dr. Mervyn Jacobson, VP Global Licensing and IP for GTG who is also separately pursuing a number of other entities recently found to be infringing the GTG patents.

During the quarter, the Company reported an agreement had been executed with Promega Corporation.

#### Other licensing activities

The Company's licensing activities in Europe continue to progress, with a legal action now under way against Hendrix Genetics NV in the Netherlands. In mid-April, there was a special Court Hearing in The Hague, to allow GTG to formally interrogate two relevant Hendrix employees.

Whilst GTG representatives were in the Netherlands, they also took the opportunity to engage in licensing discussions with another large Dutch company, and they also made contact with several large German companies, also found to be utilizing GTG's patents without the approval of GTG. The GTG team also engaged in a high level strategy session with GTG's licensing attorneys, based in Hamburg, Germany, to review in some detail the various options now open to GTG under German law.

### OTHER COMMERCIAL ASSETS

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

#### ImmunAid™

As previously reported, on 18 December 2013, the Company announced that entities associated with the Company's founder and largest beneficial shareholder, Dr. Mervyn Jacobson (collectively, the "Jacobson Entities"), had entered into transactions which, if completed, will result in the disposal by them of 105,937,500 shares in the Company. Subsequent to that date, the Jacobson Entities disposed of 30,000,000 shares in GTG.

The Jacobson Entities and GTG entered into a binding Share Exchange Agreement ("Agreement") pursuant to which, subject to GTG shareholder approval, the Jacobson Entities will exchange a total of 75,937,500 shares in GTG at an agreed price of \$0.08 per share for 4,500,000 shares in ImmunAid Limited ("ImmunAid") owned by GTG at an agreed price of \$1.35 per share.

ImmunAid and GTG have also executed an Option Agreement pursuant to which ImmunAid will, when completion occurs under the Agreement, grant to GTG options to acquire a total of 2,250,000 ordinary shares in ImmunAid.

On 13 March 2014 GTG released the notice of the Extraordinary General Meeting of shareholders and Sample Proxy for the Meeting. The notice of meeting also included the Independent Expert's Report which was required to show all of the transactions above are fair and reasonable to Non-Associated Shareholders.

## OTHER COMMERCIAL ASSETS (cont.)

On 17 April 2014 the shareholders voted on the special resolution to approve the selective capital reduction by GTG and the disposal by GTG of shares in ImmunAid Limited. The resolution was passed on a show of hands.

Based on the current number of ordinary issued shares in GTG of 664,769,002, the number of ordinary issued shares in GTG will fall by 11.4% to 588,831,502, following the cancellation of the shares acquired from the Jacobson Entities.

At the conclusion of the various transactions contemplated above, the Jacobson Entities will retain a total of 30,536,184 ordinary shares in GTG representing 5.19% of the Company's then total issued capital.

## CORPORATE MATTERS

On 8 January 2014, the Company released the investor presentation that its Acting Chief Executive Officer at that time, Tom Howitt, presented to brokers and fund managers attending the J.P. Morgan Annual Healthcare Conference in San Francisco, California. The conference commenced which on Monday, 13 January 2014.

### Convertible Notes

On 29 November 2013, the Company received approval from its shareholders for the issue to Ironridge BioPharma Co., a division of institutional investor Ironridge Global IV, Ltd. ("Ironridge"), of redeemable convertible notes to raise USD 5,000,000 (the "Notes").

On 23 December 2013, the Notes were drawn down and the Company received \$5,627,462 (being the Australian dollar equivalent of USD 5,000,000) from Ironridge, before the payment of associated costs.

On 31 December 2013, Notes with a face value of USD 250,000 were converted in return for which Ironridge received 8,714,541 ordinary shares. During the quarter ended 31 March 2014, further Notes with a face value of USD 2,000,000 were converted in return for which Ironridge received 2,193,117 American Depository Receipts (representing 65,931,240 ordinary shares). On 10 April 2014, further Notes with a face value of USD 500,000 were converted in return for which Ironridge received 550,581 American Depository Receipts (representing 16,517,420 ordinary shares). As a result of these conversions, the face value of the remaining Notes has been reduced to USD 2,250,000.

### Chief Executive Officer

On 7 January 2014, the Company announced that the temporary corporate restructure that had been announced on 15 October 2013 regarding CEO Ms. Alison Mew had been extended to 31 March 2014.

On 24 February 2014, the Company was pleased to advise that Ms. Alison Mew had confirmed that she would return to full-time work to resume her position the Company's Chief Executive Officer as from Tuesday, 1 April 2014.

In light of her return, Acting Chief Executive Officer Mr. Tom Howitt relinquished this role on Friday, 28 March 2014. Further, the Company advised that Mr. Howitt tendered his resignation as Chief Financial Officer and Company Secretary and left the Company on that date. The Company wishes to thank Mr. Howitt for his services during his tenure of almost ten years.

Until such time as a replacement for Mr. Howitt can be found, current GTG Financial Controller, Ms. Bronwyn Christie, was appointed as Acting Chief Financial Officer.

On 19 March 2014, Ms. Bronwyn Christie was appointed as the Company Secretary.



Quarterly Activities Report  
for the quarter ended **31 March 2014**

Signed on behalf of Genetic Technologies Limited

Dated this 30<sup>th</sup> day of April, 2014

---

ALISON J. MEW  
*Chief Executive Officer*

For personal use only

*Rule 4.7B*

## **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 MARCH 2014**

### **Consolidated statement of cash flows**

	Current quarter (March 2014) A\$	Year to date (nine months) A\$
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	<b>1,363,676</b>	<b>3,699,181</b>
1.2 Payments for		
(a) staff costs	<b>(2,022,332)</b>	<b>(5,806,704)</b>
(b) advertising and marketing	<b>(238,985)</b>	<b>(767,539)</b>
(c) research and development	-	-
(d) leased assets	-	-
(e) other working capital	<b>(1,585,445)</b>	<b>(4,856,168)</b>
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	<b>41,914</b>	<b>72,688</b>
1.5 Interest and other costs of finance paid	<b>(13,840)</b>	<b>(39,773)</b>
1.6 Income taxes paid	-	-
1.7 Grant and other income	-	-
<b>Net operating cash flows</b>	<b>(2,455,012)</b>	<b>(7,698,315)</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 (March 2014) A\$	Year to date (nine months) A\$
1.8 Net operating cash flows (carried forward)	<b>(2,455,012)</b>	<b>(7,698,315)</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>(11,828)</b>	<b>(27,113)</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 (refer note below)	-	-
1.13 Other (provide details if material)	-	<b>(183,011)</b>
<b>Net investing cash flows</b>	<b>(11,828)</b>	<b>(210,124)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(2,466,840)</b>	<b>(7,908,439)</b>
<b>Cash flows related to financing activities</b>		
1.15 Net proceeds from the issue of shares	<b>(3,442)</b>	<b>6,362,784</b>
1.16 Equity transaction costs	-	-
1.17 Net proceeds from borrowings	<b>(737,649)</b>	<b>4,827,532</b>
1.18 Advances to third parties	-	-
1.19 Dividends paid	-	-
1.20 Repayment of finance lease principal	-	-
<b>Net financing cash flows</b>	<b>(741,091)</b>	<b>11,190,316</b>
<b>Net increase / (decrease) in cash held</b>	<b>(3,207,931)</b>	<b>3,281,877</b>
1.21 Cash at beginning of quarter / year to date	<b>8,216,347</b>	<b>1,721,293</b>
1.22 Exchange rate adjustments	<b>(15,069)</b>	<b>(9,823)</b>
<b>Cash at end of quarter</b>	<b>4,993,347</b>	<b>4,993,347</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>122,653</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 \$87,214 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes \$35,439 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.**

**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	-	-

+ See chapter 19 for defined terms.

**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     | <b>1,743,347</b> | <b>2,716,347</b> |
| 4.2   | Term deposits                | <b>3,250,000</b> | <b>5,500,000</b> |
| 4.3   | Bank overdraft               | -                | -                |
| 4.4   | Commercial Bills of Exchange | -                | -                |
| <b>Total cash at end of quarter</b> (item 1.23) |                              | <b>4,993,347</b> | <b>8,216,347</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 |
| 5.4 | Total net liabilities                     |
| 5.5 | Nature of business                        |

Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
<b>Not applicable</b>	<b>Gtech International Resources Limited</b>
	<b>Yukon Territory, Canada</b>
	<b>\$nil</b>
	<b>\$9,172</b>
	<b>Dormant</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: **30 April 2014**  
*Chief Executive Officer*

Print name: **Alison J. Mew**

---

+ 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.

---

+ See chapter 19 for defined terms.